NCI COMMUNITY CANCER CENTERS PROGRAM

January 2012

Integrated Evaluation Report: Overall Findings for NCI's Community Cancer Centers Program Pilot

Final Report

Prepared for
National Cancer Institute
Applied Research Program
Division of Cancer Control and Population Sciences

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Contents

Section **Page**

Acronyms **xxi**

Acknowledgments **xxv**

Executive Summary **ES-1**

Part I: Evaluation Framework and Methodology

1 Introduction **1-1**

1.1 Overview of the Overall Evaluation 1-2

1.2 Overview of this Report 1-3

1.3 Presentation of Findings 1-5

2 NCCCP Evaluation Overview **2-1**

2.1 Overview of the NCCCP Evaluation Conceptual Framework 2-3
2.1.1 Organizational Learning 2-4
2.1.2 Key Domains of the Conceptual Framework 2-6

2.2 Overarching Evaluation Questions 2-20
2.2.1 Evaluation Questions for the Network Level 2-20
2.2.2 Evaluation Questions for the Organizational Level 2-21
2.2.3 Evaluation Questions for the Program Level 2-23
2.2.4 Evaluation Questions for the Program Component Level 2-24
2.2.5 Evaluation Questions for the Patient Level 2-24

3 Overview of Overall Evaluation Methodology and Analysis **3-1**

3.1 NCCCP Evaluation Data Collection 3-1
3.1.1 Case Study Overview 3-1
3.1.2 Economic Studies 3-10
3.1.3 Patient Survey 3-14
3.1.4 Comparative Evaluation 3-16
3.1.5 Environmental Analysis 3-17
3.1.6 NCCCP Clinical Trials Special Study 3-20

3.2 Overall Analysis Plan 3-20
3.2.1 Summary of the Overall Analysis Planning Process 3-21
3.2.2 Overall Evaluation Measures 3-23
3.2.3 Assessing Organizational Factors Associated with Successful NCCCP Implementation 3-25
3.2.4 Pulling it All Together: Analysis Specific to Each Overarching Evaluation Question 3-26
3.2.5 Final Analytic Strategy 3-32

Part II: Initial Capacity and Understanding of the NCCCP Among Selected Sites

4 Overview of Sites at baseline 4-1

4.1 Descriptive Overview of Types of Hospitals and Cancer Centers 4-3
4.1.1 Overview of Hospitals 4-3
4.1.2 Overview of Cancer Centers and Cancer Services 4-4
4.1.3 Capacity for NCCCP Quality of Care Activities 4-6
4.1.4 Capacity for NCCCP Clinical Cancer Research Activities 4-8
4.1.5 Baseline Indicators of Performance 4-9
4.1.6 Cancer Patient Characteristics 4-11
4.1.7 Baseline Capacity Index for NCCCP Hospitals 4-11

4.2 Environmental Context 4-11
4.2.1 Local Markets and Competition 4-12
4.2.2 Market and Competition Baseline Index 4-16
4.2.3 Community Characteristic of Poverty Rate 4-16

5 Understanding and Conceptualization of the NCCCP Pilot 5-1

5.1 Sites' Understanding of the Broad Vision 5-1
5.1.1 Understanding the Broad Vision 5-2
5.1.2 Understanding Application of the Program 5-9
5.1.3 Changes in Sites' Understanding of the Broad Vision by Year 3 5-15

5.2 Vision/Understanding of Program Application to Individuals' Roles 5-16
5.2.1 Subcommittee Members 5-16
5.2.2 Key Physicians 5-18
5.2.3 Changes in Vision/Understanding of Program Application to Individuals' Roles by Year 3 5-20

5.3 Challenges to Developing and Communicating a Common Understanding 5-21
5.3.1 Lack of Clarity about NCCCP and Formal Sharing Because of the Youth and Complexity of the Program 5-21
5.3.2 Level of Engagement/Proximity to Activities 5-21
5.3.3 Relationships with Physicians 5-22
5.3.4 Time Constraints 5-22
5.3.5 Remaining Challenges in Year 3 5-22

5.4 Summary 5-24

6 Sites' Capacity for Learning, Innovation, and Change 6-1

6.1 Reasons for Participating in the NCCCP 6-2
6.1.1 Creation of a Formal Connection with NCI 6-2
6.1.2 Opportunity to Develop and Learn How to Improve Cancer Research and Care 6-3
6.1.3 Fit between the NCCCP and the Site's Strategic Priorities 6-6

6.2 Learning and Innovation 6-8
6.2.1 Readiness for Change 6-9
6.2.2 Role of Leadership 6-9

6.3 Organizational Alignment and Internal Capacity 6-13
6.3.1 Cancer Care Capacity 6-14

6.4 Summary 6-24

7 Organizational Structure and Processes 7-1

7.1 Levels of Organizational Structure 7-3
7.1.1 Hospital's Relationship to its Cancer Service Line 7-3
7.1.2 Cancer Service Line Structure 7-11
7.1.3 Cancer Service Line's Relationship to the NCCCP 7-12
7.1.4 System's Relationship to its Participating Hospitals 7-14

7.2 Organizational Processes and Challenges for Engaging Private Practice Physician Support 7-16
7.2.1 Key Cancer Physician Relationships with Cancer Service Line 7-17
7.2.2 Barriers to Engaging Private Practice Physicians 7-18
7.2.3 Strategies to Engage Private Practice Physicians 7-22

7.3 Summary 7-25

8 Coordination across Program Components 8-1

8.1 Overview of Site Coordination Strategies 8-2

8.2 Cross-Coordination Strategies 8-3
8.2.1 Local NCCCP Subcommittees 8-4
8.2.2 NCCCP Core Team Meetings 8-4
8.2.3 Multiple components for staff members 8-5
8.2.4 Informal Communication 8-5
8.2.5 Incorporating of NCCCP into Regular Cancer Center and Top Management Meetings 8-5
8.2.6 Integration of the NCCCP into Hospital/Cancer Center Infrastructure 8-5
8.2.7 Integration of Cancer Center Departments/Services 8-6

8.3 Coordination of Biospecimens Activities with Other NCCCP Components 8-6
8.3.1 Coordination of Biospecimens with Clinical Trials 8-7
8.3.2 Coordination of Biospecimens with Disparities 8-7
8.3.3 Coordination of Biospecimens with Information Technology 8-8

8.4 Coordination of Clinical Trials Activities with Other NCCCP Components 8-9
8.4.1 Coordination of Clinical Trials with Disparities 8-9
8.4.2 Coordination of Clinical Trials with Information Technology 8-11
8.4.3 Coordination of Clinical Trials with Quality of Care 8-11

8.5 Coordination of Disparities Activities with Other NCCCP Components 8-12
8.5.1 Coordination of Disparities Activities with Information Technology 8-12
8.5.2 Coordination of Disparities Activities with Quality of Care 8-13
8.5.3 Coordination of Disparities Activities with Survivorship/Palliative Care 8-13

8.6 Coordination of Information Technology Activities with Other NCCCP Components 8-14

8.6.1 Coordination of Information Technology with Quality of Care 8-14
8.6.2 Coordination of Information Technology with Survivorship/ Palliative Care 8-14

8.7 Coordination of Quality of Care with Survivorship/Palliative Care 8-15

8.8 Facilitators to Coordinating across Components 8-16
8.8.1 Hospital Top Management, Cancer Center Physician Leadership and Physician Support 8-16
8.8.2 NCCCP Program-Level Support..... 8-16
8.8.3 Networking with Other NCCCP Sites..... 8-17

8.9 Barriers to Coordinating across Components 8-17
8.9.1 Staff Burden 8-17
8.9.2 Lack of Clarity about NCCCP Vision..... 8-18

8.10 Summary 8-18

Part III: Implementation of NCCCP Program Components

9 Disparities 9-1

9.1 NCCCP Disparities Subcommittee Priorities and Strategies 9-4
9.1.1 Priority 1: Enhance Outreach Efforts 9-5
9.1.2 Priority 2: Develop and Strengthen Patient Navigation 9-5

9.2 Development and Use of Disparities Tools..... 9-6
9.2.1 Breast Cancer Screening Tracking Tool 9-6
9.2.2 Disparities Dashboard 9-7

9.3 Disparities Implementation across NCCCP Sites 9-8
9.3.1 Increase Outreach 9-8
9.3.2 Establish or Strengthen Patient Navigation and Coordination of Care 9-9

9.4 Overall Success in Disparities Implementation 9-11
9.4.1 Collecting Race/Ethnicity Data 9-12
9.4.2 Increasing the Number of Community Partners 9-13
9.4.3 Increasing Cancer Screening 9-14
9.4.4 Staffing to Support Outreach Activities..... 9-15
9.4.5 Improving Access to Care..... 9-15
9.4.6 Establishing or Expanding Patient Navigation Services 9-17
9.4.7 Increasing Staff to Support Patient Navigation 9-18
9.4.8 Increasing the Number of Racial and Ethnic Minorities Enrolled in Clinical Trials 9-19
9.4.9 Overview of Success in Disparities Implementation 9-20

9.5 Facilitators to Disparities Implementation 9-21
9.5.1 Leveraging Community Partnerships..... 9-21
9.5.2 Creating Synergies with Other NCCCP Components 9-22

9.6 Barriers to Disparities Implementation 9-22
9.6.1 Lack of Clarity about Priorities and Strategies 9-23
9.6.2 Logistical Challenges to Serving Underserved Populations 9-24
9.6.3 Distrust of Health Care System in Underserved Communities..... 9-24
9.6.4 Organizational and Systems Challenges to Race/Ethnicity Data Collection 9-25

9.7 Value Added: Disparities Benefits Beyond the NCCCP 9-27
9.7.1 Developing New Site Capabilities..... 9-27
9.7.2 Developing New Community Linkages..... 9-29
9.7.3 Establishing New Models of Care 9-30
9.7.4 Integrating Disparities across Different Aspects of Cancer Care..... 9-30
9.7.5 Learning about Best Practices for Outreach..... 9-31

9.8 Summary 9-31

10 Clinical Trials 10-1

10.1 NCCCP Clinical Trials Subcommittee Priorities and Strategies 10-4
10.1.1 Priority 1: Increase in Accrual to All Clinical Trials (including Pharmaceutical Trials) 10-4
10.1.2 Priority 2: Increase in Underserved Patient Accrual to Clinical Trials..... 10-5
10.1.3 Priority 3: Increase in Clinical Trial Capacity 10-5

10.2 Use of Clinical Trials Subcommittee Tools and Establishment of Workgroups 10-6
10.2.1 Clinical Trials Screening and Accrual Log 10-6
10.2.2 Clinical Trials Accrual Quarterly Report Update..... 10-7
10.2.3 Cultural Awareness Webinars..... 10-7
10.2.4 Minority Matrix..... 10-8

10.3 Clinical Trials Implementation across NCCCP Sites 10-8
10.3.1 Patient Education 10-9
10.3.2 Community Outreach..... 10-9
10.3.3 Presentation of Clinical Trials at Tumor Boards..... 10-10
10.3.4 Research Infrastructure and Clinical Trials Capacity 10-11

10.4 Overall Success in Clinical Trials Implementation 10-14
10.4.1 Overall Trial Capacity..... 10-15
10.4.2 Total Patient Accrual to Clinical Trials..... 10-17
10.4.3 Minority (Non-white) Accrual to Clinical Trials 10-19
10.4.4 Proportion of Eligible Physicians Enrolling Patients 10-20
10.4.5 Patients' Awareness and Understanding of Clinical Trials 10-20
10.4.6 Summary of Overall Success in Clinical Trials..... 10-21

10.5 Facilitators to Clinical Trials Implementation..... 10-21
10.5.1 Having an Existing Research Infrastructure 10-22
10.5.2 Establishing or Enhancing Patient Navigators 10-22
10.5.3 Participating in the NCCCP Network and Establishing Linkages with NCI-designated Cancer Centers 10-23
10.5.4 Garnering Institutional Leadership Support..... 10-24

10.6 Barriers to Clinical Trials Implementation 10-24
10.6.1 Administrative/Infrastructure Barriers 10-25
10.6.2 Physician Participation 10-25
10.6.3 Patient Access to Clinical Trials 10-26

10.7 Value Added: Clinical Trials Benefits Beyond the NCCCP 10-28

10.8 Summary 10-30

11 Biospecimens 11-1

11.1 NCCCP Biospecimen Priorities 11-2

11.2 Use of Biospecimens Subcommittee Tools 11-3
11.2.1 Gap and Fill Assessment Tool 11-3
11.2.2 Process Evaluation Tool 11-3
11.2.3 Best Practices Implementation Tool 11-3

11.3 Facilitators to Biospecimen Collection 11-4
11.3.1 Having an Existing Biospecimen Infrastructure 11-4
11.3.2 Establishing External Collaborations 11-5
11.3.3 Garnering Pathology Staff Support 11-6

11.4 Barriers to Biospecimen Collection 11-6
11.4.1 Lack of Financial/Staff Resources 11-7
11.4.2 Lack of IT Support 11-7

11.5 Summary 11-8

12 Information Technology 12-1

12.1 IT Priorities 12-1

12.2 IT Implementation Workplan 12-2
12.2.1 Implementation of caBIG Components 12-3

12.3 Facilitators to Expanding IT Capabilities 12-3
12.3.1 Dedicated Resources 12-3
12.3.2 Incorporating End-Users 12-4

12.4 Barriers to Expanding IT Capabilities 12-4
12.4.1 Limited EHR Data Management System Capabilities or Linkages 12-5
12.4.2 Limited Physician Engagement 12-6
12.4.3 Challenges due to Patient Confidentiality Requirements 12-7
12.4.4 Priority of Linking to caBIG 12-7
12.4.5 Requirement of Extensive Hospital Resources 12-8

12.5 Summary 12-10

13 Quality of Care 13-1

13.1 NCCCP QOC Subcommittee Priorities and Strategies 13-2
13.1.1 Priority 1: Quality Improvement Initiatives and Increasing Use of Evidence-Based Guidelines 13-2
13.1.2 Priority 2: Enhanced Care Coordination through Multidisciplinary Care Conferences and/or Clinics and Patient Navigation Services 13-4
13.1.3 Priority 3: Developing Conditions of Participation for Medical Staff 13-4

13.2 QOC Subcommittee Tools 13-5
13.2.1 MDC Assessment Tool 13-5
13.2.2 Genetic Counseling Assessment Tool 13-6
13.2.3 Chemotherapy Consent Form 13-7
13.2.4 Conditions of Participation 13-8

13.3 QOC Implementation 13-8
13.3.1 Establishing or Expanding MDC Conferences and Clinics 13-8
13.3.2 Improving Standards of Care by Using Evidence-Based Guidelines 13-11
13.3.3 Tracking QOC Outcome Measures 13-12
13.3.4 Implementing Conditions of Participation 13-13
13.3.5 Hiring Staff and/or Training Staff to Support QOC Activities 13-15

13.4 Overall Success in QOC Implementation 13-16
13.4.1 Establishing and Expanding MDC Conferences 13-16
13.4.2 Improving Coordination of Care 13-19
13.4.3 Improving Adherence to Evidence-based Guidelines 13-19
13.4.4 Implementing the Conditions of Participation 13-20
13.4.5 Overall Experience with Care and Patient-Provider Communication 13-21
13.4.6 Overview of Success in QOC Implementation 13-22

13.5 Facilitators to QOC Implementation 13-23
13.5.1 Recognition of the Value of MDC Conferences and Other QOC Initiatives 13-23
13.5.2 MDC Infrastructure Prior to the NCCCP 13-25
13.5.3 Provision of Support for Physician Participation 13-26
13.5.4 Presence of a Physician Champion for Quality of Care 13-27
13.5.5 An Active Hospital Cancer Committee 13-28

13.6 Barriers to QOC Implementation 13-29
13.6.1 Lack of Physician Participation and Engagement 13-29
13.6.2 Institutional and Practice Culture 13-31
13.6.3 Inadequate EHR Systems 13-32

13.7 Summary 13-32

14 Survivorship/Palliative Care 14-1

14.1 NCCCP Survivorship/Palliative Care Subcommittee Priorities and Strategies 14-2
14.1.1 Breast Treatment Summary Tool 14-2
14.1.2 Breast Cancer Survivorship Care Plan 14-6
14.1.3 Psychosocial Matrix 14-6
14.1.4 Palliative Care Matrix 14-7

14.2 Survivorship/Palliative Care Implementation 14-8
14.2.1 Palliative Care Program 14-8
14.2.2 Survivorship Clinic or Program 14-9
14.2.3 Physician and Medical Staff Education/Communication 14-9
14.2.4 Psychosocial Distress Screening 14-9
14.2.5 Referrals to Hospice 14-10

14.3 Survivorship/Palliative Care Implementation: Patients' Perspectives 14-10

14.4 Facilitators to Survivorship/Palliative Care 14-10
14.4.1 Survivorship/Palliative Care Personnel 14-11
14.4.2 Patient Navigation 14-11
14.4.3 Relationships with Community Groups and Hospices 14-12
14.4.4 Linkages with Other NCCCP sites 14-12

14.5 Barriers to Survivorship/Palliative Care 14-13
14.5.1 Low Physician Engagement 14-13
14.5.2 Lack of Guidance about Standards of Survivorship/Palliative Care 14-14
14.5.3 Staffing Needs 14-14

14.6 Summary 14-15

Part IV: Conclusions and Recommendations

15 Experience with the NCCCP Network and OTHER NCI programs 15-1

15.1 Sites' Experience with NCCCP Subcommittees and Workgroups 15-2
15.1.1 Provision of Professional Support 15-3
15.1.2 Provision of Material Support 15-4

15.2 Experiences with Technical Assistance 15-8

15.3 Recommendations for Improvement 15-11
15.3.1 Reduce Administrative Burden 15-11
15.3.2 Share Evaluation and Survey Findings 15-13
15.3.3 Develop a Better Understanding of Sites' Challenges 15-14

15.4 Collaborations with NCI-Designated Cancer Centers 15-15

15.5 Summary 15-26

16 Overall Accomplishments with NCCCP Implementation 16-1

16.1 Overall Accomplishments with NCCCP Implementation 16-5
16.1.1 Site Characteristics Relevant to NCCCP Implementation 16-6
16.1.2 Innovation and Adoption/Assimilation/Implementation Process ... 16-10
16.1.3 Increased Program-Related Knowledge and Skills 16-12
16.1.4 Enhanced Infrastructure and Capacity 16-13
16.1.5 Enhanced Research Capacity 16-15
16.1.6 Delivery of Advanced Cancer Care in Local Communities 16-18
16.1.7 Sustainability 16-23

16.2 Organizational and Environmental Factors Associated with Accomplishments in the Three Major Program Components 16-30
16.2.1 Organizational and Environmental Factors Associated with Accomplishments in Reducing Disparities 16-30
16.2.2 Organizational and Environmental Factors Associated with Success in Clinical Trials 16-34
16.2.3 Organizational and Environmental Factors Associated with Accomplishments in Quality of Care 16-37

16.3 Summary 16-38

17 Conclusions 17-1

17.1 Context for Program Implementation 17-2

17.2 Overarching Themes 17-3
17.2.1 Theme 1: Baseline Variation in Organizational Characteristics Made it Difficult to Set Benchmarks for Program Implementation 17-3
17.2.2 Theme 2: The NCCCP Pilot Requires Time for Start-up and Prioritization of Goals 17-4
17.2.3 Theme 3: Establishing a Public-Private Partnership between NCI and the Participating Hospitals Provided the NCCCP with Tremendous Benefits 17-6
17.2.4 Theme 4: Support from Hospital's Top Management Facilitates Program Implementation 17-7
17.2.5 Theme 5: NCCCP Activities Require Physician Leadership 17-7
17.2.6 Theme 6: The NCCCP Requires Involvement from Numerous Cancer Physicians 17-8
17.2.7 Theme 7: Communication and Coordination across Program Components Facilitates NCCCP Accomplishments 17-9
17.2.8 Theme 8: The NCCCP Enhances Cancer Research Capacity 17-10
17.2.9 Theme 9: The NCCCP Network of Sites with NCI Guidance Provided Important Collaborative Learning Opportunities 17-11
17.2.10 Theme 10: Sustainability Depends on Maintaining a Connection to NCI 17-11

17.3 Findings for the Three Major NCCCP Program Components 17-12
17.3.1 Conclusions for Implementation of the Disparities Program Component 17-12
17.3.2 Conclusions for Implementation of the Clinical Trials Program Component 17-13
17.3.3 Conclusions for Implementation of the Quality of Care Program Component 17-14

17.4 Limitations 17-15

17.5 Summary 17-17

18 Recommendations 18-1

18.1 Recommendations Specific to the NCCCP Model 18-2
18.1.1 Aspects of the NCCCP Model Supported by Evaluation Findings 18-2
18.1.2 New Aspects to Consider for the NCCCP Model 18-3

18.2 Recommendations Specific to Organizational Requirements for Future NCCCP Sites 18-5

18.3 Summary on the Future of the NCCCP 18-8

References R-1

Glossary Glossary-1

Appendices

A Evaluation Planning Matrices of First Four Levels & Evaluation Planning Matrices By Program Components
B Site Visit Interview Guides – Year 1
C Site Visit Interview Guides – Year 2
D Site Visit Interview Guides – Year 3
E Sample of Meta-Matrix
F Evaluation Conceptual Framework
G Organizational Factors Spreadsheet
H Year 1 Organization Charts for All Sites
I Year 2 Organization Charts for Lead Sites
J Year 3 Organization Charts for All Sites
K Disparities Dashboard
L Breast Cancer Screening Tracking Tool
M Patient Survey
N Clinical Trials Worksheet (SAIC-F) and Legend
O Clinical Trials Screening and Accrual Log
P Minority Matrix
Q GAFAT
R Conditions of Participation
S Breast Cancer Treatment Summary Tool
T Donated, Matching, and Total Costs

Figures

Number		Page
2-1	NCCCP Evaluation Conceptual Framework	2-4
3-1	Schematic of the Cost Assessment Tool	3-12
9-1	NCCCP Patient Navigator Roles/Responsibilities at Different Points in Care	9-10
10-1	Sites with and without a Director of Research in Year 3	10-12
10-2	Timeline for Legislation of Health Insurance Coverage of Cancer Clinical Trials	10-27
16-1	NCCCP Evaluation Conceptual Framework	16-4

Tables

Number		Page
ES-1	Overarching Recommendations Mapped to Supporting Conclusions and Specific Recommendations	ES-10
2-1	Prioritized Primary and Secondary Evaluation Questions across the First Three Levels of Program Intervention (ie, Network, Organizational, Program)	2-26
2-2	Primary Evaluation Questions and Illustrative Methods and Outcomes for Each NCCCP Component	2-31
3-1	Data Sources and Sample Data Variables for the NCCCP Case Study	3-33
3-2	Key Words or Domains for Each Level of Evaluation to Cover through the Case Study for Each Year of Site Visits	3-33
3-3	Requested Interviewees for Year 1 Site Visits by Organizational Role and Suggested Interview Length	3-34
3-4	Summary of Year 1 Invoiced Costs, by Type of Expenditure and Core Component Activity	3-34
3-5	NCCCP Environmental Analysis Constructs, Control Variables, and Hypotheses	3-35
3-6	Key Study Variables and Data Sources	3-35
3-7	Data Sources for Overall Analysis	3-36
3-8	Sites' Baseline Capacity: Key Indicators and Data Sources	3-37
3-9	Success at the Program Component Level: Key Outcomes and Data Sources	3-38
3-10	Success at the Overall Program Level: Key Outcome Measures and Data Variables	3-39
3-11	Hypothetical Case-Ordered Descriptive Data for Two Sites by Overall Success	3-40
3-12	Rationale for Excluding Key Factors of Evaluation Conceptual Framework from Overall Analysis	3-41
3-13	Program Components and Activities Associated with Sustainability Costs	3-41
3-14	Hypothetical Array of the Association Between Overall Success and Selected Organizational Variables	3-42
4-1	Overview of Data Sources	4-17
4-2	Overview of Hospitals	4-19
4-3	Overview of Cancer Centers from Year 1, July 2007 through June 2008	4-21
4-4	Capacity at Baseline Specific to NCCCP QOC Activities	4-25

4-5 Overview of Clinical Cancer Research 4-27
4-6 Sites' Baseline Capacity: Key Indicators and Data Sources 4-29
4-7 Cancer Center Cases for 2006 4-29
4-8 Results of Baseline Capacity to Implement NCCCP 4-32
4-9 Medicare Market Share: NCCCP Hospitals, 2007 4-33
4-10 Cancer Competition from Commission on Cancer (CoC) Accredited Hospitals in NCCCP Markets 4-34
4-11 Cancer Specialists by Specialty Type per 100,000, 2007 4-35
4-12 Total Cancer Specialists in NCCCP Markets, 2007 4-36
4-13 Market and Competition Index 4-37
4-14 Percentage in Poverty: NCCCP Markets, 2006 4-38

6-1 Moderator Guide Questions by Section Theme During Year 1 6-26
6-2 Opportunity to Improve Cancer Research and Care: Themes and Definitions 6-26
6-3 Opportunity to Improve Research and Care: Theme by Respondent Role During Year 1 Interviews 6-27
6-4 Fit between the NCCCP and Site's Mission: Themes and Definitions 6-27
6-5 Fit Between the NCCCP and Site's Mission: Theme by Respondent Role During Year 1 Interviews 6-27
6-6 Number and Average of Cancer Center Physicians by Specialty in Years 1 and 3 6-28
6-7 Access to Three Types of Cancer Subspecialists in Year 3 6-29

7-1 Characteristics of the Hospital's Relationship to its Cancer Service Line 7-28
7-2 Physician Leadership Indicator: Year 1, Year 3, and Change Over Time 7-28
7-3 Cancer Center Physician Director FTE: Year 1, Year 3, and Change 7-29
7-4 Sites with Executive Directors and Whether They Were Trained as Nurses 7-30
7-5 Program Coordinator Positions for Years 1 and 3 at the NCCCP Sites 7-31
7-6 NCCCP Program Coordinator Responsibilities and Suggested Qualifications 7-32

9-1 Number of Sites Tracking Race and Ethnicity for Different Programs and Services 9-33
9-2 Sites Tracking Race/Ethnicity for Different Systems (0-9 systems): Years 1 and 3 9-34
9-3 Number of Community Partners (Including Partners that Focus on an Underserved Population): Years 1 and 3 9-36
9-4 Number of Cancer Screenings and Screening Events: Years 1 and 3 9-37
9-5 Number of Staff Focusing on Outreach: Years 1 and 3 9-38
9-6 Relationship between Number of Outreach Staff and Outcomes: Change in Numbers of Partnerships and Numbers of Screenings 9-39
9-7 Access to Care Scale Scores by Site: Years 1 and 3 9-40

9-8 Change in Access to Care Scale Score for Demographic Subgroups: Years 1 and 3 9-41
9-9 Total Number of Patients Navigated: Years 1 and 3 9-42
9-10 Types of Cancer for Which Patient Navigation Services were Provided: Year 3 9-43
9-11 Patients' Awareness and Utilization of Patient Navigation Services: Years 1 and 3 9-44
9-12 Number of Patient Navigators: Years 1 and 3 9-45
9-13 Relationship between Number of Patient Navigators and Outcomes: Numbers of Patients Navigated and Awareness of Patient Navigation 9-46
9-14 Minority (Non-White) Patients Enrolled in NCI-Sponsored Clinical Trials 9-47
9-15 Overview of Success in Disparities Implementation: Year 3 9-48

10-1 Participation in Clinical Trials Cooperative Groups by Site 10-31
10-2 Key Clinical Trials Staff (FTEs) 10-32
10-3 Dedicated Research Pharmacies in Year 1 and Year 3 by Site 10-33
10-4 IT Support of Clinical Trials 10-34
10-5 Number of Trials Open in Year 1 and Year 3 by Site 10-35
10-6 Number of Early Phase Trials Offered in Years 1 and Year 3 by Site 10-37
10-7 Number Types of Clinical Trials and Other Research Studies Open in Year 1 and Year 3 by Site 10-38
10-8 Number of Total Trials, Early Phase Trials, and Trial Types open in Year 1 and Year 3 by Site 10-39
10-9 Total Patients Enrolled in Clinical Trials in Year 1 and Year 3 by Site 10-41
10-10 Number of Trials Open and Number of Patients Enrolled in Clinical Trials in Year 1 and Year 3 10-43
10-11 Number of Physicians Eligible and Actually Accruing Patients to Clinical Trials 10-44
10-12 Patients' Reported Awareness and Understanding of Clinical Trials 10-46
10-13 Overall Success in Clinical Trials 10-47

13-1 Number of Types of MDC Conferences and Level of Physician Attendance 13-34
13-3 Coordination of Care: Members of Cancer Care Team Well-Informed and Up to Date about Patient's Care and Team Works Together: Years 1 and 3 13-36
13-4 Rates of Nonconcordance with Five RQRS Quality Measures 13-37
13-5 Conditions of Participation Implementation: Years 1 and 3 13-38
13-6 Overall Experience with Care and Patient-Centered Communication 13-40
13-7 Overall Success with Quality of Care Implementation 13-41

14-1 Implementation Level of Breast Treatment Summary Tool 14-16
14-2 Overall Success in Survivorship/Palliative Care 14-17
14-3 Treatment Summaries and Follow-up Care Information 14-18

15-1 Themes and Corresponding Interview Questions 15-27
15-2 Relationships (Formal and Informal) with NCI-Designated Cancer Centers and Community Network Programs at Baseline and Year 3 15-28

16-1 Accomplishments at the Overall Program Level: Key Outcome Measures and Data Variables 16-39
16-2 Relationships with Key Cancer Physicians and NCI Programs and Research 16-41
16-3 Sites' Participation and Input on New Initiatives and Specific Activities Facilitated by the NCCCP 16-42
16-4 Enhanced Research Capacity 16-43
16-5 Research-Related Program Components and Activities 16-44
16-6 Reduction in Nonconcordance Rates for Breast Cancer Treatment Indicators Reported for RQRS 16-45
16-7 Reduction in Nonconcordance Rates for Colon Cancer Treatment Indicators Reported for RQRS 16-46
16-8 Overall Hospital Ranking in Reduction in Nonconcordance Rates Across All Five Treatment Indicators Captured in the RQRS 16-47
16-9 Baseline Capacity for Implementing the NCCCP Relative to Improvements in RQRS Indicators 16-47
16-10 Market Competition Relative to Improvements in RQRS Indicators 16-48
16-11 Matching Costs by Program Component and Activity 16-48
16-12 Year 3 Matching Costs Excluding Fixed Institutional Overhead 16-49
16-13 Baseline Capacity Relative to Matching Investments in NCCCP-Related Activities 16-50
16-14 Market Competition Relative to Matching Investments in NCCCP-Related Activities 16-50
16-15 Total Sites by Ratio of Success for NCCCP Disparities Efforts 16-50
16-16 Ratio of Success in Reducing Disparities by Number of Outreach Workers as of Year 3 16-50
16-17 Ratio of Success in Reducing Disparities to Baseline Capacity 16-51
16-18 Ratio of Success in Reducing Disparities Relative to Local Market Competition 16-51
16-19 Ratio of Success in Reducing Disparities Relative to the Local Poverty Rate 16-51
16-20 Leadership Support for Clinical Trials and Overall Accomplishments in Clinical Trials Implementation 16-52
16-21 Relationship of Having a Physician Director of Research to the Level of Change in Clinical Trials Outcomes 16-52
16-22 Physician Engagement and Overall Accomplishments in Clinical Trials Implementation 16-53
16-23 Relationship of Proportion of Eligible Physicians Enrolling Patients in Clinical Trials to the Level of Change in Clinical Trials Outcomes 16-54
16-24 State-Mandated Insurance Coverage of Clinical Trials and Overall Accomplishments in Clinical Trials Implementation 16-54

16-25 Ratio of Accomplishments in Clinical Trials Relative to Baseline Capacity..... 16-55
16-26 Ratio of Accomplishments in Clinical Trials Relative to Local Market Competition 16-55

ACRONYMS

3CPR	Cancer Center Clinical Participant Registry
ACOS	American College of Surgeons
AMC	Academic Medical Centers
ARF	Area Resource File
ARRA	American Recovery and Reinvestment Act
ASCO	American Society of Clinical Oncology
BAS	Baseline Assessment Survey
BPIT	Best Practices Implementation Tool
C3D	Cancer Center Clinical Database
caAERS	Cancer Adverse Events Reporting System
caBIG	Cancer Biomedical Informatics Grid
CALGB	Cancer and Leukemia Group B
CAT	Cost Assessment Tool
CCC	Community Cancer Center
CCOP	Community Clinical Oncology Program
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CHCC	Community Hospital Cancer Center
CHI	Catholic Health Initiatives
CI	Confidence Interval
CMO	Chief Medical Officer
CMS	Centers for Medicare and Medicaid Services
CNP	Community Network Program
CoC	Commission on Cancer
COO	Chief Operating Officer
COP	Conditions of Participation
CPT	Current Procedural Terminology
CRA	Clinical Research Associate
CRC	Colorectal Cancer
CRN	Clinical Research Nurse
CT	Clinical Trials
CTEP	NCI's Cancer Therapy Evaluation Program
CTODS	Clinical Trials Object Data System

CTR	Certified Tumor Registrar
CTSU	Cancer Trials Support Unit
CV	Curriculum Vitae
ECOG	Eastern Cooperative Oncology Group
EDR	Evaluation Design Report
EHR	Electronic Health Record
EOC	Evaluation Oversight Committee
EPM	Evaluation Planning Matrix
e-QuIP	Electronic Quality Improvement Program
FAS	Final Assessment Survey
FTE	Full-Time Equivalent
GAFAT	Gap and Fill Assessment Tool
GEM	Generalized Exponential Models
GOG	Gynecology Oncology Group
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Services Research Association
HSAF	Hospital Service Area File
HSSC	Health Sciences South Carolina Consortium
IAS	Interim Assessment Survey
ICD	International Classification of Diseases
IOM	Institute of Medicine
IRB	Internal Review Board
IRT	Item Response Theory
IT	Information Technology
MBCCOP	Minority-Based Community Clinical Oncology Program
MDC	Multidisciplinary Care
MOU	Memorandum of Understanding
MPH	Masters of Public Health
NBIA	National Biomedical Imaging Archive
NCCCP	NCI's Community Cancer Centers Program
NCCN	National Comprehensive Cancer Network
NCDB	National Cancer Database
NCI	National Cancer Institute
NIH	National Institutes of Health
NPAC	NCCCP Program Advisory Committee

NPPES	National Plan and Provider Enumeration System
NSABP	National Surgical Adjuvant Breast and Bowel Project
OBBR	NCI Office of Biorepositories and Biospecimen Research
OMB	Office of Management and Budget
OSCAR	Online Survey Certification and Reporting System
PCC	Patient-Centered Care
PDSA	Plan-Do-Study-Act
PET	Process Evaluation Tool
PI	Principal Investigator
PN	Patient Navigation
POS	Medicare Provider of Service
PSC	Patient Study Calendar
QCA	Qualitative Comparative Analysis
QI	Quality Improvement
QOC	Quality of Care
QOPI	Quality Oncology Practice Initiative
RN	Registered Nurse
ROI	Return on Investment
RQRS	Rapid Quality Reporting System
RTI	RTI International (trade name for Research Triangle Institute)
RTOG	Radiation Therapy Oncology Group
SAIC-F	Science Applications International Corporation-Frederick
SAR	Survey Application Record
SES	Socioeconomic Status
SID	Sequential ID Number
SQL	Structured Query Language
SSL	Secure Sockets Layer
SWOG	Southwest Oncology Group
TA	Technical Assistance
TCC	Moffitt Cancer Center's Total Cancer Care Initiative
TBD	To Be Determined
UPIN	Unique Physician Identifier Number
USPSTF	United States Preventive Services Task Force

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EXECUTIVE SUMMARY

This report presents findings from the evaluation of the National Cancer Institute's (NCI's) Community Cancer Centers Program (NCCCP) pilot conducted from 2007 to 2010. The ultimate aim of the NCCCP was to expand cancer research and deliver the latest, most advanced cancer care to a greater number of Americans in the communities in which they live. To achieve the program's stated aims, NCI established a public-private partnership with a selected group of participating community hospitals and health systems and their cancer centers, with a focus on six program components:

- reducing **disparities** across the cancer continuum;
- enhancing **clinical trials** research;
- increasing capacity to collect **biospecimens** per NCI's best practices;
- improving the use of **information technology (IT)** and electronic health records (EHRs) to support improvements in research and care delivery;
- improving access to and **quality of cancer care** and related areas, such as the development of integrated, multidisciplinary care teams; and
- placing greater emphasis on **survivorship** and palliative care.

NCI awarded a contract to RTI International in 2007 to conduct an independent evaluation of the NCCCP pilot. The evaluation design initially included a case study, an economic study (which included a micro-cost study and a strategic case study), and a patient survey in order to assess the ability of the program to meet it objectives. Three overarching questions guided the NCCCP evaluation plan:

- What changes in each program component and for the cancer program overall seem to be facilitated by the NCCCP?
- What organizational requirements seem important to effectively manage/implement the NCCCP?
- What changes and elements are sustainable and potentially replicable in other community hospitals?

Given the comprehensiveness of these questions, the evaluation collected and analyzed data at five possible levels of intervention:

- the network level, including selected hospitals as a group or informal network (i.e., across the programs and within the NCCCP network),
- the organizational level (i.e., within the health systems and/or hospitals),
- the program level (i.e., within the cancer center or service line),
- the program component level (i.e., biospecimens, clinical trials, disparities, IT, quality of care, and survivorship/palliative care), and
- the patient level.

Two additional aspects to the evaluation design were added in 2009: a comparative analysis of hospitals (both NCCCP and non-NCCCP community hospitals) participating in the Commission on Cancer (CoC) Rapid Quality Reporting System (RQRS) and an environmental analysis. A report on the results from the comparative analysis is being submitted to NCI separately, but findings from that study specific to NCCCP sites have been incorporated into this final report. Selected findings from the environmental analysis have also been incorporated into the presentation of overall evaluation results. A third study added to the evaluation design in 2011 was an analysis of clinical trials data, which compares NCCCP sites to other cancer hospitals during the time of the pilot program (2007–2010). Relevant findings from all of these studies have been incorporated as appropriate throughout the overall evaluation results presented in this report.

ES.1 Background and Context of Program Implementation

The creation of the NCCCP pilot was based on the rationale that most cancer care occurs in the community (estimates are that up to 85% of cancer patients are served by community hospitals). The reasoning was that if cancer outcomes are to improve and research is to be expanded, there needs to be more attention paid to the locations where the majority of cancer patients are likely to access cancer care in their communities. Most cancer care is now multimodal (i.e., a combination of treatment that includes radiation, chemotherapy, and/or surgery), which requires improved coordination of care through strategies like multidisciplinary care (MDC) conferences. Such strategies make it possible to obtain input from a broad array of cancer specialists on the treatment plan and decision making for each new cancer case. In addition, in the context of legislation for national health care reform, requirements were specified for hospitals to implement IT systems that would allow for improved coordination of care and reduced costs for all patients. These changes will be particularly challenging for oncology care because most cancer physicians operate in private practice settings, use medical record systems that are not linked with each other or with the hospital, and work in practices that have limited resources or staff to build research capacity. Thus, implementation of the NCCCP has been quite timely in engaging these selected community hospitals such that, with NCI guidance through the NCCCP, they are able to be leaders in preparing community hospitals for the shift to more personalized medicine. However, the timing of NCCCP implementation has also occurred within the context of a severe economic downturn and amidst significant policy uncertainty due to ensuing discussions of national and state health care reform. These developments affected health care payers (e.g., state governments, private employers, and insurers), provider organizations like the NCCCP pilot hospitals and cancer centers, and patients. For example, because of the fiscal constraints the downturn placed on state budgets, several states acted to lower the federal poverty level (FPL) eligibility or increase requirements and/or raise copayments for Medicaid in order to limit coverage. It was within this context that the NCCCP hospitals and cancer centers were establishing a public-private partnership with NCI

to implement the program. This type of partnership was new to all of the key players involved and required a great deal of innovation from all. The value of implementing this program through a public-private partnership (i.e., NCI support in combination with local hospital, physician, and community investments) cannot be overstated. NCI provided a fairly small portion of the funds needed for each hospital to implement the changes necessary to be successful across NCCCP program components. Each hospital had to believe in the business case for the NCCCP and increase expenditures in IT, clinical trials research, and the disparities area at a minimum, and often for the other program components as well. These costs were tracked and itemized as part of the micro-cost study (Dalton et al., 2011). Findings indicated that implementation of the NCCCP marked a significant investment in cancer care for each participating hospital above and beyond what NCI funds would support. Specifically, each hospital was required to have a policy that included investment in cancer care that may have been new to them. First, they were required to offer treatment to patients who are screened for cancer and are subsequently diagnosed with cancer regardless of a person's ability to pay. Second, each hospital was required to provide a co-investment of funding to support the achievements of the program requirements. The hospitals agreed to these requirements without anticipating the national economic downturn.

ES.2 Methods

A theory-driven, comprehensive evaluation of the NCCCP pilot was conducted, examining five levels of implementation—network, organizational, programmatic, for each of six program component areas, and patient—using a multi-method, multi-year approach to assessing implementation for the program overall and for each of the program component areas. Through the evaluation, we learned a great deal about the extent to which sites reported being able to achieve key outcomes and the structures and processes that seemed to facilitate NCCCP implementation.

RTI used seven primary study methods: a case study, two economic studies, a patient survey, a comparative evaluation that assesses practice pattern changes over time between NCCCP sites and similar community hospitals not participating in the NCCCP, an environmental analysis of local markets and communities, and a special analysis of findings specific to clinical trials research. This seventh study was added in June 2011 to examine clinical trials data for the NCCCP in comparison to national trends in clinical trials research among similar hospitals. This report focuses on the findings for the overall evaluation, incorporating data from all data sources.

ES.3 Results

Defining success, overall and for the program components, required time and experience with the NCCCP sites. Through monthly phone conferences with the NCCCP Program

Advisory Committee (NPAC) and NCI leaders in each programmatic area, site participants worked with each other on numerous workgroups developing specific activities for each of the program component committees (e.g., developing tools for psychosocial assessments and MDC assessments). Beyond the monthly committee and subcommittee meetings, we also know that sites were actively seeking out one another to develop projects and collaborations. From what we learned, we were able to quantify that most had strengthened their relationships with their key cancer physicians, enhanced their cancer research capacity, and built an infrastructure to address ongoing growth in cancer services in the coming years. Most sites were able to achieve specific accomplishments such as

- enhancing research capacity in key areas, particularly in trial capacity and infrastructure (e.g., staff);
- improving their quality of care for key indicators of breast and colon cancer treatment;
- leveraging a high level of matching funds for implementing NCCCP activities (Dalton, et al., 2011);
- establishing stronger relationships with their key cancer physicians (e.g., more involved in MDC conferences); and
- implementing new tools developed specifically for (and in collaboration with) NCCCP sites (e.g., MDC matrix, CT accrual log).

Areas where sites had fewer accomplishments (i.e., evident at fewer sites) included building collaborations both with agencies in their community and with NCI-designated cancer centers, and increasing their knowledge and skills with respect to the entire continuum of care (e.g., survivorship had minimal measurable growth).

In terms of accomplishments specific to the cancer program components, sites that had more outreach workers seemed to be able to achieve more in the disparities program component. This finding is likely to be because outreach workers tend to focus on establishing new and/or more formalized partnerships with local agencies and use those relationships to provide more screenings to people living in low-income areas. For clinical trials, sites were able to increase the number of physicians accruing to clinical trials, but had minimal change in the total number of patients accrued to trials according to some of the self-reported data. However, CTEP data suggest that increases in patient accruals among NCCCP sites were at or above those of other similar hospitals in the United States during the same period of time (Abernethy & Locke, 2011). For quality of care, all sites were able to increase the number of MDC conferences they had and establish within their cancer programs patient navigators whose role included increasing the coordination of patient care. Although nearly all of the sites were able to increase the number of MDC conferences and the involvement of physicians in them, we were unable to identify organizational factors to explain this accomplishment (i.e., those that we did examine quantitatively do not seem to explain this change). Of the three sites that demonstrated the highest overall improvement

in the reduction to their nonconcordance rates as assessed through the RQRS, two had a physician director of their cancer program, as did one of the sites with the lowest level of overall improvements (Halpern et al., 2011). Other organizational factors were examined in terms of their relationship with changes in RQRS measures, but none appeared to be strongly linked to positive changes.

ES.3.1 Facilitators of Program Accomplishments

Organizational factors that seemed to be at least somewhat associated with overall achievements included having a physician director of the cancer program and a program coordinator (specific to the NCCCP) and having a direct reporting relationship between the cancer program and the hospital's top management. The sites' baseline capacity (i.e., composite measure of their total cancer patient volume and patients accrued to clinical trials as well as time allocated to a physician medical director of their cancer program as of 2006) was associated with clinical trials outcomes. Local market characteristics as we assessed them were not associated with any outcomes, although the environmental factor of whether the state within which a site is located mandates coverage of clinical trials was associated with accomplishments in this area.

ES.3.2 Barriers to Program Accomplishments

Community hospital characteristics that seemed to pose challenges to implementation included a heavy reliance on private practice physicians, limited capacity and/or infrastructure for increasing clinical trials, limited access to key cancer physicians (e.g., subspecialists), and a lack of integrated EHRs both between the hospital and their cancer physicians and among key cancer physician practices.

ES.3.3 Sustainability

Sustaining a program such as the NCCCP beyond the funding from NCI would require a great deal of investment from each of the participating hospitals and the belief that their ongoing work in the six program areas would help them enhance their capability to contribute to the NCI research mission and improve cancer care within their service area. During the Year 3 site visits, we asked respondents if they had plans for sustaining the NCCCP beyond the pilot (assuming NCI funding ends) and which components, if any, would be the most or least likely to be maintained through the hospital's investments. Nearly all respondents shared that they believed a few components of the NCCCP (e.g., clinical trials, quality of care) would certainly be continued, even without federal funding, but that others (e.g., disparities, biospecimens) would be far more challenging to maintain without external funding in the current economic environment. Sites noted that they would continue to provide palliative care and some services to cancer survivors but that the growth of these programs would be less likely without external funds.

ES.4 Summary

Throughout this report, we present a multitude of data, outlining a variety of opinions and perceptions about implementation of the NCCCP pilot as well as factual data on specific achievements that were made. Using qualitative analysis techniques to examine these findings, we then worked to identify cross-cutting themes for organizing high-level conclusions about the program. For the NCCCP, we identified 10 overarching themes that are well supported by multiple data sources:

- Baseline variation in organizational characteristics made it difficult to set benchmarks for program implementation.
- The NCCCP pilot requires time for start-up and prioritization of goals.
- Establishing a public-private partnership between NCI and the participating hospitals provided the NCCCP with tremendous benefits.
- Support from hospital's top management facilitates program implementation.
- NCCCP activities require physician leadership.
- NCCCP activities require involvement from numerous cancer physicians.
- Communication and coordination across program components facilitates NCCCP accomplishments.
- The NCCCP enhances cancer research capacity.
- The NCCCP network, with NCI guidance, provided important collaborative learning opportunities.
- Sustainability depends on maintaining a connection to NCI.

ES.5 Recommendations

As previously described, the NCCCP model encompassed a number of concepts that were based on the rationale that most cancer care occurs in the community. This reasoning was grounded in the thinking that if cancer outcomes are to improve and research is to be expanded, more attention needs to be paid to the locations where the majority of cancer patients are likely to access cancer care in their communities. In the final analysis, the evaluation findings support two overarching recommendations for future program development that are supported by the themes for conclusions (Table ES-1).

ES.5.1 Recommendations Specific to the NCCCP Model

ES.5.1.1 Aspects of the NCCCP Model Supported by Evaluation Findings

The NCCCP model incorporated the six key program components that were designed to address cancer care across the continuum and influence the participating hospitals to build their cancer research capacity. Although the primary focus on enhancing research was through conducting clinical trials, sites were also to identify ways to improve collection and reporting of high-quality biospecimens. These research components combined with

enhancing aspects of cancer care by improving both access to and quality of care, as well as increasing survivorship and palliative care services, established a model for the program that was quite broad and complex. Overall evaluation findings strongly support that the model should continue to be

- conducted through a public-private partnership between NCI and selected hospitals,
- focused on addressing cancer health disparities and cancer research, and
- supported by the NCCCP network and ongoing involvement from NCI staff.

ES.5.1.2 New Aspects to Consider for the NCCCP Model

Additional aspects of the NCCCP that would benefit the future development of the program include

- establishing explicitly defined phases of the program so that sites can better set priorities and direct their efforts over time, and
- encouraging formal collaborations between NCI research programs and the NCCCP.

The NCCCP pilot required a great deal of time for sites to first understand what was expected of them and then apply it to their cancer program (i.e., most sites took at least 1 year for this process). Some of the sites started out as very strong in many of the program components, but no one site was a leader in all six areas of the NCCCP. Because sites were relying mostly on physicians and others who were implementing aspects of the NCCCP in addition to their otherwise full-time positions (and not necessarily for the benefit of their private practice, when applicable), it may have helped sites to achieve more measurable outcomes if they had first prioritized where they wanted to focus their efforts and developed work plans that involved phasing or staging the components into their program over a specific period of time. In addition, NCCCP sites were encouraged by NCI to develop linkages with NCI-designated cancer centers and other members of the NCI Cancer Research Network in order to enhance their capacity for conducting cancer research. Our findings showed that sites were quite challenged in establishing these linkages. Several respondents noted how difficult it was for them to develop a working relationship with others in the research network. A new aspect of the NCCCP model that NCI could consider is to encourage the other members, such as NCI-designated cancer centers, to work with the NCCCP sites. Examples of ways this could be accomplished include providing funding opportunities to the larger cancer centers that would enable them to actively partner with NCCCP sites, publicly recognizing those centers that have established these types of relationships, and creating the expectation that these linkages are part of the responsibilities of others in the network in order to provide people with greater access to the most advanced types of treatments in their communities.

ES.5.2 Recommendations Specific to Organizational Requirements for Future NCCCP Sites

As NCI makes decisions about whether to expand the NCCCP, consideration should be given to the variation of future sites. Although it was important to have a broad diversity of sites participating in the pilot in order to learn about the variables to consider in selecting sites, these lessons learned can now be applied to the selection of future sites. From our evaluation findings, we recommend that a more similar set of hospitals with key characteristics be selected for participation and that NCI start by setting benchmarks from which each hospital needs to start in order to be selected. We recommend that program requirements for sites emphasize the following:

- **Alignment of fit** between the NCCCP aims and the hospital's mission, including
  - **History of providing charity care** to their local community and programs for their local community as part of their hospital's mission; and
  - **Demonstrated top management support** that is assessed through more than a letter of commitment from the CEO but requires details on specific ways in which the senior executives will provide ongoing support and visibility for the program and its staff;
- **Capacity for conducting clinical trials research** such that there is at least 1 clinical research nurse on staff, an NCI trial has been opened at the site within the past 2–3 years, and the site is a member of at least a small number of cooperative trial groups to ensure they have ready access to trials; although the number of patients accrued in the year prior to the NCCCP was used as the benchmark for clinical trials capacity (n=25 or more for lead sites), setting the bar higher with more specific indicators of capacity would ensure greater accomplishments;
- **Hospitals with specific organizational characteristics**, including
  - **Medium size to large hospitals** with a greater patient volume (while still allowing for variation in community size so that rural areas are included) and access to a broader array of subspecialists (e.g., require that they have at least a minimum number of medical and radiation oncologists collocated in their cancer center, have at least one type of surgical specialist, and do not rely only on general surgeons);
  - **A physician director of their cancer program** with a set minimum proportion of their time allocated to this position (e.g., 25% or greater); although lead sites were required to have this physician in place at the end of the pilot period, the leadership this role brings to the program is essential to facilitating many of the key activities (e.g., engaging physicians in attending MDC conferences, implementing conditions of participation); thus, a physician director is needed from the start;
  - **A direct reporting relationship** between the cancer program's physician director and one of the senior executives (CEO, COO) to provide ongoing access to hospital resources and support;

- **A distinct cancer service line**, although not necessarily a standalone cancer center, but an organized set of activities and staff, under the leadership of the physician director, that demonstrates coordination across key areas of cancer care;[1]

- **A program coordinator** specific to the NCCCP whose primary role includes coordinating activities across the program components; and

- **An NCCCP principal investigator with direct access to the physician director** of the cancer program and perhaps to the senior executives and who is not otherwise embedded in the hospital's structure or far removed from the cancer program that he/she will have little impact on influencing peers to participate in activities; and

▪ **A core set of physicians become engaged in and commit time** to the NCCCP, perhaps as identified leaders at baseline for each program component the site is to address. These physicians need to include more than the principal investigator and/or the cancer program medical director, perhaps including one from each of the treatment modality specialties (i.e., clinical and radiation oncology, and surgery) and together one can serve as the lead, while the others are co-leads or in some designated role from the start. Their role can include facilitating involvement in NCCCP activities among their peers.

[1] While a selection criterion for pilot sites was that they have an integrated cancer service line at baseline, we found this not to be the case for all of the sites, including some lead sites. During each site visit, we created organizational charts for each cancer program that we tracked over time to monitor how each changed. At the beginning of the pilot, eight sites had fragmented cancer service lines, with programs located in different parts of the hospital's organizational structure and reporting structures that hindered the integration of NCCCP activities.

Table ES-1. Overarching Recommendations Mapped to Supporting Conclusions and Specific Recommendations

Overarching Recommendation	Supporting Conclusions	Specific Recommendations
Changes to the NCCCP model	NCCCP pilot requires time for start-up and prioritization of goals.	▪ Establish phases of the program (e.g., sites can focus on capacity building during the first 6 months and identify focus areas). ▪ Allow sites to focus on 2–3 program component areas at a time, rather than all 6 (or more). ▪ Assign "mentors" to new sites such that those that have been implementing the NCCCP can provide specific guidance and orient new awardees.
	Establishing a public-private partnership between NCI and the participating hospitals provided the NCCCP with tremendous benefits.	▪ Federal government funding often requires a specific matching of funds for each dollar of an award. Given findings from the cost study, NCI could establish a 1:3 match such that for every $1 from NCI, the site has to demonstrate matching funds of $3.
	The NCCCP enhances cancer research capacity.	▪ Provide direction for integration of the NCI cancer research programs: – Highlight the value the NCCCP can bring to NCI-designated cancer centers and their research portfolio. – Establish the expectation that NCI-designated cancer centers have to create a formal linkage with at least one NCCCP site that involves more than patient accrual to trials.
	The NCCCP network, with NCI guidance, provided important collaborative learning opportunities. Sustainability depends on maintaining a connection to NCI.	▪ Create a plan for sustaining the collaboration across NCCCP sites: – Establish procedures for the network to become operationally self-sustaining. – Establish internal infrastructure within NCI that allocates staff to work on the program as part of their job responsibilities (e.g., a program coordinator at NCI similar to the role that several sites established).

(continued)

Table ES-1. Overarching Recommendations Mapped to Supporting Conclusions and Specific Recommendations (continued)

Overarching Recommendation	Supporting Conclusions	Specific Recommendations
Organizational requirements important to NCCCP implementation	Baseline variation in organizational characteristics made it difficult to set benchmarks for program implementation.	▪ Establish criteria that all hospitals must meet to ensure that those identified as NCCCP sites have at least a minimum set of characteristics at baseline (e.g., specific capacity for conducting clinical cancer research).
	Support from top management facilitates program implementation.	▪ Ensure that the NCCCP mission aligns with the strategic plan for the hospital's cancer program, including a history of providing charity care, and top management provides specific ways for which they will support the program.
	NCCCP activities require physician leadership. NCCCP activities require involvement from numerous cancer physicians.	▪ Select only those sites with a physician director of the cancer program already in place. Ensure support from other physician leaders by assigning responsibilities or roles at the start of the program, or somehow assess their commitment to NCCCP activities. Consider as a benchmark that hospitals have to have a minimum number of cancer physicians who are willing to take on leadership roles within the program (e.g., two cancer physicians with a minimal percentage of time available to devote to NCCCP activities, such as one to lead enhancing research capacity and another to focus on developing new MDC conferences; or consider only hospitals with at least one radiation oncology practice located in their cancer center since this was a key physician several had difficulty accessing).
	Communication and coordination across program components facilitates NCCCP accomplishments.	▪ Encourage sites to institute an NCCCP coordinating committee that works internally to effectively communicate and integrate program activities ▪ Select sites with a distinct cancer service line or with clear plans for integrating services during the program period ▪ Select sites that demonstrate that physician director of the cancer program has direct communication channels with hospital's senior executives

Part I: Evaluation Framework and Methodology

1. INTRODUCTION

The National Cancer Institute (NCI) selected RTI International to evaluate NCI's Community Cancer Centers Program (NCCCP), a pilot program that consists of community-based cancer centers designed to bring the latest scientific advances and the highest level of innovative care to patients in their home communities. During the first year of this project, RTI worked to thoroughly understand the NCCCP and develop a comprehensive evaluation plan. The overall evaluation is designed to address key evaluation questions at five possible levels of intervention:

1. inter-organizational or across the network of participating sites (henceforth referred to as the NCCCP network);

2. organizational, within the health systems and hospitals where the program is being implemented;

3. programmatic, for the impact on delivery of the cancer service line;

4. with regard to each of six program components (i.e., for accomplishments in the areas of biospecimens and clinical trials research, information technology [IT], quality of care, disparities, and survivorship care); and

5. individual, in terms of patients' perceptions of the quality of care they received during the pilot program.

Three overarching questions guide the NCCCP evaluation plan:

- What changes in each program component and for the cancer service line overall seem to be facilitated by the NCCCP?
- What organizational requirements are necessary to effectively implement/manage the NCCCP?
- What changes and elements are sustainable and potentially replicable?

For the overall evaluation as initially designed, RTI conducted a case study, two economic studies (a micro-cost study and a strategic case study), and a patient survey for providing ongoing feedback on overall program development and to document the lessons learned and impact of the NCCCP. In 2009, two additional aspects were added to the evaluation design: a comparative analysis of both NCCCP and non-NCCCP community hospitals participating in the Commission on Cancer's Rapid Quality Reporting System (RQRS) and an environmental analysis. In 2011, an additional component of the evaluation was added through a special analysis of clinical trials data, conducted by Duke University's Cancer Care Research Program, that compared NCCCP sites to similar hospitals over the course of the pilot program (2007–2010). This report incorporates findings from across all of the evaluation studies to assess the implementation of the NCCCP pilot.

1.1 Overview of the Overall Evaluation

In collaboration with NCI and the NCCCP Evaluation Oversight Committee (EOC), RTI developed an extensive Evaluation Design Report (EDR) that specified the methods and process for conducting the overall evaluation. For the case study, RTI conducted site visits during each of the 3 years of program implementation to obtain in-depth information about aspects of program design, development, and implementation. The primary evaluation outcomes specific to the case study were

- understanding NCCCP implementation,
- assessing change in site performance over time, and
- determining NCCCP structures and processes associated with successful performance.

The economic studies were designed to assess sustainability and the potential for replicability of the pilot. This part of the evaluation included both a micro-cost study of program activities and a strategic case study to identify the financial or other motivations for organizational participation in the NCCCP. For the micro-cost study, RTI developed a data collection tool that identified the funded and unfunded costs of activities attributable to participation in the pilot. The following were the primary questions addressed through the micro-cost study:

- What are the total implementation costs for the sites?
- What are the annual costs of operating the NCCCP?
- What is the distribution of costs across the core program components and across sub-activities within each component?
- What is the share of organization-matching versus government-funded costs?
- What is the contribution of donated time from community physicians, organizers, or other community-based clinicians?

RTI analyzed program cost structure by activity and source of funding for each year of program implementation. The strategic case study integrated original data gathered from executive interviews with secondary data on organizational, financial, and local market conditions. RTI conducted telephone interviews in fall 2009 with chief financial officers (CFOs) at each site (as well as follow-up interviews in 2011 for those CFOs who were still in the same position) to document expected financial returns (the traditional business case) and other short- or medium-term nonmonetary gains (the strategic case) that contribute to their notion of successful program intervention.

The overall purpose of the patient survey was to gain an understanding of the patients' perspective on the NCCCP pilot and to assess how well patients' health care and informational needs are being met. Through the survey, we assessed patients' overall

satisfaction with care, view of multidisciplinary care team coordination, knowledge of NCCCP services, emotional and financial support received from the program, and experiences with access to appointments and waiting time.

These data, in addition to secondary data analysis from surveys completed by the sites (e.g., baseline assessment survey) and other sources (e.g., Survey Application Record as reported to the Commission on Cancer), were analyzed for inclusion in the overall evaluation of the NCCCP pilot. Additional data were collected through the following methods and incorporated into this final analysis:

- a comparative evaluation of NCCCP sites, compared to similar community hospitals not participating in the NCCCP, on six key quality of care indicators for breast and colorectal cancer treatment as reported through the RQRS;
- a clinical trials study conducted by Duke University's Cancer Care Research Program to assess the progress of NCCCP sites in this program component relative to national trends in cancer research; and
- an environmental analysis of secondary data from multiple sources to assess local market competition and conditions that may influence NCCCP implementation.

Together, these data sources provide NCI with a wealth of information on the overall processes and procedures sites used in implementing the NCCCP and the lessons learned during each phase of program development.

1.2 Overview of this Report

This report presents overall findings from across all of the evaluation studies as measured over the course of the 3-year pilot program. Chapters 2 through 17 each present findings organized around our conceptual framework for the program evaluation. In Chapter 18, we conclude with a discussion of the overarching recommendations from across the NCCCP sites.

Because of the density of the findings presented, this report is divided into four large parts. Part I consists of Chapters 2 and 3. In Chapter 2, we start by presenting our evaluation framework along with relevant literature that was used to guide both the development of the framework and the protocols we used during each round of site visits. In Chapter 3, we provide details on the methods we used to collect and analyze data from across all of the evaluation methods.

In Part II, which includes Chapters 4 through 8, we present findings specific to the status of sites at the time of NCCCP implementation (i.e., at baseline) as well as their initial understanding of the program. In Chapter 4, we present baseline data for the participating hospitals, their cancer centers, and local markets and communities in order to provide an understanding of the status of these organizations prior to initiating the NCCCP. Starting with Chapter 5, we present findings from over 500 interviews conducted during Years 1, 2,

or 3 of the pilot, along with any supplemental information we have gathered from secondary data sources (e.g., Survey Application Record, tools developed by NCCCP subcommittees that provide data on site activities). Chapters 5 through 8 are each organized around aspects of our conceptual framework. Chapters 5 and 6 are based on data collected only during Year 1 site visits because that was when we focused on each site's understanding of the NCCCP and their readiness to change as an organization. In Chapter 5, we present data on how sites described their understanding of the NCCCP during the Year 1 site visits, how that understanding seemed to vary across different types of respondents, and the facilitators and barriers that are associated with sites being able to increase key stakeholders' understanding of the program. In Chapter 6, we present findings related to the hospitals' capacity for learning, innovation, and change, and the facilitators and barriers to making all the changes required to successfully implement each component of the NCCCP. Chapters 7 and 8 present findings across all 3 years of the pilot program. In Chapter 7, we review the organizational structures of each hospital and cancer program, and of the NCCCP program staff, and describe the changes that occurred between the Year 1 and Year 2 site visits. In Chapter 8, we present a detailed overview of how the sites coordinated and communicated NCCCP-related activities across the different program components. Chapter 8 also includes a description of the mechanisms and strategies sites put in place to effectively integrate the NCCCP into their ongoing cancer service line.

Part III, which consists of Chapters 9 through 14, presents findings for each program component in terms of the activities the sites were working to implement over the course of the pilot and the facilitators and barriers they were encountering. Each of these chapters focuses on one of the six NCCCP program components: disparities (Chapter 9), clinical trials (Chapter 10), biospecimens (Chapter 11), information technology (Chapter 12), quality of care (Chapter 13), and survivorship and palliative care (Chapter 14).

Finally, Part IV presents our overall conclusions for the program (Chapters 15 through 17), followed by a chapter on our recommendations (Chapter 18). In Chapter 15, we provide findings based on the linkages NCCCP sites have worked to create or enhance with each other during Years 1 and 2, or with other entities working with the NCI's national cancer research network (e.g., NCI-designated cancer centers). We present findings on the relationships that have been established as a result of the NCCCP and the barriers and facilitators associated with creating these linkages. In Chapter 16, we present overall findings specific to aspects of NCCCP implementation that seemed to be successful and those that sites found to be more challenging, as well as findings about the potential for sustainability of the program. In Chapter 17, we present our overarching conclusions from the integrated evaluation. We conclude the report with Chapter 18 in which we provide recommendations specific to future development of the program based on the overall findings.

1.3 Presentation of Findings

The results presented throughout this report are quite complex and have been reported systematically across all of the themes. The beginning of each chapter (for Chapters 5 through 15) provides an overview of the aspect of the program under review, followed by a presentation of findings as organized around themes. The development of these themes was first guided by our evaluation framework and then directed by the data as they were analyzed using state-of-the-art qualitative data analysis methods described by Miles & Huberman (2003). All data were meticulously reviewed, and themes were abstracted based on the overall findings for each topic area. Quotes presented throughout the report were selected to illustrate the themes under discussion and to provide the reader with an understanding of how each theme was envisioned by our analysis team. Much of the data described throughout Chapters 5 through 15 are presented as quotes. All quotes have been de-identified to protect the identity of both the sites and the respondents. Quotes are presented verbatim unless there are brackets around a word or phrase. These brackets indicate edits to quotes in order to assist the reader in understanding the meaning of each quote. If only a portion of a quote is used within a paragraph, it is presented as regular font and in quotation marks, but if it is separated from the text and presented on its own, it is presented in italicized font and indented. At the end of each quote, we have identified the speaker in one of five possible categories:

- system/hospital leadership staff—these individuals include all chief executive officers (CEOs), chief operating officers (COOs), chief information officers (CIOs), chief medical officers (CMOs), and other leaders responding from the perspective of either the system or the hospital;
- cancer center/program staff—these individuals include all cancer center medical directors, cancer center administrative staff, and staff who have been assigned with specific roles on the NCCCP (not including principal investigators [PIs] or program coordinators);
- principal investigators (PIs);
- program coordinators—these individuals were identified by the sites have having the role (formal or informal) of coordinating the program and were interviewed separately during the Year 2 visits; and
- key physicians—these individuals include any key cancer physicians who provide care to patients served by a participating cancer center.

In addition to quotes, we present data from multiple data sources, which are described in Chapter 3. Because this report is so long, the presentation of data in tables appears at the end of each chapter to ease the reading of findings. Within each table, we have specified the data source for each indicator so that the reader can understand the vastness of the information being presented and the variation in what was reviewed and discussed. In presenting any data in this report, we have used rigorous methods to both validate and reliably report the findings provided to us by the sites and others involved in this evaluation.

2. NCCCP EVALUATION OVERVIEW

The ultimate aims of the National Cancer Institute's (NCI's) Community Cancer Centers Program (NCCCP) pilot were to expand cancer research capacity and deliver the latest, most advanced cancer care to more Americans in the communities in which they live. To achieve these aims, NCI established an NCCCP network of participating community hospitals, systems, and their cancer centers, focusing on six program components:

- reducing **disparities** across the cancer continuum;
- enhancing **clinical trials** research;
- increasing capacity to collect **biospecimens** per NCI's best practices;
- improving the use of **information technology (IT)** and electronic health records (EHRs)[1] to support improvements in cancer research and care delivery;
- improving access to and **quality of cancer care** and related areas, such as the development of integrated, multidisciplinary care teams; and
- placing greater emphasis on **survivorship** and palliative care.

Because the NCCCP pilot was administered as a subcontract rather than as a grant, specific deliverables for each component were required from the sites chosen in 2007. However, the six program components had differing levels of importance. Disparities was the most important program component, with 40% of the funding. The clinical trials component was also very important because it is central to NCI's overall mission (i.e., conducting research) and the ultimate aim of expanding the nation's clinical trial capacity. Because the NCCCP pilot sites, which consist of the selected community hospitals and their affiliated cancer centers, in general, were relatively new to collecting biospecimens and/or developing IT systems to support cancer research and care, NCI focused on having the sites assess their capacity in these areas and addressing gaps as feasible during the 3-year pilot program. For this reason, these two components were not key elements of the overall program evaluation, primarily because the sites did not have deliverables specific to these two components that were associated with outcomes. Although sites were to invoice their costs only for the first four program components, quality of care and survivorship/palliative care were important areas of development, each with key outcomes for the sites to achieve. Survivorship was also quite active, but the sites generally had less capacity in this area from the start and, because they were receiving no funds to address this area specifically, this component was included in the overall evaluation but few outcomes were measured that we could analyze over time. Therefore, of the six program components, we focused much of the overall evaluation on disparities, clinical trials, and quality of care.

[1] Throughout this report, we refer to electronic health records (EHRs) rather than electronic medical records (EMRs) and have sometimes changed this acronym in quotes (from what the speaker used) to maintain consistency.

This report presents findings from the overall evaluation of the NCCCP pilot over the course of the 3-year pilot implementation. NCI awarded a subcontract to RTI International in 2007 to conduct an independent evaluation of the NCCCP pilot using a multimethod, multiyear evaluation design. The overall evaluation was designed to address key evaluation questions at five possible levels of intervention: (1) inter-organizational, through the network or learning collaborative developed by NCI to administer the NCCCP; (2) organizational, within the systems and hospitals where the program is being implemented; (3) programmatic, for the influence of the NCCCP activities on delivery of the cancer service line; (4) program component, for each area of activities conducted for the NCCCP; and (5) individual, in terms of the patients' views on the quality of care received during the pilot program within each participating hospital. Three overarching questions guided this evaluation plan:

1. What changes in each program component, and for the cancer service line overall, seem to be facilitated by the NCCCP?
2. What organizational requirements are necessary to effectively manage/implement the NCCCP?
3. What changes and elements are sustainable and potentially replicable?

RTI used six study methods to support the evaluation: a case study, two economic studies, a patient survey, an environmental analysis of local markets and communities, and a comparative evaluation that has assessed practice pattern changes over time between NCCCP sites and similar community hospitals not participating in the NCCCP.

Before the evaluation could be conducted, RTI needed to spend time understanding how the program was designed, what NCI hoped would be its achievements, and what underlying theories could be relied upon in developing constructs and domains of our measures. This chapter presents an overview of the current understanding of how programs like the NCCCP will likely succeed and the theoretical underpinnings used in designing the evaluation and its corresponding measures.

Before discussing the major findings and their implications for NCI and the participating hospitals, the context within which the NCCCP pilot is being implemented needs to be considered. The creation of the NCCCP pilot was based on the rationale that most cancer care occurs in the community (estimates are that up to 85% of cancer patients are served by community hospitals) and if cancer outcomes are to improve and research is to be expanded, there needs to be more attention paid to the locations where the majority of cancer patients are likely to access cancer care. Most cancer care is now multimodal (i.e., a combination of treatment that includes radiation, chemotherapy, and/or surgery), which requires better coordinated care through such strategies as multidisciplinary care conferences that can obtain input from a broad array of cancer specialists on the treatment plan for each new cancer case. This can be particularly challenging for oncology care because most cancer physicians operate in private practice and use medical record systems

that are not linked with each other or with the hospital, and the practices have limited resources or staff to build research capacities. Thus, implementation of the NCCCP through a public-private partnership with NCI has been quite timely in engaging these selected community hospitals such that, with NCI guidance through the NCCCP, they were able to be leaders in preparing these community hospitals for the shift being brought about by the national health care reform. However, the timing of NCCCP implementation has occurred within the context of a severe economic downturn, which has been a historic event with the potential to greatly influence what these hospitals could reasonably accomplish within the 3 years of the pilot.

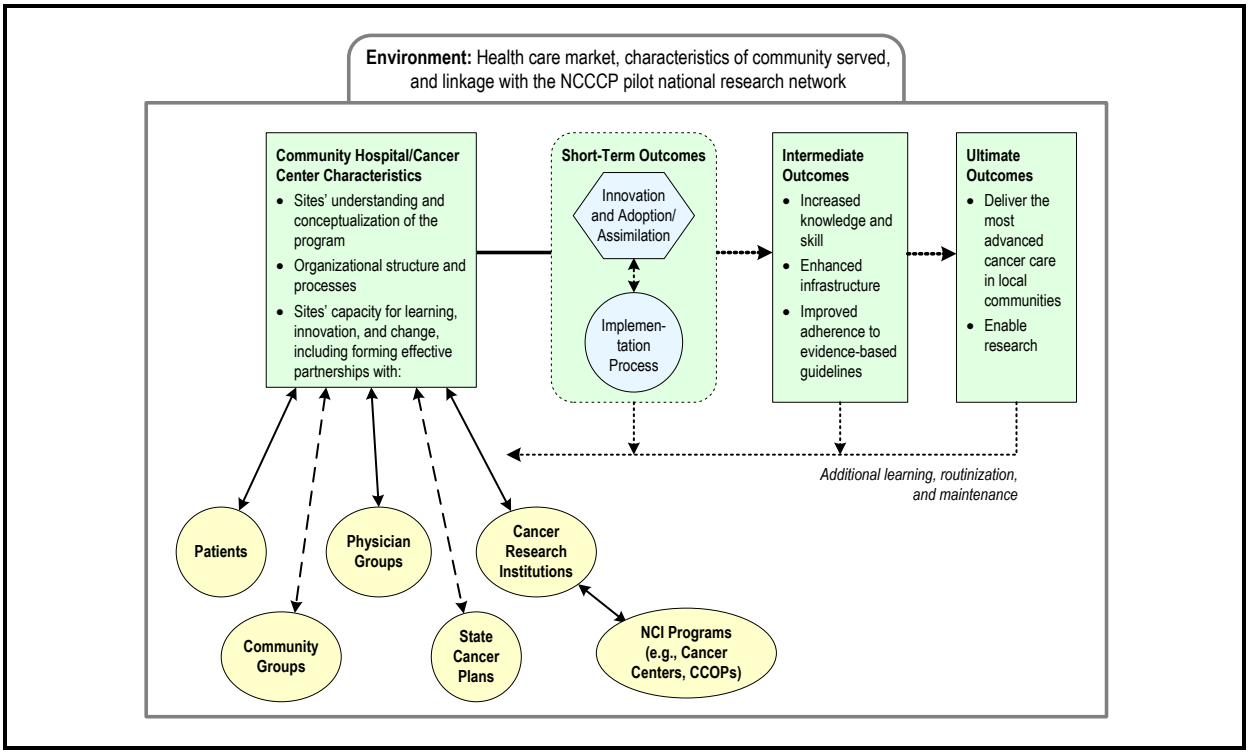
In late 2008, slightly more than a year after the NCCCP began, an economic downturn began unlike any since the Great Depression. During this downturn, the national unemployment rate rose to over 10%, and a growing number of people have lost their health insurance coverage. These developments affected health care payers (e.g., state governments, private employers, and insurers), provider organizations like the NCCCP pilot hospitals and cancer centers, and patients. For example, because of the fiscal constraints the downturn placed on state budgets, several states acted to lower federal poverty level eligibility or increase requirements and/or to raise co-payments for Medicaid in order to limit coverage. Access to capital, which supports the technology-dependent health care industry, and cancer programs specifically, was also greatly restricted. It was within this context that the NCCCP hospitals and cancer centers were establishing a public-private partnership with NCI to implement the program. Specifically, each hospital was required to have a policy that it would offer treatment to all patients who were screened regardless of a person's ability to pay, and each was required to provide a co-investment of funding to support the achievement of the program requirements. This requirement set a precedent for such a public-private partnership between NCI and the participating hospitals in that no other NCI programs have ever had this requirement. The hospitals agreed to those requirements without knowing what lay ahead in terms of their ability to meet it and without anticipating the national economic downturn.

2.1 Overview of the NCCCP Evaluation Conceptual Framework

To conduct a comprehensive program evaluation, a major step is to thoroughly describe the program under study (Holden & Zimmerman, 2009). RTI approached the NCCCP evaluation in this way by first reviewing the literature and developing conceptual frameworks to depict how the program is expected to create change. Since the NCCCP was a new program that was in the process of being designed, this was a critical step in the evaluation planning in order to clearly specify the overarching evaluation questions and design methods and measures that would assess each. For some programs, it may be useful to create more than one model or framework that depicts different levels of the evaluation. Having models to depict different levels can help the evaluator better understand the program and incorporate

corresponding processes and outcomes into the overall conceptual framework for the evaluation. A conceptual framework is generally more theoretically based and conceptual than a logic model. It can be used to conceptualize how variables related to the program go together and work to create change (Holden & Zimmerman, 2009). Wholey notes that "evaluation is unlikely to be useful unless certain 'evaluation planning standards' are satisfied—(1) program objectives are well defined, (2) causal links between program activities and objectives are plausible and testable, and (3) intended uses of evaluation information are well defined" (1978, p. 53). As RTI worked with NCI to develop the framework, we also began to specify evaluation questions of interest by creating evaluation planning matrices (described in Chapter 3). Using these matrices, RTI was able to better specify domains or areas of interest to include in the evaluation plan. This section provides an overview of the conceptual frameworks (Figure 2-1) developed to guide the NCCCP evaluation and the corresponding literature.

Figure 2-1. NCCCP Evaluation Conceptual Framework



2.1.1 Organizational Learning

Organizational learning has been defined as "the process of improving actions through better knowledge and understanding" (Fiol & Lyles, 1985, p. 803) or "the detection and correction of errors" (broadly conceived, as in gaps between actual and desired performance) (Argyris & Schön, 1978, pp. 2–3). In addition, organizational theorists have differentiated between three types of learning:

- *Single-loop (or adaptive) learning* occurs when errors are detected and corrected and organizations continue with their present policies and goals or when the learning adds to the organization's knowledge base, specific competencies, or routines without altering the fundamental nature of the organization's activities.
- *Double-loop (or generative) learning* occurs when, in addition to detecting and correcting errors, the organization questions and modifies its existing norms, procedures, policies, and objectives or more fundamentally changes its activities, knowledge base, and specific competencies.
- *Deutero (or secondary or meta-) learning* occurs when an organization learns how to carry out single- and double-loop learning. The first two forms of learning will not occur if the organization is unaware that there is a gap in performance and that learning must occur or if the organization is unable to create the conditions (e.g., structures, processes) required to learn.

Double-loop and deutero learning are fundamentally concerned with why and how to change the organization. Single-loop learning is concerned with changing the organization within the framework of existing goals, policies, and procedures.

Innovation and change simply cannot occur without learning. The term "innovation" typically refers to successfully carrying out something new and useful, such as implementing new structures (i.e., ways of organizing), new processes (e.g., methods, techniques, routines), or new products and services. In most fields, something new must be substantially different to be considered innovative, and the goal of innovation is to make something better (e.g., strengthening research capacity, improving outcomes, such as quality of care). However, some changes may deal with any modification in organizational structures, processes, or products and services and do not necessarily involve learning (particularly double-loop or deutero) or something substantially different (i.e., innovation).

In health care, a variety of techniques have been developed to facilitate organizational learning, innovation, and change. For example, within organizations, approaches that may be used include restructuring, total quality management, process re-engineering or redesign, and patient-focused or patient-centered care. Across organizations or within wider professional communities, approaches like collaboratives of various kinds can be established and used, to facilitate the exchange of ideas and approaches across organizations.

Given the nature of the NCCCP, the conceptual framework used for the evaluation primarily drew on the theoretical literature and applied research on learning, innovation, and change. We also drew on related theoretical literatures and applied research in health care, including quality improvement, process re-engineering or redesign, patient-focused or patient-centered care, implementation research, learning collaboratives, diffusion and dissemination of innovations, hospital-physician relationships, and partnerships with community-based organizations and coalitions.

2.1.2 Key Domains of the Conceptual Framework

A vast amount of theoretical literature and applied research exists in the areas of general organizational learning, innovation, and change, and related areas in health care. Therefore, we conducted a targeted literature review and relied on key experts in organizational learning and management and its application in cancer care (including from our RTI evaluation team member, Dr. Kelly Devers, and through NCI's Evaluation Oversight Committee, or EOC, led by Dr. Mary Fennell, and including members such as Drs. Arnold Kaluzny and Bryan Weiner), identifying relevant peer-reviewed articles, books, and book chapters on these subjects to identify the key constructs to incorporate into the NCCCP evaluation plan.

Based on our literature review, we found that no one theory was adequate to inform our evaluation of the NCCCP. Rather, we needed to draw upon several theories to understand and evaluate different aspects of the program. For example, some theories were more helpful than others for depending on the unit of analysis (e.g., organization or site, program, patients), the specific program component and related tasks (e.g., inventing new strategies and tactics or implementing those that are more well-established), and the specific evaluation question (e.g., how to accelerate implementation, how to disseminate proven or promising practices). In addition, there is a related literature on measurement of these organizational constructs related to program innovation and implementation, as well as the outcomes related to specific components or overarching NCCCP pilot aims.

Drawing on related literature, theories, and empirical research, we identified key domains and constructs to inform the development of the conceptual framework to evaluate the NCCCP (Figure 2-1). The major domains are

- the local and national environment in which each hospital operates, including linkages with NCCCP staff and the NCCCP network;
- characteristics of each hospital and cancer center and the "fit" between the characteristics of the cancer center and program components and related tasks required;
- relationships with patients, community groups, private practice oncology groups, and other NCI-designated cancer centers; and
- the innovation, adoption/assimilation, and implementation process.

These major domains can be thought of as encompassing the *context* (within the cancer centers and the local and national environment) in which the NCCCP is being invented and implemented, the *content* or nature of the NCCCP itself and its fit with each cancer center's characteristics, and the *process* of implementing the NCCCP both by the cancer centers and at the NCCCP network level.

Within each of these general areas (context, content, process) and key domains, there are key subdomains and constructs. In other words, these broad domains include a number of elements and key concepts, which we define and discuss below.

Based on the literature and empirical research, we also identified or developed general hypotheses about how these domains and constructs will affect cancer centers' ability to make greater progress toward achieving intermediate goals and ultimately the desired program outcomes—for example, how key aspects of the environment or cancer centers' characteristics may affect their ability to innovate, to adopt and assimilate innovations made by others, or to implement changes required by the NCCCP. These hypotheses are discussed in Chapter 6.

The following is a brief description of these key domains, subdomains, and constructs, organized around the components of our framework (Figure 2-1).

2.1.2.1 Environment

Theoretical literature and empirical research suggest that the environment (or context) in which an organization operates significantly affects its ability to learn, innovate, and change. This is because organizations like cancer centers are dependent on other organizations (e.g., insurers) for key resources for which they must compete with other organizations (e.g., other cancer centers or oncology groups). In addition, organizations attempting to learn, innovate, and change will not only utilize their own internal talents but will seek out sources of expertise and ideas in the wider environment. Collaboratives or learning networks created by national organizations, experts, and peers, as well as existing social networks, are potential sources of expertise and ideas.

With respect to the NCCCP, three aspects of the environment are likely to be particularly important: the nature of local health care policy and the health care market, the characteristics of the community served, and the linkage with the NCCCP network. As described in Chapter 1, the NCCCP pilot included 16 sites, which operate in 14 states. Although national policy (e.g., Medicare) affects all of them, each site also exists in a state and community with unique characteristics that may influence their ability to achieve the aims of the NCCCP. We describe below how these three aspects of the environment may directly impact NCCCP implementation.

Local Health Care Policy and Market

One key aspect of the local health care policy environment is whether insurers are required to cover the cost of clinical trials. States determine policy in this area and vary in their stances. There may be other policies that vary by state (e.g., Medicaid eligibility and coverage) and have an impact on cancer centers' ability to achieve some of the NCCCP aims.

Additional aspects of the local health care market that are likely to be important include the insurance (or payer) mix, the degree of insurance or health plan consolidation, the insurance or health plan behavior (e.g., quality measurement, monitoring, pay-for-performance), and the power of the cancer center relative to insurance plans and competitors (e.g., other cancer centers, physician groups, academic medical centers [AMCs]). For example, some states and markets have relatively low rates of uninsured populations and those with relatively comprehensive health insurance benefit packages. As such, these states and markets have removed or minimized one potential barrier to improving the quality of cancer care and reducing disparities. Similarly, some private insurer plans dominate certain markets, have developed quality monitoring and public reporting activities, and are beginning to develop pay-for-performance systems. Although these activities are not yet typically applied to cancer care, they give cancer centers incentives to develop the infrastructure necessary to improve quality. Finally, the market share and power of a participating cancer center relative to other hospital systems and physician groups is often important. On the one hand, greater competition and less market share power may stimulate cancer centers to work harder to learn, innovate, and improve. On the other hand, too much competition and not enough market share or power may result in cancer centers focusing on survival and devoting insufficient resources to learning, innovating, and improving.

This dimension of the environment—local health care policy and market—is clearly related to cancer centers' strategic case for the NCCCP. Other influences from the environment that might impact NCCCP implementation include the site's financial viability and operating profit margin relative to competitors in the local community. Sites will need to perceive that the NCCCP can provide them with benefits, beyond the funding provided by NCI, that are more valuable than the anticipated costs of implementing the program. The profitability of the hospital and how the NCCCP may impact it are measures incorporated into the evaluation at both the environmental level (e.g., fiscal health of the NCCCP sites relative to others in the community) and the organizational level (e.g., profitability of oncology services).

Community Characteristics

Two key aspects of the characteristics of the communities in which cancer centers are located, besides insurance coverage and insurer/payer mix, are the demographics of the community (e.g., age, race/ethnicity, education) and the existing community organization landscape. Each cancer center participating in the NCCCP exists in a community with a different demographic profile, which shapes the opportunities and challenges related to improving quality, reducing disparities, and increasing participation in clinical trials and other types of cancer research. Similarly, each community has different assets, social networks, and organizations (e.g., government, foundations, community-based organizations) on which to build efforts to improve the quality of cancer care and research. Therefore, the specific demographic profile and community organization landscape provided

unique opportunities and challenges for cancer centers or sites as they worked to achieve the ultimate aims of the NCCCP.

NCCCP Network

NCI and its support subcontractor, SAIC-F, through their programmatic or subcontract administration responsibilities and activities, provided technical assistance and facilitated communication across the 16 participating sites through the NCCCP network, which emerged over the course of the program. This network included the NCCCP sites themselves and NCI staff involved in NCCCP implementation. Initially, monthly conference calls were convened that included the site principal investigators, lead NCI staff, and others from the participating sites to discuss program activities. Over time, the network evolved to include monthly conference calls with specific subcommittees of staff from across the sites that were working on each program component. As these program component subcommittees evolved, the participants often identified activities or tools they wanted to work on together and would split off into workgroups to achieve discrete objectives (e.g., the Quality of Care [QOC] subcommittee created workgroups to develop a multidisciplinary care [MDC] matrix for sites to assess their progress in advancing their multidisciplinary care activities). Through the NCCCP network, NCI staff responsible for the NCCCP and specific program components provided information about the overarching aims of the program and mechanisms that could be used to achieve them by all cancer centers; however, they also provided input and advice to participating cancer centers on their own specific program goals and potential mechanisms for achieving them. In addition, NCI and SAIC-F worked to foster peer-to-peer learning through a variety of mechanisms, including encouraging the NCCCP cancer centers to interact with each other and seek guidance and mentoring from sites within the network. Previous research suggests that several aspects of technical assistance and learning collaboratives may influence whether and how rapidly organizations like cancer centers will be able to innovate, adopt/assimilate innovations developed elsewhere, or implement well-defined elements of the NCCCP. These aspects include the frequency, mechanism (e.g., in-person versus phone), format (e.g., highly structured versus less structured), and quality of the interactions and information shared among NCI, SAIC-F, and cancer centers, and between cancer centers. Only a few evaluation questions were specific to this level of NCCCP implementation. We had hoped to examine the extent to which the sites learned and benefited from both the network and the guidance provided them by NCI Program Advisory Committee (NPAC) members, and at least the extent to which they participated in calls and subcommittees. Unfortunately, the overall evaluation results described in this report do not include findings at the network level because data were unavailable or lacking in specificity for the level of detail needed in our analysis.

2.1.2.2 Community Cancer Center Characteristics

As shown in Figure 2-1, the next major domain included in our conceptual framework is the characteristics of the cancer center, which includes characteristics of the hospital within which each cancer center operates. Each cancer center or NCCCP site is unique, both in terms of its prior history and experiences and its structure and functioning when the NCCCP began. One understands intuitively that the "initial condition" (or starting place) of a cancer center or NCCCP site impacts its ability to learn, innovate, change, and succeed in the NCCCP. However, what specific aspects of each cancer center's characteristics might be most important in these regards?

The literature and empirical research previously described suggests that four major subdomains are likely to impact the ability of a cancer center or NCCCP site to learn, innovate, change, and succeed in the NCCCP. These include the cancer center's or NCCCP site's understanding and conceptualization of the NCCCP; existing organizational structure and processes; capacity for learning, innovation, and change; and ability to form effective partnerships with key groups in the community.

Understanding and Conceptualization of the NCCCP

In order for cancer centers or NCCCP sites to understand what they need to do to succeed in the NCCCP, they must have a clear understanding of what the NCCCP is and what success would look like, both nationally and at their own institution. Although this may seem obvious or straightforward, it is not. The NCCCP itself is a new, ambitious program that combines a number of goals and related program pillars that historically have not been part of a single program. In addition, community hospitals are central to this effort, and to date they have not been very involved in this combination of activities. Finally, the NCCCP is a pilot and, as such, is a work in progress.

Given the uncertainty associated with any new program pilot, the NCCCP network and individual cancer centers and NCCCP sites engaged in the potential examination and alteration of existing "mental models" and what researchers refer to as "sense-making." Sense-making is the process of creating situational awareness and understanding in order to make decisions and act more effectively. Sense-making consists of four interrelated activities:

- developing an awareness of key elements relevant to the situation, which entails knowing "the who, what, when, and where";
- developing an understanding of what it all means in some specific context, based upon past experiences, training, education, and cognitive capabilities, which entails
  - forming hypotheses and making inferences about future events (i.e., predictions or anticipations), and
  - forming a sense of the implications for different courses of action;

- taking action and/or making decisions by
  - generating alternative responses to the situation,
  - identifying the objectives, constraints, and factors that influence the feasibility and desirability of the alternatives,
  - conducting an assessment of these alternatives,
  - selecting alternatives and putting them into action, and
  - retaining alternatives and actions that seem to work and stopping alternatives that do not seem to work; and
- changing or refining awareness and understanding over time.

The sense-making process may be shaped by a number of factors, such as organizational factors (e.g., mission, vision, culture), professional values and beliefs, or technical issues. Theories of organizational learning, innovation, and change suggest that sense-making improves when there are rich communication networks (e.g., many different forums for exchanging ideas and information) and when people are encouraged to understand their individual role in the wider organization or program and are empowered to try new things. In addition, theory suggests that there is a mutually reinforcing relationship between individual sense-making, shared (i.e., group or organizational) sense-making, and coordination and collaboration of activity.

A related concept is that of mental models, which are deeply ingrained assumptions, generalizations, or even images that influence how we understand the world and how we take action. It has been said that mental models often resemble a "professional's repertoire." However, people are often not aware of these models or their impact on their behavior. Therefore, one fundamental task is to develop the ability to reflect on one's actions and recognize the implicit models that might underlie them. Entrenched mental models thwart change, so the ability to bring these mental models to the surface, hold them to rigorous scrutiny, and revise them if necessary is critical for learning, innovation, and change. As with sense-making, surfacing, rigorously examining, and altering mental models requires openness and rich communication networks.

Organizational Structure

Based on the work of Donabedian (1955) and others, such as the Institute of Medicine's (IOM's) *Crossing the Quality Chasm* (2001), it has long been understood that organizational structure has an impact on care processes and ultimately on organizational outcomes (e.g., efficiency, effectiveness) and patient outcomes (e.g., mortality, morbidity, patient experience). In this evaluation, the cancer centers' general structures comprise the organizational context in which the NCCCP is being developed and implemented. There are four fundamental aspects of structure that may have an impact on the ability of cancer

centers or NCCCP sites to achieve the program's aims: whether the hospital is part of a larger, organized delivery system and, if so, what kind; how the hospital structures its cancer services; whether and how the NCCCP pilot program is embedded in the existing cancer services structure; and the size of the hospital and system within which the NCCCP is being implemented, because size affects the ability to communicate and coordinate key activities.

Hospital's Relationship to a Health System. The first important aspect of structure is whether the participating cancer center or NCCCP site is a member of a larger health system and, if so, what kind of system. Some cancer centers or NCCCP sites participate explicitly as a system, others are members of a system but participate primarily as single member hospitals, and others are not members of a larger health system. Existing literature and the few empirical studies that exist suggest that some types of organized delivery systems (e.g., centralized or moderately centralized) may have some advantages relative to free-standing hospitals with respect to quality improvement and patient outcomes (see, e.g., Chukmaitov et al., 2009).

Hospital's Relationship to its Cancer Center. Another important aspect of structure is how the specific hospital participating in the NCCCP and its associated oncology program are structured. There are five classic organizational designs: functional, divisional, matrix, parallel, and service line or program; these vary with respect to how they divide work and how they attempt to coordinate and integrate work (for an overview, see Leatt, Baker, & Kimberly, 2006). These designs can be arrayed on a continuum, with the functional design emphasizing general administrative or support functions (e.g., legal/regulatory, finance, marketing, IT) and clinical functions (e.g., medicine, surgery, nursing, inpatient care, outpatient care, laboratory, pharmacy) and the service line or program design emphasizing a specific service or program (e.g., oncology) and the need to coordinate and integrate all functions of that service or program. Each of these designs has a number of strengths and weaknesses, but matrix, parallel, and service line or program structures may be best suited to the organizational learning, innovation, and change associated with tasks required by the NCCCP. However, many hospitals still have a functional or divisional structure in place, or they are in the process of migrating to these other structures and thus have structures that blend aspects of these classic designs in unique ways.

Cancer Center's Relationship to the NCCCP. Within these general structures, each cancer center develops a unique NCCCP structure. Depending on the overall organization and oncology program design, top management, that is, senior executives such as the CEO and COO, and NCCCP leaders determine which structure might work best for the NCCCP.

Organizational Size. A structural characteristic related to these other three structural features (system, cancer center, and NCCCP) is size. Generally speaking, as organizational size increases, coordination and communication become more difficult. Thus, cancer centers

and cancer programs that are larger may have a greater challenge understanding and conceptualizing the NCCCP and getting all of the pieces in place to move the program forward rapidly. Conversely, cancer centers and cancer programs may be so small that there is an insufficient number of physicians and subspecialists to enhance their multidisciplinary care or significantly increase patient accrual in clinical trials.

Organizational Processes

Beyond these fundamental organizational structures, there are a number of processes that have been identified in the theoretical literature and empirical research as creating a more receptive context for learning, innovation, change, and quality improvement. These include

- leadership qualities and processes at all levels of the organization,
- alignment of organizational goals with resource allocation and actions to achieve consistency at all levels of the organization,
- existence of a culture that supports learning and "absorptive capacity,"
- development of effective teams, and
- greater use of IT.

For further information, see IOM (2001), Ferlie and Shortell (2001), Greenlaugh et al. (2004), Grol et al. (2007), and Lukas et al. (2007). We describe below the characteristics relevant to the NCCCP for each of the processes listed above.

Leadership Qualities and Processes. There are many definitions of leadership, but one of the most useful is to think of leadership as an ongoing conversation among people who care deeply about something of great importance (Ferlie & Shortell, 2001). Leadership at all levels of an organization increases the likelihood of learning, innovation, and change. Therefore, it should be exhibited by different types of people (e.g., senior executives, physicians, nurses) and in different forms (e.g., formal or informal opinion leaders or champions). Examples of leadership at different levels of the cancer center include top management teams prioritizing or sponsoring an NCCCP-related initiative, proactive board support, clinical champions or opinion leaders, and boundary-spanning activities by all groups via the formation of ties with key external organizations (e.g., professional societies, universities). As top management, senior executives (e.g., CEOs, COOs, CFOs, CMOs) prioritize or sponsor an NCCCP-related initiative and direct the necessary resources to support program implementation at their facility. The terms "top management" and "senior executives" are used interchangeably in the overall report.

Alignment of Goals with Resources. Alignment refers to consistency of plans, processes, information, resource decisions, actions, results, and analysis to support key organizational and NCCCP-wide goals (Lukas et al., 2007). Like organizational leadership, alignment throughout all organizational levels (e.g., system, cancer center, NCCCP) increases the likelihood of learning, innovation, and change, in addition to more rapid implementation of

the NCCCP. Slack resources and the willingness and ability to invest those resources, particularly in a weak economy, could have a significant impact on cancer centers' ability to learn, innovate, and change. Implementing a new, ambitious program like the NCCCP takes money, time, and other resources (e.g., new knowledge, skills, abilities obtained through new staff or training). The resources provided by NCI and any additional funds that each cancer center is willing to invest or that can be secured from other funders (e.g., foundations) may or may not be sufficient to achieve the aims of the NCCCP in the time desired (i.e., performance outcomes through subcontract deliverables did have to be met). The issue of slack resources and willingness and ability to invest those resources relates not only to national hospital and cancer economics trends but also to local market dynamics, each hospital's mission and margin, and the economic study described in Chapter 3. Also, indicators from the micro-cost study have been incorporated into analysis of selected evaluation questions in this report.

Organizational Culture for Learning. Schein (1985) defines organizational culture as "a set of basic tacit assumptions about how the world is and ought to be that is shared by a set of people and determines their perceptions, thoughts, and feelings and, to some degree, their behavior." It involves the norms, values, beliefs, and behaviors of an organization reflecting how things are done within the organization. A culture conducive to quality improvement will encourage, if not require, double-loop learning and "meta-learning" in which an organization evaluates how it learns best and makes efforts to improve on its learning practices (Argyris & Schön, 1978; Davies & Nutley, 2000). In almost all cases, an overly hierarchical culture that emphasizes rules, regulations, and reporting relationships is negatively associated with implementation of quality improvement and related practices.

A related concept is an organization's absorptive capacity, which Greenlaugh et al. (2004) define as the ability to identify, capture, interpret, share, reframe, and recodify new knowledge; to link this new knowledge with its existing knowledge base; and to put it to appropriate use. Precursors of absorptive capacity include the knowledge and skills of key staff and the organization overall, as well as some of the other structural features described in this section.

Effective Team Building. To develop effective teams, it is first important to define a team. A team is a type of formal group or collection of individuals who see themselves, and are seen by others, as a socially intact entity; who share responsibility for tasks and outcomes; and who operate within a broader organizational context, interacting with the larger organization or specific organizational subunits.

There are four different types of teams:

- *Work teams* are continuing work units responsible for producing goods or services. They tend to be ongoing and relatively permanent in nature.

- *Parallel teams* pull together people from different work units or jobs to perform functions that the regular organization is not equipped to perform. They usually have limited authority and generally make recommendations to people who are higher within the organizational structure (e.g., quality improvement teams).
- *Project teams* are time-limited teams that produce one-time outputs such as new products or services.
- *Management teams* are teams that coordinate and provide direction to the subunits under their jurisdiction.

A program like the NCCCP will certainly involve a project team and perhaps parallel teams, but ultimately needs to be integrated into the oncology work and management teams. If the NCCCP pilot is to be successful and continue, it needs to shape the departments and people providing cancer services on a daily basis. The literature on teams identifies a host of factors that are associated with team effectiveness (for an overview, see Fried, Topping, & Edmondson, 2006). Team characteristics, the nature of the task, and the environmental context may all affect team processes and ultimately team performance.

Use of IT. Finally, IT is an important structural feature of participating cancer centers and health systems. Improving cancer center information sharing is a goal of the NCCCP. However, the initial IT conditions are important to understand, because the IT infrastructure has a significant impact on what data are already available about each oncology program and how easy or difficult it will be to collect the information needed to assess the program's current structures, processes, and outcomes; related strengths and weaknesses; opportunities and challenges; and any progress made toward meeting the NCCCP goals. In addition, IT can be used to track patients for clinical trials research and management of biospecimens.

Capacity for Learning, Innovation, and Change

In addition to some of the structural issues outlined in the previous section, we discuss four organizational characteristics that are uniquely associated with the capacity for learning, innovation, and change: the impetus for change and how it aligns with internal and external sources of change, power dynamics within each organization, monitoring and feedback of performance, and the fit or match between the characteristics of the social structure and the NCCCP.

Impetus for Change. The first characteristic is the impetus for change and the degree of urgency regarding the need for change. Theoretical literature and empirical research suggest that external sources of change (e.g., new policies, regulations, payment or funding) are necessary but often insufficient to stimulate innovation or deep and lasting change. Rather, internal sources of change (e.g., intrinsic motivation, organizational goals) must complement these external sources not only to create but also to sustain learning and change. In addition to the sources of change, it is important for there to be a sense of urgency regarding change. There has to be a sense that the status quo is unacceptable and

that failure to change would have serious consequences for the organization. In the absence of such a sense of urgency, learning, innovation, and change are likely to occur at a much slower pace and may even stall before results can be realized (on these issues, see, e.g., Kotter, 1996; Lukas et al., 2007).

Power Dynamics. Another important organizational characteristic associated with an organization's capacity for learning, innovation, and change is the power dynamic between key groups and stakeholders within the organization, particularly between proponents and opponent of change (or a program like the NCCCP) (see, e.g., Greenlaugh et al., 2004; Grol et al., 2007; and for an overview of power and politics in organizations, see Alexander et al., 2006). Rational theories of organizational learning, innovation, and change assume that key groups and stakeholders in the organization have the same goals and interests, that there is sufficient information to identify and assess all the alternatives, and that there is a sufficient evidence base to select the best option. To the degree that key groups and stakeholders have unique goals and different interests or the other two conditions are not met, power (i.e., the ability of one person or group to influence others to bring about desired outcomes), influence (i.e., actions that directly or indirectly cause a change in the behavior or attitudes of another individual or group), and politics (i.e., activities to acquire, develop, and use power and other resources to obtain preferred outcomes) will play a role. Several situations that may exist in the case of the NCCCP—such as the need for structural changes, the need to increase interdepartmental coordination, changes in managerial or leadership roles, and resource allocation and budgeting—are often associated with increased power and politics in organizations. It is also important to note that power and politics may increase conflict, undermine trust, and have other negative consequences over time (e.g., managerial or staff turnover or dissatisfaction). Therefore, if organizations and leaders are more capable of managing and resolving conflict and building and maintaining trust, they may be more capable of learning, innovation, and change.

Monitoring and Feedback of Performance. Another major feature that influences an organization's capacity for learning, innovation, and change is the timely monitoring and feedback regarding performance. Individuals and teams must have access to high-quality, timely information in order to understand where the gaps in performance are, what is causing the performance problem, whether interventions are being implemented to address the problem, and what impact they are having. Information systems capability plays an important role here, as do incentives (financial and non-financial) for performance and mechanisms for accountability.

Fit or Match between the Organization and the NCCCP. A final factor that influences the capacity of cancer centers or sites to learn, innovate, and change is the fit or match between the characteristics of the social structure and the nature of the innovation or aspect of the NCCCP pilot. The nature of the innovation or the NCCCP pilot includes the perceived advantages relative to current practice (e.g., the NCCCP results in superior quality

of cancer care and research); compatibility with values, beliefs, and mission/vision (e.g., the goals of the NCCCP are or are not consistent with the mission/vision of community hospitals, cancer centers, and their affiliated oncologists); complexity (e.g., whether the innovation, in this case the NCCCP pilot itself, is relatively easy to understand and use/implement); trialability (i.e., the ability to experiment with the innovation on a limited basis as opposed to an all-or-nothing approach); and observability (i.e., the extent to which the results of the NCCCP—for the organization and the NCCCP network—are observable to key groups and stakeholders).

We have already discussed the characteristics of cancer centers (e.g., structures and processes, such as leadership, absorptive capacity, and readiness to change) and the NCCCP network. Several other aspects of the social structure that are thought to be important include homogeneity (i.e., the degree of similarity between participating individuals, groups, or organizations) and network structure (i.e., whether there is greater variation between communities than within them). The organizations and communities with greater homogeneity may be more likely to adopt, assimilate, and implement an innovation. In other words, people and organizations are more likely to adopt and implement approaches and strategies used and perceived to be effective by others like them.

Ability to Form Effective Partnerships with Key Groups in the Community. Cancer centers and NCCCP sites also have to develop, enhance, or maintain ties with a variety of external groups and stakeholders, including patients, physician groups, those developing and implementing state cancer plans, and cancer research institutions, including other NCI programs. As with internal groups and stakeholders, these external groups and stakeholders may share many of the same goals as cancer centers, including those related to the NCCCP, but there may be some goals and interests that are not fully shared or that seem to conflict; it is also possible for various groups or stakeholders to disagree on the means for moving forward. The evaluation design for the NCCCP includes collection of measures specific to relationships with patients, physician groups, and cancer research institutions (i.e., the relationships depicted by the solid lines in Figure 2-1) but not for the community groups or state cancer plans (i.e., relationships depicted by the dotted lines in Figure 2-1). Assessing these aspects of the program was beyond the scope of this evaluation.

2.1.2.3 Short-term Outcomes: Innovation, Adoption/Assimilation, and Implementation Process

As described in Section 2.1.1, innovation typically means successfully carrying out something new and useful, such as the development and implementation of new structures, processes, or services that are substantially different from what had previously existed. Adoption and assimilation refers to an organization's decision to adopt or implement an innovation developed by another organization, blending or combining the innovation with existing structures, processes, or services. Implementation refers to the transition period

when the organization and its members become increasingly skillful, consistent, and committed in their use of the innovation. In the case of the NCCCP, all three of these outcomes (innovation, adoption/assimilation, and implementation) are occurring simultaneously and at potentially different rates in each of the pillars and in the program overall.

There is a significant body of theoretical literature about adoption/assimilation and implementation processes and the organizational factors that might affect them. Although there is no consensus as to which theoretical or conceptual framework is best, there are many areas of agreement. Empirical research has also produced inconsistent results, in part due to the different frameworks and a lack of agreement on definitions of key constructs. However, one general finding is clear: Innovation, adoption/assimilation, and implementation processes are complex and somewhat unpredictable; large-scale, transformational change is likely to occur through emerging, non-linear non-sequential, and incremental steps. Potential problems and solutions often arise through repeated interactions within and across teams and organizations, making communication and coordination very important. The nature of the task or innovation, the organization, and the wider environment will affect the implementation process.

Despite these challenges, several models are helpful for thinking about these processes. They include Rogers' (2003) model of the innovation process, Lewin's (1951) classic three-stage change process, and Kotter's (1996) model of transformational change.

Rogers (2003) provides a relatively simple, five-stage model of the organizational innovation process. This model includes agenda setting, matching, restructuring, clarifying, and routinizing. In the agenda-setting phase, important problems and performance gaps are identified, and new expectations and goals are set by external and internal groups. The development of or search for innovations also begins at this stage. Two important factors at this stage of the innovation process are who participates in the agenda setting and how they perceive or interpret various pieces of information. The second stage is matching, in which the needs and capacities of the organization are matched with an innovation. This may include the identification of innovations within the organization or in other organizations, an assessment of their feasibility and fit, and the decision as to whether to adopt them. As previously described, aspects of the social systems (the organization and its wider social network) and the innovation itself will have an impact on the matching process. The third stage is restructuring. This generally consists of the formalization of strategies and plans for putting the innovation into practice. This may include little or no change in the organization's goals, policies, and procedures (as in single-loop learning) or may involve significant changes in these areas (as in double-loop learning). The fourth stage is clarifying, in which more people gain experience with the innovation, learn about its implications, and assess the actual versus expected benefits and costs. At this stage, either the innovation is disseminated further or it stalls. Diffusion is a relatively passive process in

which information about the innovation is initially absorbed and acted upon by a small body of highly motivated recipients. Dissemination is a more active process in which special efforts are made to ensure that intended users become aware of the innovation and then receive, accept, and use it.

The final stage is routinization. During this stage, the innovation ceases to be identified as something new and becomes fully incorporated into the organizational fabric (e.g., goals, policies, procedures). Whether an innovation is routinized and hence more likely to be sustained depends upon whether key outside groups and stakeholders, as well as organizations and their members, view it as legitimate and valuable. Routinization and sustainability are also likely to be influenced by resources (e.g., budget, personnel, training), the extent to which the end users were involved in developing or adopting the innovation, and the latitude to reinvent, adapt, and improve it over time.

Lewin's (1951) model of organizational change is a bit simpler, consisting of three steps: unfreezing, moving, and refreezing. Unfreezing involves creating an awareness of the need for change and efforts to remove any resistance to change. Moving involves putting into place new strategies, structures, or practices. This stage can be challenging because it requires organizational members to accept new ideas and alter existing attitudes and behavior. Refreezing involves stabilizing the change by integrating new strategies, structures, or practices into existing operating procedures and reinforcing changes in attitudes through a variety of mechanisms (e.g., recognition and reward systems).

Finally, Kotter's (1996) model of transformational change provides more guidance to managers attempting to engage in large-scale change. Kotter's model consists of eight stages: establishing urgency, creating a guiding coalition, developing a vision, communicating the change vision, empowering broad-based action, creating short-term wins, consolidating gains, and anchoring new approaches in culture. Building on these models, Berwick (2003) and others (e.g., Greenlaugh et al., 2004; Lukas et al., 2007) have written about how to disseminate innovations in health care, including the role that learning collaboratives and other "change agents" can play. Although the process is not as linear and sequential as these models seem, they do provide useful ideas and frameworks for thinking about the innovation, adoption/assimilation, and implementation processes.

2.1.2.4 Intermediate and Ultimate Outcomes

Collectively, these organizational aspects of the cancer centers, the local environments in which they exist, and the innovation and implementation process all impact several key intermediate outcomes: improved knowledge and skills of the cancer centers and their cancer program staff; enhanced infrastructure (e.g., IT/EHR capability or timely access to important program information); and increased adherence to evidence-based guidelines. Evidence of these intermediate outcomes can be assessed via the case studies and other programmatic information, such as program surveys, quarterly reports, and other measures

or analyses. These and ultimate outcomes, such as whether sites have enhanced their cancer research capacity or improved the quality of cancer care, are the primary topics of this report assessed through the overall analysis conducted in the final year of the evaluation (2011).

2.2 Overarching Evaluation Questions

The development of thoughtful evaluation questions consistent with the evaluation's purpose is central to the design of a well-structured evaluation plan (Rossi et al., 2004). In this chapter, we used three primary evaluation questions as our guide in designing the overall evaluation:

- What changes in each program component, and for the cancer service line overall, seem to be facilitated by the NCCCP?
- What organizational requirements seem necessary to effectively manage/implement the NCCCP?
- What changes and elements are sustainable and potentially replicable?

Section 2.1 describes the theoretical underpinnings of how the NCCCP pilot might work, particularly what factors affect sites' ability to implement it and successfully achieve the ultimate aims of the program and the conditions under which it will likely work best. Based on this evaluation framework and our understanding of the NCCCP, in order to address each of the overarching questions, the evaluation needed to collect and analyze data as available at five possible intervention levels:

- the network level (i.e., across the programs and within the NCCCP network),
- the organizational level (i.e., within the systems and/or hospitals),
- the program level (i.e., within the cancer center or service line),
- the program component level (i.e., biospecimens, clinical trials, disparities, IT, quality of care, and survivorship), and
- the patient level.

2.2.1 Evaluation Questions for the Network Level

The primary goals of the NCCCP network were to provide formal and informal linkages between participating NCCCP sites and NCI staff involved in program implementation. The formal NCCCP network was created specifically for the benefit of the NCCCP and involved monthly conference calls for NCI staff and all of the principal investigators (i.e., the Executive Subcommittee) as well as monthly meetings of subcommittees created to address each of the program components. These subcommittees were co-led by staff members from the NCCCP sites, and an NPAC member with relevant expertise served on each subcommittee. A primary evaluation question at the network level was the extent to which

these linkages occur between the NCCCP sites and with NCI staff and what benefits the sites derive from these linkages.

In addition to these formal "internal" linkages between the program participants, NCI encouraged sites to create formal "external" linkages (i.e., outside the NCCCP network) with other cancer research programs, including NCI-designated cancer centers and community clinical oncology programs (CCOPs). Because several of the NCCCP sites were also CCOP sites or participated in regional CCOPs, the evaluation plan included questions specific to how CCOP sites may differ in what they were able to accomplish relative to non-CCOP sites. The linkages established among NCCCP sites and external partners in the NCI cancer research network could have potentially been used to address the following:

- providing more patients for accrual into earlier phases or other types of clinical trials,
- increasing the number and types of biospecimens available in biorepositories housed at AMCs, and
- serving as sites for or partners in implementation of interventions and other types of research projects.

Therefore, the evaluation at the network level was to focus on the linkages created as a result of the NCCCP (both internal and external), the benefits these linkages bring to the NCCCP sites, and the association between the technical assistance (TA) provided to the sites. We know from the documentation of the NCCCP network that sites generally attended all conference calls and were active in implementing new activities and/or tools, but data were not collected in terms of the extent to which sites were participating in the network and how this information was used within their cancer program to change their operations. Although we could not quantify their level of involvement, we have described what respondents told us about the utility of the NCCCP network (Chapter 15).

2.2.2 Evaluation Questions for the Organizational Level

As described in Section 2.1, organizational-level factors (e.g., the sponsoring hospital's top management and cancer center/program leadership) will likely be strongly associated with the extent to which sites are able to effectively manage and sustain NCCCP efforts. These factors are related to each site's

- effective management practices,
- infrastructure,
- physician practice models,
- plans for sustainability, and
- systems-based effects (when applicable).

In terms of effective management practices, it was expected that senior executives as well as clinical leaders would put the structures and processes in place that led to learning,

innovation, and change, as described in Section 2.1. It was important for the evaluation to understand both the processes and structures of the management styles at each site in order to better recognize which styles seemed to lead to more effective implementation of the NCCCP (i.e., whether established program goals were met in the 3-year time period). If reasonable progress was made toward achieving intermediate and potentially ultimate outcomes (such that NCI extends and/or expands the program), the evaluation needed to be able to identify the key features of the organizational structures and processes that seemed to be related to each site's readiness to implement the NCCCP, including effective NCCCP network and site management. These features could then be used to better identify potential NCCCP sites in the future.

During the evaluability assessment RTI conducted in 2007 and 2008 in order to design the evaluation, a key finding was the extent to which the NCCCP sites relied on private practice physician models for their cancer service line and how these practice models (and others) seemed to be impacting initiation of the NCCCP. In the private practice models, physicians have various forms of legal agreements with the hospital (e.g., leasing space only, serving in an administrative role for a stipend or as a volunteer) that can influence the extent to which physicians have the time and ability to become engaged in various NCCCP components. In most cases, sites that rely heavily on private practice physicians are asking these physicians to donate their time to the NCCCP-specific work. This "free" time commitment on the part of physicians was often in addition to other responsibilities that go well beyond a typical 40-hour work week. For this reason, primary evaluation questions needed to address how the sites engaged these physicians within the medical model in which they operated and which strategies seemed to be the most effective in obtaining physicians' ongoing involvement.

Infrastructure was another key factor to include in the evaluation plan. This included the extent to which sites already had infrastructure in place at the start of the NCCCP to provide comprehensive care to patients (e.g., screening and outreach, survivorship services) and how that changed over time as a result of NCCCP participation. As noted in Section 2.1, changes could occur in part because of top management's support and allocation of funds to make the changes happen. Such changes included how the hospital addresses care to their local disparate populations and what lessons they learned from the NCCCP with regard to meeting the needs of these individuals.

One of the overarching evaluation questions involved the extent to which the NCCCP may be sustainable at the participating sites. This question was particularly important to address at the organizational level. It was important to measure the factors that were proposed to be related to sustainability (e.g., program champion to support and/or guide implementation, organizational structure adaptations to include the program, alliance of program goals with organizational mission and goals) so that those factors that seemed to

be most strongly associated with whether a site had specific plans to institutionalize the changes brought about by the NCCCP could be specified.

The last primary question included under the organizational level was specific to only the two system sites participating in the NCCCP (Ascension Health and Catholic Health Initiatives). System sites were selected for the NCCCP in order to see the extent to which, by funding a system, NCI was able to impact cancer care within more hospitals. The theory is that the lead sites participating in the NCCCP will learn from the program and disseminate knowledge and products to other hospitals within their systems and perhaps more rapidly than individual, unaffiliated hospitals exchanging information (i.e., hospitals in the same system have a greater incentive to share approaches, strategies, and best practices with each other) that are not necessarily NCCCP sites. Information specific to this question is primarily descriptive in understanding what the relationships were between the lead and developing system sites, what developing sites were able to accomplish relative to where they started, and how the system worked to support the NCCCP.

2.2.3 Evaluation Questions for the Program Level

The program level, or where NCCCP is implemented within the cancer service line or center, is important to examine in terms of the overall impact of these features on outcomes. Three aspects of implementation were assessed at the program level:

- changes to the cancer service line overall,
- value added by the NCCCP (to what each site was already doing with respect to cancer care), and
- economic indicators to invest in NCCCP efforts.

In terms of changes to the cancer service line at each site, many of these hospitals were not providing "comprehensive" cancer care at the time the NCCCP began. Comprehensive cancer care spans the cancer continuum such that efforts are underway to reach out to the community to provide cancer screening and diagnostic care, state-of-the-art treatment, and survivorship care, and to include in those services palliative and end-of-life care. Although NCI did not expect these sites to become AMCs providing comprehensive care within the 3 years of the NCCCP pilot, there was an expectation that more (i.e., across the cancer continuum of care) and better (i.e., higher-quality) services would be provided to patients over time. The evaluation was designed to describe the types of services provided to patients (i.e., specific to the NCCCP, such as patient navigation), how those services changed or were enhanced over time, and the extent to which these services were provided in a seamless, patient-centered way to enhance the patients' experience.

Another key evaluation question addressed the economic indicators for sites to become involved in the NCCCP. As described in Chapter 5 of the Evaluation Design Report, a specific component of the evaluation was an economic study that collected micro-cost study data on

the implementation of the NCCCP over the 3-year pilot as well as evidence of the strategic case for implementing the NCCCP. This evaluation measured the incremental costs of implementing the program over time and whether there remained a strategic case for participating in the NCCCP by the end of the pilot.

2.2.4 Evaluation Questions for the Program Component Level

Because of the complexity of the NCCCP, in addition to the three levels described in Sections 2.2.1 through 2.2.3, there was a fourth level—the program component level—at which outcomes for some of the components (i.e., biospecimens, clinical trials, disparities, IT, quality of care, and survivorship) were tracked and measured over time. As described in the Evaluation Design Report, a set of prioritized questions for each program component was developed and finalized in February 2009 (see Table 2-2). For the detailed evaluation planning matrices across all levels of measurement, please refer to Appendix A.

2.2.5 Evaluation Questions for the Patient Level

Priorities at the patient level for NCCCP were to enhance the quality of care patients received and to ensure that all patients were able to access that care, regardless of insurance status, racial or ethnic background, or other potential barriers to care. The following three issues related to questions at the patient level:

- the extent to which sites are able to identify disparate populations in their patient pool and increase the proportion of these patients receiving care,
- how well disparities are addressed across sites, and
- overall impressions among patients of improvements in care along several indicators.

During the first year of the NCCCP, a Baseline Assessment Survey (BAS) was collected from all of the sites to collect indicators for each program component, as well as organizational-level factors. From the BAS, it was discovered that many of the sites did not already collect race or ethnicity data on their patients or did not record such data in a system that could be accessed for the evaluation. Therefore, much of the effort during Year 1 of the project focused on helping sites build the capacity to collect these data, while also identifying the populations in their communities that receive less than adequate cancer care. In some regions, this includes elderly patients and/or rural residents, and in most regions it also includes specific racial and/or ethnic groups. Therefore, an evaluation question addressed how well sites are able to build their capacity to identify these populations and then record data on the extent to which they access cancer services.

A large proportion of funding from NCI was allocated to the disparities component (40%), in recognition of the fact that the country's most disparate populations are likely to reside in many of these communities. Based on findings from the evaluability assessment, sites had varying levels of expertise in knowing how to conduct outreach to special populations and recruit them for services. Therefore, the evaluation focused on how sites were able to better

address care to these disparate groups. The focus of this second patient-level evaluation question is on what the organization was able to do to build capacity in meeting the needs of these groups and in providing more services to a broader range of patients. The comparative evaluation of the NCCCP, which includes analysis of registry data specific to six key indicators of breast and colorectal cancer care, will allow for a comparison of NCCCP hospitals to non-NCCCP hospitals in terms of patient characteristics served by each and any disparities in care across patient subgroups (e.g., by race or ethnicity).

The patient survey and focus groups were used to measure patients' overall impressions of their quality of care. Aspects of care that the patient survey addressed include the extent to which patients feel providers communicated with them about their care, patients' awareness and use of available services, and an overall patient evaluation or assessment of the care they received. The patient focus groups also addressed these issues but were used as a means to explore barriers and facilitators to patients accessing care and enabled probing of specific responses to obtain more details about patients' experiences.

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Three Levels of Program Intervention (i.e., Network, Organizational, Program)

Level of Analysis and Domain from Conceptual Framework	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
Network Level (i.e., among the participating hospitals)—*Environment* in Figure 2-1	NCCCP linkages (internal)	▪ How well has the NCCCP network facilitated sites to establish linkages with each other (i.e., NCCCP sites connecting to each other)?	▪ What are the relationships of NCCCP sites to each other? ▪ What did these linkages contribute to NCCCP implementation within each site?	Specific ways the NCCCP network impacted how individual sites operate/provide care	Case Study[a]
	NCCCP linkages (external)	▪ How well has the NCCCP network facilitated sites to establish linkages with other NCI cancer research programs (e.g., NCI-designated cancer centers, CCOPs)?	▪ What is the relationship of the NCCCP to other NCI cancer research programs? ▪ What new linkages between sites and other NCI cancer research programs have been created as a result of the NCCCP?	▪ Description of changes in relationships with other NCI research programs ▪ Degree to which new relationships met NCCCP site expectations	Case Study
	Benefits of NCCCP linkages	▪ What do these new relationships with NCI staff, other NCI cancer research programs, and/or other NCCCP sites seem to provide the sites in terms of resources or patient services that they did not have prior to NCCCP involvement?	▪ What did NCCCP sites learn through network connections that has helped them improve relationships with physicians, etc.? ▪ What is the perceived impact of participation in the NCCCP on the site's abilities to collaborate with other NCI cancer research programs and/or other related organizations (e.g., Commission on Cancer, American Society of Clinical Oncology)?	Specific examples of partnerships with NCI staff, NCI cancer research programs, other NCCCP sites	Case Study
	Impact of technical assistance (TA)	▪ What is the impact of TA provided by NCI on the sites' ability to reach NCCCP goals and objectives?	▪ What do sites believe they have gained from direct TA from NCI and each other?	▪ Perceptions of usefulness of TA ▪ Examples of how activities within subcommittees have been implemented at each site	Case Study

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Three Levels of Program Intervention (i.e., Network, Organizational, Program) (continued)

Level of Analysis and Domain from Conceptual Framework	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
Organizational Level (i.e., within the systems and/or hospitals)—*Community Hospital Characteristics* (see Figure 2-1)	Effective management practices	▪ What are the organizational factors that seem necessary to effectively manage/implement the NCCCP?	▪ What are the key measures of readiness to implement the NCCCP at any one site (for replication)? ▪ How much time does the physician director, if there is one, dedicate to the NCCCP? How do both the time commitment and responsibilities change over time? ▪ What are the roles and responsibilities of the program coordinator at each site? Is this position essential to effective management of the NCCCP? How should it complement the role of the lead physician? ▪ What is the "location" of the NCCCP within the hospital's/system's organizational structure and associated reporting structures? How does this change over time? ▪ What seems to be the association between the structure and the site's success implementing the NCCCP?	▪ Role/priority of cancer services in overall hospital/system strategy ▪ Organization of cancer services within hospitals/systems	▪ Case Study ▪ Micro-Cost Study
	Physician practice models	▪ What are the physician practice models through which the NCCCP is being implemented? ▪ What factors of each model seem to impede or facilitate NCCCP implementation?	▪ To what extent does each site rely on private practice physicians? ▪ What strategies do sites use to effectively engage physicians in the NCCCP pillars?	▪ Organizational charts of relationships between leaders ▪ Barriers to each model and how these differ across sites	▪ Case Study ▪ Micro-Cost Study ▪ Multimethod Analysis

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Three Levels of Program Intervention (i.e., Network, Organizational, Program) (continued)

Level of Analysis and Domain from Conceptual Framework	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
Organizational Level (cont'd)	Infrastructure	▪ What infrastructure has the site developed (e.g., staff, data, program related) to implement the NCCCP? ▪ What lessons did the organizations learn on the infrastructure required to implement the NCCCP successfully?	▪ What was the "human and physical capital" in place, and how has that changed as a result of the NCCCP? ▪ What institutional support for the NCCCP has been provided by which offices (e.g., CEO, board) within the hospital or system? ▪ What has the organization learned from the pilot about their approach to addressing health care disparities and whether they have improved their ability to track their efforts?	▪ Linkages between cancer program and other hospital departments (e.g., pathology, surgery) ▪ Assessment of changes in infrastructure over time and the impact on NCCCP activities	Case Study
	Plans for sustainability	▪ What program-related changes are likely to be sustained or institutionalized within the existing sites?	▪ What factors seem to be associated with (i.e., facilitate or impede) the likelihood of institutionalization (or routinization per framework)?	▪ Staff hiring for key roles related to the NCCCP ▪ Increased infrastructure for the NCCCP ▪ Investments relative to the NCCCP (i.e., matching costs)	▪ Case Study ▪ Micro-Cost Study ▪ Multi-method Analysis
	System-level effects[b]	▪ What are the characteristics and/or features of the system-funded sites that impede/facilitate achieving system goals (i.e., dissemination of program activities) and program goals (i.e., within each site)?	▪ What is the relationship of the system lead site to the developing sites? ▪ What are developing sites able to accomplish relative to their baseline? ▪ How is the overall system structure and support associated with NCCCP implementation?	▪ Evidence of knowledge networks in place and how info is shared ▪ Examples of ways hospitals work together with regard to NCCCP activities	Case Study

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Three Levels of Program Intervention (i.e., Network, Organizational, Program) (continued)

Level of Analysis	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
Program Level (i.e., within the cancer center or service line)—*Cancer Center Characteristics* (Figure 2-1)	Cancer service line changes	▪ How has the NCCCP helped sites redefine or revise their cancer service line?	▪ What types of services are provided to patients and how does that change during the pilot? Is there evidence that there are services to "focus on the full continuum of cancer care, including risk assessment, prevention, screening, treatment, follow-up care, and appropriate end of life care" for all, including the uninsured? ▪ How does the NCCCP facilitate development of a "seamless delivery system" to the patient?	▪ Changes in scope and use of care/services provided during the pilot study and the extent to which these are related to NCCCP efforts (and not what they would have done otherwise) ▪ Patient's perceptions of coordination of their care	▪ Case Study ▪ Patient Survey and Patient Focus Groups
	Economic indicators	▪ What financial commitments do sites need to make to implement the NCCCP relative to key outcomes (e.g., patients accrued to clinical trials)? ▪ Do sites believe the NCCCP is a worthwhile investment in advancing their cancer service line?	▪ What are the incremental (direct, indirect, opportunity) costs of the NCCCP? ▪ What is the "strategic case" or return on investment (ROI) for sites to participate in the NCCCP?	▪ Labor/time commitments, both invoiced and matched ▪ Opportunity costs of physicians ▪ Outcomes of interest relative to costs ▪ Profitability (or lack thereof) of cancer service line; staff's perceptions of the NCCCP's impact on profitability	▪ Micro-Cost Study ▪ Strategic Case Study

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Three Levels of Program Intervention (i.e., Network, Organizational, Program) (continued)

Level of Analysis	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
Patient Level	Population served	▪ How does the population of patients served by the sites change during the time that they are an NCCCP pilot site? ▪ How do the patients served by NCCCP hospitals differ (if at all) from patients served by similar non-NCCCP community hospitals?	▪ How well are sites able to identify their minority patients? ▪ Are sites able to increase the proportion of minority/disparate patients served? ▪ What organizational factors seem to be related to how well they were able to increase the number of patients served (by specific groups of patients)?	▪ Improved tracking of patient race/ethnicity ▪ Number of patients served by zip code and/or race/ethnicity ▪ Evidence of support for increasing care to disparate groups	▪ Case Study ▪ Comparative Evaluation

[a] Case study includes data collected during site visits, document review, and secondary data analysis (see Chapter 3).

[b] Relevant only to the NCCCP system sites.

Table 2-2. Primary Evaluation Questions and Illustrative Methods and Outcomes for Each NCCCP Component

Program Component	Primary Evaluation Questions for Each Program Component	Evaluation Methods	Evaluation Outcomes
Disparities	▪ To what extent do sites enhance awareness, communication, and use of services (e.g., clinical trials, continuum of cancer care) for identified disparate populations? ▪ What strategies (e.g., increase in formal community partners and screening events) do sites use to outreach to disparate populations in their region? ▪ What are the organizational characteristics of sites that are best able to increase their activities addressed disparities (as specified by NCI)?	▪ Changes in baseline and repeat of patient survey ▪ Descriptions from staff during site visits of the strategies used that they consider to be a success in reaching disparate groups ▪ Assessment of organizational characteristics	▪ Increased proportion of patients in identified disparate groups (e.g., by race/ethnicity, age) reporting awareness and usage of specific cancer services ▪ Key features of organizational structure and support that seem to lead to enhanced services for disparate groups
Clinical Trials	▪ What organizational factors are related to increases in the – types of clinical trials implemented at each site (e.g., Phase 2), – changes in patient accrual (e.g., by race/ethnicity), or – number of physicians accruing patients?	▪ Assessment among staff during site visits of the level of support and infrastructure available to increase all aspects of clinical trials research ▪ Self-reported data from sites on clinical trials accomplishments	▪ Facilitators and barriers (e.g., administrative, financial, medical care model) to begin earlier phase clinical trials and increasing clinical trials accrual ▪ Patient perceptions of access to clinical trials ▪ Changes in trial capacity, patient accruals, and physician referrals to trials
Biospecimens	What factors influence whether sites choose to or are able to implement (either in part or in whole) NCI's best practices for biospecimen collection and reporting?	Assessments by staff at sites of the progress made in addressing gaps in biospecimen collection and reporting through site visit interviews	Lessons learned in terms of implementing biospecimens collection and reporting (per best practices) in community-based hospital settings
IT	▪ What factors influence the extent to which sites choose to or are able to implement (either in part or in whole) of caBIG? ▪ What is the status of EHR implementation within the cancer center and related hospital departments and linkages with the cancer center-affiliated private practice physicians? How does that change over time?	Perception among key staff during site visits on advantages and disadvantages to implementing components of caBIG	▪ Lessons learned in terms of aspects of caBIG that may or may not be applicable to community based hospital settings ▪ Assessment of EHR implementation among hospital staff and key cancer physicians

(continued)

Table 2-2. Primary Evaluation Questions and Illustrative Methods and Outcomes for Each NCCCP Component (continued)

Program Component	Primary Evaluation Questions for Each Program Component	Evaluation Methods	Evaluation Outcomes
Quality of Care	▪ To what extent do sites increase multidisciplinary care conferences and other aspects to enhance quality of care for their patients? ▪ How is patient-centeredness of care increased across sites? ▪ How does quality of care (for key quality indicators) change at NCCCP sites when compared to other, similar hospitals?	▪ Collect MDC specific data through baseline, interim, and final assessment survey of sites and case study ▪ Survey of patients early in the program and at the end of the pilot ▪ Track performance based on RQRS reporting, within the NCCCP and compare (potentially) to similar non-NCCCP RQRS community cancer centers	▪ Improved coordination of care and decreased time from diagnosis to treatment for patients newly diagnosed with cancer ▪ Increased perceptions among patients about communication among physicians involved in their care ▪ Increased infrastructure for enhance quality of care (e.g., MDC care conferences, conditions of participation)
Survivorship	▪ To what extent do sites provide treatment summaries and follow-up care plans to all patients? ▪ How comprehensive is survivorship care by the end of the pilot (e.g., support services, health promotion)?	▪ Track distribution of treatment summaries through baseline and subsequent site surveys ▪ Assess changes in types of care/services survivors are aware of and/or using through the patient surveys and focus groups	▪ Increased proportion of patients receiving treatment summaries and follow-up care plans post-treatment ▪ Enhanced awareness and use of post-treatment services among patients

3. OVERVIEW OF OVERALL EVALUATION METHODOLOGY AND ANALYSIS

To support the evaluation of the NCCCP, RTI used seven primary study methods: a case study (which included site visits each of Years 1–3, along with patient focus groups in Year 3), two economic studies, a patient survey, a comparative evaluation that assesses practice pattern changes over time between NCCCP sites and similar community hospitals not participating in the NCCCP, an environmental analysis of local markets and communities, and a special analysis of national clinical trials data. To conduct the clinical trials data analysis, we worked with Duke University's Cancer Care Research Program to conduct an analysis of clinical trials data for the NCCCP in comparison to national trends in clinical trials research among similar hospitals. Separate reports for the two economic studies, the comparative evaluation, and the special study on clinical trials data were developed for NCI. This report focuses on the findings for the overall evaluation, which incorporates data from these seven available data sources. The following sections describe the overall evaluation design and an overview of the final analysis presented in the remainder of this report.

3.1 NCCCP Evaluation Data Collection

The following sections describe the data collection for each of the datasets used in the overall analysis, followed by an overview of how the final analysis was conducted during 2011.

3.1.1 Case Study Overview

As noted by Denzin (1978), there is a type of triangulation that uses multiple techniques within a given case study to collect and interpret data. This type of "within method" triangulation essentially involves cross-checking for internal consistency or reliability across data sources (Jick, 1979). For the NCCCP case study, three primary types of data sources were collected and used in the final analysis:

- site visits (e.g., key informant interviews, patient focus groups, observations),
- document review (e.g., progress reports), and
- secondary data sources (e.g., site surveys).

Sample data variables for each of these data sources are presented in Table 3-1, and each data source is described in more detail in the following sections, followed by a description of the process of data coding and analysis for the comparative case study.

3.1.1.1 Site Visits

Site visits provide a unique opportunity for researchers to collect in-depth information about the processes, activities, and barriers experienced by NCCCP sites. Annual site visits were

conducted at all NCCCP sites throughout the 3-year pilot. Prior to each round of site visits, RTI implemented a process to obtain input and prioritize topics to cover during our planned 2- or 3-day site visits. The selection of domains, topics, and the primary and secondary evaluation questions to address during each site visit were drawn directly from the evaluation planning matrices (EPMs) (Appendix A). Table 3-2 provides a summary of the level of evaluation and corresponding key words addressed during the site visits in Years 1-3.

During the site visits, we collected two types of data: observational data and data from in-depth interviews with individuals or small groups at each site. The following provides an overview of the planning process for the site visits, including how interviewees were identified and recruited, and the design of the interviews and protocol for conducting each round of site visits.

Year 1 Site Visits

Beginning in February 2008, RTI planned and conducted site visits to the 16 NCCCP sites, including both lead and developmental sites (see Chapter 4). During the first year, the main objectives of the site visits were to gain an understanding of each program's conceptualization of the NCCCP, how they were implementing the program overall, the level of leadership support the program was receiving, and other key factors related to best describing the following components of the NCCCP evaluation conceptual framework (Figure 2-1):

- sites' understanding and conceptualization of the program;
- sites' organizational structure;
- sites' general capacity for learning, innovation, and change, including forming effective relationships with both physician groups and cancer research institutions; and
- processes underway to begin implementation specific to NCCCP program components.

Conduct Interviews. During each site visit, we conducted qualitative interviews with key program, cancer center, and hospital staff. Qualitative interviews are especially useful for providing a comprehensive understanding of issues because an experienced interviewer can clarify and amplify individual responses through guided follow-up and the use of clarifying questions. The interview format allows the interviewer to follow up on various views or statements that may have been unanticipated in either the design of the interview protocol or in the development of study hypotheses. This flexibility can lead to the discovery of new information or different viewpoints on existing information. Interviews can be designed on a continuum from very rigid, or standardized, to very flexible, or informal and conversational (Patton, 2008). Standardized interviews are carefully worded and arranged with the intention of taking each respondent through the same sequence and asking each

respondent the same questions with essentially the same wording. Because many of the respondents, particularly the local decision makers, had only a short period of time to talk with us and many of the topics of interest were site-specific, we knew that we needed a more flexible approach than a standardized interview format would allow. We also realized the constraints imposed by the Office of Management and Budget (OMB), which requires that any questions to be asked of more than nine people undergo a lengthy review (which can take up to 2 years) to assess burden to the respondent. Thus, we needed to be careful about how the questions were worded so that they could be adapted to each site rather than risk their being asked the same way to more than nine respondents.

Therefore, we designed our interviews to be semi-structured. For these types of interviews, the issues and questions to be explored are outlined, but the order and wording of the questions are not predetermined. The interview guide or protocol serves as a basic checklist of issues to be covered during the interview, as time allows. To assess the NCCCP's overarching constructs, as described in Section 2.1, RTI and NCI worked together to develop interview discussion guides (Appendices B–D), each of which was adapted and modified to fit each respondents' role with respect to the NCCCP. The questions in the discussion guides addressed the following domains in addition to the factors listed above:

- individuals' roles and responsibilities both within the site and specific to the NCCCP,
- understanding of the overall NCCCP,
- sites' reasons for participating in the NCCCP,
- vision for and understanding of the NCCCP within each site,
- level of support among top management for NCCCP implementation,
- strategies for implementing the NCCCP in the coming year, and
- mechanisms for coordinating NCCCP efforts.

The discussion guides consist of primary or lead questions, along with additional probing questions to allow researchers to increase the depth of information addressed and modify the interview based on the respondents' availability and knowledge. Based on these question domains, we determined the most appropriate individuals within each site to ask the related questions and planned for the site visits accordingly. RTI and NCI worked together to identify two groups of individuals with whom it was essential to meet during each site visit: (a) senior executives and (b) key cancer center program staff. Table 3-3 lists the roles of hospital staff with whom we requested to meet during each visit and our suggested length of each interview.

Prior to each site visit, RTI developed and disseminated a site visit planning packet, which included information about the purpose of the NCCCP evaluation and the site visits. RTI then followed up with the principal investigator (PI), administrative director, and other key staff via a planning call and e-mail correspondence to introduce ourselves, identify with

whom we should meet during the site visit, review the purpose of the site visit, obtain additional pre–site visit documents, field questions, and determine site visit logistics.

Each site visit was attended by a team of two (sometimes three) researchers, each with a well-defined role (i.e., one focused on conducting the interviews, one served as notetaker and observer, and, for some site visits, a third researcher participated as an additional observer). Each year, every site visit was led by a senior researcher because so much was unknown about how the sites were implementing the NCCCP and we needed a seasoned individual who could thoroughly probe any issues that arose during the interviews. The lead interviewer needed to be knowledgeable about the issues pertaining to organizational theory and management practice as well as cancer service delivery, community-based and disparities research, and hospital management, among other topics. Therefore, we teamed lead interviewers for each site visit with notetakers whose expertise complimented one another. In the first year, we also retained the expertise of three medical oncologists (i.e., all three were from academic medical centers: two from Duke University and one from the University of North Carolina at Chapel Hill) to accompany our teams during the first four site visits in order to provide expertise on issues specific to physician and hospital relationships, cancer care, and service delivery.

Collect Observational Data. For case study designs, interview responses provide a large amount of data. However, observational information can provide additional information above and beyond what can be ascertained during discussions. Likewise, relying only on what people say can be misleading. Observations of the site—such as impressions of the cancer center infrastructure, spatial composition, availability of patient reading material, and organizational culture and norms—capture additional information about the local context.

During the site visits, we attempted to gather impressions of the local context through a variety of strategies:

- guided cancer center tours to get a sense of how easy or difficult it might be for patients to find cancer services,
- observational opportunities identified by the site (e.g., attending NCCCP subcommittee meetings or tumor board conferences), and
- observations of the notetakers and lead interviewers during the interviews (e.g., interactions between staff members and the tone and mannerisms of the interviewees).

For each site visit, we set aside time throughout the day and in the evening over dinner for the team to debrief. During these debriefings, team members shared their impressions, identified areas of questions where more clarity was needed or where inconsistent information had been provided, and discussed whether it was necessary to interview staff who were mentioned during interviews but who were not already on the site visit schedule.

The lead interviewer and notetaker then utilized these observational data to inform the site-specific reports and data coding and analysis.

Year 2 Site Visits

Planning for the Year 2 site visits began in January 2009 so that site visits could be conducted from March through June. The planning process for protocol development and scheduling of site visits closely mirrored the one described for Year 1. Beginning in March 2009, RTI conducted site visits to 10 locations across the country, limiting the site visits to only lead system sites during Year 2. In addition, we conducted telephone interviews with key staff at the six developmental sites. As shown in Table 3-2, the focus on Year 2 was to thoroughly understand the processes and outcomes for each program component. During Year 1, sites were not yet at a point where they had determined their focus for each program component. By Year 2, they had developed work plans that were guiding their implementation for each component. Year 2 questions therefore focused on what sites had worked on in each area, what they had accomplished, and the barriers and facilitators for each step. We also obtained updates from the sites on topics addressed during Year 1 visits, such as interactions with the NCCCP network of sites; changes in their organizational structure and staffing, physician relationships, and/or leadership support; and changes in their cancer service line and delivery of care. As we worked to refine the questions to address during the visits, we identified the people to interview at each site:

- the PI,
- the cancer center director (if this individual was not the PI),
- the program coordinator,
- all key physicians who should be involved in NCCCP implementation, and
- any other staff members involved in implementation of the NCCCP program components.

We also requested a brief meeting (up to 30 minutes) with each chief executive officer (CEO) to touch base with them about the program during every site visit. The purpose of these interviews was to explore the nature of the private-public partnership between the hospital and the NCCCP, the perceived benefits to the hospital, and the level of support the hospital was providing to the program. In Years 2 and 3, we also explored how the economic downturn had impacted their hospital operations. Prior to each site visit, the RTI team members again reviewed all program materials (e.g., progress reports, work plans, available Assessment Survey responses, subcommittee minutes) and listened in on NCCCP subcommittee calls to get up to speed with all the work that was underway.

Year 3 Site Visits

Year 3 site visits were conducted in May through September 2010. Much of the focus during the Year 3 site visits was on issues similar to those addressed during Year 1, such as

- individuals' roles and responsibilities both within the site and specific to the NCCCP and how those have changed over time,
- vision for and understanding of the NCCCP within each site,
- level of support among hospital senior executives for NCCCP implementation,
- strategies for implementing the NCCCP in the coming year, and
- mechanisms for coordinating NCCCP efforts within the site.

We were particularly interested in how sites have effectively managed the program and what the staff's general impression of the NCCCP was at the end of the pilot. As with Years 1 and 2, we planned for the Year 3 site visits by first convening key stakeholders to discuss the purposes of the visits and to outline the specific issues to be addressed during each. We proposed the people with whom to meet during each site visit and then worked with the sites to create schedules for the interviews. We conducted 2- to 3-day site visits with two-person teams. All 16 sites were visited during this final year of the evaluation. Although we also conducted patient focus groups at the 10 lead sites during the Year 3 site visits, those results are not presented here because different topics were addressed at the sites. Four modules were used for the focus groups, including on the topics of access to care, coordination of care, clinical trials, and survivorship, such that five groups of patients were convened for each topic area, which did not provide us with cross-site findings on any one topic.

Patient Focus Groups. Starting in 2008, RTI worked with NCI to prepare for conducting patient focus groups during the final round of site visits. A total of 20 focus groups were planned in order to meet with patients about their experiences in one of four areas:

- clinical trials awareness and participation,
- access to and awareness of cancer program services,
- cancer patient survivorship care, and
- coordination of their care during active treatment.

We developed four focus group modules—access to care, coordination of care, clinical trials, and survivorship—and randomly assigned the modules across the 10 lead sites so that each module was implemented in five sites. This method allowed us to capture patients' experiences with these aspects of care in cancer centers that vary in terms of the patient population served, geographic region, and other characteristics. We worked closely with designated liaisons in each site to recruit participants based on eligibillity criteria for each module. A total of 180 patients participated in the 20 groups. The number of participants per module ranged from 40 to 48. More than three-quarters of participants were female (77.2%), and 79.5% were 50 years of age or older. The majority of participants were white (86.7%) and not Hispanic (92.2%), and almost half had a college degree or higher

(47.2%). RTI developed a comprehensive report of the findings from the focus group, which has already been submitted to NCI separately.

3.1.1.2 Document Review

Triangulation of data is particularly useful when relying heavily on qualitative data for particular findings. In addition to site visit interviews and observations, we used data from additional documents to triangulate findings from the site visits. These include a record review and abstraction of relevant cancer center documents and reports (such as site applications for funding), subcommittee minutes, NCI and hospital Web sites on related program characteristics, all of which address program component activities, program barriers, and processes that emerge throughout the course of the program. To prepare this information for cross-site analysis and answer specific research questions, we coded data from these sources and incorporated them into our data files as described in the NCCCP Evaluation Design Report (updated February 2010).

3.1.1.3 Secondary Data Sources

Secondary data sources are data that were not collected for the purposes of the primary research study. Secondary data sources can also be used to triangulate findings when possible. For the NCCCP, secondary data sources include

- responses from the sites on the baseline, interim, and final assessment surveys;
- review of Web site information on each site's cancer services;
- local demographics and market data as obtained through Centers for Medicare & Medicaid Services (CMS) files; and
- Survey Application Record data from the Commission on Cancer (CoC).

For Year 1, RTI site visit teams reviewed each of these data sources prior to site visits, thereby allowing the interviewers to obtain prior knowledge of the local site, identify any discrepancies in reporting, and adapt their interview discussions accordingly. Moving forward with the analysis, specific variables from each of these sources were identified and incorporated into the overall analysis presented in this report.

3.1.1.4 Case Study Data Coding and Analysis

Qualitative interviews for the case study were chosen as an appropriate research technique because of their capacity for generating rich, detailed information. Interviews can provide a thorough understanding of the issues from varied perspectives. Therefore, interviews are also subject to wide variations in interviewer/observer bias and interpretation, which creates analytic challenges.

In qualitative research, data analysis begins during data collection, as analysts begin to identify potential themes based on interviews and observations. By using a grounded theory approach (Glaser & Strauss, 1967), the researcher becomes immersed in the data, thus

allowing for openness to nonforced and nonpreconceived discovery of emergent themes (Glaser, 2005) and generation of theories based on interpretive procedures (Haig, 1996). In this way, the evaluation conceptual framework for NCCCP provided our team with the theoretical grounding for structuring the questions to be asked and a basis for beginning the coding and analysis. This evaluation, however, was not a test of our framework or of the theories from which it is built but rather an attempt to understand the extent to which the NCCCP model could work and under what circumstances.

For the NCCCP evaluation, we used both inductive and deductive analytic approaches. The inductive approach involves identifying themes through a close reading of the data for each case study (i.e., the person being interviewed). Emergent themes across cases serve as working hypotheses that are subsequently tested against the data by reviewing additional case studies (Yin, 2003; Miles & Huberman, 1994). The following sections describe how we prepared the case study data for analysis and track inter-rater reliability, and how we used the coded data to conduct the overall analysis.

Preparing the Data for Analysis

A major challenge in qualitative analysis is the enormous amount of data that results from the document reviews, interviews, focus groups, field notes, etc. (Patton, 2002). A common solution to this issue is to code the transcriptions, field notes, and observations, using a consistent set of terms. A code is "an abbreviation or symbol applied to a segment of words—most often a sentence or paragraph of transcribed field notes—in order to classify the words" (Miles & Huberman, 1994, p. 56). Codes are categories that are typically derived from the research questions, key concepts, or important themes. For the first year of site visits for the NCCCP, codes were developed based on the conceptual framework described in Chapter 2 and on accompanying constructs included in the interview protocols. Team members who attended all the sites drafted and reviewed the initial list of codes so that the list could be informed by our field experiences. The codes were carefully defined so that coders could follow their meaning and know when to apply the codes to text within an interview. This step enhances inter-rater reliability and ultimately improves the quality of data interpretation. As noted by Miles and Huberman, "clear operational definitions are indispensable, so that [codes] can be consistently applied by a single researcher over time, and so that multiple researchers will be thinking about the same phenomena as they code" (1994, p. 60). A dictionary (or codebook) with these definitions was developed for coders to follow and revised before each year of site visits.

Coding and Interpreting the Data

Once the codes were finalized and all of the analysts were trained on their use and meaning, we began the coding process. To facilitate the coding, we used NVivo, a qualitative analysis software program. Data from the various sources (e.g., notes from interviews, progress reports) were imported into NVivo and assigned as an "internal

document" that included site visit field notes and observations, organizational charts, and other secondary data files included in the analysis. NVivo facilitates analysis by allowing data to be categorized by both "node"—what NVivo defines as a code—(e.g., outreach strategies, barriers to biospecimen collection) and respondent (e.g., Cancer Center director, key physician). Once all the data were coded, the findings could be compiled based on the codes and organized by the node and/or respondents within and across sites. However, because of how the interviews were conducted, such as we often met with groups of people at the same time and did not obtain polls for responses of all individuals, we did not code the data such that we could ultimately provide counts of the number of respondents who were in agreement. Instead, the purpose of the analysis plan was to identify themes across respondents and sites to identify cross-site patterns and characteristics.

Cross-Site Analysis

When conducting a case study analysis, there are generally two types of analyses: within-site or cross-site. A within-site analysis uses methods to identify and verify conclusions about a single site: "the phenomena in a bounded context that make up a single "case study," whether that case is an individual in a setting, a small group, or a larger unit such as an organization or community" (Miles & Huberman, 1994, p. 79). For this evaluation, the analysis of individual cases provided rich descriptions of each site's processes, barriers, and facilitators in implementing the NCCCP. A cross-site analysis allows the evaluation team to assess more fully the broad evaluation questions than they would be able to with a single-case analysis. A cross-site analysis is used when there is a multicase, multisite design and a focus on understanding common processes or patterns that occur across many sites. Because common elements were being assessed for each case (e.g., NCCCP implementation processes, change in performance over time, and structures/processes associated with success), it was possible to analyze the data across the sites to derive meaningful commonalities that could inform ongoing program development and implementation. The cross-site analysis also contributes to increased "user-generalizability" (Merriam, 1995), a parallel construct to external validity used in qualitative research. The inclusion of multiple cases supports the consumer of the study in making more confident conclusions about the extent to which findings may apply to other situations.

NVivo facilitated a cross-site analysis by allowing for data to be coded and analyzed across all respondents, and several codes were combined for further analysis. In this study, the identification of commonalities, as well as contradictions, across the pilot sites contribute to answering the overall evaluation questions. For example, respondents' discussions of the cancer Biomedical Informatics Grid (caBIG) were combined to gain a better understanding of the extent to which sites were able to implement it into their daily workflow. Similarly, cross-site discussions provided valuable information about key organizational factors related to success in clinical trial accrual.

Based on the codes developed for the Year 1 site visits, we examined findings specific to Year 1 to ensure that our codes adequately addressed the evaluation questions and hypotheses contained in this report. As Year 2 findings were coded and added to the dataset, we began to analyze our findings across our themes as guided by our evaluation framework in Figure 2-1 (e.g., sites' understanding and conceptualization of the program, comparison of organizational structures across sites). Findings were first grouped into these themes and then analyzed as a group, across all NCCCP sites and respondents.

Once all the data were coded, data reports were then generated on a single code (e.g., "clinical trials") or combination of codes (e.g., "clinical trials" and "barriers"). Once these data reports were produced, the lead author for each chapter of this report then worked to synthesize and interpret the findings. At this stage in data analysis, we relied on the data to "tell the story" or create the categories of findings to present within each theme. For each chapter, we worked to develop themes around the topic areas to summarize their status or activities around each topic, and then the barriers and facilitators noted by respondents specific to each theme. Sometimes the themes, as informed by the findings, aligned with our conceptual framework and sometimes they did not but, again, we were not testing the framework as much as we were examining patterns across the findings and using contemporary theory to help explain what was found. A second member of the core analysis team then reviewed the initial draft of each chapter and provided reliability checks on the interpretation of findings. In this way, the findings presented in this report have been carefully summarized to ensure both the comprehensiveness and reliability of findings across the sites.

3.1.2 Economic Studies

The NCCCP economic studies were designed to assess the sustainability, effectiveness, and potential replicability of the NCCCP concept. This part of the RTI evaluation includes both a micro-cost study of program activities and a strategic case study to identify the financial or other strategic motivations for organizational participation in the NCCCP. The following specific questions were answered in the micro-cost study:

- How much did the sites spend to implement and operate each of the key components of this program, and how were these expenditures funded?
- For activities with measurable outcomes, how much was spent per unit change in specific outcomes, and how does this vary across sites?
- What are the organizational correlates of higher or lower incremental spending per gain in unit outcomes?

The overall findings specific to the micro-cost study and the strategic case study are presented in a separate report. For the overall analysis described in this report, both studies have been incorporated into the analysis as appropriate to answer key questions about the success of NCCCP implementation. The findings from the two economic studies are

presented in a separate report because that was a separate deliverable of the evaluation contract and is written for an audience interested only in those findings.

3.1.2.1 Micro-Cost Study

Micro-Cost Assessment Tool

The cost assessment tool (CAT) is a Microsoft Excel-based workbook that has been customized by RTI staff to capture costs related to NCCCP participation regardless of the source of funding. RTI staff originally developed and validated the CAT for use in earlier evaluations of cancer screening programs (Subramanian et al., 2009a, 2009b; Tangka et al., 2008). The CAT was extensively adapted to accommodate the needs of the NCCCP evaluation and allow for self-report of how much each site spent to implement each of the key components of the NCCCP. The task leader for the economic evaluation has also used a similar approach as part of an evaluation of a mental health intervention (Dalton et al., 2003). The workbook is "pre-loaded" with previously invoiced costs that were covered by the NCCCP contract, but it required additional input from site administrators or budget analysts to allocate these costs across specific activities and to load other costs related to the project.

The core components of the NCCCP were used as the underlying structure to estimate activity-based costs. Originally, these were the four program "pillars": biospecimens, clinical trials, disparities, and IT. Later, the core components were expanded to include quality of care (QOC) and survivorship.

At each site and for each core program component, CAT was designed to document the following:

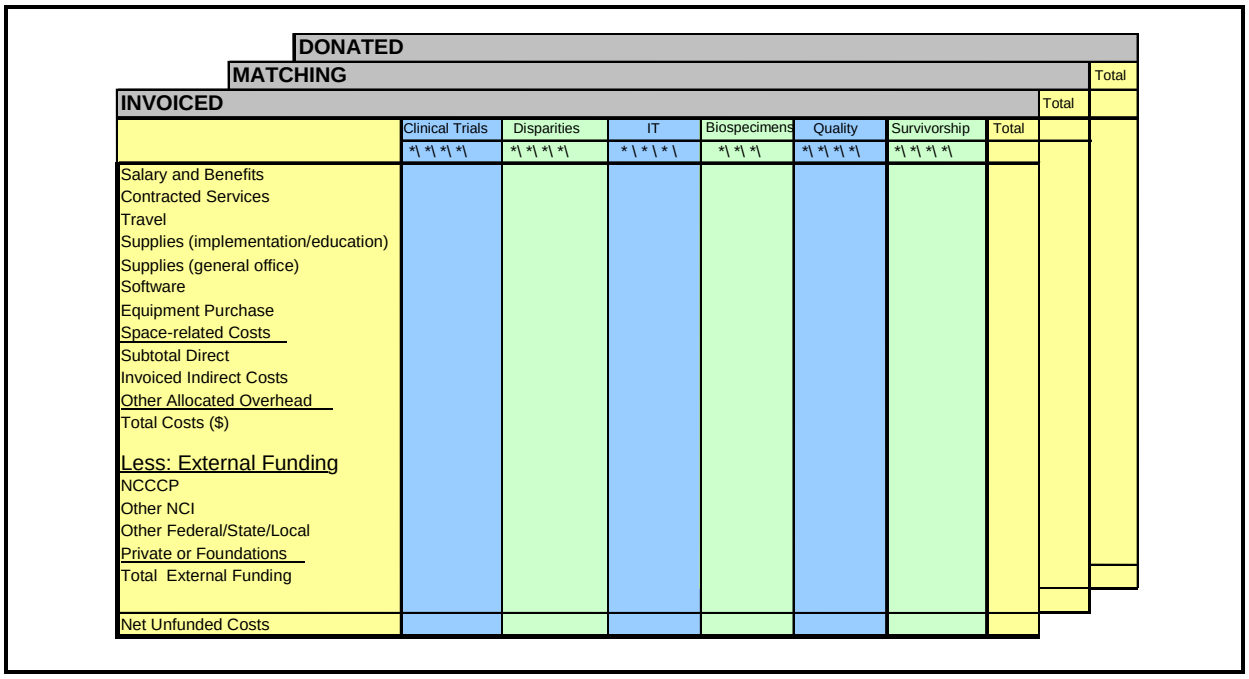
- total implementation and operating costs by type (e.g., salary, materials, contract services, travel);
- distribution of costs across activities within the core component;
- share of costs funded by the NCCCP contract, by other external sources, and by the sponsoring organizations; and
- contribution of donated time from community physicians and other participants.

Data collection was separated into three worksheets representing three cost "domains" distinguishing costs that are (1) covered under the NCCCP contract (invoiced), (2) those that are incurred by the sponsoring site but either funded from operations or covered by other external grants or contracts (matching), and (3) those that are incurred through unreimbursed efforts of clinicians and others in the community (donated). The value of

donated services was calculated by RTI based on the number of hours reported by the sites, with RTI obtaining national or regional data on annual income and hourly rates.[1]

Figure 3-1 presents a schematic representation of CAT specific to the NCCCP evaluation. Cost types are identified by row and are defined consistently across each domain worksheet. Each domain worksheet contains the same six sections covering the six core component activities. Within each core component section are columns describing key sub-activities that are specific to that component (represented by "*\" in the schematic). Site administrators or budget managers are asked to allocate core component costs across these columns. The column definitions vary by core component but are consistent within each core component across the three domain worksheets.

Figure 3-1. Schematic of the Cost Assessment Tool



Data Collection Logistics

General. CAT was forwarded electronically to each pilot site administrator, who could then forward it to the most appropriate individuals for completion. Although we use the term "pilot site" throughout this section, single NCCCP contracts made to a system head office (such as Catholic Health Initiatives) but covering expenditures at multiple hospitals are considered one site for purposes of completing the forms. Although data collection across organizations can be challenging, it was particularly difficult for the two system sites.

[1] For physician specialties, we used regional income data reported by the Medical Group Management Association. For other staff, we used the Bureau of Labor Statistics national hourly wage estimates by job category and adjusted these to add benefits.

Invoiced Costs. For the invoiced costs domain worksheet, data by core component were loaded directly to the CAT worksheets from electronic files that were transferred quarterly from SAIC-F to RTI. At each site, the designated administrative person was responsible for allocating invoiced costs to the individual activity columns using percentage estimates, from which the worksheet set up to compute allocated amounts. The first round of cost allocations incorporated all invoiced costs for Year 1 of the contract (July 1, 2007 to June 30, 2008) and were distributed in November 2008 for completion by February 2009. For Years 2 and 3, RTI distributed the updated CAT worksheets to sites within 2 weeks of receiving the final (June 30) contract invoices and requested turnaround from the sites within 4 weeks. Table 3-4 provides an example of invoiced costs provided by sites to SAIC-F on a quarterly basis.

Matching Costs. Sites were given some leeway in identifying and quantifying matching costs related to NCCCP activities as long as these costs were incremental. CAT instructions (accessed by right-clicking the cell containing the domain worksheet description) explicitly instructed users to exclude any costs that were part of the organization's operations prior to participating in the NCCCP pilot, even if these costs directly overlap with newly funded NCCCP activities. RTI recognizes, however, that such distinctions were difficult to operationalize and that there was some potential for overstatement. As with the invoiced costs, sites were asked to allocate matching costs across the specific activities within NCCCP core components using percentages based on time or other criteria as appropriate.

Matching costs can reflect contributions of the sponsoring organization to NCCCP activities or they can be funded from other grants or contracts. The lower portion of the CAT input worksheet includes lines to identify other funding sources. If applicable, these amounts were entered by specific activity within the core components.

Sites were first asked to document Year 1 matching costs in one worksheet. After that, RTI requested matching costs information on the same quarterly update schedule used for invoiced costs.

Donated Costs. From conversations with site administrators and medical directors, we expected the majority of donated services documentation to relate to uncompensated time from community physicians and their staff. From discussions with site staff, we expected most of this time to relate to trial enrollments and MDC committees. Site personnel were asked to estimate only the number of hours spent on NCCCP activities, by type of professional as listed on the specific lines for this worksheet.

3.1.2.2 Strategic Case Study

As part of RTI's evaluation of the feasibility and sustainability of the NCCCP pilot, we interviewed CFOs to gather data on

- their motivations for participating as an NCI pilot site, including the extent to which they perceived there to be a business case for NCCCP participation,
- the perceived fit between the NCCCP and the strategic plan for their cancer program or service line,
- their expectations for financial or other returns (i.e., profitability) on NCCCP investment (e.g., enhancing cancer research), and
- the conditions under which they would commit to carrying on the activities in the future or planning for sustainability.

Telephone interviews were conducted with the 10 CFOs at the lead NCCCP sites in 2009 and repeated in 2011. Unfortunately, of the 10 CFOs initially interviewed, only 4 were still in this position to be interviewed again in 2011. Of these 4, only 3 could be scheduled for interviews in time for this analysis. Much like the interviews from site visits, we coded and analyzed the responses based on themes and present the data in quotes in Chapter 17 where sustainability is addressed.

3.1.3 Patient Survey

The primary purpose of the NCCCP patient survey was to gain an understanding of the patients' perspective on the NCCCP pilot by assessing how well patients' health care and informational needs were being met. RTI collected survey data from patients at two points in time, approximately 18 months apart, to examine if and how the overall patient experience changed over the course of the pilot. The first survey collected data from a group of patients who received treatment at the 10 participating cancer centers around the time that the NCCCP pilot began; this survey provided the baseline data. The second group of survey participants received treatment after the pilot program had been operational for approximately 2 years. Thus, we are able to examine changes over time in patient experiences as the pilot program developed and became more established in the sites.

The patient survey was specifically designed to assess patient experiences and perspectives related to access to and coordination of care, patient navigation, post-treatment/ survivorship care, patient-centered communication, and patient awareness and use of selected cancer center resources. The survey also requested some sociodemographic and health status information. Limited data from cancer registries were merged into the dataset. Together with the patient focus groups, the patient survey complements other elements of the NCCCP evaluation by providing the patients' perspective.

3.1.3.1 Data Collection

To increase the survey response rate, RTI initially administered the patient survey using three modes (i.e., mail, telephone, and Web-based). However, because of the low number of responses through the telephone approach, for the second patient survey, we limited data collection to the mail and Web modes. The majority of completed surveys were submitted through the mail. The 10 lead NCCCP sites participated in the patient survey.

RTI trained designated staff on how the survey was to be conducted. Because of patient confidentiality issues, we were unable to access patient records directly to administer the survey and therefore had to rely on the sites to assist with preparing the mailing packages and sending them out from their locations. To qualify for the study, a patient must (1) have had one or more outpatient cancer treatment visits at the cancer center within the past 12 months, (2) have been 21 years of age or older at the time of diagnosis, and (3) have been diagnosed with cancer based on specific International Classification of Diseases (ICD) and/or Current Procedural Terminology (CPT) codes.

3.1.3.2 Randomization

RTI randomly selected 475 patients from each cancer center from the de-identified and password-protected list of eligible patients submitted by the cancer centers via e-mail attachment to the RTI statistician. RTI then returned the master list to the cancer centers indicating which patients were selected for the study using a flag (a variable indicating whether a patient was selected). At no time did RTI have participants' personally identifiable information, such as name, address, or social security number (with the exception of patients who volunteered their names when calling to complete the telephone survey during the first round of data collection).

RTI supplied the cancer centers with survey packets to send to potential participants. Each of the 10 cancer centers were responsible for mailing the survey packet to the 475 randomly selected patients from each cancer center. Cancer center staff referred to the randomization list provided by RTI and matched the SID with the corresponding SID on the patient packet.

3.1.3.3 Follow-up with Nonrespondents

Approximately 4 to 8 weeks after the initial mailings, RTI generated a list of people, using their SID, who had yet to complete the patient survey by any mode. RTI carefully monitored the response rate and determined the appropriate timing for the second mailing. Once the list was verified by the cancer centers, RTI shipped additional survey packets to the cancer centers to mail to nonrespondents. Patients not interested in participating in the survey could choose to contact their cancer center or RTI to express this preference after receiving the first packet. Those patients were not mailed a second survey packet.

3.1.3.4 Response Rate

Through a variety of proven methods for increasing response rates, including repeated mailings, stamped return envelopes, and access to Web administration, we were able to achieve a 52% response rate in 2009, for a total sample of 2009 respondents. In 2011, we achieved a 48% response rate for a total sample of 1,946 respondents. The lower response rate in 2011 was larger due to a shorter data collection time period.

3.1.4 Comparative Evaluation

NCI funded RTI in collaboration with the CoC to perform a comparative evaluation, assessing how participation in the NCCCP changed the quality of cancer care provided at these hospitals both over time (i.e., before versus after NCCCP initiation) and in comparison to a similar group of hospitals that have not participated in the NCCCP. This comparison group allows us to assess changes in QOC associated with NCCCP participation in the presence of ongoing secular trends producing improved QOC, patient outcomes, and attention to underserved populations. This aspect of the evaluation also explores the impacts of different NCCCP components on changes in QOC to determine the pilot program factors most important in improving care for individuals with cancer. The overall findings specific to the comparative evaluation are presented in a separate report. However, data from this study specific to only the NCCCP sites have been incorporated into the overall analysis presented in this report (see Chapters 13 and 16).

3.1.4.1 Comparative Evaluation QOC Measures

Outcomes for the comparative evaluation include six QOC measures collected by the CoC's Rapid Quality Reporting System (RQRS). In contrast to standard clinical outcomes and QOC measures, which can involve lags of 2 years or longer, the RQRS permits assessment of patient-level outcomes in near real-time. RQRS information is being collected from all NCCCP sites and a group of approximately 50 comparison (i.e., non-NCCCP) hospitals. These quality measures focus on two of the most commonly diagnosed types of cancer: breast and colorectal cancer.

The following are the six QOC measures collected by the RQRS.

The three QOC measures for breast cancer patients are

1. timely and appropriate radiation therapy for women under age 70 who are diagnosed with breast cancer and receive breast-conserving surgery:
    - recommended/offered, and
    - administered within 1 year (365 days) of diagnosis for women;
2. timely and appropriate combination chemotherapy for women under age 70 with AJCC T1cN0M0 or Stage II or III hormone receptor negative breast cancer:
    - recommended/offered, and
    - administered within 4 months (120 days) of diagnosis; and
3. timely administration of Tamoxifen or third generation of aromatase inhibitor for women with AJCC T1cN0M0 or Stage II or III hormone receptor positive breast cancer:
    - recommended/offered, and
    - administered within 1 year (365 days) of diagnosis.

The three QOC measures for colorectal cancer patients are

1. timely and appropriate adjuvant chemotherapy for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer:
   - recommended/offered, and
   - administered within 4 months (120 days);
2. appropriate examination for resected colon cancer:
   - at least 12 regional lymph nodes removed and pathologically examined regardless of age; and
3. timely and appropriate radiation therapy for rectal cancer patients under the age of 80 with clinical or pathologic AJCC T4N0M0 or Stage III rectal cancer receiving surgical resection:
   - recommended/offered,
   - administered within 6 months (180 days) of diagnosis.

Although these outcome measures are all dichotomous (i.e., yes or no), we used these data to explore temporal differences among individuals who received the indicated QOC measures within the specified timeframes. For the overall analysis, we calculated the nonconcordance rates for each site at both Time 1 and Time 2 and determined which changes were statistically significant. Because we were performing site-level comparisons, we were unable to include the sixth indicator, specific to rectal cancer treatment, as the sample sizes were too small. Analyses for all of the quality of care measures, including of data from both NCCCP and non-NCCCP hospitals, are discussed in a separate report on the comparative evaluation because this is a separate deliverable of the evaluation contract and includes data from non-NCCCP comparison hospitals.

3.1.5 Environmental Analysis

The environment is one of the key domains of the conceptual framework (see Figure 2-1). The purpose of the environmental analysis study was to examine the market environments in which the NCCCP sites are operating. Profiling the environmental characteristics of the NCCCP sites′ service areas allows NCI to assess macro-level factors that may impact the NCCCP sites′ ability to improve QOC, patient outcomes, and attention to underserved populations. This analysis was conducted to examine temporal trends in key dimensions of the environment in which the NCCCP sites are located and to cover time periods both before and after the implementation of the NCCCP pilot. Unfortunately, once we began the environmental analysis, we soon learned that the majority of data to be used would not be available for the time periods after NCCCP initiation. We therefore have incorporated only a small proportion of environment variables from this analysis into this report.

The four main aspects of the markets that were examined in the environmental analysis were hospital competition, managed care penetration/market concentration, cancer services

competition, and local poverty rate. In assessing the environmental variables to include in the overall analysis, we used the following criteria: (1) selected measures had to be available for the majority of sites for the same time period and (2) based on the literature, selected measures would be the ones most likely to be associated with a site's ability to successfully implement various aspects of the NCCCP. Table 3-5 presents the constructs, control variables, and hypotheses for this analysis.

3.1.5.1 Data Sources

Data from the environmental analysis were derived from four key data sources, as described below. In addition to these four, U.S. Census data from 2006 were used to obtain local poverty rates.

Area Resource File (ARF)

The ARF, developed by the U.S. Health Resources and Services Administration (HRSA), is a database containing more than 6,000 variables for each county in the United States. The ARF contains information on health care supply (e.g., numbers of facilities and numbers of health professionals by type), economic activity (e.g., employment), and sociodemographic factors (e.g., population by age, race and ethnicity, income, education, and population density).

Unique Physician Identifier Number (UPIN)

The UPIN Directory and its successor report, the downloadable National Plan and Provider Enumeration System (NPPES), provide data on every participating Medicare participating provider and include the UPIN (or, since 2007, the National Provider Identifier [NPI]), provider name, specialty, and state and ZIP codes of practice locations. We used these files to identify the number of hematology/oncology, medical oncology, radiation oncology, and gynecologic oncology specialists within the market area of the NCCCP sites.

CMS Hospital Service Area File (HSAF)

CMS also maintains the HSAF, which is derived from the calendar year inpatient claims data. The records contain number of discharges, length of stay, and total charges summarized by provider number and ZIP code of the Medicare beneficiary. This file is produced annually and is usually available in May. This file was used to determine inpatient Medicare market share for each NCCCP site and market.

Commission on Cancer (CoC) Web site

The CoC has accredited more than 1,400 cancer programs in the United States and Puerto Rico. This number represents close to 25% of all hospitals in the United States and its territories. The Web site maintains a public, searchable database that we used to determine the presence (and number) of CoC-accredited hospitals in the market. The database is maintained at http://web.facs.org/cpm/CPMApprovedHospitals_Search.htm.

3.1.5.2 Data Indicators

Four environmental indicators have been incorporated into the overall analysis, including Medicare market share, two aspects of cancer services competition, and one indicator for local population characteristics. Table 3-6 presents the key study variables and data sources for these indicators, each of which is described below.

Medicare Market Share

The concentration for the NCCCP sites' share of Medicare inpatient days were calculated as the total number of Medicare inpatients at the hospital by the total Medicare cases in the market. This indicator combines information on the hospital and its market and describes the extent to which the hospital has captured a proportion of the market of Medicare recipients. The Medicare market share is a percentage, ranging from 0% (no Medicare cases) to 100% (all the Medicare cases in a market). NCCCP sites operating in markets with a high concentration of Medicare inpatient days may be more likely to have high performance than NCCCP pilot sites operating in markets with a low concentration of Medicare inpatient days.

Cancer Services Competition

We developed one broad hypothesis regarding the relationship between cancer services competition in the market and outcomes, and we measured cancer services competition incorporated in the overall analysis in two ways: the per capita number of oncologists in the market and the presence of CoC-accredited hospitals in the NCCCP market. It is likely that NCCCP sites operating in markets that are less competitive for cancer services from other cancer programs would have higher performance than NCCCP sites operating in markets that are more competitive for cancer services.

- *Per capita number of oncologists in the market.* We identified the number of hematology/oncology, medical oncology, radiation oncology, and gynecologic oncology specialists within each NCCCP market area and report them per capita.
- *Presence of CoC-accredited hospitals in the market.* We used the online CoC database to search by ZIP codes in the NCCCP markets to assess information about the presence (and number) of CoC-accredited hospitals in the market.

Population Characteristics

Although numerous population characteristics, such as the local level of unemployment, or distribution of age in the community, could potentially influence a site's ability to be innovative and implement a program like the NCCCP, we hypothesized that the local poverty rate would be the best indicator for these types of influences on a site's growth. Our overall analysis had to be limited to a small number of indicators because of the low number of sites involved (and thus limited power). Therefore, in discussions with NCI and the EOC, we determined that poverty rate would be the best indicator among local characteristics to be associated with NCCCP success.

3.1.6 NCCCP Clinical Trials Special Study

Since clinical trials activity as a result of NCCCP participation is such an important outcome of the program, NCI requested that a study be conducted to compare pilot sites to national trends in clinical trials activity, using the Cancer Therapy Evaluation Program (CTEP) data. The CTEP data captures information on trials and accrual and was provided to RTI for conducting this special analysis. Given their expertise in this area, RTI requested that Dr. Amy Abernethy, Director of Duke University's Cancer Care Research Program, conduct this study in the summer of 2011. Her team developed a summary of a global evaluation of the clinical trials activity of the NCCCP pilot period from July 2007 to July 2010. Their summary report includes an assessment of the clinical trials portfolio and accrual for the pilot sites and a review of the temporal relationship of the organizational characteristics and clinical trial activities. In addition to summaries of activities, sites were considered in the context of their NCCCP lead versus developmental designation, as well as their CCOP affiliation. Two main outcome assessments were considered:

- clinical trials **portfolio** (e.g., the number of open clinical trials at a site, sponsor, types of trials [phase, intervention under investigation]); and
- clinical trials **accrual** (total accrual and accrual for underserved populations [racial and ethnic minorities, rural residents, over 65 years of age]).

As previously noted, the findings from this analysis are presented in a separate report but have been incorporated into the overall findings specific to the NCCCP where applicable.

3.2 Overall Analysis Plan

In the NCCCP Evaluation Design Report (EDR) updated in February 2010, three major questions were stated as the priorities for the final evaluation:

- What changes in each program component and for the cancer service line overall seem to be facilitated by the NCCCP?
- What organizational requirements are necessary to effectively manage/implement the NCCCP and selected program components?
- What changes and elements are sustainable and potentially replicable?

During this time, NCI expanded resources to support the additional study questions necessary for an environmental analysis, comparative evaluation, and a clinical trials special study. In meetings convened from October through December 2010, RTI and NCI worked to refine the study questions for the final analysis. The following study questions have been added to the original study questions:

- How is initial capacity for NCCCP implementation linked to successful implementation of the overall program?
- How do specific environmental factors influence an organization's ability to achieve success with NCCCP implementation?

- What were the changes in practice patterns (i.e., adherence to clinical guidelines/National Comprehensive Cancer Network [NCCN]) among NCCCP sites?
- How did clinical trials activity among NCCCP pilot sites compare to other hospitals from July 2007 to June 2010?

Consequently, the final analysis of the evaluation data had to be adjusted. RTI had initially planned to provide separate analyses for each of the original studies (e.g., case study, patient survey, economic studies) as described in Chapters 3, 4, and 5 of the EDR, respectively. The patient survey analysis was still performed for the overall evaluation but was not reported separately. Instead, the findings from the patient survey have been incorporated, as appropriate, within the overall evaluation report. The following four reports were developed for the fourth and final year of the pilot:

- the overall evaluation report of findings across the data sources (described in this section);
- the micro-cost study, across all 3 years of data collection, as well as the strategic case study;
- the comparative evaluation of RQRS findings for NCCCP and non-NCCCP sites; and
- the clinical trials activity report prepared by Duke University's Cancer Care Research Program.

As the overall integrated evaluation report was being developed in the fall of 2011, data from all sources, where applicable, were incorporated into the analysis. This section provides an overview of how the analysis planning process proceeded throughout the fall of 2010 and early 2011, followed by a description of the overall evaluation measures and the final steps in pulling together the dataset to interpret and report the findings. Note that here we describe how the overall analysis was conducted, incorporating multiple data sources, and do not describe analyses for individual data sources, which are described elsewhere (e.g., comparative evaluation).

3.2.1 Summary of the Overall Analysis Planning Process

Following two meetings with senior NCI leadership in the fall of 2010, NCI and RTI convened key members of the EOC on December 10, 2010, to make final decisions about the overall analysis. Discussion during the EOC meeting centered around the overall analysis and how the "meta-matrix" of items would be populated and analyzed in order to conduct a time-ordered cross-case analysis (Miles & Huberman, 1994). The following sections provide a summary of the data sources used in the overall analysis, methods for data abstraction, and the method for developing composite measures of selected variables.

3.2.1.1 Data Sources for Overall Analysis

Although the NCCCP itself (through SAIC-F) and the evaluation team have each collected a multitude of data, only selected data sources were relied upon for the final overall analysis. We used the following criteria to identify data sources:

- data are available for all 16 sites (not just the 10 lead sites) for most variables;
- data are available for at least the baseline (as of July 1, 2007) or in some cases for the first quarter of Year 1 (July 1 to September 30, 2007) and Year 3 (as of June 30, 2010) of program implementation;
- data are considered to be reliable, or a secondary data source is available for validating each variable; and
- data are able to be abstracted within the specified timeline of this analysis (i.e., findings need to be made available to RTI by the end of April 2011 to be included in the overall analysis).

Table 3-7 provides a summary of the data sources as well as how the data were used and the strengths and limitations for each source.

3.2.1.2 Methods for Data Abstraction

Many of the variables used in the final analysis were derived from qualitative data sources (e.g., interviews during site visits, assessment of program accomplishments) and, where possible, converted to quantitative values for comparisons across sites. Although there were only 16 sites (sometimes 10, depending on the variables being analyzed) and therefore a regression analysis was not feasible, the RTI team used well-documented means for creating a dataset to allow for cross-case analysis over the 3 years of program implementation (Ragin, 1987). Following guidelines described in the literature, RTI created a meta-matrix of all of the variables described in this section (Miles & Huberman, 1994). A sample of the meta-matrix appears in Appendix E. As with processes used to prepare data for quantitative analysis, we worked to make all of the data comparable across cases by standardizing them into common metrics (e.g., "no" or "none" responses were designated as a zero in the coding). A meta-matrix is a master chart that assembles descriptive data from each of several cases into a standard format (Miles & Huberman, 1994). To create the meta-matrix, we followed the process outlined below:

1. Clearly define each construct (e.g., "leadership support") and state an operational definition of each.
2. Identify the most appropriate data source and variables to approximate each construct (e.g., successful implementation is evident when sites have made strides in implementing a cancer-specific physician credentialing program).
3. Identify a secondary data source to be used as a backup if there is an issue of missing, questionable, or unusable data from the primary data source.

4. Abstract data for each identified variable into the meta-matrix for consistent analysis and create a codebook that provides details on what values have been assigned to characteristics of the sites.
5. Check the reliability of the data abstraction, both in the value assigned to the variable and in how it was interpreted, by reviewing a secondary data source in some cases and/or by having a second analyst independently enter data and then measuring the degree of agreement between analysts.
6. Develop means for presenting comparisons across sites to address overarching evaluation questions.

3.2.1.3 Development of Composite Measures

For the overall program and for each program component, we developed four sets of composite measures: (1) baseline capacity for sites to implement the NCCCP; (2) baseline indicators related to the local context for the hospitals (i.e., market competition, poverty rate of the local population); (3) success at implementing each of three program components (i.e., disparities, clinical trials, and quality of care); and (4) overall successful implementation of the program. These scores were derived from data elements described in the rest of this section. For example, we developed a composite score specific to "clinical trials" that includes all indicators of success (e.g., number and type of trials, number of patients, and number of providers involved) and rank each site based on their level of development at the time of the initial site visits. We then assessed their success relative to their baseline capacity to implement the NCCCP. A final step was to assess which organizational factors may be associated with what each site was able to achieve in clinical trials. The following provides an overview of the development of measures to assess sites for their capacity at the time of program initiation as well as for each program component and overall implementation.

3.2.2 Overall Evaluation Measures

For the overall evaluation, measures were developed from the raw data elements to attempt to answer each of the overarching evaluation questions. The following sections explain the process for assessing the sites' capacity at baseline to implement the NCCCP as well as how overall success were measured for each of the three program components and for the program overall.

3.2.2.1 Assessment of Sites' Capacity at Baseline for NCCCP Implementation

For the final analysis of the NCCCP pilot, the evaluation assessed the progress sites have toward achieving key outcomes by considering the capacity of the sites at baseline (i.e., on or before June 30, 2007) for achieving the aims of the NCCCP. This capacity measure provided a control variable for assessing which sites have achieved success for each program component and/or the program overall. For example, those sites that started the program performing at a relatively high level for cancer care were measured against their own progress during the pilot, as opposed to comparing them to the progress made by

other sites at different baseline levels. Working with NCI and the EOC, RTI identified three key indicators (Table 3-8) to use in assessing sites' capacity for NCCCP implementation at baseline.

To abstract the data, we followed the process described in Section 3.2.1.2. We then separated the data into quartiles and rank accordingly. Those sites that are at or above the median of each range of scores were considered "high" on the related scale, and those below the median were ranked as "low."

3.2.2.2 Assessing Baseline Environmental Influences on NCCCP Hospital Performance

Empirical research suggests that the environment (or context) in which an organization operates significantly affects its ability to learn, innovate, and change. This is because organizations like community cancer centers are dependent on other organizations (e.g., insurers) for key resources and must compete for these resources with other cancer care providers. With respect to the NCCCP, two aspects of the environment are likely to be particularly important: the nature of health care competition in the local market and the characteristics of the community served. To assess environmental influences, we followed a process similar to that for baseline capacity and select variables from an overall environmental analysis that was conducted by RTI in 2010. The data sources used were from periods of time before or simultaneous with NCCCP implementation, so the measures we developed incorporated the baseline market competition and characteristics of the local community.

3.2.2.3 Assessing Success with NCCCP Implementation

In stating the evaluation questions, it is important to determine the outcomes or dependent variables that were incorporated into the final analysis. Most of the analyses conducted relied on the operationalization of "success" of NCCCP implementation for each of the three measured program components (i.e., disparities, clinical trials, and quality of care) and overall. The following sections describe key outcomes and data sources that we used to create these measures.

Success at the Program Component Level

During 2009–2010, RTI worked with NCI and SAIC-F to further refine the list of outcomes or dependent variables for the major program components (i.e., disparities, clinical trials, quality of care, survivorship/palliative care) that sites were expected to track and monitor over the course of the pilot. Table 3-9 provides a summary of the key outcomes and data sources for each of these program components. As with the indicators for capacity at baseline, weightings for these variables were determined in order to create a composite score for the level of success in each component. Hypotheses that were tested for each program component are discussed in Section 3.2.4.

Success at the Overall Program Level

In addition to examining successful implementation of specific program components, we examined successful implementation of the NCCCP overall. As shown in Appendix F, we relied on the evaluation conceptual framework for specifying indicators to use in assessing overall success. We developed a matrix to quantify some of these outcomes by sites. However, several outcomes were not quantifiable based on the data collected to date; these are described in Chapter 16 of this report. In Table 3-10, we provide the short-term (less than 1 year), intermediate (1–3 years), and ultimate (beyond 3 years, or after the pilot) outcomes as depicted in our evaluation conceptual framework matched to evaluation indicators and variables from data sources to be included in the overall analysis. Data for each variable used to develop the composite score were compiled into an analysis matrix to assess the relationships and test hypotheses (Section 3.2.4) specific to organizational and program characteristics on the "success" of the NCCCP. Similar to the capacity indicators in Section 3.2.2.1, we worked with community oncologists (via the American Society of Clinical Oncology [ASCO]) to determine the weighting for some of the indicators. Once weights were assigned to each indicator, sites were ranked in low, medium, and high categories of overall achievement.

Because many of these variables were not quantifiable with the data available to us, we present summaries of these findings in tables throughout this evaluation report. As shown in Table 3-11, it is during this process that we used coded interview data from site visits to help elucidate the patterns and we presented relevant details to help with the interpretation of the overall findings.

The following section describes the operationalization of the independent variables to assess with regards to their association with the overall success of NCCCP implementation, followed by a description of how the overall comparative analysis was conducted.

3.2.3 Assessing Organizational Factors Associated with Successful NCCCP Implementation

As noted in Section 3.2.1, there are numerous independent factors at the organizational level that need to be operationalized in order to prepare for data coding, preparation, and analysis. Appendix G provides a listing of the organizational factors and corresponding data elements for each. The following section presents the evaluation questions and hypotheses addressed through the final analysis for the organizational and program levels and demonstrates how each factor was operationalized using data that meet our criteria described in Section 3.2.1.1. However, many of the concepts incorporated into the evaluation conceptual framework (Appendix F) are difficult to operationalize (e.g., effectiveness of teams) or are derived from data that lack sufficient variation across sites (e.g., whether or not sites added multidisciplinary care conferences) to test the relationship of these factors with successful implementation of the NCCCP. Table 3-12 presents those

factors that have been depicted in the organizational theory supporting the evaluation conceptual framework but that would not be examined due to these limitations.

3.2.4 Pulling it All Together: Analysis Specific to Each Overarching Evaluation Question

This section provides an overview of the measures that were combined to test specific associations between individual and/or composite measures at the organization and program levels. As shown in Appendix G, these two levels are critical to understanding the factors that influenced whether the NCCCP worked well and reached the achievements specified by NCI.

3.2.4.1 Organizational-Level Analysis

As shown in Appendix G, there are five major factors that are likely to affect an organization's ability to learn, change, and succeed in the NCCCP: (1) the environmental context within which the organization (or hospital) is operating; (2) each site's understanding and conceptualization of the NCCCP; (3) existing organizational structures and processes; (4) capacity for learning, innovation, and change; and (5) ability to form effective partnerships with key groups in the communities. The following presents the evaluation questions for assessing the association between organizational success in implementing the NCCCP and the following factors: each organization's local environmental context, each organization's baseline capacity for the NCCCP, organizational processes and structures within each hospital, and sustainability of the program.

Environmental Context

As described in Section 2.1.2.1 of the EDR, there are numerous factors of the local environment that are expected to influence a site's ability to successfully implement the NCCCP. For the overall analysis, we strived to address the following question with specific environmental data:

- How are specific baseline environmental factors associated with each organization's ability to achieve success with NCCCP implementation?

Working with the EOC, we determined that four variables from the environmental analysis could be used to develop a composite score for each hospital's environmental context:

- total hospital Medicare market share (for 2007),
- number of CoC hospitals per 100,000 (as of 2007),
- number of cancer specialists in the market per 100,000 (as of 2007), and
- local poverty rate (as of 2006).

As previously described, we defined the Medicare market as the ZIP codes that make up 80% of each hospital's total Medicare discharges. We also incorporated the local poverty rate (as of 2000, the closest time period available prior to NCCCP implementation) as the

community characteristic to examine specific to the environmental context. The results for this baseline environmental composite score are presented in Chapter 4.

Baseline Capacity

After grouping sites based on their baseline capacity for implementing the NCCCP (see Section 3.2.2.1 for description, Chapter 4 for results), we reviewed the findings to determine which of these sites were able to achieve success in overall implementation (Section 3.2.4). We then reviewed the data to assess the following question:

- How is initial capacity for NCCCP implementation linked to successful implementation of the overall program?

As described in Section 3.2.2.1, sites' performance at the end of the pilot was compared to their capacity level at the time of initiation (the results are presented in Chapter 16). It is possible that those sites that started at lower levels of capacity may be able to achieve great success for most, if not all, of the NCCCP implementation and that sites with higher levels of capacity at baseline may be able to expand their cancer care in ways they might not have otherwise accomplished had it not been for the NCCCP. Once the baseline capacity groupings were finalized, a number of different analyses were able to be conducted (as time allowed) to explore these types of associations.

Key Organizational Factors

The essence of the NCCCP is that it is an initiative that is attempting to change how these community cancer centers operate in order to improve their overall quality of cancer care. Therefore, one of the major overarching evaluation questions for the NCCCP is the following:

- What are the organizational requirements necessary to effectively manage/implement the NCCCP?

As shown in Appendix G, there are multiple organizational factors that are being operationalized to assess the association between these factors and the sites' level of success with NCCCP implementation. For this analysis, we reviewed the data to determine the organizational factors that seem to be associated with whether sites succeeded. Appendix G provides specifics on what the factors are and the data sources from which they were derived, while the hypotheses to be tested included examining the extent to which cancer centers that are successful in NCCCP implementation have the following characteristics:

- hospital senior executives who
  - are committed to and supportive of the cancer program and
  - perceive the overall benefits of the NCCCP to be greater than the overall costs;

- an organizational structure that
  - relies more heavily on employed physicians or stronger participation agreements with private practice oncologists than on private practice physicians;
  - has an increasing number of oncologists and sub-specialists associated with the cancer center; and
  - includes a full-time medical director, NCCCP-capable cancer center administrator, and/or "program champion" who provides for a direct reporting relationship between this director and the hospital's senior executives;
- an infrastructure that
  - enhances involvement of physicians and other key departments/staff early and often in program development;
  - provides for administrative support of the NCCCP (e.g., having program coordinator assigned to NCCCP);
  - provides for staff working in specific roles in support of program activities (e.g., director of research, outreach workers specific to cancer); and
  - encourages linkages with other NCI cancer programs; and
- capacity that includes
  - greater operating margins and resources to dedicate to the oncology program and
  - development of a better integrated information systems (e.g., a hospital system that can communicate effectively with systems in each private practice) to support the cancer program and NCCCP goals.

Sustainability

Sustainability has been defined as the "capacity to maintain program services at a level that will provide ongoing prevention and treatment for a health problem after termination of major financial, managerial, and technical assistance from an external donor" (LaPelle, Zapka, & Ockene, 2006, p.1,363). For the overall evaluation, the following question were addressed using data primarily from the micro-cost study as well as from the strategic case study (i.e., interviews with CFOs) and the site visit interviews:

- What changes and elements are sustainable and potentially replicable?

Micro-cost study data from Years 1–3 were used primarily to assess the potential for sustainability of the NCCCP. In determining the variables of interest for this aspect of the analysis, we examined each of the cost indicators to assess the extent to which they seem to be associated with activities that benefit the organization and not just NCI, thus making them likely to continue even if NCI funds were unavailable. To start, we proposed using certain categories of matching costs as collected through the CAT to serve as markers for

sustainability, in that they suggest sites' willingness to invest in research infrastructure. We also proposed that costs for activities associated exclusively with the NCCCP would be less likely to be continued without NCI funding (e.g., NCCCP program administration, cross-site coordination). With these criteria in mind, we agreed with NCI to use the cost indicators specified in Table 3-13 in assessing the overall cost to the organizations for continuing the NCCCP without NCI funding (results are presented in Chapter 17).

3.2.4.2 Program-Level Hypotheses

The program level includes the cancer service line through which the hospital is providing all of their cancer services. In some hospitals these service lines are quite fragmented, while in others these service lines are well integrated, often led by a physician director who specializes in cancer care (e.g., a medical or radiation oncologist). The overarching evaluation question specific to the program level is the following:

- What changes in each program component and for cancer research overall seem to be facilitated by the NCCCP?

The following section describes the hypotheses that were tested for each of the three major program components: disparities, clinical trials, and quality of care. To quantify the "cancer service line overall," we used an operationalization similar to overall success as described in Section 3.2.4.

Disparities

For the NCCCP, the overall evaluation examined how participation in the program is associated with how well sites increased their capacity to address cancer health disparities. The overarching evaluation question for this program component is the following:

- What changes in the cancer program relative to disparities seem to be facilitated by the NCCCP?

The outcomes specific to disparities appear in Table 3-9. In the final analysis, we examined whether increases in disparities outcomes are best demonstrated by sites that have had success with NCCCP implementation, particularly with these characteristics:

- top management support,
- staff leadership for disparities activities (i.e., a person identified in a lead role for addressing disparities), and
- sufficient infrastructure for addressing a variety of patients' needs (e.g., patient navigators, outreach workers).

Clinical Trials

Enhancing each site's capacity to conduct research, particularly through increased clinical trials capacity, is a primary goal of the NCCCP. For this reason, we conducted two types of

analyses for clinical trials data. For this overall analysis, we examined the following question:

- What changes in the cancer program relative to clinical trials seem to be facilitated by the NCCCP?

Much like the analysis for disparities program component, we examined the extent to which the following variables seem to be associated with increases in clinical trials outcomes (Table 3-9):

- leadership support for their research program,
- more elements of a research infrastructure,
- more linkages with other NCI research programs (e.g., Community Clinical Oncology Program [CCOP], Cancer Trials Support Unit [CTSU], Cooperative Groups), and
- greater environmental support for clinical trials research (e.g., insurance coverage for trials).

In addition to this analysis, a separate analysis was conducted to examine the trends in clinical trials research growth among NCCCP sites relative to national trends in hospitals represented in NCI's Cancer Therapy Evaluation Program (CTEP) dataset. These analyses, which are described in a separate report, were led by a medical oncologist at Duke University, Dr. Amy Abernethy. The overall findings from this separate analysis have now been incorporated into this overall integrated report as appropriate.

Quality of Care

The following overarching evaluation questions guided the final analysis for quality of care:

- What changes in the cancer program relative to quality of care seem to be facilitated by the NCCCP?
- What were the changes in practice patterns (i.e., adherence to clinical guidelines/NCCN) among NCCCP sites?

Using data from RQRS and other outcomes specified in Table 3-9, we assessed whether the following organizational factors seem to be associated with sites' changes in the RQRS indicators:

- physician leadership of their cancer program;
- employed physician model (as opposed to private practice);
- sufficient infrastructure for addressing a variety of patients' needs (e.g., number of cancer physicians, patient volume, broader electronic health record (EHR) implementation);
- more comprehensive "conditions of participation" implementation; and
- stronger support of hospital top management.

Cancer Research Capacity

In addition to enhancing NCCCP sites' capacity to conduct clinical trials, another goal was to increase their overall research capacity, including the ability to support the collection of high-quality biospecimens (Chapter 2). Although the evaluation did not capture many outcomes specific to the biospecimens and information technology (IT) program components, we did capture some specific data elements to examine the extent to which each site expanded their research capacity. This analysis includes the following in order to describe whether and how sites expanded this capacity over the course of the 3-year pilot (the results are presented in Chapter 16):

- clinical trials capacity:
  - whether there is a director of research for the cancer program who is a physician,
  - whether the site is a lead CCOP (n=3) or performance CCOP site (n=4),
  - number of cooperative group trials groups of which the site is a member,
  - number of Clinical Research Nurses (CRNs) and Clinical Research Associates (CRAs),
  - whether clinical trials enrollment is part of their conditions of participation,
  - whether the site has a dedicated research pharmacy,
  - whether there is IT support of clinical trials, and
  - whether there is an Institutional Review Board (IRB) at the hospital;
- biospecimens:
  - whether the site was selected to receive funding for Moffitt's biorepository, and
  - whether the site has an onsite biorepository; and
- research investments (matching costs):
  - clinical trial administration/planning,
  - enrollment activities,
  - IT planning and development,
  - IT implementation,
  - IT training,
  - biospecimens planning and development, and
  - biospecimens storage and processing.

3.2.5 Final Analytic Strategy

This section describes the process that we used to interpret the findings and develop the final report once the meta-matrix and composite measures were completed.

3.2.5.1 Interpretation of the Results

Once the data had been validated and entered into the meta-matrix (see Section 3.2.1.2), we developed several very large Excel spreadsheets of the variables organized by each site. We then began to divide the data into logical ways and cluster data that fall together so that contrasts between sets of variables could become more clear (Miles & Huberman, 1994). For example, assessing the relationship of indicators of success in implementation of quality of care activities to organizational support and structure may suggest next steps in the analysis. With each variation, we checked to see what other relationships may exist (e.g., if having a greater number of outreach workers is associated with a greater number of minority patients receiving patient navigation services). A simple 2 x 2 matrix sorting case-level data helped answer that question (as presented in Chapter 16) and potentially suggested where to look next, moving beyond a descriptive analysis to a more explanatory one (Miles & Huberman, 1994). Note that all of the analyses we conducted were guided by the hypotheses and conceptual frameworks presented in Chapter 2. To standardize the review of data, we followed several rules:

- We reviewed each topic area for items that have too many missing variables and dropped those from analysis.
- We calculated the change from Year 1 to Year 3 in most of the variables and dropped those with little or no net change.
- We reviewed the list of variables in the analysis plan that should be included in each analysis and matched these to variables in the meta-matrix to determine if there were others that should be used and/or needed to be dropped from the analysis plan.

3.2.5.2 Synthesizing Findings

Case-ordered displays array data case by case, but the cases are ordered according to some variable of interest (e.g., "success" in NCCCP implementation), so that the analyst can easily see the differences between "high," "medium," and "low" cases (Miles & Huberman, 1994). For the synthesizing of findings into case-ordered displays, we relied heavily on the categories of the sites by their level of success on either the relevant program component or the program overall (Table 3-14). Once the overall meta-matrix was constructed (see Section 3.2.1) and all of the variables filled in, the analyses that could have been conducted across cases and time were endless. Ultimately, the change in each composite score from Year 1 to Year 3 was analyzed to determine characteristics of the sites that seem to impede or facilitate the greatest degrees of change.

Table 3-1. Data Sources and Sample Data Variables for the NCCCP Case Study

Data Source	Sample Data Variables or Indicators
Site visits to collect data through interviews and observation	▪ Organization structure of the cancer service line and the NCCCP ▪ Hospital's relationship with cancer physicians providing care within their organization ▪ Top management support of the NCCCP ▪ Processes followed in program implementation and accomplishments within each program component
Document review	▪ Applications for funding ▪ Subcommittee minutes and documents created by work groups ▪ Web sites of NCI and individual NCCCP sites
Secondary data	▪ Site surveys (i.e., baseline, interim, and final assessment surveys) ▪ Local demographics ▪ Internet searches on each hospital's Web site ▪ Survey Application Record data from the CoC

Table 3-2. Key Words or Domains for Each Level of Evaluation to Cover through the Case Study for Each Year of Site Visits

Level of Evaluation	Key Words or Domains	Year 1	Year 2	Year 3
National	NCCCP linkages (internal and external)	•	•	•
	Benefits of NCCCP linkages	•	•	•
	Impact of technical assistance	•	•	•
Organizational	Environmental factors	•	•	•
	Effective management practices	•	•	•
	Physician practice models	•	•	•
	Infrastructure	•	•	•
	Plans for sustainability			
	System-level effects	•	•	•
Patient	Health disparities	•	•	•
	Patient experience			•
Program	Cancer service line changes	•	•	•
	Value added (of the NCCCP)		•	•
Program Components	Implementation of each program component		•	

Table 3-3. Requested Interviewees for Year 1 Site Visits by Organizational Role and Suggested Interview Length

Organizational Role	Suggested Interview Length
Hospital Senior Executives	
▪ Chief Executive Officer or Chief Operating Officer	30 minutes
▪ Medical Director	45–60 minutes
Key Cancer Program Staff	
▪ Principal Investigator	90 minutes
▪ Physician Director of Cancer Center if not PI	60 minutes
▪ Administrative Director of Cancer Center	60 minutes
▪ Members of NCCCP Subcommittees (no more than nine individuals per group meeting)	90 minutes
▪ Lead Nurse for NCCCP	45–60 minutes
▪ Key Cancer Center Physicians (number will vary by site), including some key physicians for clinical trials; site can suggest group or individual meetings	90 minutes
▪ NCCCP Program Coordinator (if applicable)	60 minutes

Table 3-4. Summary of Year 1 Invoiced Costs, by Type of Expenditure and Core Component Activity

	Salaries and Benefits						
	Medical Director/ PI	Administrative Director/ Program Coordinator	All Other	Other Direct Costs	Invoiced Allocated Indirect Costs (if applicable)	Total	
Total Contract Awards	$388,166	$2,606,358	$145,459	$166,545	N/A	$3,306,529	100%
By Component:							
Disparities	$182,339	$1,047,343	$42,636	$18,667		$1,290,986	39%
Clinical Trials	$67,265	$641,425	$73,755	$18,600		$801,045	24%
Information Technology	$53,886	$351,740	$10,472	$67,000		$483,098	15%
Biospecimens	$31,212	$340,473	$18,596	$2,500		$392,781	12%
Quality Initiatives		$113,844				$113,844	3%
Survivorship Initiatives		$111,532				$111,532	3%
Other Program Components[a]	$53,464			$59,778		$113,243	3%
Percent	12%	79%	4%	5%		100.0%	

[a] These costs were not invoiced as part of a specific pillar. RTI worked with sites to reassign to appropriate core component.

Table 3-5. NCCCP Environmental Analysis Constructs, Control Variables, and Hypotheses

Environmental Construct	Environmental Hypotheses
Managed Care Penetration/Market Concentration	▪ Community hospital cancer centers (CHCCs) in health care markets with relatively low levels of uninsured and generous payer mix (private coverage with comprehensive benefit package) would be more likely to improve their clinical trials accrual rate, offer more MDC conferences, and have a higher use of evidence-based guidelines than CHCCs in health care markets with relatively high levels of uninsured and a less generous payer mix (Medicare, Medicaid). For this measure, we used the Medicare market share for each hospital to assess the local health care market. ▪ CHCCs in states that mandate private insurance coverage of clinical trials would be more likely to improve their clinical trials accrual rate than CHCCs in states that do not mandate private insurance coverage of clinical trials.
Cancer Services Competition	▪ CCHCs that have more competition for cancer services from other hospital based cancer programs, NCI-designated centers, and/or CCOPs would be less likely to successfully implement and achieve the aims of the NCCCP. ▪ CCHCs that have more oncologists in the community/population would be less likely to successfully implement and achieve the aims of the NCCCP.
Other Market (Control) Variables	
Poverty Rate	Proportion of local residents living at or below the national poverty level

Table 3-6. Key Study Variables and Data Sources

Key Market Dimension	Variable	Data Source
Medicare Market Share	Medicare market share	HSAF
Cancer Services Competition	▪ CoC-accredited hospitals per 100,000 ▪ Total number of oncologists per 100,000 (e.g., radiologist, medical)	▪ CoC Web site ▪ UPIN/NPPES
Population Characteristics	Percentage of population below poverty	ARF

Table 3-7. Data Sources for Overall Analysis

Data Source	Description of Data Source	Strengths/Limitations
Baseline, Interim, and Final Assessment Surveys (BAS/IAS/FAS)	Surveys completed by sites at the end of each calendar year of program implementation: These include characteristics of their hospital and NCCCP components	Self-reported data were often reported for varying points in time (some items were asked for the prior fiscal year, others for the calendar year), and numerous variables were not clearly operationalized to ensure standardized responses.
Micro-Cost Study	Data collected for each fiscal year on the start-up and incremental costs (invoiced, donated, and matching) associated with NCCCP implementation	Some findings provided by sites are inconsistent (e.g., amount of donated costs for clinical trials). Data were presented to programs each year such that measures and methods for collection could be improved.
Patient Survey	Survey data collected in 2009 and 2011 from cross-sectional samples of cancer patients at the 10 lead sites: Overall analysis included tests of significance for change over time on key patient survey variables	Cross-sectional data do not assess changes over time. Self-reported data from samples of patients may be somewhat biased (e.g., only those well enough to complete survey responded).
Outcomes Worksheets	Worksheets developed by SAIC-F to collect specific outcomes for each program component during the summer and fall of 2010	Worksheets were standardized across sites and checked for quality, but inconsistencies still exist. Self-reported data were collected retroactively.
Site Visits and Organizational Charts	Data collected through multiple interviews with key individuals involved with NCCCP implementation at the 16 sites in Years 1 and 3 and the 10 sites in Year 2: The site visits initially included development of standard organizational charts for the cancer centers and hospitals that were updated each year	Domains covered across sites were the same and rigorously coded for qualitative data analysis. Semi-structured interviews were conducted such that questions were not standardized and tailored to the sites.
Rapid Quality Reporting System (RQRS)	A pilot project implemented by CoC in order to collect real-time data through cancer registries on six key quality indicators (three for breast cancer care, two for colon cancer, and one for rectal cancer): Overall analysis included tests of significance for change over time on RQRS measures	RQRS is being collected in NCCCP and non-NCCCP hospitals to allow for comparisons, so this also controls for results related to improved data collection at the sites.
Environmental Data	Data used in an analysis of baseline factors associated with the local environment within which the sites are operating	Secondary data were standardized across the community. Secondary data were available only at baseline, so trends cannot be examined.

Table 3-8. Sites' Baseline Capacity: Key Indicators and Data Sources

Capacity Indicator	Rationale for Indicator	Data Source	Operationalization
Total cancer patient volume	A measure for patient care capacity, number of physicians, and cancer services	Baseline Assessment Survey (BAS)	Raw number of new cancer patients for 2006
Research capacity	A measure for level of activity in clinical trials research	Request for Proposal (RFP) Applications from sites	Ranges of patients accrued (based on data supplied by SAIC-F)
Full-time equivalent (FTE) for physician leader	A measure for hospital's fiscal support for cancer program leadership	BAS	Raw number for FTE proportion (e.g., 0.5 for half-time FTE); otherwise, 0 if there is no physician leader or if leader has no FTE dedicated to position

Table 3-9. Success at the Program Component Level: Key Outcomes and Data Sources

Program Component	Outcomes	Primary Data Source
Disparities	▪ Number of cancer screening events provided ▪ Whether sites are collecting race/ethnicity data, by Office of Management and Budget (OMB) category, across their patient registration, clinical trials, screening, and navigation ▪ Number of cancer patients provided patient navigation (PN) ▪ Number of community partners ▪ Number of formal relationships with identified community partners ▪ Number of non-white patients enrolled in clinical trials	Outcomes Worksheets provided by sites to SAIC-F
	▪ Adherence to three breast and three colorectal cancer treatment guidelines by race, ethnicity, age, and education ▪ Timeliness of care by patient demographics	RQRS
Clinical Trials	▪ Number of trials opened (e.g., NCI, Pharmaceutical) ▪ Number of early phase trials (i.e., Phases 1 or 2) ▪ Number of trial types (i.e., prevention, control, treatment, symptom amelioration) ▪ Total number of patients enrolled in trials ▪ Total number of non-white patients enrolled in trials as well as by age and insurance status ▪ Number of physicians eligible for enrolling patients in trials ▪ Proportion of physicians enrolling patients in trials (Note: For the analysis of the physicians who are enrolling patients in clinical trials, the denominator would be those who are eligible to enroll patients.)	Outcomes Worksheets provided by sites to SAIC-F; Cancer Therapy Evaluation Program (CTEP) data
	▪ Whether patients are aware of trials ▪ Whether patients are provided with information about trials	Patient Survey
	▪ NCCCP clinical trials data in comparison to national trends	CTEPs
Quality of Care	▪ Number of multidisciplinary care (MDC) conferences ▪ Types of MDC conferences (whether or not sites have breast and/or colorectal cancer MDC conferences) ▪ Proportion of physicians by cancer care specialty regularly participating in relevant MDC conferences ▪ Whether site has implemented "conditions of participation" and the number of participating physicians ▪ Number of patients presented prospectively at MDC conferences	Outcomes Worksheets provided by sites to SAIC-F
	▪ Perceived coordination of care	Patient Survey
	▪ Adherence to three breast and three colorectal cancer treatment guidelines ▪ Timeliness of care	RQRS

Note: Because sites have few deliverables specific to information technology or biospecimens activities, it was agreed with NCI that these two program components would not be included in the overall NCCCP evaluation analysis except when assessing enhanced research capacity. Also, the program component of survivorship/palliative care yielded no quantifiable accomplishments and therefore are not included here.

Table 3-10. Success at the Overall Program Level: Key Outcome Measures and Data Variables

Evaluation Outcomes from Conceptual Framework	Evaluation Indicators	Available Data Variables (and Data Sources)
Innovation and adoption/assimilation/ implementation process (Short-term Outcomes)	▪ New initiatives and/or approaches to outreach, providing cancer care, doing research developed at the site ▪ Communication and coordination across the program components	▪ Changes in approach with disparate populations (site visits) ▪ Mechanisms in place for ongoing coordination across components (site visits)
Increased program-related knowledge and skill (Intermediate Outcome)	▪ Increased adherence to breast and colorectal evidence-based guidelines ▪ Implementation of a physician credentialing program ▪ Development of additional partnerships	▪ Change in adherence to guidelines over time (RQRS) ▪ Conditions of participation implementation (Outcomes Worksheets) ▪ Changes in community partners (Outcomes Worksheets)
Enhanced infrastructure/capacity (Intermediate Outcome)	▪ Establishment of relationships with key physicians ▪ Development of staffing to support the NCCCP ▪ Commitment of leadership to the program ▪ Allocation of adequate resources to the program ▪ Linkages with other NCI programs and/or research	▪ Proportion of physicians who have signed conditions of participation, an indication of whether physicians are "active" members of hospital (Outcomes Worksheets) ▪ Physician leader of cancer program and FTEs specific to the NCCCP (organizational charts) ▪ Participation of hospital senior executives in NCCCP meetings ▪ Level of total and matching funds (Micro-Cost Study) ▪ Number of relationships with NCI-designated cancer centers, Community Clinical Oncology Programs (CCOPs), and/or Community Network Programs (CNP) (site visits)
Enable research (Ultimate Outcome)	▪ Infrastructure in place for conducting research (added biospecimens capacity, increase in clinical trials work)	▪ Clinical trials outcomes (Outcomes Worksheets) ▪ Biospecimens updates (SAIC-F)
Deliver advanced cancer care in local communities (Ultimate Outcome)	▪ Outcomes met for each program component (see Table 3-9) ▪ Increased levels of improved experience of care at aggregate levels ▪ Improved quality of care	▪ Composite scores on QOC, clinical trials, and disparities ▪ Perceived satisfaction with care (Patient Survey) ▪ Breast and colorectal cancer quality indicators (RQRS)

(continued)

Table 3-10. Success at the Overall Program Level: Key Outcome Measures and Data Variables (continued)

Evaluation Outcomes from Conceptual Framework	Evaluation Indicators	Available Data Variables (and Data Sources)
Routinization and spread (Feedback Loop)	▪ Sites' plan for sustainability ▪ Extent to which the NCCCP has become their strategic plan for cancer care ▪ Application of the NCCCP to other hospital service lines (e.g., cardiology)	▪ Specific plans to continue NCCCP-related efforts (site visits, strategic case interviews) ▪ Alignment of the NCCCP with future goals for cancer care (site visits) ▪ Whether site was using the NCCCP model for other service areas (site visits)

Table 3-11. Hypothetical Case-Ordered Descriptive Data for Two Sites by Overall Success

Site Numbers	Success Rating	Increased program-related knowledge and skill	Deliver the most advanced cancer care in local communities	Enable Cancer Research	Sustainability
1	High (H)	Added a virtual MDC conference Increased physician participation in MDC conferences by 30%	"We're now the leader in the community for patient referrals" (PI)	New translational research center	"NCCCP has become so much a part of what we're doing that we can't see an end to this work" (CEO)
2	H	"We now make sure that all new cancer patients meet our patient navigators" (PI)	Level of satisfaction with care improved among patients surveyed at Time 1 compared to Time 2 (survey)	"We moved the clinical research department from the hospital to the cancer center so we could quickly establish trials" (PI)	"Cancer is our most profitable service line so we will continue to invest in it" (CFO)

Table 3-12. Rationale for Excluding Key Factors of Evaluation Conceptual Framework from Overall Analysis

Factors from Evaluation Conceptual Framework	Variables to be Assessed through NCCCP Evaluation	Rationale for Excluding from Analysis
Each site's understanding and conceptualization of the NCCCP	Reasons or impetus for participating in the NCCCP	All sites gave the same response as their primary reasons (i.e., to have a linkage with NCI and to facilitate their cancer service line development)
	Good "fit" between the organization and the nature of the NCCCP	All sites stated that the NCCCP fit in with their plans for growth in their cancer service line
Existing structures and processes	Effective teams that can communicate and coordinate key departments/units/teams	Data were unavailable to quantify across all sites for this variable
	Rich communication networks (also fits with understanding of the NCCCP)	Data were unavailable to quantify across all sites for this variable
	Full-time Cancer Program Director at the systems levels	With only two system sites, there was not enough variation for testing this relationship
Capacity for learning, innovation, and change	Hospital makes and celebrates tangible improvements or progress	Data are unavailable to quantify across all sites for this variable

Table 3-13. Program Components and Activities Associated with Sustainability Costs

Program Component	Activity
Biospecimens	▪ Planning and development ▪ Storage and processing
Clinical Trials	▪ Enrollment activities ▪ Trial administration/planning
Disparities[a]	▪ Care coordination/navigation
Information Technology	▪ Implementation
Quality of Care	▪ Genetic counseling ▪ Multidisciplinary care ▪ Quality improvement program development
Survivorship	▪ Patient-level activities

[a] Sites reported their costs specific to care coordination and navigation within the disparities program component on their complete CAT surveys.

Table 3-14. Hypothetical Array of the Association Between Overall Success and Selected Organizational Variables

Organizational Variables	Success		
	High	**Medium**	**Low**
Strong established relationship with key cancer physicians	10	0	0
No or weak relationship with key cancer physicians	0	4	2
Linkages with four or more other NCI programs (e.g., NCI-designated cancer centers)	3	4	5
Linkages with three or fewer other NCI programs	3	0	1
High level of investment in cancer program (over $2M over all 3 years)	10	1	0
Medium or low level of investment in cancer program	0	2	3

Part II: Initial Capacity and Understanding of the NCCCP Among Selected Sites

4. OVERVIEW OF SITES AT BASELINE

Overview

Hospital Selection Criteria

NCI funded 10 programs to participate in the NCCCP pilot, which includes 16 hospitals located in 14 states. During the process of site selection for the NCCCP pilot, NCI purposefully selected hospitals that had varying levels of development for their cancer programs or service lines. Several sites had limited capacity or history with conducting clinical trials research, working with disparate populations, or coordinating care across the cancer continuum to ensure that patients received evidence-based care. In addition, five hospitals that were part of two national health systems (Ascension Health with two and Catholic Health Initiatives with four[1]) were named as "developmental" sites, as opposed to lead sites, since they met fewer benchmarks in terms of selection criteria. NCI set benchmarks that included all of the "lead" sites had to have had a cancer patient volume of at least 1,000 new cases during 2006 (the year prior to NCCCP initiation) and to have enrolled at least 25 patients in clinical trials, among others.

Hospital Characteristics

The selected hospitals ranged in size from having as few as approximately 9,000 inpatient discharges in 2006 (Good Samaritan) to as many as 78,000 (Brackenridge). The proportion of their inpatient cases that were cancer-related discharges ranges from 1.9% (St. Joseph Medical Center) to 6.9% (St. Joseph's/Candler). Eight of the lead sites reported having a physician director for the cancer center or program, with varying degrees of time devoted to this position. All but 2 of the 16 hospitals relied primarily on cancer physicians working in private practices.

Baseline Capacity

Since sites varied so much at baseline, it was hypothesized that the "high-capacity" sites would be able to meet the NCCCP deliverables with less change in some of the program elements because they started out as integrated and relatively advanced cancer programs. For these reasons, the evaluation assessed successful implementation of the NCCCP relative to sites' capacity at the time of award. Hospitals varied greatly in terms of their capacity to implement activities in each of the six program components for the NCCCP. Overall baseline capacity (i.e., defined as a composite score of their total cancer patient volume, patients accrued to clinical trials, and time devoted to the cancer program by a physician leader) was assessed as "high" in seven sites, and "low" in the remaining nine sites.

[1] Catholic Health Initiatives (CHI) named two of their five hospitals as "leads": Penrose-St. Francis and St. Joseph Medical Center. For the purposes of this evaluation (and the constraints of the contract we operated under), however, we had to name only one of these as a lead site. We selected St. Joseph Medical Center because that is where the NCCCP principal investigator is located. Penrose-St. Francis is therefore categorized as a "developmental" site within this chapter and report.

Baseline Environmental Context

Much of what the NCCCP required participating hospitals to accomplish relied greatly on their ability and willingness to invest their own funds into developing their cancer programs. Hospitals' level of investment and support from senior executives could potentially be associated with factors from their local environment, such as the local competition for cancer care (i.e., share of the Medical market as well as the number of local hospitals that had cancer programs certified by the Commission on Cancer [CoC] and cancer specialists in their area per 100,000 residents). The majority of the participating hospitals (n = 11) operate within a highly competitive market for cancer care. We also examined the local poverty rates of each community because that could influence the extent to which each hospital has to provide charity care. We found that an equal number of sites were operating within a high or low poverty level (based on 2000 data).

The eight individual or "lead" sites consist of one hospital each, whereas the two system sites, Ascension Health Systems (Ascension) and Catholic Health Initiatives (CHI), consist of three and five hospitals, respectively. The system sites selected one or more lead sites to facilitate the implementation of the NCCCP among one or more "developmental" sites within their system. These developmental sites often did not meet the criteria to participate as a lead site (e.g., 1,000 cancer cases each year) but had the potential to do so by the end of the 3-year pilot. Ascension selected St. Vincent Indianapolis Hospital as the lead site and two additional hospitals as developmental sites: Columbia St. Mary's in Milwaukee, WI, and University Medical Center (UMC)/Brackenridge Hospital in Austin, TX. CHI selected two lead sites: St. Joseph Medical Center in Towson, MD, and Penrose-St. Francis Health Services in Colorado Springs, CO. CHI selected as a developmental site a coordinated regional program of three hospitals in Nebraska: Good Samaritan Hospital in Kearney, St. Elizabeth Regional Medical Center in Lincoln, and St. Francis Medical Center in Grand Island. For the purposes of this evaluation, we are considering St. Joseph Medical Center as the primary lead site for CHI.

In this chapter, we provide an overview of the baseline data for the 16 hospitals that participated in the NCCCP pilot. We first present a description of these sites with references to tables of data that are located at the end of the chapter. We describe the characteristics of the pilot sites, including the type of pilot site, geographic location, hospital size, and patient volume. We also include a comprehensive overview of the cancer centers and cancer programs affiliated with the pilot sites. Throughout this chapter, we refer to cancer centers and cancer programs as "cancer centers," regardless of whether they have dedicated locations. Next, we describe characteristics of each cancer center, including whether there is a dedicated location, the organizational structure, services offered, and collaboration with cancer specialty practices. We also list the top five cancer types treated by each cancer center and describe the race and ethnicity of the patient population served by these sites in the year prior to the start of the NCCCP pilot. Throughout the descriptions, we highlight available baseline data related to the six program components of the NCCCP when

applicable: biospecimens, clinical trials, disparities, information technology (IT), quality of care, and survivorship/palliative care.

We then describe the pilot sites' local market and competition, followed by a description of the community characteristics surrounding each site. The findings represent information collected from several sources, including the Baseline Assessment Survey (BAS) conducted in 2007; the Commission on Cancer's (CoC's) Survey Application Records (SAR), which were submitted as part of the BAS; Area Resource Files (ARFs); and a summary of community data specific to 2006, which we are using to inform the Strategic Business Case Study. It is worth noting that the baseline data are presented from a variety of sources, with heavy reliance on sites' self-reported data provided on the BAS administered by SAIC-F (and NCI) in December 2007. The BAS was specific to only four of the program components presented in this report (though there were other instruments we have not included here): clinical trials, disparities, quality of care, and survivorship/palliative care. For the remaining two components (biospecimens and IT), baseline data were collected through a gaps assessment specific to their topic areas. These data are not presented in this report. We specify the reporting period for each data element presented (see Table 4-1 for details of the data sources). Tables referred to in this chapter appear at the end of the text.

4.1 Descriptive Overview of Types of Hospitals and Cancer Centers

4.1.1 Overview of Hospitals

As previously described, the pilot sites varied significantly at baseline in hospital characteristics, including hospital size, patient volume, and organizational structure. In Table 4-2, we present some overall characteristics of all 16 hospitals to demonstrate how they compared on these variables at baseline and to help show how varied the hospitals were from the start (e.g., from their total revenues to their baseline level of cancer patient care). Most hospitals were community hospitals that were part of a larger health care system, even if the system was not participating in the NCCCP. Although only two were "lead" hospitals serving as the system sites, several others were also part of a larger health system but were participating as independent entities (e.g., Our Lady of the Lake, St. Joseph Hospital). In 2007, the pilot sites' hospitals had an average total revenue of $471,062,500 (ranging from $143,000,000 to $1,120,000,000).[2] Hospitals had between 212 and 2,378 inpatient discharges for cancer care in 2006, which represented 1.9% to 6.9% of their total inpatient discharges.[3] The hospital occupancy rates ranged from 54% to 87% in 2007.[4]

[2] Data source: Cost Reports for 2007.
[3] Data source: Baseline Assessment Survey for calendar year 2006.
[4] Data source: Cost Report Data for 2007.

4.1.2 Overview of Cancer Centers and Cancer Services

All 10 lead sites offered cancer services either through dedicated locations or from within the main hospital buildings. At the time of the Year 1 site visits, all but two of the lead sites had a dedicated location for their cancer centers either on or near the main hospital campus[5] (Table 4-3). Two of the lead sites had recently constructed a new location to house their cancer centers. At the time of the Year 1 site visits, we learned about Billings Clinic's plans to open a new building designated for their cancer center in the summer of 2009. The cancer program of Our Lady of the Lake and Mary Bird Perkins Center had integrated their cancer services and were in the process of developing a combined organizational chart, but they operated in two adjoining buildings. Cancer services were being offered at both facilities at the time of the Year 1 site visits. For the remainder of this section, we refer to all sites' cancer centers and programs as "cancer centers," regardless of whether their cancer center or program had a dedicated location or was housed within the main hospital building.

4.1.2.1 Overview of Cancer Services Offered at the 10 Lead Sites

During the Year 1 site visits, we learned about each cancer center's cancer services and recent initiatives.[6] The following are highlights for each lead cancer center based on what interviewees pointed out to us during Year 1 site visits.[7]

Site 4 reported having among the most extensive telemedicine systems in the country due to its vast and rural population. Site 4 had established eight disease site-focused programs, each led by a physician or surgeon and supported by a nurse navigator. Site 10 offered both radiation oncology and medical oncology services; it also had developed two multidisciplinary care (MDC) teams for breast and prostate cancer cases. Site 1 served as a hub for cancer services offered by both two of their hospitals. This center had experienced turnover in their cancer center medical director and was in the process of recruiting for that position. The cancer program of Site 3 was housed within the main hospital building, providing medical and surgical oncology services as well as radiation oncology services. Site 9 operated from a newly constructed full-service facility across the street from the main hospital. Site 9 included services offered by both their clinic and their medical center; it housed radiation oncology, the breast health institute, and other inpatient and outpatient cancer services. Site 16 provided services that spanned the cancer care continuum, including cancer screenings, radiation and chemotherapy services, and an inpatient care

[5] Data source: Text is taken directly from Topline Reports written by our teams based on Year 1 site visits (see Chapter 3).
[6] Data source: Topline Reports from Year 1 site visits.
[7] During each site visit in Year 1, our team toured each facility to get a sense of the breadth of services provided, the ease with which patients could find clinics and/or assistance, and so forth, and took detailed notes. This section summarizes our impressions from these visits and what the staff told us during the tour. The information is meant to provide the reader with a description of each cancer center and is not standardized across the cancer centers.

unit. This cancer center housed a medical oncology practice and a radiation oncology practice at the time of the Year 1 site visits.

Site 12 included a network of 112 physicians and was housed in a building that did not include physicians' offices. A new building was expected to open shortly after the Year 1 site visits, which would include a radiation oncology center, outpatient infusion, genetic counseling, and a multipurpose conference room. Site 6 housed two medical oncology practices, infusion clinics, radiation oncology, basic diagnostic radiology, and lab services. Key informants reported having 16 multidisciplinary care (MDC) clinics at the time of the Year 1 site visits. Site 15 provided outpatient cancer care and housed several radiation oncology groups, a private practice for hematology and oncology, and two gynecologic oncology practices. Site 15 also had an inpatient unit, a hospice program, and a standalone breast cancer center. Site 7 had opened in a dedicated location prior to the Year 1 site visits. The new building was designed to support a patient-centered approach to cancer care delivery, and leaders were pursuing the participation of private practice oncologists and surgeons through joint venture agreements.

4.1.2.2 Physician Involvement in the Cancer Programs

Physicians with three different relationships (or combination of relationships) with the cancer programs at the NCCCP sites were potential participants in program implementation. At many sites, the cancer program had a physician director who also served in the role of principal investigator (PI) for the NCCCP. In a few sites, however, the person serving in each of these roles was different. The other relationship physicians had with the programs was as a "key cancer physician," which meant that the cancer program considered them to be critical to their care of cancer patients. Usually these key cancer physicians were collocated in the cancer center and/or employed by the hospital, but in some cases these physicians operated offices outside of the hospital and used the cancer program for providing care to some or all of their cancer patients.

By the time of the Year 1 site visits, all but two lead sites had a physician serving in the role of PI for the NCCCP. Of the eight lead sites with a PI who was a physician, five had a physician serving as both the cancer center director and PI, with full-time equivalent (FTE) time ranging from 0.15 to 1.0. As of early 2008, one site had an interim PI while they conducted a national search to replace the physician who had previously served as PI. An additional site was also actively recruiting for a physician leader of the NCCCP who they envisioned would also assume the role of PI. For the developmental sites, two had no physician director of their cancer program. In terms of leadership for their cancer programs, those who did not have a physician director included one that had a director who was an administrator, three that were recruiting to fill this position, and one that had no plans to create a similar position.

In terms of the cancer programs' relationship with physicians (Table 4-3), most pilot sites reported that their cancer centers operated based on an all or mostly private practice model; only two cancer centers had an all or mostly hospital-employed model, and three cancer centers had a mix of both private practice and hospital-employed physicians.[8]

4.1.2.3 Differences in Specialized Cancer Services and Care

Examining the types of specialized cancer services provided across the hospitals helps to illustrate their differences. These types of services are significant purchases by the hospital and signify investments in cancer care perhaps beyond the average community hospital. These services also require purchasing related equipment and could be a proxy for sites that are providing care with technology or new procedures that are considered cutting-edge. According to the SAR, each cancer center offered between 8 and 11 diagnostic imaging services at their site in 2006, prior to their participation in the NCCCP pilot. Some of the specialized services reported by sites included

- CyberKnife (1 sites),
- bone marrow transplant (3 sites),
- stem cell transplant (13 sites),
- cryosurgery (3 sites),
- radiofrequency ablation (3 sites), and
- ultrasound surgical aspiration (1 site).

Related to the equipment and services of specialized cancer care is each facility's access to specialized cancer clinicians (e.g., gynecologic oncologists). Access to these specialized physicians can be indicative of not only the level of quality of cancer care patients are provided but also the hospital's interest in developing their cancer service line because, in several cases, the hospital may have worked to actively recruit these practices or individuals to their community. All cancer centers reported having at least one cancer specialty practice that operated within their facility (Table 4-3).[9] On average, each cancer center had established six formal relationships with cancer specialty physician practices outside of the center.[10] When counting the number of physicians listed among the clinical staff with cancer specialties on the BAS, sites ranged from having as few as one (Good Samaritan) to as many as 32 (Our Lady of the Lake). Eleven cancer centers had between 1 and 10 relationships with outside cancer specialty practices.

4.1.3 Capacity for NCCCP Quality of Care Activities

A major program component of the NCCCP is a site's activities to improve quality of care (QOC). For the NCCCP, NCI focused on activities such as increasing care coordination (e.g.,

[8] Data source: Topline Reports from Year 1 site visits.
[9] Data source: Baseline Assessment Survey for calendar year 2006.
[10] Data source: Baseline Assessment Survey for calendar year 2006.

increasing MDC conferences or clinics, patient navigation services), setting "conditions of participation" for their key cancer physicians, and participating in quality improvement studies (Table 4-4). In addition, if a site has access to certified tumor registrars, they may be better able to improve their reporting of quality indicators so we have also included this as a measure as of baseline.

The information about cancer centers' disease-specific MDC conferences or clinics was somewhat inconsistent across the data sources that we reviewed (Table 4-4). Based on the 2006 SAR (the most conservative measure and therefore the one reported here), nine cancer centers had at least one disease-specific MDC conference or clinic that met on a regular basis in 2006.[11] According to the SAR, eight of these cancer centers each had between one and four MDC conferences; Christiana had six MDC clinics. Common cancer sites included breast, lung/thoracic, and gynecologic. Most of the cancer centers had patient navigation services that they offered to treatment patients for at least one cancer type (most often these were provided for breast cancer patients only). One lead site (Sanford Clinic) and two developmental sites (St. Elizabeth Regional Medical Center and St. Francis Medical Center) had no patient navigation services as of baseline. Those hospitals that did provide these services had as few as one navigator (Good Samaritan) to as many as 16 (Penrose-St. Francis).

"Conditions of participation" is an initiative that NCI facilitated with the cancer center in order to establish minimum requirements for physicians to be affiliated with each cancer center. Minimum requirements of "affiliated" physicians were to include criteria such as accruing to clinical trials, attending a minimum number of MDC conferences, and attending continuing medical education courses specific to oncology. According to the BAS, two sites already had these types of requirements in place at the start of the NCCCP, both of which operated as private practice physician models (Christiana, St. Francis Medical Center). One site had partially implemented conditions of participation (St. Joseph Hospital) and one site had approved the implementation of conditions of participation (St. Joseph's/Candler).

The final aspect of quality of care is specific to the infrastructure the sites had in place for maintaining, monitoring, and improving their quality of care. For monitoring cancer care, sites need to have a current cancer registry such that data are entered within a short period of time. This process allows sites to more closely track where they are meeting National Comprehensive Cancer Network guidelines and where they need to improve. It is reasonable to assume that sites with a greater number of certified tumor registrars (CTRs) on staff would be better able to maintain a current registry such that they are able to keep up with the demands of ongoing data entry. In the SAR, sites reported how many CTRs they had on staff prior to the start of the NCCCP. Sites had as few as one CTR (at three developmental sites) to as many as five. In addition, as the data are entered and the sites

[11] Data source: Commission on Cancer's Survey Application Records for 2006.

monitor their outputs, they are able to potentially conduct quality studies for improving an aspect of their cancer care. According to the baseline SAR data, all of the sites had conducted at least one quality study prior to NCCCP implementation with one site (St. Francis Medical Center) reporting completion of as many as five.

4.1.4 Capacity for NCCCP Clinical Cancer Research Activities

Another major component of the NCCCP was to enhance cancer research capacity at each site. At baseline, some of the sites had low levels of clinical trials participation, while seven sites were involved with the Community Clinical Oncology Program (CCOP) as either a lead CCOP or a performing CCOP site (Table 4-5). One of the selection criteria for NCCCP lead sites was that they had accrued at least 25 patients to clinical trials in 2006. Across all 16 hospitals, the range of patients accrued varied from as few as 6 (Site 8) to as many as 408 (Site 6). We were able to estimate the proportion of cancer patients each site had accrued to trials by calculating the total number of patients accrued divided by the total cancer patient volume for the same time period.[12] The sites varied greatly in the proportion of patients accrued to trials, from 0.4% at Site 8 to as high as 14.2% at Site 6 (a lead CCOP site).

Sites varied as well in terms of the infrastructure they had in place for clinical cancer research. Seven sites had established research directors which seemed to indicate that the site had placed an emphasis on clinical research development and were allocating resources to related infrastructure. Sites also varied in terms of research support staff with two sites having no clinical research nurses (CRNs) at baseline (St. Joseph′s/Candler, St. Elizabeth Regional Medical Center) and the rest having from 0.2 to as many as nearly 20 FTE (Christiana). There were no clinical research associates (CRAs) or trial coordinators at two sites (Hartford Hospital, St. Elizabeth Regional Medical Center) with 0.2−9 at other sites (Table 4-5). To facilitate clinical cancer research, sites could have preexisting partnerships with academic medical centers conducting their own research. On average, each cancer center reported having or creating partnerships with three NCI-designated cancer centers as of June 2007, mostly for referrals or enrolling patients in active trials.[13] Finally, biospecimens collection and reporting is another aspect of their capacity for conducting clinical research. Only one site, Christiana, had their own biorepository on site at the time of NCCCP initiation.

[12] For all data elements, the time period for which the data are applicable often lacked specificity. For these data on patient accruals, sites provided the number of patients accrued to clinical trials in 2006 in their applications for the NCCCP, which could include NCI trials and other types of trials. The total cancer patient volume (Table 4-8) was reported by sites on their BAS for all analytic cases for 2006. We have assumed these counts correspond to calendar year, not fiscal year, but this was unspecified.
[13] Data source: Baseline Assessment Survey for calendar year 2006.

4.1.5 Baseline Indicators of Performance

When selecting the sites to participate in the NCCCP pilot, NCI purposefully identified hospitals that were quite varied in their potential capacity for NCCCP implementation and in their local environments. The primary reason for this variation was to determine the types of characteristics hospitals need to have to achieve success with NCCCP implementation. For this reason, we created baseline indicators for two factors associated with hypotheses for the evaluation: one to address whether sites' baseline capacity for implementing the NCCCP seems to be associated with their ultimate success in program implementation, and another to evaluate sites' local environments, including key data variables that are likely to influence their performance over time. For each set of indicators, we reviewed the data for elements that research has shown might be related to program implementation and/or organizational change. To abstract the data, we followed the process described in Section 3.2.1.2. We then separated the data into quartiles and ranked them accordingly. Those sites that were at or above the median of each range of scores were ranked as "high" on the related scale, and those below the median were ranked as "low."

4.1.5.1 Baseline Capacity Indicator

This capacity measure provides a control variable for assessing which sites have achieved success for each program component and/or the program overall. For example, those sites that started the program performing at a relatively high level for cancer care were measured against their own progress during the pilot, as opposed to comparing them to the progress made by other sites at different baseline levels. Working with NCI and the Evaluation Oversight Committee (EOC), RTI identified three key indicators (Table 4-6) to use in assessing sites' baseline capacity for NCCCP implementation.

4.1.5.2 Baseline Environmental Indicators

As Clauser and colleagues (2009) have noted, the NCCCP emphasizes establishing new partnerships of cancer research and care delivery. Indeed, the structure, functioning, and performance of the NCCCP pilot can be conceptualized as a process of organizational innovation that is happening within the context of the market. This market includes environmental factors that influence how the pilot sites develop and succeed over time. For the overall analysis, we focused on two aspects of the environment that may be associated with how well sites are able to implement the NCCCP: their local market competition and a selected community characteristic (i.e., local poverty rate).

4.1.5.3 Local Markets and Competition

One key environmental construct that has been noted to affect the success and sustainability of organizational innovations is market position. NCI considers this measure to be one of the key environmental measures because the market position of the community hospital in which the NCCCP pilot is operating is likely to impact NCCCP outcomes of

program-specific accomplishments and sustainability/institutionalization over time. Market position indicates whether an organization is the dominant player, or one of the major players, within a market. Organizations that are high in terms of market position generally have more slack resources, fewer resource constraints, and more leverage or decision-making power. It is likely that NCCCP sites in these types of sites will have more support and may be more successful and sustainable in terms of the desired NCCCP goals. For the overall analysis, RTI and NCI worked with the EOC to determine which variable to include to assess market. After careful review and assessment of the indicators (see Section 3.2), we determined that the best indicator for local market would be the Medicare market share for each hospital.

In 2010, RTI conducted an extensive analysis of environmental factors that may be associated with NCCCP implementation. This analysis relied primarily on data from prior to 2007 (i.e., pre-NCCCP implementation) because that was what was available at the time of the analysis. For that analysis, we hypothesized that NCCCP pilot sites operating in less competitive markets would be more likely to achieve NCCCP goals compared to NCCCP pilot sites operating in more competitive markets. This is because the more competitive a market is, the less likely it is for an NCCCP site to have flexible resources available to support NCCCP activities, such as the use of multidisciplinary and evidence-based guidelines or improving clinical trials accrual rates. Furthermore, we hypothesized that NCCCP pilot sites operating in less competitive markets would likely be better able to leverage resources to sustain the goals of the NCCCP. NCCCP hospitals that are more dominant players in their markets would be less likely to feel market constraints that may undermine support for their NCCCP activities. Furthermore, NCCCP pilot programs in hospitals that are dominant players in their markets may have more direct support of the NCCCP by top management. After review of the data and in consultation with the EOC, we determined that the following variables would provide a good estimation of the local competition for cancer care: (1) the number of local hospitals that had a cancer program certified by the CoC per 100,000 people, and (2) the number of cancer specialists per 100,000 people.

4.1.5.4 Community Characteristics

In the environmental analysis conducted in 2010, we examined multiple key external environmental characteristics that are commonly used to describe geographic areas and hospital markets. However, for the overall analysis, we had to limit the number of variables in order to enhance our power and restrict comparisons to be made across the 16 communities. Therefore, in consultation with the EOC, we determined that the percentage of the population in poverty would be the ideal indicator to include in the overall analysis since it is a variable that tends to be highly correlated with health care disparities. As a local economic factor, poverty rate may be an indication of the need for charity care, which can put a fiscal strain on local health care facilities. Because all NCCCP sites are nonprofit hospitals, their strategic planning in terms of how much funding to allocate to charity care

and how funds can be invested in infrastructure will likely be influenced by these characteristics of the local population.

4.1.6 Cancer Patient Characteristics

The capacity to provide care varied greatly varied across these cancer centers. The cancer centers at the 10 lead sites ranged from serving 1,057 (Site 1) to 2,863 (Site 6) cancer cases in 2006 (Table 4-7).[14] As previously noted, the developmental sites were serving fewer cancer patients at baseline but had the potential to enhance their cancer programs through participation in the NCCCP. Those sites served from 409 (Site 11) to 1,662 (Site 8) cancer patients in 2006. Six of the most common cancer sites were the respiratory system, the digestive system, the urinary system, the breast, the male genital system, and the female genital system. All of the sites reported serving a majority white population, although five sites had limited racial and/or ethnic data available for their cancer patients.

4.1.7 Baseline Capacity Index for NCCCP Hospitals

As presented in Section 4.1.5, we selected three variables for creating an index of the baseline capacity for NCCCP implementation: the 2006 values for total cancer patient volume, number of patients accrued to clinical trials, and the FTE time of a physician director for the cancer program. Table 4-8 presents the findings for these three variables, as well as the rating for each. We determined the ratings for each variable by separating the values into quartiles and then assigning a number from 1 to 4 to correspond to the quartile level (e.g., 1 = first quartile). We then totaled the ratings for each site, with results ranging from 2 to 12. We next calculated the median of 5.5 and assigned those with a score at or above the median to be "high" in baseline capacity and those below the median to be "low" in baseline capacity. As expected, the six developmental sites were among the sites with the lowest baseline capacity for NCCCP implementation, with scores ranging from 2 to 5. Other sites with low levels of baseline capacity included Sites 4 and 9. The site with the highest baseline capacity was Site 6 with a score of 12. Other sites with high levels of baseline capacity were Sites 7, 10, 12, and 15.

4.2 Environmental Context

In 2010, RTI conducted a fairly extensive analysis of environmental factors that may influence the extent to which sites are able to implement the NCCCP. Because this is such an important aspect of whether each site will have the resources and local environment within which to enhance their cancer program, we worked with the EOC to determine the measures from the analysis to include in incorporating baseline measures for environmental context into the final overall analysis. These variables would also serve as controls (like the baseline capacity measures) in determining what sites were able to accomplish over the 3-year pilot. In this section, we present the results for the three variables used in assessing

[14] Data source: Baseline Assessment Survey for calendar year 2006.

the local markets and competition (i.e., Medicare market share, the number of local hospitals with cancer programs accredited by the CoC per 100,000 people, and the number of cancer specialists per 100,000 people) and the community characteristic of poverty rate.

4.2.1 Local Markets and Competition

We examined the hospitals' share of Medicare beneficiaries in the total NCCCP market. Research has shown that hospitals with a high proportion of Medicare cases relative to their market have improved cash flow (McCue & Diana, 2007) and are more efficient, such that they reduce their uncompensated care (Hsieh, Clement, & Bazzoli, 2010; Rosko, 2004). This indicator combines information on the hospital and its market and describes the extent to which the hospital has captured a proportion of the market for Medicare recipients. We hypothesized that Medicare market share would be positively associated with the likelihood of achieving NCCCP program goals and would be in a stronger market position than those with a smaller Medicare market share (Carpenter et al., 2006). For assessing local competition, we examined the number of local hospitals with cancer programs accredited by the CoC per 100,000 people in the local market as well as the number of local cancer care specialists per 100,000 people.

4.2.1.1 Medicare Market Share

The Medicare market share results are shown in Table 4-9. On average, across all NCCCP sites, the Medicare market share was 20.84%. Three sites had about 10% or less of the Medicare market share in their markets: Brackenridge (4.92%), St. Joseph Hospital (9.25%), and St. Vincent (10.8%). It is notable that St. Vincent had the third most Medicare patients among all NCCCP hospitals in 2007 (10,118), behind only Christiana and Hartford Hospital, yet St. Vincent was among the three NCCCP hospitals with the lowest market share of all Medicare patients.

On the other hand, the hospitals with the highest share of Medicare patients in their market were Christiana (69.12%), Columbia St. Mary's (58.24%), and Spartanburg Regional Medical Center (53.89%). These were the only three hospitals that had more than 50% of Medicare patients in their markets.

4.2.1.2 Local Competition for Cancer Services

NCCCP pilot sites do not operate in a vacuum; they are located in markets that may have varying degrees of hospital competition. Similarly, NCCCP pilot sites operate in markets that may have variable levels of competition for cancer services. An NCCCP pilot site operating in a highly competitive market for cancer services may be less likely to implement and achieve the aims of the NCCCP because the site has to compete for patients with their neighboring hospital-based cancer programs. We included measures for cancer services competition in the NCCCP markets in two ways:

- the presence and number of CoC-accredited hospitals, and
- the presence and number of cancer care specialists.

In the following sections, we describe the results for these variables, followed by those for the community characteristic of poverty rate.

Number of CoC-Accredited Hospitals

The CoC Accreditation Program encourages hospitals, treatment centers, and other facilities to improve their quality of patient care through various cancer-related programs that focus on prevention, early diagnosis, pretreatment evaluation, staging, optimal treatment, rehabilitation, surveillance for recurrent disease, support services, and end-of-life care. Today, approximately 80% of all newly diagnosed cancer patients are treated in CoC-accredited cancer programs (http://www.facs.org/cancer/coc/whatis.html). The CoC has accredited more than 1,400 cancer programs in the United States and Puerto Rico (http://www.cancer.org/Treatment/FindingandPayingforTreatment/ChoosingYourTreatmentTeam/choosing-a-doctor-and-a-hospital). This number represents close to 25% of all hospitals in the United States and its territories.

Every CoC-accredited cancer program must provide the following six basic services either on site, by referral, or through coordination with other facilities or local agencies:

- diagnostic services (clinical laboratory or diagnostic imaging),
- treatment services (medical oncology, radiation oncology, or surgical procedures),
- other clinical services (tumor staging, research guidelines, pain management),
- rehabilitation services,
- support services (counseling, discharge planning, hospice care, nutritional support, pastoral care), and
- prevention and early detection.

The CoC Web site maintains a public, searchable database, which we used to determine the presence (and number) of CoC-accredited hospitals in the market (http://web.facs.org/cpm/CPMApprovedHospitals_Search.htm). We searched this database using the ZIP codes of the NCCCP markets to determine the presence and number of CoC-accredited hospitals in these markets.

As Table 4-10 shows, nearly all of the NCCCP sites have local CoC hospitals with which they compete for patient care. The numbers in this table do not include the NCCCP sites: all NCCCP sites are CoC accredited (and three—Christiana, Sanford Clinic, and Spartanburg Regional Medical Center—are CCOPs). The numbers in Table 4-10 refer to other hospitals in the market. All but three NCCCP pilot sites (Spartanburg Regional Medical Center, St. Francis Medical Center, and Good Samaritan) have at least one CoC-accredited hospital in the market (other than the NCCCP pilot site itself). The NCCCP sites with the greatest

number of CoC-accredited hospitals in their local market are St. Joseph Hospital and Christiana, each of which has 32. St. Joseph Medical Center has 20 CoC-accredited hospitals in its market, and Columbia St. Mary's has 13. The remaining NCCCP sites each have fewer than 10 CoC-accredited hospitals in their markets.

The Spartanburg Regional Medical Center, St. Francis Medical Center, and Good Samaritan pilot sites operate in markets that have no other cancer centers with which they compete. The NCCCP pilot site that is located in the market with the highest number of CoC-accredited hospitals per 100,000 people is St. Elizabeth Regional Medical Center. Although this hospital is located in a market that is less populous and has relatively few cancer centers with which to compete, there are almost 2 cancer centers per 100,000 people in the market. This is followed by St. Joseph Hospital (which has 1.1 cancer centers per 100,000 people).

Overview of Medical Workforce

Medical workforce availability is an important factor for NCI to consider when evaluating the success of the NCCCP. To profile the markets in terms of cancer specialist availability, we identified the number of hematology/oncology, medical oncology, radiation oncology, gynecologic oncology, and surgery oncology specialists within each NCCCP market area. All measures are standardized to 100,000 people. The Unique Physician Identification Number (UPIN) Directory and its successor report, the National Plan and Provider Enumeration System (NPPES), provide data on every participating Medicare provider, and include the UPIN, provider name, specialty, state, and ZIP codes of practice locations. We selected the ZIP codes that make up the NCCCP markets and summed the measures across ZIP codes to obtain the total number of specialists in the markets.

Using the Healthcare_Provider_Taxonomy_Co variable in the UPIN/NPPES data, we flagged the following provider types:

- 207VX0201X (Gynecology Oncology),
- 207RX0202X (Medical Oncology),
- 2086X0206X (Surgical Oncology),
- 2080P0207X or 207RH0003X (Hematology/Oncology), and
- 2085R0001X (Radiation Oncology).

This section profiles the markets in terms of the number of cancer specialists available in 2007, showing the actual number of cancer specialists and the number of cancer specialists per 100,000 people. Table 4-11 shows the number of cancer specialists by specialist type in the markets per 100,000 people as of 2007.

Gynecologist Oncologists. In the United States in 2007, there was an average of fewer than one gynecologist oncologist per 100,000 people (0.52 per 100,000). Overall, there

were very few gynecologist oncologists in the NCCCP markets (8.4 total in 2007). The markets of St. Joseph Hospital and Christiana had the most total gynecologist oncologists. When standardized to 100,000 people, the markets with the most were Billings Clinic and St. Joseph′s/Candler, which were the only two markets to have more than one gynecologist oncologist per 100,000 people.

Medical Oncologists. There were 1.74 medical oncologists per 100,000 people in the United States in 2007. Overall, there were more medical oncologists than gynecologist oncologists, with 21.44 medical oncologists on average across all NCCCP markets. When standardized to the markets′ populations, the average number of medical oncologists in the markets was 16.79 in 2007. The market with the most medical oncologists per 100,000 people was Spartanburg Regional Medical Center, which had 43.36 medical oncologists per 100,000 people.

Surgical Oncologists. There were 0.34 surgical oncologists per 100,000 people in the United States in 2007. Across all NCCCP markets, there was an average of 8.31 surgical oncologists, standardized to an average of 2.83 across all NCCCP markets. The market of St. Joseph′s/Candler had the most surgical oncologists per 100,000 people (9.10).

Hematologist/Oncologists. In 2007, hematologist/oncologists were the most common type of cancer specialist in the United States; there were 4.67 hematologist/oncologists per 100,000 people. Across all NCCCP markets, the average number of hematologist/oncologists was 57.56, standardized to an average of 33.95 hematologist/oncologists per 100,000 people. Other markets with high numbers of hematologist/oncologists included St. Vincent, Columbia St. Mary′s, and Christiana. The markets of St. Francis Medical Center, Brackenridge, and Penrose-St. Francis all had relatively few hematologist/oncologists (about 20 or fewer per 100,000 people).

Radiation Oncologists. In 2007, radiation oncologists were the second most common type of cancer specialist in the United States. There were 3.64 radiation oncologists per 100,000 people. Across all NCCCP markets, the average number of radiation oncologists was 38.00, standardized to an average of 32.12 radiation oncologists per 100.000 people. The market with the most radiation oncologists per 100,000 people was Good Samaritan (although this market had only 10 total radiation oncologists). Other markets with high numbers of radiation oncologists per 100,000 people were Billings Clinic, St. Vincent, and St. Joseph Medical Center. Conversely, St. Francis Medical Center, Hartford Hospital, and St. Joseph Hospital were in markets that had relatively few radiation oncologists (about 15 or fewer per 100,000 people).

Table 4-12 shows the total number of cancer specialists in the markets. We obtained this number by adding the numbers for all the cancer specialists within the market. Across all NCCCP markets, the average number of total cancer specialists was 134.31. The markets with the most total cancer specialists were St. Joseph Hospital and Christiana. The markets

with the fewest total cancer specialists were the three Nebraska markets: Good Samaritan, St. Elizabeth Regional Medical Center, and St. Francis Medical Center.

Table 4-12 also shows the total number of cancer specialists in the markets in 2007, adjusted per 100,000 people. This shows that by far the market with the largest concentration of cancer specialists was Good Samaritan, which had 252.62 cancer specialists per 100,000 people. Billings Clinic and St. Joseph Medical Center also had large numbers of cancer specialists per 100,000 people in their markets (153.54 and 100.76, respectively). The market with the fewest cancer specialists per 100,000 people was St. Elizabeth Regional Medical Center, which had 37.83 cancer specialists per 100,000 people. Other markets with relatively few cancer specialists per 100,000 people were Brackenridge, Hartford Hospital, and St. Joseph Hospital.

4.2.2 Market and Competition Baseline Index

Similar to the baseline capacity index, we used the three indicators described to create an index of the market and local competition for cancer care. As shown in Table 4-13, we divided the values for each of the three indicators into quartiles and assigned the values of 0 to 4 based on their relationship with the level of competition (e.g., if the variable was hypothesized to be positively associated with local competition level, then the highest values were assigned a 4). Five sites were calculated to have a low level of competition in their markets: Christiana, Spartanburg Regional Medical Center, Columbia St. Mary's, Penrose-St. Francis, and St. Francis Medical Center. The remaining hospitals were operating within an environment with a high level of competition as of 2007.

4.2.3 Community Characteristic of Poverty Rate

Table 4-14 presents the NCCCP markets in terms of the percentage of the population that was in poverty as of 2006. Across all NCCCP markets, the average proportion of the population in poverty was 10.39. Our Lady of the Lake had the largest percent of its market in poverty (18.48%). Spartanburg Regional Medical Center also had a relatively high proportion of its population in poverty (13.70%). The market with the lowest proportion of its population in poverty was Hartford Hospital (6.93); Sanford Clinic and St. Joseph Medical Center also had relatively low proportions of their population in poverty (less than 8%).

Table 4-1. Overview of Data Sources

Data Source Name	Description	Time Period of Data
Baseline Assessment Survey (BAS)	Survey completed by all pilot sites on the organizational characteristics of their cancer center as well as characteristics specific to four program components (clinical trials, disparities, quality of care, survivorship/palliative care): data were collected in 2007 and reflect the time period prior to the start of the NCCCP pilot	Calendar year 2006 unless otherwise noted
Online Survey Certification and Reporting System (OSCAR)	Database of operational characteristics of health care facilities	Calendar year 2007
Cost Report Data	Data collected from each pilot site for the cost study component of the NCCCP evaluation	Calendar year 2007
Topline Reports from Year 1 Site Visits	Compilation of findings from site visits and key informant interviews conducted within Year 1 of the NCCCP pilot: data reflect Year 1 of participation in the NCCCP pilot	July 2007 through June 2008
Commission on Cancer's (CoC's) Survey Application Record (SAR)	Standardized data regarding the cancer center's resources, services, and organizational structure in 2006: submitted as part of the BAS	Calendar year 2006
CoC's Web site	The Web site maintains a public, searchable database that we used to determine the presence (and number) of CoC-accredited hospitals in the market. The database is maintained at http://web.facs.org/cpm/CPMApprovedHospitals_Search.htm.	Calendar year 2007
Area Resource File	A national, county-level health resource information database collected by the Health Resources and Services Administration: includes demographic statistics for core-based statistical area (CBSA) in 2007	Calendar year 2007
Pilot Site Profiles	Information about pilot sites available at http://ncccp.cancer.gov/About/Sites.htm	June 2007
National Cancer Institute State Cancer Profiles	Cancer statistics presented on a state and county level	Calendar year 2008
Unique Physician Identification Number (UPIN) based on CBSA, National Plan and Provider Enumeration System (NPPES)	Dataset containing selected information on health care providers who are enrolled in the Medicare program	Calendar year 2007 (updated quarterly; each update is considered a replacement file)

(continued)

Table 4-1. Overview of Data Sources (continued)

Data Source Name	Description	Time Period of Data
Census	The Census Bureau's Population Estimates Program publishes total resident population estimates and demographic components of change (births, deaths, and migration) by year and by demographic characteristics for the nation, states, and counties: http://www.census.gov/popest/metro/metro.html	2006
Medicare Provider of Service (POS) File	The POS File is created from the Online Survey and Certification Reporting System (OSCAR) database. These data include provider number, name, and address and characterize the participating institutional providers. The data are collected through the Centers for Medicare & Medicaid Services (CMS) Regional Offices. The file contains an individual record for each Medicare-approved provider and is updated quarterly.	2009

Table 4-2. Overview of Hospitals[a]

Site	Location	Type of NCCCP Site	Total Revenue 2007	Occupancy Rate in 2007	Number of Inpatient Discharges	Number of Inpatient Cancer-related Discharges	Percentage of Inpatient Cases with Cancer-related Discharges
Data Source:			**Cost Report Data for 2007**	**Cost Report Data for 2007**	**2006 BAS For CY 2006**	**2006 BAS For CY 2006**	**2006 BAS For CY 2006**
Billings Clinic[b] *Billings Clinic Cancer Center*	Billings, MT	Lead	$402,000,000	0.799629	14,783	407	2.7%
Christiana Health System *Helen F. Graham Cancer Center*	Newark, DE	Lead	$1,120,000,000	0.8712654	56,719	1,725	3.0%
Hartford Hospital *Helen & Harry Gray Cancer Center*	Hartford, CT	Lead	$740,000,000	0.8657978	39,842	1,171	2.9%
Our Lady of the Lake Regional Medical Center *The Cancer Program of Our Lady of the Lake and Mary Bird Perkins*	Baton Rouge, LA	Lead	$540,000,000	0.6204287	33,230	1,289	3.9%
St. Joseph Hospital *St. Joseph Hospital Cancer Center & Cancer Institute*	Orange County, CA	Lead	$521,000,000	0.630042	26,922	805	3.0%
St. Joseph's/Candler *Nancy N. and J.C. Lewis Cancer & Research Pavilion*	Savannah, GA	Lead	$186,000,000	0.6919765	18,804	1,294	6.9%
Sanford Clinic *Sanford Cancer Center*	Sioux Falls, SD	Lead	$436,000,000	0.7076719	25,343	737	2.9%
Spartanburg Regional Medical Center (RMC) *Gibbs Regional Cancer Center*	Spartanburg, SC	Lead	$524,000,000	0.8503259	28,833	966	3.3%

(continued)

Table 4-2. Overview of Hospitals[a] (continued)

Site	Location	Type of NCCCP Site	Total Revenue 2007	Occupancy Rate in 2007	Number of Inpatient		Percentage of Inpatient Cases with Cancer-related Discharges
					Discharges	Cancer-related Discharges	
Ascension Health							
St. Vincent *St. Vincent Oncology Center*	Indianapolis, IN	Lead System Site	$892,000,000	0.696529	22,821	1,503	6.6%
University Medical Center (UMC)/Brackenridge Hospital (Brackenridge) *Shivers Center*	Austin, TX	Developmental System Site		0.7262495	77,933	2,378	3.0%
Columbia St. Mary's *Columbia St. Mary's Cancer Center*	Milwaukee, WI	Developmental System Site		0.5431967	28,853	1,053	3.6%
Catholic Health Initiatives							
St. Joseph Medical Center *St. Joseph Cancer Institute*	Towson, MD	Lead System Site	$345,000,000	0.7185318	26,642	504	1.9%
Penrose-St. Francis Health Services *Penrose Cancer Center*	Colorado Springs, CO	Lead System Site		0.6689574	26,308	1,331	5.0%
Good Samaritan Hospital *Good Samaritan Cancer Center*	Kearney, NE	Developmental Regional System Site		0.6190268	9,109	270	2.9%
St. Elizabeth Regional Medical Center (RMC) *St. Elizabeth Cancer Center*	Lincoln, NE	Developmental Regional System Site		0.7424551	16,159	308	1.9%
St. Francis Medical Center *St. Francis Cancer Treatment Center*	Grand Island, NE	Developmental Regional System Site		0.6051574	7,070	212	3.0%

BAS = Baseline Assessment Survey for calendar year 2006; CY = calendar year.

[a] Sites are listed alphabetically by their copyrighted names available on their Web sites. Lead sites are listed first, followed by hospitals grouped within each of the two systems. Where names are the same (e.g., St. Joseph), they are presented in alphabetical order based on their location.

[b] Pilot site reported inpatient discharges based on fiscal year 2007 instead of calendar year 2006.

Table 4-3. Overview of Cancer Centers from Year 1, July 2007 through June 2008

Site	Cancer Center Location	Number of Cancer Specialty Practices that Operate in the Cancer Center	Types of Cancer Specialty Practices	Number of Key Cancer Physicians	Physician Model at Year 1, July 2007 to June 2008	Cancer Center and NCCCP Leadership Structure at Year 1
Data Source:	**Topline Report from Year 1 Site Visits**	**BAS for CY 2006**	**BAS for CY 2006**	**BAS for CY 2006**	**Topline Report from Year 1 Site Visits**	**Year 1 Org Charts**
Billings Clinic[a] (Billings, MT)	No dedicated location in 2006, but new cancer center building to open in summer 2009	1	• Medical Oncology • Radiation Oncology • Gynecologic Oncology • Naturopathy	• 5 Medical Oncologists • 2 Radiation Oncologists • 1 Gynecologic Oncologist • 1 Pediatric Oncologist • 1 Naturopathic Physician	Hospital-employed; performance-based model	CC MD is NCCCP PI is Dr. Thomas Purcell
Christiana (Newark, DE)	Dedicated location located on the Christiana campus	8	• Medical Oncology • Radiation Oncology • Thoracic Oncology • Gynecologic Oncology • Pain and Symptom Management	• 14 Medical Oncologists • 3 Genetics Counselors • 7 Radiation Oncologists • 1 Physician (Pain & Symptom Management)	Mix of private practice, hospital-employed, some physicians receive stipends or percent pay for roles; performance-based model for those employed	CC MD and NCCCP PI is Dr. Nicholas Petrelli
Hartford Hospital (Hartford, CT)	Dedicated location next to the inpatient hospital	4	• Radiation Oncology • Hematology-Medical Oncology • Neurology & Neuro-oncology • Psycho-Oncology & Palliative Care	• 8 Medical Oncologists • 9 Radiation Oncologists • 1 Neurologic Oncologist • 1 Psycho-Oncologist	Mostly private practice, few hospital-employed with performance-based model in place	CC MD and NCCCP PI is Dr. Andrew Salner

(continued)

Table 4-3. Overview of Cancer Centers from Year 1, July 2007 through June 2008 (continued)

Site	Cancer Center Location	Number of Cancer Specialty Practices that Operate in the Cancer Center	Types of Cancer Specialty Practices	Number of Key Cancer Physicians	Physician Model at Year 1, July 2007 to June 2008	Cancer Center and NCCCP Leadership Structure at Year 1
Our Lady of the Lake (Baton Rouge, LA)	Housed in hospital facility	6	• Medical Oncology • Radiation Oncology • Head & Neck Cancer Surgery • Palliative Care • Diagnostic/ Interventional Radiology	• 13 Medical Oncologists • 3 Head & Neck Surgeons • 1 Otolaryngologist • 2 Palliative Care Physicians • 13 Diagnostic/ Interventional Radiologists	All physicians in private practice	CC MD was vacant at time of Year 1 site visit; PI is Kevin Guidry
St. Joseph Hospital (Orange County, CA)	Dedicated location next to the hospital emergency room; new building is located across the street (opening spring 2008)	2	• Bone Marrow Transplant & NMDP • Radiation Oncology	• 1 Medical Oncologist • 3 Radiation Oncologists	Private practice; Professional service contract agreements	Interim CC MD before 2008 was Dr. Jim Padova; incoming CC MD is Dr. Larry Wagman; NCCCP PI is Dr. Jay Harness
St. Joseph's/Candler Hospital (Savannah, GA)	Dedicated location across from the Candler campus	5	• Medical Oncology • Radiation Oncology	• 5 Medical Oncologists • 3 Radiation Oncologists	All physicians in private practice	Recruitment for CC MD underway
Sanford Clinic (Sioux Falls, SD)	Dedicated location across the street from main hospital	14	• Medical Oncology • Radiation Oncology • Palliative Care • Gynecologic Oncology • Thoracic Surgery • Pediatric Oncology • Diagnostic Radiology	• 7 Medical Oncologists • 5 Radiation Oncologists/ Radiologists • 1 Gynecologic Oncologist • 2 Thoracic Surgeons • 1 Pediatric Oncologist • 1 Palliative Care Physician	Mostly hospital-employed; few private practice specialties; performance-based model	CC MD and NCCCP PI positions were vacant at time of Year 1 site visit; Interim NCCCP PI is Dr. Morris Geffen

(continued)

Table 4-3. Overview of Cancer Centers from Year 1, July 2007 through June 2008 (continued)

Site	Cancer Center Location	Number of Cancer Specialty Practices that Operate in the Cancer Center	Types of Cancer Specialty Practices	Number of Key Cancer Physicians	Physician Model at Year 1, July 2007 to June 2008	Cancer Center and NCCCP Leadership Structure at Year 1
Spartanburg RMC (Spartanburg, SC)	Dedicated location adjacent to Spartanburg RMC's buildings	3	• Medical Oncology/ Hematology • Radiation Oncology • Surgical Oncology	• 5 Medical Oncologists • 3 Radiation Oncologists • 1 Breast Surgeon • 1 Surgical Oncologist	Mostly private practice; some physicians receive stipend for specific roles and some specialists (e.g., surgeons) are employees; performance-based model	CC MD and NCCCP PI is Dr. James Bearden
St. Vincent (Indianapolis, IN)	Dedicated location located on the St. Vincent campus	6	• Medical Oncology • Radiation Oncology • Gynecologic Oncology • Hospice	• 1 Medical Oncologist • 6 Radiation Oncologists/ Radiologists • 2 Gynecologic Oncologists	Mostly private practice	CC Director is Amy Starling; NCCCP PI was Dr. Michael Weimann until January 2008; current PI is Dr. Richard Freeman
Brackenridge (Austin, TX)	Dedicated location within UMC/Brackenridge	10	• Medical Oncology • Breast Surgery • Radiation Oncology • Pain manage-ment/ Palliative Care	• 2 Medical Oncologists • 2 General Surgeons • 3 Radiation Oncologists • 1 Palliative Care Physician	Mainly private practice model with professional service agreements and stipends; hospital employs two medical oncologists	
Columbia St. Mary's (Milwaukee, WI)	Dedicated location within new medical office building	2	• Radiation Oncology • Medical Oncology	• 4 Radiation Oncologists • 2 Medical Oncologists	Private practice	
St. Joseph Med. Ctr. (Towson, MD)	Dedicated location on main grounds in a new building	5	Thoracic Surgery	• 10 Physicians • 2 Surgeons	Mix of private practice and joint ventures	CC MD and NCCCP PI is Dr. Mark Krasna

(continued)

Table 4-3. Overview of Cancer Centers from Year 1, July 2007 through June 2008 (continued)

Site	Cancer Center Location	Number of Cancer Specialty Practices that Operate in the Cancer Center	Types of Cancer Specialty Practices	Number of Key Cancer Physicians	Physician Model at Year 1, July 2007 to June 2008	Cancer Center and NCCCP Leadership Structure at Year 1
Penrose-St. Francis (Colorado Springs, CO)	Dedicated location next to hospital	2	• Medical Oncology • Radiation Oncology	• 2 Medical Oncologists • 2 Radiation Oncologists	Private practice model with medical oncology, general surgery, pathology and radiation oncology groups	
Good Samaritan (Kearney, NE)	Dedicated free-standing location adjacent to main hospital	1	Radiation Oncology	• 1 Radiation Oncologist	Mostly private practice with 1 hospital-employed radiation oncologist	
St. Elizabeth RMC (Lincoln, NE)	Housed in the main building of St. Elizabeth RMC; services and staff in various locations throughout the hospital	1	Radiation Oncology	• 6 Radiation Oncologist • 1 Palliative Care Physician • 1 RN • 1 Physicist • 1 Dosimetrist	Mostly private practice	
St. Francis Medical Center (Grand Island, NE)	Dedicated location a few blocks from the main hospital; administrative offices and cancer services are not contained in the Cancer Center	2	Medical Oncology Radiation Oncology	• 1 Medical Oncologist • 1 Radiation Oncologist	Mixed model; private practice and hospital-employed	

Table 4-4. Capacity at Baseline Specific to NCCCP QOC Activities

Site	Number of Regularly Scheduled Disease Site-focused Cancer Conferences in 2006	Status of Patient Navigation Services (Y/N)	Number of Patient Navigators (for Treatment)	Status of Whether Site Had Conditions of Participation (Y/N)[a]	Number	
					Certified Tumor Registrars	Quality Studies
Data Source:	**Survey Application Records (SAR) for 2006**	**BAS**	**BAS**	**Outcome Worksheet**	**SAR**	**SAR**
Billings Clinic (Billings, MT)	3 (neurooncology, breast, lung/thoracic)	Y	7	N	3	3
Christiana (Newark, DE)	6 (breast & solid tumor, chest, genitourinary, gynecology, lymphoma/leukemia, neurology)	Y	12	Y	N/A	N/A
Hartford Hospital (Hartford, CT)	4 (breast, thoracic, obstetrics/gynecology, genitourinary oncology)	Y	5	N/A	5	1
Our Lady of the Lake (Baton Rouge, LA)	0	Y	3	N	2	2
St. Joseph Hospital (Orange County, CA)	4 (lung, breast, colorectal, head & neck)	Y	6	N[b]	4	3
St. Joseph's/Candler (Savannah, GA)	0	Y	3	N	2	3
Sanford Clinic (Sioux Falls, SD)	1 (lung/thoracic)	N	0	N	2	3
Spartanburg RMC (Spartanburg, SC)	2 (thoracic, breast)	Y	3	N	3	4
Ascension Health						
St. Vincent (Indianapolis, IN)	3 (musculoskeletal, thoracic, and gynecologic oncology)	Y	5	N	2	2
Brackenridge (Austin, TX)	2 (breast, gynecology)	Y	4	N	5	4
Columbia St. Mary's (Milwaukee, WI)	1 (breast)	Y	7[c]	N	2	2

(continued)

Table 4-4. Capacity at Baseline Specific to NCCCP QOC Activities (continued)

Site	Number of Regularly Scheduled Disease Site-focused Cancer Conferences in 2006	Status of Patient Navigation Services (Y/N)	Number of Patient Navigators (for Treatment)	Status of Whether Site Had Conditions of Participation (Y/N)	Number	
					Certified Tumor Registrars	Quality Studies
Catholic Health Initiatives						
St. Joseph Med. Ctr. (Towson, MD)	N/A	Y	4	N	3	1
Penrose-St. Francis (Colorado Springs, CO)	0	Y	16	N/A	4	3
Good Samaritan (Kearney, NE)	0	Y	1	N	1	3
St. Elizabeth RMC (Lincoln, NE)	0	N	0	N	1	5
St. Francis Medical Center (Grand Island, NE)	0	N	0	Y	1	3

Not Applicable = data are missing

[a] Billings Clinic and Sanford Clinic are mostly hospital-employed models; conditions of participation at these sites would only apply to private practice physicians

[b] Site reported having "partially implemented" COPS as of Year 1.

[c] Includes only part-time "Breast Health Clinicians" (per site's response).

Table 4-5. Overview of Clinical Cancer Research

Site	Patients Accrued to Clinical Trials (2006)	Percentage of Patients on Clinical Trials (of 2006 Total Patient Volume in Table 4-7)	CCOP Status[a]	Does Site Have a Director of Research? (yes/no)	Number		Does Site Have a Biorepository?
					CRN FTEs	Trial Coordinators/ CRA FTEs	
Data Source:	**RFP Applications**	**RFP/BAS**	**NCI**	**Site Visits**	**BAS**	**BAS**	**BAS**
Billings Clinic[a] (Billings, MT)	104	7.3%	Performance Site	Yes	3	1	N
Christiana (Newark, DE)	408	14.2%	Lead Site	Yes	19.75	2	Y
Hartford Hospital (Hartford, CT)	242	9.3%	N/A	Yes	5	0	N
Our Lady of the Lake Regional (Baton Rouge, LA)	39	1.5%	Performance Site	No	1	4	N
St. Joseph Hospital (Orange County, CA)	133	8.7%	N/A	No	9.9	2	N
St. Joseph's/Candler Hospital (Savannah, GA)	28	2.6%	N/A	No	0	2	N
Sanford Clinic (Sioux Falls, SC)	111	9.0%	Lead Site	No	11	9	N
Spartanburg RMC (Spartanburg, SC)	139	10.1%	Lead Site	Yes	19	2	N
Ascension Health							
St. Vincent (Indianapolis, IN)	115	5.0%	N/A	No	11.15	2	N
Brackenridge (Austin, TX) Hospital *Shivers Center*	17	4.2%	N/A	Yes	0.2	0.2	N
Columbia St. Mary's (Milwaukee, WI)	6	0.4%	N/A	No	0.7	1	N

(continued)

Table 4-5. Overview of Clinical Cancer Research (continued)

Site	Patients Accrued to Clinical Trials (2006)	Percentage of Patients on Clinical Trials (of 2006 Total Patient Volume In Table 4-7)	CCOP Status[a]	Does Site Have a Director of Research? (yes/no)	Number		Does Site Have a Biorepository?
					CRN FTEs	Trial Coordinators/ CRA FTEs	
Catholic Health Initiatives							
St. Joseph Med. Ctr. (Towson, MD)	27	2.5%	N/A	Yes	1	2	N
Penrose-St. Francis (Colorado Springs, CO)	50	4.1%	Performance Site	No	1	1.5	N
Good Samaritan (Kearney, NE)	17	3.1%	N/A	Yes	1	1	N
St. Elizabeth RMC (Lincoln, NE)	50	6.5%	Performance Site	No	0	0	N
St. Francis Medical Center (Grand Island, NE)	16	2.9%	N/A	No	1.2	2.2	N

[a] Personal communication, Dr. Worta Stevens-McCaskill, NCI, June 15, 2011

Table 4-6. Sites' Baseline Capacity: Key Indicators and Data Sources

Capacity Indicators	Rationale for Indicator	Data Source	Operationalization
Total cancer patient volume	A measure for patient care capacity, number of physicians, and cancer services	Baseline Assessment Survey (BAS)	Raw number of new cancer patients for 2006
Research capacity	A measure for level of activity in clinical trials research	Request for Proposal (RFP) applications from sites	Ranges of people accrued (based on data supplied by SAIC-F)
Full-time equivalent (FTE) for physician leader	A measure for hospital's fiscal support for cancer program leadership	BAS	Raw number for FTE proportion (e.g., 0.5 for half-time FTE); otherwise, 0 if there is no physician leader or if leader has no FTE dedicated to position

Table 4-7. Cancer Center Cases for 2006

Site	Top 5 New Cancer Cases According to Site's Cancer Registry	Total New Cancer Cases in 2006
Data Source:	**Baseline Assessment Survey for calendar year 2006**	
Billings Clinic (Billings, MT)	Male Genital System (219) Digestive System (216) Breast (186) Skin excluding Basal and Squamous (185) Respiratory System (168)	1,429
Christiana (Newark, DE)	Breast (533) Respiratory System (469) Male Genital System (380) Digestive System (238) Urinary System (178)	2,863
Hartford Hospital (Hartford, CT)	Breast (544) Male Genital System (500) Respiratory System (304) Urinary System (248) Digestive System (215)	2,595
Our Lady of the Lake (Baton Rouge, LA)	Respiratory System (625) Male Genital System (383) Breast (362) Digestive System (220) Urinary System (161)	2,591

(continued)

Table 4-7. Cancer Center Cases for 2006 (continued)

Site	Top 5 New Cancer Cases According to Site's Cancer Registry	Total New Cancer Cases in 2006
St. Joseph Hospital (Orange County, CA)	Breast (385) Respiratory System (162) Digestive System (139) Male Genital System (126) Female Genital System (117)	1,527
St. Joseph's/Candler (Savannah, GA)	Respiratory System (268) Breast (227) Digestive System (130) Urinary System (93) Male Genital System (92)	1,057
Sanford Clinic (Sioux Falls, SD)	Breast (187) Respiratory System (185) Male Genital System (147) Digestive System (142) Female Genital System (116)	1,236
Spartanburg RMC (Spartanburg, SC)	Respiratory System (280) Breast (244) Digestive System (200) Male Genital System (199) Urinary System (99)	1,379
Ascension Health		
St. Vincent (Indianapolis, IN)	Breast (573) Female Genital System (383) Respiratory System (300) Digestive System (223) Male Genital System (197)	2,290
Brackenridge (Austin, TX)	Breast (371) Respiratory System (324) Digestive System (315) Female Genital System (182) Endocrine (160)	409
Columbia St. Mary's (Milwaukee, WI)	Breast (417) Male Genital System (239) Respiratory System (180) Female Genital System (166) Digestive System (156)	1,662

(continued)

Table 4-7. Cancer Center Cases for 2006 (continued)

Site	Top 5 New Cancer Cases According to Site's Cancer Registry	Total New Cancer Cases in 2006
Catholic Health Initiatives		
St. Joseph Med. Ctr. (Towson, MD)	Breast (205) Male Genital System (162) Digestive System (127) Respiratory System (126) Female Genital System (110)	1,075
Penrose-St. Francis (Colorado Springs, CO)	Breast (208) Male Genital System (206) Digestive System (146) Respiratory System (126) Rectum & Rectosigmoid Junction (99)	1,223
Good Samaritan (Kearney, NE)	Digestive System (113) Male Genital System (97) Breast (87) Respiratory System (83) Urinary System (54)	553
St. Elizabeth RMC (Lincoln, NE)	Breast (215) Digestive System (107) Respiratory System (89) Rectum & Rectosigmoid Junction (60) Female Genital System (44)	772
St. Francis Medical Center (Grand Island, NE)	Breast (104) Digestive System (100) Male Genital System (90) Respiratory System (71) Rectum & Rectosigmoid Junction (37)	559

Table 4-8. Results of Baseline Capacity to Implement NCCCP

	Total Cancer Patient Volume	Rating	Research Capacity: Number of Patients Accrued to Clinical Trials	Rating	FTE for Physician Leader	Rating	Total Rating *(median= 5.5)*	Capacity Designation
Data Source:	**RFP Applications**		**RFP Applications**		**BAS**			
Site 1	1,057	2	28	1	0.6	3	6	High
Site 2	1,223	2	50	1	0.2	1	4	Low
Site 3	2,591	4	39	1	0	0	5	Low
Site 4	1,429	2	104	1	0.15	1	4	Low
Site 5	772	1	50	1	0.2	1	3	Low
Site 6	2,863	4	408	4	1	4	12	High
Site 7	1,075	2	27	1	1	4	7	High
Site 8	1,662	3	6	1	0.25	1	5	Low
Site 9	1,236	2	111	2	0	0	4	Low
Site 10	2,595	4	242	3	0.5	2	9	High
Site 11	409	1	17	1	0	0	2	Low
Site 12	1,527	2	133	2	0.8	3	7	High
Site 13	553	1	17	1	0	1	3	Low
Site 14	559	1	16	1	0.11	1	3	Low
Site 15	2,290	4	115	2	0.25	1	7	High
Site 16	1,379	2	139	2	0.4	2	6	High

Table 4-9. Medicare Market Share: NCCCP Hospitals, 2007[a]

	Market Total Medicare Cases	NCCCP Hospital, Medicare	
		Total	Market Share (%)
Data Source:	**Medicare Provider of Service (POS) File**		
Average Over NCCCP Hospitals	32,539	6,782	20.84%
Billings Clinic (Billings, MT)	16,658	4,423	26.55%
Christiana (Newark, DE)	26,479	18,303	69.12%
Hartford Hospital (Hartford, CT)	53,099	11,510	21.68%
Our Lady of the Lake (Baton Rouge, LA)	25,190	8,771	34.82%
St. Joseph Hospital (Orange County, CA)	46,059	4,259	9.25%
St. Joseph's/Candler (Savannah, GA)	26,825	4,562	17.01%
Sanford Clinic (Sioux Falls, SD)	27,482	6,331	23.04%
Spartanburg RMC (Spartanburg, SC)	16,206	8,733	53.89%
St. Vincent (Indianapolis, IN)	93,651	10,118	10.80%
Brackenridge (Austin, TX)	38,384	1,888	4.92%
Columbia St. Mary's (Milwaukee, WI)	8,084	4,708	58.24%
St. Joseph Med. Ctr. (Towson, MD)	81,355	9,034	11.10%
Penrose-St. Francis (Colorado Springs, CO)	16,810	5,938	35.32%
Good Samaritan (Kearney, NE)	15,633	2,979	19.06%
St. Elizabeth RMC (Lincoln, NE)	22,615	4,410	19.50%
St. Francis (Grand Island, NE)	6,091	2,543	41.75%

[a]Medicare market is defined as the ZIP codes that make up 80% of total Medicare discharges.

Table 4-10. Cancer Competition from Commission on Cancer (CoC) Accredited Hospitals in NCCCP Markets

	CoC-Accredited Hospitals	
	Total	**per 100,000 People**
Data Source:	**CoC Web site**	**CoC Web site**
Billings Clinic (Billings, MT)	1	0.647
Christiana (Newark, DE)	32	0.536
Hartford Hospital (Hartford, CT)	6	0.502
Our Lady of the Lake (Baton Rouge, LA)	3	0.381
St. Joseph Hospital (Orange County, CA)	32	1.057
St. Joseph's/Candler (Savannah, GA)	1	0.291
Sanford Clinic (Sioux Falls, SD)	1	0.420
Spartanburg RMC (Spartanburg, SC)	—	—
St. Vincent (Indianapolis, IN)	8	0.459
Brackenridge (Austin, TX)	7	0.411
Columbia St. Mary's (Milwaukee, WI)	13	0.834
St. Joseph Med. Ctr. (Towson, MD)	20	0.743
Penrose-St. Francis (Colorado Springs, CO)	2	0.319
Good Samaritan (Kearney, NE)	—	—
St. Elizabeth RMC (Lincoln, NE)	1	1.913
St. Francis Medical Center (Grand Island, NE)	—	—

Table 4-11. Cancer Specialists by Specialty Type per 100,000, 2007

	Medical Oncologists	Gynecologic Oncologists	Surgical Oncologists	Hem/Oncs	Rad Oncs
Data Source:	**UPIN/ NPPES**				
Average over NCCCP Markets	16.79	0.51	2.83	33.95	32.12
Billings Clinic (Billings, MT)	26.70	2.00	0.00	60.08	46.73
Christiana (Newark, DE)	17.42	0.63	6.09	39.58	29.26
Hartford Hospital (Hartford, CT)	5.90	0.67	2.53	29.50	5.90
Our Lady of the Lake (Baton Rouge, LA)	3.89	0.78	6.48	40.15	19.43
St. Joseph Hospital (Orange County, CA)	5.52	0.35	5.20	23.79	12.53
St. Joseph's/Candler (Savannah, GA)	3.03	1.21	9.10	30.35	21.24
Sanford Clinic (Sioux Falls, SD)	17.55	0.44	0.00	39.48	26.32
Spartanburg RMC (Spartanburg, SC)	43.36	0.36	3.61	25.30	18.07
St. Vincent (Indianapolis, IN)	10.60	0.47	0.00	44.18	31.81
Brackenridge (Austin, TX)	7.53	0.25	0.00	19.44	18.19
Columbia St. Mary's (Milwaukee, WI)	11.00	0.52	1.94	44.02	27.83
St. Joseph Med. Ctr. (Towson, MD)	29.22	0.49	5.24	32.59	28.84
Penrose-St. Francis (Colorado Springs, CO)	14.82	0.99	1.65	21.41	19.76
Good Samaritan (Kearney, NE)	0.00	0.00	0.00	58.30	194.33
St. Elizabeth RMC (Lincoln, NE)	0.00	0.00	3.44	20.63	13.75
St. Francis Medical Center (Grand Island, NE)	72.02	0.00	0.00	14.40	0.00

Table 4-12. Total Cancer Specialists in NCCCP Markets, 2007

	Cancer Specialists	
	Total	**per 100,000 People**
Data Source:	**UPIN/NPPES**	
Average over NCCCP Markets	**134.31**	**91.42**
Billings Clinic (Billings, MT)	23	153.54
Christiana (Newark, DE)	583	98.60
Hartford Hospital (Hartford, CT)	60	50.58
Our Lady of the Lake (Baton Rouge, LA)	60	77.72
St. Joseph Hospital (Orange County, CA)	642	50.58
St. Joseph's/Candler (Savannah, GA)	25	75.87
Sanford Clinic (Sioux Falls, SD)	20	87.73
Spartanburg RMC (Spartanburg, SC)	26	93.96
St. Vincent (Indianapolis, IN)	155	91.30
Brackenridge (Austin, TX)	76	47.66
Columbia St. Mary's (Milwaukee, WI)	139	89.98
St. Joseph Med. Ctr. (Towson, MD)	269	100.76
Penrose-St. Francis (Colorado Springs, CO)	41	67.52
Good Samaritan (Kearney, NE)	10	252.65
St. Elizabeth RMC (Lincoln, NE)	11	37.83
St. Francis Medical Center (Grand Island, NE)	6	86.42

Table 4-13. Market and Competition Index

NCCCP Hospital	Medicare Market Share, %	Rating[a]	CoC Hospitals per 100,000	Rating	Cancer Specialists per 100,00	Rating	Total	
							Total	Ranking
Data Source:	**Medicare Provider of Service (POS) File**		**CoC Web site**		**UPIN/ NPPES**			
Billings Clinic (Billings, MT)	26.55	3	0.647	2	153.54	3	8	High
Christiana (Newark, DE)	69.12	1	0.536	2	98.6	2	5	Low
Hartford Hospital (Hartford, CT)	21.68	3	0.502	2	50.58	1	6	High
Our Lady of the Lake (Baton Rouge, LA)	34.82	3	0.381	1	77.72	2	6	High
St. Joseph Hospital (Orange Co., CA)	9.25	4	1.057	3	50.58	1	8	High
St. Joseph's/Candler (Savannah, GA)	17.01	4	0.291	1	75.87	1	6	High
Sanford Clinic (Sioux Falls, SD)	23.04	3	0.42	1	87.73	2	6	High
Spartanburg RMC (Spartanburg, SC)	53.89	1	0	0	93.96	2	3	Low
St. Vincent (Indianapolis, IN)	10.80	4	0.459	1	91.3	2	7	High
Brackenridge (Austin, TX)	4.92	4	0.411	1	47.66	1	6	High
Columbia St. Mary's (Milwaukee, WI)	58.24	1	0.834	2	89.98	2	5	Low
St. Joseph Med. Ctr. (Towson, MD)	11.10	4	0.743	2	100.76	2	8	High
Penrose-St. Francis (Colorado Springs, CO)	35.32	3	0.319	1	67.52	1	5	Low
Good Samaritan (Kearney, NE)	19.06	4	0	0	194.33	4	8	High
St. Elizabeth RMC (Lincoln, NE)	19.50	4	1.913	4	37.83	1	9	High
St. Francis Medical Center (Grand Island, NE)	41.75	2	0	0	86.42	2	4	Low

[a] Medicare market share is hypothesized to be positively associated with less competition in the local market, such that those hospitals with less of the Medicare market are operating in a more highly competitive market.

Table 4-14. Percentage in Poverty: NCCCP Markets, 2006

	2006	Rating
Data Source:	**Census**	
Average over NCCCP Markets	**10.39**	
Median over NCCCP Markets	**9.97**	
Billings Clinic (Billings, MT)	10.35	High
Christiana (Newark, DE)	9.27	Low
Hartford Hospital (Hartford, CT)	6.93	Low
Our Lady of the Lake (Baton Rouge, LA)	18.48	High
St. Joseph Hospital (Orange County, CA)	11.75	High
St. Joseph's/Candler (Savannah, GA)	11.97	High
Sanford Clinic (Sioux Falls, SD)	7.75	Low
Spartanburg RMC (Spartanburg, SC)	13.70	High
St. Vincent (Indianapolis, IN)	8.32	Low
Brackenridge (Austin, TX)	12.72	High
Columbia St. Mary's (Milwaukee, WI)	8.00	Low
St. Joseph Med. Ctr. (Towson, MD)	7.63	Low
Penrose-St. Francis (Colorado Springs, CO)	8.70	Low
Good Samaritan (Kearney, NE)	10.20	High
St. Elizabeth RMC (Lincoln, NE)	9.75	Low
St. Francis Medical Center (Grand Island, NE)	10.73	High

5. UNDERSTANDING AND CONCEPTUALIZATION OF THE NCCCP PILOT

Overview

The ability within sites to develop and share a common understanding of NCCCP goals and objectives has played a key role in their implementation of the NCCCP pilot.

Understanding of the NCCCP as of Year 1

In Year 1, sites experienced challenges in understanding the vision and how it could be adapted and shared with key program staff, physicians, and hospital senior executives. In Year 1, many respondents understood how important enhancing clinical cancer research was to the NCCCP, but far fewer understood the broader goals of the NCCCP (e.g., disparities, IT, survivorship) and how to integrate those components into their daily work. In part, this is because sites were charged with figuring out how to implement NCCCP activities locally; NCI deliberately did not prescribe methods for implementing the program components. Early challenges in communicating a shared vision of the NCCCP were motivated by a lack of information sharing between hospital's top management and cancer center leadership, lack of effective communication strategies among core members, and a lack of engagement and time constraints by physicians.

Changes in the Understanding of the NCCCP by Year 3

By Year 3, most sites had developed strategies for addressing these challenges by improving communication between hospital's top management and cancer center leadership and core program staff and finding ways to effectively engage private practice physicians. We noticed great increases in the number of respondents who could express an understanding of the comprehensiveness and application of the NCCCP to their cancer programs and hospital operations by Year 3, when compared to Year 1. However, after 2 years of pilot funding, some sites still had respondents who struggled with communicating a common understanding of NCCCP goals. The findings in this chapter reflect the most common challenges across sites and summarize the benefits gained for those sites that have found ways to address these barriers.

5.1 Sites' Understanding of the Broad Vision

As discussed in Chapter 2, in order for NCCCP sites to understand what they needed to do to succeed in the NCCCP, they needed to have a clear understanding of what the NCCCP is and what success would look like, both nationally and at their own institution. This chapter explores how sites developed and changed their awareness and understanding of the NCCCP over the course of the pilot.

According to NCI, the vision for the NCCCP is to bring the latest scientific advances and the highest level of innovative care to patients in their home communities. In this section, we discuss how respondents at each site understood the NCCCP's broad vision and translated its applicability to their site. First, we detail how sites described the NCCCP pilot; then, in Section 5.1.2, we elaborate on how core team members described the application of the

NCCCP goals to their site and the interaction between program components within their specific organizational structures. Year 3 changes are indicated as appropriate.

5.1.1 Understanding the Broad Vision

Respondents who voiced an overall understanding of the program overwhelmingly shared NCI's vision of improving cancer care and contributing to the larger NCI research mission. In explaining how to accomplish that vision, respondents offered various answers, which coalesced around several strategies and themes:

- expanding community hospitals' capabilities (e.g., making cancer care at community hospitals comparable to cancer care at academic medical centers and NCI-designated cancer centers);
- minimizing fragmentation of care and building comprehensive cancer care in community hospitals;
- expanding access to clinical trials, especially for the underserved, and increasing accrual and biospecimen representation among underrepresented groups;
- reducing cancer care disparities by improving access to care and providing outreach, prevention, and access to underserved populations; and
- developing and disseminating best practices across NCI-designated cancer centers and NCCCP sites.

One respondent provided an illustrative example of nearly all of these elements:

> *Well, my vision of it, having trained at university hospitals, is what we'd like to do is take the model that exists within a university hospital for comprehensive cancer care delivery and bring it to[the] private practice sector. This involves coordinating care for patients so that they get unified care and a treatment plan approach that utilizes the best evidence-based protocols, so patients in our community can get anything and everything available in the highest quality of care. It will allow us to fulfill our mission as a hospital (for example, clinical trials) and will help stimulate further things (tissue banking, for example). What we want to do is have a collaborative, community effort to provide the highest standard of care.* (Cancer center/program staff, Year 1)

This respondent noted that the NCCCP should bring best practices and university-level comprehensive cancer care to a community and private practice setting (i.e., expand capacities and disseminate best practices[1]), coordinate and unify patient care (i.e., reduce fragmentation), expand access to clinical trials and tissue banking (i.e., expand access to

[1] Because respondents used the term "best practices," we have used it here. Their use of best practices, however, does not refer to evidence-based practices and might more accurately be considered "promising practices" (i.e., practices that appear to work but have not yet been rigorously evaluated).

research), and provide patients in the community with the highest standard of care (i.e., improve quality and access for the community the hospital serves).

Each of these themes relates directly to the NCCCP components. These components, whether explicitly mentioned or implicitly addressed by respondents, provide a point of reference for their understanding, are detailed below.

5.1.1.1 Expanding Community Hospitals' Capabilities

Across all roles and sites, respondents routinely spoke of improving cancer care by enabling community hospitals to provide care on par with that of academic medical centers:

> *We're attempting to do what university or academic-level hospitals do, in a community hospital environment: raising the bar of what we can do for our cancer patients. Basically, taking best practices and things that drive better outcomes from that academic setting and put[ting] them into a community setting.* (System/hospital senior executives, Year 1)

> *In a nutshell, to bring the advancements and qualities you would find in a larger institution to the community level.* (Cancer center/program staff, Year 1)

> *I think they're trying to bring out what's usually done in university systems to community-based practices. Most patients are treated in communities.* (Key physician, Year 1)

> *My perception is NCI is trying to do some work to help community cancer programs take it to the next level.* (PI, Year 1)

These data suggest that respondents envisioned emulating academic-based cancer centers, but the extent to which they might achieve that vision was not detailed. How much the sites could reasonably achieve in comparison to academic medical centers remains an empirical question. Sites could likely provide evidence-based care for common cancers and offer greater access to clinical trials, either on site or through linkages to NCI-designated cancer centers. However, sites probably could not re-create the highly specialized cancer care or the level of research common in academic medical centers.

Although NCI-designated cancer centers do not embody the same approach as the NCCCP, a handful of respondents at one developmental site perceived the NCCCP to align with the focus of NCI-designated cancer centers on research. These respondents wondered whether achieving the status of an academic-based cancer center was possible; they felt that some aspects of this vision were achievable (e.g., outreach, improvements in quality of care), while other aspects were much less feasible (e.g., traditional multidisciplinary clinics, participation in Phase I trials). From their perspective, the realities of working in a community hospital with resource and infrastructure constraints, challenging relationships

with physicians, and the tendency for NCI-designated cancer centers to compete rather than collaborate with them made some aspects of the NCCCP difficult.

Finally, one respondent had a slightly different vision of expanding community hospitals' capabilities. This respondent suggested that sites' capabilities might be expanded by creating linkages with one or more of the NCI-designated cancer centers and drawing on their research capacities:

> *So, it is almost like a wheel and spoke. The hub would be an NCI-designated cancer center and the geographic footprint, and then you would have access to all of the clinical trials … Phase I, Phase II, Phase III [trials], obviously. And you would also be able to enroll people who would not ever have had access, but you would also influence the quality of care through large populations of patients. So we look at this as a very ground-level grassroots beginning to set the standard of what that would be.* (PI, Year 1)

In this respondent's analogy, the hub represents the NCI-designated cancer centers, and the spokes signify the community hospitals. The community hospitals are linked to the NCI-designated cancer centers, can refer patients to them for clinical trials, and can exchange information with them. The NCI-designated cancer centers benefit from having wider recruitment for clinical trials.

5.1.1.2 Minimizing Fragmentation of Care

Respondents defined the NCCCP vision in terms of creating access to comprehensive cancer care. Having comprehensive care meant several things to respondents. It meant having care available locally, having care available in one place, and having a seamless continuum of care. These definitions often went hand in hand with each other.

Respondents regularly spoke of local access to care. According to respondents, ideally, access within the community would also translate into excellent, comprehensive care at their local hospital. In this vision of the program, the NCCCP would give patients the option of getting, as one subcommittee member put it, "state of the art care in coming to our [hospital in the] community where they live." Other respondents reiterated this hope:

> *I look at it as a way to extend and advance how cancer care is provided to patients in their local communities. It's a holistic program looking to provide excellent cancer care.* (System/hospital senior executives, Year 1)

> *I also feel that, amongst all the cancer centers, we're trying to bring together what we're all doing into a comprehensive area…so you don't have to go into one of the bigger cancer centers.* (Subcommittee member, Year 1)

> *I describe it as looking at ways to bring NCI cancer care or best practices to your community cancer center, and that's comprehensive cancer care, not just state-of-the-art clinical trials.* (Subcommittee member, Year 1)

Local availability of excellent care typically overlapped with having a "one-stop shop" for care and a seamless continuum of care:

> *This is a program from NCI, and we want people to be able to navigate cancer centers. I give them the example that my dad had prostate cancer, and he went to the hospital. And it's like one-stop shopping. [The overall goals of the program are] seamless care throughout the continuum, from diagnosis through end of life.* (Cancer center/program staff, Year 1)

> *I'm on [the] same page as [other respondent] in that it's holistic cancer care—all the way from knowledge of prevention and screening activities to survivorship. You can stay at home and have this in your community.* (Subcommittee member, Year 1)

As seen by these responses, reducing fragmentation involved facilitating patients' encounters by centralizing care and offering all necessary aspects of cancer care.

5.1.1.3 Expanding Access to Clinical Trials

Of all the components, clinical trials figured most prominently into how sites understood the vision of the program. This vision traversed all roles and sites:

> *[The goal of the program is] to raise the standards of cancer care in community hospitals through engaging community hospitals in research and raising the bar in cancer care. That means giving cancer patients access to more sophisticated protocols and allowing their specimens in research.* (Subcommittee member, Year 1)

However, respondents seldom spoke of research purely as an end; rather, they consistently linked clinical trials to issues of access closer to home. They discussed having "access to emerging trials closer to home" (System/hospital senior executives, Year 1). For example, several respondents noted the linkages between access, research, and disparities; and explained their visions of the NCCCP in those terms:

> *[The NCCCP] is an opportunity to do some research, as it's been explained to me, to look at a diverse population, uninsured folks, and do some outreach and draw in a wide disparity of persons into the research that is being done. It's a more diverse group. We need to look at how to meet their needs.* (Key physician, Year 1)

> *I know with research we're looking into getting more … minorities to come in for clinical trials and…and trying to reduce the disparities and reach the underserved.* (Subcommittee member, Year 1)

> *My understanding is to give underserved patients, which is a politically charged word, the opportunity to participate in clinical trials that they might not otherwise have if they had to travel to an NCI-designated cancer center. That is what most of us feel like the ultimate goal is. By "underserved," that doesn't mean uninsured or destitute people. It means people who didn't have access before. It's a mix of people who are uninsured or who live geographically far from a designated cancer center. The ultimate goal is to develop not only the infrastructure in centers, but also to share data and independent research and conduct research. It gives the institution a gift that will serve them well.* (PI, Year 1)

Respondents said that expanding underserved populations' clinical trial access and accrual could increase participation and diversity and could benefit cancer research nationally:

> *[The NCCCP] is multi-purposed. Initially my vision was that we were missing huge segments of the population because almost all of oncology care is done in community hospitals. Not many people go to the academic facilities. I think [NCI] were putting out their feelers and seeing if we could work with community hospitals to recruit patients into [clinical trials] to have a broader population in [clinical trials]. They were trying to wrap their arms around the definition of a community hospital and how that fits into NCI and what we have to offer. The research piece is a key element because that is the backbone of what they wanted to accomplish—to get those groups into research.* (Subcommittee member, Year 1)

Likewise, expanding trial access would generate a wider pool of potential participants, which, in turn, would help build a national tissue repository available to researchers outside the academic setting:

> *In large part, there is a research emphasis in that trying to find ways to enroll folks in [clinical trials]—reaching underserved groups—created a possibility to obtain tumor tissue samples that are not dedicated to one academic center but [instead are] put in a national repository. Those are the goals. [The NCCCP] also gives private practice communities access to research.* (Key physician, Year 1)

As outlined in the NCCCP components, expanding access and accrual are critical parts of the program's vision. The NCCCP vision for clinical trials and the respondents' understandings of it aligned well across all sites and multiple roles. Similarly, respondents consistently discussed the correspondence of the disparities component and clinical trials component. Clinical trial access and accrual provided one means to bring in underserved populations and ultimately to "raise the standards of cancer care in community hospitals through engaging community hospitals in research" (Subcommittee member, Year 1).

5.1.1.4 Reducing Cancer Care Disparities

In describing their visions of the program, respondents across roles and sites discussed some aspect of the disparities component. For respondents, reducing disparities involved improving outreach, prevention efforts, and access for underserved populations. Improving outreach and prevention efforts meant going into the community, gaining trust, and encouraging participation in cancer screenings and cancer care:

> *My understanding is to go out in the community to get people who don't have insurance to get them in to have routine mammograms and screenings that could detect a cancer, to get them in to have those kinds of procedures, to catch stuff in that population before it becomes full blown.* (System/hospital senior executives, Year 1)

> *[The goals of the NCCCP involve] gaining trust, building trust [such] that when people have to come here it's not just the white coats; and if we go to them, then they'll feel comfortable coming to us.* (Subcommittee member, Year 1)

> *[The NCCCP is] trying to get the people into the community—to do more outreach to get them early in their diagnosis and get them the care they need.* (Subcommittee member, Year 1)

> *The concept I have is about [the] hope of having comprehensive cancer care in an indigent community.* (Key physician, Year 1)

> *There are multiple areas that go from global to microscopic. But when you think about the true goals of the project, they are in outreach and to be able to reach these different goals to people who are not being served well.* (Key physician, Year 1)

These data suggest that the respondents understand outreach generally, but, strikingly, they do not discuss differences in care patterns and outcomes.

According to respondents, the vision of the NCCCP involved outreach activities that help to improve access for underserved patients:

> *It is the intentional effort to bring cancer care in an interdisciplinary way to those that are underserved, underrepresented, disparity groups in a preventive way in the communities we serve.* (System/hospital senior executives, Year 1)

> *The primary vision is to create an opportunity to have cancer care, and particularly [clinical trials], available at local community settings so that people can get their comprehensive cancer care in their community, particularly vulnerable populations.* (Cancer center/program staff, Year 1)

Reaching underserved populations played a central role in respondents' understanding of the NCCCP's vision. This is unsurprising because disparities is a key component of the NCCCP. In fact, many respondents identified disparities as part of the NCCCP vision indicates that NCI has provided clear articulation of its importance.

5.1.1.5 Developing and Disseminating Best Practices

Respondents pointed to the development and dissemination of best practices and lessons learned as aspects of the NCCCP's vision. According to respondents, the dissemination of knowledge involved information sharing not only among NCCCP sites, but potentially with other NCI-funded centers as well. NCI and NCI-designated cancer centers, which are nationally recognized for premier care, could provide expertise and collaborate with NCCCP sites:

> *We have the ability to tap into the best minds of NCI and all the different agencies to get best practices in so many areas that we don't have the expertise in right now. To be developing the best practices that could be used in the future is real exciting.* (Subcommittee member, Year 1)

> *I see it as looking at the traditional NCI-designated cancer centers, but recognizing that not all of the care takes place for cancer patients there. The majority of care takes place in community settings, and we take care of the underserved, and we're going to learn how to serve them better. By working together, we're going to take the best practices and be able to share those among the centers to develop the best way to reach folks to give them the same sort of care they would expect from an NCI-designated cancer center, but from a community hospital setting like this. I think we do a lot of great and fun innovative things here, and this is a great way to share it with other people.* (Subcommittee member, Year 1)

Similarly, respondents commented on the guidance they could receive from NCI and fellow NCCCP sites:

> *It's a recognition of the value of places like this at a central organizational level in terms of the provision of health care—that there's a good amount of cancer care that happens in places like this—and it's an effort to bring institutions like this into the mainstream of cancer research and assisting us to better ourselves in various aspects of cancer care and using other institutions to help us set benchmarks that we can then potentially exceed in an organized way: taking best practices from other institutions to improve our own efficiency and quality.* (Subcommittee member, Year 1)

> *What are the important points to make about the program? The elevator points are: there are different sites chosen to be in a pilot study, 16 sites, 10 locations. The focus is on these six areas: You are taking the baseline survey of strengths,*

> *weaknesses, best practices, and networking these folks together [plus] setting goals based on baseline or on community needs to try to get us up to the top. [The] NCCCP provides a structure and a think tank for this.* (Cancer center/program staff, Year 1)

According to respondents across the sites, a key aspect of the NCCCP's vision was networking and sharing of best practices. This information sharing, in the words of one respondent, made the future "real exciting" and offered the opportunity "to improve our own efficiency and quality." Such improvements are consistent with NCI's vision to improve cancer care in community hospitals through the NCCCP.

5.1.1.6 Summary

At the time of the Year 1 interviews, respondents' understanding of the NCCCP's vision centered on improving cancer care through the integration of various NCCCP components. In the respondents' views, the components shared common activities, such as providing access to the underserved and thereby improving their enrollment in clinical trials. Respondents' ability to articulate elements of the vision shows that NCI has successfully shared goals with program leadership. However, as discussed in Section 5.3, information had not been disseminated uniformly across staff at the site level.

5.1.2 Understanding Application of the Program

In this section, we examine the core team's understanding of how NCCCP goals will be applied to their site and how different components will be implemented or interact within their specific organizational structures. Unlike the previous section on the broader NCCCP vision, this section focuses on how the core team extrapolates this vision into tangible, local goals.

Because interviews occurred early in program implementation, many respondents did not articulate particular plans for their site; rather, they spoke of general goals often centering on the NCCCP components (e.g., expanding clinical trials and outreach). Several respondents noted that they were still in the planning phase for their program:

> *I've said I think we need to set up a strategic plan in the next few weeks and get input perhaps from [team member]. But we need to convene it. Part of it has been the learning curve: What is expected? What are the in-house committees? When are the calls? What are all the inputs?* (Subcommittee member, Year 1)

Virtually all sites had respondents who mentioned having goals without specific implementation plans and processes. One cancer center director commented, "We have concrete goals, but the metrics are not necessarily there yet." Another respondent said that the purpose of the program is "to accelerate cancer care and our work in disparities and

provide access and coverage for everyone." One key physician said, "I think NCCCP enhances the good things [in our cancer program]."

> *[The application of the program to the site involved] how to structure things to make some sort of collaborative effort for a high standard of patient care. I thought that's what the grant was for: establishing and enhancing relationships. So I was hopeful there would be specific programs out of the grant to drive that.* (Subcommittee member, Year 1)

> *It's really focused on the community, how to provide seamless cancer care and make sure physicians know what's going on: it'll make their lives easier, and it makes the patients' lives easier.* (Subcommittee member, Year 1)

Respondents' generalities about how the program would apply to their site can be grouped thematically:

- alignment between the NCCCP's broad vision and local hospitals' mission and goals;
- coordination across program components;
- the role of particular components, especially clinical trials; and
- dissemination of knowledge across hospital systems, NCI-funded sites; and nationally.

Respondents spoke of how the NCCCP's broad vision corresponded to their hospital's mission and fit into their existing goals for improving cancer care. Some respondents said that they intended to examine how each component will fit together at their site. Other respondents discussed the relevance of specific components. Of all the components, clinical trials was discussed most often, especially among key physicians. Respondents also discussed how collaboration across sites would apply to their sites. This collaboration included sharing lessons learned with and providing mentorship for hospitals in their system, in the NCCCP, and nationally. It also included learning from other NCI-funded sites (Community Clinical Oncology Programs [CCOPs] and NCI-designated cancer centers). We address each of these themes in more detail in the following sections.

5.1.2.1 Alignment between the NCCCP's Broad Vision and Local Hospitals' Mission and Goals

Approximately one-quarter of the respondents saw the NCCCP's goals as overlapping with their hospitals' existing mission and goals. These respondents felt that their hospitals' goals would be advanced or enhanced by the NCCCP:

> *It all goes in with the generalized mission of the cancer center. It's the cancer center initiative. My suspicions are that this is going to expand resources for the cancer program. Once we committed to the cancer center itself, we committed to*

> *multidisciplinary care and reducing the incidence of cancer in this community. What we do for [the] NCCCP is no different than what we were committed to do before, which was to participate in research, multidisciplinary care centers, and to provide additional input about how the cancer program can thrive. The NCCCP probably is just another one of the avenues to help us with more resources to fulfill that mission.* (Key physician, Year 1)

> *Very early on, I was sitting down with one of our private surgical oncologists here, and we were hashing out what we needed to do. He asked, "What's the strategy here?" I told him this is the same as what we are doing. We are going to be organized differently. We might talk about pillars, but basically this is our work. The incremental dollars are not that significant or that big a deal. It's nice to have the dollars from [our hospital system]. What are we going to do if tomorrow we get a call from NCI that they cancel the pilot project? Are we going to not do this? The answer is this is our work, and it will keep going.* (PI, Year 1)

A respondent at one site explained that the NCCCP provided a framework or outline for the local vision of improving cancer care. In this way, the NCCCP directed how the site would pursue improving cancer care and generated the necessary momentum to advance that goal:

> *I think it's to improve patient care at the base of all of it. Cancer has been an area of emphasis for us for a long time, but there's no question that with the grant, there's become an increased amount of activity, and good activity…. For example, we invested in a site visit to [another NCCCP site] to go look at how they handle some disparities issues with teleconferencing, and [the university] with some of the biometrics and those sort of things. I think it was definitely the grant that was the catalyst. It was the thing that made us start thinking along those lines. And cancer awareness…those activities were things that we had always tried to do, but I think the grant propelled us to be more intentional about it and get at it more quickly, and all of those things ultimately result in the improved patient care. It's opening opportunities and connections for us that we just didn't have before.* (System/hospital senior executives, Year 1)

5.1.2.2 Coordination across Program Components

Respondents, primarily subcommittee members, translated the NCCCP's broad vision to their site by explaining how the NCCCP components would be coordinated at their sites. One subcommittee member commented, "We're going to use the overlap with disparities and clinical trials to work together and get things in place. Another added, "In the discussions on clinical trials, everything kind of loops through the [other pillars]: biospecimens, disparities and getting people on clinical trials, and IT with caBIG."

However, in discussing coordination across program components, subcommittee members only sketched out plans. These plans centered on creating processes to promote communication and understanding across program components. Two subcommittee members were representative of this perspective:

> *What I think might be helpful in the future is some type of a working committee coming together. [Another subcommittee member] and I were talking about how survivorship overlaps, and disparities and outreach, so how do we come together so that we're formulating plans together? Because each pillar can't stand alone.* (Subcommittee member, Year 2)

> *A thought that's bubbling up for me is: we almost need cross-training in each other's pillars to understand how I can contribute, if at all. To align pillars and say, "This is in my box and your box, so let's team up on it…." There's the clinical navigator and then the outreach navigator, so as I work with our outreach individuals, what are the outreach messages that we should be delivering that will enhance this contract and ultimately perhaps bring in people of ethnic diversity to the trials? It struck me clearly: This isn't just outreach or disparities in a tunnel; I need to know how to overlap or interconnect.* (Subcommittee member, Year 2)

Because the components fall under subcommittee members' purview and experience with the NCCCP, unsurprisingly, the subcommittee members focused on program components. However, their emphasis on alignment and coordination suggests that NCI's broader vision for the NCCCP has encouraged them to focus on linkages between components. How they actually accomplish these linkages will be explored in future evaluation efforts.

5.1.2.3 Role of Particular Components

In explaining how the program applied to their site, respondents also discussed the NCCCP components and how components would work at their site. For example, two subcommittee members provided an overview of the program components at their site:

> *[The application of the program to the site has involved] increased access to clinical trials and more fully developing our support and educational programs [as well as] working with rural outreach and disparate populations.* (Subcommittee member, Year 2)

> *[The NCCCP will] help us get some of the [clinical trials] available in larger cancer centers [and] make them available in rural Nebraska [and to] provide more resources. Inpatient services see a lot of newly diagnosed patients.* (Subcommittee member, Year 2)

When asked how the components come together at the site, one subcommittee member enumerated the role of each component in greater detail:

> *I think what we've found is that the disparities piece—and this was identified by [the] NCCCP—runs across all of the pillars, and maybe we've got a little work here in that area, and I think that's why [core team member] really wanted to set up that task force. IT, of course, runs across all of them, and right now our big initiative is to implement caTissue to go along with our biorepository. We have a clinical trials system. We're not using the caBIG at this point because that was just recently implemented. Biospecimens: everybody's involved in that we're trying to collect specimens and trying to build this repository. Again, you have to address disparities there, but I can't really speak to that since we've been collecting specimens but we haven't really been recruiting for specimens.* (Subcommittee member, Year 2)

Among all the components, research figured heavily into discussions of how the program applied to each site. All types of respondents mentioned the importance of trials, but physicians tended to discuss the relevance of clinical trials:

> *My understanding is they are going to put freezers in place and put protocols in place.* (Key physician, Year 2)

> *Clinical trials is a huge focus. [We] want to expand what we can offer in research and expand the number of patients we can reach with research.* (Key physician, Year 2)

> *NCI wants to get some smaller communities to do [clinical trials] and see how it works within them vs. these big universities, [to see if we] can get Phase I [clinical trials] here without having to go through universities. (Key physician, Year 2)*

> *To me, it's making sure that communities who couldn't be served in some fashion by their local resources…can be taken care of in the same way as at a major university or academic center. It entails that studies which are available elsewhere are sometimes available here. Certainly there are no holes [in how we provide care].... Also [the NCCCP involves] making sure that the underserved are also going to have access to the standard screenings. (Key physician, Year 2)*

Physicians' focus on clinical trials might be the result of how the program was marketed to them. One subcommittee member explained how she "sells" the program to physicians:

> *In my two-sentence "elevator speech" about the NCCCP, I tend to emphasize the research. When we say we are trying to expand research, that hooks physicians in. They don't think of us as doing research in [our hospital] and other places, even though we have been doing it. If they have more time, then I get into more detail.* (Subcommittee member, Year 2)

During the Year 1 interviews, respondents often relied on explaining the components to describe how the program applied to their site. As seen in these data, rather than specific applications of the components to the site, respondents tended to speak in generalities.

These generalities illustrate sites' initial difficulties in articulating how they planned to implement the program and particular components. However, this finding is unsurprising in light of NCI's plan for the NCCCP. NCI designed the NCCCP so that sites could create a system of care that fit with their local models of care. Indeed, NCI anticipated that sites would experience challenges—even discomfort—with trying to take the basic NCCCP guidance and apply it innovatively in their particular circumstances.

5.1.2.4 Dissemination

Respondents also emphasized the dissemination of information as an application of the program to their site. Information sharing could occur through various mechanisms and come from multiple sources. System respondents mentioned how they could share information across their hospital system. Other respondents pointed to the collaboration and sharing across NCCCP sites and NCI-designated cancer centers. One respondent envisioned how lessons learned from the NCCCP might influence cancer care nationally.

Respondents from system sites suggested that lessons learned from the NCCCP might be shared with other hospitals in their system:

> *Our involvement in this is to use the system as a platform for dissemination of learning across the system to benefit as many communities as possible. We recognize at [our system] that that's what makes us distinct, our opportunity to do that. There's shared learning that's going back and forth both from the NCCCP to [other system hospital] members, and from [other system hospital] members to the NCCCP.* (System/hospital senior executives, Year 2)

Other respondents saw sharing information with and learning from NCCCP sites and NCI-designated cancer centers as a way the program applied to their site. One respondent felt that his site could serve as an example and mentor to other sites:

> *As this thing has evolved, I've gotten the sense that why we're in this thing is perhaps for mentorship. What I see in terms of our growth isn't going to be as big as [for] the other institution. I've gotten the sense that we're bigger mentors in helping others and helping design what we're going to do. Our level of growth isn't going to be as high because we've already achieve a lot before this thing started, at least on the clinical trials. On the other hand, I think we've certainly helped sites with our clinical trials expertise here. I've gotten e-mails from other sites [about] getting a protocol approved through IRB. We've helped other sites get focused, so at the end we're going to have something to show for meeting goals.* (Subcommittee member, Year 2)

Respondents also believed that learning from NCI-designated cancer centers would benefit their sites and improve cancer care. One subcommittee member, who was representative of this perspective, said, "When I explain [the] NCCCP I say it is a way for [our system] to

collaborate with NCI to enhance our delivery of cancer care in our area or region." Another respondent, who was less familiar with the program, hoped that the NCCCP would promote linkages between academic medical centers and NCCCP sites:

> *I don't know if they want a big brother–type program. I think 90% of what we do here is very similar to what I did back at [academic medical center]. But there's 10% that's unique, and I don't know if that's going to require an affiliation between an NCI-designated cancer center and a community cancer center—like I said, a big brother–little brother program—or if it's going to be a loose association. Wouldn't that be nice? If I needed something or had an issue, I could call my partners back at [academic medical center] or telemed with them. I don't know how that's going to shape up, but I think that's something we'll find out going down this 4-year path.* (Key physician, Year 2)

One respondent posited that lessons learned from his site's participation in the NCCCP might have an impact on cancer centers across the nation:

> *We are a pilot chosen because of the infrastructure that we have. We were chosen by NCI to implement the program for 3.5 years. Based on our success, this will be rolled out across the nation to other community cancer centers.* (Subcommittee member, Year 2)

Consistent with NCI's vision of promoting collaboration among sites, respondents routinely emphasized information sharing as a key element of the NCCCP. Respondents highlighted various paths for information sharing, such as through their hospital system (for system sites), reciprocally with academic medical centers, and across the nation with other community hospitals. This understanding of the program, and perhaps willingness to share information, shows promise in helping NCI further its goals of improving cancer care more broadly.

5.1.3 Changes in Sites' Understanding of the Broad Vision by Year 3

In Year 3, respondents were not asked specifically how their understanding of the broad vision of the NCCCP has changed. However, there was anecdotal support for increased understanding of the NCCCP goals and mission:

> *[The NCCCP] has allowed us to go in directions that we might not have gone and allowed us to be creative when we weren't at a creative point in our development. It is truly a pilot so it has allowed me to shift my thoughts on how it should look. (Program coordinator, Year 3)*

> *I think our goals are much more in keeping with what needs to be done in a rural [and/or] community setting, where most oncology takes place. Rather than focusing on putting patients on trials, we have a whole set of pillars that we're supposed to*

pay attention to. I believe those goals are much more broad [than CCOP]. (PI, Year 3)

I think [the NCCCP] is out to create a level playing field for what is available to physicians, and to create a standard of care for all patients, and a standard by which all physicians in the U.S. should practice, whether you are in an academic center or a community center. (Key physician, Year 3)

5.2 Vision/Understanding of Program Application to Individuals' Roles

In this section, we examine how individual respondents believed that the NCCCP will fit with or change their existing roles. Their understanding of the compatibility of the NCCCP with their roles demonstrates how these individuals made sense of the program and its relevance to their work lives. Understanding this sense-making provides insight into whether staff "buy in" to the program and identifies what actions staff may take to enact the perceived requirements of the program.

This section contains Year 2 data from 41 interviews and discussion groups. Of these, 16 come from subcommittee members, 18 from key physicians, 2 from top management, and 5 from cancer center/program staff. Because subcommittee members and key physicians represent the majority of respondents in these groups, this section focuses on their perspectives.

5.2.1 Subcommittee Members

With the exception of three respondents, all subcommittee members elaborated on whether and how they thought the NCCCP would affect their role. Biospecimens subcommittee members, including pathologists, saw their role as relatively unchanged, because tissue collection is part of their regular job responsibilities. As one said, "I think the main role is to provide viable tissue: first of all, that it's mainly tumor and not necrotic, and also proper handling and proper classification of the tumor." Another added, "We know what our role is in pathology. We are ready to tackle our role."

Similarly, IT subcommittee members defined their role as modifying the hospital's IT to accommodate research and creating an interface with caBIG. They anticipated that these changes would pose challenges for the team:

> *From my perspective in IT, it is less a matter of support than trying to determine how we will migrate our data stream, which is currently focused on strict clinical support. We need to reconfigure our systems through some of the tools that will be available to us to get it into overall data stream. We're struggling mightily at this point. To this point, we have just been focused on patient management within a facility. It is a huge change for us.* (Subcommittee member, Year 2)

One IT subcommittee member said that implementing such changes would create a common platform for tissue registries and information sharing, which would ultimately promote cancer research nationally. This subcommittee member explained, "With IT, [the] NCCCP is trying to create a platform across the community cancer centers and the NCI-designated cancer centers so that clinical research can be shared across the nation." Only one subcommittee member expressed concerns about implementing and "selling" caBIG; this individual said, "What can we do [with] caBIG? How do we get our arms around it? How do [we] communicate it? And, I'm not use to selling. We don't usually say, 'We're going to use it.'"

Clinical trials subcommittee members described their role as increasing accrual to clinical trials and educating the public about trials. One subcommittee member said, "For clinical trials, the goal is not only increasing accruals, but also educating people about cancer care and clinical trials specifically. We educate patients and families and also educate physicians about what trials we are offering."

Subcommittee members representing the other program components tended to speak of their roles in broader strokes and generalities. Quality of care subcommittee members described several applications of the NCCCP to their roles. These subcommittee members discussed increasing the number of multidisciplinary clinics, gathering more data on patient satisfaction, and collaborating with other cancer centers to learn best practices:

> *In the quality of care pillar, the focus is on increasing the number of multidisciplinary care clinics. Also, we are looking at how we can evaluate the success of these clinics. The other half of [quality of care] is looking at patient satisfaction data. Historically, we have only gotten satisfaction data from infusion patients. Now we are expanding that to assess patient satisfaction for all patients, using [our hospital's] tool. The questions are geared towards patients and families.* (Subcommittee member, Year 2)

> *My focus is in quality of care, and it's [my role] to see what other cancer centers have and collaborate together to help best suit the cancer center.* (Subcommittee member, Year 2)

Three subcommittee members spoke of survivorship. Two of these had a general vision for survivorship at their respective sites; both described how they might expand survivorship:

> *Survivorship is one of the areas of cancer care that has been lacking here. The focus has been more on diagnosis and treatment. We forget that people need care for the long term. That is one of the criticisms I have heard here…that people feel they are left out in the cold when their treatment is finished. They have developed close relationships with the staff here, and then they feel cut off.* (Subcommittee member, Year 2)

> *The tools for palliative care and survivorship issues are forefront in the nurses' minds. I think that's true for most of the facilities in the nursing workgroup. Now we are looking at how we can develop that aspect of nursing care at the chairside for our patient.* (Subcommittee member, Year 2)

Only two disparities subcommittee members described how the disparities component would fit with their role. Like some other subcommittee members, they spoke in generalities:

> *I explain my position more than I describe [the] NCCCP. I talk about working to reduce disparate populations in cancer care, helping people learn from the information we give them, [and] survivorship issues.* (Subcommittee member, Year 2)

> *In terms of disparities, we are reaching out to the entire community and bringing the best quality of care to everyone.* (Subcommittee member, Year 2)

Three subcommittee members had more specific visions of how the NCCCP would apply to their roles because the program overlapped with many of their existing work responsibilities (e.g., preparing tissues for research) and because the goals for their component were more concrete (e.g., increasing clinical trial enrollment). The remaining subcommittee members had broad visions for their respective components.

5.2.2 Key Physicians

Key physicians varied in their understanding of how the program applied to their roles. About one-third of key physicians did not have a clear understanding of the program, another third had a general understanding (e.g., "have an impact on cancer care"), and the rest could offer specifics about what they would do as part of the NCCCP (e.g., clinical trials accrual).

The first third of key physicians could not articulate what their role would be in the NCCCP. Some noted that they were still learning about the program. One explained, "[PI] has told us some, but we're still learning about it." Trying to figure out his new role, another key physician expressed excitement. When asked how he responded when he heard about receiving the NCCCP grant, he said:

> *It's definitely a challenge. New ways of doing things and then growing: that wow factor. Then it's wow…we need to do it! Just learning about it and understanding it more and seeing how the pieces fall and how we will deliver our care. I think that's what's made it kind of interesting, but over the past year…learning about it and getting our arms around it, and how it will affect our patients and how we deliver our care.* (Key physician, Year 2)

Other key physicians who did not know their role ventured a guess as to what they might do in the future. One said that she has been confused in the local meetings and that she "didn't

have a complete picture," but that she "really wants to do the clinical trials." Another key physician posited some things he might do: "I don't know my role. We are here to serve. If people ask us to give a lecture, we are happy to do that. Our goal is not to know what the programs are, but to deliver a product as it relates to gynecological oncology." As these data suggest, some key physicians could not articulate their role relative to the program as a whole. Their inability to explain how their services fit into broader hospital cancer care goals raises the question of whether these key physicians can "deliver a product" consistent with the NCCCP's goals.

Although the majority of key physicians who could not articulate their role expressed interest in the program, some expressed frustration and felt disengaged. One key physician commented, "No one has made it personal to me. I don't want to come off like a jerk.... Another reason I haven't said anything is probably just the sense that I wouldn't have much influence. Administration is the one that decides where to put the money."

The second third of key physicians saw the program as corresponding with their work, but could provide only generalities about how it applied to their role. For example, one key physician explained, "I've been involved. As a radiology oncologist at [site], I have a lot to offer. Certainly we have a lot that we need to do in terms of expanding access to care." Another key physician commented:

> *The NCCCP provides a wonderful service for our patients, and that's what I can get from it. … [There is] not much for me personally to gain. [The NCCCP] won't enhance my career standing that much; [I] won't be monetarily rewarded. It's something that is for the patients; that is where the value comes in.* (Key physician, Year 2)

This third of key physicians saw a fit between their work and the NCCCP, but did not offer specific applications of the program to their role. However, these key physicians expressed strong interest in the program (e.g., "wonderful service for our patients"). Even though this group did not have specifics, they did have a general understanding of the NCCCP and the value that they might add to the program.

The final third of key physicians described some activities they engaged in for the NCCCP. These included participating in multidisciplinary clinics, being a champion for the program, interfacing with senior executives, and generating quality metrics and assessments. One physician emphasized his participation in multidisciplinary clinics:

> *From a practical standpoint, my participation is in the head/neck multidisciplinary care center, and I'm the surgical component of that, and we have up to 10 people in our multidisciplinary care group, which includes MDs, social workers, psych, nutrition, etc. We formulate in that setting the synthesis of the best therapeutic plan which will also include clinical trials that we participate in.* (Key physician, Year 2)

One key physician described his multiple roles, which included championing the program, supporting physicians, serving on various committees, and communicating with their senior executives. This key physician described all of the activities he does for the program:

> *My role is supporting [the] physicians' side of operations. My scope is pretty broad. I also chair [the] operating/leadership council, which is like internal board where all major decisions run through that committee. … My role in terms of [the] NCCCP has been varied. I have a lot of interactions with the community (e.g., community health center, I chaired the board there), and in terms of education, I am the medical advisor to the telemedicine program. I am on the disparities committee and I also participate in the core steering group. There are two people from [executive team], and we're the two ties from [the] NCCCP to our senior leadership.* (Key physician, Year 2)

Several physicians discussed service to committees and efforts to improve quality of care assessments and metrics:

> *I'm on a few of the committees. I think some of the committees may have been more busy than we have. We're going to hopefully establish a way to measure quality in terms of what we can do with radiation oncology.* (Key physician, Year 2)

This final group of key physicians could explain their specific roles in the program, which points to their greater engagement in and proximity to everyday program activities.

Strikingly, most key physicians did not draw a specific connection to improving the research infrastructure, such as serving as a PI on clinical trials, recruiting and/or discussing with patients clinical trials/tissue sampling, or serving on an IRB, nor did they discuss specifics about improving quality of care, such as increasing guideline implementation and adherence, looking at outcome data, reviewing cases, or participating in committees. In short, they had difficulty tying the larger goals to specific things they could do.

5.2.3 Changes in Vision/Understanding of Program Application to Individuals' Roles by Year 3

In Year 3, there seemed to be an increased understanding of the NCCCP's applicability to individuals' roles. This was apparent not only in those who have been more directly involved with the program, but also from hospital senior executives and cancer physicians, especially among those in private practice:

> *When I stepped in, my role is really to advocate at the executive level for this program, and to the point of sustainability, this has been a really important year for me to understand the program (NCCCP).* (Cancer center/program staff, Year 3)

> *Private practice physicians play a big role in determining what trials exist. If there is a patient that [is eligible], [I] will make a recommendation that they should be on a trial.* (Key physician, Year 3)

> *They [nurse navigators] provide a great deal of support for the patients. The original role of the nurse was focused more on the physician than the patient. Now there is greater patient centered care. The nurse navigator is fundamentally different from physician centered care, with the priority being to improve the patient experience.* (Key physician, Year 3)

5.3 Challenges to Developing and Communicating a Common Understanding

Sharing a common vision across staff promotes program implementation as staff understand how the broad vision of the NCCCP applies to their particular site. In Year 1, program leadership articulated an understanding of the NCCCP's vision (see Section 5.1.1), although some noted that the program had not been fully shared with hospital and cancer center staff. More broadly, many barriers concerned communication, while others dealt with organizational and contextual factors, such as resource constraints, differences in perspective/opinion, uncertainty about what might work best, and concern about what could be accomplished in a 3-year period. Because this complex program was new to the sites when the Year 1 site visits were conducted, most sites had not yet developed a common vision or strategy to disseminate information consistently and universally. As such, sites faced several challenges to developing a shared understanding of NCCCP's goals and vision. These challenges are briefly described in the following sections.

5.3.1 Lack of Clarity about NCCCP and Formal Sharing Because of the Youth and Complexity of the Program

In Year 1, the NCCCP was new to respondents, and they wrestled with the program's broad and ambitious goals and with the application of the program components to their sites. As a result, (1) core team members had not well outlined how the program would fit in with their cancer plan, (2) the goals had not been well articulated and were therefore not communicated hospital-wide, and (3) a lack of formal advertisement and sharing about the program among staff hindered the creation of a common understanding at several sites. These challenges suggest that future implementation efforts may require more time at start-up to allow sites to develop a common understanding of how to integrate the NCCCP at their site.

5.3.2 Level of Engagement/Proximity to Activities

In Year 1, those who were more directly involved in implementing the NCCCP had a clearer understanding of the program, whereas those who were less engaged may not have had a clear picture because the program did not yet have a daily impact on their work. Of all

respondent types, key physicians, especially private practice physicians, were the least proximal to daily program activities (e.g., planning meetings, calls) and thus had lower levels of engagement in and understanding of the program.

5.3.3 Relationships with Physicians

In Year 1, relationships between hospitals and physicians (employed and private practice) posed some challenges to developing a common understanding of and vision for the NCCCP. In particular, respondents discussed challenges associated with fragmentation in the health care delivery system, competition between hospitals and physicians, and issues of buy-in and resistance.

5.3.4 Time Constraints

In Year 1, time constraints proved to be a challenge to establishing a common vision. Such constraints limited stakeholders' ability to rethink the cancer care delivery system or care processes, to develop new and improved ways of operating, and to sustain program momentum. Managing program requirements and a heavy workload hindered communication, and sites found themselves needing to focus more narrowly on understanding the program to support broader hospital-wide communication.

5.3.5 Remaining Challenges in Year 3

During the Year 3 site visits, most sites reported having developed systems, processes, and a more coordinated staffing hierarchy for implementing the NCCCP. However, after 2 years of funding, a few of the same challenges for some sites remained, while others reported experiencing a new set of challenges. The main barriers to communicating a common understanding and vision of the NCCCP noted in Year 3 were

- limited involvement among hospital's top management,
- continued lack of clarity about the program, and
- lack of integration and coordination.

We describe each of these below in greater detail.

5.3.5.1 Limited Involvement Among Hospital's Top Management

By Year 3, some sites reported an increase in involvement by their hospital's top management:

> *I serve on the executive committee of [the] NCCCP, and we have conference calls with the hospital presidents once every other month. The PI and Admin lead that and set the agenda. From the [site] system perspective, it allows us to see all of the moving parts.* (System/hospital senior executives, Year 3)

There were other sites, however, that still found it difficult to consistently stay informed about the program:

> *It's a challenge for me, personally. I wear two hats: CEO of the hospital and CEO of the health system. My connection is really through my meetings with [names of program staff], which periodically happen around meetings about the strategy.* (System/hospital senior executives, Year 3)

5.3.5.2 Continued Lack of Clarity about the Program

In Year 1, respondents revealed that even when program leaders and champions made initial efforts to disseminate program information, some felt that they also needed to have a better understanding. In Year 3, this lack of clarity about the program remained, especially among key physicians:

> *The program seems nebulous. I am not sure with a crisp understanding of what this program is…Is the purpose to promote research in a nonacademic setting? I feel as though a program like this should be more encompass[ing] of medical oncologists. I still feel like I do not know what this program expects medical oncologists to do. Every time I see a patient I should be able to say what the purpose of this program is.* (Key physician, Year 3)

> *We have some opportunities to better integrate and involve, probably more so on some of our surgeons. I think they know the concepts of what we support in [the] NCCCP. In [multidisciplinary care conferences], we have leads that are wedded to the conference, but if you said, "What is [the] NCCCP?", they would not necessarily know what I am referring to.* (Cancer Center/program staff, Year 3)

The comments of one key physician illustrate the remaining uncertainty about how the goals of the sites are aligned with those of NCI:

> *I think there is a lack of clarity that we are part of NCI. That lack of visibility is an issue. The potential is still there. The lack of creating a cohesive brand is what leaves most physicians a little lost. That was one of the things that was marketable. Is it a long-term goal to have us collaborate with NCI?* (Key physician, Year 3)

5.3.5.3 Lack of Integration and Coordination

One issue that has made communicating a shared understanding of the NCCCP challenging has been a lack of integration between clinic and hospital staff. This fragmentation of staff has minimized communication about the NCCCP both hospital-wide and at an intraprogram level:

> *One barrier is [that the] clinic and hospital are not as integrated as could be yet, so people can still be siloed.* (PI, Year 3)

> *[The] NCCCP team hasn't met all together for a while but meet separately for subcommittee teams. People either didn't have time or didn't attend given competing priorities. [It] seemed more effective to work with subcommittee teams individually.* (PI, Year 3)

5.4 Summary

Despite the challenges that some sites still face in developing a shared understanding of NCCCP goals, most sites have found effective ways to overcome these challenges. The involvement of top management and the establishment of formal lines of communication for the NCCCP goals and vision have played a key role in developing this shared vision, which has been consistent with NCI's goal of improving cancer care. The benefit of this broader and shared understanding was expressed by one system CEO:

> *Oncology services have been elevated as a strategic priority overall as a result of participating. There has never been this type of infrastructure. Our hospital likes it because it has high visibility, includes research, and focuses on taking care of the poor. We have handfuls of centers of excellence, including oncology, and we see oncology as one of our top three priorities.* (System/hospital senior executives, Year 3)

The integration of the goals and structure of the NCCCP has also been an important benefit realized by sites as a result of this shared understanding. Many sites have "hardwired" the NCCCP into their current systems and processes, facilitating how the NCCCP is communicated across hospitals and cancer center departments:

> *We've integrated [the] NCCCP into the cancer center; if asked about [the] NCCCP they would say, "What?" It isn't this thing that sits out here.* (Key physician, Year 3)

This integration for some sites has translated into providing an increased understanding not only among leadership and staff, but also, perhaps more importantly, to their patient community:

> *I think one of the biggest accomplishments is the enhanced marketing and awareness of our NCCCP participation internally with other departments and in the community. It benefits us because there is greater support of an understanding of what we do. Some of it is resources. It is helpful for patients who refer themselves and family members. Patients highlight coming here because we are an NCI cancer community.* (Cancer center/program staff, Year 3)

6. SITES' CAPACITY FOR LEARNING, INNOVATION, AND CHANGE

Overview

The sites' capacity for learning, innovation, and change is associated with their reasons for participating in the NCCCP, their culture, and their organizational alignment and internal capacity.

Reasons for Participating in the NCCCP

Early on, sites shared that their primary reasons for participating in the NCCCP were (1) creation of a formal link with NCI, (2) the opportunity to develop and learn how to improve cancer research and care, and (3) alignment of fit between the NCCCP and their strategic priorities.

Organizational Culture

Each organization's culture seems to be associated with their readiness to change, which is strongly influenced by their leadership both in the hospital and for their cancer program. Sites initially indicated experiencing major barriers to initiating the program (primarily because of the bureaucratic processes for staff hiring) and engaging physicians in program initiatives. The rates of change across the sites were varied and seemed to be associated with how well the leadership was able to work through these types of issues. Strategies for building capacity included having direct and regular communication between the hospital and cancer program leaders and with key cancer physicians.

Organizational Alignment and Internal Capacity

Cancer centers with formal mechanisms to incorporate top management in cancer center infrastructure, direct reporting relationships between the hospital and cancer program leaders, and a physician director for the cancer program (with at least 25% of the physician director's time allocated to his/her leadership role) seem better equipped to innovate, change, and implement a wide-scale multi-component program such as the NCCCP. However, many of these items are not simple to incorporate or change during the course of the NCCCP. Given the barriers to change, NCI should consider examining these key indicators during the application and selection process.

Sites also varied in their ability to enhance their capacity in cancer care, IT, and research. Centers with greater levels of physician specialty involvement, dedicated time from both formal and informal physician leaders, and program support staff may be better equipped to provide care of higher quality or a broader range. During the course of the NCCCP, hospitals made sustainable and long-term staffing investments in the cancer center, particularly for roles (such as patient navigators) that are essential to integrating cancer-related specialists and increasing the quality of patient care coordination.

Although several sites were able to move forward with plans to implement a unified electronic health record (EHR) system, the majority of sites in Year 1 and Year 3 cited this as a barrier. According to Year 3 findings, funding remained a barrier to selecting and implementing a unified EHR. Enhancements in cancer research were consistently supported by hospital senior executives across NCCCP sites and are addressed in more detail in Chapter 10 and Section 16.1.5 of this report.

In this chapter, we discuss three organizational characteristics uniquely associated with the capacity for learning, innovation, and change (as described in Chapter 2):

- the reason for participating and how it aligns with internal and external sources of change,
- the culture within each organization, and
- the organizational alignment and internal capacity.

Sample questions asked of respondents appear in Table 6-1 with a full set of discussion guides in Appendices B–D.

Some of these topic areas are difficult to assess through direct questions. For example, interviewers did not pose specific questions about the alignment of fit between the NCCCP and the strategic goals of the site. Rather, this major topic area was a theme that emerged from sites' discussion of their reasons for participating. Greater overlap between the strategic goals of the site and the NCCCP indicated greater alignment of fit, which corresponds with increased adoption, implementation, and program success. The alignment of fit between the NCCCP and organizational strategic goals was cited as a primary reason for participation; it is therefore presented in the Section 6.1. This chapter presents what respondents believed to be the qualities of their hospitals and cancer centers that influenced them to participate in the NCCCP. In Chapter 16, we describe in greater detail how these perceived characteristics seem to have been associated with whether the sites achieved key outcomes.

6.1 Reasons for Participating in the NCCCP

There were several frequently cited reasons for participating in the NCCCP. Our analysis identified three core reasons for participating:

- creation of a formal connection with NCI,
- the opportunity to develop and learn how to improve cancer research and care, and
- alignment of fit between the NCCCP and the site's strategic priorities.

In this section, we explore each reason for NCCCP involvement in detail, providing definitions, frequency counts, and examples of each emergent theme.

6.1.1 Creation of a Formal Connection with NCI

In response to the moderator guide question regarding the sites' reasons for participating in the NCCCP, respondents indicated that creation of a formal connection with NCI was a key factor. Specifically, respondents noted that affiliation with NCI could help distinguish the site as a recognized leader in cancer care and help advance their local market position:

> *Just being affiliated with NCCCP and NCI helps us open doors and gives us more credibility*. (Subcommittee member, Year 1)

> *Credibility by the public of NCI [is a core reason for participating]. They're not aware of the Commission on Cancer, but they are aware of NCI. We have a really good CCOP but we needed to go beyond that, and this was an opportunity to label us as an NCI institution*. (PI, Year 1)

> *We want to pursue NCI designation, to become a full-blown program. Outside of benchmarking, it is a strong differentiator*. (Cancer center/program staff, Year 1)

> *We had completed our internal cancer business plan and we became aware of this program, and the thought process with our CEO was, "If we're going to do this, we want to be one of the premiere cancer centers in the nation."* (System/hospital senior executives, Year 1)

> *There was an interest to try and distinguish ourselves within NCI and within our market.* (PI, Year 1)

> *We want to become a leader in community-based cancer care. We thought that research and clinical trials are critical for us to distinguish ourselves.* (System/hospital senior executives, Year 1)

Sites reported that the heightened external recognition and visibility due to their NCI affiliation helped to garner resources:

> *Just association and the grant is important to adding staff and resources that we need to do some of these things that we'd all love to do.* (System/hospital senior executives, Year 1)

> *Partly because we are an NCCCP program, there is more recognition; respect gets us in the door. Others think if NCI is willing to deal with these guys [us], it must mean we met some kind of threshold. It means there is commitment on our part.* (PI, Year 1)

6.1.2 Opportunity to Develop and Learn How to Improve Cancer Research and Care

Respondents also discussed the opportunity to improve cancer research as a main reason for participating in the NCCCP. Respondents reported that the NCCCP had the potential to increase their internal capacity via enhancements in clinical trials, research infrastructure, quality of care, and reduction of disparities (see Table 6-2).

Table 6-3 provides data regarding the frequency with which each emergent theme related to reasons for participating was discussed during the Year 1 interviews. Key physicians in the NCCCP discussed increases in clinical trials more than other respondents. It is possible that

key physicians were more engaged in the clinical trial process or that this component of the NCCCP was more readily understandable, perceived to be valuable to them and their patients, and/or presented direct and observable benefits compared to other program components, such as disparities or quality of care, which often require longer-term change processes to see results and may be perceived to be of less value to them professionally. System/hospital senior executives were more likely to discuss how the NCCCP could increase standards, or raise the bar, for quality of care. System/hospital senior executives were also more likely to note that reduction of disparities was an integral reason for participating in the NCCCP.

6.1.2.1 Offer More Clinical Trials

Respondents noted that involvement in the NCCCP could potentially increase the number and types of clinical trials available to patients:

> *Accelerating access to trials and offering hope and maybe coming up with answers.* (PI)

> *Benefits to the science to increase the number going to these Phase I clinical trials…. I worked as a research nurse for a number of years and I know what it takes to put patients on [clinical trials], and I see that [the] contribution to science is huge.* (Cancer center/program staff, Year 1)

As indicated in Table 6-3, key physicians discussed clinical trials as a reason for NCCCP involvement more than any other type of respondent.

6.1.2.2 Strengthen Research Infrastructure

Cancer center/program staff also indicated that strengthening existing research infrastructure was a key reason for participating in the NCCCP. In particular, respondents enthusiastically discussed how they believed they now have the potential to bring academic research into community centers through an increased potential to partner with NCI-designated cancer centers since they were selected as NCCCP sites:

> *Clinical trials are one thing, but to be able to bring basic research, clinical research, and clinical care is a pretty cool thing—to have those opportunities around us and together is pretty magical.* (Key physician, Year 1)

> *To bring research that is concentrated in big hospitals into the community as well as their practices. At this site, it will be beneficial to get some of those practices started here.* (Key physician, Year 1)

6.1.2.3 Reduce Disparities

System/hospital senior executives cited reduction in cancer disparities as one of their core missions and pointed out that the NCCCP fit nicely into their existing outreach efforts. As

described in Chapter 4, all of the NCCCP hospitals were not-for-profit, with many having a prior mission of serving the poor (e.g., Catholic health systems) and/or were often located in low-income, high-unemployment areas. System/hospital senior executives mentioned reduction in cancer disparities more than any other respondent type (Table 6-3):

> *We have been in dialogue with others leaders and our physicians about how to deliver care to the un- and underinsured [populations]. The opportunity for them to get care has been limited.… That's one of the reasons we were interested in pursuing this grant.* (System/hospital senior executives, Year 1)

> *I think one of the things that attracted us to [the NCCCP] was that the grant wanted to access the disparities piece. We have competence and a track record with that: reaching out to them.… Part of the grand call to bring in the populations, to screen them more, to bring them into [clinical trials].* (System/hospital senior executives, Year 1)

> *[Our] focus is making sure that patients get proper care. Bringing this in will give them the opportunity to help the poor even more.* (Subcommittee member, Year 1)

> *I see an opportunity for expanded outreach both in rural and urban [populations], also to engage more people who are underserved [and] underinsured in [clinical trials] and screening and then in overall patient care.* (Subcommittee member, Year 1)

> *One reason is we thought we had a health disparities issue. Native Americans have huge issues of access [as do] the underserved in the rural areas. Those aspects of the program were really consistent with our environment.* (System/hospital senior executives, Year 1)

> *It is the intentional effort to bring cancer care in an interdisciplinary way to those that are underserved, underrepresented, disparity groups in a preventive way in the communities we serve. That's the primary reasons why we saw such a good strategic fit for us—because of our commitment to the poor and vulnerable in communities.* (Cancer center/program staff, Year 1)

6.1.2.4 Improve the Quality of Cancer Care

Respondents noted that the NCCCP had the potential to improve the quality of cancer care provided to their patients by increasing internal capacity (e.g., increasing hiring of staff with expertise, recruiting cancer specialists) and interaction among core cancer center members (e.g., multidisciplinary care [MDC] conferences). In particular, care would be improved by creating multidisciplinary teams and/or better coordination among private practice physician specialties, a form of integration that will have a meaningful impact on patient care:

> *[The NCCCP] raises the bar in terms of the level of care that we provide. Being a community-based [cancer center], 95% of our physicians are private practice, and it was a way to provide a continuum of care. Everyone was working in their silos. We saw this as a way to incorporate all of the components we had out there working on an individual level. It was a way to bring everyone together.* (Cancer center/program staff, Year 1)

> *We're attempting to do what university or academic-level hospitals do, in a community hospital environment: raising the bar of what we can do for our cancer patients.* (System/hospital senior executives, Year 1)

> *[The NCCCP] has been a catalyst for us to raise the bar. It drives growth. We want to have more patients go through our program to show those outcomes, because greater numbers prove a lot more. We already had a lot of strengths in the program before the grant came along—this takes us to the next level.* (System/hospital senior executives, Year 1)

6.1.3 Fit between the NCCCP and the Site's Strategic Priorities

As discussed in Section 6.1, fit between the goals of the program and the goals of the site is an integral factor in sites' capacity for innovation and change. When asked to describe their reasons for participating in the NCCCP, respondents indicated that the goals of the NCCCP fit well with existing priorities for the future, including prioritization of oncology cancer care, creation of synergies across program pillars and components, and acceleration of change. Thus, the NCCCP was not perceived as a "new" idea, but rather as a complement to the preexisting strategic priorities and future direction of the sites. Table 6-4 presents the definitions for each type of theme related to fit between the program and the hospital's mission.

NCI purposefully selected pilot sites with preexisting strategic priorities that aligned with the goals of the NCCCP. Thus, it comes as no surprise that fit between the NCCCP and the site's mission was one of the most frequently discussed reasons for participation. System/hospital senior executives, who are integrally involved in setting strategic priorities for the sites, cited alignment of fit more frequently than any other type of respondent during the Year 1 interviews (Table 6-5).

Alignment of fit often overlapped with other reasons for participation. For example, respondents indicated that one of their strategic priorities was to distinguish their site as a leader in oncology and to improve cancer care:

> *As part of our strategic plan for 2010, we wanted to advance our major centers of excellence: cancers, orthopedics, and heart disease. We want to become a leader in community-based cancer care. We thought that research and clinical trials are critical*

> *for us to distinguish ourselves.* (System/hospital senior executives leadership, Year 1)

> *The mission of the hospital is to improve health care for the community. The NCCCP project just fits right into that. It gives us a wonderful opportunity to improve health care, especially through addressing disparities in prevention and early detection activities, also the palliative and supportive care, to do what we can for those who already have the disease. The NCCCP is a wonderful fit. The hospital is very committed to oncology.* (Cancer center/program staff, Year 1)

Respondents cited three specific ways in which the NCCCP aligned with their hospital's or cancer center's pre-existing mission: prioritization of oncology cancer care, creation of synergies across pillars and components, and acceleration of change. Although sites noted their fit as a reason for participating, it became evident early on that they may have had plans to advance their cancer care but they were not working across all of the program components prior to the NCCCP, so the integration of the program with their cancer care and coordination across hospital services became major challenges during Years 2 and 3 (see Chapter 8).

6.1.3.1 Prioritization of Oncology Cancer Care

Respondents reported that the NCCCP had the power to increase the priority of oncology in the hospital above other service lines. The increase in prioritization of cancer care may also be related to heightened visibility within the hospital:

> *Oncology has been a sleeper at this hospital. We are poised to get to the next level—to do that and do research and collaborate more. This was a natural fit to us. This was an opportunity to bring people together and align goals.* (PI, Year 1)

6.1.3.2 Creation of Synergies across Pillars and Components

Respondents from several sites indicated that the NCCCP corresponded well with efforts to collaborate across hospital departments and program components, augmenting existing efforts to increase internal integration and improve coordination, although they were struggling with finding mechanisms for making all of the pieces fit together:

> *I think the effectiveness of our own internal leadership, paired with the infrastructure of grant reporting and subcommittees, has given us opportunities to effectively engage lab, IT, quality, outreach, etc., that the cancer team would have naturally done, but this has provided a focus. The timing of this with our own facilities and programs was serendipitous.* (System/hospital senior executives, Year 1)

> *The project helps you because you have all these people working on subcommittees together and people working on a roadmap for cancer services: not just hospital, all*

> *health services divisions. The NCCCP sits in between and brings it all together.* (Cancer center/program staff, Year 1)

6.1.3.3 Acceleration of Change

Acceleration of change and improvement was one of the most frequently cited reasons for participation in the NCCCP, particularly among system/hospital senior executives. The majority of respondents indicated that their sites were already engaged in activities central to the NCCCP, such as clinical trials research, outreach, and survivorship. However, respondents reported that the NCCCP was capable of accelerating change in their organization:

> *A lot of the activity we are going through now as part of the deliverables and the NCCCP is what the cancer program had in mind further down the road. This seemed to be a big catalyst to provide a push or impetus, infrastructure, initiative to make some of those things happen.* (Cancer center/program staff, Year 1)

> *I think that [the NCCCP] is just a continuation of a path we are already on and integrating it [into our existing structures]. This just represents another path of it. We have two IRBs already and are looking for a third. We have an active peer review.… I don't see this as being a piece. It comes as a natural addition. This is what we are about.* (System/hospital senior executives, Year 1)

> *For survivorship and disparities, a lot of the things: we were already moving in that direction, and the pilot lit a fire to get us to go ahead and get it done. We were doing some patient navigation, but it wasn't very formalized. This is an opportunity to formalize that process and do even more. I think this NCCCP is encouraging us to move multiple initiatives forward on a faster basis.* (Cancer center/program staff, Year 1)

> *It helped us to escalate quicker than we would have been able to do. We were already on this journey. This helped us get more focused and structured in a quicker timeframe than had we not had this opportunity.* (System/hospital senior executives, Year 1)

6.2 Learning and Innovation

As indicated in the conceptual framework (Figure 2-1), innovation, adoption, and assimilation are important processes that facilitate program implementation and success. To effectively implement components of the NCCCP, it is important for sites to be able to strategically and intentionally modify existing activities. RTI identified several organizational factors that are indicators of a cancer center's level of innovation and readiness for change (i.e., the site's ability to incorporate new approaches to cancer care), including top management support and resource allocation for the NCCCP. The following section describes

these factors. (Refer to Table 6-1 for the list of innovation and change factors and related protocol questions.)

6.2.1 Readiness for Change

Respondents from several sites indicated that they were slow, methodical, and purposeful in making strategic decisions and enacting change. Although it is important for sites to recognize this as their approach to change, it would ultimately present challenges to them in implementing the NCCCP because so much change was expected by NCI in such a short period of time (3 years):

> *We are going slow and we are taking baby steps. We have the right people involved, but if it's not the right person's idea it's not going to happen.* (Cancer center/ program staff, Year 1)

> *I describe [this organization] as the Starship Enterprise. It takes a while to make the change.* (System/hospital senior executives, Year 1)

> *I think the lab is totally different than the rest of the organization. The lab is so much easier. When you start talking about other directors who have to work through other departments, it's like they have zero control. But in the lab, I have control over everything in the lab. So I think if you're talking the change limited to path and lab [my department], it's way simpler than if you move it out. If you move out to include anesthesiology and surgery, it becomes a lot more difficult.* (Subcommittee member, Year 1)

The slow rate of initial change is not necessarily a barrier to program success. As indicated in the first quotation presented above, sites may take time to ensure that all of their resources are positioned strategically prior to enacting change. It is possible that the sites that carefully weigh their options and account for resources are able to make exponential progress once implementation commences. However, by Year 3, it became clear that although many of the sites had accomplished change in some key areas, it was more of a challenge than expected to establish key aspects of their capacity, such as hiring staff to work on key components, eliminating barriers to recruiting cancer specialists, and building trust in the communities to easily reach out to disparate populations.

6.2.2 Role of Leadership

According to respondents, leadership at multiple organizational levels plays an integral role in sites' ability to implement NCCCP activities. For the purposes of this study, leadership was categorized into two types: senior executives/top management of the hospital/system (i.e., CEOs, CMOs, and COOs) and cancer center/program leadership (administrative and medical directors). Each level of leadership provides unique advantages to program development, expansion, and integration. Respondents were asked to describe their

perception of leadership support within their organizations; to illustrate specific resources allocated to the NCCCP; and to identify key hospital and cancer center/program leaders.

6.2.2.1 Top Management: CEOs, CMOs, COOs

As top management, these senior executives prioritize or sponsor an NCCCP-related initiative and direct the necessary resources to support program implementation at their facility. The terms "top management" and "senior executives" are used interchangeably in the overall report. These roles are referred to in organizational charts and tables by their job titles, including the roles of chief executive officer (CEO), chief medical officer (CMO), and chief operating officer (COO).

According to respondents, the support of senior executives plays a powerful role in cancer centers' ability to implement new programs:

> *I wouldn't take it on without administration buy-in and support. It took 15 years to get our breast-imaging program off the ground.* (Key physician, Year 1)

> *The whole thing has evolved, and the leadership at the top and the alignment with everybody has made it work.* (Cancer center/program staff, Year 2)

> *I want to figure out how to have a hospital within a hospital and how to get physicians involved so they get some skin in the game. That's what I've been pushing towards. We have most of the pieces of the puzzle—the physicians, administration, and cancer center personnel. We just need support from upper levels.* (Cancer center/program staff, Year 2)

Specifically, senior executives play a fundamental role in organization-level decision making by garnering and allocating funds, staff, and resources in support of NCCCP initiatives. Supportive and well-informed CEOs were able to allocate funding for new positions, such as medical directors and patient navigators. The provision of funding for staff positions represents a long-term and sustainable investment in NCCCP components:

> *My responsibilities are not as direct as others. My role is to ensure that services provided on this campus are within the scope of the grant. We need to have the clinical staff, educators, case managers to support the activities of the grant. It's interesting…if the grant went away, we'd continue those activities. It's not about the grant, it's about the services we want to provide.* (System/hospital senior executives, Year 2)

> *We set aside $750,000 and said from the system perspective these [are] strategic dollars that will help launch the seed efforts in the early years [and] that may grow over time. We pooled these dollars with our CEOs who've committed $8 million or $9 million dollars over this initiative.* (Cancer center/program staff, Year 1)

In several sites, respondents indicated that frequent and direct communication between the CEO and the cancer center/program leaders was an effective means to obtain additional resources to support the grant and underlying initiatives. Specifically, medical directors with direct reporting relationships and NCCCP management teams that included the senior executives were reportedly successful in engaging leadership and obtaining resources at crucial stages of program development. Chapter 7 provides an overview of the organizational structures in place within each hospital and which sites were afforded the opportunity for the medical director of the cancer program to have direct access to top management. The theme of the importance of a strong relationship with the hospital's top management in a supportive role continued in Year 3. Seven of the 16 NCCCP sites identified several ways in which the senior executives demonstrated support: prioritizing the cancer program above other service lines, increasing staffing infrastructure, and providing financial support for the NCCCP.

Prioritizing Cancer Service Line

Respondents were asked to identify ways in which hospitals' top management demonstrated support for the NCCCP. Hospitals' senior executives exhibited visible support for the NCCCP by prioritizing the cancer center requests above other service lines and providing immediate financial and resource support to the program:

> *We have tremendous support from the CEO and the board. While other service areas across the hospital struggled, I was able to get what I needed in a low-key way.* (Cancer center/program staff, Year 2)

> *There's competition for the dollars when services are divided (between cardiovascular, cancer, and other). The dollars that are required are a lot. It just happened that the cancer program got that push first, and there are other areas in the clinic that are envious.* (Key physician, Year 1)

> *It was a difficult conversation to say that we have very little funding and have to subsidize and, oh, by the way, the economy has gone bad too. We have support from our CEO, who has continued to subsidize this project and done everything they can to make it work.* (PI, Year 3)

Prioritization of the cancer service line allows cancer center/program leaders to obtain needed staffing and financial resources to implement and sustain the NCCCP. In some cases, when the economic downturn began to hit local communities in 2008, the role of top management became more of a focus on protecting the existing funds for cancer care, and cutting costs elsewhere.

Providing Staff Infrastructure and Financial Support

Increasing staff size, as well as full-time equivalent (FTE) positions, and supplying bonuses for NCCCP-related activities is a mechanism through which hospitals' top management demonstrated commitment to increase NCCCP capacity. Respondents indicated that the top management was willing to augment existing resources (i.e., those already allocated to the cancer program) to enhance staffing capacity, which is a particularly important component of program sustainability for cancer centers whose existing staff are initially supported through contract funds:

> *I think the best are concrete examples. With our NCCCP work, we have a lot of finance department support to have formal meetings, setting up budgets, positions, and providing support for reconciling flow of income in and out. For this fiscal year, we created different cost centers so that we could more easily track dollars based on the funding source. With recent ARRA [American Recovery and Reinvestment Act] grants, leadership supported our request to hire a dedicated grants/financial staff who will be reporting to accounting. The hospital provides funds for us to be a sponsor for Relay for Life, [and] we received a nurse manager from our hospital to help support the program* (Cancer center/program staff, Year 3)

> *[The] hospital has been very supportive. They paid for service bonuses for physicians if they participate in Quality Oncology Practice Initiatives and score satisfactory.* (PI, Year 3)

> *First and foremost, the support from the top [demonstrates hospital support]. It literally was a 5-minute conversation with the CEO to see if I could spend money to get a grant writer help me write this proposal.* (PI, Year 3)

Two of the sites identified grant writers as core staff retained in Year 3. Although these staff members may not directly perform NCCCP activities, they work to obtain alternative funding sources to sustain the NCCCP over time, representing a substantial commitment of the hospital's top management to the program.

6.2.2.2 Cancer center/program leadership: Administrative and Medical Directors

Cancer center/program leaders (i.e., medical directors, who may or may not be PIs of the NCCCP, as well as executive directors if there is one) play an important role in program implementation. During the first year of site visits, respondents pointed out that cancer center/program leaders were essential to engaging physicians, providing linkages across departments, and providing program oversight. The importance of cancer center/program leaders was most notable in sites where this leadership was absent or played a limited role (i.e., fewer hours were allotted to the cancer center/program medical director or this person did not serve as an NCCCP PI):

> *I think our main weakness is not having a medical director with enough FTEs to have enough time to do the role of a medical director. The organization has to have*

> *someone with a larger than 25% time [commitment] to develop the program. Administration is not searching for someone.* (Cancer center/program staff, Year 3)

> *I think the leadership—with all due respect to them—there seems to be a tendency to sit back and wait to be told what to do, instead of being proactive. It makes it very difficult for those of us who are trying to do the best that we can with this project.* (Subcommittee member, Year 2)

> *[What are gaps or areas in need of improvement?] Definitely communication and a leader and having our leadership make it a priority. We need someone to say, "Yes, this is important, and this is stuff we're going to work on."* (Subcommittee member, Year 1)

Subcommittee members involved in the NCCCP noted that cancer center/program leaders are essential to developing strategic plans and providing information regarding the NCCCP needs to hospital senior executives:

> *We need a dynamic person to do strategic planning with all of the stakeholders. … We should have everyone weigh in. If everyone is running off to do something, then nothing ever gets done. Can we just have a plan?* (Subcommittee member, Year 2)

> *On quality of care, we are pillars of one. Mine requires physician participation, but without a seat at the table, we have to count on [administrative director] to take our issues to the table. I don't know how our message changes or what happens.* (Subcommittee member, Year 2)

Clearly, leadership at the hospital and cancer center levels is an integral factor in NCCCP implementation, success, and sustainability, with the power to both catalyze and curb program momentum. Cancer center/program leaders who have formal, consistent, and tight-knit reporting mechanisms with their senior executives report being better positioned to obtain both external and internal resources (see Chapter 7). Likewise, cancer center/program leaders who are well-informed, proactive, and engaged in integrating program components seem to act as catalysts for program implementation.

6.3 Organizational Alignment and Internal Capacity

One of the elements involved in effective implementation of complex programs such as the NCCCP is internal alignment between departments or units within the organization toward a common goal (Lukas et al., 2007). In this study, we are interested in understanding the capacity for the cancer centers and associated departments to change and incorporate new activities. During the first year of site visits, we asked sites to identify hospital departments that interface with the cancer center and the NCCCP. Respondents indicated that pathology, IT, and research were critical to NCCCP program success. These departments only increased in their importance to NCCCP implementation during Years 2 and 3, particularly for IT and

research capacity. Several sites provided additional information about the current infrastructure and capacity of each department. In addition to alignment of departments with the cancer center, leaders must demonstrate dedication to change by setting goals and providing resources. In this section, we describe factors involved in sites' capacity for change and, where possible, identify areas of alignment between activities in the hospital and NCCCP components.

6.3.1 Cancer Care Capacity

The ability to provide high-quality cancer care relies heavily on the expertise and availability of cancer center/program staff. Centers with greater levels of cancer physician specialty and subspecialty involvement, dedicated time for the cancer center/program medical director, and available support staff may be better equipped to provide high-quality care. Chapter 4 presents the baseline data for the NCCCP sites in terms of physicians who are specialists and subspecialists in providing cancer care. We also present a composite score for the baseline capacity of each NCCCP site for implementing the NCCCP (Section 4.1). In some cases, such as for Billings Clinic in rural Montana, respondents told us that they had the only board-certified gynecological oncologist (in Year 1) available to women in a four-state region. For many of the NCCCP activities, such as establishing MDC conferences, increasing patient accrual to clinical trials, or increasing the availability of cancer screenings, it is likely that those sites with a greater capacity (e.g., more staff and physicians) would be better able to implement these activities. The following sections provide an overview of the capacity by physician specialty, pathology laboratory services, IT, and cancer research.

6.3.1.1 Physician Specialty Capacity

Sites' capacity for cancer care and several NCCCP initiatives (e.g., MDC conferences, clinical trials accruals) are determined in part by the number and range of clinical specialists and subspecialists, since these factors indicate a greater capacity to provide a broader range of care to their cancer patients. The total number of key cancer physicians affiliated with each cancer center is an indicator of the volume of patients for which they can provide care, the infrastructure and support they will need to provide their services, and the ancillary or support services that patients are likely to need (e.g., sites with fewer cancer patients will have less demand for subspecialists such as gynecological oncologists). The total number of key cancer physicians affiliated with each cancer center could also be an indicator of the level of competition for cancer services in the area such that communities with higher numbers of cancer physicians are less likely to be able to facilitate the engagement of physicians (Chapter 4). That is, if physicians are functioning primarily in private practices and in order to participate in cancer center activities they have to reduce their amount of direct patient time, they would have a financial disincentive for participation in NCCCP initiatives.

During Years 1 and 3, sites provided data in the Baseline Assessment Survey (BAS) and the Final Assessment Survey (FAS) regarding the type and number of physician specialists involved in the cancer center. As shown in Table 6-6, the 10 lead sites tended to have more key cancer physicians than the developmental sites. In Year 1, sites had an average of 11 key cancer physicians, with a range of 1 (Site 13) to as many as 25 (Site 6). The average number of key cancer physicians in Year 3 nearly doubled to 20, ranging from 1 key cancer physician (Site 13, Site 5)[1] to as many as 39 (Site 12).

In examining the changes in access to these subspecialists from Year 1 to Year 3, two of the hospitals (Site 7 and Site 5) reported an overall decrease in the total number of cancer physicians. Site 13 maintained their single cancer physician, and the remaining sites increased their total number of cancer physicians by 1 (Site 4, Site 2, Site 14) to 35 (Site 12). Site 11 was an outlier with an increase of 50 cancer physicians, likely due to the large number of private practice physicians they counted. Given the variety of data sites provided, perhaps the most important finding here is whether they lost or gained cancer physicians. Although some sites shared with us how the NCCCP had provided an opportunity to recruit physicians to their cancer centers that they may have not otherwise been able to hire (e.g., the two cancer center medical directors hired at sites during Year 2 told us that the hospital being affiliated with the NCCCP is part of what convinced them to come), this finding was inconsistent across the sites.

However, having more physicians does not necessarily equate to patients receiving better care. Those hospitals that relied primarily on private practice physicians and had a large number of cancer physicians may have been more likely to have greater challenges coordinating care across those physicians or informing physicians on changes in their cancer program (e.g., initiation of a new MDC conference) because of the logistics of having to communicate with so many physicians. In addition to the total number of cancer physicians, sites also provided data on which cancer subspecialties they had affiliated with their cancer program. Although we attempted to provide counts of the numbers of medical and radiation oncologists at each site, we found these numbers to be inconsistent, so we have reported only the total. Across the sites, two developmental sites reported having no access to medical oncologists, and one lead site reported no access to a radiation oncologist (i.e., they had lost the one who was there during Year 1). Overall, by the end of Year 3, five cancer programs had access to at least one surgical oncologist who was a key cancer physician for them, eight could provide access for their patients to at least one gynecological oncologist, and two had at least one palliative care specialist. Table 6-6 provides data regarding the total number of key cancer physicians in Years 1 and 3 as well as the change over time.

[1] These findings are based on self-reported information from the sites during the end of year 2007 (BAS) and as of June 2010 (FAS). RTI did not collect these data; they were provided by the implementation contractor, SAIC-F.

Based on analysis of the Year 3 organization charts (Appendix J), sites did vary in terms of their accessibility to three types of cancer subspecialists: surgical oncologists, gynecological oncologists, and palliative care specialists. Only two sites reported having access to all three of the reported subspecialists, while five cancer programs had no access to these subspecialists. This compromises the capacity of these hospitals to provide care to patients who are diagnosed with one of these related types of cancer (e.g., ovarian) or who are in need of more complicated surgery or palliative care.

6.3.1.2 Pathology Laboratory Capacity

The pathology laboratory is an important hospital unit involved in implementation of the NCCCP. The pathology laboratory is responsible for analyzing specimens to aid specialists in disease diagnosis, treatment, and prevention. Thus, employees in the pathology department are integrally involved in changes occurring in the cancer center, including new standards of care, increases in the number of cancer patients, and particularly implementation of the biospecimens program component. To meet the growing and changing needs of the cancer centers that correspond with the NCCCP, pathology departments need to be flexible and fluid and have the ability to expand and change their internal capacity.

Expanding Services/Hiring Staff

One pathologist indicated that, since the inception of the NCCCP, the laboratory had received an influx of cancer cases. To adapt to the increase in patients, the laboratory expanded their department and hired additional staff, an indication of absorptive capacity and resource support:

> *In the lab, we're definitely seeing significant increases in the number of cancer cases. Our bone marrow cases have tripled. We're doing a lot more hematology pathology than we ever did. We're bringing in specialists. We're expanding and trying to provide more subspecialties.* (Key physician, Year 2)

Hospital Support for Pathology. One site reported that senior executives procured and directed funds to develop a new lab and hire new pathology staff, demonstrating high levels of leadership support and alignment between strategic organizational goals and departments within the hospital organization:

> *The lab will cost $2.7 million. We got just $15,000 from NCCCP. We will be hiring nine new FTEs: managers, scientists. Money comes out of the R & D funds. [The hospital] didn't have the money. We had to convince R & D and we just got approval 2 weeks ago.* (Subcommittee member, Year 2)

Several hospitals contract with pathology private practices for their laboratory services such that increasing or changing their services has to be negotiated through contract revisions.

Therefore, taking on these areas for change was a significant undertaking in many of the hospitals funded by the NCCCP.

Staffing Barriers. Several respondents indicated that their pathology departments were well positioned to incorporate the NCCCP. However, other respondents noted barriers to programmatic change. One respondent reported that top management was slow to provide the laboratory resources needed to handle their existing caseload, signifying a major limitation in the pathology department's ability to expand their capacity alongside the NCCCP:

> *The pathology department is short-staffed in histology. It took 1 year to find qualified, certified histotechs. They [leadership] are slow to recognize they have to spend more money. At some point you have to pay for what you want.* (Key physician, Year 2)

Pathology Laboratory Structure Barrier. In addition, one respondent noted that the complex structure of the pathology lab was not clearly understood among surgical staff, demonstrating a lack of integration between departments and a potentially serious barrier for future biospecimens procurement:

> *The OR considers the lab as one department, but there are multiple departments in it. What happens is in the past we had problems with a lung biopsy going to microbiology for cultures and it doesn't go to pathology at all. We have to agree to do our requisitions and [determine] what kind of information does biospecimens need with these requisitions.* (Subcommittee member, Year 2)

6.3.1.3 IT Capacity

An integral part of the NCCCP is IT, a component that helps coordinate and integrate the NCCCP components and intra-organizational interactions and potentially helps to better integrate patient care coordination. Respondents indicated that IT capability can have a powerful effect on NCCCP implementation (see Chapter 12). However, several sites indicated in Year 2 that their current IT equipment and infrastructure were not sufficient:

> *It gets to universal medical records…we have not gotten there yet to figure out how to use it. We haven't gotten that far…one of our challenges [is] looking at what systems can do with each other.* (Cancer center/program staff, Year 2)

To implement NCCCP tools and track data, the IT infrastructure needs to be flexible enough to incorporate new data abstraction requests and modules:

> *The IT pieces are a pretty significant issue. It's a moving target for us. Projects are coming our way, and we don't have a good system for knowing what is in what system. Doing data collection manually is costly and overwhelming and could bury*

> *us. That is a really big barrier. Data management is a really big barrier.* (Cancer center/program staff, Year 2)

One respondent noted that IT personnel could meet their needs, but the system itself was cumbersome and complicated:

> *If I wanted to access their inpatient record, it takes 10 minutes for me to load all of that information, especially if I am covering for someone on the weekend. Every time we have an upgrade, it is presented but not uploaded until highly technologically savvy individuals come in and decide they need some subtle change to the EHR.* (Key physician, Year 2)

Hospital Support for IT

Respondents from several hospitals reported providing IT support in terms of funding for IT/central EHR and IT support staff:

> *We have a health informatics service organization. One of the first things we did with this initiative is we reached out and said we will need a full-time representative that is our direct liaison to this initiative so we have continuity.* (Cancer center/program staff, Year 1)

> *I have worked with all of these departments a long time. The lab reports to me. IT is always a challenge…They are engaged and willing, but there are still challenges. I've worked with [IT staff member] for 10 years. I told him I need a lead and I need someone to own this, so they agreed at the CIO level that that would be [the IT staff member], and he has been available.* (Cancer center/program staff, Year 2)

Other sites indicated that, although a full-time IT staff member should be allocated to the cancer center and the NCCCP, the hospital was not yet able to provide the necessary level of funding:

> *There are IT resources around that we can allocate and assign to this project. It would be good to have an IT resource on all these committees, but if that person existed, we couldn't afford it. The problem is that it takes multiple IT resources [people], all of whom have different projects and resources. Being able to allocate time to do this is a challenge.* (Key physician, Year 1)

Changes in IT Capacity

Creating an integrated EHR system that incorporates private physician offices, which 14 of the 16 NCCCP hospitals mostly rely upon, requires a substantial time and financial commitment on the part of sites. IT capacity was an aspect of care that was an even greater priority by 2010 because of the national trends—through the provisions of ARRA's Health Information Technology for Economic and Clinical Health (HITECH) Act and indirectly

through the Patient Protection and Affordable Care Act—to encourage hospitals and providers to have integrated IT systems in the near future. As noted in Year 1, financial investment in IT and EHR was not required but was an essential ingredient that tied practices together and enhanced communication and integration across the NCCCP. In Year 3, however, respondents cited IT as a continuing barrier, noting challenges related to funding and a lack of unified EHR systems linking physician office data to hospital networks.

Funding Barrier

Site respondents noted that IT remains a financial challenge for institutions and is considered one of the most challenging NCCCP components to implement. Although all of the components require hospital investment, creating a unified EHR system is one of the more financially costly endeavors:

> *When it comes to IT, because of the capital limitations there is a system-wide constraint. Around the IT piece, we have decided not to do caBIG. That decision was made by our IT folks. I am not sure what they are thinking. The NCCCP is not high priority because of all the other things that they are tasked to do. If anything has been hard, it is the IT component. There is no funding for technology, which is one of the bigger struggles for us.* (PI, Year 3)

Lack of a Unified EHR Barrier

One of the major aims of the NCCCP was to integrate the cancer center, both clinically and electronically. In Year 3, however, several sites reported that physicians' offices remain disconnected from the hospital EHR system, thereby lessening cancer center efficiencies and integration:

> *Private practice physicians can access Powerchart [the hospital EHR system] from offices, but the system is not integrated.* (PI, Year 3)

> *They still have problems with the interface. Private practice docs are still on INTERFACE, and the CIO is stressing about this.* (PI, Year 3)

> *There's not one integrated system for inpatient and outpatient.* (Subcommittee member, Year 3)

Although sites continue to emphasize the essential role IT plays in integrating internal networks and overcoming barriers to physician involvement, developing and implementing a viable EHR system between the hospital and physicians' offices remains a barrier. To implement a useful and efficient system, top management must incorporate IT as part of their strategic planning and vision for the entire hospital.

6.3.1.4 Cancer Research Capacity

Respondents indicated that the research department is a key element to implementing new clinical trials and abstracting data relevant to the NCCCP. We describe in detail the clinical trials (research work in Chapter 10 and in a separate report on a supplemental analysis conducted on clinical trials accrual data by researchers at Duke University. We also provide an assessment on which sites were able to enhance their cancer research capacity over the course of the pilot in Chapter 16. However, cancer research capacity includes several elements, including sites' pathological laboratory and the extent to which they are participating in biospecimens collection and reporting as well as clinical trials. During Years 1 and 2, respondents noted several issues important to enhancing their sites' cancer research capacity, including staffing, top management support, alignment of the research with the cancer program's and physician's goals, and physician engagement. In the following sections, we describe initial findings during the Year 1 and 2 site visits and then describe sites' levels of success in enhancing their cancer research capacity in Section 16.1.5.

Staffing

Several participants reported staffing shortages in the research department, which could pose a potential barrier to opening new clinical trials and accruing patients:

> *We have a research department, but it needs to be expanded.* (Key physician, Year 1)

> *[The] office of research needs more data managers. This is a lot to ask from having just one or two. We have a dedicated research nurse in my office, which helps. So we have two coordinators right now. We have 30 trials to each research nurse…. They have to know all of the clinical trials. Those are the two biggest areas where we could use more funding and support in data management and research coordinators.* (Key physician, Year 1)

In the majority of sites, respondents reported a recent growth in other research department staffing, which may lead to greater internal capacity as the NCCCP expands patient services:

> *Other than pediatrics, we were the first department to have our own research staff. It used to be like "rent a nurse"; they just did the research job and did not get involved with the patient. I was like, "Thank you, Jesus" when they opened this role [research staff]. I think we have a strong research department now. It becomes busy, but we have a good place to do research now.* (Subcommittee member, Year 2)

> *The research office is staffed with over 12 people (expect to get up to 25 people), including a biostatistician, data manager, and epidemiologist, as well as CRAs [clinical research assistants]. We are working on a very academic model.* (PI, Year 3)

> *There's a full-time research nurse. I'm about to post a position for a research nurse for cancer.* (Key physician, Year 1)

> *On [the] trials piece, the research coordinator position is funded, and that's a good start.* (Key physician, Year 1)

Hospital Support for Research

Two respondents reported funding support, allocated by their senior executives for research at their respective sites:

> *We are looking at our investment in research infrastructure. We use that as a catalyst. There's a fair amount of money out there, but also community benefit.* (System/hospital senior executives, Year 1)

Cancer center/program leaders and staff reported one primary example of support for the NCCCP: funds to enhance infrastructure through increased staffing. According to respondents, staffing was one of the most prevalent barriers to program success. To increase organizational support and cancer center capacity for change, top management allocated additional funding toward staff FTEs:

> *Because of that, our CEO realizes that we need more. We realize that more resources have to be put into clinical research, so we have a department of five FTEs and just received approval for two more FTEs and a student worker and a research nurse position. So part of the NCCCP and providing resources to clinical trials is to increase the resources in terms of infrastructure in terms of space and employees, so that is a direct result of having this program. To get the NCCCP is just icing on the cake.* (Cancer center/program staff, Year 2)

> *NCCCP set the stage for this being important and that it needs institutional support. In other words, the biospecimen support—there's not enough dollars for a Master's science–trained person who can do that work. You need someone with experience. My dollars will help to augment that so we can pay for that.* (PI, Year 1)

Alignment between Research Goals and Physicians

Several respondents highlighted the alignment between hospital research infrastructure and physician engagement in clinical trials:

> *From the clinical research perspective, the organization has allowed [us] to have the infrastructure to do clinical research without the expense to us. On the other hand, the expense to us is time, and we do have practice expense, but we've also*

> *developed a cadre of private practice physicians that have the goals that clinical trials is a key part of good cancer care and therefore it all meshes together.… That's the type of physician we recruit here. That has to be part of their practice. That has to be part of their mission in providing good cancer care: clinical trials is part of it. If you don't start with that, you can have all the infrastructure in the world and people aren't going to spend the extra time to do it, so we've been lucky to be able to recruit physicians who want to do that.* (Subcommittee member, Year 2)

Physician Engagement in Research

The majority of respondents also provided examples of physician engagement and research integration, which are vital factors in expanding research capacity:

> *Now we're spreading out. We have disease group leaders. We've empowered mostly surgeons and non-oncologists to get them interested. I think it was a good move to designate people outside of our group as disease-specific leaders. I think we've formed our core and we're spreading throughout the organization. Within the region, we're starting to see referrals to us based on the knowledge that we do more clinical and innovative trials than anyone in the state. We're now up to eight people in the clinical research division, from one 6 years ago.* (Subcommittee member, Year 3)

> *Our physicians are biting at the bit to be involved in research. So dangling the research piece in front of the community physicians [might increase their willingness to participate]. If [our network] can facilitate that, then it's a homerun.* (Subcommittee member, Year 1)

According to one respondent, a physician group reportedly funded a research nurse in their private practice office to assist in clinical trials accrual:

> *We have a clinical research nurse at our office. It was time consuming and it was revenue negative. Our group is committed to clinical research. You have to have the infrastructure. Research is one of my big areas of interest.* (Key physician, Year 2)

6.3.1.5 Equipment Infrastructure

In addition to the pathology laboratory, research department, and IT infrastructure, respondents also discussed their sites' capacity in terms of cancer center equipment. The NCCCP did not allow sites to use the award to pay for equipment purchases or costs. Several sites indicated that they were in need of equipment to provide outreach and screening to disparate populations:

> *In terms of having the resources, if we really wanted to bring in 500 women into the site, we should have digital mammography in [the] family care program. So there is an infrastructure piece that we need to focus on.* (Subcommittee member, Year 2)

Cancer center/program staff and physicians also identified pieces of equipment that would streamline or expand available services:

> *The more important resources like support for our teams…they want a CT scanner in the worst way but don't have the resources…they know it will come eventually but [are] not sure when.* (Key physician, Year2)

> *With RTOG [Radiation Treatment Oncology Group] we're limited by some of the equipment that is at the radiation center. I think that will be an opportunity for us, when we get into the new cancer center.* (Subcommittee member, Year 2)

Some of the equipment shortage may be due to the recent economic downturn, as one respondent noted:

> *The one thing I'd like to see is gamma-specific breast imaging. I think it's going to be as good as MRI and it will be one-quarter of the cost. Right now, we have a moratorium on purchasing new equipment because of the financial situation in the region and the hospital. That's something we'll keep pushing for. Probably by the time we get money for it, it will no longer be the correct thing to do.* (Key physician, Year 3)

Despite the reported insufficient equipment at some sites, respondents from other sites indicated that their hospital allocates resources effectively and anticipates the cancer center's equipment needs. Cancer centers with supportive top management and corresponding resources may be better able to modify existing practices, expand services, and provide better patient care:

> *The hospital's been pretty good about doing that, and I think the hospital really supports the cancer program. In 5 years, we bought five robots [for robotic surgery], and they've done that not with the idea that they're going to make money on the cases, but they saw that as one area where we can excel as part of the cancer program and they have been receptive for that.* (Key physician, Year 2)

> *Current strengths include facilities and equipment. [We] just opened a new cancer center. We've invested in the equipment, so for technology we are in good shape. We do very well in certain aspects.* (System/hospital senior executives, Year 3)

> *We're bringing up our radiation oncology department and we had already budgeted for two linear accelerators, a CT simulator, etc. We've made space for future stereotactic. We're getting the ultrasounds we need. There's nothing else we need in the cancer center. Down the line, we'll take things one step at a time.* (Cancer center/program staff, Year 3)

> *We have millions in equipment, scanning, that would create an opportunity for physicians to create standards but also help us on the cost side. I want to look at*

> *those opportunities now, move them forward in Year 3, and this will continue even after the grant.* (System/hospital senior executives, Year 2)

6.4 Summary

As noted at the beginning of this chapter, there are three primary factors involved in a site's capacity for learning innovation and change:

- the reason for participating and how it aligns with internal and external sources of change,
- the culture for learning within each organization, and
- the organizational alignment of "fit" between the characteristics of the social structure and the NCCCP.

Respondents reported strong internal impetus for change, focusing most heavily on the desire to expand clinical trials and create a formal connection with NCI. Likewise, respondents indicated that the NCCCP fits well with their organizations' strategic mission, indicating that the NCCCP helped to catalyze and accelerating existing change.

In Year 1, the sites' culture for learning and capacity for change varied greatly. Some sites reported high levels of internal alignment, as evidenced by the priorities of the departments, top management commitment, and corresponding resource allocation. However, other sites reported several barriers to alignment, including the economic downturn, structural complexities, equipment shortages, and staffing needs. Some hospitals seemed well equipped to implement new activities, as evidenced by their engaged directors of pathology, full staffing, and flexibility for IT and research staff. Other sites were struggling to garner appropriate financial and resource investment, with a shortage of staff, equipment, and structural barriers to success. Some of these barriers were due to low levels of engagement from top management, while others were due to the recent economic downturn. One potentially hopeful finding is that sites lacking internal alignment seemed aware of their shortcomings and deficits and were actively conducting inventories of their capacity and seeking to effect change.

Clearly, not all sites were ready or able to integrate a complex program such as the NCCCP during the first year of site visits. However, despite the barriers to implementation, it was clear that sites were conducting inventories and seeking new resources, activities that may help to overcome barriers and allow for innovative problem solving.

In Year 3, several sites indicated involvement by top management and reported consistent regular meetings with them and the ability to obtain needed resources and funds. By Year 3, not all sites had been successful in changing key indicators associated with the support of their senior executives, including obtaining a physician director, hiring an executive director with a nursing background, developing direct reporting relationships to top management,

and embedding senior executives in cancer center infrastructure. NCI should consider these key indicators at baseline during the selection process.

Table 6-1. Moderator Guide Questions by Section Theme During Year 1

Theme	Moderator Guide Questions
Reasons for participating (Section 6.1)	• What were the major reasons your hospital decided to participate in the NCCCP? • What are the benefits (financial and nonfinancial, such as reputation) of participation to your organization? • What are the costs (financial and nonfinancial, such as time)? Have the costs been more, less, or about the same as you expected?
Culture for learning and innovation/readiness for change (Section 6.2)	No discussion guide questions for this theme.
Readiness for change (Section 6.2.1)	• How well does this cancer center and hospital/system handle challenges and change?
Role of leadership (Section 6.2.2)	• Who are the major proponents of your site's participation? Who are the leaders and champions of this program? • What are some specific ways you have provided support for the NCCCP? • What financial and nonfinancial support are you providing, or intending to provide, to the NCCCP pilot overall? • Have you provided any support specific to the four pillars (i.e., biospecimen, clinical trials, disparities, and IT) of the program? If so, please briefly describe. • Have you provided any support specific to other core areas of the program (e.g., quality of care, survivorship)? If so, please briefly describe.
Organizational alignment and internal capacity (Section 6.3)	• How have you conceptualized the NCCCP program's structure? What is the program's relationship to the hospital structure? • What departments or services that your NCCCP program needs to interface with (e.g., pathology, IT) are housed within the hospital? • What is the reporting structure of these units to the hospital? • How does the NCCCP fit into the mission/vision and current strategy of the cancer center and hospital/system? • Similarly, how would you expect the NCCCP to alter the contributions of the cancer center in the short term (1 year), intermediately (3 years), and in the long term (10 years)?

Table 6-2. Opportunity to Improve Cancer Research and Care: Themes and Definitions

Theme	Definition
Offer more clinical trials	Site's ability to offer additional trials to patients
Strengthen research infrastructure	Extent to which the NCCCP adds to/strengthens the site's research infrastructure
Improve the quality of cancer care	Extent to which the NCCCP increases quality of care
Reduce disparities	Provision of high-quality health care to all patients, removal of barriers to access

Table 6-3. Opportunity to Improve Research and Care: Theme by Respondent Role During Year 1 Interviews

Reasons for Participating[a]	System/ Hospital Senior Executives	PIs	Cancer Center/ Program Staff	Key Physicians	Subcommittee Members	Total Number of Interviews by Role
Opportunity to develop and learn how to improve cancer research and care	13	3	5	4	4	29
Offer more clinical trials	7	5	4	16	4	36
Strengthen research infrastructure	7	0	2	5	3	17
Reduce disparities	9	2	3	5	5	24
Improve the quality of cancer care	12	2	3	8	8	33

[a] The data presented in this table represent the number of interview files in which the theme was discussed during the Year 1 site visits and do not represent counts by person nor does it represent the number of times the topic was raised in a given interview. The interview files could include several respondents who were interviewed in the same group.

Table 6-4. Fit between the NCCCP and Site's Mission: Themes and Definitions

Theme	Definition
Prioritization of oncology cancer care	Extent to which the NCCCP goals fit with the hospital's/ cancer center's mission and priorities around cancer care
Creation of synergies across pillars and components	Sites indicate that the NCCCP helped to integrate staff and departments across components
Acceleration of change	Most sites saw the NCCCP as an opportunity to accelerate change and realign or strengthen their strategic priorities along the lines of the NCCCP pilot pillars

Table 6-5. Fit Between the NCCCP and Site's Mission: Theme by Respondent Role During Year 1 Interviews

Reasons for Participating[a]	System/ Hospital Senior Executives	PIs	Cancer Center/ Program Staff	Key Physicians	Subcommittee Members	Total Number of Interviews by Role
Fit between the NCCCP and site's mission	27	9	9	12	14	71
Prioritization of oncology cancer care	11	3	2	2	0	18
Creation of synergies across pillars and components	3	2	4	1	2	12
Acceleration of change	20	2	9	4	9	44

[a] The data presented in this table represent the number of interview files in which the theme was discussed during Year 1 site visits and do not represent counts by person. The interview files could include several respondents who were interviewed in the same group.

Table 6-6. Number and Average of Cancer Center Physicians by Specialty in Years 1 and 3[a]

Physician Specialist	Total Key Cancer Physicians (Total)		Change
	Year 1	Year 3	
Data Source:	**BAS**	**FAS**	
Site 4	10	11	1
Site 6	25	30	5
Site 10	19	24	5
Site 3	32	37	5
Site 12	4	39	35
Site 1	8	11	3
Site 9	17	38	21
Site 16	10	16	6
Site 15	9	18	9
Site 11	8	58	50
Site 8	6	9	3
Site 7	12	10	-2
Site 2	4	5	1
Site 13	1	1	0
Site 5	7	1	-6
Site 14	2	3	1
Mean	11	19	8

[a] Total Key Cancer Physicians is the sum of medical oncologists, radiation oncologists, surgeons, and "other" MDs reported in the BAS and FAS. Sites varied in the types of roles they included as other; we included ONLY other medical doctors and excluded physician assistants, physicists, dosimetrists, therapists, techs, geneticists, and phlebomotomists.

Table 6-7. Access to Three Types of Cancer Subspecialists in Year 3[a]

Physician Specialist	Oncologists, Year 3		Palliative Care Specialists Year 3
	Surgical	Gynecological	
Data Source:	**Org Charts**	**Org Charts**	**Org Charts**
Site 15	0	1	0
Site 11	1	1	1
Site 8	0	0	0
Site 7	0	1	0
Site 2	0	1	0
Site 13	0	0	0
Site 5	0	0	0
Site 14	0	0	0
Site 4	0	1	0
Site 6	1	1	1
Site 10	1	1	0
Site 3	0	0	0
Site 12	0	0	0
Site 1	1	0	0
Site 9	0	1	0
Site 16	1	0	0
Total	**5**	**8**	**2**

[a] 0 = No; 1 = Yes.

7. ORGANIZATIONAL STRUCTURE AND PROCESSES

Overview

Aspects of the organizational structure and process are critical to the success of implementing a program as cross-cutting and complex as the NCCCP. From the start, the hospitals participating in the NCCCP were quite diverse, having a wide array of strengths and weaknesses of their cancer programs (Chapter 4). Strengths could include the cancer service line's relationships with the hospital's and the extent to which the NCCCP, through the PI who was often a physician leader, could access hospital support and resources. Weaknesses could include cancer service lines that were so small that they had no medical directors (or ones who spend very little time on related responsibilities) and were relying solely on private practice physicians who were typically volunteering part of their time to address NCCCP-related activities. Some hospital structures (i.e., fully or partially employed physicians) seemed to lend themselves more than others (i.e., primarily private practice models) to more quickly and efficiently integrating the NCCCP with existing cancer service line activities, as summarized below.

Organizational Support Structures

Senior executives across all the sites expressed support for the NCCCP, and most gave tangible examples of how they allocated resources to demonstrate this support (e.g., hiring new staff, buying equipment, leading negotiations with physicians to engage them in program). Sites where the PI had a direct reporting relationship with the hospital's top management, particularly if the PI was also the cancer program director, seemed to have the best success in accessing resources and receiving the financial support needed for aspects of program implementation. These organizational structures also seemed to facilitate quicker engagement of key cancer physicians in NCCCP activities.

Over time, the relationship between the NCCCP and the overarching cancer service lines became clearer and, in some cases, more seamless. In a few cases, PIs noted that their NCCCP executive committee had become part of their cancer program in that they were using it to advance their cancer care agenda across all of the components. Two hospitals, in particular, were even using the "NCCCP model" to facilitate improvements in other clinical areas, such as cardiovascular care.

Processes for Physician Engagement in NCCCP Activities

All of the sites experienced barriers to engaging their physicians, particularly in engaging key cancer physicians who were in private practice. Common barriers included a lack of time for physicians to spend on these types of relatively voluntary efforts; resistance to collaboration among physicians; lack of financial incentives or an infrastructure to support physicians to participate in activities; and limited IT infrastructure to facilitate communication. Over the 3 years of the pilot, several sites implemented three key strategies for addressing these barriers and engaging physicians: engaging them early and often in program implementation, using their growth in research and quality of care initiatives to attract physicians' attention and interest in how this work could benefit their practices and patients, and incorporating incentives (e.g., marketing, staff support, patient referrals) into the process of NCCCP participation.

As described in Chapter 2, key factors affecting the implementation of the NCCCP pilot are how each organization (hospital, cancer center, or cancer service line) is structured and how the NCCCP relates to that existing structure. In particular, for the NCCCP, the relationships

of these structures with their key cancer physicians are critical to the success of many program activities and outcomes. There are five classic organizational designs (i.e., functional, divisional, matrix, parallel, and service line or program), which vary with respect to how they divide, coordinate, and integrate work (for an overview, see Leatt, Baker, & Kimberly, 2006). These designs can be arrayed on a continuum, with the functional design emphasizing general administrative or support functions (e.g., legal/regulatory, finance, marketing, information technology [IT]) and clinical functions (e.g., medicine, surgery, nursing, inpatient care, outpatient care, laboratory, pharmacy) and the service line or program designs emphasizing a specific service or program (e.g., oncology) and the need to coordinate and integrate all functions of that service or program. Each of these designs has a number of strengths and weaknesses, but theory suggests that matrix, parallel, and service line or program structures may be better suited to the organizational learning, innovation, and change associated with tasks required by the NCCCP. We found, however, that most hospitals implementing the NCCCP pilot still have a functional or divisional structure in place, and were at varying stages in migrating to the more matrixed or integrated structures and thus had blended these classic designs in unique ways. In addition, the processes (e.g., communication, coordination) that organizations use to implement and integrate the NCCCP into their ongoing cancer service line or activities will be key to bringing together all aspects of the program. Building on the work of Donabedian (1965), the Institute of Medicine's (IOM's) *Crossing the Quality Chasm* (2001), and other research on quality improvement and system redesign and transformation, we recognize that organizational structure has an impact on care processes and ultimately on organizational outcomes (e.g., efficiency, effectiveness) and patient outcomes (e.g., mortality, morbidity, patient experience). There are four fundamental aspects of structure that may have an impact on the ability of cancer centers or NCCCP sites to achieve the program's aims:

- organizational structure of the system and/or hospital itself,
- hospital relative to its cancer services,
- structure of the cancer services (or program) relative to that of the NCCCP, and
- coordination and communication that the cancer program has implemented to integrate the NCCCP into their existing cancer services.

NCI funded two lead hospitals participating in the NCCCP as "system" sites such that they are also attempting to implement the program in selected developmental sites as described in Chapter 4. In this chapter, we briefly describe those structures, as well as those of the 16 individual sites.

We begin with a description of the levels of organizational structures for these first three aspects and a brief description of implementation for the system hospitals, followed by findings specific to processes the sites reported using to communicate and coordinate

NCCCP-related activities. We present descriptive baseline information on the size and services provided by sites in Chapter 4.

7.1 Levels of Organizational Structure

For levels of organizational structure, we have focused on the three levels of the NCCCP sites that will have the greatest impact on program implementation. As noted by Leatt, Baker, and Kimberly (2006), "organizational design can be represented by the boxes and lines on an organizational chart" (p. 316). Since it was important to understand how the cancer program is structurally conceptualized, its relative importance to other departments of medicine or service lines, and the positions allocated to the cancer program for leadership roles, we created three types of organizational charts for each of the 16 sites during the Year 1 site visits. We revised those charts for just the 10 lead sites during the Year 2 site visits, and for all 16 sites during the Year 3 site visits. These three types of charts depict

- the site's overall structure and relationship to its cancer service line,
- the cancer service line's structure and its relationship to the network of cancer physicians, and
- the cancer service line's relationship to the NCCCP structure.

In addition, we examined the relationship of the two system sites to their developmental sites or hospitals and describe these in this section. We provide a summary of those charts and the relationships they depict as well as changes in relationships over time that may directly impact NCCCP implementation. During each of the site visits conducted from 2008 to 2010, we worked with the sites to create organizational charts for each of these three levels. Appendix H provides the organizational charts for all 16 NCCCP sites from the Year 1 site visits (in spring 2008) presented by these three levels of structure. The revised organizational charts for the 10 lead sites are presented in Appendix I (developmental sites were not visited during Year 2), and the revised charts for all 16 sites from Year 3 are presented in Appendix J. Although we did not create system-level organizational charts relative to the hospitals in the Ascension Health or Catholic Health Initiatives (CHI) systems, we briefly describe in Section 7.1.4 the structure of each and what respondents said during the Years 1 and 3 site visits about the advantages and disadvantages of participation as a system site.

7.1.1 Hospital's Relationship to its Cancer Service Line

In this section, we describe the relationship between the NCCCP hospitals and their respective cancer centers and the changes that were noted from Year 1 to Year 3 of the program. For the charts that depict these relationships, we focused on only those individuals and departments that are directly related to the implementation of the NCCCP and not on the entire hospital structure. Each of the organizational charts provides a visual depiction of the hospital's top management and the reporting structures that directly impact the NCCCP

program at each site. For each of these areas, we report perspectives on the strengths and challenges of the various types of structures during all 3 years.

It is important to understand the variations in the structures of the participating hospitals. All of the individual hospitals had senior executives such as CEOs and/or COOs who were providing direct oversight to most of the hospital's programs. Within each hospital, the cancer program may or may not have been an independent part of their structure in that it had its own service line with a physician director. In fact, many of the sites did not have physician directors of their cancer "programs," and several did not have a building that was distinguished as their cancer "center" but instead were housed within a section of the main hospital. As theory suggests, hospitals that would have the best chance of implementing a program like the NCCCP, which requires a great deal of innovation and integration across hospital departments (e.g., IT, pathology) and top management to make these changes happen, would be those where the cancer program is organizationally located with direct access to their top management in order to readily access hospital resources. Leadership of the cancer program is also important because these sites relied predominately on physicians in private practice, whose incomes rely on their availability to see patients. The more time physicians spend out of the office on activities such as MDC conferences or enrolling patients to clinical trials, the greater the negative impact on their income, which provides a disincentive for these physicians to participate. If the cancer programs in these hospitals are not led by physicians they respect, they will be less likely to become involved in NCCCP activities.

We next provide an overview of the sites' structures with respect to their cancer programs or services lines, followed by respondents' feedback on the perceived strengths and limitations.

7.1.1.1 Overview of Cancer Service Line Structures within NCCCP Sites

As can be seen in Appendices H–J, the NCCCP sites tended to be organized with a mix of structures. Functional designs, which are those designs that exist when labor is divided into departments specialized by functional areas (Leatt, Baker, & Kimberly, 2006), are incorporated into aspects of each NCCCP hospital's structure. These community-based hospitals tended to have clinical care departments (e.g., departments of medicine organized by specialty area as well as nursing care departments), departments that focused on functions such as IT, and various hospital operations departments. Most of the senior executives described their structure as a mixed or matrix design, characterized by a dual-authority system. In these types of systems, functional and program or product line managers report to both a corresponding functional and program or product line manager (Leatt, Baker, & Kimberly, 2006). In a product or service line structure, the person in charge is responsible for all budgetary and financial responsibilities associated with that service line (e.g., cancer). Although "mixed" is how many of the hospitals were described, in

reality they tended to mostly have traditional functional structures, with some hospitals progressing more rapidly toward a service line or matrix structure than others. In a hospital with a true service line for cancer care, the person in charge would be responsible for the entire continuum of care provided by the hospital and its cancer center (e.g., prevention, screening, outpatient, inpatient, survivorship, palliative care, hospice). None of the NCCCP hospitals had this structure. In nearly all of the hospitals, if there was a medical director of their cancer program, they were focused on outpatient care and generally did not interact with staff involved with inpatient care. Each of the areas of cancer care in most hospitals tended to be led by someone different, with no one person serving in the role of fully integrating their service line.

In the structures specific to the NCCCP sites, four roles are particularly important. First, we examined whether each cancer program has a "medical director," who is a physician assuming responsibility for the cancer services. Depending on the structure of the site, these physicians served in one of two types of roles: either as the overall cancer center medical director or as the medical director for the cancer program but with minimal time allocated to this role (i.e., <10% time). In cases where the physician was the overall cancer center medical director, they tended to have a larger proportion of their time allocated to this role and also had a third role as an "executive director." The executive director who could be a nurse by training primarily provided administrative and staffing support. If there was not a physician director of the overall cancer program, there then was a fourth role of a cancer program director and the hospital had identified a physician who was willing to be named as "medical director" for the cancer program. Oftentimes, this physician was in private practice and allocated minimal time to their role as medical director (<10%) but this varied across sites. We hypothesized that sites with clear lines of authority between the hospital and a physician director of the cancer program who was allocating at least half-time to the position (or enough of their time to be perceived as a leader among their peers) would have the best chance of integrating the NCCCP into their cancer program and achieving many or most of the program's goals.

To complicate matters further, the principal investigator (PI) for the NCCCP may or may not have been this medical director or the cancer center director. In a number of cases in fact, the PI was not a physician and sometimes seemed to have little influence over what physicians did within the cancer program. Some sites were able to recruit a physician to serve as the cancer program director, where previously the position had been vacant or did not exist; this person also assumed the role of the PI.

Overall, the structures that the hospitals had in place during Year 1 changed little over time, although aspects of how they functioned did change at some hospitals. In a few sites, physician groups were purchased by the hospital, and the physicians were then employed. Although the overall structures, such as whether they relied primarily on private practice physicians, changed little over time, we did observe that their functioning improved as the

awareness and recognition for the cancer program increased, staff were added, and roles were more clearly defined so that better alignment among the cancer services could be achieved. During the Year 3 site visits, respondents were asked to share what they perceived as the biggest changes in the past 3 years. Many respondents noted that their cancer program structure in the hospital had managed to become better integrated:

> *I've only been here for 3 years and the number of personnel has increased. There's been attention and growth of clinical trials, integration with radiation oncology and gynecologic oncology*. (Key cancer physician, Year 3)

> *For the cancer program, I think it is continuing to refine our infrastructure. When I compare where we are today to 3 years ago, I am amazed at the strength of our program in terms of staff growth (size), improved cancer committee participation, enhanced programmatic performance improvement/involvement and recognition of us as a solid contributing department by the rest of the hospital.* (Cancer center/program staff, Year 3)

> *The changes that are most embedded are how we work together as a team. The collaboration is more than it was 3 years ago, and people see how it is valuable and benefits the patients. Inter-department, inter-physician collaboration in a formal manner.* (PI, Year 3)

7.1.1.2 Physician Leadership of Each Cancer Service Line

For most NCCCP hospitals, physician leadership of the cancer program (i.e., often referred to as the Medical Director) was specific to outpatient cancer services and not applicable to inpatient care. Although hospitals could have "physician leaders" who were respected by others and provided oversight of some aspect of the cancer program (e.g., research department), we refer here to the one person named as medical or physician director of the cancer program. By June 2010, six sites (two lead sites and four developmental sites) did not have a physician leader for their cancer program.

A change that occurred between the Year 1 and Year 2 site visits was that one hospital had hired a physician into the director role that was vacant in 2008, and another hospital was in the process of recruiting for this position. This hospital had no distinct cancer service line, and cancer services were provided across two partner organizations in 2008. By 2009 (and continuing through 2010), the two organizations were moving toward an integration of their services into a service line structure with the hiring of a medical director. Another lead hospital had organized oncology services into a service line led by an executive director who is not a physician, and the oncology services are embedded in the hospital structure, with functional managers for such services as hospice care and radiation oncology. The remaining hospital without a medical director of their cancer program in 2008 had no distinct cancer service line, but instead a functional structure where the cancer services

were located within various units of the hospital, depending upon their focus. One lead site's cancer program structure had not changed by 2010 except that they had named one of their medical oncologists as the cancer medical director (to start part-time in July 2010, after the end of the NCCCP pilot), although he was not the PI for the NCCCP.

7.1.1.3 Reporting Structures of Cancer Service Line to Hospital Top Management

As noted in Chapter 6, cancer service lines that had a medical director reporting to senior executives seemed to have greater capacity for gaining key support of their effort (e.g., acquiring approval for purchase of new equipment). Sites varied as to whether the cancer medical director, if they had one, was also the NCCCP PI. As shown in Table 7-1, two cancer center directors (who were also physicians and the NCCCP PIs) had direct reporting relationships to their hospital's CEO (Christiana, St. Joseph's/Candler) in 2008, which did not change during the course of the NCCCP. However, one site that did not have a medical director for their cancer program in 2008, had established a direct reporting relationship to the CEO for the one they hired in late 2009. In 2008, this site had a non-physician as the NCCCP PI who reported directly to the chief medical officer (CMO). Three sites initially had structures such that the cancer medical director reported directly to their chief operating officer (COO), and by 2010, two additional sites had this structure, thereby providing these physician leaders with potentially more direct access to their top management and resources. As of Year 3, eight sites (all six developmental sites and two leads) had structures that did not provide a direct reporting relationship between the cancer center director and their hospital's top management (Table 7-1). Because many had a mixed structure, generally with a traditional functional structure where they were moving more toward a matrix structure, four cancer center directors who were also physicians also reported indirectly to their respective CMOs. By 2010, physician directors of the cancer program in NCCCP hospitals (if they had one) were also the PIs. Table 7-2 provides cumulative counts across sites for the types of reporting structures during each year of NCCCP implementation and how they changed over time. There were relatively small changes over time, perhaps signifying that these features are not easily changed and thus are essential baseline variables that should be considered during the site application and selection process.

In our site visits, we made a point of meeting with the cancer center or program directors, NCCCP PIs, who may or may not be the same person, and either the CEO or COO of the hospital. Respondents we interviewed who had a direct relationship with their hospital's CEO, or with a COO who is relatively established within the organization, seemed to more often indicate that they had fewer difficulties obtaining the resources they need for the cancer program's development when compared to directors within hospitals that did not have that direct reporting relationship. If the medical director for the cancer program was also the NCCCP PI, this individual reported having fewer challenges with obtaining the resources they needed from their top management in support of the NCCCP. One of these

PIs noted that he has never been told "no" when making a request of his senior executives. Although the empirical evidence shows that half of the sites had this type of direct reporting relationship between the cancer service line and the hospital's top management, quotes from respondents tended to support the notion that having this direct line of communication and access for influencing decisions about the allocation of resources tended to result in receiving the requested support. Those few who do not have these direct relationships consistently reported having greater difficulty obtaining support to implement the NCCCP activities because of competing priorities for hospital resources and their lack of direct access to decision makers. These responses also tended to support that most of the hospitals were structured primarily in traditional, functional ways and were not yet fully operating with a service line structure:

> *[Hospital name] is responsible for equipment, but at times it's like pulling teeth to find out who's responsible for how to hire a new person or other staff* (Subcommittee member, Year 1)

> *The biggest challenge to me overall is our structure because sometimes it takes so much time to get the right person or persons to the table because there's no one person who has budgetary responsibility for the cancer piece.* (PI, Year 2)

> *We're somewhat horizontally oriented. The clinic is all in the clinic. The hospital is all in the hospital. Cancer cuts horizontally across them, but we're fighting the goals and objectives of clinic, hospital, and research, so that makes getting some things done challenging.* (PI, Year 1)

7.1.1.4 Hospital's Top Management Support of the NCCCP

During the first site visits in spring 2008, a focus of our interviews was on understanding the role of key members of hospitals' top management both in terms of providing support for the NCCCP PI and/or program in general and oversight of cancer services. During all 3 years of site visits, we met with all CEOs and/or COOs. In Chapter 6, we present findings of how senior executives at some of the participating hospitals seemed to be facilitating necessary changes to implement the NCCCP. We describe in Chapter 16 the level of matching funds (reported through the micro-cost study) that were reported as being provided by the hospital in support of the NCCCP, which is an indication of their level of investment in ensuring the program's success. These totals ranged from approximately $375,000 to as much as $2.98 million for the third year of funding,[1] indicating wide variation in the level of financial support allocated by the hospitals' senior executives for cancer services. In this section, we discuss the actual reporting structures of the leaders to the cancer program and the barriers the sites had encountered related to hospitals' top management relationships.

[1] Matching fund totals exclude indirect costs.

Across the sites and years, all CEOs verbally expressed support for their hospital's participation in the NCCCP, but some were more active than others in providing support, both visibly through their public involvement or fiscally through allocation of matching funds. In two hospitals in particular, the CEOs were actively attending NCCCP-related meetings, providing visibility to the program (e.g., making presentations to hospital boards, placing the NCCCP on the agenda of key meetings), and allocating important financial (i.e., these two hospitals were among the five receiving the highest level of matching funds in Year 3) and nonfinancial resources (e.g., office space, new staff positions, equipment purchases) to support the program's efforts. In another hospital, the CEO had allocated fiscal support for the program, but the cancer center medical director operated fairly independently of the hospital and had not involved the hospital's top management in program activities. In two additional hospitals where the CEO was less visible, the COOs were providing very active and visible support. In Chapter 16, we examine how hospitals' top management support, through the allocation of matching funds, seems to be related to success in key outcomes for the NCCCP.

There were some notable changes in support and knowledge of the NCCCP from CEOs and COOs between Years 1 and 3. In one hospital, the CEO had just been hired prior to the first site visit (they were promoted from within the system and so were familiar with their cancer program structure), and by the time of the second site visit, there was evidence that he had been very active in allocating key resources to the cancer service line, attending meetings to provide visible support for the program, and actively working to encourage private practice physicians to become more involved in NCCCP activities. One hospital has had the vice president of operations for the hospital integrally involved with the program. In two hospitals, CEO or COO departures in 2008 had led to less visible top management support in the second year of the program, although by 2010 the CEO at one of those hospitals had become more involved partly because he had been treated for cancer at the hospital and reported learning to appreciate what that program provides the hospital. Another hospital experienced turnover in their top management in late 2007, which resulted in minimal public involvement from their CEO, although he did authorize matching funds from their hospital budget to support the program.[2] The remaining hospital had minimal involvement and matching funds allocated from their top management.

Over time, respondents (including CEOs) reported varying degrees of participation and involvement in the NCCCP by their top management. By Year 3, several respondents indicated an association between frequent and formal communication mechanisms with their senior executives and subsequent resource investment in the program. Cancer centers with strong connections with their top management and formal, consistent, and direct

[2] Matching funds information were collected from the 10 lead sites through the micro-cost study, but not from the developmental sites. Because the two system sites reported only matching funds for their system (i.e., across their participating hospitals), their total reported matching funds are likely lower than what each hospital actually allocated to the cancer program.

communication mechanisms are better equipped to vie for additional resources, avert competing priorities, and maintain the NCCCP as a core hospital priority:

> *They created this as a center of excellence and we meet on a frequent basis with the CEO. We talk a lot about the competition. [The] CEO sees [the NCCCP] as marketing and for something good for all the institutions. We have a high priority.* (Key cancer physician, Year 3)

> *My involvement has been about the same. I serve on the executive committee of [the] NCCCP, and we have conference calls with the hospital presidents once every other month.* (System/hospital senior executive, Year 3)

Other respondents indicated that the CEOs remained infrequently or peripherally involved in the program. Unlike participants who associated formal top management participation with additional resource support, these respondents did not discuss any positive outcomes from their interactions related to the NCCCP:

> *I meet with the program coordinator and PI regularly and get updates. I get newsletters. Other than hearing about the project reports, all I can do is allocate resources or knock down barriers. Mostly I just sit back and watch what happens.* (System/hospital senior executive, Year 2)

> *We are recognized, and they [leadership] are appreciative of the work that we do, but on a day-to-day basis our leadership is not cognizant on what we do. We are built on a very hierarchical model.* (Cancer center/program staff, Year 3)

Given the complexity of the NCCCP and the need for coordination across each hospital's functional units, commonly reported barriers to implementing the NCCCP included the time it takes to make and implement decisions within the hospitals and the competing priorities of funding and/or people's time in addressing changes related to the NCCCP:

> *Sometimes I think folks would say that our decision-making process is long. It may take a while to process a decision, but that processing time does get the issues sorted out appropriately so that the implementation time is much more efficient.* (System/hospital senior executive, Year 2)

> *It takes a while to make the change…I think that is one of the reasons why this institution has gone with the service line model, which lends itself to a speedier transition.* (PI, Year 2)

> *In this structure, which is really mission driven, there are physicians who think we don't move fast enough.* (System/hospital senior executive, Year 1)

In addition to direct qualitative interview data, the NCCCP evaluation collected data regarding key indicators associated with leadership capacity. Key indicators include the

reporting structure between cancer center service line and top management (Section 7.1) and whether top management is part of the cancer center infrastructure (e.g., executive committee members). Only four sites had this type of direct and regular contact between the cancer program and the CEO or COO. Interestingly, three of these hospitals had among the highest levels of matching funds reported by the hospitals in Year 3 (each above $1.5 million). Because it is the top management's decision on how to allocate funds, it would seem that a direct reporting relationship with one of these individuals is critical to obtaining necessary funds.

7.1.2 Cancer Service Line Structure

Nearly all of the NCCCP hospitals had organizational structures that have been functional and were moving more toward having their cancer programs organized as a service line (at least for the outpatient components, and sometimes for the inpatient components as well) or operate through a matrix design such that the cancer-related activities overlap with all other aspects of care. One respondent from a hospital with a matrix organizational design noted that cancer overlaps the hospital's structure "anywhere cancer touches [in terms of health care]." The cancer-related services have somewhat varied positions within the NCCCP hospitals. By the end of June 2010, 11 of the 16 hospitals had designated a medical director for the cancer program for some percentage of time, with a twelfth site adding this role by July 2010 (after the NCCCP pilot). Of the 11 with a designated medical director of their cancer program, 8 were lead sites and 3 were developmental sites. Physicians in this role had varying levels of full-time equivalent (FTE) coverage reported on the Baseline Assessment Survey (BAS) and Final Assessment Survey (FAS) or billed for in their NCCCP invoices (all sources were used when possible in order to create estimates) (Table 7-3). Some sites have a greater level of time provided by their cancer program medical director than others.

As of Year 3, only 3 of 16 sites had a dedicated full-time physician of their cancer center and each of these were also the NCCCP PIs. Of the remaining eight with a medical director, two reported having one physician spend at least 0.5 FTE in this role, while six reported having a physician serving in this role for less than 0.5 FTE. Two lead sites and three developmental sites had no medical director for either their cancer program or the NCCCP. Note that although we collected the time that was invoiced for a "physician leader of the NCCCP," it is unclear whether sites reported this time relative to the role of physician director of their cancer center. It could be a physician integrally involved in a component of the NCCCP but not the overall PI or a physician who is serving in a key role with their time allocated to the NCCCP intermittently. Data to determine this are not available. The level of time a physician director can spend on NCCCP activities is likely to be associated with the extent to which these sites were able to have greater physician support to develop a strategic plan, lead implementation of various NCCCP initiatives (e.g., medical staff conditions of participation) and gain physician specialist buy-in.

In addition to how the sites differed in terms of their time allocation for a physician leader of the NCCCP, sites had various organizational structures that could support that leader's role. Respondents indicated that centers that are larger, with a broader range of services and more staff, tend to have an executive director and that those executive directors who are nurses by training may be best equipped for carrying out their duties (e.g., facilitating coordination across cancer center units, serving as liaison to all the cancer physicians and medical staff in the hospital). Only two centers had no executive director of their cancer program, while 5 of the 14 executive directors at other sites were nurses by training. Table 7-4 provides a summary of those sites that had an executive director present as of June 30, 2010, and which of these were nurses.

In terms of the cancer program structure, we quickly learned how heavily the majority of NCCCP pilot sites rely on physicians in private practice and that most, if not all, of the NCCCP activities to be implemented were influenced by the extent to which the hospitals skillfully managed their relationships with these key cancer physicians. Although we recognize that these physicians are conceptualized as key partners external to the hospitals in our conceptual framework (Figure 2-1), because they proved to be vital to successful NCCCP implementation, later in this chapter we present findings specific to these relationships, the barriers presented by them for NCCCP implementation, and the strategies some sites used to address this aspect of the structures of the NCCCP sites.

7.1.3 Cancer Service Line's Relationship to the NCCCP

Within these general structures, each cancer center has taken a different approach to incorporating the NCCCP into their ongoing cancer activities. Although we had hoped to understand in detail the effectiveness of the teams the sites created to implement and how they functioned, we were only able to obtain input from sites on their team structures and some of their processes for coordination (see Chapter 8) due to the need to focus on other topics during site visits.

All cancer centers started by creating a distinct organizational structure unique to the NCCCP (Appendix H) such that leaders were identified for each of the six program components (or more in some cases, such as for "advocacy" or "communication") and were responsible for attending the corresponding NCCCP network subcommittee meetings and working to incorporate NCCCP activities into their cancer care efforts. For these efforts, most sites developed subcommittees that were internal to their cancer program or center and directly matched the subcommittee structure of the NCCCP network. For example, in Year 1, most sites had a clinical trials subcommittee that included their own staff working to implement NCCCP-related activities internally; the leaders of this internal subcommittee also attended the monthly subcommittee meetings convened by NCI. This work was overseen internally by the PI and typically an NCCCP executive committee that consisted of at least one member of the hospital's top management (e.g., COO), the cancer center

medical director, NCCCP PI (who may or not be the medical director), and sometimes key physicians and/or others in the cancer program in each hospital (e.g., executive director of cancer center if they had one). By Year 3, some sites described how they had worked to integrate the NCCCP with their overall cancer program and that, even if NCCCP were to be discontinued, they planned to continue incorporating aspects of it into their daily operations (Chapter 17):

> *It has become our playbook in the day-to-day operational structure. We take the NCCCP model and overlay it over operations and structure. When [the PI] says model, he means how to utilize the engaged docs in day-to-day operations. This has been a key ingredient.* (Cancer center/program staff, Year 3)

7.1.3.1 Creation of the New Role of NCCCP Program Coordinator

Over the course of NCCCP implementation, a new position within the cancer program's structure began to emerge across the sites (Appendices I–J). In Year 1, when we asked respondents to identify who was responsible for "pulling all of the NCCCP activities together," the general response across most sites was the PI or executive director of the cancer program. By Year 2, these findings changed somewhat as the organizational structures specific to the NCCCP seemed to become more distinct. As shown in Table 7-5, five sites initiated the NCCCP with a program coordinator This person generally attends all internal and NCI subcommittee meetings and works to ensure that the NCCCP activities are implemented within each site. During the time of the application or soon after award, five sites had added this role either by creating a new position for this role or by relying on a person who served in a similar coordination or management role for the hospital and adding this to their responsibilities.

A few of these program coordinators had clinical training, while most had administrative backgrounds and were hired from within another area of the hospital or had experience in managing other related types of programs (e.g., clinical research department). Table 7-6 provides a summary of program coordinator responsibilities across sites and what respondents reported as qualifications for this position. Because so many sites had established the role of program coordinator, during the Year 2 site visits, we asked specifically about this position and the extent to which respondents believe it to be essential to guiding NCCCP implementation. For most sites, the role was created to take over some of the administrative oversight of the program from the PI and focus on working across program components to create integration. To describe this role, respondents used metaphors such as the "glue that holds the program together":

> *I think I'm like the thorn in people's sides to say, "This is what we said we'd do and where we'd be."* (Program coordinator, Year 2)

> *I have to negotiate, inform, threaten. I'm the typical product line manager.* (Program coordinator, Year 2)

> *That person is the connecting point, the nexus, for tracking and interfacing between departments and programs…the program coordinator is where rubber meets the road.* (PI, Year 2)

> *I would say this role is critical for the success of the program. It is evolving as any new position would, but I find to have somebody who is the go-to person as a resource to help pull things together is really critical.* (PI, Year 2)

> *The cement among the bricks. I am the link because many of the components overlap each other, so that it is my role: to make sure that there is work being done.* (Program coordinator, Year 2)

> *Her job is to make the NCCCP a part of our daily operations…finding where the holes are and bringing it to everyone's attention.* (PI, Year 1)

Although all respondents in sites where this role was established said they believe it is essential to successful program implementation, they varied in how much time they thought should be allocated for this role. Respondents said that the amount of time allocated to the role of program coordinator ranged from 20%) to as much as 100% for several sites. Regardless of how the sites decided to set up this role, respondents generally felt that by Year 2 it was this role that was helping to "bring it all together" for the NCCCP:

> *We struggled a bit and spun our wheels…then we got our committees together. This [role] helps us put it in focus. Having this structure is beneficial to us.* (Cancer center/program staff, Year 1)

7.1.4 System's Relationship to its Participating Hospitals

During each site visit at lead system sites, we met with their senior executives to ask them questions similar to those we asked hospitals' senior executives across all of the freestanding sites. We also asked respondents that were working within one of the system hospitals to describe the role of the system in NCCCP implementation. Although we agreed early on that exploring these systems in depth for this evaluation was outside the scope of this project, we did obtain descriptive information about these sites from our site visits.

As described in Chapter 4, there are two systems involved in implementing the NCCCP: Ascension and CHI. Ascension's lead hospital (St. Vincent) is located in Indianapolis, IN, and their two developmental sites (Brackenridge and Columbia St. Mary's) are in Austin, TX, and Milwaukee, WI, respectively. Although CHI selected two hospitals to serve as leads (Penrose-St. Francis in Colorado Springs, CO, and St. Joseph/Towson in Towson, MD), for purposes of the evaluation, St. Joseph/Towson was ultimately considered the lead hospital for that system because it is where the PI of the NCCCP works. CHI is also implementing the

NCCCP in a "regional" developmental site among three hospitals in Nebraska. An important distinction between the two system and eight individual NCCCP sites is that the system sites received the same level of funding (approximately $500,000 per year) to administer the program across both their lead and developmental sites. For Ascension, this funding meant they divided the $500,000 per year across three hospitals, while CHI divided the same amount of funding among five hospitals. The assumption was that, although system-level sites would have to invest more of their own money into NCCCP implementation (compared to the individual hospitals), they would potentially be able to disseminate NCCCP-related knowledge and expertise across a broader range of hospitals. Unfortunately, we were unable to collect data on dissemination of the NCCCP within each system so are unable to test that assumption.

In terms of how the systems managed NCCCP across the participating hospitals, both assigned an individual to be the system-level NCCCP administrator. Their role was to facilitate communication and coordination across the participating sites and to allocate resources to assist in program implementation. System-level staff serve as a major communication hub and link between NCI and the participating sites.

As noted, the expertise of the selected program coordinators relative to the NCCCP varied greatly. One was a nurse with training and experience in oncology care who was also very familiar with the system organization and thus seemed capable of identifying resources and establishing mechanisms and processes for implementing the program. For example, this particular system instituted a regional cancer program and began convening monthly seminars that included all participating sites and addressed both operational and clinical issues. At the system level for the other system organization during Year 1, the program coordinator had no oncology training and seemed to struggle with understanding the nuances of this type of care and the processes needed to better improve coordination of services within and across participating hospitals. By Year 3, a new person had been hired as the coordinator across the system hospitals who did have a relevant background specific to the NCCCP.

One of the reported benefits of having the program implemented within system sites was that in some cases the system had allocated funding to help their participating hospital with NCCCP-related efforts. For one system's sites, however, staff noted that although they had hoped the system would provide funds or help raise them, each participating site ultimately had responsibility for finding their own funds to implement aspects of the NCCCP that were not fully funded in their NCI award. Based on follow-up telephone interviews we conducted with these sites, this aspect of program implementation seemed to be a growing challenge as local economies worsened during Year 2. One system seemed to have allocated more resources to the NCCCP than the other system had ($2.6 million in matching funds in Year 3, compared to $2.2 million), the result of which was that this system's hospitals were having fewer challenges in obtaining the necessary support to implement the program. This

may have been related to the fact that the system had decided to enhance oncology services throughout their system prior to NCCCP implementation and had hired a cancer program leader for the system who was also working as the NCCCP PI for one of the participating hospitals. Other potential benefits of the system-level approach to NCCCP implementation included the ability to share best practices across sites, to learn about new innovations, and to have a broader reach than one local site can offer in impacting cancer care.

Challenges to implementation at the system level included the added complexity of coordinating efforts across more entities that were not in close proximity geographically and lead sites that, by definition, may have been quite different from their developmental site counterparts. In addition, one system was quite decentralized, so ultimately decisions about oncology were made at the hospital or regional levels (rather than at the national level), while the other system was more centralized. The system sites have to coordinate efforts across a broader structure in which people who may have never met are attempting to work together. Respondents noted that there is not always an alignment between what they want to accomplish as a cancer program and what the system expects from them as a hospital service. Some hospital level respondents reported that if the system staff did not see the revenue-producing value of a proposed new program or strategy, it was difficult, if not impossible, to obtain their support for making the necessary changes. Many respondents provided input emphasizing the difficulty they had seeing the overall value added of implementing the program at the system level:

> *I don't know that having the additional level in the system is an advantage. In some ways, it makes things more complicated. They do a nice job of coordinating the sites. I don't know if that's a huge advantage. The system office doesn't add anything in terms of tools or advice. We are far away from each other. They don't have cancer experience.* (Key physician, Year 1)

> *[The] big question is what happens at the top. We are different from other hospitals in that we have the intervening structure of [the system]. It makes it difficult on our end to feel that we have control. One of our weaknesses here at the local level is not having enough control over hiring, finances, and firing. We're struggling with that extra layer of administration.* (Key physician, Year 2)

7.2 Organizational Processes and Challenges for Engaging Private Practice Physician Support

As previously noted, the relationships of hospitals and cancer programs to their physicians has been an integral aspect of NCCCP implementation and an area on which sites have focused a great deal of effort. First, we describe some of the nuances about the relationships of the key cancer physicians to the cancer programs implementing the NCCCP. This section then focuses on the strategies and challenges for engaging private practice

physicians. Because so many of the NCCCP sites rely almost entirely on these types of physician models, it will be important to describe and assess the impact of these relationships on NCCCP implementation. The data presented reflect interview findings from all 3 years of site visits. Participants were asked to provide information regarding barriers to physician involvement and effective strategies for engaging them in the NCCCP.

7.2.1 Key Cancer Physician Relationships with Cancer Service Line

As described in Chapter 4, the cancer services provided across sites varied and included a broad range of program sizes and physicians working in specialty areas. Over the 3 years of NCCCP implementation, it became increasingly apparent from the evaluation findings how important it is for the sites to be able to manage and negotiate a strong relationship with their key cancer physicians. Only 2 of the 16 sites operate with a predominately employed physician model (Table 4-3) and even those offer a performance-based payment model to the physicians such that the more patients they serve the greater their income. In the 14 sites that relied mostly on private practice models, there were some variations across sites. Several sites had a mixed set of arrangements where some physicians, often by specialty type (e.g., all the medical oncologists) were employed, some were provided stipends to serve in specific roles such as medical or research director, while all the others operated entirely in private practices. No matter the array of formal relationships, physicians generally had a disincentive for spending time away from patients because doing so could impact their personal income:

> *In this hospital, the private practice model is an inherent burden that any leader has to deal with because sometimes they're in line and sometimes they're not. But practices need to make some decisions about what benefits them corporately and what benefits them programmatically. Those things should be in line. If they're cancer-related practitioners, anything that enhances the cancer program should enhance what they're doing until they start mandating behaviors, and that's where you start to get pushback. That's where we're feeling our way….It's one thing to get them in the boat and another to get the oars going in the same direction.*
> (Subcommittee member, Year 1)

During each site visit, we made a point of meeting with any "key cancer physicians." These physicians were defined as those who had been involved in at least one program component for the NCCCP, who had a strong relationship with the cancer program, and who were often co-located within each cancer center or hospital. As described in Chapter 4, many of the NCCCP sites were quite small and had only a small number of physicians to engage in program activities. Most had at least one or more medical or clinical oncologist and a radiation oncologist. A few only had access to a radiation oncologist practice that provided care to patients at two (or more) major hospitals in the community so they would have to share his/her time with the other competitors. Very few cancer programs had access to

surgical oncologists, and only a few more had access to gynecological oncologists. Far fewer had access to surgical subspecialists such as breast surgeons, thoracic surgeons, etc. In many sites, even those with employed surgeons, the cancer program had experienced tremendous resistance from their general surgeons in recruiting a subspecialist to their hospital because of their anxiety about losing patients. Most general surgeons we interviewed believed they were providing high-quality care to their patients and that the hospital did not need to hire a subspecialist who would "take" all the breast cancer patients, for example, or other patients that may benefit from a specialty area. There was a great deal of resistance to this type of change even at hospitals that employed most of their physicians.

The following sections describe the major themes we identified from the discussions with key cancer physicians, PIs, and others at the sites during each year of visits. We start by describing the primary barriers people reported, following by strategies they were using to counteract those barriers.

7.2.2 Barriers to Engaging Private Practice Physicians

During Year 1, respondents noted a number of barriers to engaging private practice physicians:

- time/scheduling given the competing priorities on physicians' time and the fact that time away from their practices results in reduced income,
- resistance to collaboration, particularly among competing groups of physicians or because of concern over losing patients,
- lack of financial incentives or infrastructure for engaging physicians in the program, and
- limited IT integration.

During the first 2 years of the evaluation, we also found that there was a less-supported theme of the influence on physicians of accepting more charity care patients, even though this theme was expected by NCI. However, few respondents supported this theme, so we have not included it as a barrier to engaging physicians.

7.2.2.1 Time/Scheduling

Respondents noted that time/scheduling was the most common barrier for private practice engagement. The following quote perhaps best exemplifies the challenges physicians encounter in trying to add work to their schedules:

> *It's not just overworked. I don't think we're lacking sleep or getting traumatized by work. But I think it's hard to find time outside of your daily work and keeping your office going. Oncologists are hit the worst because they do oncology for all organ systems. So they have to go to breast, liver, head and neck, and then CME*

> *[continuing medical education], and then journal clubs. Those are all great things, but when you're doing them you're not seeing a patient in your office or doing surgery; you're not doing stuff to generate revenue and keep your office going. If we could have a system that reimburses for everything that needs to be done for patient care—not just the surgery but everything that goes into the thought process—that would be great. (Key physician, Year 2)*

For physicians, participation in the NCCCP involves attending subcommittee and management meetings and multidisciplinary care (MDC) conferences as well as potentially increasing enrollment of their patients into clinical trials, which is a very time-consuming task. As noted above, this was particularly an issue for medical, and often radiation, oncologists, whose specialty involves the majority of disease sites and associated MDC teams and conferences:

> *They have a lot of competing things for their time. They want to know how it [NCCCP] will help their patients and care here and how much work time do they have to put into it.* (Key physician, Year 1)

> *The challenge is in getting doctors integrated because they are so busy.* (Cancer center/program staff, Year 2)

> *Surgeons won't come; they are too busy and don't see an advantage. They will call, though, and ask about cases.* (Key physician, Year 1)

> *Clinical trials are very time-consuming for physicians. It takes about 2 hours to explain the clinical trial to patients and families. It really has to be the doctor doing this [rather than a nurse] as patients trust the doctor. Nurses can give some information and send patients home with information to read, but patients will still want to come back and discuss with the doctor whether to join a trial.* (Key physician, Year 2)

7.2.2.2 Resistance to Collaboration

Some respondents indicated that private practice physicians were reticent to collaborate with other physician groups, particularly those groups with whom competition was high or with those where the referral patterns may change as a result of the collaborations. In general, the concern was over losing patients and thereby losing revenue. If private practice physicians collaborate with other physician groups, they may lose their patients to these groups, particularly in a market where the competition for cancer care is very high (e.g., Towson, MD; Orange County, CA):

> *The real hard nut to crack is outside competing oncology groups. We have a group down the street that sees 30% to 40% of the cancer patients. I think I enroll more clinical trials patients than they do as a group. There's not a lot of cross-*

> *communication and cooperation. They see us as a threat. But talking to other people who've tried to establish regional research referral centers, it's a long process. That's a huge barrier for increasing enrollment in this area.* (Subcommittee member, Year 2)

Resistance also came from potentially losing a case to another type of treatment. For example, a few physicians shared with us that if they instituted an MDC conference, surgeons, who often see newly diagnosed cancer patients first, were reticent to discuss their cases at the conference first because it may mean the group would recommend another type of treatment before or instead of surgery. In this example, this reluctance was not the result of the surgeons not wanting to provide evidence-based care, but rather that they did not believe that the guidelines being followed were necessarily the best care for their patient and/or were in conflict with their own training.

> *In a private practice world, a surgeon sees the patient and they want to operate before the radiologist sees them and says they just need radiation.* (Key physician, Year 3)

7.2.2.3 Lack of Financial Incentives and/or Infrastructure

Another commonly reported barrier to private practice physician engagement was the lack of financial incentives for involvement, even with the huge time commitment from physicians to make changes encouraged by the NCCCP. As previously noted, NCCCP involvement means participating in meetings (e.g., more MDC conferences, subcommittee meetings) for which physicians are not reimbursed. In some cases, there is not only a *lack* of incentive, but sometimes *conflicting* incentives between physicians and hospitals who compete for certain services. Thus, one challenge is finding a win-win balance for physicians and hospitals or among competing physicians:

> *It's hard to come up with enough money to entice them. They just want the freedom. I have the same problem with trying to get doctors [to] take [my] call. So what actually motivates them is being a cut above.* (PI, Year 2)

> *Unfortunately, medicine is not money. Everyone is stressed for time and they're all trying to see as many patients as they can. It's frustrating, but they don't see it's worth their time to do it.* (Cancer center/program staff, Year 1)

> *At the same time, physicians are committed. It's also a time when reimbursement is being ratcheted down, and they have pressure to increase productivity, so there's kind of a battle between the cancer center needs, hospital needs, and their practice needs.* (PI, Year 2)

> *It is hard for me to take time out of my practice to go to conferences and take part in this program. In other places you get compensated for your role as PI. Right now*

> *we do it as pro bono. We asked the hospital for the sake of it for a stipend but we haven't received compensation.* (Key physician, Year 3)

Another related barrier was the extent to which each cancer program had infrastructure in place to provide ongoing support for physicians to be involved in related NCCCP activities. Early on, this was a common concern because fewer programs had the research, registry, and/or support services staff to guide patients onto clinical trials, improve data reporting, among other related NCCCP activities (see Chapter 4):

> *If you think about putting a patient in the trial and all of the additional work it takes. We are all willing to give our time but we need other people and support staff to help it run more smoothly.* (Key physician, Year 3)

7.2.2.4 Information Technology Integration

As described in Section 6.3.1.3, most oncologists working at the NCCCP participating sites do not have electronic health records (EHRs) or have different EHRs than the hospitals and their cancer center with which they are affiliated, so finding solutions to integrate the systems is costly and time-consuming. As part of the NCCCP, the sites were to conduct a needs assessment of their EHR and IT systems in order to help them create strategic plans for addressing needs. During the course of the pilot, however, the environment specific to IT in hospitals and physician offices changed greatly due to the national attention on health care reform. The ultimate hope is that all the health IT systems are better integrated and linked so that patient information can be safely shared among organizations and physicians providing their care. As of Year 1 site visits, several sites had identified a person whose job included building the interfaces to enable communication and information sharing across the various IT systems. Some sites were unable to devote many resources to this effort but had prioritized the systems with which to build interfaces first in order to improve care coordination:

> *In the private practice setting, you want to see things happen quickly, without all the politics and red tape. One of the challenges is going into these private practice settings and getting the data because [of] issues of confidentiality.* (Subcommittee member, Year 1)

> *The concept is great. Let's talk about the IT piece. How do you create an IT piece when almost every practice is electronically based and not all interface together? Part of how to do it is to create an electronic record for this program and create a program that interfaces all electronic records. Right now, I get a form that pops up that I sign in my office. I am not in my office; I am here in the cancer center. So it is electronic, but it is not integrated*. (Subcommittee member, Year 2)

> *If you have a platform, that does not mean others have access to all of my information. An IT piece does not mean that all of the record is completely*

> *transferred. Outside of this program, NCI should make IT interfacing a priority.* (PI, Year 2)

7.2.3 Strategies to Engage Private Practice Physicians

Given the resistance to NCCCP involvement among some key cancer physicians during the first year, sites worked to develop and continuously improve strategies to positively engage physicians. These strategies were implemented at several sites throughout the 3-year pilot program and seemed to have some degree of success with the following:

- engage physicians early and often,
- promote the research and quality of care components of the NCCCP, and
- incorporate appropriate incentives into program development.

7.2.3.1 Engage Physicians Early and Often

Respondents from a few sites indicated that early on they had made the mistake of not informing community physicians about their NCCCP-related activities, which created resistance when the physicians learned about the initiatives through indirect sources. A few respondents noted that it is wise to engage key physicians early in program development and often over time during implementation:

> *If you have a private practice community, get their endorsement before you start. We did that with most of them, but not all. We had a key oncologist but not the surgeons. Now the surgeon's more on board.* (System/hospital senior executive, Year 3)

For example, respondents reported that some key cancer physicians were particularly resistant to what they perceived to be major changes in accountability and quality of care, including guidelines that some saw as a form of care standardization that was not good or appropriate for all patients, the pressure for specialization or board certification, and CME credits. Some cancer centers sought to abate these fears by enacting small incremental changes to illustrate the potential effectiveness and utility of some program components:

> *The virtual clinic approach to colorectal cancer is a great segue into seeing how people can get along better when you dilute the people that are in competition by having the surgeons, pathologists, [and] tumor registry working together to do something for the patients. You have better behavior when you have that group together. So it will help expose what impediments there are and see what needs to be done to fix them.* (Key physician, Year 2)

7.2.3.2 Promote the Research and Quality of Care Components of the NCCCP

Across sites, a common response to the question of how they engaged their physicians during NCCCP implementation was that they emphasized how the NCCCP allowed them to

provide access to research and quality of care initiatives, as well as the related infrastructure, that their sites had previously had on only a limited basis. Several respondents indicated that some, if not most, physicians are highly interested in engaging in research because doing so can increase their professional development, professional stature, and reputation in the patient community, particularly if they have sufficient support. However, these same respondents recognized the time commitment required of physicians to start enrolling patients in trials. To address this barrier, several sites had begun placing research nurses within or near physician offices to make them more accessible to the practices, thereby raising the awareness of and potentially increasing accrual to clinical trials. Discussing or promoting the research component of the NCCCP (i.e., clinical trials, biospecimens, and enhanced quality of care) may also increase physicians' willingness to participate:

> *I think the physicians would have had a great inclination to withdraw, instead of participate, if it weren't for research.* (Cancer center/program staff, Year 1)
>
> *Our physicians are biting at the bit to be involved in research, so dangling the research piece in front of the community physicians [might increase their willingness to participate].* (PI, Year 1)
>
> *In my two-sentence "elevator speech" about the NCCCP, I tend to emphasize the research. When we say we are trying to expand research, that hooks physicians in.* (Cancer center/program staff, Year 1)
>
> *With clinical research infrastructure, we have increased staff, conducted research, increased the number of research protocols (trials), and having more physicians who are coming to us. That is significant. As we have more trials, we can put the resources behind them.* (System/hospital senior executive, Year 1)

Another strategy that seemed to be working to engage physicians was through NCI's Quality Oncology Practice Initiative (QOPI) in which all but one site had recruited several medical oncologists to participate by the time of the Year 2 site visits. During Year 2, cancer centers reported the same types of strategies to engage physicians. However, cancer centers were also able to hire more support staff, including patient navigators and research staff, which made the NCCCP and its benefits more tangible to physicians. Moreover, some sites indicated that by Years 2 and 3, physicians were less resistant to NCCCP involvement:

> *The single most important strategy is making specialists aware of the MDC conferences. If we all sit in the same conference, we can increase the state of the art care. They realize they will have access to the patient coordinator. [The] coordinator figures out the stage of cancer, whether they should see a medical oncologist, and if they should be discussed at the conference. When you figure out that there will be MDC [conference] with one consult, and their patient is getting access to clinical*

trials, we increase the volume. It is something they [physicians] don't get from the academic medical center. (PI, Year 3)

Across the board, there is some physician resistance, but overall the resistance is decreasing. I think there is a lot of resistance, [but] as there are more resources [and] increased benefits, that resistance diminishes and acceptance increases. We are moving towards a blend of academia and community; [the] NCCCP gives you the best of both worlds. (Cancer center/program staff, Year 3)

Navigation was one of the first things where we have partnered with others and really reached fruition immediately. It works with increasing physician buy-in. (PI, Year 2)

7.2.3.3 Incorporate Incentives into Program Development

By Year 3, respondents from many of the sites said that they had learned ways to provide incentives to physicians for participating in NCCCP-related activities. As noted above, in addition to increasing physician access to research and quality of care initiatives, the NCCCP also provided for infrastructure to support these key activities. Sites tended to use three strategies for providing incentives, including ensuring that participation would increase (or at least not decrease) their patient referrals (e.g., one site rotates physicians through their MDC clinics such that those who attend on a given day will have any new patients referred to them by the cancer center), establishing job titles or ways to recognize leaders for the cancer program, and arranging marketing opportunities for those who agreed to be involved. In particular, they had set up processes such that the physicians who attended the MDC conferences may receive patient referrals of any newly diagnosed patients. These sites had developed rotation lists for ensuring that the referrals were equitable across physician groups and were finding this to be an effective means to ensure that key physicians participated:

Part of that is because of our model. If you miss the MDC [conferences], you may not get the referral that you want. (PI, Year 3)

Participating in the weekly conference makes things better for the physicians. I started sending more patients to the other oncologists who come to the clinics. In little ways that aren't written down, it benefits the physicians. If you come to the conferences, you also get your picture on the Web site. (Cancer center/program staff, Year 2)

Once you get physicians to understand the positive benefits of this approach [MDC conferences], they're on board. (Key physician, Year 1)

One reason to participate is that they get more patients. Another reason is we do all the work for them. My research team, we put them on clinical trials. My navigators

> *take care of it. They don't have to have their own nurse to do that. They come to the meetings because they have trials they want their patients to be on.* (PI, Year 3)

> *The incentive for physicians was that they were assured [that] for their assigned cases, that their referral patterns would not change. There's at least 50% attendance rate at conferences.* (PI, Year 1)

To engage physicians, some cancer centers planned to ask key private practice physicians to act in NCCCP leadership roles, such as being a PI or subcommittee leader:

> *Our plan is to give them a role once we have something for [the physicians] to do, like helping with our community outreach and helping to get interest and buy-in for the multidisciplinary clinics. Our plan is once we actually have some task we can give them, we plan on having physicians step into key positions.* (Cancer center/program staff, Year 1)

As previously noted, other incentives included providing mechanisms for participating physicians to obtain marketing and/or promotional materials through the hospital. This promotional material can provide outreach and, at the same time, increase recognition of the NCCCP and its collaborating physicians:

> *Marketing, recognition, [making the] patient care coordinator an integral part of their practice, not offering them services that are inappropriate. As far as monetary support, that's a strategic initiative that comes from administration.* (Subcommittee member, Year 2)

> *You have to give them some benefits. Having their pictures available on a Web site that people can see when they Google you is easy. You sign the conditions of participation, and they get their picture.* (System/hospital senior executive, Year 1)

> *The institution makes attending MDC [conferences] nice and easy. There's a nice meal at tumor board. It's fairly painless. In the past, we had to pull our own films. Now there's infrastructure support; things are prepared. Everything's ready.* (Key physician, Year 2)

7.3 Summary

Aspects of the organizational structure and process are critical to the success of implementing a program as cross-cutting and complex as the NCCCP. From the start, the hospitals participating in the NCCCP were quite diverse, each having an array of strengths and weaknesses to their cancer service line. From the start, the structures were somewhat similar in that they were mostly functional designs that were moving toward mixed designs that include aspects of matrix or service line organizations. However, the hospitals were quite varied with regards to where the cancer service line was embedded within the

organizational structure and what type of leadership it benefited from. Strengths included the cancer service line's relationship with their hospitals and the extent to which the NCCCP, through direct relationships between the cancer center's medical director and the hospital's top management, could access hospital support and resources. Weaknesses included cancer service lines that were in some cases so small that they had no physician directors and needed to rely solely on private practice physicians who were volunteering part of their time to address NCCCP-related activities. Some hospital structures seemed to lend themselves to better and faster integration of the NCCCP with existing cancer service line activities. Those organizational structures that seem to be best prepared for NCCCP integration already have a clear cancer service line or a distinct cancer program or center in place, at least from a clinical perspective, with an established physician director.

Senior executives across all the sites expressed support for the NCCCP, and most gave tangible examples of how they allocated resources to demonstrate this support (e.g., hiring new staff, buying equipment, leading negotiations with physicians to engage them in program). Although we interviewed senior executives during all of the site visits, they each had different views of the program depending on their level of interaction with the PI. Only a few CEOs or COOs were likely to be so involved with the program that they were attending meetings regularly with key staff or receiving frequent updates. Sites where the PI had a direct reporting relationship with a senior executive particularly if the PI was also the cancer program medical director, seemed to be better able to access resources and financial support for program implementation.

In terms of the relationships between the participating hospitals and their key cancer physicians, most relied on a structure in which physicians were in private practice and varied in terms of the extent to which they could or did provide a stipend for selected physicians to work directly with the cancer program. The extent to which hospitals had these more formal relationships with their cancer physicians was also varied. Most of the sites reported having allocated a physician to serve in the role of PI for the NCCCP, but several of these PIs were not the cancer program director. Sites that had a PI who was also the cancer program director, seemed to have greater and quicker success engaging their physicians (e.g., influencing increased attendance at multidisciplinary care conferences). All of the sites experienced barriers to engaging their physicians, particularly if they were in private practice. Common barriers included a lack of time for physicians to spend on these types of relatively voluntary activities; resistance to collaboration among physicians, particularly if they compete against each other for patient care; a lack of financial incentives or an infrastructure to provide support for physicians to become engaged; and limited information technology infrastructure to facilitate communication. Over the 3 years of the pilot, several sites applied and continuously refined three key strategies for addressing these barriers and engaging physicians: finding ways to engage physicians early and often in program implementation so that they quickly become collaborators and remain that way,

using their growth in research and quality of care initiatives to attract physicians' attention and interest them in how this work could benefit their practices and patients, and incorporating incentives (e.g., marketing, staff support, patient referrals) into the process of NCCCP participation. Sites that also had a program coordinator whose job included coordinating efforts across the program components also seemed to be more successful at engaging physicians in their ongoing NCCCP activities.

Over the course of the 3-year pilot, it was interesting to see how the sites perceived their "usual" cancer care activities as fitting in with NCCCP and vice versa. During Year 1, most PIs said that they saw the NCCCP as a direct overlay of their cancer program (one noted this is what they should be doing anyway), but other cancer physicians were less clear about what the program meant to them. Over time, the relationship between the NCCCP and their overarching cancer programs became clearer and, in some cases, more seamless than in previous years. In a few cases, PIs noted that the NCCCP had become their cancer program in that they were using it to advance their cancer care agenda across all of the components. In particular, two sites were even using the "NCCCP model" to facilitate improvements in other clinical areas, such as cardiovascular care.

Table 7-1. Characteristics of the Hospital's Relationship to its Cancer Service Line[a]

Site	Cancer Center Director Reports to		Is Cancer Center Director a Physician?
	CEO	COO	
Site 15	0	0	0
Site 11	0	0	0
Site 8	0	0	0[b]
Site 7	0	1	1
Site 2	0	0	0
Site 13	0	0	1
Site 5	0	0	0
Site 14	0	0	1
Site 4	0	1	1
Site 6	1	0	1
Site 10	0	1	1
Site 3	1	0	1
Site 12	0	1	1
Site 1	1	0	1
Site 9	0	0	0
Site 16	0	1	1

[a] 0 = No; 1 = Yes; data presented are as of the end of the NCCCP pilot (June 30, 2010) and were collected through the site visits.

[b] Interim medical director was in place but not on a permanent basis.

Table 7-2. Physician Leadership Indicator: Year 1, Year 3, and Change Over Time

Physician Leadership Indicator	Year 1	Year 3	Change Over Time
Cancer center director reports directly to CEO	2	3	1
Cancer center director reports directly to COO	5	5	0
Cancer center director is a physician	8	10	2
NCCCP PI is also the cancer center director	5	7	2

Table 7-3. Cancer Center Physician Director[a] FTE: Year 1, Year 3, and Change[b]

Site	FTE for Physician Leader[c]		Change in Physician Leader FTE (Year 1 to Year 3)
	Year 1 (0-1 scale)	Year 3 (0-1 scale)	
Data Source:	**BAS**	**FAS**	
Site 4	0.1	0.2	0.1
Site 6	1	1	0
Site 10	0.5	0.5	0
Site 3	0	1	1
Site 12	0.8	1	0.2
Site 1	0.6[d]	0.1	-0.5
Site 9	0	0	0
Site 16	0.4	0.5	0.1
Site 15	0	0	0
Site 11	0	0	0
Site 8	0	0[f]	0
Site 7	1	0.4	-0.6
Site 2	0	0	0
Site 13	0.2	0.1	-0.1
Site 5	0	0	0
Site 14	0.2	0.2	0

[a] This person is the medical director of the overall cancer center or program and is not necessarily the NCCCP PI.

[b] Data are self-reported from the sites in their baseline and final assessment surveys (BAS and FAS, respectively). Comparison to data provided as part of the micro-cost study resulted in few matches (i.e., in many cases, the numbers presented in this table do not match what the site invoiced for the time their "physician director" spent on the NCCCP). We opted to use the BAS/FAS since that question asked sites to do the following: Please indicate the percent FTE the physician director(s) position(s) was/were funded as of (date provided based on when survey administered). For example, if the physician director was funded for 8 hours (or 1 day) a week, that would be 0.20 FTE (assuming a 40 hour workweek). We did encounter problems by relying on the BAS/FAS. Some sites indicated that they had a physician director of their cancer program serving part of a FTE even though we knew from our site visits that this was not the case. We suspect that sites were confused about what was meant by "physician director" and did not reliably understand that this person was part of the cancer program or center (i.e., not necessarily part of the NCCCP). Therefore, these data are our best estimates and should be reviewed with caution.

[c] Only permanent physician directors are presented.

[d] The original medical director for the cancer center at this site resigned his position in late 2007. He was not at the cancer center when we created the first organizational charts, but the site did report his time on the BAS.

[e] Although this site had a physician serving as the NCCCP co-PI, this site did not report any time allocated to NCCCP activities for this physician nor did they bill for her time in their NCCCP invoices.

[f] Although Interim medical director was in place but not on a permanent basis

Table 7-4. Sites with Executive Directors[a] and Whether They Were Trained as Nurses[b]

Site	Executive Director	
	Present	Nurse
Site 15	1	0
Site 11	0	—
Site 8	1	0
Site 7	1	1
Site 2	1	0
Site 13	1	1
Site 5	1	1
Site 14	1	0
Site 4	1	1
Site 6	1	0
Site 10	1	0
Site 3	1	0
Site 12	1	1
Site 1	1	0
Site 9	0	—
Site 16	1	0

[a] An executive director (ED) of a cancer center is an established job description that includes the responsibilities of managing personnel, financial, and material resources for their cancer center. Some EDs are clinically trained, such as oncology nurses, while others are administrative directors. Several sites started the NCCCP with an ED serving in the role of NCCCP program coordinator, but over time, five sites decided to distinguish the two roles. Most sites that had program coordinators by Year 3 considered this role to be administrative and at a lower salary and with fewer credentials than an ED.

[b] 0 = No; 1 = Yes; data presented were collected during the Year 3 site visits.

Table 7-5. Program Coordinator Positions for Years 1 and 3 at the NCCCP Sites[a]

	Does Site have an NCCCP Program Coordinator or Manager Whose Role Includes Coordination Across Components?	
Site	**Y1**	**Y3**
Site 4	0	1
Site 6	0	1
Site 10	0	1
Site 3	0	0
Site 12	0	1
Site 1	0	1
Site 9	1	1
Site 16	1	1
Site 15	1	1
Site 11	1	1
Site 8	1	1
Site 7	0	0
Site 2	0	0
Site 13	0	0
Site 5	0	0
Site 14	0	0
Total	5	10

[a]0 = No; 1 = Yes; data presented were collected during the Year 3 site visits.

Table 7-6. NCCCP Program Coordinator Responsibilities and Suggested Qualifications

Responsibilities for Program Coordinator	Qualifications
Makes sure representatives of each program component are following through on assigned tasks	Coordination skills and ability to handle multiple tasks at one time
Ensures implementation of approved work plan	Background and understanding of budgetary oversight
Educates staff about the NCCCP and the ways to integrate efforts across program components	Prior grant or program management experience
Sits in on all NCCCP network subcommittee calls (several also attend the Executive Subcommittee calls with the PI)	Data management experience (e.g., ability to set up spreadsheets to maintain information about the program or patients)
Manages the grant and draft deliverables to SAIC-F	Experience managing multidisciplinary teams of people
Pursues additional funding opportunities (i.e., identifies and submits for grant opportunities)	Strong organizational skills
Oversees program financials	
Facilitates communication across program components	

8. COORDINATION ACROSS PROGRAM COMPONENTS

Overview

The NCCCP is intended to be a comprehensive program to address cancer research and care across the cancer continuum, from increasing outreach and screening in hospitals to providing appropriate follow-up care for survivors after treatment has been completed. This chapter focuses on sites' coordination across program components; subsequent chapters provide detail on each respective program component. With the six NCCCP components, particularly for disparities and IT, sites needed to work across organizational boundaries to achieve their goals. Disparities was a major program component that was intended to overlay every other activity of the NCCCP, which required sites to establish mechanisms for communicating across multiple departments and implement activities potentially in other areas of the hospital where they had little or no control over whether changes could be made. Sites also needed to coordinate across the components so that staff involved in these efforts would be aware of all the various activities, would know how each potentially overlaps with their own work, and could actively address any potential areas of duplication of effort.

Coordination During Year 1

As noted in Chapter 5, many respondents did not fully understand the scope of the NCCCP and how broadly the program would affect their cancer program. For this reason, there was minimal understanding of how the components could potentially overlap and what it would take to coordinate efforts across each component and among the related hospital departments (e.g., IT, pathology). By Year 2, we were able to observe changes in how sites were approaching their NCCCP work, particularly through the creation of a "program coordinator" role at many of the sites, whose job included coordinating efforts across the components (Chapter 7).

Changes in Coordination by Year 3

In Year 3, respondents were asked to describe more generally their efforts to coordinate across program components rather than focusing on specific components. Sites seemed to have gained a better understanding of the "connectedness" between program components and were therefore able to implement strategies for improving their coordinating efforts. The main strategies identified in Year 3 focused on enhancing communication systems between core staff, top management, and physicians; modeling the NCCCP structure into cancer center processes and systems; and integrating cancer center departments and services for improved cancer care. Several facilitating factors were identified in achieving these goals, including the support of senior executives and cancer center/program leadership, dedicated program staff, and networking across NCCCP sites. As in previous years, the burden on staff resources (e.g., time, competing priorities) and the lack of a shared vision of the NCCCP have remained barriers to coordination for several sites. Despite these barriers, coordination across components has remained a priority for sites as the need increases for non-duplicative, efficient program systems and improved patient care.

As described in Chapter 2, the ultimate aim of the NCCCP was to use a public-private partnership to expand cancer research; deliver the latest, most advanced cancer care to a greater number of Americans in the communities in which they live; and contribute to NCI's

research mission. To achieve the program's stated aims, NCI developed six program components for which specific deliverables are required from the sites:

- reducing **disparities** across the cancer continuum;
- enhancing **clinical trials (CT)** research;
- increasing capacity to collect **biospecimens** per NCI's best practices;
- improving the use of **information technology (IT)** and electronic health records (EHRs) to support improvements in research and care delivery;
- improving **quality of cancer care (QOC)** and related areas, such as the development of integrated, multidisciplinary care (MDC) teams; and
- placing greater emphasis on **survivorship** and palliative care.

Tracking deliverables necessitates that outcomes for each of the components be tracked and measured over time. The focus of the evaluation was to thoroughly understand the processes and outcomes for each program component.

As described in Chapter 2, a set of prioritized questions for each program component was developed during the evaluation planning process for the NCCCP (Table 2-1). During the early stages of the NCCCP pilot, sites developed work plans to guide their implementation of each component. Year 3 questions focused on how sites have coordinated efforts across program components, what they have worked on in each area, what they have accomplished, and the barriers and facilitators for each step. For each of the program components, separate semistructured protocols were developed that asked about the activities sites had implemented and the barriers and facilitators they had encountered in implementing their work plans.

In Year 3, respondents were not asked how specific program components were being coordinated with others (e.g., disparities and IT) but were asked more broadly about the types of strategies used to promote coordination and facilitators and barriers to these efforts. As background for the reader, this chapter will provides a summary of sites' efforts in Years 2 and 3 to coordinate across program components followed by an overview of key factors influencing how well sites have been able to coordinate across components, and barriers that have hindered progress in these areas. Lastly, we provide a summary of the benefits of these collaborations as expressed by respondents and key recommendations for NCI to consider for future funding efforts.

8.1 Overview of Site Coordination Strategies

As described in Chapter 7, organizational processes like communication and coordination will be key to bringing all aspects of the NCCCP together through implementation. There is a significant body of theoretical literature addressing adoption/assimilation and implementation processes and the organizational factors that might affect them (see

Chapter 7). As such, potential issues often arise through repeated interactions within and across teams and organizations, making communication and coordination very important for problem-solving and lessons learned. One important aspect of this synergy is how sites have been implementing NCCCP goals across program components.

During the Year 2 and Year 3 site visits, interviewees were asked about ways in which they have coordinated their efforts across the various components. Evaluators were particularly interested in the following:

- mechanisms sites used to coordinate efforts across components (e.g., communication),
- examples of coordination activities,
- factors influencing how successful sites were able to coordinate efforts across components, and
- challenges to component coordination.

8.2 Cross-Coordination Strategies

As described in Chapter 7, several sites addressed their needs for improved coordination specific to the NCCCP by creating the position of a "program coordinator," whose role included meeting with all of the leads for each component to help them set goals and complete activities. In addition to this strategy for coordinating efforts, sites described several different mechanisms to coordinate activities between program components, including

- development of formal NCCCP subcommittees,
- regular NCCCP core team meetings,
- assignment of multiple program components to one staff member, and
- informal interactions (as needed).

Particularly during the Year 3 site visits, it was apparent that sites had gained a better understanding of the linkages between the various components and thus improved their coordinating efforts across components. These efforts made it possible for sites to refine their program infrastructure, strengthen core management and staff capacity, improve their cancer committee participation, and enhance their overall programmatic performance. The main strategies identified in coordinating across program components in Year 3 include

- improved internal communication with core staff, top management, and physicians by incorporating NCCCP discussions into regular cancer center and senior executive meetings;
- integration of the NCCCP into hospital/cancer center infrastructure; and
- integration of cancer center departments/services.

8.2.1 Local NCCCP Subcommittees

Respondents cited the development of local NCCCP subcommittees that mirror the structure of the national NCCCP subcommittees (for each program component) as an effective way for program staff to communicate across program components:

> *Much like there are calls that originate from [the] NCCCP, we have subcommittees at [site]. People from each of the three sites participate, and we have folks be national leads on NCCCP calls. We use SharePoint as a mechanism to share documents [and] resources that are desirable. We use e-mail [and] conference calls through a phone bridge from the corporate office. We've been trying to use videoconferencing. Everyone is communicating with their counterparts with their ministries. I'm on those calls and NCCCP calls. On the second or third week of the month, I'm on eight or nine phone calls.* (Program coordinator, Year 2)

> *Each pillar of NCCCP has an internal workgroup. We get together to meet for the conference call and…ensure that whatever activities we work on, we try to link them to our NCCCP activities to make sure they are in line with those as well.* (Subcommittee member, Year 2)

8.2.2 NCCCP Core Team Meetings

For several sites, monthly core team meetings were an integral part of "bringing all the pillars together." Core team members may include the principal investigator (PI), program coordinator, cancer leadership staff, and representatives from each of the program component areas:

> *We have a monthly core team meeting. We bring together all the pillar leads and people who are most actively involved in each of the pillars and give an update on the major topics over the past month. Outside of those meetings, our team is crossing paths and meeting on a regular basis and working together when anything comes up in relation to [the] NCCCP.* (System/hospital senior executives, Year 2)

Among other sites, having less frequent (e.g., quarterly) meetings was considered a useful way to coordinate and streamline their efforts across components:

> *We have a quarterly meeting of all committees where we ask people to share just as a way to keep the group together. I think the people that work most closely together are quality of care, disparities, and survivorship, although now that IT is moving forward they think about [how] that might fit in.* (Program coordinator, Year 2)

> *We have a quarterly meeting, which we just had last week, in terms of getting updates on what each of the other NCCCP committees are working on, and then e-mails and then we're all linked in through the Web with shared files [so] that we can access other group's information.* (Subcommittee member, Year 2)

8.2.3 Multiple components for staff members

In addition, several sites designated the same personnel for more than one NCCCP component subcommittee. For example, at one site, a staff member served dual roles as lead for both the survivorship and disparities subcommittees. Although this may burden staff with a heavy workload, it was a necessary means for some sites to streamline the work across components:

> *The pillars can't operate on their own. We have created a system. The outreach coordinator and the PCC [patient care coordinator] go hand in hand…they sit in the same office. PCCs have a dual role. The outreach folks send patients to the PCC to help them coordinate.* (Program coordinator, Year 2)

8.2.4 Informal Communication

Although across sites there were systematic measures to coordinate components, the majority of interviewees agreed that nothing takes the place of informal communication:

> *One of the good things about having a small program is that the pillar heads know each other and they just pick up the phone and call each other. They work back and forth—it's not an issue.* (System/hospital senior executives, Year 2)

8.2.5 Incorporating of NCCCP into Regular Cancer Center and Top Management Meetings

To effectively communicate with core staff, top management, and physicians regarding NCCCP, sites incorporated discussions about the NCCCP in regular meetings (e.g., tumor boards, MDC conferences, hospital-wide meetings), convening regular program staff meetings, and making announcements about the NCCCP at related meetings (e.g., cancer care committee meetings). For these sites, holding regular team meetings not only plays an important role in improving communication among the key stakeholders, but also allows everyone to "see all of the moving parts":

> *We have a standing NCCCP committee that meets once every couple of months. With the hospital at large, we use the directors' [of all service lines] meetings, and the executive director and the CEO who disseminates information.* (PI, Year 3)

> *There is 1 hour of cross-coordination per month. All subcommittee leads come together to discern milestones regarding the workplan [and to] discuss projects, barriers, and ways to overcome [them].* (Program coordinator, Year 3)

8.2.6 Integration of the NCCCP into Hospital/Cancer Center Infrastructure

Realizing the need for coordination, many sites have integrated NCCCP structures and processes into existing cancer center communication and performance systems. For

example, the NCCCP has become a priority agenda item for hospital cancer care committees, and some departments (e.g., quality assurance) have patterned regulatory compliance after the NCCCP:

> *We try to hardwire [the NCCCP] into everyday operations. It has become our "playbook" in the day-to-day operational structure.* (Program coordinator, Year 3)

> *We were having duplicate [NCCCP] meetings [along with] separate cancer center meetings, so we decided to incorporate the NCCCP structure…and modeled it for the cancer center.* (PI, Year 3)

> *We take the NCCCP model and overlay it [with] operations and structure….This year, we've tried to harmonize the NCCCP QOC [committee] with internal QOC processes. This has been a key ingredient.* (Cancer center/program staff, Year 3)

8.2.7 Integration of Cancer Center Departments/Services

Many sites realize the importance, and perhaps necessity, of coordinating their efforts across the various program components as a response to, or way of enhancing, their existing cancer services:

> *The integration of [our cancer] services is more than it was before. [We] added [gynecologic oncology] and basically integrating everything into the new building.* (Key physician, Year 3)

> *There's a more unified approach to cancer. When we applied for this [NCCCP grant], we said we were going to build a new cancer center. We're already providing a lot of disparate care. With the opening of the cancer center and the direction of [our leadership], we now have a breast program, lung program, [and] head and neck program. Administratively, it's organized better than it's ever been. The fact that we're [an] NCCCP [site] has helped drive that effort.* (PI, Year 3)

Across sites, it was generally agreed that implementing these communication methods would facilitate bringing together each of the program component subcommittee leaders and integral cancer center personnel, all while providing an opportunity to discuss opportunities for cross-component synergy and coordination. In the following sections, we provide examples of coordinated activities across each of the program components.

8.3 Coordination of Biospecimens Activities with Other NCCCP Components

Coordination efforts were evident between biospecimens activities and those working to address clinical trials, disparities, and IT. There were no reported examples of coordination between those working in biospecimens and those working to implement either QOC or

survivorship/palliative care activities. The following sections provide an overview of how those working in biospecimens research were working with others.

8.3.1 Coordination of Biospecimens with Clinical Trials

Coordinating biospecimens collection and clinical trials activity is important for advancing NCI's research mission, which includes developing a common biorepository infrastructure that promotes research sharing and team science (U.S. National Institutes of Health, 2011). Through collaborations with organizations such as the Moffitt Cancer Center and Research Institute, some sites have benefited from the natural fit between biospecimens and clinical trials. Through Moffitt's Total Cancer Care (TCC) initiative, samples of blood, urine, and tumor tissue are being collected from thousands of patients to identify those who may be eligible for clinical trials:

> *We are using a portion of the patients' biospecimens to build a national repository and develop CT. We just wrote an esophageal study, and [it] is linked into clinical trials.* (Subcommittee member, Year 2)

> *In the last 12 months, they [Moffitt Cancer Center] have contributed 50 specimens. The physicians put 100 patients on clinical trials.* (Cancer center/program staff, Year 2)

8.3.2 Coordination of Biospecimens with Disparities

As described in Chapter 9, most people working within sites to address disparities understood the importance of ensuring that their efforts spanned each of the other five program components. We found evidence that this coordination was occurring with biospecimens-related activities:

> *I think our intent is to make people aware that disparities cross over every pillar. If you are in biospecimens, you may need to be aware of cultural issues for Native American cultural issues. I think it is happening, and by our discussion and our calls, it is not just one committee's work; it crosses all committees.* (Subcommittee member, Year 2)

> *Disparities is 40% of what we do. NCI has done a Disparities Dashboard. Now we're charged with how are we incorporating disparities into all of our subcommittees? When we come together as a whole, it's really nice because we're all connecting the dots as a whole.* (Program coordinator, Year 2)

One of the major challenges sites faced in linking their biospecimens and disparities activities was the distrust they encountered among their targeted populations for participating in any type of medical research. As a result, a few sites had tried to spread the word about biospecimens to these disparate groups through the use of Webinars and telemedicine. The Webinars, which emphasized methods for approaching minorities about

biospecimens issues in culturally sensitive ways, included panel discussions with patients, physicians, and other experts. The sessions were framed primarily as professional education, but they also provided strategies for carrying messages to the target population communities by building a system of trust:

> *It takes a long time to build trust. [Disparate populations] can sometimes be leery of health care, and some things are sacred. Now we're going to tell them we want to submit their tissue to a biospecimens repository. If we do get some research with [disparate populations] for tumor sites or data collection, we can share those things there isn't a lot of research on.* (Program coordinator, Year 2)

> *One of the things that helps is we're active in the Native American community. We're getting out there and doing testing. Hopefully when we do get out there to do testing for biospecimens, it won't be foreign to them. We're trying to go out into their communities. A lot of times they think their cancer symptoms are a cold and they're getting diagnosed at later stages. Hopefully by going out there and trying to help them, we'll get some relationships formed, so that if we do the biospecimens repository they'll be familiar with it and understand it.* (Subcommittee member, Year 2)

All sites either implemented or began planning to implement standard operating procedures for the special disposal of biospecimens as requested by patients with specific religious, cultural, or other requests. However, only one respondent talked about this type of coordination between biospecimens and disparities in Year 3:

> *With biospecimens, we've implemented a disposal policy. It's a different situation for the native American population where they want the entire body and don't want to lose hair. Parker's been able to do SOPs; we're trying to work on best practice implementation.* (Program coordinator, Year 3)

8.3.3 Coordination of Biospecimens with Information Technology

The NCCCP goal of biospecimens data collection has highlighted the priority of implementing IT systems across sites and vice versa. Hence, the coordination between biospecimens and IT efforts has largely focused on the adaption of the caTissue suite. In Years 1 and 2 of the pilot, a focus of the NCCCP biospecimens subcommittee has been to encourage sites to use the caTissue suite, where appropriate, to facilitate the exchange of biospecimens data and test results within the NCCCP. As discussed in Section 11.4, for some sites, the implementation of biospecimens efforts has been haltered by the availability of IT resources, making it difficult to integrate systems like caTissue into their biospecimens work. Other sites, however, have been successful at adapting their current IT systems to enhance their biospecimens infrastructure:

> *We have an IT infrastructure. There are a lot of caBIG-compatible components, so we use their guidance about screening products that will be useful for our needs. We have some people coming in to show us an onsite demo. This will be integrated with MEDITECH, so if we have a tumor sample we can hit a button and de-identify the information and upload into caTissue.* (Subcommittee member, Year 2)

8.4 Coordination of Clinical Trials Activities with Other NCCCP Components

As described above, we found evidence that sites were working to coordinate their clinical trials activities with those to address biospecimens research. We also found evidence that coordination of activities was occurring between clinical trials and disparities, QOC, and IT. Only one site reported efforts to coordinate clinical trials activities with survivorship/palliative care. This finding is expected because few clinical trials were being implemented within the sites that would address survivors or those receiving palliative care. For the site that did note coordination between these two components, respondents explained that it was due to their recent partnership with a local biomedical research center to conduct a survivorship clinical trial. The following sections provide an overview of the coordination efforts underway between clinical trials and the remaining program components.

8.4.1 Coordination of Clinical Trials with Disparities

As will be discussed in Chapter 9, one of the main goals of the NCCCP pilot is to increase the number of minority and disparate populations accrued to clinical trials. Across sites, the natural fit between clinical trials and disparities is apparent:

> *Disparities and clinical trials work hand in hand, and when we go out we try to do education. We have a population of West Indians that have the highest mortality from prostate cancer and [we] believe that if you screen you're going to find something.* (Program coordinator, Year 2)

Sites reported three specific strategies they were using to link these two program components:

- outreach,
- patient navigation, and
- physician involvement in minority clinical trials accrual.

8.4.1.1 Outreach

For the majority of sites, clinical trials are introduced through outreach activities, and some sites were planning focus groups to understand barriers to clinical trials participation for disparate populations:

> *We define our disparate [populations] in two ways: as Native American and as rural. The majority of patients are rural. We have a clinical model where we do outreach…right now what we're trying to do is use the spoke and hub, offering more trials at our outreach clinics.* (Subcommittee member, Year 2)

> *We received another grant…to develop some culturally sensitive materials using focus groups then find out what it is that patients would need in the community that would help get the message out there that would be appropriate. So based on the focus groups, we'll develop a brochure or tool of some sort that we can use [for CT recruitment].* (Subcommittee member, Year 2)

8.4.1.2 Patient Navigation

One of the most common ways clinical trials interfaced with disparities was through the role of the patient navigator. The role of the patient navigator varied across sites. Depending on the site, this role was analogous to such terms as "nurse navigator," "care coordinator," "patient care coordinator," and "outreach coordinator." Patient navigators not only differed in the disease site that was their focus, but some were engaged in activities from care coordination—from diagnosis to treatment—to cancer screening and clinical trial accrual:

> *In terms of the Native American population, we overlap with our outreach navigator, so we try to interface with her as much as possible to introduce screening opportunities to the Native population.* (Subcommittee member, Year 2)

> *We've had great success in clinical trials with bringing outreach to the community. Part of the new navigator's focus will be to inform patients about the clinical trials piece.* (Subcommittee member, Year 2)

> *Our navigators participated in the training that NCCCP did in clinical trials. Our navigators are very well versed. Every patient that they touch, they refer to be screened.* (Subcommittee member, Year 2)

8.4.1.3 Physician Involvement in Minority Clinical Trials Accrual

The work to increase clinical trials participation among disparate populations through outreach has been a team effort. In addition to the patient navigator, physicians have also played a role in addressing minority clinical trials accrual:

> *Having the physician and clinical research nurse together is key. When we are with the physician, the physician discusses the clinical trial first and then they call the nurse to discuss the clinical trial. I think that has been the most effective way.* (Subcommittee member, Year 2)

> *In terms of outreach, our physicians from minority populations do a lot of educating [for] patients who are underserved and having them talk and educate the groups.* (Subcommittee member, Year 2)

8.4.2 Coordination of Clinical Trials with Information Technology

As will be described in Chapter 10, the tracking of clinical trials data was a major priority during Years 1 and 2 of the pilot. During the Year 2 site visits, several sites were still behind in developing mechanisms to systematically collect race and ethnicity data per Office of Management and Budget (OMB) guidelines. Others have explored ways to enhance the functionality of their EHRs to assess eligibility for clinical trials. For example, one site was piloting a trial version of an EHR tool for one particular clinical trial:

> *They [physicians] were previously trying to track this [CT eligibility] by hand. The EHR addresses the medical oncology and radiation oncology and clinical trials solutions and could [be] integrate[d] into CT software pieces.* (Subcommittee member, Year 2)

In addition, a few sites have adopted various strategies to implement caBIG (see Chapter 12). Through the use of various caBIG suite applications, some sites have been able increase their technological abilities to manage and track clinical trials accrual:

> *With disparities, we implemented the [clinical trials management system] suite application that's being adapted to CT. We have already implemented the [cancer central clinical database] suite application. It will help us collect and manage all CT data points. We are looking at integrating [the] CT screening accrual log into our clinical trials tracking database tool.* (Subcommittee member, Year 2)

> *We are just starting. The first project is to implement the NCI tool, which is an imaging component of caBIG. The purpose is to archive all images relevant to patients in CTs.* (Subcommittee member, Year 2)

8.4.3 Coordination of Clinical Trials with Quality of Care

Described by many as the "gold standard" of care, clinical trials have been an important mechanism in achieving quality patient care. Some NCCCP sites have used their MDC conferences and/or clinics as a strategy through which to facilitate patient accrual into clinical trials. Many sites agree that clinical trials accrual is a necessary component of MDC. These MDC conferences often provide a useful venue for assessing patients for clinical trials eligibility:

> *When the breast cancer navigator gets a new referral, she shoots it over to my coordinator. Also, my coordinators attend all the tumor boards. We get the lists ahead of time and we're able to prescreen all those patients in clinical trials.* (Subcommittee member, Year 2)

> *We all agree that MDC is better care. It is better communication, more efficient, and focused on enrollment in clinical trials.* (PI, Year 2)

8.5 Coordination of Disparities Activities with Other NCCCP Components

As previously described, the majority of people working within sites to address disparities recognize this as a program component that should span all other areas of care. Respondents reported strategies their sites were using to create linkages between their efforts to address disparities and those to address biospecimens and clinical trials research. In addition, coordination with disparities and all other program components was evident.

8.5.1 Coordination of Disparities Activities with Information Technology

The convergence of disparities and IT has been most noticeable in the form of two implementation efforts: collection and tracking of OMB race and ethnicity data and the use of telemedicine.

8.5.1.1 Collection and Tracking of OMB Race and Ethnicity Data

OMB has standards for the classification of federal data on race and ethnicity (http://www.whitehouse.gov/omb/fedreg_race-ethnicity). Collection of these data, using the OMB categories, has been a national challenge, primarily because of the limited integration of IT systems within many U.S. hospitals and the inconsistency of data requirements to be reported to insurers by hospitals. Improving the collection of race and ethnicity data using OMB categories was a main priority of the NCCCP pilot in Year 2:

> *We were not tracking ethnicity or race in our database—we only started to do that last year. We have not followed OMB guidelines, and for us to really move forward we really need to have ethnicity first to meet OMB guidelines.* (Subcommittee member, Year 2)

By requiring sites to conform to OMB standards for collecting race and ethnicity data, it is hoped that sites may be better able to link these data to patient outcomes.

8.5.1.2 Telemedicine

NCI defines telemedicine as "the delivery of health care from a distance using electronic information and technology such as computers, cameras, videoconferencing, the Internet, satellite, and wireless communications". As mentioned in Chapters 10 and 13, sites have used telemedicine as an effective means to increase awareness of cancer screening and other important health issues to disparate populations (e.g., minority, rural, elderly):

> *For our area, everything that we do ties back into disparities because we're so rural and have so much outreach. When you're looking at IT, telemedicine is something big we can offer.* (Program coordinator, Year 2)

8.5.2 Coordination of Disparities Activities with Quality of Care

As with clinical trials, the importance of patient navigation has played a major role in linking disparities and QOC. During Years 1 and 2, there were two key areas of focus by the disparities subcommittee: outreach and patient navigation. These are described by the subcommittee as follows:

- Outreach involves getting people to obtain primary and secondary cancer prevention (e.g., smoking cessation, mammography). The pilot hopes to accomplish this by increasing community partnerships, primary care provider linkages, screening resources, and capacity.
- Patient navigation helps patients make their way through the health care system from the time of abnormal finding through treatment.

For some respondents, the connection between disparities and QOC was apparent:

> *Another piece that came out of this was we had the disparities committee and QOC committee partner to look at the needs regarding care navigation. The disparities group was looking at an outreach/educational standpoint, and my group was looking at [it] once the patient is diagnosed.* (Cancer center/program staff, Year 2)

> *There's a disparities link with QOC…[the] goal is to provide QOC to disparate populations. Tracking cancer endpoints and improving documentation will increase QOC for all patients. These boxes of committees are really "artificial" because there's so much overlap.* (Subcommittee member, Year 2)

8.5.3 Coordination of Disparities Activities with Survivorship/Palliative Care

Sites have primarily coordinated survivorship efforts with disparities staff. Respondents reported that they actively seek to incorporate disparate populations in survivorship activities, such as support groups:

> *We work really hard on outreach. Our difference and our uniqueness is that we are so spread out. We're reaching a greater number of patients…by doing our Partnership Through Survivors program using telemedicine.* (Subcommittee member, Year 2)

One site has relied on minority survivors to participate in focus groups and strategic planning initiatives:

> *In the application for the grant, one of the activities that will be supported is the education for minority groups on the concepts of palliative care, so one of the major activities that each site will be doing for specific groups is that they will be able to educate and bring palliative care to that group. Here, we will focus on the palliative care education for the African American community, and we will be targeting*

> *churches to make that available; and the other [focus] is the Hispanic community. We will be having people who are diverse in either culture or race as part of our focus groups as we develop our palliative care initiatives here.* (Subcommittee member, Year 2)

8.6 Coordination of Information Technology Activities with Other NCCCP Components

IT was clearly another program component for which sites were attempting to coordinate efforts with all other NCCCP components. Coordination efforts with clinical trials and biospecimens research, as well as disparities, have been previously described. There were also good examples of coordination efforts between their IT activities and those addressing QOC and survivorship/palliative care.

8.6.1 Coordination of Information Technology with Quality of Care

Data tracking systems, implementation of EHRs, telemedicine, and teleconferencing are just some of the IT efforts across sites that have been associated with affecting patient QOC. When asked about the ease of readily pulling data for QOC purposes, one PI responded:

> *Yes, we have everything from Excel spreadsheets to specific databases. We have a database for different disease sites and [staff member] keeps a database for a lot of the MDC information so we can look back and see the number of patients we've seen and self-referrals. We keep a log of that on a monthly basis.* (PI, Year 2)

Telemedicine not only has been a beneficial mechanism for reaching isolated and remote regions, it has also proven to be a useful communication tool between physicians:

> *This room we're in is linked by teleconference to other sites. If we are doing [the] multidisciplinary breast conference, we can link in with information to present cases from other sites. We are just starting to do this. I'm planning to begin to do that regularly, but still dealing with some IT difficulties.* (PI, Year 2)

8.6.2 Coordination of Information Technology with Survivorship/ Palliative Care

As indicated in Chapter 14, IT has been a significant factor in implementing the survivorship tools. Respondents felt that IT integration would help lessen the workload and ease survivorship data collection and post-treatment referrals:

> *IT is going to tie it all together so that we can develop survivorship programs, linking everything that person has had done through our MEDITECH program so they can take that information with them. We are in a transient area…and have people that come from other regions, so we want to make sure that they can take their medical records with them. So developing survivorship care plans is going to be tremendous,*

> *so we can lessen duplication and have a single populated EHR*. (Subcommittee member, Year 2)

However, several sites reported that the existing IT infrastructure and financial investment is insufficient for the amount of time, effort, and cost associated with developing a survivorship-compatible EHR:

> *On the survivorship piece, we're also looking at opportunities…we looked at how do we pull [diagnostic] information on those patients and get them into a system that can then have a plan? But again it's a challenge because there are all these disparate systems. Our health information exchange is going to play a major role in trying to pull these things together.* (Subcommittee member, Year 2)

Moreover, limited cancer center/physician access to patient data was perceived as a key barrier to pulling survivorship data:

> *Some of it involves networking with the EHR and connecting with the clinical registry and tumor registry. There were a lot of roadblocks on our own and concerns about confidentiality, and it took a long time to work out, and it seems to have been worked out, but people have limited access that I hope could be broadened. It's primarily for clinical trials and to coordinate the tumor registry more efficiently.* (Key physician, Year 2)

8.7 Coordination of Quality of Care with Survivorship/Palliative Care

Respondents indicated that tracking survivorship and palliative care information helped to improve the overall QOC for patients:

> *My partner and I also track what happens to patients: How many days did they stay in the hospital? Where did they go after they left the hospital? How often did they get readmitted to the hospital for similar symptoms? Tracking this information helps their treatment for readmission.* (Subcommittee member, Year 2)

Subcommittee members indicated that survivorship was a natural fit in the continuum of care for patients:

> *I've seen it as an individual. We talk about hospice as a continuum. I've seen it where it is initiated by the nurse and patient and family. In terms of strict guidelines, I am not aware that we use any algorithm. It's individualized. [Staff member] will see patients on any given day and follow up with the patients and can help when the patient isn't ready but the family needs them to go the hospice*. (Subcommittee member, Year 2)

It is important to note that respondents did not report any formal mechanisms for coordinating survivorship efforts with QOC. The majority of respondents simply pointed to existing activities that helped to improve care and did not indicate any additional activities due to or related to the NCCCP.

8.8 Facilitators to Coordinating across Components

Respondents noted several factors that have facilitated the cross-coordination of program components. Three main areas were identified:

- Hospital top management, cancer center leadership and physician support,
- NCCCP program-level support, and
- networking with other NCCCP sites.

8.8.1 Hospital Top Management, Cancer Center Physician Leadership and Physician Support

Several respondents cited the level of leadership support as a key factor for promoting the coordination of program components. This support was seen at various levels, including from the hospital, cancer center, and physicians:

> *We've had great leadership, specifically our [department] chairman. There was institutional buy-in for improving cancer care. It's a favorable revenue department, which creates buy-in. The institution wouldn't be pushing if it weren't for leadership from within the department.* (Key physician, Year 3)

> *The highest level of support is the [hospital's] community board. I don't think there are any more enthusiastic people than the board; there just isn't. There's some smart business people on the board. It's hard to explain and hard to understand; these people [the board] have never had cancer before, but they want a top-notch cancer center. It's high on their priority.* (Key physician, Year 3)

> *Navigation was one of the first things where we have partnered with others and really reached fruition immediately. It works with increasing physician buy-in.* (PI, Year 3)

8.8.2 NCCCP Program-Level Support

In sharing their perspectives on what has aided the cross-coordination of program components, respondents overwhelmingly attributed the dedication and commitment of program leadership and staff:

> *The support has been more during the last year, which is due to the higher visibility of both [the PI] and [program coordinator] in different forums and being able to share very concrete metrics. The other [factor] is having more staff involved that*

> *aren't necessarily NCCCP-funded in our conference calls and meetings. We decided [to do this] a year ago, when I realized that staff support the NCCCP mission, regardless of funding stream.* (Program coordinator, Year 3)

> *There's been organization within the pillars because they've been able to bring in dedicated staff to those positions.* (Subcommittee member, Year 3)

Sites pride themselves on the staff that have remained committed to the NCCCP goals and vision. Respondents' understanding of this vision has been largely focused on the need to streamline efforts across program components.

8.8.3 Networking with Other NCCCP Sites

According to respondents across the sites, one facilitating factor for improving the cross-coordination across components was networking with other NCCCP sites:

> *I was thinking, when I went into this, "What's it going to do for us here?" There was great congruency between what we wanted to do with our program and the pillars. We were building budgets and making investments that took us right in that direction. I didn't understand biospecimens or caBIG—and I still don't know a lot—but I understand the power of networking. That's probably the piece I underestimated…how building your networks can fuel your efforts.* (System/hospital senior executives, Year 3)

> *The major benefits of linkages are having the learning opportunity to see how others are doing things and thinking about what [we] can accomplish…Partnership and collaboration with others that are outside your competitive sphere [allows you to] be free and open about struggles and challenges.* (Program coordinator, Year 3)

This relationship-building with other community cancer centers was described by some respondents as "powerful" and provided an opportunity to "expedite changes that were really important."

8.9 Barriers to Coordinating across Components

Potential barriers and solutions often arise through repeated interactions within and across teams and organizations, making communication and coordination very important. During the Year 3 site visits, there were two major barriers presented to coordinating across the various program components: staff burden and a lack of shared NCCCP vision.

8.9.1 Staff Burden

The extra burden placed on existing staff and the limited resources available to hire new staff have been challenging in effectively managing day-to-day operations and coordination between components. Given competing staff priorities, several sites have opted to meet less frequently and convene for NCCCP updates only via individual subcommittee meetings:

> *It's hard. [Staff member] tries to do a good job, but everybody's busy and you get 30 e-mails a day, and then I don't have time to respond to something. How people are in different places makes it difficult for people to get together to have discussions.* (Key physician, Year 2)

> *The NCCCP team hasn't met all together for a while. People either didn't have time or didn't attend given competing priorities.* (PI, Year 3)

> *There was a period of time when we were having regular meetings. We get updates as far as the number of patients we are screening for clinical trials. We stay very well informed. As a broader program, I can't say we are up to date.* (Key physician, Year 3)

8.9.2 Lack of Clarity about NCCCP Vision

As discussed in Chapter 5, a lack of clarity about NCCCP goals and vision still remained across some sites in Year 3. This lack of vision presented conflicting perceptions about the role of the NCCCP and its possible impact on how well sites have been able to coordinate across program components:

> *I think some of the negative things that came as an outcropping [were that] some folks perceived that [the] NCCCP took precedence over everything, and others felt like their areas of responsibility were not appropriately integrated with the goals of [the] NCCCP. New staff brought enthusiasm to impart the vision of the future to them. Again, so we had people who were already here [and we] assigned them with subcommittees, and they never understood how they fit into [the] NCCCP.* (Program coordinator, Year 3)

8.10 Summary

The level of coordination among NCCCP components has generally been high. Staff members are "making the link" between components, which was not as apparent during Years 1 and 2 of the pilot, and respondents shared lessons learned in the process:

> *When I came in, I had to earn the trust of the team. I think I came off too hard in the beginning versus letting people evolve…Team building has to evolve. You can't force it. You have to know the players.* (Program coordinator, Year 3)

> *I feel like we're coordinating better across the NCCCP team now. When I saw that [the] disparities and quality of care [committees] were both working on navigation, I would say, "These two groups need to get together." I make the link…I wasn't great at that the first year.* (Program coordinator, Year 3)

Several respondents expressed the benefits sites realized by encouraging synergies between program components. These sentiments were motivated by the need to decrease

redundancy, improve cancer care, enhance program efficiency, and reach the aims of the NCCCP:

> *[The NCCCP] has allowed us to go in directions that we might not have gone [in] and allowed us to be creative when we weren't at a creative point in our development.* (Program coordinator, Year 3)

> *Oncology services have been elevated as a strategic priority overall as a result of participating [in the NCCCP]. There has never been this type of infrastructure. Our hospital likes it because it has high visibility, includes research, and focuses on taking care of the poor. We have handfuls of centers of excellence, including oncology, and we see oncology as one of our top three priorities.* (System/hospital senior executives, Year 3)

Lastly, several respondents offered recommendations for NCI in helping to provide sites with basic guidance for coordinating across program components. Although NCI was deliberately not prescriptive with implementation protocol for the NCCCP pilot, there was general agreement among respondents on the need for a clear translation of what NCI wants to accomplish when the mutual responsibilities and benefits are discussed:

> *In the first 2 years, [NCI] looked to throw it out to us and say "make this work." If you are going to look at a community hospital, you need to look at where the funding is and what the realistic expectations are. The resources are allocated completely differently between the academic medical and community cancer center.* (Program coordinator, Year 3)

> *The first year of the pilot required a lot of figuring out how things were in the first year. NCI should spend more time figuring things out beforehand. But, [I] recognize that was part of being a pilot.* (PI, Year 3)

Part III: Implementation of NCCCP Program Components

9. DISPARITIES

Overview

A major focus of the NCCCP is on addressing health disparities. NCI established the following priorities for the disparities program component: (1) enhancing outreach to increase the underserved population's participation in primary and secondary cancer prevention and (2) developing and strengthening patient navigation programs. As a cross-cutting program component, disparities activities and metrics were defined for each of the other program components (e.g., increasing minority accrual as a metric linked with the clinical trials program component).

Early in the pilot, sites struggled to identify and prioritize underserved populations in their communities. Most sites had few (or no) outreach staff focusing on cancer prior to the NCCCP at the start of the program, so it took some time to develop priorities and effective strategies for their disparities work. Sites were initially frustrated by what they perceived as lack of clear direction from NCI with regards to this program component. The *Disparities Dashboard* and other tools provided helpful guidance to sites as they developed the disparities program.

Improving Race and Ethnicity Data Collection

Improving collection of race and ethnicity data for screening, clinical trials and other systems was a first step for the sites to track and evaluate disparities activities and presented a significant challenge for most sites. At the start of the pilot, few sites were tracking race and ethnicity using the standard OMB categories. Interview respondents reported a number of challenges to changing their reporting systems, including various IT issues and lack of top management support. By Year 3, sites had made significant progress in collecting race and ethnicity data. As reported in the Final Assessment Survey, all sites were using the standard OMB categories for NCI clinical trials (which was required), and the majority of sites were also doing so for other systems (e.g., non-NCI clinical trials, screening programs, hospital admissions).

Building Community Partnerships and Enhancing Patient Navigation

By Year 3, most sites felt they had made real progress in disparities and "gained traction" in terms of building partnerships and relationships in underserved communities. Specific accomplishments were as follows:

Although there were slight increases in some sites for minority accruals to clinical trials, the overall numbers remained low, with an average of seven per site in Year 3. In the CT special study conducted by Abernethy and Locke (2011) using CTEP data, findings indicated that accrual in both race/ethnic groups and patients 65 years of age or older increased across the NCCCP sites. At baseline, CTEP data showed an accrual of 83 patients classified as "racial/ethnic minority," which rose steadily to 151 in Year 3. The accrual of patients classified as "age 65 or over" increased more dramatically from 200 in Year 2 to 641 in Year 3. Barriers to minority accruals are well documented, and it takes to build relationships and trust in underserved communities necessary to increase enrollment.

Relationships between Staffing and Disparities Outcomes

We examined relationships between staffing—numbers (and changes in numbers) of outreach workers and patient navigators—and disparities outcomes. In general, we did not find clear patterns between staffing and changes in partnerships, screenings, or numbers of patients navigated.

Challenges and Sustainability

Sites faced challenges to implementation of the disparities program component, including IT systems barriers to collection of race/ethnicity data across different systems. Sites also found that it required significant time to develop partnerships—especially formalized partnerships—and trust in underserved communities. Of all the program components, respondents considered the disparities program, specifically the outreach and screening activities, to be most "at risk" if NCCCP funding ends because the outreach staff were largely funded through the NCCCP. In contrast, respondents thought that patient navigation was more likely "here to stay" because this model improved patient satisfaction and retention.

A major focus of the NCCCP is on addressing health disparities, defined by NCI as "differences in the incidence, prevalence, mortality, and burden of cancer and related adverse health conditions that exist among specific population groups in the United States" (http://ncccp.cancer.gov/about/). For the NCCCP, the Executive Subcommittee defined the populations affected by health disparities to include racial and ethnic minorities, and other underserved populations: residents of rural areas, women, children, the elderly, persons with disabilities, the uninsured, the underinsured, and those who are socioeconomically disadvantaged.

Racial and ethnic disparities in cancer care have been well documented (AHRQ, 2010). Racial and ethnic minority populations are less likely to receive cancer screening tests than whites; as a result, they are more likely to be diagnosed with late-stage cancer (AHRQ, 2010; Berry et al., 2009; Chornokur et al., 2011). For those with a positive test result, racial and ethnic minorities are more likely to experience delays in receiving the diagnostic tests needed to confirm a cancer diagnosis (AHRQ, 2010, Allard & Maxwell, 2009; Ries et al., 2003; Battaglia et al., 2007). Similarly, disparities are found in primary cancer treatment as well as appropriate adjuvant therapy (AHRQ, 2010; Terplan et al., 2009). Disparities in cancer care among other populations, such as rural populations, the elderly, and the disabled, have also been well documented. For example, elderly African Americans are less likely than whites to receive PSA screening for prostate cancer (Gilligan et al.,

2004) and screening tests for colorectal cancer (Cooper & Koroukian, 2004). African American Medicare patients are less likely than whites to receive chemotherapy for colorectal cancer (Baldwin et al., 2005) and surgical treatment for early-stage lung cancer (Bach et al., 1999; Lathan et al., 2006). Although African American populations have been more frequently studied, comparable disparities have been noted for other minority groups (AHRQ, 2010).

The NCCCP disparities program component was envisioned as cross-cutting, spanning across all other program components. The goal of the disparities component was to actively reach out to underserved populations and bring more Americans into the system of care to help NCI better understand and address the underlying causes of cancer health disparities. The NCCCP Executive Subcommittee defined the "vision" of the disparities work as being "to expand state-of-the-art cancer care and research to populations experiencing healthcare disparities (those with an excess burden from cancer) across the continuum, from prevention and screening through treatment, follow-up and end of life care (see Appendix K).

The following are the specific requirements and priority initiatives for the disparities program component, as defined in the *Disparities Vision, Program Overview, and Dashboard* (hereafter referred to as the *Disparities Dashboard*):

- offer treatment to all patients screened and diagnosed with cancer by sites (required);
- implement race and ethnicity tracking using OMB categories;
- support underserved accrual to clinical trials; and
- support improved linkages between outreach, treatment, and survivorship navigation with a focus on underserved populations.

Addressing health disparities in the NCCCP communities is complex and approaches and priorities differ depending on the underserved populations. The participating hospitals are situated in different types of communities, and the underserved populations vary from rural populations to the elderly, different racial and ethnic minorities, and others. For this reason, at the start of the program, the approach to addressing the disparities component across sites was formative and somewhat less defined than for other components. The formative process included thoroughly assessing each site's history and capacity to address disparities, then determining priorities and strategies. This formative work was accomplished through the Disparities Vision Planning Group, which comprised leaders across NCI who serve on the NCCCP Program Advisory Committee (NPAC) and representatives from some sites. This group developed the *Disparities Vision and Program Overview* to provide sites with specific direction about how to focus their disparities efforts including guidance for community outreach. With input from all NCCCP subcommittee, a *Disparities Dashboard* was also developed (see Section 9.1).

9.1 NCCCP Disparities Subcommittee Priorities and Strategies

The NCCCP disparities subcommittee provided oversight and input into the disparities activities across the pilot sites. The subcommittee worked with the sites in the following priority areas for the disparities component:

- **Enhancing outreach to increase the underserved populations' participation in primary and secondary cancer prevention** (e.g., smoking cessation, screening). The strategy was to develop local partnerships, linkages with primary care providers, and screening resources, and to increase outreach staffing capacity.
- **Developing and strengthening patient navigation programs** that help patients make their way through the health care system from the time of abnormal finding through treatment and survivorship. Patient navigation is intended to improve coordination of care and ensure that all patients receive appropriate and timely care.[1]

At baseline, most sites were not systematically tracking racial and ethnic data across different services and programs (e.g., screening, navigation, clinical trials), and they were not using standard Office of Management and Budget (OMB) categories for race/ethnicity. Developing this capacity was essential so that sites could assess the extent to which they were providing services to and meeting the needs of their target populations. NCI determined that, at the outset of the program, the sites should focus on data collection for disparities, specifically collecting race and ethnicity data and tracking patients across the continuum of care, and on setting priorities and determining strategies for their disparities work. Thus, NCI developed the *Disparities Dashboard*, which established priorities and specified metrics for ensuring that disparities issues were addressed in the biospecimens, clinical trials, information technology, quality of care, and survivorship components (see Appendix K). The *Disparities Dashboard* was intended as a tool to guide sites in planning and managing initiatives to address health care disparities. Specifically, the purpose of the *Disparities Dashboard* was to

- present a framework for the disparities efforts and provide a summary of activities,
- assist with coordination and minimize duplication of effort,
- serve as a planning tool so that the pilot activities are noted on a timeline,
- note the technical support that is needed to support activities,
- track specific activities by pilot pillar, and
- provide a set of standard metrics.

[1] Note that patient navigation also addresses quality of care; for purposes of this evaluation navigation is discussed in the context of the disparities program component as it was defined as a priority area for this component.

9.1.1 Priority 1: Enhance Outreach Efforts

For most of the hospitals selected for the NCCCP, community outreach to increase participation in screening was not a major focus prior to participation in the program. According to the Baseline Assessment Survey (BAS), sites had an average of about three staff members involved in outreach at the start of the program, and four sites did not have any staff involved in outreach. By Year 3, all but one site had dedicated outreach staff (see Section 9.4.4 for discussion of changes in outreach staff over the course of the pilot). Most sites were already partnering with some local organizations at the start of the program; excluding one outlier site that reported 117 partners, on average sites had six local partners. Over the course of the pilot, on average, sites increased the number of community partners (see Section 9.4.2 for discussion of changes in partnerships over the course of the pilot). At the time the program started, 7 sites had active community advisory groups for cancer "focused on the needs of the underserved"; by Year 3, 11 sites had established such advisory groups.

As part of their outreach efforts, sites were expected to increase cancer screenings to improve early detection of cancer. Outreach efforts can increase screening rates among underserved populations, leading to earlier detection and better outcomes (Engelstad et al., 2005; Gabram et al., 2008; Lasser et al., 2009). At the time of the BAS, most sites offered mammography screening (14 of 16 or 87.5%), 12 provided colorectal cancer screening (with 3 specifying that this service included only fecal occult blood tests [FOBT]), 12 provided prostate cancer screening through prostate-specific antigen (PSA) tests, and 5 provided Pap smears. By Year 3, all 16 sites offered mammography and colorectal cancer screening (including FOBT, sigmoidoscopy, and/or colonoscopy), 14 sites offered prostate cancer screening through PSA tests, and 10 provided Pap smears.

NCI developed a Template for Community Outreach as part of the *Disparities Vision and Program Overview* (http://ncccp.cancer.gov/about/reports-and-tools.htm), which outlines a suggested process for planning, implementing, and evaluating focused community outreach efforts targeting specific cancer care disparities in underserved populations.

9.1.2 Priority 2: Develop and Strengthen Patient Navigation

Patient navigation programs have gained attention in the past decade as a way to address cancer disparities and improve quality of care (Dohran & Schrag, 2005; Institute for Alternative Futures, 2007; Marcus et al., 2011; Vargas et al., 2008; Wilcox & Bruce, 2010). The patient navigation programs originally developed by Dr. Harold Freeman in Harlem were specific to women who had had a breast abnormality identified with the goal of decreasing the time from diagnosis of an abnormality breast cancer patients and initiation of treatment. His program was delivered by lay people (Freeman, Muth, & Kerner, 1995). Patient navigation has been shown to be an effective approach to reducing the time of delivery of care, beginning with follow-up of abnormal screening results (Robinson-White et al., 2010;

Zapka et al., 2010). As the evolution of cancer care delivery becomes more complex and multifaceted, patient navigation has taken on an increasingly important role in the coordination of patients' cancer care across the continuum (Hede, 2006). Since that time, patient navigation programs have evolved to span the cancer care continuum, and services continue to be provided in some cases by lay people or by a range of professionals, including nurses and social workers. NCI defines patient navigation in cancer care as "the assistance offered to health care consumers (patients, survivors, families, and caregivers) to help them access care and then chart a course through the health care system and overcome any barriers to quality care" (http://nci.nih.gov/cancertopics/factsheet/NCI/Fs1_25.pdf).

At the start of the program, 13 sites reported providing patient navigation services to at least some patients. Sites varied in how they defined the role of a patient navigator. Most sites had this person focus on coordinating patient care for those diagnosed with treatment and had nurses working in these positions. However, some sites defined patient navigators as those who were focused on setting up cancer screening programs and guiding people through the process of screening to the point of diagnosis of any abnormalities. Across the different programs, only five sites had systems in place to track and report the numbers of patients navigated. The status of patient navigation services by Year 3 of the pilot is discussed in Section 9.4.6.

9.2 Development and Use of Disparities Tools

The disparities subcommittee created workgroups to develop tools to track and assess cancer care for the underserved. During the Year 2 site visits, respondents were asked to provide feedback on two tools developed by the disparities subcommittee and share whether and how they had used the tools:

- **The Breast Cancer Screening Tracking Tool** (Appendix L) was developed to provide a mechanism for monitoring the time from initial screening to diagnosis and care, and recruitment for clinical trials, particularly for the underserved. This tool was voluntary and offered as a guide for sites.
- **The *Disparities Dashboard*** (Appendix K), as discussed in Section 9.1, establishes priorities and specified metrics for ensuring that disparities issues were addressed in the biospecimens, clinical trials, information technology, quality of care, and survivorship components (see Appendix K).

9.2.1 Breast Cancer Screening Tracking Tool

The Breast Cancer Screening Tracking Tool was designed for sites to systematically track women participating in mammography screening. Using the tool, sites can collect characteristics of women who are screened and track screening outcomes and any follow-up diagnostic care received.

We found that most sites had previously developed their own systems for tracking screening participants. Some sites preferred to continue use of their own tools. Other sites adopted the Breast Cancer Screening Tracking Tool developed by the subcommittee. One respondent explained the choice to use the newly developed tool as follows:

> *The breast cancer screening log is one that our IT guy helped set up, so we implemented it immediately. … We will use that tool for our assessment about how minority patients are evaluated in our breast program. That tool facilitates bringing out that information.* (PI, Year 2)

Although all of the sites were aware of the Breast Cancer Screening Tracking Tool, some sites chose not to adopt it because they already had their own systems in place or because of IT or other challenges:

> *The breast screening tool—we did not implement this. I met with key people in our system and said, "Do we need to use this for tracking?" and the answer was at this point "no." We have a mammography queue that tracks a lot of this data, and I'm working with the data people to see if we can get some key information out versus using the tool.* (Subcommittee member, Year 2)

> *[The] colorectal tracking tool and breast tracking tool—we had high hopes that we could use our EHR for that. We have struggled with abstracting data that we want the way we want it. We're using it in a manual form and we're continuing to work and try and get it in an electronic form.* (Cancer center/program staff, Year 2)

> *The Breast [Cancer] Screening Tracking Tool is difficult to do without a data system to support it. We have a lot of IT challenges.* (Subcommittee member, Year 2)

> *We've implemented the breast tracking tool, but it's manual. It's an Excel sheet, so trying to pull data points out of it is hard.* (Program coordinator, Year 2)

9.2.2 Disparities Dashboard

Sites were aware of the *Disparities Dashboard*, and some respondents said it was helpful in terms of understanding the metrics and what they had to track:

> *The NCCCP Disparities Dashboard was really helpful at giving some concrete [indicators] so you can see across the pillars some understanding of what it means for disparities.* (Subcommittee member, Year 2)

> *After we reviewed it and got familiar with it, we realized we were already doing it, so it kept us in check.* (Subcommittee member, Year 2)

However, some sites were unsure how to use the dashboard or apply it their site and wanted more guidance from NCI:

> *[NCI] introduced the Disparities Dashboard quite a few months ago, and we didn't hear much more about it until a recent call. They didn't really tell us how to use it—they introduced it, but didn't give a lot of dialogue behind it.* (Subcommittee member, Year 2)

> *It came from the Executive Committee, and they created this Disparities Vision Dashboard. They just talked about it on the last call on [recent date] asking if everyone is going to implement it. So sometimes when they ask questions like that, we have to ask, "When do you want us to implement it? How do you want us to implement it? What's your vision for this?"* (Subcommittee member, Year 2)

9.3 Disparities Implementation across NCCCP Sites

Over the pilot period, sites used various strategies to meet the disparities priorities set forth by NCI and the subcommittee. In this section, we discuss sites' approaches to increasing outreach and establishing or strengthening patient navigation and coordination of care.

9.3.1 Increase Outreach

As part of their efforts to increase outreach, sites focused on developing new local partnerships and strengthening existing partnerships. These partnerships generally focused on screening specific populations depending on the constituency of each partner organization. All but one site noted a marked increase in the number of partnerships over the course of the pilot (see discussion of changes in numbers of partnerships in Section 9.4.2). The sites developed partnerships with the following types of organizations:

- state cancer programs,
- NCI-designated cancer centers and Community Networks Programs (see Chapter 15),
- foundations (e.g., Susan G. Komen Foundation, Lance Armstrong Foundation),
- nonprofit cancer advocacy organizations (e.g., American Cancer Society),
- area clinics or screening facilities,
- other local hospitals,
- physician groups,
- organizations serving and representing special populations (e.g., 100 Black Men, Santiago, faith communities),
- federal government agencies or programs (e.g., Indian Health Service, Head Start programs), and
- local businesses, both large (e.g., Walmart, casinos, grocery stores) and small (e.g., barber shops, beauty salons).

Sites reached out to potential partners to explore areas of mutual interest and possible collaborative activities. In some cases, key physicians made the contacts through their work on boards and workgroups of local agencies. Cancer center staff and physicians explained how the partnership could benefit the partner organization and its constituents:

> *One of the things for the rural elderly—I sit on a regional health workgroup for [city]—there are 24 regional hospitals represented [owned, managed, or leased by the city], and we've been very intentional about telling them about NCCCP and the [multidisciplinary care] conferences and brought them here to see the services that we could offer, hopefully increasing their knowledge too about how to care for these patients—because we may care for the patients here, but then when they go home they may have issues—and how to treat the patient in their local areas should issues arise.* (Key physician, Year 2)

Respondents gave examples of the synergies created by working with partner organizations:

> *The other thing we have done is partnered with the outreach program, and we had the first Minority Cancer Awareness Day, which the cancer program of [two local hospitals] sponsored on [date]. Clinical research had never been a part of any of these outreach opportunities, so this was our first time to participate in that. We had a clinical research nurse who is Spanish speaking, so she could go out into the community to help patients who spoke no English to help sign up patients to the breast cancer screening program.* (Cancer center/program staff, Year 2)

9.3.2 Establish or Strengthen Patient Navigation and Coordination of Care

Patient navigators are engaged in coordinating patient care across the cancer care continuum beginning with follow-up of abnormal screening results and through treatment, and, in some cases, survivorship. Figure 9-1 provides a summary of the roles and responsibilities of patient navigators across different points in care.

Figure 9-1. NCCCP Patient Navigator Roles/Responsibilities at Different Points in Care[a]

Phases of Cancer Care Continuum	Roles/Responsibilities
Screening to diagnosis	▪ Arranges physician appointments for follow-up of abnormal screening results, including further diagnostic procedures ▪ Links patients to financial resources ▪ Arranges for patients' transportation and/or childcare during scheduled appointments ▪ Arranges for translation/interpretation services ▪ Provides patients with screening results, as appropriate
Treatment	▪ Assists patients to initiate treatment if diagnosed ▪ Arranges physician appointments for treatment ▪ Links patients to financial resources ▪ Arranges for patients' transportation and/or childcare during scheduled appointments ▪ Arranges for translation/interpretation services
Follow-up/Survivorship	▪ Links patients and families with appropriate follow-up services ▪ Reminds patients of follow-up appointments ▪ Communicates with providers to ensure follow-up care plan is provided ▪ Educates patients on follow-up care plans

[a] As reported in the BAS, IAS, and FAS.

Respondents described the important roles that patient navigators play in the community and throughout patient care. Patient navigators work closely with providers in various ways to coordinate patient care:

> *[The patient navigator] will do outreach into communities with prevention, education, and screening. She also works closely with the resources in those communities.* (Program coordinator, Year 2)

> *[Patient care coordinators] may follow the patient wherever they go. Our stand is you go where the patient is. If the patient needs you to hold their hand while they're getting a CT scan, you go do that. We don't care where the patient came from, we'll get involved.* (Program coordinator, Year 2)

> *The breast health coordinator is located in the diagnostic center and provides calls to patients to come back for diagnostic screening. She calls the [physicians] with results and educates them on breast health. She's with the radiologist when [the patients] are told [that they have] cancer*. (Subcommittee member, Year 2)

> *If someone is diagnosed with cancer in [city], she will link them with physicians there. She is finding out about resources in the community, so she can help promote them.* (Program coordinator, Year 3)

> *Our nurse navigator communicates with surgeons and family practice physicians and has gotten her name out there, so we have gotten calls that way from the physicians prior to patients visiting the cancer center and prior to their surgeries.* (PI, Year 2)

Several respondents said that patient navigators help to identify and refer patients to appropriate clinical trials. In states where clinical trials participation is not covered by private insurers, navigators may be able to assist patients with identifying financial resources:

> *A lot of navigators refer patients to clinical trials, so that deals with underserved [populations], because a lot of times insurance doesn't cover clinical trials.* (Program coordinator, Year 2)

> *[We've] had great success in clinical trials with bringing outreach to the community. Part of the new navigator's focus will be to inform patients about the clinical trials piece.* (Subcommittee member, Year 2)

> *Now, [disparities is] the other component that I felt was lacking, and philosophically [it] is a closer relationship with the nurse navigators, who are the face of clinical trials and care for the institution. The nurse navigators work closely with our nurses to be supportive of research. At every [multidisciplinary care conference], they sit at the table. They review all patients prior to the conference and review [the] current clinical trials available.* (Subcommittee member, Year 2)

One site took another approach to improving coordination of care for disparate populations with the development of a multidisciplinary clinic for underserved populations. The program coordinator discussed the success of this approach:

> *One of the coolest things is our underserved multidisciplinary care clinic for low-income populations. That's even helped us from a clinical trials point of view because we have access to those patients and can screen them quickly.* (Cancer center/program staff, Year 3)

9.4 Overall Success in Disparities Implementation

For the purposes of the evaluation, success in disparities program implementation encompasses achievements in the following areas:

- collecting race/ethnicity data for cancer patients at different points in care (e.g., screening, navigation, clinical trials referral),
- increasing the number of community partners,

- increasing the number of cancer screenings,
- improving access to care,
- establishing or expanding patient navigation services,
- increasing the numbers of racial and ethnic minorities enrolled in clinical trials, and
- improving adherence to QOC standards for breast and colorectal care for all patients.

In the following sections, we present evaluation findings related to each of these areas. We also present data about staffing to support these disparities activities, specifically the numbers of staff focusing on outreach and the numbers of patient navigators.

9.4.1 Collecting Race/Ethnicity Data

One of the disparities requirements of the NCCCP was for all sites to track race and ethnicity data by Year 3, preferably using standard OMB categories.[2] Tracking refers to the ability to routinely identify and collect race/ethnicity for all patients across multiple points of patient contact (e.g., screening, hospital admission, clinical trials). Ideally, race/ethnicity is collected through patient self-report (as opposed to hospital staff inferring the patient's race/ethnicity) according to standard OMB categories. Table 9-1 presents the number of sites tracking race/ethnicity for different hospital department systems (e.g., hospital admitting, outpatient registration) by any means, by patient self-report, and according to OMB categories for Years 1 and 3. At the start of the program, sites were most likely to report tracking race/ethnicity data (by any means) for hospital admissions and outpatient registration (12 and 10 sites respectively) (see Table 9-1). However, few sites were using standard OMB categories to track race/ethnicity data for these systems (three and two sites, respectively). Over the course of the pilot, collection of race/ethnicity data using the preferred approach (i.e., patient self-report and using OMB categories) increased for all systems. Sites were most likely to report race/ethnicity tracking using OMB categories for clinical trials (16 sites for NCI trials and 14 sites for non-NCI trials) and screening programs (15 sites).

Table 9-2 presents the number of systems (e.g., hospital admission, outpatient registration) for which each site tracked race/ethnicity data by any means, by patient self-report, and using standard OMB categories in Years 1 and 3. Sites could potentially track race/ethnicity for up to nine different systems: hospital admission, outpatient registration, cancer center patient registration, screening programs, survivorship programs, nurse navigation, NCI clinical trials, non-NCI clinical trials, and cancer center medical staff offices. The mean number of systems for which sites tracked race/ethnicity using OMB categories increased

[2] The five OMB race categories are Black or African American, White, Asian, American Indian or Alaska Native, and Native Hawaiian or Other Pacific Islander. The only ethnicity choice is one of "yes" or "no" to Hispanic/Latino ethnicity.

from two in Year 1 to seven in Year 3. The mean number of systems for which sites tracked race/ethnicity using patient self-report increased from two to six (see Table 9-2).

Sites faced a number of challenges in tracking race/ethnicity by OMB category across all services. For example, sites had to gain buy-in from top management and private practice physicians to change long-standing protocols in order to collect race/ethnicity data. Many sites also had to deal with multiple data systems that essentially prohibited them from developing a standardized system for collecting race/ethnicity data. These and other barriers are discussed in Section 9.6.

9.4.2 Increasing the Number of Community Partners

As discussed in Section 9.3, sites worked with community partners to expand their outreach efforts and increase access to screening for underserved populations. During the summer of 2011, SAIC-F asked sites to complete some tables indicating their outcomes for specific measures to be included in this evaluation. Since data previously collected for community partners was somewhat incomplete, this was an outcome where SAIC-F requested some clarifications from sites. In the outcomes worksheet provided to sites, they were asked to provide counts of their community partners, defined as "an organization or group that agrees to collaborate with the NCCCP sites to reach the public in support of the work of a healthcare or cancer initiative, especially with a focus on minority and underserved populations". Table 9-3 presents the total number of community partners and the number of formal community partners as reported by the sites for Years 1 and 3. The table also indicates how many of these partnerships focused on underserved populations. Formal community partners refer to those that involve "an ongoing relationship with a formal agreement or Memorandum of Understanding (MOU) to provide specific services to the community with a defined outcome." Informal partnerships could involve a limited collaboration or a new partnership that may become more formalized over time.

All but one site reported increases in their total number of community partners from Year 1 to Year 3. The numbers of community partners reported by sites spanned a wide range, from fewer than 10 partners in 4 sites to 123 partners reported by 1 site for Year 3. The median number of partners increased from 5 to 16 from Years 1 to 3 (median is a more useful measure than mean in this case given the one outlier site with a large number of partners). These large differences may in part be due to sites' interpretation of what constitutes a partnership. For example, some sites may have counted an organization as a partner if they conducted a single activity together (e.g., a one-time screening or educational event), whereas other sites may not have counted an organization as a partner in this situation.

For the purpose of the disparities program, it is most informative to examine community partnerships that focus specifically on the underserved. All but two sites reported increases in these partnerships from Year 1 to Year 3. Sites reported from 2 to more than 50

community partners focusing on the underserved. Fewer sites reported formal partnerships focusing on the underserved (from 0 such partnerships in 4 sites to 14 in 1 site). The smaller number of formal partnerships focusing on the underserved may have implications for the sustainability of the sites' outreach efforts. An informal partnership may involve a one-time collaboration rather than an ongoing partnership that will impact the cancer center's ability to reach and better meet the needs of targeted populations.

9.4.3 Increasing Cancer Screening

Increasing cancer screening is an important focus area for the NCCCP in order to increase early detection and potentially improve timely initiation of treatment. For the evaluation, we examined both the number of screenings and the number of screening events in each site. Each of these measures has some limitations, as discussed below.

Over the pilot period, the number of cancer screenings conducted annually by the cancer centers—either directly or in conjunction with community partners—increased in all but one site (see Table 9-4). The reported volume of screenings at baseline varied widely, from none at Site 14 to almost 17,000 at Site 1. The percent change in the number of screenings over the pilot period ranged from 13% (Site 4) to more than 400% at Site 16. In comparing the percent change across different sites, it is important to note the baseline levels. For example, at Site 4 the percent change was modest (13%); however, given the large number of screenings in Year 1, the actual change in the number of screenings was one of the highest (7,006 more screenings in Year 3 than Year 1).

Another way to assess the sites' progress in expanding screening is to examine the number of screening events (see Table 9-4). From Year 1 to Year 3, the number of screening events increased in 10 sites, stayed the same in 3 sites, and decreased in 3 sites. The reported number of screening events in Year 3 spanned a wide range, from 2 events each at Site 2 and Site 13 to 484 events at Site 9.

In interpreting the findings, it is important to note some limitations of these screening data. First, sites reported their Year 1 number of screenings and number of screening events on the Interim Assessment Survey (IAS), so there may be issues with accuracy due to the time lag in reporting. Second, sites may have taken somewhat different approaches to which screenings or screening events they counted as "theirs" when screening was conducted in conjunction with a community organization. Third, in terms of the count of screenings, counts likely reflects the number of screening tests completed rather than the number of individuals screened. Thus, individuals who underwent more than one type of screening test could have been double-counted. In addition, some sites included screenings done as part of routine physical exams, while others counted only the number of individuals reached via screening events. Finally, in terms of the counts of screening events, what sites counted as events could vary both in terms of the number of individuals screened and the number of

different types of cancer screenings offered. Thus, comparing the number of screening events across sites is not straightforward.

9.4.4 Staffing to Support Outreach Activities

Conducting outreach activities is dependent on having sufficient staff who can dedicate their time to it. Table 9-5 presents the number of staff focusing on outreach in Years 1 and 3. For this analysis, we considered site staff who focused exclusively or largely on outreach activities, and excluded those who played only a limited role in outreach (e.g., clinicians who sometimes conduct outreach screenings). We based these decisions on job titles and roles as well as knowledge of the sites. However, there may still be some inconsistencies across sites and over time in the types of roles each site counted as focusing on outreach (e.g., outreach directors, outreach coordinators, community health workers, transportation coordinators, health educators, mobile mammography coordinators).

At the start of the program, four sites did not have any outreach staff, and the mean number of staff focusing on outreach was three. By Year 3, all but one site had at least one outreach staff person; however, the mean number was unchanged, and five sites saw a decrease in outreach staff (Site 6, Site 1, Site 11, Site 7, and Site 2).

We examined the relationships between the number of outreach staff and the expected outcomes: increases in the number of partnerships and the number of screenings and screening events (see Table 9-6). No clear patterns emerged. In only three sites, an increase in the number of outreach workers was associated with an increase in the number of formal community partners focused on the underserved, the number of screenings, and the number of screening events. For example, Site 4 added four outreach staff and there was an increase of 2 community partners, a 13% increase in the number of screenings, and a 320% increase in the number of screening events. However, we did not find this pattern in other sites. For example, Site 13 had no outreach workers as of Year 3, yet there had been an increase in both the number of community partners and the number of screenings. These findings suggest that other factors—in addition to the number of outreach workers—determine success in terms of building partnerships and expanding cancer screening. Support of senior executives and involvement of key physicians are also critical (see discussion of leadership support and physician involvement in Section 9.8). For example, through their roles in community boards and committees, key physicians help to forge community partnerships. Environmental factors likely also influenced screening rates, such as changes in screening guidelines for prostate or breast cancer that occurred during the pilot period.

9.4.5 Improving Access to Care

The Patient Survey assessed access to care, which refers to cancer patients' ability to get the care they need in a timely manner. The survey included cancer patients age 21 and

older who had been treated at the cancer center within the past 3 months (see additional detail on the Patient Survey in Section 3.1.3). The access to care scale is based on the following three items from the Patient Survey (see Appendix M):

In the past 12 months…

- How often did the people on your cancer care team help you get the medical appointments you needed?
- How often were you able to get an appointment as soon as you wanted at the cancer center?
- How often were you able to get the tests and other procedures you needed done without delay?

Scale scores were computed as the number of items for which respondents gave an "always" response; higher scores indicate greater access to care. We conducted a series of exploratory and confirmatory factor analyses using the Mplus software programs to examine the factor structure of the scale. The items grouped together into one factor, representing overall access to care, and all items had factor loadings or 0.40 or higher. Because the items were dichotomous, we computed 2-parameter logistic (2PL) item response theory (IRT) models. All items had IRT slopes higher than one, suggesting good discrimination. The Chronbach's alpha coefficient for the scale was 0.63 for the baseline survey and 0.71 for the follow-up survey.

Table 9-7 presents the mean access to care scale scores at Years 1 and 3 for all sites and by individual site.[3] Across all sites, access to care increased significantly from Year 1 to 3 $t(3635) = 2.98$, $p = 0.003$). The mean scale scores increased in 7 of the 10 sites (and remained the same in one site), although the change was statistically significant in only 3 sites ($p < 0.05$). Overall, these findings suggest that during the pilot period, patients' experiences with getting appointments and tests in a timely manner improved, possibly due to patient navigation programs or other improvements in coordination of care.

Due to small sample sizes, it is not possible to examine access to care by subgroup at the site level. For all sites combined, we find that access to care increased significantly from Year 1 to Year 3 for whites, but not non-whites, and for all education and income levels (see Table 9-8). However, the increases were significant only for patients with less education, whites, and those with higher income.

These findings present a mixed picture in terms of progress in increasing access for underserved populations, with improved access for less educated patients but not for non-whites. No data are available to examine rural populations who may be underserved.

[3] The Patient Survey was conducted in the 10 lead sites only.

9.4.6 Establishing or Expanding Patient Navigation Services

We assessed the increase in patient navigation services both from the perspective of patients (based on the Patient Survey) and also as reported by the sites. We present the site-reported data first, followed by findings from the Patient Survey. We then compare the findings from both.

9.4.6.1 Site-reported Data

In Year 1, only five sites reported having systems in place to track the number of patients navigated (see Table 9-9). In Year 2, nine sites were tracking the number of patients navigated, and by Year 3, all sites were tracking the number of patients navigated and were able to report those data. At baseline, 13 of the 16 pilot sites reported that they offered patient navigation services to at least some patients. By Year 3, all 16 sites were offering patient navigation services to at least some patients, and reported navigating an average of 1,085 patients. As shown in Table 9-9, most sites were not tracking the number of patients navigated in Year 1, making it difficult to calculate the percent change from Year 1 to Year 3 for all sites. For the five sites that were tracking patients navigated in Year 1, the percent change in the numbers of patients navigated from Year 1 to Year 3 ranged from 67% (Site 4) to 6123% (Site 10). Reported increases in the numbers of patients navigated may be due in part to sites having better systems to track their patient navigation services.

In Year 3, all sites reported providing patient navigation to at least some patients, and 11 reported providing these services to patients with all types of cancer (see Table 9-10). Of the 16 sites, 15 provided patient navigation services for breast, thoracic, and GI cancer patients.

In interpreting these findings, it is important to note the limitations of these data. There were some inconsistencies on how sites reported the types of cancer for which they provided patient navigation. For example, some sites reported that they provided patient navigation for all types of cancer, whereas other sites reported providing patient navigation for specific types of cancer. Because of this inconsistency, we assumed that, although not explicitly stated, sites that reported providing patient navigation for all types of cancer were providing services to each of the specific types of cancer listed in Table 9-10.

9.4.6.2 Patient Survey Findings

The introduction to the patient navigation questions provided an explanation of patient navigation as follows: "Some cancer centers have 'patient navigators' to help cancer patients and their families get the help they need. A patient navigator can be a nurse, social worker, community health workers, or other trained person. A patient navigator can help with scheduling appointments and making referrals. They can also help with transportation, childcare, or health insurance issues" (see Patient Survey, Appendix M). The following two

survey questions assessed awareness of patient navigators and whether patients had received assistance from a patient navigator:

- Does your cancer center have someone who acts as a "patient navigator"?
- In the last 12 months, have you ever been helped by a patient navigator? (This question applied only to patients who answered "yes" to the first.)

Across the 10 lead sites, awareness of patient navigation services increased from 37% in Year 1 to 48% in Year 3 ($p < 0.0001$) (see Table 9-11).[4] Awareness of patient navigation services increased in 8 out of the 10 sites, with statistically significant increases in 6 sites. However, there was no significant change in reported utilization of patient navigation services for all sites combined. A significant increase in reported utilization was found in only two sites (Site 15 and Site 9).

9.4.6.3 Comparison of Patient Survey Findings and Site-Reported Data

The Patient Survey findings and the site-reported data led to different conclusions about the increase in patient navigation services. The sites reported increases in the number of patients navigated; in contrast, the Patient Survey found an increase in awareness of patient navigation services but not in the percentage of patients (among those who were aware of patient navigators) who reported that they were helped by a patient navigator. It may be that in some cases patients were not aware that the individual assisting them was a patient navigator (e.g., they may have had a different title) or that the services provided were considered patient navigation. In addition, in some cases a site may have considered a certain service to be patient navigation whereas, from the patient's perspective, the services did not "provide the help they need" to navigate the system (e.g., this could have occurred in the case of one-time assistance with making an appointment).

9.4.7 Increasing Staff to Support Patient Navigation

Most sites increased the number of patient navigators over the course of the pilot (see Table 9-12). The mean number of navigators increased from four in Year 1 to six in Year 3. However, in three sites the number of patient navigators decreased over this time period (by half in the case of Site 2). Sites used a variety of patient navigation models, with most using a mix of RNs and other staff as navigators. In 12 sites, at least 1 of the navigators was an RN. Unless they were identified specifically as navigators (e.g., patient navigator/MSW), social workers were not counted as navigators because patient navigation was not indicated as their primary role.

We examined the relationship between the number of patient navigators and change in the number of patient navigators from Year 1 to Year 3 and the following outcomes: percent change in the number of patients navigated and awareness of patient navigators (see Table

[4] The Patient Survey was conducted in the 10 lead sites only.

9-13). In four sites, an increase in the number of patient navigators was associated with an increase the number of patients navigated and in patients' awareness of patient navigators. For example, Site 9 had no patient navigators in Year 1, the number of patients navigated grew from 0 to 634, and awareness of the patient navigation program also increased significantly. However, in other sites the relationship was not as expected or there was insufficient information. For example, in three sites (Site 6, Site 11, and Site 2) there was a decrease in the number of navigators yet an increase in the reported number of patients navigated. One explanation could be that although the number of navigators decreased, the proportion of individuals' time devoted to navigation increased (data on the number of FTEs were not available). Improved tracking of the number of patients navigated could also explain these findings.

9.4.8 Increasing the Number of Racial and Ethnic Minorities Enrolled in Clinical Trials

Increasing minority accrual into clinical trials is an important priority of the NCCCP. Underserved populations face numerous barriers to participation in cancer-related trials, and recruitment challenges are well-documented (Ford et al., 2008; Lai et al., 2006). Table 9-14 presents the number of minority (non-white)[5] patients enrolled in NCI-sponsored clinical trials in Years 1 and 3 as reported by the sites. Over the pilot period, nine sites increased minority accruals. However, the number of minority accruals remained under 10 in most sites, and five sites reported no minority accruals in Year 3. Site 6 had the largest number of minority accruals, with a total of 40 patients (up from 32 in Year 1).

Data reported by the sites differ from data in the Clinical Therapy Evaluation Program (CTEP) database likely because of how patients are counted in each data source. CTEP data are more standardized and have been collected for a longer period of time so are perhaps the most reliable. As reported by Abernethy and Locke (2011), there was an annual increase in the accrual of patients of underserved populations. At baseline, CTEP data showed an accrual of 83 patients classified as "racial/ethnic minority," which rose steadily to 151 in Year 3. This represents an 82% increase in accrual among "racial/ethnic minority" patients. The accrual of patients classified at baseline as "age 65 or over" numbered 200 and this rose to 641 in Year 3. This represents a 221% increase in accrual. Total overall accrual during this period was 539 at baseline and 1,068 in Year 3, which is a 98% increase over baseline. The relative increase in accrual for "racial/ethnic minority" was fairly consistent with the total accrual (15% of total accrual at baseline and 14% in Year 3); thus, accrual of these patients rose in proportion with the increase in total accrual (Abernethy & Locke, 2011). Sites affiliated with CCOPs showed the most consistent relative increases in accrual of underserved populations, although their overall clinical trials activity did not increase. As Abernethy and Locke describe, this finding could be related to the phases of

[5] "Non-white" was as defined by the sites and could have included Hispanic patients.

development through which sites have to progress in order to be able to accrue patients to trials. Sites need to first establish the infrastructure and organization to be able to open one trial and enroll their first patient. Once sites become organized, they are able to gradually increase their accrual and expand their capacity by opening more trials and supports for trials (e.g., IRBs, research pharmacy). Minority accrual can then become more of a focus once these basic capacities are in place and operational. As one cancer center director noted: "We spent much effort on minority accrual, but I don't think the numbers have changed. That's a tough nut to crack." Sites participating in CCOP may be the ones best positioned to focus on recruitment of disparate patients, while other non-CCOP sites begin to organize their clinical trials activities and attempt to open more trials and establish the infrastructure to build their trials capacity. Barriers to clinical trials accrual are discussed in Section 10.5.

9.4.9 Overview of Success in Disparities Implementation

For the purposes of this evaluation, we assessed the success of the disparities program component using a number of different indicators, each of which is discussed separately in the previous sections. Each of the indicators (e.g., change in the number of patients provided with patient navigation services, minority accruals for clinical trials) has strengths and limitations. To provide a more comprehensive understanding of the disparities activities at each site, it is important to look across all of the indicators. Table 9-15 summarizes the findings for different indicators of success for each site in Year 3.[6] For some indicators, data are not available for all sites because the data were not collected in all sites (e.g., the Patient Survey was conducted in the 10 lead sites only) or sites had missing data.

None of the sites had positive findings for all of the indicators. Four sites had positive findings for all but one indicator. Almost all sites improved in the areas of race/ethnicity data collection, number of screenings, and number of patients navigated (among those sites for which it was possible to calculate change). There was less improvement over time in other areas. We found the least progress in minority accruals to trials; accrual increased in only 9 of the 13 sites for which data are available, and the number of patients accrued remained low.

In interpreting these indicators of success in the disparities program, it is important to consider the context of each specific finding, such as the baseline level in sites for a particular indicator. For example, a site may have had a relatively well-established screening program in Year 1, and thus the percent increase may be less than in sites that were starting from a lower level.

[6] Sites in this section and in Table 9-15 have been de-identified to protect their identity.

9.5 Facilitators to Disparities Implementation

During the Year 2 site visits, respondents were asked to describe the factors that influenced how well they were able to implement disparities-related activities. This topic was not specifically explored in Year 3, although respondents did share some experiences with both facilitators and barriers to disparities implementation. Respondents discussed two main factors that facilitated disparities implementation: leveraging community partnerships and creating synergies with other NCCCP components.

9.5.1 Leveraging Community Partnerships

All of the sites noted how their partnerships had helped them achieve more than was originally expected in the area of disparities. Collaborations with NCI cancer research organizations (e.g., NCI-designated cancer centers, and the Community Network Program [CNP]) were particularly important and provided the NCCCP sites with a foundation from which to leverage and expand their disparities work. Several sites used their partnerships to expand their efforts in disparities and, in some cases, to obtain additional funding:

> *[For NCI CNP] we entered into a collaborative agreement that provides two studies with [the university]. That has really expanded our reach here because there are so many programs we are involved in. That has been really positive with reaching our underserved. (*Subcommittee member, Year 2)

> *[The local] NCI-designated cancer center is based [nearby].…Among the most important [program components] is disparities research, and we just received a [type of grant] … I am the PI along with [the university's] PI. We are finishing IRB [approval] and we hope to be recruiting patients within the next month. We are looking at disparities questions related to geography where we collect tissue, and we will do the research using new technology that we just acquired*. (PI, Year 2)

Respondents also discussed the importance of partnering with physicians. By involving physicians, the outreach program can provide more comprehensive screening. In addition, partnerships with physicians can facilitate follow-up care for individuals who receive abnormal screening results:

> *Originally, we were just going to health fairs handing out FOBTs but not getting the returns. What we found was it is better to partner with health care providers to focus on follow-through.* (Program coordinator, Year 3)

> *[Physician group] is going to do a screening project with us this year, doing GI screenings as part of our outreach. They'll do colonoscopies for us. We'll be working with [partner organization]. The physicians will do the colonoscopies, and we'll be doing the FOBTs. People will end up going to these guys for endoscopies.* (Cancer center/program staff, Year 3)

Involvement with the NCCCP network was also mentioned as a facilitator for implementing the disparities program component:

> *Networking and interaction with other NCCCP sites in terms of program development and initiatives [is a facilitator]…It's the sharing of data, information, and ideas that is really helpful for us out here in [location].* (System/hospital senior executive, Year 3)

9.5.2 Creating Synergies with Other NCCCP Components

Initially, some respondents were not clear how the disparities work could be integrated with the other NCCCP components. Over time, they came to appreciate the importance of building a disparities focus into all aspects of the program and the potential synergies that could result:

> *I think our intent is to make people aware that disparities cross over every pillar. If you are in biospecimens, you may need to be aware of … Native American cultural issues. I think it is happening, and by our discussion and our calls, it is not just one committee's work, it crosses all committees.* (Subcommittee member, Year 2)

> *For our area, everything that we do ties back into disparities because we're so rural and have so much outreach. You have survivorship programs, and how will you reach out to them—survivors, family members, caregivers—in rural areas. Disparities is 40% of what we do. NCI has done a Disparities Dashboard. Now we're charged with how are we incorporating disparities into all of our subcommittees. When we come together as a whole, it's really nice because we're all connecting the dots as a whole.* (Program coordinator, Year 3)

> *[Disparities has] been an age-old tough nut to crack … How to better penetrate your underserved communities. The important thing is to get the clinical trials done and get accruals up, and then reaching minorities goes hand in hand. We need to get clinical trials done and reach underserved communities simultaneously.* (Key physician, Year 3)

> *We are working on a Webinar for [clinical trials] awareness and cultural competency as a partnership between [clinical trials] and disparities.* (Subcommittee member, Year 2)

9.6 Barriers to Disparities Implementation

Perhaps because disparities was a relatively new area of focus for most of the hospitals participating in the NCCCP, sites initially faced a number of barriers to implementing activities in this area. During site visits in Years 2 and 3, respondents were asked to describe some of the challenges they faced with implementing NCCCP disparities-related priorities. The following were the major barriers discussed:

- lack of clarity about priorities and strategies for disparities program component,
- logistical challenges to serving underserved populations,
- distrust of health care system in underserved communities, and
- organizational and systems challenges to race/ethnicity data collection.

9.6.1 Lack of Clarity about Priorities and Strategies

For the disparities component, respondents expressed frustration in Years 1 and 2 about not having the direction they would like from NCI in terms of priorities and strategies. Specifically, respondents expressed frustration about a lack of understanding of disparate populations in different communities and a lack of clarity about how disparities is linked with other program components:

> We *are trying to work within [the] NCCCP around the terms of disparities and minority populations; the terminology doesn't make sense here. [Our region] is 98% white. [City] is focusing on underserved and rural populations. We constantly need to get people to understand this. We need to revisit this at every meeting.* (Program coordinator, Year 2)

> *I'm missing some pieces here—minority outreach—and I don't have some good direction on where I need to go for that.* (Subcommittee member, Year 2)

> *With disparities, I get the sense that we don't even know the baseline of what any of the sites are doing. Then we need to go from there. Nobody has stated that's what we're doing and then here's where we're going from there and here's what we're doing in Year 2.* (Subcommittee member, Year 2)

> *We didn't quite identify how [patient navigators] fit into our role with disparities. It seems to be mass confusion about what we're doing. If we need to work on breast cancer and colon cancer, what is [the] baseline? We need something.* (Subcommittee member, Year 2)

Also in Years 1 and 2, some respondents expressed that the data collection demands for the disparities component were unrealistic and that the tools developed were not useful:

> *What they want us to report is not always what we track. It just seems very discombobulated. A lot of times, what they're asking for is impossible. They want to know from September to November who's been diagnosed to treatment, and they want this December 15, and if you're going through November 30 we might not even have some of these path reports back, and they're like, "Oh no, we need this." So there's a real miscommunication from the top down.* (Subcommittee member, Year 1)

> *With disparities, we could spend a year developing a tool that we are not even going to use. We are 1 year into this and have not had one conversation on how to reach the disparate population. We have been focusing on the Breast [Cancer] Screening Tracking Tool. I thought the whole purpose of the disparities is how to reach out and navigate them from abnormal finding to resolution.* (Subcommittee member, Year 2)

By the Year 3 site visits, the sites had made significant progress in clarifying their disparities priorities and developing strategies and respondents indicated that the *Disparities Dashboard, Template for Community Outreach* and other tools had been helpful in this respect (see Section 9.2.2). In addition, by Year 3 the sites had a better grasp of how the disparities work could be integrated across the other program components, and most sites had taken steps to focus on disparities within the clinical trials and quality of care program components in particular (see Section 9.7.4).

9.6.2 Logistical Challenges to Serving Underserved Populations

The sites encountered a number of logistical challenges to improving care for underserved populations, including transportation issues, languages barriers, and need for services during nontraditional working hours. These types of challenges are commonly reported for health and other programs working with underserved populations (Peek & Han, 2009; Lin et al., 2008; Green et al., 2008). Sites implemented a variety of partnership and outreach strategies to address these challenges.

> *Our public transportation is not great. So the logistical challenges of getting transportation, finding childcare, making the appointment: none of those things happen at the clinic level.* (Subcommittee member, Year 2)

> *[The] challenge is what can be done in rural areas and what really needs to come back to a major hospital…Very few physicians have embraced telemedicine aside from [doctor].* (Key physician, Year 3)

> *Many people do not speak English, so that creates a challenge for reaching them about getting screened and getting care. We held a very large breast cancer mammography day and we had zero people sign up [for mammography]. As much as we thought we reached those populations, we didn't.* (PI, Year 2)

9.6.3 Distrust of Health Care System in Underserved Communities

Another challenge encountered in the disparities program was distrust of the healthcare system among target communities. By Year 3, however, some sites felt that they had made significant progress in building trusting relationships with the targeted communities. They stressed that building relationships takes time and can be "an uphill battle":

> *It takes time to weave yourself into community settings.* (Program coordinator, Year 3)

> *With disparities, finally we've gotten some traction. We're not just giving talks, we're actually giving screenings…It's taken a couple of years to get buy-in and build relationships.* (PI, Year 3)

> *It's still an uphill battle with tribal leadership; we've worked with the Indian Health Services, community leaders at [tribe]. We probably haven't made [the] linkage that we really need to. We have entry points, but haven't sat down with tribal leadership and said, "This is what we're doing. This is what we'd like to do. We have resources to address cancer issues in your reservation."* (System/hospital senior executive, Year 3)

9.6.4 Organizational and Systems Challenges to Race/Ethnicity Data Collection

Initially, some respondents questioned the importance of collecting race/ethnicity data using the OMB standards. One site had discontinued collecting this information prior to the NCCCP for philosophical reasons:

> *Many years back, [hospital] stopped tracking demographics because they wanted everyone to be treated the same. We need to come up with a philosophy that it's good to track that and definitions on how to assign categories. We need some help on that.* (System/hospital senior executive, Year 2)

> *[Manager] didn't really see the importance of tracking race/ethnicity, then a light went off at the last NCCCP meeting.* (Program coordinator, Year 3)

> *That's why I decided not to go to the calls anymore, because they were talking so much about the race/ethnicity issue. It is so confusing to people, and when you're dealing with a population who's worried about where they're going to sleep tonight and you ask them, "Do you consider yourself Hispanic?" they look at you like, "Are you serious?"* (Subcommittee member, Year 3)

As mentioned in Section 9.4.1, sites faced a number of challenges in collecting race/ethnicity data in accordance with standard OMB categories. At the start of the program, many sites were tracking this information in a limited way, if at all, so it has taken time to implement this process and make the necessary systems changes. Gaining top management support for collecting race/ethnicity data across different services and programs was an issue for some sites:

> *We were not collecting it in the fashion that OMB has recommended. We were collecting race before ethnicity, and ethnicity was not a required field. It took us a full year to convince our organization that we need this.* (Cancer center/program staff, Year 2)

Respondents frequently mentioned IT issues as a challenge to collection of race/ethnicity data:

> *It is a challenge now the way systems are set up. We need to figure out how we will collect this type of information and make sure the system is user-friendly.* (Key physician, Year 2)

> *One of the big things in disparities, for instance, is the collection of race versus ethnicity, and medical records don't differentiate those. It could be Hispanic or Black. With the registry, we really go out of our way to document both.* (Subcommittee member, Year 2)

> *There are a lot of different data systems used here, and some of the private practice doctors still rely on paper. There is an issue of collecting race/ethnicity data because it is not consistent across databases and doesn't capture all racial/ethnic groups.* (Subcommittee member, Year 2)

> *Some of it has been slowed down because of the slowdown of getting electronic health records at the hospital. There was an interim system put in place, and they're not exactly collecting according to the OMB standards. When the new EHR comes in, it will collect data according to OMB standards.* (Program coordinator, Year 3)

Despite these challenges, most sites made significant progress toward systematic collection of race/ethnicity data over the pilot period (see discussion of changes in race/ethnicity tracking in Section 9.4.1):

> *We've seen progress in our disparities/outreach and our attention to the collection of ethnic data. Across the organization, this has merged with an effort in the institution around disparities care.* (System/hospital senior executive, Year 2)

> *We always have had the information for the patients put on trials, but now the institution has a policy for all patients coming in to collect that information.* (Subcommittee member, Year 2)

> *[We have] worked on collecting the race/ethnicity information in an integrated way here. The medical center was collecting but not using the categories. The clinic was not collecting, and the network was collecting somewhat.* (Subcommittee member, Year 2)

Respondents said that the NCI focus on collection of high-quality race/ethnicity data and the technical support provided helped the sites move forward in this area:

> *I think [the NCCCP] helped us understand how data is really important for outcomes, and I think everyone working together helped. We always talk about data and how we're going to collect it.* (Program coordinator, Year 3)

> *The working group is addressing problems with data collection through the provision of data collection training.* (Program coordinator, Year 3)

> *NCCCP helped to spearhead the OMB categories and collecting race/ethnicity [data]. There were initiatives already happening related to disparities at [institution], but NCCCP brought the OMB categories.* (PI, Year 3)

> *Something that helped get this implemented was someone like [NCI staff member] saying, "You're not going to get funding from NCI if you don't collect race/ethnicity data," and with us wanting to be a research institution it required little discussion as to whether we were going to do it, but more of how we were going to do it.* (Subcommittee member, Year 2)

9.7 Value Added: Disparities Benefits Beyond the NCCCP

The concept of value added is difficult to define, and some aspects of it will be impossible to measure during the NCCCP pilot. However, for this evaluation, it is important to specify the extent to which the NCCCP sites were able to build on their disparities efforts in ways that they would not have done, or known how to do, had it not been for the program. The added benefits of the NCCCP as it relates to disparities were described across five main areas:

- developing new site capabilities,
- developing new community linkages,
- establishing new models of care,
- integrating disparities across different aspects of cancer care, and
- learning about best practices for outreach.

In this section, we present a few examples of ways respondents said the NCCCP pilot has enhanced their capacity to address cancer care disparities in these areas.

9.7.1 Developing New Site Capabilities

Respondents said that participation in the NCCCP had helped the sites to develop and expand initiatives to reach and better serve underserved populations, including initiatives to expand minority enrollment in clinical trials. Hospital senior executive and others expressed pride in these achievements and said that the NCCCP had provided a needed push to improve outreach and care for underserved populations:

> *If it hadn't been for this program, I'm not sure that the scope, and depth, and magnitude of initiatives that we've undertaken would have occurred.* (System/hospital executive, Year 2)

> *I definitely think NCCCP has pushed [our hospital] internally to do better things and to do a better job promoting the cancer center. We did get a grant to do some focus*

> *groups to assess minority enrollment in clinical trials.* (Subcommittee member, Year 2)

> *Over the 4 years, we could definitely say that our outreach and screening programs have increased and expanded…We have made significant intentional efforts to reach out to communities that we never would have reached out to before.* (System/hospital senior executive, Year 3)

> *The work in disparities has been great. It's all advancing our mission in the world of cancer care in a way we haven't been able to do before.* (System/hospital senior executive, Year 3)

The sites created new positions and added staff in outreach and patient navigation to support the disparities work. A number of respondents commented on the value of having dedicated outreach staff, often for the first time:

> *We never had a director of outreach. To actually have a person who can connect with the community is terrific.* (PI, Year 2)

> *[The NCCCP] has provided the opportunity for senior leadership to really understand the value of disparities and outreach. We've done really well because we've got the right folks. We're creating more of an outreach department.* (System/hospital senior executive, Year 3)

> *We never had a full-time outreach person before, and the program enabled us to hire her and for her to really go out and research what the needs are in the community.* (PI, Year 2)

> *We would not have considered having a regional care navigator. We always worked through our internal care navigators.* (PI, Year 2)

Respondents in several sites expressed concern about the sustainability of the disparities work and noted that the outreach coordinators were generally fully funded by the NCCCP. They considered this program component to be most at risk if the NCCCP funding ended. This was of particular concern in the rural sites because the cost of conducting outreach in these areas is very high (due to travel costs):

> *The [multidisciplinary care conferences] and nurse navigators are here to stay because the institution sees the value. The one most at risk logically is disparities because you can't put an ROI on it. [The] primary person doing disparities work is funded through NCCCP.* (System/hospital senior executive, Year 3)

> *It may be challenging to sustain the outreach coordinator position. I imagine if I was at the executive table arguing about what to keep, that one would be a little harder*

to keep than the patient navigators because we hear the value of [navigators] from the patients. (Cancer center/program staff, Year 3)

9.7.2 Developing New Community Linkages

Respondents reported that the affiliation with NCI, and specifically the focus on community partnerships and outreach to disparate populations, raised the stature of the cancer center and opened the door for new community linkages. Over time, the sites have had success in overcoming distrust among some populations. One respondent noted that the cancer center had become more culturally diverse and "culturally responsive" through the disparities work:

I think we've gotten to a deeper level … gaining the level of trust within the community so that they co-partner with you to work on screening within their constituency in a meaningful way. Things like the outreach to the [specific] population—I don't think that would have been possible 2 years ago. (PI, Year 2)

Things are going wonderfully in the community. We have a lot of outreach in the underserved neighborhoods. We established a community advisory board. These neighborhoods are difficult to navigate, so we decided to get people trained who have lived in those areas. That advisory committee will then go out in those respective areas to get people enrolled. That's going quite well. (System/hospital senior executive, Year 3)

It's taken a couple of years to get buy-in and build relationships. It's taken [outreach worker] quite a long time, but I think she did it quickly in comparison with a lady from [academic cancer center]. (Program coordinator, Year 3)

We are slowly improving reaching disparate populations. We have seen more African Americans, Asians, and Hispanics in screening, based on years of working in the community. (Key physician, Year 3)

The NCCCP has forced us to integrate out into the community. Like the tribal programs: we wouldn't have thought to do that. Having the NCCCP helps us think, "We know we should be doing this. OK, let's do it." (Key physician, Year 3)

Our medical director has worked to open a clinic and attends the community clinic once a month to forge relationships with disparate populations in our southern part of the state. We have a prominent African American church and we recently had a screening event after the service. We had 20 nurses who volunteered and we did screening after the service. The pastor used the entire sermon to talk about taking care of your body along with your soul. (Program coordinator, Year 3)

As site participants indicated, there are multiple mechanisms through which community linkages can be developed, such as through community advisory boards, or working directly with established community leaders.

9.7.3 Establishing New Models of Care

Although sites indicated that their outreach efforts would be difficult to sustain in the absence of NCCCP support, respondents thought that the benefits of patient navigation were well recognized and that this model of care was "here to stay." From an institutional perspective, patient navigation is a valuable model because it brings more patients into care and increases patient satisfaction and retention:

> *We have had the opportunity to look at our care delivery models. The patient navigation piece [is beneficial] from a retention and patient satisfaction stance. Patient navigation brings people to the hospital and retains people in the hospital* (Program coordinator, Year 3)

> *One of the things about the multidisciplinary low-income clinic is it's the first example of a multidisciplinary clinic [at the site]. It's not in the office like the rest of our practice. It works pretty well, and we use it to address our disparities and quality of care issues. We hope that sometime in the future we can expand it to how we practice care in general.* (Key physician, Year 3)

9.7.4 Integrating Disparities across Different Aspects of Cancer Care

NCI conceived the disparities component as spanning all of the other program components. Early in the pilot, some sites were unclear about how the disparities focus could be integrated with other aspects of the NCCCP. As the program matured in different sites, coordination and integration across program components improved:

> *I feel like I am coordinating better across the NCCCP team now. When disparities and quality of care were both working on patient navigation, I saw the two groups needed to get together. Finally I made the link. I wasn't great at that the first year.* (Program coordinator, Year 3)

> *Because of the disparities pillar, more effort is put into the possibility and reality of doing clinical trials at the teaching hospital where we have the underserved populations.* (Key physician, Year 3)

> *We have an opportunity because of the NCCCP structure.… [We are examining] how we can get clinical trials better linked with patient navigation.* (PI, Year 3)

> *There are pillars—clinical trials, biospecimens, survivorship—that tie into disparities, which is 40% of the project.* (Program coordinator, Year 3)

9.7.5 Learning about Best Practices for Outreach

One of the aims of the disparities subcommittee was to identify and develop best practices related to the disparities program (e.g., best practices in outreach, community partnerships). Respondents felt that sharing information among sites was valuable; for example, they learned about successful strategies and ways to address common challenges:

> *Networking and interaction with the other NCCCP sites in terms of disparities program development and initiatives [and] sharing of ideas and data is really helpful to a site that is quite isolated and rural.* (System/hospital senior executive, Year 3)

> *[It is] good to hear what some of the sites are doing, and some are mobile. [The subcommittee information sharing] has really made [cancer center leaders] look at mobile mammography as an option.* (Subcommittee member, Year 2)

> *The calls usually start with a presentation from one of the sites, so I find it intellectually fascinating to learn the challenges from the rural or Native American communities. We're a diverse group, so it gets you thinking about different models for care that I find interesting.* (Subcommittee member, Year 2)

9.8 Summary

Sites found the disparities work challenging but also very rewarding. During the first year of site visits, many respondents expressed frustration about this program component and the lack of clarity about NCI expectations. Sites were struggling to define and prioritize underserved populations in their communities and to identify appropriate partners and strategies for reaching out to these populations. By the time of the Year 2 site visits, most sites had made progress, but they were still unsure how best to focus their efforts: on outreach, screening, navigation, or all of the above. With limited resources and the downturn in the national economy, there was a growing need for sites to streamline their efforts and determine what they could feasibly do to address disparities with the remaining time and resources. The *Disparities Dashboard* and other tools provided important guidance to sites as they developed their disparities priorities and strategies.

By the time of the Year 3 site visits, most sites felt like they were making progress in disparities. Many of the sites had established new partnerships and expanded their outreach and screening activities. Staff members involved in outreach were beginning to see payoffs from their efforts to develop relationships with partner organizations and underserved communities, some of whom were wary of the health care system. Respondents discussed the challenges of learning about different communities and noted that "it takes time to weave yourself into community settings." Overall, though, sites were pleased with their progress:

> *We have made significant intentional efforts to reach out to communities we never would have reached out to before.* (System/hospital senior executive, Year 3)

> *With disparities, finally we've gotten some traction. We're not just giving talks, we're actually giving screenings.* (PI, Year 3)

At the start of the program, NCI overestimated the status of disparities-related efforts within these communities. It is in the area of disparities that the impact of the technical assistance from NCI is perhaps most obvious. Although our evaluation does not include measures from within NCI and their level of effort for this program, we are aware of the sustained efforts on the part of NCI staff to guide sites in building their disparities programs. From arranging for the sites to receive training on race/ethnicity data collection to providing leadership in development of the *Disparities Dashboard, Template for Community Outreach*, and other tools, NCI has worked closely with the sites to determine priorities and strategies for each community. Although respondents voiced some frustration over the lack of guidance from NCI early in the program, they were also very appreciative of the time, effort, and expertise NCI devoted to this program component over time. Sites also valued the team learning that occurred through the NCCCP network of sites (i.e., the disparities subcommittee and work groups), particularly learning about disparities best practices from other sites.

The sites took great pride in their achievements in disparities and felt strongly that the work was in line with the mission of their hospitals. In fact, each hospital's level of institutional support for disparities activities was quite high, with sites reporting the highest level of total matching funds for this component at $9.4 million over the 3-year pilot. This level of investment was remarkable for sites, particularly given the ongoing economic downturn occurring over the same time period. Sites' funding and that from NCI was used in a variety of ways. Having a dedicated outreach staff member allowed the sites to reach out to underserved communities and partners in a systematic and sustained way. There was also value added in terms of establishing new models of care, specifically patient navigation services and, in one some cases, a multidisciplinary clinic focused on underserved populations. Sites were aware and concerned that at least some aspects of the disparities program, particularly the outreach, could be at risk if NCCCP funding ended.

Table 9-1. Number of Sites Tracking Race and Ethnicity for Different Programs and Services

	Race/Ethnicity Tracking Method								
	Any Means[a]			Self-Report[b]			Standard OMB Categories[c]		
Category	**Year 1**	**Year 3**	**Change**	**Year 1**	**Year 3**	**Change**	**Year 1**	**Year 3**	**Change**
Data Source:	**Outcomes Worksheet**								
Hospital admitting	12	16	4	5	10	5	3	11	8
Outpatient registration	10	15	5	4	9	5	2	10	8
Cancer center patient registration	9	15	6	4	9	5	2	11	9
Cancer community screening programs	9	16	7	6	13	7	2	15	13
Survivorship programs	3	13	10	1	11	10	1	12	11
Nurse navigation	6	13	7	2	10	8	1	12	11
Clinical trials database for NCI clinical trials	9	16	7	6	13	7	7	16	9
Clinical Trials database for non-NCI clinical trials	9	15	6	6	13	7	6	14	8
Cancer center medical staff offices (employed)[d]	7	12	5	4	9	5	2	9	7

[a] Any means refers to a site's ability to identify race and ethnicity for all patients and that race and ethnicity data are included on all patient data collection forms (electronic or paper) for the given category.

[b] Self-report refers to race/ethnicity is reported by the patient rather than inferred by the hospital staff.

[c] Standard OMB categories refers to race/ethnicity tracked using OMB categories (Hispanic/Non-Hispanic, White, African American, American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, more than one race).

[d] Not applicable to all sites.

Table 9-2. Sites Tracking Race/Ethnicity for Different Systems (0-9 systems)[a]: Years 1 and 3

Site	Tracked by Any Means[b]		Change	Self-Report[c]		Change	Standard OMB Categories[d]		Change
	Year 1	Year 3		Year 1	Year 3		Year 1	Year 3	
Data Source:	**Outcomes Worksheet**								
Site 4	6	8	2	6	8	2	1	8	7
Site 6	3	6	3	0	6	6	1	3	2
Site 10	3	9	6	3	6	3	1	4	3
Site 3	7	9	2	1	6	5	2	9	7
Site 12	6	7	1	0	5	5	8	8	0
Site 1	8	9	1	0	1	1	0	3	3
Site 9	3	9	6	2	9	7	2	9	7
Site 16	8	9	1	3	4	1	2	4	2
Site 15	5	6	1	1	2	1	0	3	3
Site 11	7	8	1	6	8	2	2	8	6
Site 8	1	7	6	1	7	6	1	7	6

(continued)

Table 9-2. Sites Tracking Race/Ethnicity for Different Systems (0-9 systems)[a]: Years 1 and 3 (continued)

Site	Tracked by Any Means[b]		Change	Self-Report[c]		Change	Standard OMB Categories[d]		Change
	Year 1	Year 3		Year 1	Year 3		Year 1	Year 3	
Site 7	6	9	3	6	9	3	6	9	3
Site 2	9	9	0	9	9	0	0	9	9
Site 13	0	8	8	0	8	8	0	8	8
Site 5	0	9	9	0	0	0	0	9	9
Site 14	0	9	9	0	9	9	0	9	9
Mean	5	8	3	2	6	4	2	7	5

[a] Sites can potentially track race/ethnicity for nine systems: hospital admission, outpatient registration, cancer center patient registration, screening programs, survivorship programs, nurse navigation, NCI clinical trials, non-NCI clinical trials, and cancer center medical staff offices.

[b] Any means refers to a site's ability to identify race and ethnicity for all patients and that race and ethnicity data are included on all patient data collection forms (electronic or paper) for the given category.

[c] Self-report refers to race/ethnicity as reported by the patient rather than inferred by the hospital staff.

[d] Standard OMB categories refers to race/ethnicity tracked using OMB categories (Hispanic/Non-Hispanic, White, African American, American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, more than one race).

Table 9-3. Number of Community Partners (Including Partners that Focus on an Underserved Population): Years 1 and 3

	Community Partners (Number Focusing on an Underserved Population)[a]					
	All Informal and Formal[b]			Formal Only[c]		
Site	**Year 1**	**Year 3**	**Change**	**Year 1**	**Year 3**	**Change**
Data Source:	**Outcomes Worksheet**					
Site 4	5 (4)	29 (20)	24 (16)	4 (3)	7 (5)	3 (2)
Site 6	5 (5)	14 (14)	9 (9)	2 (2)	2 (2)	0 (0)
Site 10	8 (8)	96 (51)	88 (43)	0 (0)	0 (0)	0 (0)
Site 3	3 (3)	5 (4)	2 (1)	2 (2)	2 (2)	0 (0)
Site 12	3 (1)	16 (5)	13 (4)	2 (0)	3 (2)	1 (2)
Site 1	6 (2)	9 (6)	3 (4)	3 (1)	4 (3)	1 (2)
Site 9	2 (1)	10 (6)	8 (5)	0 (0)	0 (0)	0 (0)
Site 16	17 (17)	16 (16)	-1 (-1)	6 (6)	0 (0)	-6 (-6)
Site 15	2 (0)	11 (4)	9 (4)	1 (0)	0 (0)	-1 (0)
Site 11	117 (22)	123 (20)	6 (-2)	49 (15)	50 (14)	1 (-1)
Site 8	3 (3)	17 (12)	14 (9)	0 (0)	5 (2)	5 (2)
Site 7	4 (4)	21 (11)	17 (7)	2 (2)	8 (5)	6 (3)
Site 2	21 (5)	43 (12)	22 (7)	5 (1)	9 (0)	4 (-1)
Site 13	9 (1)	27 (2)	18 (1)	1 (0)	3 (0)	2 (0)
Site 5	0 (0)	6 (6)	6 (6)	0 (0)	1 (1)	1 (1)
Site 14	3 (3)	4 (4)	1 (1)	0 (0)	1 (1)	1 (1)
Mean	13 (5)	28 (12)	15	5 (2)	6 (2)	1
Median	5	16	11	2	3	1

[a] This includes the total number of community partners, and in parentheses, the number of community partners that focus specifically on the underserved. The Outcomes Worksheet defined underserved populations as "Hispanic or Latino, American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, Black or African American, Uninsured, Homeless, Undocumented, Rural Poor."

[b] The sum of all informal and formal community partners that focus on an underserved population. Informal partners are those partnerships that are primarily for networking and information exchange (e.g., referral information, education material) as well as joint program sponsorship (not a screening location but a partner who works with the NCCCP site on coordinating or sponsoring a screening and education event, etc.). Formal partners are those partners with whom the NCCCP site has an ongoing relationship with a formal agreement or MOU to provide specific services to the community with a defined outcome.

[c] Includes only formal partners (defined above).

Table 9-4. Number of Cancer Screenings and Screening Events: Years 1 and 3

	Number of Cancer Screenings[a] (Across All Screening Events)				Number of Screening Events[b]			
Site	**Year 1**	**Year 3**	**Change**	**Percent Change[c]**	**Year 1**	**Year 3**	**Change**	**Percent Change**
Data Source:	**Disparities Dashboard**							
Site 4	53,711	60,717	7,006	13.0%	10	42	32	320.0%
Site 6	1,544	2,121	577	37.4%	59	216	157	266.1%
Site 10	1,688	3,514	1,826	108.2%	90	188	98	108.9%
Site 3	4,382	6,016	1,634	37.3%	129	233	104	80.6%
Site 12	6,879	14,133	7,254	105.5%	148	204	56	37.8%
Site 1	16,928	22,861	5,933	35.0%	197	172	-25	-12.7%
Site 9	8,376	7,314	-1,062	-12.7%	588	484	-104	-17.7%
Site 16	366	1,844	1,478	402.8%	6	79	73	1,216.7%
Site 15	3,347	3,874	527	15.7%	183	234	51	27.9%
Site 11	2,013	2,563	550	27.3%	97	126	29	29.9%
Site 8	132	278	146	110.6%	1	6	5	500.0%
Site 7	193	249	56	29.0%	4	4	0	0.0%
Site 2	Missing	5,167	Unknown	Unknown	2	2	0	0.0%
Site 13	4,577	6,317	1,740	38.0%	2	2	0	0.0%
Site 5	Missing	4,130	Unknown	Unknown	28	53	25	89.3%
Site 14	0	651	651	100%[d]	0	9	+9	100%[e]
Mean	7,438	8,859	1,421	19.1%	97.8	128.4	30.6	1.6
Median	2,680	4,002	1,322	49.3%	43.5	102.5	27	0.3

Missing = Data are missing for the site.
Unknown = Value cannot be calculated due to missing data at Year 1 and/or Year 3.

[a] The number of cancer screenings should be interpreted with caution. Sites counted the number of cancer screenings differently; some sites may have double-counted individual patients who received more than one screening test. In addition, some sites included screenings done as part of routine physical exams, while others counted only the number of individuals reached via screening events.

[b] The number of cancer screening events includes the total number of screening events in each year (Year 1 = July 1, 2007 to June 30, 2008; Year 3 = July 1, 2009 to June 30, 2010). These data should also be interpreted with caution; some sites may have counted screening events that offered screenings for other chronic diseases, like cardiovascular disease.

[c] Percent change is calculated as (Y3-Y1 total)/Y1 total*100.

[d] Site 14 reported 0 screenings in Year 1 and 651 screenings in Year 3; for the purposes of this analysis, we are considering any positive increase from 0 to be 100% change.

[e] Site 14 reported 0 screening events in Year 1 and 9 in Year 3; for the purposes of this analysis, we are considering any positive increase from 0 to be 100% change.

Table 9-5. Number of Staff Focusing on Outreach[a]: Years 1 and 3

Site	Year 1	Year 3	Change
Data Source:	**BAS**	**FAS**	
Site 4	0	4	4
Site 6	9	2	-7
Site 10	5	5	0
Site 3	6	6	0
Site 12	7	8	1
Site 1	7	1	-6
Site 9	1	1	0
Site 16	4	4	0
Site 15	2	11	9
Site 11	3	2	-1
Site 8	0	3	3
Site 7	6	3	-3
Site 2	3	2	-1
Site 13	0	0	0
Site 5	1	2	1
Site 14	0	1	1
Mean	3	3	0

[a] Sites reported the number of staff focusing on outreach differently; some sites included social workers and volunteers as outreach staff. For the purposes of this analysis, RTI excluded social workers, volunteers, and other administrative positions (e.g., "office manager") that were not specific to outreach in the total count.

Table 9-6. Relationship between Number of Outreach Staff and Outcomes: Change in Numbers of Partnerships and Numbers of Screenings

Site	Number of Outreach Staff[a]		Change in Number of Formal Partnerships (Focusing on Underserved),[b] Year 1–3	Percent Change in Number of Screenings and Events[c]	
	Year 3	Change, Year 1–3		Year 1–3 (Across All Events)	Events Year 1–3
Data Source:	**FAS**	**BAS-FAS**	**BAS-FAS**	**Disparities Dashboard**	
Site 4	4	4	3 (2)	13.0%	320.0%
Site 6	2	-7	0 (0)	37.4%	266.1%
Site 10	5	0	0 (0)	108.2%	108.9%
Site 3	6	0	0 (0)	37.3%	80.6%
Site 12	8	1	1 (2)	105.5%	37.8%
Site 1	1	-6	1 (2)	35.0%	-12.7%
Site 9	1	0	0 (0)	-12.7%	-17.7%
Site 16	4	0	-6 (-6)	402.8%	1216.7%
Site 15	11	9	-1 (0)	15.7%	27.9%
Site 11	2	-1	1 (-1)	27.3%	29.9%
Site 8	3	3	5 (2)	110.6%	500.0%
Site 7	3	-3	6 (3)	29.0%	0.0%
Site 2	2	-1	4 (-1)	Unknown	0.0%
Site 13	0	0	2 (0)	38.0%	0.0%
Site 5	2	1	1 (1)	Unknown	89.3
Site 14	1	1	1 (1)	100%[d]	100%[e]

Note: Shaded rows indicate an increase in number of outreach staff was associated with an increase in number of formal partnerships, number of screenings and number of screening events.

Unknown = Value cannot be calculated due to missing data at Year 1 and/or Year 3.

[a] Sites reported the number of staff focusing on outreach differently; some sites included social workers and volunteers as outreach staff. For the purposes of this analysis, RTI excluded social workers, volunteers, and other administrative positions (e.g., "office manager") that were not specific to outreach in the total count.

[b] This includes the total number of community partners, and in parentheses, the number of community partners that focus specifically on the underserved. The Outcomes Worksheet defined underserved populations as "Hispanic or Latino, American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, Black or African American, Uninsured, Homeless, Undocumented, Rural Poor."

[c] The number of cancer screening events includes the total number of screening events in each year (Year 1 = July 1, 2007 to June 30, 2008; Year 3 = July 1, 2009 to June 30, 2010).

[d] Site 14 reported 0 screenings in Year 1 and 651 in Year 3; for the purposes of this analysis, we are considering any increase from 0 to be 100% change.

[e] Site 14 reported 0 screening events in Year 1 and 9 in Year 3; for the purposes of this analysis, we are considering any increase from 0 to be 100% change.

Table 9-7. Access to Care Scale Scores by Site[a]: Years 1 and 3[b]

Site	Mean (SD) Year 1 (N=2,009)	Mean (SD) Year 3 (N=1,946)	p Year 1 vs. Year 3
Data Source: Patient Survey			
All Sites	2.14 (0.99)	2.24 (1.01)	**0.003**
Site 4	2.02 (1.07)	2.00 (1.09)	0.878
Site 6	2.06 (1.03)	2.20 (1.02)	0.219
Site 10	2.00 (1.05)	2.23 (1.05)	**0.037**
Site 3	2.42 (0.82)	2.27 (1.00)	0.220
Site 12	2.03 (0.99)	2.16 (1.04)	0.248
Site 1	2.17 (0.95)	2.50 (0.77)	**0.001**
Site 9	2.23 (0.96)	2.28 (1.01)	0.579
Site 16	2.03 (1.04)	2.24 (1.07)	**0.046**
Site 15	2.45 (0.77)	2.39 (0.93)	0.506
Site 7	2.07 (1.00)	2.15 (1.01)	0.346

Note: Data are unweighted. Bold indicates change between Years 1 and 3 was statistically significant (at $p < 0.05$).

[a] The Patient Survey was conducted in the 10 lead sites only.

[b] The access to care scale score is based on three Patient Survey questions: In the past 12 months… How often did the people on your cancer care team help you get the medical appointments you needed? How often were you able to get an appointment as soon as you wanted at the cancer center? How often were you able to get the tests and other procedures you needed done without delay? Scale scores were computed as the number of items for which respondents gave an "always" response; higher scores indicate greater access to care.

Table 9-8. Change in Access to Care Scale Score for Demographic Subgroups[a]: Years 1 and 3

	Year 1 (N=2,009)		Year 3 (N=1,946)		P
Data Source: Patient Survey Characteristic	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**Year 1 vs. Year 3**
Race/Ethnicity					
White	1,681	2.12 (0.99)	1,628	2.23 (1.01)	**.001**
Non-White	285	2.30 (0.91)	284	2.30 (0.99)	.985
Education					
Less than high school	195	2.23 (0.95)	135	2.46 (0.92)	**.035**
High school graduate/GED	552	2.21 (0.95)	573	2.36 (0.94)	**.007**
Some college	569	2.15 (0.98)	554	2.21 (1.01)	.346
College graduate	651	2.06 (1.02)	639	2.13 (1.07)	.249
Income					
< $40,000	639	2.18 (0.99)	596	2.28 (1.00)	.084
≥ $40,000	1,045	2.11 (0.98)	1,040	2.21 (1.02)	**.025**

Note: Data are unweighted. Bold indicates a statistically significant difference compared to the reference group.

[a] The access to care scale score is based on three Patient Survey questions: In the past 12 months… How often did the people on your cancer care team help you get the medical appointments you needed? How often were you able to get an appointment as soon as you wanted at the cancer center? How often were you able to get the tests and other procedures you needed done without delay? Scale scores were computed as the number of items for which respondents gave an "always" response; higher scores indicate greater access to care.

Table 9-9. Total Number of Patients Navigated[a]: Years 1 and 3

Site	Year 1	Year 3	Change	Percent Change
Data Sources:	**BAS**	**FAS**		
Site 4	508	846	338	67%
Site 6	1,552	4,558	3,006	194%
Site 10	69	4,294	4,225	6,123%
Site 3	Missing	1,100	Unknown	Unknown
Site 12	Missing	840	Unknown	Unknown
Site 1	227	1,126	899	396%
Site 9[b]	0	634	634	100%[a]
Site 16	196	1,137	941	480%
Site 15	Missing	139	Unknown	Unknown
Site 11	Missing	690	Unknown	Unknown
Site 8	Missing	279	Unknown	Unknown
Site 7	Missing	252	Unknown	Unknown
Site 2	Missing	671	Unknown	Unknown
Site 13	Missing	131	Unknown	Unknown
Site 5[b]	0	513	513	100%[c]
Site 14[b]	0	151	151	100%[c]
Mean	510 (n = 5)	1,085	1,338 (n = 8)	1,452%

Missing = The site reported offering patient navigation services, but data are missing for this site because they did not have systems in place to track race/ethnicity.

Unknown = Value cannot be calculated due to missing data at Year 1 and/or Year 3.

[a] The BAS and FAS define patient navigation as "a program that provides personal assistance to patients in order to help them obtain timely and adequate medical care."

[b] Site did not offer patient navigation services in Year 1.

[c] Sites reported 0 patients navigated in Year 1; for the purposes of this analysis, we are considering any increase from 0 to be 100% change.

Table 9-10. Types of Cancer for Which Patient Navigation Services were Provided: Year 3[a]

Site	Breast	Thoracic	GI	Head & Neck	GYN	GU	Neuro	All Types[b]
Data Source:				**FAS**				
Site 4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Site 6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 10	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 12	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 9	No	Yes	Yes	No	No	No	No	No
Site 16	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 15	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Site 11	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 8	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 2	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Site 13	Yes	No	No	No	No	No	No	No
Site 5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site 14	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Total	15	15	15	14	14	14	12	11

[a] The FAS defines patient navigation as "a program that provides personal assistance to patients in order to help them obtain timely and adequate medical care."

[b] Some sites specified which types of cancer patient navigation services were provided while others simply indicated "All Types." For any site that indicated "All Types," RTI assumed that site was providing services for breast, thoracic, GI, head and neck, gynecologic, GU, and neurologic cancers.

Table 9-11. Patients' Awareness and Utilization of Patient Navigation Services:[a] Years 1 and 3

	Awareness[b] (%)			Utilization[c] (%)		
	Year 1	**Year 3**	**p-value**	**Year 1**	**Year 3**	**p-value**
Data Source: Patient Survey						
All sites	37.0%	48.0%	.000	66.4%	64.7%	0.470
Site 4	41.0%	59.6%	**0.000**	63.5%	71.4%	0.231
Site 6	43.5%	43.8%	0.949	64.9%	57.9%	0.345
Site 10	21.8%	41.8%	**0.000**	63.6%	52.6%	0.229
Site 3	37.2%	43.1%	0.296	60.7%	62.9%	0.798
Site 12	28.2%	38.8%	**0.048**	66.0%	63.0%	0.747
Site 1	48.6%	43.1%	0.373	79.7%	62.3%	**0.035**
Site 9	31.8%	53.9%	**0.000**	56.4%	71.7	**0.023**
Site 16	50.7%	44.7%	0.234	70.5%	62.8	0.263
Site 15	23.9%	34.6%	**0.019**	65.2%	65.8%	0.952
Site 7	44.2%	62.6%	**0.000**	70.1%	64.8%	0.375

Note: Bold indicates difference between Years 1 and 3 is statistically significant.

[a] The Patient Survey was conducted in the 10 lead sites only.

[b] The Patient Survey provides a brief explanation of patient navigators. Based on response to the question: "Does your cancer center have someone who acts as a 'patient navigator'?"

[c] Among respondents who were aware of patient navigation services. Based on response to the question: "In the last 12 months, have you ever been helped by a patient navigator?"

Table 9-12. Number of Patient Navigators[a]: Years 1 and 3

Site	Year 1	Year 3	Change	Were any Patient Navigator RNs? (Year 3)
Data Source:	**BAS**	**FAS**		**FAS**
Site 4	7	9	2	Yes
Site 6	12	11	-1	Yes
Site 10	5	14	9	Yes
Site 3	3	3	0	Yes
Site 12	6	10	4	Yes
Site 1	3	6	3	No
Site 9	0	2	2	Yes
Site 16	3	4	1	No
Site 15	5	7	2	Yes
Site 11	4	1	-3	Yes
Site 8	0	6	6	Yes
Site 7	4	4	0	Yes
Site 2	16	8	-8	No
Site 13	1	1	0	Yes
Site 5	0	1	1	No
Site 14	0	2	2	Yes
Mean	4	6	2	

[a] The BAS and FAS define patient navigation as "a program that provides personal assistance to patients in order to help them obtain timely and adequate medical care." Sites reported the number of staff who provide patient navigation services. The number of patient navigators presented here excludes social workers unless their role was indicated primarily as patient navigators.

Table 9-13. Relationship between Number of Patient Navigators and Outcomes: Numbers of Patients Navigated and Awareness of Patient Navigation

Site	Number of Patient Navigators[a]		Percent Change in Number of Patients Navigated	Significant Increase in Awareness of Patient Navigation[b]
	Year 3	Change, Years 1-3		
Data Source:	**FAS**	**BAS-FAS**	**BAS, FAS**	**Patient Survey**
Site 4	9	2	67%	Yes
Site 6	11	-1	194%	No
Site 10	14	9	6,123%	Yes
Site 3	3	0	Unknown	No
Site 12	10	4	Unknown	Yes
Site 1	6	3	396%	No
Site 9	2	2	100%[c]	Yes
Site 16	4	1	480%	No
Site 15	7	2	Unknown	Yes
Site 11	1	-3	Unknown	Data not collected
Site 8	6	6	Unknown	Data not collected
Site 7	4	0	Unknown	Yes
Site 2	8	-8	Unknown	Data not collected
Site 13	1	0	Unknown	Data not collected
Site 5	1	1	100%[c]	Data not collected
Site 14	2	2	100%[c]	Data not collected

Unknown = Value cannot be calculated due to missing data at Year 1 and/or Year 3.

Data not collected = These data were not collected for this site.

[a] The BAS and FAS define patient navigation as "a program that provides personal assistance to patients in order to help them obtain timely and adequate medical care." Sites reported the number of staff who provide patient navigation services

[b] The Patient Survey provides a brief explanation of patient navigators. Based on response to question: "Does your cancer center have someone who acts as a 'patient navigator'?"

[c] Site did not have patient navigation and therefore 0 patients in Year 1; for the purposes of this analysis, we are considering any increase from 0 to be 100% change.

Table 9-14. Minority (Non-White) Patients Enrolled in NCI-Sponsored Clinical Trials[a]

	Minority Accrual		
Site	**Year 1**	**Year 3**	**Change**
Data Source:	**CT Worksheet[b]**		
Site 4	3	8	5
Site 6	32	40	8
Site 10	3	0	-3
Site 3	6	9	3
Site 12	6	13	7
Site 1	0	9	9
Site 9	0	5	5
Site 16	13	11	-2
Site 15	0	4	4
Site 11	0	0	0
Site 8	1	0	-1
Site 7	0	2	2
Site 2	4	8	4
Site 13	2	0	-2
Site 5	0	0	0
Site 14	Unknown	0	0
Means	5	7	2

Unknown = Site reported "unknown"

[a] According to SAIC-F, sites were asked to report "minority accrual for this quarter" as a single number with all races/ethnicities combined. For the majority of the data, sites were asked to report "minority accrual" without any differentiation between race and ethnicity. The quarterly report instructions were: "Minority Accrual: Provide the number of minority patients accrued to each protocol for the period of this quarterly report." However, in Year 3 Quarter 4 (and for all of Site 16's NCI-sponsored-trial data), a few began reporting this information by OMB race and ethnicity category, "minority accruals" include American Indian, Native Hawaiian, Asian, Black and More than one race. Thus, for Year 3 Quarter 4 and Spartanburg's NCI-sponsored trial data, we did NOT include each accrual entered into one of the following categories: White, Not reported/patient refused, Not reported/data not available. Also, we did not count any accruals in the "ethnic minorities" category.

[b] Self-reported data from sites as reported on the CT Worksheet provide patient accrual data that are well below CTEP data. We believe this is likely due to sites excluding physician practices from their counts that are included in CTEP and therefore believe CTEP to be more reliable. Sites were also asked to report minority accruals only by race/ethnicity and not by age or whether they reside in rural areas.

Unknown= site reported "unknown"

Minority accruals were tallied for these types of trials: "therapeutic, symptom management/cancer control, and prevention" Other trials are classified as anything other than "therapeutic, symptom management/cancer control, and prevention"; minority accruals were not collected for these types of trials.

Table 9-15. Overview of Success in Disparities Implementation: Year 3[a]

Site[b]	Collection Race/Ethnicity Using OMB Categories[c] Change in Number of Systems	Change in Number: Formal Partners Focusing on Underserved[d]	Change in Number: Screenings and Percent Change[e]	Change in Number: Screening Events and Percent Change[f]	Change in Access to Care Statistically Significant Change (Yes/No)[g]	Patient Navigation: Percent Change Number of Patients Navigated[h]	Patient Navigation: Statistically Significant Change in Patient Awareness (Yes/No)[i]
1	3	2	5,933 (35.1%)	-25 (-12.7%)	Yes	396%	No
2	9	22	Unknown	0 (0.0%)	Data not collected	Unknown	Data not collected
3	7	0	1,634 (37.3%)	104 (80.6%)	No	Unknown	No
4	7	2	7,006 (13%)	32 (320%)	No	67%	Yes
5	9	6	Unknown	25 (89.3%)	Data not collected	100%[i]	Data not collected
6	2	0	577 (37.4%)	157 (266.1%)	No	194%	No
7	3	3	56 (29%)	0 (0.0%)	No		Yes
8	6	2	146 (110.6%)	5 (500%)	Data not collected	Unknown	Data not collected
9	7	0	-1,062 (12.7%)	-104 (-17.7%)	No	100%[k]	Yes
10	3	0	1,826 (108.2%)	98 (108.9%)	Yes	6,123%	Yes
11	6	-1	550 (27.3%)	29 (29.9%)	Data not collected	Unknown	Data not collected
12	0	2	7,254 (105.5%)	56 (37.8%)	No	Unknown	Yes
13	8	18	1,740 (38%)	0 (0.0%)	Data not collected	Unknown	Data not collected
14	9	1	651 (100%)[j]	-11 (-55.0%)	Data not collected	100%[j]	Data not collected
15	3	0	527 (15.8%)	51 (27.9%)	No	Unknown	Yes
16	2	-6	1,478 (403.8%)	73 (1216.7%)	Yes	480%	No
Summary	▪ 15 sites increased ▪ 1 site had no change ▪ 0 sites decreased	▪ 15 sites increased ▪ 0 sites had no change ▪ 1 site decreased	▪ 13 sites increased ▪ 0 sites had no change ▪ 1 site decreased ▪ 2 sites unknown due to missing data	▪ 10 sites increased ▪ 3 had no change ▪ 3 sites decreased	▪ 3 sites changed significantly ▪ 7 sites did not change significantly ▪ 6 sites: data not collected	▪ 5 sites increased ▪ 11 sites unknown due to missing data	▪ 6 sites changed significantly ▪ 4 sites did not change significantly ▪ 6 sites: data not collected

(continued)

Table 9-15. Overview of Success in Disparities Implementation: Year 3[a] (continued)

[a] We initially included the number of minority accruals to clinical trials in this table but have now deleted this information because the self-reported data across sites are well below what was available in the analysis of CTEP data. Because CTEP data are de-identified, they have not been included in this table.

[b] Sites have been de-identified and random numbers assigned in order to present their data.

[c] See Table 9-2 for supplemental data on race/ethnicity tracking in various systems by site. Data source: Outcomes Worksheet

[d] See Table 9-3 for supplemental data on total number of community partners and number of formal community partners. The Outcomes Worksheet, the data source used for this table, defines a community partner as "an organization or group that agrees to collaborate with the NCCCP sites to reach the public in support of the work of a healthcare or cancer initiative, especially with a focus on minority and underserved populations" and defines formal partnerships as "ongoing relationships with a formal agreement or MOU to provide specific services to the community with a defined outcome."

[e] See Table 9-4 for supplemental data on the number of screenings provided by site in Year 1 and Year 3. Data Source: Disparities Dashboard

[f] See Table 9-4 for supplemental data on the number of screening events provided by site in Year 1 and Year 3. Data Source: Disparities Dashboard

[g] See Table 9-7 for supplemental data on patients' perceived access to care in Year 1 and Year 3; significance determined at $p < 0.05$. The Patient Survey, the data source used for Table 9-7, was conducted in the 10 lead sites only.

[h] See Table 9-9 for supplemental data on the number of patients navigated in Year 1 and Year 3. Data source: BAS/FAS

[i] See Table 9-11 for supplemental data on patients' reported awareness of patient navigation services in Year 1 and Year 3; significance determined at $p < 0.05$. The Patient Survey, the data source used for Table 9-11, was conducted in the 10 lead sites only.

[j] See Table 9-14 for supplemental data on minority accruals in Year 1 and Year 3; data represent the change in number of minority accruals to NCI-sponsored clinical trials only.

[k] For the purposes of this analysis, we are considering any increase from 0 to be 100% change.

10. CLINICAL TRIALS

Overview

Enhancing the sites' capacity for conducting clinical trials was a primary goal of the NCCCP. This effort included increasing sites' capacities for opening trials and conducting different types and phases of trials so that they could greatly increase the proportion of cancer patients enrolled in active trials and thus contribute to the NCI research mission. NCI purposefully selected sites at varying levels of capacity to test the ability of the NCCCP network to strengthen the developmental sites. Several of the sites selected for award are affiliated with the NCI's Community Clinical Oncology Program (CCOP)/Minority-Based Community Clinical Oncology Program (MBCCOP). Overall, performance improvements among NCCCP sites (i.e., increases in clinical trials portfolio and accrual outcomes) were slightly higher than national trends (Abernethy & Locke, 2011).

Enhancing Clinical Trial Capacity and Infrastructure

Many of the sites increased their capacity to conduct different types and phases of trials and to have more trials open at any one time. As reported by Abernethy and Locke (2011), the number of Phase 3 CTEP-sponsored trials launched nationally increased by 8% during the pilot time period, yet the NCCCP sites increased their local activations of these trials by 16%. Sites also tended to increase their clinical trials infrastructure, adding staff, dedicated research pharmacies, Institutional Review Boards (IRBs), and information technology (IT) tracking systems. A majority of the sites also increased their affiliations with more Clinical Trials Cooperative Groups, and required physicians to enroll at least a few patients per year in clinical trials as part of their conditions of participation. Sites reported the proportion of their key cancer physicians who were enrolling patients into trials as of Year 3. Sites reported a median increase of 5.2% in the proportion of physicians who were enrolling patients in trials.

Increasing Patient Clinical Trials Accrual

Many of the sites, particularly those that were "developmental," had minimal experience in conducting clinical trials research at baseline. NCI placed the minimum at 25 patients accrued to clinical trials in 2006 as the baseline number sites had to report in order to qualify as a potential NCCCP lead site. At baseline, sites varied on number of patients enrolled. By Year 3, patient accrual increased, especially in Phase 3 trials, and the overall patient-per-trial ratio increased over the evaluation period. Increases in overall patient accruals were higher among NCCCP sites when compared to national trends included in the CTEP data (Abernethy & Locke, 2011). Lead NCCCP sites contributed most to accrual and showed higher proportional increases in accrual. Nearly all sites increased their accrual to underserved populations in either the racial/ethnic minority, rural, or over age 65 categories. Sites affiliated with the CCOP showed the most consistent relative increases in accrual of underserved populations, although their overall clinical trials activity did not increase.

Patients' Perspective on Clinical Trials

During the same time period, significantly fewer patients reported receiving education materials about clinical trials. Patients were also significantly less likely across sites to participate in clinical trials if offered the chance.

Barriers and Facilitators

One of the barriers that influenced the extent to which sites could demonstrate progress in clinical trials research is the limited 3-year period of the NCCCP pilot. Even if sites strive to add more trials, a great deal of time and effort is needed before significant changes in accruals can be demonstrated. Given this limitation, we worked to incorporate additional outcomes (i.e., other than patient accrual) into the clinical trials component and we found that sites were generally able to increase aspects of their clinical trials capacity (e.g., number of open trials, staffing), often facilitated by increased infrastructure and physician participation in trials. Understanding these findings in the national context is critical to assessing the ultimate success of the NCCCP. For this reason, NCI has funded a special study, being conducted by Duke University's Cancer Care Research Program (http://www.cancer.duke.edu/dccrp/) to examine the clinical trials statistics of the NCCCP relative to the national, secular trends. The additional findings should elucidate how to better interpret those presented in this chapter.

Building the NCI capacity for expanding clinical trials research within a community setting was a priority of the NCCCP pilot. NCI asserts that "making these trials available locally will draw more participants into trials and enable researchers to more rapidly develop and evaluate effective prevention and treatment strategies" (http://ncccp.cancer.gov/Program/index.htm). To achieve these aims, NCI established priorities for sites to increase their clinical trials accrual: receipt of community input from a local advisory board, expansion of types of trials, expansion of trial complexity, enhancement of clinical trials infrastructure, improvement of protocol timelines, expansion of collaborations, expansion of outreach to the underserved, improvement in accrual tracking, and improvement in communication systems. This evaluation will focus on the following priorities:

- accrual to all clinical trials, including therapeutic, prevention, and symptom management/cancer control, with specific focus on increasing accrual to NCI-sponsored trials;
- accrual of underserved patients; and
- the capability to offer early phase (i.e., I and II) trials and develop protocols for appropriate referral of patients for Phase I trials to NCI-designated cancer centers or academic medical research institutes.

In establishing its expectations of sites, NCI carefully considered the varying degrees of "start up" implementation with regards to clinical trials. For example, some sites were already participating as lead or affiliate sites in the Community Clinical Oncology Program (CCOP)/Minority-Based Community Clinical Oncology Program (MBCCOP), a network for conducting cancer prevention and treatment clinical trials within a community setting. For NCCCP sites that were also lead CCOPs at the start of the program, it was difficult to articulate what they were doing differently in each of the program components, especially in clinical trials:

> *The CCOP is an independent organization. I don't think [NCI] had any understanding of our participation in the research process. They didn't realize how active we were already in the research process. I was concerned on the emphasis on the clinical trials.* (PI, Year 2)

> *We have kind of a long-established program with the CCOP, so it has been a challenge to try to increase accrual when you've been trying to do that all along.* (Subcommittee member, Year 2)

In addition, historically, most sites have offered Phase III trials to their patient populations. These are trials in which multiple treatments (e.g., drugs) are compared with one another to address research questions such as how effective a drug is in comparison with commonly used or current "gold standard" treatments. Early phase studies (Phase I and Phase II), conduct research on new treatments or drugs to test for safety, effectiveness, and toxicity. The capability to offer more Phase I and Phase II trials, particularly through their partnerships with NCI-designated cancer centers, posed challenges for several sites:

> *Most sites wanted to know, "How do we become cutting edge? How do we go from Phase III to Phase I offering NCI-level innovative trials without patients having to travel?" It's win-win for sites and for NCI. That's absolutely the long-term goal.* (Subcommittee member, Year 2)

> *One of the limitations with GOG [Gynecologic Oncology Group] is we don't have access to Phase I trials because you have to be a member; now we have the opportunity to do this through Colorado and Moffitt, so we can bridge that gap.* (Key physician, Year 3)

Given the importance of enhancing clinical cancer research across NCCCP sites, over the course of the pilot there were numerous clinical trials-related activities specific to the NCCCP, including four major areas of work:

- development of a clinical trials subcommittee as part of the larger NCCCP network to set priorities and develop strategies for reaching objectives by the end of the pilot;
- formation of four workgroups, each focusing on a specific set of objectives: clinical trials portfolio, Clinical Trials Screening and Accrual Log, underserved populations accrual, and best practices;
- creation of tools by the clinical trials subcommittee (and workgroups) to support sites in reaching their objectives; and
- implementation of strategies and tools at the site level.

The following sections provide details for each of these areas of activity and present data from a variety of sources collected during the pilot.

10.1 NCCCP Clinical Trials Subcommittee Priorities and Strategies

As with the structure of other program components (e.g., disparities, survivorship), the NCCCP network consisted of a clinical trials subcommittee that provided oversight and input into the clinical trials activities across the pilot sites. The goal of the subcommittee was to assist the pilot sites to

- broaden clinical trial menu to increase trial complexity to include earlier phase trials and increase trial types to include cancer control and prevention,
- increase overall accruals to clinical trials,
- increase accruals to clinical trials among underserved patient populations, and
- increase overall clinical trials capacity over the course of the pilot.

In order for the NCCCP sites to meet the priorities for the program, in 2007 the clinical trials subcommittee initiated a number of activities, including

- development of a screening and accrual log for tracking, to gain an understanding of barriers to clinical trials accrual and track clinical trials screening and accrual across sites,
- completion of site-specific workplans for clinical trials, and
- implementation of a clinical trials "portfolio" to focus the subcommittee's efforts on a select group of clinical trials to track in the screening and accrual log.

Furthermore, it was hoped that through the NCCCP, sites would be able to increase their physician involvement in clinical trials, increase the participation of underserved populations in clinical trials, and increase their involvement in early phase trials. The following is an overview of the strategies implemented to address each of the three priorities.

10.1.1 Priority 1: Increase in Accrual to All Clinical Trials (including Pharmaceutical Trials)

After a series of NCCCP network subcommittee discussions in 2007, sites agreed to focus on accruing patients to a group of Phase III trials supported by NCI's Cancer Trials Support Unit (CTSU). The CTSU is a pilot project sponsored by NCI to support a national network of physicians participating in NCI-sponsored Phase III cancer treatment trials. The objectives of the CTSU are to increase physician and patient access to NCI-sponsored clinical trials, to streamline and standardize clinical trials data collection and reporting, and to reduce regulatory/administrative burden on investigators participating in NCI-sponsored cooperative group clinical trials (Phases 1–3) (http://ncccp.cancer.gov/Related/index.htm).

The NCCCP sites selected three CTSU trials (Breast-NSABP B-42, Colorectal-CALGB 80405, and Lung-ECOG E1505) to serve as the initial network project trials with the goal of increasing participation in clinical trials, including accrual among populations and motivating

investigators to accrue to those trials. Of the 16 NCCCP sites, 12 participated in the CTSU in Year 1, and 13 sites participated by Year 3. Overall progress in clinical trials accrual since Year 1 of the pilot, including on underserved accrual, and early phase trials are summarized data (where available) from an Excel spreadsheet (Appendix N) provided by NCI and SAIC-F in April 2011. The data contain a list of all open clinical trials by site and reflect periods of accrual from July 1, 2007 through June 30, 2008 (Year 1), July 1, 2008 through June 30, 2009 (Year 2), and July 1, 2009 through June 30, 2010 (Year 3). The data also characterize, where available, each clinical trial by phase, trial type (e.g., therapeutic, prevention), and underserved populations accrual for each reporting period.

10.1.2 Priority 2: Increase in Underserved Patient Accrual to Clinical Trials

The emphasis on underserved clinical trials accrual has made tracking of patients a major priority and focus during the pilot. The lack of race/ethnicity data available in many patient records presents a challenge when evaluating the impact of clinical trials efforts within and across sites. According to the Baseline Assessment Survey (BAS), only 38% of all 16 sites reported having a system in place for tracking individual clinical trial activities. Approximately 31% had a mechanism in place for tracking non-white accrual across all trials at their center, based on Office of Management and Budget (OMB) national tracking standards. It was hoped that data collected from the baseline assessment would assist the subcommittee in identifying common barriers to clinical trials accrual across sites (see Section 10.6). With this information, it was anticipated that sites would utilize NCCCP resources to begin addressing the clinical trials priorities.

Because few sites were tracking clinical trials accrual among their non-white and underserved populations, the clinical trials subcommittee worked to develop processes and tools for enhancing data tracking via worksheets and Web-based logs, which are discussed in Section 10.2. Overall success in non-white accrual is discussed in Section 10.4.3.

10.1.3 Priority 3: Increase in Clinical Trial Capacity

In addition to underserved clinical trials accrual, there has been a special emphasis on enhancing sites' overall clinical trials capacity by helping them to conduct early phase trials (i.e., Phase I and II), offer more types of trials, and maintain more open trials. It was hoped that by offering sites access to early phase and more types of trials, they would be able to

- establish priorities and baseline metrics (e.g., standards of comparison) for early phase clinical trials accrual,
- utilize NCI resources and tools (e.g., NCI's Clinical Trials Portal and Cancer Trials Support Unit) to improve or increase access to therapeutic strategies, and
- develop important community linkages (e.g., NCI-designated cancer centers, CCOPs) to develop protocols for appropriate patient referrals to early phase trials.

The trial capacity in Year 1 and Year 3 as well as the change over time by site are discussed in Section 10.4.1.

10.2 Use of Clinical Trials Subcommittee Tools and Establishment of Workgroups

The clinical trials subcommittee created workgroups (as subgroups of the subcommittee) to develop tools, and guidelines to facilitate sites' implementation of the NCCCP deliverables. Based on discussions during the 2008 annual meeting in June, four clinical trials workgroups were formed to better manage efforts related to clinical trials:

- Screening and Accrual Log Workgroup,
- Best Practices Workgroup,
- Clinical Trial Portfolio Workgroup, and
- Minority/Underserved Accrual Workgroup.

The following sections describe some of the workgroups' efforts, including the use of various tools created to track and manage clinical trials accrual, such as cultural awareness webinars and the minority/underserved accrual matrix; linkages with other NCI programs (e.g., CCOPs); and overall facilitators and challenges in clinical trials accrual. For the site visits, NCI was most interested in two tools created specifically for clinical trials accrual on which all sites were asked to provide feedback:

- the Clinical Trials Screening and Accrual Log, and
- the Clinical Trials Accrual Quarterly Report Update.

10.2.1 Clinical Trials Screening and Accrual Log

The Clinical Trials Screening and Accrual Log (Appendix O) was launched in February 2008 and provided a way for sites to track patients screened and enrolled on those clinical trials "targeted" by the NCCCP and included features for capturing race/ethnicity data. To enhance its potential for data mining and reporting, the Accrual Tracking Log Workgroup revised and updated the tool later that year. Most importantly, sites enter data for all of the reasons patients do not participate in clinical trials in order to elucidate barriers and develop strategies to improve clinical trials accrual. The IT subcommittee provided support and worked collaboratively with the Accrual Tracking Log Workgroup to implement this web-based tool.

As of the site visits in Years 2 and 3, although not all sites were using the Screening and Accrual Log, the respondents who indicated that their site was using the Clinical Trials Screening and Accrual Log found it to be a very useful tool. Overall, respondents agreed that it has streamlined their data accrual process and made it easier to track patients for eligibility, especially non-white populations:

> *It has become better now that we have a streamlined way to show accrual, whereas before every pilot site was showing their accrual however they want. Now that it is standardized, it makes a lot more sense.* (Subcommittee member, Year 2)

> *The accrual log is a great tool and it is working.* (Key physician, Year 3)

There was variation among the sites, however, as to the types of trials that are tracked using the Clinical Trials Screening and Accrual Log. Some sites utilized the system more broadly by capturing data on all of their open clinical trials:

> *The CT screening log is used for all trials system-wide, so any trials that we have opened here, and we use that log…to determine how many people are screened, eligible, and went on to the clinical trial.* (PI, Year 2)

On the other hand, there are sites that have adapted their own analogous screening tools to track non-NCCCP trials, while using the Web-based version of the Clinical Trials Screening and Accrual Log to track only NCCCP trials:

> *I view it as we have to use it if it's an endorsed trial by [the] NCCCP. We're expanding to hopefully around 10. We all have to use what's been set up by [the] NCCCP, and it's online.* (Subcommittee member, Year 2)

When further asked if the tool was simply for reporting to NCI or if it was used for other trials, this respondent replied, "No, there's no time for other trials. It's labor intensive." The Clinical Trials Screening and Accrual Log enhanced sites' ability to track barriers to enrollment, race, and ethnicity data and to generate reports.

10.2.2 Clinical Trials Accrual Quarterly Report Update

The Accrual Tracking Log Workgroup developed a data collection tool to track clinical trials activity by sites on a quarterly basis. The template, which is primarily used as a supplement to the quarterly reports, was developed so that there would be consistent reporting of clinical trials activity by the sites in their quarterly reports. The purpose of the tool is to compile and summarize quarterly data about active clinical trials among the pilot sites. This tool was not used or mentioned by the majority of sites. The three sites that mentioned this tool felt that the update worksheet was redundant with the Web-based Clinical Trials Screening and Accrual Log in the type of information required. For that reason, they adapted their data systems to produce "data dumps" for quarterly progress report requests. However, one clinical trials subcommittee member noted a benefit of the periodic reporting in that the update worksheet provides a good "handle on what we have accrued."

10.2.3 Cultural Awareness Webinars

In spring 2008, in collaboration with the disparities subcommittee and NCI's Cancer Information Service (CIS), the clinical trials subcommittee developed its first in a series of

four webinars titled "Clinical Trials 101." The webinar highlighted factors related to clinical trials participation, the process of patient accrual and protection, barriers to clinical trials participation and ways to address them, and NCI clinical trial resources available to patients and providers. The webinar was well-received, and many participants expressed an interest in additional webinars on cultural awareness. The webinars include panel discussions with patients, physicians, and other experts, and emphasize culturally sensitive ways to approach non-white populations about biospecimens issues and clinical trials participation. The second cultural awareness webinar was held in May 2009 and focused on the Hispanic/Latino community. The objectives of the webinar were to

- describe cancer incidence, prevalence, and mortality trends for the Hispanic/Latino population;
- identify differences among Hispanic/Latino population groups (e.g., Mexicans, Puerto Ricans, Cubans, Central and South Americans);
- describe how Hispanic/Latino health care beliefs influence interactions with the health care team and system;
- identify challenges and barriers to Hispanic/Latino enrollment in clinical trials based on the case study presented; and
- identify promising practices related to increasing Hispanic/Latino enrollment in clinical trials.

The third webinar focused on African American cultural health care beliefs with an emphasis on clinical trials, and the fourth webinar focused on Native American Cultural Awareness. The target audience for these webinars included health care professionals and physician support staff.

10.2.4 Minority Matrix

In spring 2009, under the guidance of the Minority/Underserved Accrual Workgroup, a data collection matrix (Appendix P) was developed to help pilot sites systematically capture barriers to clinical trial participation, pair NCCCP sites based on disparate populations to disseminate best practices, and monitor opportunities that arise in the NCCCP network.

10.3 Clinical Trials Implementation across NCCCP Sites

Sites used various internal strategies to meet the clinical trials priorities set forth by NCI and the workgroups, many of which were focused on building research infrastructure and capacity to implement the clinical trials component. This section describes sites' research infrastructure and capacity as well as some of the strategies sites used during the pilot to successfully enroll patients into clinical trials, particularly among minority/underserved populations. In addition to enhancing research infrastructure and capacity to implement clinical trials, sites focused their clinical trials efforts on three main areas: (1) patient education, (2) community outreach, and (3) presentation at tumor boards.

10.3.1 Patient Education

Direct patient education has been a major focus across sites in increasing clinical trials accrual. Changes in patients' reported understanding of clinical trials are discussed in Section 10.4.6. This area has involved not only the work of the patient navigator but also coordinated efforts across multiple patient providers, including nurses, physicians, outreach coordinators, and research staff. In fact, from 2007 to 2008, 88% of sites demonstrated increases in educational activities about clinical trials, such as educating staff, local patients, non-white patients, community physicians, and non-white community physicians:

> *When we are with the physician, the physician discusses the clinical trial first and then they call the nurse to discuss the clinical trial. I think that has been the most effective way.* (Subcommittee member, Year 2)

> *In terms of outreach, our physicians from minority populations do a lot of educating patients who are underserved and having them talk [to] and educate the groups.* (Subcommittee member, Year 2)

> *[It's] definitely a collaboration. With CT, we want to increase minority participation, so I encourage people and talk about CTs…. We talk about how protection is important and that we are using human subjects and be considerate about what is going to happen and making sure we have demographic-specific information.* (Subcommittee member, Year 2)

10.3.2 Community Outreach

Sites sought to increase clinical trials access to their minority/underserved populations via various outreach strategies. According to the 2008 Interim Assessment Survey (IAS), 25% of the 16 sites reported beginning to use surveys to determine the preferences and needs of the local community regarding clinical trials:

> *I think there is support for clinical trials, and we want to work to have a diverse representation of people on clinical trials. We are going to be doing a project of focus groups asking people of diverse populations about their feelings about clinical trials. I think everything we're trying to do starts with not even having cancer to getting the best care possible, which includes access to clinical trials.* (Subcommittee member, Year 2)

Sites' efforts to spread the word to their local populations about the benefits of clinical trials participation has positioned them to make necessary linkages/partnerships in their broader communities:

> *Clinical trials are part of everything we talk about when we talk about the partnership [with Moffitt]. When we talk about risks and give education sessions, we do talk about clinical trials there. When we are together with some other outreach*

> *programs like at health fairs, we'll have information there about clinical trials…* (Subcommittee member, Year 2)

> *Right now, what we're trying to do is use the spoke and hub, offering more trials at our outreach clinics.… The overall plan long-term is to offer clinical trials onsite at various outward sites.* (Subcommittee member, Year 2)

These linkages to enhance clinical trials accrual were not only defined broadly across a community, but also offered an opportunity for networking and integration within sites. Many sites described their clinical trial efforts as being a "natural fit" with coordinating efforts across other components, especially disparities (see Chapter 9):

> *Clinical trials and outreach work together because those people can put people into clinical trials, outreach and QOC in care management…outreach can refer people to [clinical trials], and care management can help with clinical trials.* (Program coordinator, Year 2)

Several sites also used technology as an outreach medium to increase clinical trials accrual. The following are just a few site-specific examples:

- Billings Clinic has worked on building relationships with the surrounding Native American communities and introduced creative outreach strategies (e.g., conducting outreach activities in casinos, Walmart stores, and the prison). They are also expanding the use of telemedicine to serve rural populations, including facilitating participation in clinical trials.
- St. Vincent posts available clinical trials on their internal website. Interested visitors can click an icon to link in with a patient care coordinator for more information.
- St. Joseph Medical Center (Towson, MD) makes available in each exam room a list of all open studies and posts protocols and informed consents online. Interested patients are able to view and print consent forms and check their eligibility.

10.3.3 Presentation of Clinical Trials at Tumor Boards

Across sites, tumor boards have proven to be an effective way of "getting the word out" about clinical trials. According to results from the 2008 IAS, 75% of sites reported using additional clinical trials screening activities, such as discussions at tumor boards, identification by patient navigators, and electronic health records (EHRs), as part of their efforts to enhance clinical trials accrual:

> *Another thing that's happened is that now we have a tumor board, and someone from the cancer center is at the tumor board to discuss clinical trials, and there's a discussion [as to] whether the person is eligible for the clinical trials or not.* (Key physician, Year 2)

> *Clinical trials nurses are at the conferences, and for every patient [they] can pull up relevant clinical trials as [they] present the case, so it makes sure we are thinking upfront about clinical trials as we're looking at the patient.* (Key physician, Year 3)

10.3.4 Research Infrastructure and Clinical Trials Capacity

Many of the NCCCP sites, particularly the developmental sites, had limited research infrastructure and capacity to implement the clinical trials component at baseline. Specifically, sites varied in terms of the following key indicators:

- whether there was a director of research of the Cancer Program who was a physician;
- whether the site was a lead CCOP site, performance site, or unaffiliated;
- the number of Clinical Trials Cooperative Groups the sites were members of;
- the number of clinical trials staff (e.g., clinical research nurses [CRNs] and clinical research associates [CRAs]);
- whether they had incorporated clinical trials accrual as part of their conditions of participation (COPs) with their key cancer physicians;
- whether the site had a dedicated research pharmacy; and
- whether the site had some sort of IT support of clinical trials.

10.3.4.1 Director of Research

Having a director of research, particularly one who is a physician, is critical for building a clinical research program. As described by one key physician in Year 3, "There needs to be a manager for all [clinical research staff] and someone who has a goal" in order to successfully implement and sustain the clinical trials–related activities.

Notably, half of the NCCCP sites still did not have a director of research in place at their cancer center by Year 3. Of the eight sites with a director of research in place by Year 3, seven already had a director in place in Year 1, meaning that only one site hired a director during the course of the pilot (who also served as the medical director for the cancer center). Furthermore, only six sites had a physician acting as the director of research. Figure 10-1 shows which sites had a director of research at their cancer center by Year 3 and which sites did not:

Figure 10-1. Sites with and without a Director of Research in Year 3[a]

Sites with a Director of Research	Sites without a Director of Research
▪ Billings Clinic	▪ Our Lady of the Lake
▪ Christiana	▪ St. Joseph/Orange
▪ Hartford Hospital	▪ Sanford Clinic
▪ St. Joseph's/Candler	▪ St. Vincent
▪ Spartanburg RMC	▪ Columbia St. Mary's
▪ Brackenridge	▪ Penrose-St. Francis
▪ St. Joseph/Towson	▪ St. Elizabeth RMC
▪ Good Samaritan	▪ St. Francis Medical Center

[a] Data Source: Site visit organizational charts

10.3.4.2 CCOP Status

The NCCCP sites also had different levels of affiliation with CCOPs. According to NCI's website, the primary goal of the CCOP is to "accelerate implementation of NCI clinical trials for cancer prevention, control and treatment" (http://prevention.cancer.gov). Christiana, Sanford Clinic and Spartanburg Regional Medical Center are considered by NCI to be "lead" CCOP sites. Billings Clinic, Penrose-St. Francis, St. Elizabeth Regional Medical Center, and Our Lady of the Lake are defined by NCI as "performance" CCOP sites, meaning they are supported on the cooperative agreement (i.e., through a subgrant or subcontract) that funds the CCOP but are not the lead (i.e., funded) institution. The seven sites that are lead CCOP sites or performance sites should have had greater capacity to implement the clinical trials component than unaffiliated sites because they were already plugged into a network designed to support clinical trials activity. The relationship between CCOP status and outcomes is presented in Chapter 16, and explored in depth in the supplemental report completed by Duke University's Cancer Care Research Program.

10.3.4.3 Participation in Clinical Trials Cooperative Groups

Participating in Clinical Trials Cooperative Groups increases access to large-scale trials in multi-institutional settings. All 16 pilot sites were members of at least one Clinical Trials Cooperative Group in Year 1 (Table 10-1), and the number of groups each site participated in ranged from 1 (Site 14) to 12 (Site 16). Over the course of the pilot, 13 sites increased the number of Clinical Trials Cooperative Groups they were members of, thus increasing access to the number and types of trials they were able to open. Site 6, Site 11, and Site 13 experienced no change, maintaining the number of groups they were participating in from Year 1 to Year 3.

10.3.4.4 Clinical Research Staff

Clinical trials personnel capacity is essential to implementing the NCCCP clinical trials component, because an increase in personnel indicates commitment to the NCCCP and

increases a site's ability to screen patients and provide immediate support for clinical trials. Table 10-2 provides data on clinical trials staff in Year 1 and Year 3.

Five of 16 sites increased their full-time equivalency (FTE) for clinical trials coordinators or clinical research associates, while six sites decreased the FTE committed to these positions. Most sites (12 of 16) increased the FTE for research nurses, and almost all of the sites (15 of 16) increased the total number of staff involved in clinical trials. The majority of sites expanded their clinical trials personnel capacity. It is important to note the differences in how sites seem to have counted these staff. Although the counts of the CRNs and CRAs are fairly consistent over time, with relatively little variation across sites, the counts for total staff supporting clinical trials varies greatly across sites. These differences are likely due to the fact that sites were provided minimal instruction on how to calculate this total. Many sites seemed to have counted any physicians who may have referred even one patient for enrollment in a trial while other sites counted far fewer staff. Therefore, the "total staff supporting clinical trials" data should be used with caution when explaining changes in capacity over time.

10.3.4.5 Physician Engagement

Sites explored several ways to increase the interest and involvement of clinical research staff, especially among private practice physicians. Across sites, these physicians varied in their level of interest, and time commitment was a huge barrier to accruing their patients to clinical trials:

> *Physicians have an obligation to participate in clinical trials. It is what makes the cancer center key. The staff is really good about pushing for clinical trials. I wish I had more time personally, because I get the patient involved and turn them over to someone else and then I lose them. I think patients listen to their clinicians.* (Key physician, Year 2)

Some physicians saw the value in clinical trials accrual and were actively referring patients:

> *In terms of [the] NCCCP, I'm aware of the initiatives they're trying to do…and [I'm] trying to make clinical trials a more active part of life here.* (Key physician, Year 2)

> *We have increased the research staff and increased doctors' knowledge about existing clinical trials…. Physicians are allowing research staff to come to their offices…. I try to present whatever is available to the patient. We have three trials that are actively available between the hospital and my office. I present all three options to the patients to assess their interest.* (Key physician, Year 2)

As discussed in Chapter 13, an important aspect of engaging private practice physicians was implementing conditions of participation. The NCCCP required the private practice sites to include clinical trials enrollment as part of their conditions of participation. In Year 1,

according to the BAS, two lead sites already had fully implemented conditions of participation and already required participating physicians to enroll a certain number of patients (see Table 10-2). One of these sites stipulated that physicians must accrue at least four patients to a clinical trial to be able to call themselves an "NCI investigator." By Year 3, 9 of the 14 private practice sites had partially or fully implemented conditions of participation and included clinical trials enrollment as a condition. Sites that were requiring physicians to enroll patients in clinical trials should, theoretically, have had a greater proportion of eligible physicians accruing patients by Year 3. The sites requiring clinical trials enrollment as part of their conditions of participation and the number of eligible physicians actually accruing patients is presented later in Table 10-11.

10.3.4.6 Dedicated Research Pharmacy

Another aspect of research infrastructure is whether each site had a dedicated research pharmacy (see Table 10-3). A dedicated research pharmacy provides oversight and direction for the use of investigational medications in clinical research and is generally staffed by research-trained pharmacists and pharmacy technicians who share responsibility for facilitating investigational drug utilization and for providing the safest care for patients participating in research studies (http://ctsa.mayo.edu/resources/research-pharmacy.html). By Year 3, five sites reported having dedicated research pharmacies (Site 6, Site 16, Site 8, Site 7, Site 14). Of these, two were lead sites that were also lead CCOP sites (Site 6, Site 16).

10.3.4.7 IT Support of Clinical Trials

A major barrier to implementing the clinical trials component, as well as every other program component, was a lack of sufficient IT support. Nine of the NCCCP sites reported having insufficient IT support for clinical trials in Year 1 (see Table 10-4). By Year 3, 14 of the 16 sites reporting having some sort of IT support to keep track of their studies, accruals, and funding. The two sites that still lacked any sort of IT support in Year 3 were Site 15 and Site 5.

10.4 Overall Success in Clinical Trials Implementation

Overall success in clinical trials implementation is difficult to define. The NCCCP focused on nine key areas for clinical trials: receipt of community input from a local advisory board, expansion of types of trials, expansion of trial complexity, enhancement of clinical trials infrastructure, improvement of protocol timelines, expansion of collaborations, expansion of outreach to the underserved, improvement in accrual tracking, and improvement in communication systems. For the purposes of this evaluation, success in clinical trials implementation focused on aspects of these eight key areas, including

- overall trial capacity, including the number of trials opened, number of early phase trials opened (Phases I and II), and number of trial types offered (e.g., therapeutic, prevention);

- total patient accrual to clinical trials;
- minority (non-white) accrual to clinical trials;
- proportion of eligible physicians who are actually enrolling patients; and
- patients' awareness and understanding of clinical trials.

In the following sections, we present evaluation findings related to each of these areas. All findings should be interpreted within the broader context of overall trends in clinical trials observed nationwide. For this reason, because clinical trials activity as a result of NCCCP participation is such an important outcome of the program, NCI requested that a study be conducted to compare pilot sites to national trends in clinical trials activity, using the Cancer Therapy Evaluation Program (CTEP) data. The CTEP database captures information on trials and accrual and was provided to RTI for conducting this special analysis. Given their expertise in this area, RTI requested that Dr. Amy Abernethy, Director of Duke University's Cancer Care Research Program, conduct this study in the summer of 2011. Her team developed a summary of a global evaluation of the clinical trials activity of the NCCCP pilot period from July 2007 to July 2010. Their summary report includes an assessment of the clinical trials portfolio and accrual for the pilot sites and a review of the temporal relationship of the organizational characteristics and clinical trial activities. In addition to summaries of activities, sites were considered in the context of their NCCCP lead versus developmental designation, as well as their CCOP affiliation. Two main outcome assessments were considered:

- clinical trial **portfolio** (e.g., the number of open clinical trials at a site, sponsor, types of trials [phase, intervention under investigation]); and
- clinical trials **accrual** (total accrual and accrual for underserved populations [racial and ethnic minorities, rural residents, over 65 years of age]).

As previously noted, the findings from this analysis are presented in a separate report but have been incorporated into the overall findings specific to the NCCCP where applicable. We have incorporated relevant findings from Abernethy and Locke (2011) into this section.

10.4.1 Overall Trial Capacity

One goal of the NCCCP was to increase sites' overall capacity to conduct clinical trials by increasing the number of open trials, early phase trials, and types of trials. Results for each of these indicators for capacity are described in the following sections.

10.4.1.1 Number of Open Clinical Trials

Increasing the number of open trials offered was one way for sites to enhance opportunities for research and reach a greater number of patients. The types of clinical trials included in this analysis are therapeutic, prevention, and symptom management/cancer control. Other clinical research studies (i.e., screening, early detection, diagnostic, epidemiologic, observational, outcome, ancillary and correlative studies) were excluded. With more open

trials, patients are more likely to be eligible to enroll in at least one trial (Table 10-5). The total number of NCI trials open across all sites in Year 1 ranged from 0 (Site 7) to 132 (Site 4), and in Year 3 ranged from 0 (Site 11) to 132 (Site 6). The total number of all trials[1] open in Year 1 ranged from 1 (Site 11, Site 7) to 164 (Site 4), and in Year 3 ranged from 0 (Site 11) to 157 (Site 6). From Year 1 to Year 3, 12 sites increased their total number of NCI-sponsored clinical trials. All of the participating sites in one of the system organizations showed increases in the number of NCI-sponsored trials open as well as the total number of all trials open from Year 1 to Year 3. Three sites decreased the number of NCI-sponsored trials (Site 4, Site 9, and Site 11) from Year 1 to Year 3, and five sites (Site 4, Site 3, Site 9, Site 16, and Site 11) decreased the total number of all clinical trials open from Year 1 to Year 3. As reported by Abernethy and Locke (2011), the lead NCCCP sites increased their portfolio of Phase 3 trials by 50% over the 3-year pilot period with little change in the number of Phase 2 trials. Developmental sites tripled the number of Phase 3 trials and also had little change in the number of Phase 2 trials.

It is important to note that the sites reported every trial open during each reporting period. The data presented in Table 10-5 reflect the number of trials open, regardless of whether patients were being enrolled. Sites reported that several of the open trials had recruited no patients.

10.4.1.2 Number of Early Phase Trials Open

The NCCCP also aimed to build sites' capacity to offer early phase trials (i.e., Phases I and II), potentially "reducing the need for patients to travel to larger academic centers to access these trials" (http://ncccp.cancer.gov). Conducting early phase trials requires significant research infrastructure. Phase I and II trials require more physical exams, laboratory tests, and biological sampling within a shorter time period than later-phase trials (Craft et al., 2009).

Table 10-6 presents the number of early phase trials offered in Years 1 and 3. Over the course of the pilot, 11 sites increased the number of early phase trials offered, and 5 sites decreased the number of early phase trials offered. Trials conducted by NCCCP sites were predominately NCI-sponsored Phase 2 and Phase 3 trials. The majority of Phase 2 studies were conducted by the lead sites.

[1] All trials includes NCI-sponsored, industry/pharmaceutical-sponsored, and "other-sponsored" trials. SAIC-F defines "other-sponsored" trials as "Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center."

10.4.1.3 Number of Types of Clinical Trials and Other Clinical Studies Offered

Table 10-7 presents the number of types of clinical trials and other clinical research studies open in Years 1 and 3. Sites categorized clinical trials into three categories: therapeutic, prevention, and symptom management/cancer control. Clinical research studies were categorized as screening/early detection/diagnostic, epidemiologic/observational/outcome, ancillary, and correlative. Some trial types demand greater research capacity than others; expanding the types of clinical trials offered requires sufficient research infrastructure but allows patients from across the cancer continuum to potentially enroll in a trial (e.g., symptom amelioration and prevention are included as trial types). According to the Clinical Trials Worksheet received from SAIC-F (Appendix N), all but one site (Site 11) offered therapeutic trials in Year 1. All 16 sites were offering at least one therapeutic trial by Year 3. Six sites (Site 10, Site 12, Site 16, Site 2, Site 5, and Site 14) increased the number of types of clinical trials and other clinical studies offered from Year 1 to Year 3, and three sites (Site 4, Site 9, and Site 8) decreased the number of types of clinical trials and other clinical studies offered from Year 1 to Year 3. Six sites experienced no change in the number of types of clinical trials and studies offered from Year 1 to Year 3. Site 6 already offered all seven types of clinical trials and studies in Year 1.

10.4.1.4 Total Trial Capacity by Year 3

Looking at the total number of trials, the total number of early phase trials, and the total number of trial types offered (Table 10-8), five sites achieved positive change in all three indicators (Site 10, Site 12, Site 2, Site 5, and Site 14). Six sites had positive change in two of the three indicators, and three sites had positive change in one of the three indicators. Site 4 and Site 9 were the only two sites that did not experience any positive change in the number of trials, early phase trials, or types of trials and other studies offered over the course of the pilot. During the Year 3 site visits, respondents from Site 4 openly discussed having to suspend clinical trials activity until their new cancer center building was constructed, which accounts for the negative changes observed (e.g., they lost 80% of their NCI trials and 75% of all trials from Year 1 to Year 3, closing over 100 trials during the time of the move). According to CTEP data, the median number of trials per site was 8 (aggregate = 223) at baseline compared to 13 (aggregate = 263) by Year 3. These numbers reflect a 63% increase in the median number of trials per site between baseline and Year 3 (Abernethy & Locke, 2011).

10.4.2 Total Patient Accrual to Clinical Trials

One of the goals of the NCCCP pilot was to increase the number of patients enrolled in clinical trials. Table 10-9 presents the total number of patients accrued to NCI-sponsored trials and to all trials in Years 1 and 3. For the purposes of this evaluation, all trials includes those sponsored by NCI, industry/pharmaceutical sponsors, and "other" sponsors (e.g., externally peer-reviewed trials: R01s and P01s or other trial mechanisms funded by NIH or

supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc.). Nearly half of the NCCCP sites increased the total number of patients enrolled in all clinical trials from Year 1 to Year 3, and the remaining sites experienced declines in patient accrual.

It is important to note that efforts were made by both NCI and SAIC-F to reconcile differences in how sites reported accruals; the extent to which differences still existed after extensive data cleaning is unknown. For example, in Year 3, SAIC-F discovered that some sites counted accruals recruited by any physician in the broader community whereas other sites counted only accruals that were recruited by employed physicians.

CTEP data provide a different perspective on NCCCP pilot site findings. Differences emerged between developmental and lead sites in terms of performance, change in performance, and role. Lead sites, particularly those involved in the CCOP, evidenced a "maturation effect," that is, lead sites with already-established research capacity had greater numbers of open trials, and higher accrual to trials, at the outset; due to this prior maturation, they exhibited lower growth in number of trials and accrual than did the less mature non-CCOP and NCCCP developmental sites. Developmental sites evidenced a "sequencing effect," that is, during the NCCCP pilot they accomplished numerous steps and infrastructure development tasks necessary to establish a functional research operation at their sites; their progress was apparent in greater numbers of open trials, but the timeframe of this evaluation was likely too short to detect impact on accrual. Although accrual increased among all NCCCP sites overall, lead sites contributed most to accrual and showed the higher proportion increases in accrual. Lead sites that were also CCOP sites contributed both the greatest accrual numbers at baseline and the greatest numbers to new accrual, but non-CCOP lead sites demonstrated greater relative growth in accrual over the pilot period. These findings support the hypothesis (posed by Abernethy and Locke, 2011) that the sites were at varying stages of development for clinical trials implementation at baseline and therefore were able to develop at different paces. Those sites that were developmental NCCCP sites and not affiliated with the NCCCP likely had limited infrastructure ready at baseline for conducting trails (e.g., few CRNs, off-site IRB with limited meeting times, few physicians interested in or actively accruing to trials). With the selection of sites to the NCCCP, each was able to improve their organization around trials and initiate patient enrollment. On the other hand, sites like those that are lead CCOPs were likely to already be well organized and highly specialized in clinical trials implementation and could focus more on increasing trials among underserved populations.

Another potential explanation for the observed differences has to do with regulatory barriers. When a national trial undergoes any type of modification, sites are required to close the trial, amend their IRB application, and wait for approval to start up again. In addition, sites located in states that do not mandate insurance coverage of clinical trials

likely had greater difficulty enrolling eligible patients as well, which is discussed in greater detail in Section 10.6.3.

When comparing the number of trials open to the number of patients enrolled to explain decreases in accrual (see Table 10-10), the data become even less clear. This could be because some trials are easier to accrue patients to than others. The total number of trials open does not speak to the complexity of the trials being offered through each site's portfolio.

Site 6, Site 10, Site 2, Site 13, and Site 5 all increased the number of trials open in Year 3 but had fewer accruals in the same year. One explanation is that although they reported opening more trials by Year 3, these sites may not yet have started enrolling any patients. Alternately, Site 16 had fewer trials open in Year 3 but increased the number of total accruals. One explanation could be that the site focused on increasing accrual in a smaller subset of trials.

10.4.3 Minority (Non-white) Accrual to Clinical Trials

According to the NCI, racial and ethnic minorities are underrepresented in clinical trials (http://ncccp.cancer.gov). Increasing non-white accrual to clinical trials presents one avenue for reducing disparities in treatment outcomes. Thus, another key goal of the NCCCP was to increase access to clinical trials among underserved populations, including racial/ethnic minorities, through increased non-white accrual.

In Chapter 9, we presented the number of non-white patients enrolled in clinical trials as reported by sites on the Clinical Trials Worksheet. Because these numbers are quite different from the CTEP data, details in the changes in minority accrual are discussed in the context of national trends in a separate study by Duke University's Cancer Care Research Program. Overall, based on self-reported data, nine sites increased non-white accrual to all trials, three sites decreased, one site maintained, and four sites showed no change.[2]

Sites acknowledged the difficulty of increasing minority accruals; as one cancer center director put it in Year 3, "[We] spent some effort on non-white accrual, but I don't think those numbers have changed. That's a tough nut to crack." There are many patient-level barriers to enrolling non-white patients in clinical trials, including fear, mistrust of research, fatalistic perspectives, language barriers, and family and/or work responsibilities (Springfield, 2010). Improving the research infrastructure and capacity to implement clinical trials (e.g., language translators, engagement of minority physicians and lay-community representatives, advisory boards with minority/community participants, staff for extended hours) can help assuage these barriers. Sites used most of the pilot period to enhance these structures and may experience greater increases in minority accrual after the completion of the pilot.

[2] Unable to determine change in minority accrual at one site because of missing data in Year 1.

10.4.4 Proportion of Eligible Physicians Enrolling Patients

Physicians are key to increasing enrollment in clinical trials. One of the most common reasons patients decide to enroll in clinical trials is because their physician recommends doing so (Jenkins & Fallowfield, 2000). For the most part, sites were successful in increasing the total number of eligible physicians enrolling patients, but these gains were not always reflected in the proportion of eligible physicians who were actually accruing patients out of those eligible.

Table 10-11 presents the number of eligible physicians accruing patients to clinical trials. All but one site (Site 2) increased the number of physicians eligible to enroll patients in clinical trials, and 12 sites increased the number of physicians actually enrolling patients. Three sites (Site 6, Site 11, and Site 2) experienced no change in the number of physicians who were actually enrolling patients from Year 1 to Year 3. Site 6 had fully implemented COPs since Year 1 and required clinical trials enrollment, which could explain the lack of change observed at this site. Site 3 was the only site that decreased the number of physicians accruing patients from Year 1 to Year 3.

Six sites increased the proportion of eligible physicians who were accruing patients from Year 1 to Year 3, five sites experienced no proportional change, and five sites experienced negative change.

10.4.5 Patients' Awareness and Understanding of Clinical Trials

Overall, patients' reported awareness and understanding of clinical trials did not increase over the course of the pilot (see Table 10-12). In fact, the percentage of patients who reported receiving educational materials about clinical trials, the mean rating of patients' understanding of clinical trials, and the mean rating of patients' reported likelihood of participating in a clinical trial all decreased significantly. One possible explanation for these findings relates to timing. Sites used the 3-year pilot period to build their capacity and research infrastructure to support clinical trials and patient enrollment. Changes in patients' awareness and understanding will likely occur as more of an ultimate outcome than a short-term outcome (see Chapter 2, Figure 2-1). Another possible explanation is that physicians and other clinical trials staff are approaching patients more frequently, but due to the complex nature of clinical trials, they may not yet have figured out the best way to communicate information about what it means to participate in a clinical trial. Therefore, these findings, although negative, should not undermine the sites' achievements in clinical trials.

10.4.6 Summary of Overall Success in Clinical Trials

Table 10-13 presents the indicators for success in clinical trials across all of the sites.[3] We found that the majority of sites were able to increase the following:

- the number of open trials (11 of 16 sites),
- the number of early phase trials (11 of 16 sites),
- the number of total patient accrual (7 sites), and
- the number of non-white patient accrual (9 sites).

Fewer sites were able to increase the number of trial types (seven sites) or the proportion of eligible physicians enrolling patients in trials (six sites), and none of the lead sites achieved significant improvements in patients' perspectives on trials.

For the eight indicators we used to assess clinical trials implementation, sites had varying degrees of success (ranging from positive changes in one indicator to as many as six as shown in Table 10-13). The seven sites that demonstrated greater levels of change (four to six out of eight indicators improved) included four lead sites and three developmental sites. In Chapter 16, we examine organizational and environmental factors that may be associated with this higher level of change. It is important to note that all six of these sites with greater levels of change are located in states where insurance coverage of clinical trials participation is mandated, which indicates that this environmental variable may be of great importance to increasing clinical trials implementation (Table 10-2).

10.5 Facilitators to Clinical Trials Implementation

During the Year 1 and Year 3 site visits, respondents were asked to describe the factors that have influenced how well they have been able to implement clinical trials activities at their site. Some have credited internal factors such as their long histories of engaging in clinical trials research as well as supportive leadership and support staff. Others have benefited from external linkages (e.g., partnerships with NCI-designated cancer centers) and participation in the NCCCP network. This section describes four main foci that have provided sites with the momentum to enhance accrual to clinical trials:

- having an existing research infrastructure,
- establishing or enhancing the role of patient navigators,
- participating in the NCCCP network and establishing linkages with NCI-designated cancer centers, and
- garnering institutional leadership support.

[3] Sites in this section and in Table 10-14 have been de-identified to protect their identity.

10.5.1 Having an Existing Research Infrastructure

For several sites, implementing the clinical trials component of the NCCCP has been an almost seamless process. For sites with a history of enrolling patients in clinical trials, like Hartford Hospital and St. Joseph/Towson, building capacity for clinical trials research has posed few challenges. For a community hospital, St. Vincent has a strong history of and experience with clinical trials and research. One respondent noted that the size of the hospital, the physicians working there, and aspects of the local environment (e.g., the presence of Eli Lilly and other drug and device manufacturers, competition with Indiana University) have meant that the hospital and physicians have always been engaged in clinical trials and research, albeit not at the level of an academic institution:

> *I think we're a little ahead of the game because we already do Phase I trials. We already do a lot of the regulatory stuff. We have a good staff. We have a committed medical director. We already have a mission here to provide clinical trials to the region.* (Subcommittee member, Year 2)

> *The minority accrual for [the] CT area, we are doing a lot of that already and were doing it before [the] NCCCP. We focused a lot on the community outreach side. Our care network has a goal of reaching the un- and underinsured.* (Subcommittee member, Year 2)

10.5.2 Establishing or Enhancing Patient Navigators

During the NCCCP pilot, there was an increase among sites in the use of patient navigators to promote clinical trials. According to the BAS and FAS, the number of sites using patient navigators to refer patients with abnormal findings, as a result of cancer screening, for clinical trials consideration increased from 3 sites to 15 sites. Moreover, tumor board registrars, who support physicians, help to facilitate more timely access to patient information and sometimes help start the discussion about clinical trials:

> *Because the coordinators are disease site-specific, they work very closely with the navigators. So when the breast cancer navigator gets a new referral, she shoots it over to my coordinator. Also, my coordinators attend all the tumor boards. We get the lists ahead of time and we're able to prescreen all those patients in clinical trials.* (Cancer center/program staff, Year 2)

> *Our navigators participated in the training that [the] NCCCP did in clinical trials. Our navigators are very well versed. Every patient that they touch they refer to be screened.* (Subcommittee member, Year 2)

> *We have a wonderful research team with nurse navigators, and we have pamphlets about what clinical trials are open, and we have the research nurses at the*

> *conference that can help remind us about the appropriateness of trials for certain patients.* (Key physician, Year 2)

Chapter 9 describes in more detail the role of the patient navigator across sites and how these individuals have helped to facilitate coordinating efforts across components.

10.5.3 Participating in the NCCCP Network and Establishing Linkages with NCI-designated Cancer Centers

A primary evaluation question across sites is the extent to which linkages occur between the NCCCP sites and with NCI staff via the NCCCP Program Advisory Committee, and what benefits the sites derive from these linkages. NCCCP staff at the pilot sites took the initiative to collaborate with other NCCCP sites. They perceived the networking as mutually beneficial in terms of benchmarking and sharing best practices. For example, Hartford Hospital will be adapting elements of the Christiana clinical trials model for a new program funded through a grant from the Connecticut Clinical Trials Oncology Network:

> *What we're really trying to do is work with the other sites to come up with a uniform way of approaching clinical trials in a way [that] we can measure baseline and outcomes, accrual, and reaching disparate populations. We're trying to work with already-established NCI-designated sites.* (Subcommittee member, Year 2)

In addition to these formal "internal" linkages between the program participants, NCI encourages the sites to create formal "external" linkages with other cancer research programs, including NCI-designated cancer centers and CCOPs. Various approaches have been used to develop partnerships with community-based organizations and coalitions that share an interest in QOC and research.

Pilot community hospitals have placed patients into clinical trials at the H. Lee Moffitt Cancer Center and Research Institute, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, University of Wisconsin Carbone Cancer Center, Yale Cancer Center, City of Hope, Huntsman Cancer Institute, University of California (San Francisco and Irvine), Memorial Sloan-Kettering Cancer Center, Kimmel Cancer Center at Jefferson University, and MD Anderson Cancer Center:

> *We worked with [local university] to get an esophageal clinical trial open, and that involves educating physicians as part of the cancer symposium and education of the general public.* (Subcommittee member, Year 2)

> *We run a variety of cooperative studies, we have some industry studies, and we have a formal relationship to do research with [NCI-designated cancer center]. They share some of their studies with us, and we are a CALGB [Cancer and Leukemia Group B] affiliate with them. We are not a CCOP. We accrue patients to some [of their] studies. The relationship has been since 2000. The pilot has opened up a little*

> *bit more for us to do some research studies compared to where we were before.* (Subcommittee member, Year 2)

10.5.4 Garnering Institutional Leadership Support

As discussed in Chapter 5, cancer center leadership and hospital top management seemed to be facilitators of necessary changes to implement the NCCCP. During the site visits, respondents were asked about the extent to which there was existing institutional support for facilitating clinical trials goals. Most respondents felt that their institutions were very supportive in their efforts but did not provide specifics:

> *We're going to be probably initiating a Phase II trial here related to HPV [Human Papillomavirus] and head/neck, and the institution has been very supportive of that.* (Key physician, Year 2)

> *Our interim executive director and PI are major proponents. I get the sense that our administrators are in support, but I don't have access to their conversations. I don't see them come to cancer committee meetings or where I practice oncology. Our CEO is visible when there is a need and they are receptive to listening to what we need.* (Key physician, Year 3)

Other respondents embraced their hospital's efforts in building research infrastructure but were concerned about its impact on future staffing:

> *They [institution] are waking up to this as important. They never saw it as important historically. Historically, the private practice docs ran studies out of our offices. We're trying to expand research. The hospital is trying to build infrastructure. The hospital has enough resources for now, but in a year and a half, we'll come up short on staff. PCCs [patient care coordinators] have dual role, but as we get more studies and patients enrolled, the study coordinator will be too busy soon. The docs complained that we're short staffed; the rebuttal is that we're underwhelmed with participation.* (Key physician, Year 2)

Institutional support for clinical trials was best evidenced by the matching investment that sites made in the clinical trials program component. Funds allocated to clinical trials was the component receiving the second highest investment (i.e., after the disparities component) across the hospitals, ranging from 21% to nearly 35% of the total matching funds each year, for a total of $9.3 million invested in clinical trials across sites over the course of the pilot.

10.6 Barriers to Clinical Trials Implementation

As noted in the previous section, there have been several facilitating factors related to clinical trials implementation across sites. For the evaluation, it was equally important to glean from sites what has not worked so well with regards to clinical trials accrual. During

the Year 2 site visits, respondents were asked to describe some the barriers or challenges faced with implementing NCCCP clinical trials priorities. Based on their responses, it became clear that many of the barriers spanned administrative, physician, patient, and geographic boundaries.

10.6.1 Administrative/Infrastructure Barriers

As mentioned in Chapter 9, the ability to capture race/ethnicity data at screening has been a challenge across sites. At the beginning of the pilot, many sites were not tracking this information, so it has taken time for many to catch up with OMB requirements:

> *When we started this venture, we thought, "Oh, the regional care manager will identify patients for clinical trials." And then we realized we had to go back to the beginning. We were not tracking ethnicity or race in our database—we only started to do that last year. We have not followed OMB guidelines, and for us to really move forward we really need to have ethnicity first to meet OMB guidelines.* (Subcommittee member, Year 2)

The national clinical trials subcommittee worked to address this barrier by having sites track clinical trials accrual, especially among their underserved populations, via the online clinical trials accrual log. Although the accrual log helped, IT barriers persisted in Year 3:

> *Another goal that was internal…was to make clinical trials more electronic. That group's been working on a database for tracking and working on different logs. It's been a struggle…[Staff] tried to keep up with regulatory contract, keeping logs, to make it electronic. It's still paper, and that's frustrating.* (Cancer center/program staff, Year 3)

10.6.2 Physician Participation

Involving private practice physicians in clinical trials continues to be a challenge for many sites, with few strategies to provide incentives for enrolling patients. Sites remain interested in working on early phase trials, but most are still encountering significant challenges in adding these to their portfolio:

> *I think everyone agrees that there are a lot of barriers to having Phase 1 trials…. It is admittedly a tough time for hospitals to make large investments in these areas…and clinical trials are not a money producer for hospitals unless you get involved with pharma [pharmaceutical company trials], which we haven't. Every patient that is involved in a clinic trial takes more time and is decreasing productivity in general. I think those other areas are falling nicely in place. We are better than we were, but that is still the area of my greatest concern.* (Key physician, Year 2)

Another major barrier among physicians in clinical trials accrual has been the amount of time and staff resources needed to place patients on protocol. While many physicians

express interest in clinical trials research, they readily admit that it takes time away from their other clinical obligations:

> *This is a private practice setting…if I'm going to take the time to enroll patients, I could be seeing three others and be more productive to my group. The institution does not have any Phase 1 or 2 trials, and we can't get one if we can't get numbers for Phase 3.* (Key physician, Year 2)

> *The barrier is the time element of these complex trials and the presentation to the patients and the frustration of the time you put into it and then the people don't go on the trial. I think this is becoming a real problem—the time constraint on the practice and the physician in an era of shrinking reimbursement for your time. That is a huge problem here and across all sites because we're asking physicians for more and more time for complex trials and more and more data, and you don't have time to do all of this. That, to me, is one of the biggest detriments to clinical trials right now.* (Key physician, Year 2)

> *They have all these people on paper, but I don't see them. There's still a lot to be done. We need a research nurse. My colleagues in other places have good systems in place for flagging patients.* (Key physician, Year 2)

10.6.3 Patient Access to Clinical Trials

Bringing cancer care "closer to home" by providing patients local access to clinical trials has been a main goal of the NCCCP pilot. Making these trials readily available, however, is not always an easy draw for patients.

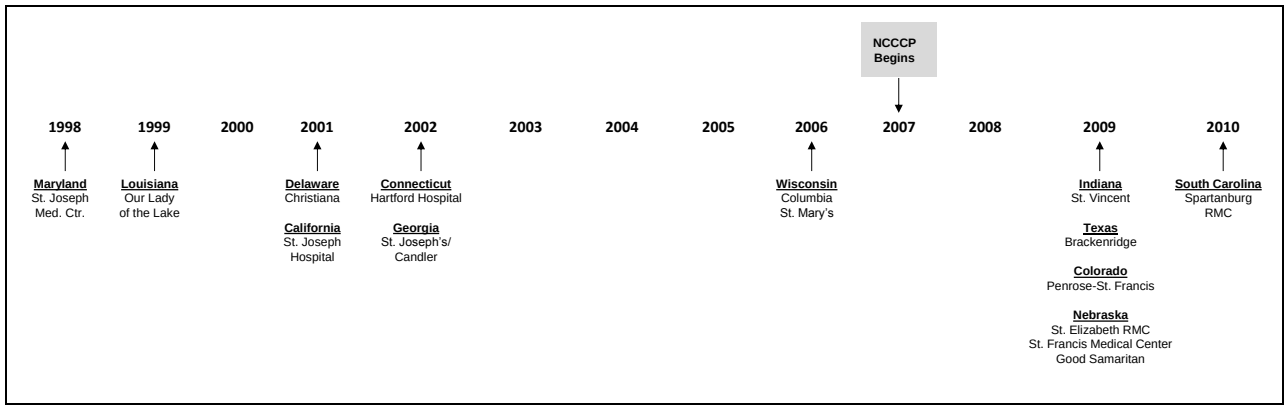
The surrounding communities of the NCCCP sites vary widely in population. All but four sites are located in predominantly urban, or mixed urban and rural, locations. For some sites, wide geographic dispersion is a challenge to expanding clinical trials participation among their patient populations. For example, Billings Clinic serves residents in remote, frontier communities spanning as many as 40 counties. Therefore, many patients needing access to cancer care lack the necessary transportation. To help address this challenge, many sites are increasingly using telemedicine (e.g., for brief follow-up visits required in clinical trials protocols):

> *The barriers with that in the rural population is that they would have to come here to be evaluated, and that's where telemedicine could assist with that. The distance is somewhat of a barrier for the patients on trials because they do have to come more often.* (PI, Year 2)

Lack of insurance coverage for clinical trials has been another major challenge in meeting clinical trials priorities. Currently, several states do not require insurers to cover the cost of participation in clinical trials, which places eligible patients at a disadvantage.

Of the 16 NCCCP pilot sites examined in this study, two were located in states that *do not* mandate any insurance coverage of cancer clinical trials: Billings Clinic and Sanford Clinic. All of the other NCCCP pilot programs operate in states that have some type of mandated insurance coverage of clinical trials. Figure 10-2 shows the timeline for enactment of legislation in the NCCCP states.

Figure 10-2. Timeline for Legislation of Health Insurance Coverage of Cancer Clinical Trials



Sites in States Without Mandated Insurance Coverage as of 2010: Montana (Billings Clinic) and South Dakota (Sanford Clinic).

Of the 12 states that currently have legislation regarding health insurance coverage of cancer clinical trials, seven enacted the legislation prior to the start of the NCCCP pilot: Maryland (1998), Louisiana (1999), Delaware (2001), California (2001), Connecticut (2002), Georgia (2002), and Wisconsin (2006). Four states enacted legislation after the start of the NCCCP pilot; Indiana (2009), Texas (2009), Colorado (2009), Nebraska (2009), and South Carolina (2010).

Several subcommittee members described the impact this has had on their efforts to increase clinical trials participation:

> *One of the other problems we've had is insurance companies denying patients. It's gotten much worse. I think part of it was there was a push in the state to try and get clinical trials covered. That made the insurance companies really dig their heels in. So we've had a huge problem with denials and delays. And patients don't want to wait that long. So we've had quite a number of people who have been eligible and would have gone on a study [but decided not to].* (Subcommittee member, Year 2)

> *Our largest barrier for clinical trials is insurance, and I imagine we'd be into the 20th percentiles if we had insurance coverage. We never want to put a patient at financial risk to go on a clinical trial they have to pay for.* (Subcommittee member, Year 2)

> *[State] still doesn't cover clinical trials. Some insurance companies do. Patients are really worried about it; they don't want to be stuck with the bill…You kind of almost have to say, "What kind of insurance do you have?"* (PI, Year 3)

Finally, sites have had to deal with the "guinea pig" notion held by many in the public with regards to clinical trials participation:

> *There's a perception that clinical trials are experimentation on people randomly and don't really help patients. People don't necessarily see how clinical trials fit with oncology.* (Subcommittee member, Year 2)

> *It is patient education. People say they don't want to be a placebo… I mean for some it is one of three different dosages. By the time the patients get finished reading through the pages and they get ready to sign, the overwhelming majority don't want to do it. I think that the informed consent information scenario is where a lot of it falls apart.* (Key physician, Year 2)

Despite these challenges, sites have worked hard toward eliminating patient-related barriers to clinical trials participation by providing interpreters, financial assistance programs, and community education. In the 16-month period from BAS to IAS, 56% of the sites noted an appreciable reduction in barriers to clinical trials due to factors such as increases in physician interest, hospital top management and cancer center leadership support, and staffing.

10.7 Value Added: Clinical Trials Benefits Beyond the NCCCP

The concept of value added is difficult to define, and some aspects of it were not possible to measure during the NCCCP pilot. However, for this evaluation, it was important to specify the extent to which these NCCCP sites are building on their efforts in clinical trials research in ways that they would not have done, or known how to do, had it not been for the program. The following are a few examples of respondents sharing ways in which the NCCCP pilot has influenced their clinical trials efforts above and beyond pilot funding:

> *I think [the] NCCCP has brought about a significant change…. They are now getting accruals from the charity hospital, and have a meeting with CT to see how our patient navigation can interact with CT to see if the patients are good candidates for CTs.* (Subcommittee member, Year 2)

> *It all fits together so much—the reason clinical trials are improving is because of the [multidisciplinary care conferences] and the disparities, and people are talking to each other and suddenly people are energized and we haven't seen this before in cancer services* (System/hospital senior executive, Year 2)

> *[The] NCCCP has not only increased participation but [also] the way patients are seeking out information, and this has really changed within the past 2 to 3 years.* (Subcommittee member, Year 2)

In some ways, the NCCCP has brought about new funding opportunities allowing for the hiring of new staff to address clinical trials accrual. Some sites have actively sought grant opportunities to complement the NCCCP and extend cancer center services, including facilitating participation among disparate populations into clinical trials. As one program leader proudly noted, "Our NCCCP participation helps us to stand out in the grants process."

> *We have new funds in our office. There's a new trial looking at how Native Americans report new symptoms of cancer and decide when to go see the doctor. It's allowed us to have more navigators.* (Key physician, Year 2)

> *We have dedicated nurses and data managers that handle the paperwork. The new patient navigator has been great; the NCCCP has brought this. We have known we're a top-notch research outfit…and the NCCCP has legitimized [this feeling].The NCCCP thinks we're okay, and we can do this.* (Key physician, Year 2)

By Year 3, sites were also gaining recognition in their communities and among academic cancer centers. The NCCCP, being an NCI-sponsored program, brought a level of prestige to some sites that enabled them to attract highly qualified staff and/or explore new relationships that they would otherwise not have had the opportunity to:

> *The fact that [the] NCCCP was here was an attraction for [CT workgroup leader] to come here. If someone is going to make a career move, then having [the] NCCCP is part of the synergy that brings them here.* (PI, Year 3)

> *[The] NCCCP has changed how we work with [NCI-designated cancer center]. Because of our success with Moffitt, they are more interested in us. They recognize that we are a large community hospital.* (Cancer Center/program staff, Year 3)

The value added by the NCCCP to the pilot sites likely extends beyond that which respondents discussed in site visit interviews. Respondents described the specific ways in which the NCCCP enhanced their hospital and/or cancer program, but there has been tremendous value added in terms of the NCCCP contributing to NCI's research mission. Findings from the NCCCP pilot, although exploratory, suggest that the clinical trials component of the NCCCP facilitated accomplishments in key areas for specific types of sites. Most NCCCP sites that started the program with low capacity and little research infrastructure seemed to be able to enhance their trial capacity in begin to increase patient accruals. This seems to be supported by the analysis of CTEP data, which revealed that developmental sites accomplished numerous steps and infrastructure development tasks necessary to establish a functional research operation at their sites; their progress was apparent in greater numbers of open trials, but the timeframe of this evaluation was likely

too short to detect impact on accrual. Lead sites that were not CCOPs seemed to show the most promise in accomplishments with their overall increase in patient accruals. Through a program like the NCCCP, community hospitals seemed to become more equipped to bring cutting-edge research to patients who likely do not have access to an NCI-designated cancer center or academic medical center.

10.8 Summary

Overall review of results indicates that the investment in the NCCCP is stimulating accrual to clinical trials of patients who are not being accrued through other NCI programs (e.g., CCOP, NCI-designated cancer centers). There is also evidence from the CTEP data analysis that the NCCCP pilot achieved meaningful results, including increasing patient accrual and the overall patient per trial ratio. Nearly all sites increased their accrual to underserved populations in racial/ethnic minority, rural, and/or over age 65 categories. Sites also improved their other, non−clinical trials research activities.

Across sites, many physicians mentioned clinical trials as one of the primary reasons for engaging in the NCCCP; they noted that clinical trials increase physicians' visibility in the community, patient interest, and subsequent intake. Surgeons have taken on a more active role in discussing clinical trials with their patients. Clinical trials have created a sense of pride, healthy competition, and collegiality among physicians, with some physicians being acknowledged for their active clinical trials enrollment. Respondents viewed clinical trials as having clear priorities, objectives, and strategies, all of which are in line with physicians' evidence-based treatment perspective. Furthermore, successful implementation of the clinical trials component of the NCCCP helps build a new frontier upon which to expand NCI's research mission; participating community hospitals are in a unique position to reach more patients with quality of care on par with less accessible academic medical centers.

Many respondents expressed the value of the network in forging positive relationships and developing best practices with regards to clinical trials. This includes work done through the Best Practices Workgroup and sites having access to a variety of online training tools for conducting clinical trials. Having these linkages has enabled sites to work together to identify benchmarks as they relate to various aspects of clinical trials, or, as one clinical trials subcommittee member put it, "We want to see if there's any way to standardize the good stuff."

Table 10-1. Participation in Clinical Trials Cooperative Groups by Site

Site	Number of Clinical Trials Cooperative Groups Site Participates In		
	Year 1	**Year 3**	**Change**
Data Source:	**Outcomes Worksheet**		
Site 4	4	6	2
Site 6	7	7	0
Site 10	7	8	1
Site 3	4	6	2
Site 12	3	4	1
Site 1	3	4	1
Site 9	6	7	1
Site 16	12	14	2
Site 15	3	4	1
Site 11	2	2	0
Site 8	3	5	2
Site 7	3	3	0
Site 2	3	7	4
Site 13	4	4	0
Site 5	3	8	5
Site 14	1	3	2
Mean	4	5	1
Median	3	6	3

Table 10-2. Key Clinical Trials Staff (FTEs)

	Clinical Research Nurses (CRNs)			Clinical Research Associates (CRAs)			Total Staff Supporting Clinical Trials[a]		
Site	**Year 1**	**Year 3**	**Change**	**Year 1**	**Year 3**	**Change**	**Year 1**	**Year 3**	**Change**
Data Source:	**BAS**	**FAS**		**BAS**	**FAS**		**BAS**	**FAS**	
Site 4	3	5	2	1	0	-1	13.25	17.7	4.45
Site 6	19.75	23.5	3.75	2	2	0	68.5	76.55	8.05
Site 10	5	6	1	0	2	2	46.5	46	5.5
Site 3	1	5	4	4	1.5	-2.5	5.25	10	4.75
Site 12	9.9	7	-2.9	2	3	1	26.4	95	68.6
Site 1	0	0	0	2	3	1	7.75	14	6.25
Site 9	11	18	7	9	7	-2	31.3	43	11.7
Site 16	19	11	-8	2	4	2	33.75	37.5	3.75
Site 15	11.15	4	-7.15	2	0	-2	26.3	19	-7.3
Site 11	0.2	5	4.8	0.2	0	-0.2	0.5	13	12.5
Site 8	0.7	1.4	0.7	1	1	0	5.7	10.45	4.05
Site 7	1	2	1	2	2	0	16	33.4	17.4
Site 2	1	3	2	1.5	2.5	1	10.3	12.5	2.2
Site 13	1	2	1	1	1	0	3	6	3
Site 5	0	0.8	0.8	0	0	0	0	3.6	3.6
Site 14	1.2	3	1.8	2.2	2	-0.2	8.9	12	3.1
Mean	5.3	6.0	0.7	2.0	1.9	-0.1	19.0	28.1	9.1
Median	1.1	4.5	3.4	2	2	0	11.8	15.9	4.1

[a] Total Staff supporting clinical trials is expressed in FTEs, and is the total number of physicians, clinical trials coordinators/CRAs, CRNs, pharmacists, pharmDs, nurse navigators, data managers, outreach coordinators, and social workers based on site self-reported data on the BAS/FAS.

Table 10-3. Dedicated Research Pharmacies in Year 1 and Year 3 by Site

	Dedicated Research Pharmacy (DRP)		
Site	**Year 1**	**Year 3**	**Change**
Data Source:	**BAS**	**FAS**	
Site 4	No	No	No
Site 6	Yes	Yes	No
Site 10	No	No	No
Site 3	No	No	No
Site 12	No	No	No
Site 1	No	No	No
Site 9	Yes	No	Lost DRP
Site 16	Yes	Yes	No
Site 15	Yes	No	Lost DRP
Site 11	No	No	No
Site 8	No	Yes	Yes
Site 7	No	Yes	Yes
Site 2	No	No	No
Site 13	No	No	No
Site 5	No	No	No
Site 14	No	Yes	Yes
Number of sites with dedicated research pharmacy	4	5	2 sites dropped their pharmacy; 3 sites added a DRP (for a net change of +1)

Table 10-4. IT Support of Clinical Trials

Site	Whether Site Reported having IT Support of Clinical Trials[a]		
	Year 1	Year 3	Change
Data Source:	**BAS**	**FAS**	
Site 4	Yes	Yes	No
Site 6	Yes	Yes	No
Site 10	Yes	Yes	No
Site 3	No	Yes	Yes
Site 12	Yes	Yes	No
Site 1	No	Yes	Yes
Site 9	Yes	Yes	No
Site 16	Yes	Yes	No
Site 15	No	No	No
Site 11	No	Yes	Yes
Site 8	No	Yes	Yes
Site 7	No	Yes	Yes
Site 2	No	Yes	Yes
Site 13	Yes	Yes	No
Site 5	No	No	No
Site 14	No	Yes	Yes
Number of sites with IT support	7	14	7
Number of sites without IT support	9	2	7

[a] Sites responded Yes or No to the following question on the BAS/FAS: "Did your cancer center use any kind of clinical trials IT support to keep track of all your studies, accruals, funding, and trial management?"

Table 10-5. Number of Trials Open in Year 1 and Year 3 by Site[a]

Site	Number of NCI Trials Open[b]			Number of All Trials Open[c]			Proportion of Open Trials Sponsored by NCI, Percent[d]		
	Year 1	Year 3	Change	Year 1	Year 3	Change	Year 1	Year 3	Change
Data Source:				**Clinical Trials Worksheet**					
Site 4[e]	132	23	-109	164	37	-127	80.5%	62.2%	-18.3%
Site 6	130	132	2	152	157	5	85.5%	84.1%	-1.4%
Site 10	9	48	39	9	52	43	100%	92.3%	-7.7%
Site 3	35	37	2	47	46	-1	74.5%	80.4%	6.0%
Site 12	18	35	17	19	46	27	94.7%	76.1%	-18.6%
Site 1	43	49	6	49	53	4	87.8%	92.5%	4.7%
Site 9	37	23	-14	37	25	-12	100.0%	92.0%	-8.0%
Site 16	38	38	0	51	42	-9	74.5%	90.5%	16.0%
Site 15	23	58	35	26	66	40	88.5%	87.9%	-0.6%
Site 11	1	0	-1	1	0	-1	100.0%	0.0%	-100.0%
Site 8	15	16	1	15	19	4	100.0%	84.2%	-15.8%

(continued)

Table 10-5. Number of Trials Open in Year 1 and Year 3 by Site[a] (continued)

Site	Number of NCI Trials Open[b]			Number of All Trials Open[c]			Proportion of Open Trials Sponsored by NCI, Percent[d]		
	Year 1	Year 3	Change	Year 1	Year 3	Change	Year 1	Year 3	Change
Site 7	0	13	13	1	16	15	0.0%	81.3%	81.3%
Site 2	22	81	59	23	85	62	95.7%	95.3%	-0.4%
Site 13	9	45	36	10	50	40	90.0%	90.0%	0.0%
Site 5	2	8	6	2	8	6	100.0%	100.0%	0.0%
Site 14	8	22	14	10	35	25	80.0%	62.9%	-17.1%
Mean	33	39	6	39	46	8	86.9%	85.2%	-1.7%
Median	20	36	16	21	44	23	95.2%	81.8%	-13.4%

[a] Total number of trials open does not necessarily reflect the total number of trials open *and* accruing patients.

[b] The total number of NCI trials open is the sum of all site self-reported trials categorized as Therapeutic, Prevention, and Symptom Management/Cancer Control. The following types of research activities were excluded: Screening/Early Detection/Diagnostic, Epidemiologic/Observational/Outcome, Ancillary, and Correlative.

[c] The total number of all trials open is the sum of all site self-reported trials categorized as Therapeutic, Prevention, and Symptom Management/Cancer Control that were open during each reporting period for trials sponsored by NCI, Industry/Pharmaceutical Sponsors, and "Other" Sponsors. "Other" Sponsors includes Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by the National Institutes of Health (NIH) or supported by other peer-reviewed funding organizations, such as the American Cancer Society (ACS), the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center.

[d] Calculated using the number of NCI Trials divided by the number of All Trials.

[e] Site 4 cited the construction of their new cancer center as a huge barrier to sustaining all clinical trials activity during the pilot. Clinical trials activity was suspended until the new building was complete and the radiation oncology equipment re-certified.

Table 10-6. Number of Early Phase Trials Offered in Years 1 and Year 3 by Site[a]

Site	Number of Early Phase NCI Trials (Phases I-II)[b]			Number of Early Phase Trials: All Sponsors[c]		
	Year 1	Year 3	Change	Year 1	Year 3	Change
Data Source:						
Site 4*	56	10	-46	74	12	-62
Site 6	51	50	-1	61	65	4
Site 10	0	19	19	0	20	20
Site 3	8	9	1	14	17	3
Site 12	1	4	3	1	7	6
Site 1	2	6	4	5	8	3
Site 9	13	5	-8	13	7	-6
Site 16	15	17	2	26	21	-5
Site 15	6	21	15	9	27	18
Site 11	1	0	-1	1	0	-1
Site 8	2	1	-1	2	1	-1
Site 7	0	2	2	0	3	3
Site 2	1	29	28	2	30	28
Site 13	2	5	3	2	6	4
Site 5	0	3	3	0	3	3
Site 14	2	6	4	3	12	9
Mean	10	12	2	13	15	2
Median	2	6	4	3	10	8

[a] The total number of early phase trials includes all trials open, regardless of whether patients were being enrolled.

[b] The total number of early phase trials is the sum of site self-reported trials open in Phase I, I/II, and II during each reporting period.

[c] Includes Phase I, I/II, and II trials sponsored by NCI, Industry/Pharmaceutical Sponsors, and "Other" Sponsors. "Other" Sponsors includes Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center.

[d] Site 4 cited the construction of their new cancer center as a huge barrier to sustaining all clinical trials activity during the pilot. Clinical trials activity was suspended until the new building was complete and the radiation oncology equipment re-certified.

Table 10-7. Number Types of Clinical Trials and Other Research Studies Open in Year 1 and Year 3 by Site

	Number of Trial Types[a] (Scale 0 to 7)		
Site	**Year 1**	**Year 3**	**Change**
Data Source:			
Site 4[b]			
	5	3	-2
Site 6	7	7	0
Site 10	4	5	1
Site 3	4	4	0
Site 12	4	6	2
Site 1	5	5	0
Site 9	5	4	-1
Site 16	4	5	1
Site 15	3	3	0
Site 11	1	2	1
Site 8	3	2	-1
Site 7	3	3	0
Site 2	5	7	2
Site 13	5	5	0
Site 5	1	3	2
Site 14	3	4	1
Mean	4	4	0
Median	4	4	0

[a] The total number of types of clinical trials and other research studies was based on which types of trials and research studies each site had open out of the following seven types: therapeutic, prevention, symptom management/cancer control, screening/early detection/diagnosis, epidemiologic/observational/outcome, ancillary, and/or correlative. The data reflect NCI-Sponsored, Industry/Pharmaceutical-Sponsored, and Other-Sponsored Trials. Other-Sponsored Trials are defined by SAIC-F as "Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center."

[b] Site 4 cited the construction of their new cancer center as a huge barrier to sustaining all clinical trials activity during the pilot. Clinical trials activity was suspended until the new building was complete and the radiation oncology equipment re-certified.

Table 10-8. Number of Total Trials, Early Phase Trials, and Trial Types open in Year 1 and Year 3 by Site[a]

Site	Number of All Trials Open[b]			Number of Early Phase Trials (Phases I-II)[c]			Number of Types of Clinical Trials and Other Research Studies[d] (Scale 0 to 7)			Total Indicators with Positive Change (0 to 3)
	Year 1	Year 3	Change	Year 1	Year 3	Change	Year 1	Year 3	Change	
Data Source:	**Clinical Trials Worksheet**									
Site 4[e]	164	37	-127	74	12	-62	5	3	-2	0
Site 6	152	157	5	61	65	4	7	7	0	2
Site 10	9	52	43	0	20	20	4	5	1	3
Site 3	47	46	-1	14	17	3	4	4	0	2
Site 12	19	46	27	1	7	6	4	6	2	3
Site 1	49	53	4	5	8	3	5	5	0	2
Site 9	37	25	-12	13	7	-6	5	4	-1	0
Site 16	51	42	-9	26	21	-5	4	5	1	1
Site 15	26	66	40	9	27	18	3	3	0	2
Site 11	1	0	-1	1	0	-1	1	2	1	1
Site 8	15	19	4	2	1	-1	3	2	-1	1
Site 7	1	16	15	0	3	3	3	3	0	2
Site 2	23	85	62	2	30	28	5	7	2	3
Site 13	10	50	40	2	6	4	5	5	0	2
Site 5	2	8	6	0	3	3	1	3	2	3
Site 14	10	35	25	3	12	9	3	4	1	3
Mean	39	46	8	13	15	2	4	4	0	
Median	21	44	23	3	10	8	4	4	0	
Number of sites with positive change		11			11			7		
Number of sites with no change		0			0			6		
Number of sites with negative change		5			5			3		

(continued)

Table 10-8. Number of Total Trials, Early Phase Trials, and Trial Types open in Year 1 and Year 3 by Site[a] (continued)

[a] The number of trials open and the number of early phase trials open are not mutually exclusive; some trials may be counted in both categories.

[b] The total number of NCI-sponsored, Industry/Pharmaceutical-Sponsored, and "Other-Sponsored" trials open is the sum of all site self-reported trials categorized as Therapeutic, Prevention, and Symptom Management/Cancer Control; other research activities (i.e., Screening/Early Detection/Diagnostic, Epidemiologic/Observational/Outcome, Ancillary, and Correlative) were excluded. "Other-Sponsored" trials is defined by SAIC-F as, "Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center."

[c] The total number of early phase trials is the sum of site self-reported trials open in Phase I, I/II, and II during each reporting period.

[d] The total number of types of clinical trials and other research studies was based on which trials each site had open out of the following seven types: therapeutic, prevention, symptom management/cancer control, screening/early detection/diagnosis, epidemiologic/observational/outcome, ancillary, and/or correlative.

[e] Site 4 cited the construction of their new cancer center as a huge barrier to sustaining all clinical trials activity during the pilot. Clinical trials activity was suspended until the new building was complete and the radiation oncology equipment re-certified.

Table 10-9. Total Patients Enrolled in Clinical Trials in Year 1 and Year 3 by Site[a]

Site	NCI Clinical Trials[b]				All Clinical Trials[c]			
	Year 1	Year 3	Number Change	Percent Change[d]	Year 1	Year 3	Number Change	Percent Change
Data Source:	**Clinical Trials Worksheet**							
Site 4[e]	108	46	-62	-57.4%	142	83	-59	-41.5%
Site 6	229	202	-27	-11.8%	254	251	-3	-1.2%
Site 10	97	28	-69	-71.1%	97	32	-65	-67.0%
Site 3	74	29	-45	-60.8%	86	42	-44	-51.2%
Site 12	35	33	-2	-5.7%	35	48	13	37.1%
Site 1	4	32	28	700.0%	6	35	29	483.3%
Site 9	141	80	-61	-43.3%	141	85	-56	-39.7%
Site 16	84	94	10	11.9%	85	101	16	18.8%
Site 15	16	37	21	131.3%	27	58	31	114.8%
Site 11	51	0	-51	-100.0%	51	0	-51	-100.0%
Site 8	3	22	19	633.3%	3	23	20	666.7%
Site 7[f]	0	15	15	100.0%	3	22	19	633.3%
Site 2	91	39	-52	-57.1%	92	59	-43	-46.7%
Site 13	20	12	-8	-40.0%	21	12	-9	-42.9%

(continued)

Table 10-9. Total Patients Enrolled in Clinical Trials in Year 1 and Year 3 by Site (continued)

	NCI Clinical Trials[b]				All Clinical Trials[c]			
Site	**Year 1**	**Year 3**	**Number Change**	**Percent Change[d]**	**Year 1**	**Year 3**	**Number Change**	**Percent Change**
Site 5	2	1	-1	-50.0%	2	1	-1	-50.0%
Site 14	27	42	15	55.6%	31	62	31	100.0%
Mean	61	45	-16		67	57	-10	
Median	43	33	-10		43	45	2	

[a] The number of NCI trials and the number of All trials are not mutually exclusive; NCI trials are included in the total presented for All trials.

[b] The total number of patients enrolled was calculated by RTI as the sum of site-reported accruals to therapeutic and cancer control trials; accruals to "other" types of research studies were excluded. "Other" trials are classified as anything other than therapeutic, symptom management/cancer control, or prevention. Moreover, accruals were counted differently across sites; during Year 3, NCI discovered that some sites were "counting" patients who were accrued through ANY community doctor into a trial, WHETHER OR NOT they were a doctor associated with their hospital, while others were being ultra conservative by "counting only patients that were accrued through their hospital staff specifically (so not even private practice physicians associated with their hospital).

[c] The total number of patients enrolled was calculated by RTI as the sum of site-reported accruals to therapeutic and cancer control trials sponsored by NCI, Industry/Pharmaceutical sponsors, or "other sponsors." "Other-Sponsored" trials is defined by SAIC-F as, "Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center." Accruals to "other" types of trials, regardless of sponsor, were excluded. "Other" trials are classified as anything other than therapeutic, symptom management/cancer control, or prevention. Moreover, accruals were counted differently across sites; during Year 3, NCI discovered that some sites were "counting" patients who were accrued through ANY community doctor into a trial, WHETHER OR NOT they were a doctor associated with their hospital, while others were being ultra conservative by "counting" only patients that were accrued through their hospital staff specifically (so not even private practice physicians associated with their hospital).

[d] Percent change was calculated by dividing their Year 1 patient accrual total into their Year 3 patient accrual total. This change is important to present to give the reader a sense of how much change occurred relative to a specific site since all the sites differed in terms of their cancer patient base, types of cancers treated, as well as other indicators that could influence their ability to identify more patients for clinical trials. Although it is mathematically impossible to calculate percent change with a denominator of 0, for the purposes of presenting change, we considered increases from "0" in Year 1 to be 100% change.

[e] Site 4 cited the construction of their new cancer center as a huge barrier to sustaining all clinical trials activity during the pilot. Clinical trials activity was suspended until the new building was complete and the radiation oncology equipment re-certified.

[f] Although Site 7. increased the number of patients enrolled in NCI trials from Year 1 to Year 3, we were unable to calculate the percent change from 0 in Year 1.

Table 10-10. Number of Trials Open and Number of Patients Enrolled in Clinical Trials in Year 1 and Year 3

	Number of Trials Open[a]			Number of Patients Enrolled in All Clinical Trials[b]		
Site	**Year 1**	**Year 3**	**Change**	**Year 1**	**Year 3**	**Change**
Data Source:						
Site 4[c]	164	37	-127	142	83	-59
Site 6	152	157	5	254	251	-3
Site 10	9	52	43	97	32	-65
Site 3	47	46	-1	86	42	-44
Site 12	19	46	27	35	48	13
Site 1	49	53	4	6	35	29
Site 9	37	25	-12	141	85	-56
Site 16	51	42	-9	85	101	16
Site 15	26	66	40	27	58	31
Site 11	1	0	-1	51	0	-51
Site 8	15	19	4	3	23	20
Site 7	1	16	15	3	22	19
Site 2	23	85	62	92	49	-43
Site 13	10	50	40	21	12	-9
Site 5	2	8	6	2	1	-1
Site 14	10	35	25	31	62	31
Mean	39	46	8	67	57	-10
Median	21	44	23	43	45	2

[a] The total number of NCI-sponsored, Industry/Pharmaceutical-Sponsored, and "Other-Sponsored" trials open is the sum of all site self-reported trials categorized as Therapeutic, Prevention, and Symptom Management/Cancer Control; other research activities (i.e., Screening/Early Detection/Diagnostic, Epidemiologic/Observational/Outcome, Ancillary, Correlative) are excluded. "Other-Sponsored" trials is defined by SAIC-F as, "Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center."

[b] The total number of patients enrolled was calculated by RTI as the sum of site-reported accruals to therapeutic and cancer control trials; accruals to "other" types of trials are excluded. "Other" trials are classified as anything other than therapeutic, symptom management/cancer control, or prevention. Moreover, accruals were counted differently across sites; during Year 3, NCI discovered that some sites were "counting" patients who were accrued through ANY community doctor into a trial, WHETHER OR NOT they were a doctor associated with their hospital, while others were being ultra-conservative by "counting" only patients that were accrued through their hospital staff specifically (so not even private practice physicians associated with their hospital).

[c] Site 4 cited the construction of their new cancer center as a huge barrier to sustaining all clinical trials activity during the pilot. Clinical trials activity was suspended until the new building was complete and the radiation oncology equipment re-certified.

Table 10-11. Number of Physicians Eligible and Actually Accruing Patients to Clinical Trials

Site	Whether Clinical Trials enrollment Included in COPs by Year 3[a]	Eligible to Enroll Patients in Clinical Trials[b]			Actually Accruing Patients to Clinical Trials			Percentage of (Eligible) Physicians Enrolling Patients in Clinical Trials[c]		
		Year 1	Year 3	Change	Year 1	Year 3	Change	Year 1	Year 3	Change
Data Source:	**FAS**				**Outcomes Worksheet**					
Site 4	Yes	7	9	2	7	9	2	100.0%	100.0%	0.0%
Site 6	Yes	31	32	1	31	31	0	100.0%	96.9%	-3.1%
Site 10	Yes	52	83	31	39	62	23	75.0%	74.7%	-0.3%
Site 3	Yes	14	30	16	10	7	-3	71.4%	23.3%	-48.1%
Site 12	Yes	25	57	32	5	21	16	20.0%	36.8%	16.8%
Site 1	Yes	3	12	9	2	9	7	66.7%	75.0%	8.3%
Site 9	N/A	6	7	1	6	7	1	100.0%	100.0%	0.0%
Site 16	Yes	33	44	11	20	22	2	60.6%	50.0%	-10.6%
Site 15	Yes	25	28	3	3	9	6	12.0%	32.1%	20.1%
Site 11	COP not implemented by Year 3	6	12	6	5	5	0	83.3%	41.7%	-41.7%
Site 8	Yes	10	12	2	3	5	2	30.0%	41.7%	11.7%

(continued)

Table 10-11. Number of Physicians Eligible and Actually Accruing Patients to Clinical Trials (continued)

Site	Whether Clinical Trials enrollment Included in COPs by Year 3[a]	Eligible to Enroll Patients in Clinical Trials[b]			Actually Accruing Patients to Clinical Trials			Percentage of (Eligible) Physicians Enrolling Patients in Clinical Trials[c]		
		Year 1	Year 3	Change	Year 1	Year 3	Change	Year 1	Year 3	Change
Site 7	Yes	14	20	6	7	10	3	50.0%	50.0%	0.0%
Site 2	COP not implemented by Year 3	12	12	0	11	11	0	91.7%	91.7%	0.0%
Site 13	COP not implemented by Year 3	3	4	1	3	4	1	100.0%	100.0%	0.0%
Site 5	COP not implemented by Year 3	8	11	3	4	10	6	50.0%	90.9%	40.9%
Site 14	No	3	4	1	2	3	1	66.7%	75.0%	8.3%
Mean	10 of 11 sites with fully implemented COPs included clinical trials enrollment	16	24	8	10	14	4	67.3%	67.5%	0.2%
Median		11	12	1	6	9	3	69.0%	74.8%	5.8%

[a] COPs only apply to mostly private practice models; Site 9 is a mostly hospital-employed model and thus COPs do not apply. Site 4 is also mostly hospital-employed but reported implementing COPs in Year 3.

[b] RTI was not provided reliable data on the total number of cancer physicians to be able to calculate the proportion of physicians eligible to enroll patients; RTI does have the total number of key cancer physicians, but in many instances sites reported a greater number of physicians eligible to enroll patients than their total number of key cancer physicians.

[c] Calculated by dividing the number of physicians actually accruing patients to clinical trials by the number of eligible physicians to enroll patients in clinical trials.

Table 10-12. Patients' Reported Awareness and Understanding of Clinical Trials[a,b]

Site	Percentage of Patients Aware of Clinical Trials as a Treatment Option[c]			Percentage of Patients Who Received Educational Materials about Clinical Trials[d]			Understanding of Clinical Trials (Mean Score 1-10)[e]			Likelihood of Participating in a Clinical Trial (Mean Score 1-10)[f,g]		
	Time 1	Time 2	p-Value	Time 1	Time 2	p-Value	Time 1	Time 2	p-Value	Time 1	Time 2	p-Value
Data Source:						**Patient Survey[h]**						
All Sites	27%	27%	0.77	36%	32%	**0.01**	6.9	5.8	**0.00**	6.1	5.8	**0.01**
Site 4	28%	23%	0.20	31%	29%	0.67	6.9	6.2	**0.02**	6.1	6.2	0.75
Site 6	38%	28%	**0.04**	48%	32%	**0.00**	6.9	5.6	**0.00**	6	5.6	0.24
Site 10	16%	3%	**0.00**	23%	31%	0.06	6.9	5.9	**0.00**	5.9	5.9	0.95
Site 3	22%	15%	0.16	36%	32%	0.46	6.7	6	**0.05**	6	6	0.98
Site 12	16%	25%	0.07	3%	29%	0.84	6.9	5.7	**0.00**	5.9	5.7	0.57
Site 1	37%	26%	0.06	42%	31%	0.08	6.7	6.4	0.43	6.6	6.4	0.71
Site 9	32%	36%	0.32	37%	43%	0.18	7.1	5.8	**0.00**	6.5	5.8	**0.02**
Site 16	38%	28%	**0.03**	49%	36%	**0.00**	7.1	5.4	**0.00**	6	5.4	0.07
Site 15	15%	19%	0.36	24%	24%	0.96	6.5	5.9	**0.04**	6.2	5.9	0.24
Site 7	27%	31%	0.34	67%	28%	0.07	7.1	5.7	**0.00**	5.9	5.7	0.43

[a] All data presented is unweighted; Significant changes ($p < 0.05$) are in bold text.

[b] Significant increases were observed at the site level as well, but the findings should be interpreted with caution because sites did not have an optimal sample size for calculating significant change.

[c] Time 1 and 2 data represent the percent of respondents who answered "yes" to whether someone mentioned that a clinical trial might be an option for them.

[d] Time 1 and 2 data represent the percent of respondents who answered "yes" to whether they received educational materials about clinical trials.

[e] Time 1 and 2 data represent the mean scores of all participants across sites on a scale of 1 to 10, with 1 being the lowest and 10 being the highest.

[f] Time 1 and 2 data represent the mean scores of all participants across sites on a scale of 1 to 10, with 1 being the lowest and 10 being the highest.

[g] The patient survey, the data source for these indicators, was collected in the 10 lead sites only.

[h] The patient survey, the data source for these indicators, was collected in the 10 lead sites only.

Table 10-13. Overall Success in Clinical Trials

Sites	Trials[a]			Clinical Trials Accrual[b]		Patient Perspectives[c]		Total
	Increase in Number of All Trials Open (Y/N)	Increase in Number of Early Phase Trials Offered (Y/N)	Increase in Number of Types of Clinical Trials and Other Research Studies Offered (Y/N)	Increase in Number of Pts. Enrolled in All Trials (Y/N)	Percentage of Eligible Physicians Enrolling Patients in Trials[d] Increase in Percentage of Eligible Physicians Enrolling Patients (Y/N)	Significant Increase in Patients' Reported Awareness of Clinical Trials? (Y/N)	Significant Increase in Patients' Reported Receipt of Information about Clinical Trials? (Y/N)	Number of Indicators for Which Site Increased Activity (out of 9 indicators)
Data Source:	**Clinical Trials Worksheet**				**BAS/FAS**	**Patient Survey**		
1	Yes	Yes	No	Yes	Yes (8.3%)	No	No	5
2	Yes	Yes	Yes	No	No (0%)	Data not collected	Data not collected	4
3	No	Yes	No	No	No (-48.1%)	No	No	2
4	No	No	No	No	No (0%)	No	No	1
5	Yes	Yes	Yes	No	Yes (40.9%)	Data not collected	Data not collected	4
6	Yes	Yes	No	No	No (-3.1%)	No	No	3
7	Yes	Yes	No	Yes	No (0%)	No	No	4
8	Yes	No	No	Yes	Yes (11.7%)	Data not collected	Data not collected	3
9	No	No	No	No	No (0%)	No	No	1
10	Yes	Yes	Yes	No	No (-0.3%)	No	No	3
11	No	No	Yes	No	No (-41.7%)	Data not collected	Data not collected	1
12	Yes	Yes	Yes	Yes	Yes (16.8%)	No	No	6
13	Yes	Yes	No	No	No (0%)	Data not collected	Data not collected	2

(continued)

Table 10-13. Overall Success in Clinical Trials (continued)

	Trials[a]			Clinical Trials Accrual[b]		Patient Perspectives[c]		Total
Sites	**Increase in Number of All Trials Open (Y/N)**	**Increase in Number of Early Phase Trials Offered (Y/N)**	**Increase in Number of Types of Clinical Trials and Other Research Studies Offered (Y/N)**	**Increase in Number of Pts. Enrolled in All Trials (Y/N)**	**Percentage of Eligible Physicians Enrolling Patients in Trials[d] Increase in Percentage of Eligible Physicians Enrolling Patients (Y/N)**	**Significant Increase in Patients' Reported Awareness of Clinical Trials? (Y/N)**	**Significant Increase in Patients' Reported Receipt of Information about Clinical Trials? (Y/N)**	**Number of Indicators for Which Site Increased Activity (out of 9 indicators)**
14	Yes	Yes	Yes	Yes	Yes (8.3%)	Data not collected	Data not collected	5
15	Yes	Yes	No	Yes	Yes (20.1%)	No	No	5
16	No	No	Yes	Yes	No (-10.6%)	No	No	2
Total Sites with Positive Change	11	11	7	7	6	3	2	

[a] See Tables 10-5, 10-6, and 10-7 for supplemental data on number and types of trials offered.

[b] See Tables 10-9 for supplemental data on total patient accrual to NCI trials.

[c] See Table 10-12 for supplemental data on changes in patients' awareness and understanding of clinical trials. The Patient Survey was completed in the 10 lead sites only.

[d] See Table 10-11 for supplemental data on the proportion of eligible physicians enrolling patients. This was calculated by dividing the number of physicians actually accruing patients by the number of physicians eligible to enroll patients.

[e] See Table 10-12 for supplemental data; the proportion of patients in clinical trials was calculated using the total number of patients accrued to ANY type of trial (including NCI-sponsored, industry/pharma-sponsored, and other-sponsored trials) divided by the total number of Unduplicated Cancer Patients reported in the BAS.

Missing = Data are missing for this site

Unknown = Value cannot be calculated due to missing data at Year 1 and/or Year 3

Data not collected = This data was not collected for this site

Shading = Change in a positive direction

11. BIOSPECIMENS

Overview

Few sites had previous experience with collecting and reporting biospecimens for cancer research before the NCCCP pilot. If they did, most generally did not follow NCI's guidelines for how to provide high-quality specimens. The NCCCP pilot created a unique opportunity for sites to participate in biospecimen initiatives by providing a number of tools, including the Gap and Fill Assessment Tool, the Process Evaluation Tool, and the Best Practices Implementation Tool. For the biospecimens component, however, the only deliverable the NCCCP subcontract required from the sites was for each to complete the three tools and develop strategies for improving this area of their research.

Facilitators and Barriers to Biospecimens Research

Across all sites, three main areas were associated with sites' ability to enhance their capacity to build a biospecimen infrastructure:

- having an existing infrastructure for the collection and/or processing of tissue biospecimens,
- establishing external collaborations (e.g., with H. Lee Moffitt Cancer Center and Research Institute and the Cancer Genome Atlas), and
- garnering staff support from their pathology departments, which were usually composed mostly of private practice pathologists.

Some of the key barriers identified across sites were the lack of financial, staff, and IT resources. At the end of the pilot, there is still some concern among sites with regard to a lack of necessary infrastructure and resources to implement best practices regarding biospecimens.

In the age of molecular or "personalized" and genomically informed precision medicine, biospecimen collection, annotation, and reporting play a crucial role in cancer research by allowing researchers to study both cancerous and normal cells provided through tissue and blood samples. This has paved the way for biospecimen research efforts relating to the diagnosis, targeted treatment, and prevention of disease at the molecular level. The *NCI Best Practices for Biospecimen Resources*, developed by the NCI Office of Biorepositories and Biospecimen Research (OBBR) identifies best practices and guiding principles for biospecimen annotation, collection, processing, storage, distribution, and retrieval, and for "addressing concepts of good laboratory practice to ensure a level of consistency and standardization across NCI-supported biospecimen resources" (U.S. National Institutes of Health, 2009a). However, there is no national standardization for obtaining consistently high-quality biospecimens, and access to them for research purposes is limited. The NCCCP pilot is well positioned to "test" these best practices by creating a unique opportunity for pilot sites (i.e., community hospitals) to participate in biospecimen initiatives that will advance cancer research. Although the NCCCP pilot does not focus on collecting biospecimens, the deliverables specific to this program component require sites to

- review the *NCI Best Practices for Biospecimen Resources*,
- describe their current efforts related to biospecimens,
- assess their infrastructure requirements necessary for implementation of the best practices,
- assess policies and procedures necessary for implementation of the best practices,
- assess cost issues related to implementation of the best practices, and
- assess internal and external collaborations necessary for biospecimen collection and storage.

In addition, the proper collection and reporting of biospecimens does relate directly to whether sites enhanced their cancer research capacity during the course of the pilot. In Chapter 16, we address this outcome specifically, incorporating findings from both the clinical trials and biospecimens program components to assess accomplishments in enhancing research.

During the course of the pilot, the NCCCP biospecimens subcommittee created several initiatives to assist sites in their biospecimen efforts. This chapter describes some of those subcommittee initiatives, what sites have indicated to be facilitators in their biospecimen efforts, and the barriers and challenges noted in their efforts.

11.1 NCCCP Biospecimen Priorities

The goal of the biospecimens subcommittee is to prepare pilot sites for standardizing the annotation, collection, transport, processing, storage, distribution, and retrieval of biospecimens for cancer research to improve patient care. There are no workgroups (or subgroups) specific to the committee; therefore, efforts are conducted primarily through monthly subcommittee telephone calls. Since the beginning of the pilot, the subcommittee has introduced several tools to move sites forward in their biospecimen data collection efforts:

- the Gap and Fill Assessment Tool (GAFAT),
- the Process Evaluation Tool (PET), and
- the Best Practices Implementation Tool (BPIT).

The GAFAT (Appendix Q) was developed for evaluating each site's progress in identifying the gaps and their fills for each of the 112 best practice checklist standards. The sites will produce quality biospecimens if they adhere to as many of the 112 standards specified in the GAFAT checklist as feasible. The PET is used by sites to quantitatively determine the status of their gap and fill project assignment, and the BPIT is used by sites to demonstrate the implementation of the best practices.

The following sections are based on site visit data describing sites' experiences using these tools and their overall facilitators and challenges in biospecimen collection efforts.

11.2 Use of Biospecimens Subcommittee Tools

11.2.1 Gap and Fill Assessment Tool

As of June 2009, all 16 sites had completed the GAFAT, which was designed for sites to assess and report progress on implementing the best practices for biospecimens. Particularly during the Year 2 site visits, most sites noted that the GAFAT was quite burdensome but that it had helped them to effectively identify gaps related to biospecimen collection:

> *I thought [the tools] were great. I think a lot of them, like the GAFAT, were geared as though you were already in operation. So, there were a lot of [things that were not applicable], but once you begin to become operational, it helps you figure out what you need to do.* (Subcommittee member, Year 2)

> *We completed them almost a year ago now. We had to complete them, but they helped us. We used the PET and GAFAT. We not only completed it, but we do use it on a pretty regular basis. Today we even use it as a guide.* (Subcommittee member, Year 2)

> *The GAFAT has really helped us to identify areas we need to work on, like policies written on training of staff who send out biospecimens, freezer specs, radiation safety.* (Subcommittee member, Year 2)

The GAFAT is a Microsoft Word document that sites had to complete manually. Therefore, several respondents described it as "very time consuming" and something they "had to do." However, respondents offered several suggestions to help alleviate some of the burden of completing this tool. Suggestions included making the tool available online and condensing it as a "checklist" to facilitate data entry.

11.2.2 Process Evaluation Tool

During the Year 2 site visits, respondents from only two sites mentioned using the PET. Respondents from both sites described the benefits of the tool and said that they have found it to be a useful supplement to the GAFAT:

> *Once I get [the GAFAT] where I want it, then I go to the PET, and we send it in quarterly to [senior management]. For the PET, I'm just repeating what's on the GAFAT. [The PET] is an assessment of where you are with the other programs and it's useful.* (Subcommittee member, Year 2)

11.2.3 Best Practices Implementation Tool

Respondents from three sites described their use of and experience with the BPIT. For these sites, the BPIT has been useful in helping to clarify items that may be unclear on the GAFAT and in making connections with other sites:

> *I have used the BPIT. It explains sometimes what they're asking for in the GAFAT. It also gives a lot of Web sites and where to go get information.* (Subcommittee member, Year 2)

> *I think the best practices [implementation tool] has also helped us in handling the tissue. If you look at the tissue that we've been sending to Moffitt, I think we rank it at the top of the entire project and the quality of the material we're providing to them, there's a connection there. The best practices [implementation tool] has helped us*. (Subcommittee member, Year 2)

> *The best practices [implementation] tool is very useful. I think this was a way of connecting sites to see what sites were strong in what areas.* (Subcommittee member, Year 2)

11.3 Facilitators to Biospecimen Collection

One of the main purposes of the Year 2 and Year 3 site visits was to gain a thorough understanding of the factors that have influenced how successful sites have been with assessing and implementing their biospecimen efforts. Across all sites, three main areas were associated with sites' ability to enhance their capacity to build a biospecimen infrastructure:

- having an existing infrastructure for the collection and/or processing of biospecimens tissue,
- establishing external collaborations (e.g., with H. Lee Moffitt Cancer Center and Research Institute and the Cancer Genome Atlas program), and
- garnering pathology staff support.

11.3.1 Having an Existing Biospecimen Infrastructure

NCI is aware that many of the pilot sites lacked the infrastructure to "get off the ground quickly" with regards to biospecimen efforts. Based on SAIC-F data confirmed during the Year 1 site visit, Christiana was the only site to have an on-site repository during the first year of the pilot. However, those few sites that had some biospecimen infrastructure in place prior to the NCCCP have credited this feature for how quickly they have been able to move forward with their efforts:

> *I think in biospecimens, we have a great foundation…we spent hours with a team that had developed biospecimens so we have some models and resources, and I believe with a strong research focus of this organization, this will not be a large barrier. I think we're in a pretty good position.* (Cancer center/program staff, Year 2)

> *Biospecimens was existing strongly here before. NCI was surprised how far along we were. We are ready to open a tissue bank. On this particular pillar, we were ahead of the curve.* (PI, Year 2)

> *We are at one end of the spectrum among the sites because we already had a biorepository program set up, and then it was more [a matter] of identifying the gaps.* (Subcommittee member, Year 2)

Based on SAIC-F data, four sites built an on-site biospecimens repository by the end of Year 3: St. Joseph Medical Center (Towson, MD), Penrose-St. Francis, Our Lady of the Lake, and Sanford Clinic. The Year 3 site visits also revealed that, according to the cancer center medical director, St. Joseph Hospital (Orange County, CA) was "weeks away from having our own biospecimens repository."

11.3.2 Establishing External Collaborations

Biospecimens is an area that has facilitated interaction between the NCCCP sites and other research organizations (e.g., NCI-designated cancer centers) to work together to support cancer research (see Chapter 15). Hence, one noticeable benefit of the NCCCP pilot is that it has been a catalyst for sites to establish collaborations they may not have otherwise made. One such collaboration has been with the Cancer Genome Atlas, a joint effort of the NCI and the National Human Genome Research Institute; three NCCCP sites are participating by providing high-quality tissue samples for genomic research. Another important collaboration has been with the H. Lee Moffitt Cancer Center and Research Institute (Moffitt) in Tampa, FL:

> *There are things beyond the deliverables that we are going to be doing above and beyond. With biospecimens, our personnel are filling out the GAFAT, and our participation in Moffitt is actually implementing the gaps. Our ultimate goal is to provide research quality biospecimens, and that is exactly what we are doing.* (Cancer center/program staff, Year 2)

As an NCI-designated cancer center, Moffitt ultimately established contracts with four NCCCP sites to collect biospecimens for its Total Cancer Care (TCC) initiative (http://www.moffitt.org/):

- Hartford Hospital,
- Our Lady of the Lake,
- St. Joseph's/Candler, and
- St. Vincent.

During the Year 2 site visits, it was clear that sites participating as Moffitt TCC programs were moving forward quickly with biospecimen collection and reporting.

Even for sites not involved with Moffitt, there has been a heightened recognition of the need to follow best practices with regards to biospecimens. For example, Spartanburg has a unique partnership with the Health Sciences South Carolina (HSSC) consortium. HSSC is a public–private partnership that was formed in 2004 to coordinate patient care among all of

the state's hospitals and academic medical centers. This partnership provides Spartanburg with opportunities to expand their IT and biospecimens work. Before agreeing to participate in the effort, however, Spartanburg required that HSSC follow NCI's best practices.

11.3.3 Garnering Pathology Staff Support

Staff support was another key facilitator with regards to biospecimen implementation efforts across sites. Respondents from several sites acknowledged that staff support, especially from pathology staff, has not only helped to identify future directions with regards to biospecimen efforts, it has also shown a collective commitment to helping the sites reach their goals:

> *The lab is very taxed by what we are asking for this initiative. This is an overachieving group. When [name] says that existing staff have stepped up, it's absolutely true. People have full-time jobs, [have] stepped up and have been doing this because they so much want to prove its success and value…Everyone hopes to help it grow.* (System/hospital senior executive, Year 2)

> *Really, it was the cooperation of the pathology department and the med techs. Because we have two campuses, that can really be hard with surgeries at the same time. The cooperation of them jumping in, helping to collect and label…. Everybody has been very willing to work with us on that. We have never missed a specimen or had to cancel anything because of their support.* (Subcommittee member, Year 2)

> *The first couple of years, people were a little cynical or didn't understand what a more comprehensive type program would bring to the table for themselves and their patients. There's still some physicians who feel this way. In this last year, especially, I found that I don't hear those things anymore. People are excited to bring their cases to conferences. They hear about these trials more, even if we're not accruing. It's just a lot more momentum. They're proud that we're a center that's been designated as an NCCCP site. I think, more and more, as time goes on, they're seeing that it's better for the patients they have. I think they're actually learning something from the conference. It takes the burden off yourself if you can have the biospecimens person go over and consent the patient.* (Key physician, Year 3)

11.4 Barriers to Biospecimen Collection

The site visits not only enabled us to learn more about what has worked well for sites regarding biospecimen collection, they also provided a valuable opportunity to probe for challenges and barriers to implementing NCCCP biospecimen priorities. Some of the key barriers identified across sites have been the lack of financial and staff resources and the lack of IT support.

11.4.1 Lack of Financial/Staff Resources

As previously noted, the sites that have joined Moffitt's TCC initiative have made the greatest strides with regards to biospecimens. However, due to growing fiscal constraints, it has been difficult for many sites to identify resources and staff to establish strong biospecimen programs. As one PI noted, "Biospecimens has moved along, but has been stalled because of low funding."

> *So we're not getting any additional funding to do this. Until we get the commitment in terms of time and resources, I think it will continue to move slow.* (Subcommittee member, Year 2)

> *I don't think we have the personnel in place. I would imagine as far as tissue procurement and dispensing the tissue…you need more personnel to do that.* (Subcommittee member, Year 2)

> *I think the biggest thing is that there's been no funding so no dedicated staff—that would be the two biggest things.* (Subcommittee member, Year 2)

> *As for the biospecimens repository, we'll never be up there. It's a continuous struggle. "Total Cancer Care" fell through…[company] pulled some of the funding.* (Cancer center/program staff, Year 3)

Moreover, the economic downturn has had a measurable impact on several cancer centers, primarily due to the freezing of capital expenditures. For example, during the Year 2 site visits, St. Joseph/Orange reported they had not yet implemented their biospecimen repository as planned. They were confident, however, that a recent philanthropic donation would help provide some of the financial incentive to move forward. During the Year 3 site visits, they confirmed that they were "unfrozen" now, having received a donation to get started and buy a freezer. The economic downturn seemed to have a continued impact on other sites; during the Year 3 site visits, a number of respondents reported decreased funding or freezing of capital expenditures.

11.4.2 Lack of IT Support

For some sites, the implementation of biospecimen efforts has been haltered by the availability of IT resources. Without these resources, it is difficult for sites to maximize and/or integrate systems like caTissue into their biospecimen work. The caTissue suite is caBIG's biorepository tool for biospecimen consenting and inventory management, tracking, and annotation. This tool permits users to enter and retrieve data concerning the consenting, collection, storage, quality assurance, and distribution of biospecimens:

> *We don't have the resources to implement caTissue when the freezer and actual tissue collection will happen. I foresee a window of 6 months between specimen collection and application of the caTissue suite. Until then, I'll have to develop an Excel spreadsheet.* (Subcommittee member, Year 2)

> *I'm hoping that with the implementation [of biospecimen efforts], by Year 3, we will share more internally and pull in modules that are more common like caTissue…and patient study calendar.* (Subcommittee member, Year 2)

11.5 Summary

Although there is a definite commitment among the sites to work closely with NCI on these efforts, there is still some concern among sites at the lack of necessary infrastructure and resources to implement best practices regarding biospecimens. However, it is reasonable to consider NCCCP pilot sites as pioneers in building the capacity and establishing the organizational policy and procedures necessary for continuous, reproducible high-quality biospecimen collection and storage within community-based hospitals. This capability will not only help to improve cancer research, it will serve as the foundation for developing advanced treatments tailored to individual patients.

12. INFORMATION TECHNOLOGY

Overview

Since the start of the NCCCP, development of integrated IT systems through which doctors and hospitals can access shared patient records has become a national priority. NCI included IT as one of the four initial program components of the NCCCP pilot to study the unique needs of community cancer centers in technology expansion, to support program growth and the expected increase in data collection needs, and to help the community cancer centers organize IT shops according to best practices in order to improve efficiencies and capabilities. Because NCI recognized that these sites would have a broad array of IT capabilities and systems available to them, they asked sites only to determine the requirements necessary to support their cancer center's expanding programs, and to provide workplans outlining the resources necessary to address system integration, develop interfaces, and determine if and how caBIG components would support their unique community-based needs. The IT component of the NCCCP pilot also included an assessment of progress and requirements toward implementation of an oncology-extended EHR system for integrated use and with the potential for linking community hospitals with various caBIG initiatives.

Facilitators and Barriers to Expanding IT Capabilities

Sites reported many more barriers than facilitators to implementing the IT component. The most common caBIG component for sites to work on was caTissue. Toward the end of Year 3, one site fully implemented caTissue, and several sites were on track to implement it. Those that had explored implementing caBIG components reported major barriers in the system costs for expanding IT capabilities and in garnering adequate top management support to spend funds on this effort. Other barriers included the level of difficulty in linking multiple EHR systems and lack of physician engagement to change or develop interfaces with their office systems. IT facilitators included having dedicated resources, incorporating end-users into the initial stages of IT planning, and having private practice physician engagement.

Information technology (IT) is a key priority for NCI, highlighted by the development of caBIG, a national network to support cancer research and personalized medicine. The NCCCP provided an opportunity for the NCI to learn how to connect community-based cancer care into this national network. The IT component of the NCCCP includes an assessment of the costs and requirements for linking community hospitals with the various components of caBIG and of progress toward implementation of an electronic health record (EHR) system for the cancer centers.

12.1 IT Priorities

Despite the benefits of IT, development of an integrated IT platform is a costly venture involving hospital financial support, hardware infrastructure, and personnel resources. Given these costs and the fact that each NCCCP site is in a different stage of IT development, NCI did not require implementation of caBIG as a program activity. Instead, the NCCCP goal for

IT was to conduct an inventory of each site's existing IT infrastructure while evaluating potential ways to enhance or expand IT to incorporate caBIG tools and interfaces.

The deliverables specific to the IT program component are

- to develop a detailed report with recommendations on IT infrastructure requirements, necessary interfaces, and applicability of specific components of caBIG for community hospital settings to support NCI research goals;
- to implement and integrate EHRs and electronic tumor registry data into the cancer program activities at each pilot site; and
- to develop a group report on the above items.

In addition, the IT subcommittee focused on exploring

- requirements for EHR systems in the community cancer center and community hospital settings,
- requirements for patient interactions with EHRs, and
- privacy and data sharing issues surrounding EHRs (U.S. National Institutes of Health, 2009b).

This chapter briefly describes sites' implementation of the IT implementation workplan and adoption of various caBIG initiatives and focuses primarily on barriers and facilitators of expanding IT capabilities. The goal of the pilot was to identify common themes across community cancer centers so that NCI will be better equipped to understand, evaluate, and overcome IT barriers in order to improve caBIG implementation with more cancer centers in the future. The qualitative examples provided in this section were selected from Year 2 and 3 site visit interviews.

12.2 IT Implementation Workplan

Pilot sites were asked to develop a workplan that outlines the resources necessary to build a sufficient IT infrastructure, develop interfaces, and incorporate caBIG components (U.S. National Institutes of Health, 2009b). Only two respondents mentioned the IT implementation plan, both of whom indicated that the document was difficult to accomplish in the initial phase of the pilot:

> *The implementation plan was required by the grant, and that was an absolutely horrible document. They're asking you to write this very detailed plan when we didn't even know what caBIG was. They were asking us what components we need,… maybe by Year 3, that would have been a better time. The implementation plan was premature. We had just done that goals document, and my perspective was that this should be done from an implementation standpoint. Other sites had the same experience, and we were told the NCI-designated sites had to do it as well.* (Subcommittee member, Year 2)

Despite some of the difficulty sites experienced in developing a relevant and feasible IT implementation plan, respondents indicated that creating the plan helped them discern the stages for development and more tangible future steps for full integration. These efforts also resulted in a collective report on sites' experiences in assessing the feasibility and potential of integrating caBIG tools into community cancer centers.

12.2.1 Implementation of caBIG Components

Although not required by NCI, several sites worked toward implementation of various caBIG components throughout the NCCCP pilot. According to SAIC-F data, 12 of the 16 sites explored or worked toward implementing caTissue. Other components that sites explored or worked toward implementing include the National Biomedical Imaging Archive (NBIA), the Cancer Adverse Events Reporting System (caAERS), the Patient Study Calendar (PSC), the Lab Viewer (CTODS), caXChange, the Cancer Center Clinical Participant Registry (3CPR), and the Cancer Center Clinical Database (C3D). By June 2010, three sites had one or more caBIG components "in production." Christiana had fully implemented caTissue and NBIA, Our Lady of the Lake had implemented NBIA, and St. Joseph Hospital (Orange County, CA) had implemented C3D. Facilitators and barriers to expanding IT capabilities, including implementation of caBIG, are described in the following sections.

12.3 Facilitators to Expanding IT Capabilities

The sites were asked to describe factors that helped to facilitate IT implementation and integration. The most frequently cited facilitating factors were

- dedicated resources,
- incorporating end-users into the initial stages of IT planning, and
- private practice physician engagement.

12.3.1 Dedicated Resources

Several respondents indicated that enhancing and integrating their IT system is aligned with their hospital's strategic goals. Thus, their hospital provided dedicated resources necessary to expand their IT infrastructure:

> *The allocation of this resource has been the attitude from the start. They've been willing to put the resources in there. The work involved with IT was much more than I anticipated, but our site is doing a lot more with IT than others. We have a very advanced IT system here.* (Subcommittee member, Year 2)

> *$1.6 million just for the cancer center was approved, and we hired the initial project manager for EHR selection.* (Cancer center/program staff, Year 2)

One site even designated a system-wide IT staff member to handle the emerging needs related to the NCCCP:

> *Our system allocated a person to work with them on IT because of the demands related to NCCCP—that was a huge resource allocation from their system. We kept sending requests to IT, and finally the IT department asked what this was all about and why we needed so much support. Once they realized what we were doing, they assigned a system IT person to take care of our data requests.* (Subcommittee member, Year 2)

12.3.2 Incorporating End-Users

Sites that incorporated end-users into the IT software and hardware decision-making process reported successful IT implementation. By discerning IT needs during the initial staging process, sites were better equipped to overcome barriers:

> *We interrogated our end-users and tried to really understand what their requirements were and involve them in the final identification of what should be in an EHR and demo site visits, and ultimately they helped us. We built our own project. We purchased a vendor-owned system, but you have to do a lot of your own configuration, and it was a very end-user–driven process where IT supported that.* (Subcommittee member, Year 2)

Furthermore, one respondent found it helpful to have engaged physicians who are willing to participate, even during the initial stages of IT implementation:

> *We're working with practices who are interested in participating in that to be able to support in sharing key data across the continuum, but we're early in the process right now. We're testing the process out with admission discharge transfer information as a start, not specifically clinical information yet, but the intent would be that—we have practices willing to share.* (Subcommittee member, Year 2)

12.4 Barriers to Expanding IT Capabilities

During Year 2 and Year 3, sites were asked to describe any barriers they experienced with regards to IT implementation. Respondents provided examples of factors that hindered their ability to fully implement IT activities on site, including

- limited EHR data management system capabilities, including a lack of linkages between multiple EHR systems,
- limited physician engagement,
- challenges due to patient confidentiality requirements,
- the priority of linking to caBIG, and
- the requirement of extensive hospital resources to implement IT as needed.

Sites reported similar types of barriers during Year 3 site visits, most notably challenges with linking multiple EHRs. This section describes these IT barriers and provides examples from the Year 2 and Year 3 site visit interviews.

12.4.1 Limited EHR Data Management System Capabilities or Linkages

As indicated in Section 12.1, one of the goals in the IT subcommittee was to determine the IT capabilities of the existing onsite EHR systems. Several respondents indicated that the EHR software systems were not able to meet the NCCCP data abstraction needs:

> *We have a software program through [our clinical research program], and I'm not sure it's the greatest software program developed for clinical trials. Data software helps on a CCOPs level, so as far as reporting requirements it's a great program, but as far as tracking patients it's not. We use the tickler method: data on index cards. We have no real software system here. We would love to get a study manager–type of database for research, but of course that's a funding issue.* (Subcommittee member, Year 2)

In addition to the limitations of the software system, one of the most common barriers reported by sites during Year 2 and Year 3 site visits was the issue of having more than one EHR or clinical information system in the hospital or among the different medical practices. Having multiple EHRs created challenges to interfacing, integrating, and abstracting patient data:

> *IT is an area where we've got numerous systems—each of the medical oncology practices has a different EHR. Radiation oncology has yet another one. The hospital has yet another one. The cancer registry has another one. And they don't talk to each other. We've got a commitment from the information systems folks to designate a person to work on the project, but those systems—how compatible they are and how much information can be exchanged, and how much it would cost in terms of human hours and hardware hours and software purchases—is unclear.* (Cancer center/program staff, Year 2)

> *It seems to me that it is a problem of the format of the data. They have to come up with all these solutions to get them to talk to each other. Paper is still a big part of medical records, and even paperless doesn't match up, and there is a lot of manual stuff as well as making sure that the info gets translated precisely. That is the big problem: getting the computers to talk to each other.* (Key physician, Year 2)

> *It gets to universal medical records…we have not gotten there yet to figure out how to use it. We haven't gotten that far…one of our challenges [is] looking at what systems can do with each other.* (Cancer center/program staff, Year 2)

> *We have IT, but any time you have multiple software packages, you tend to get a lot of "it's their problem" [crosses arms and points both ways].* (Key physician, Year 3)

> *The one pillar that's lacking is IT… There are initiatives to work on that, and it's not unique to this program. It's unique to all health care, this EHR thing. The federal government should have had compliance issues addressed before mandating EHR. The holdup on our end is how do we get these different EHRs to communicate?"* (Key physician, Year 3)

> *The concept is great. Let's talk about the IT piece. How do you create an IT piece when almost every practice is electronically based and not all interface together. Part of how to do it is to create an electronic record for this program and create a program that interfaces all electronic records. Right now I get a form that pops up that I sign in my office. I am not in my office. I am here in the cancer center. So it is electronic, but it is not integrated.* (Key physician, Year 3)

12.4.2 Limited Physician Engagement

Full IT integration requires the involvement of staff across departments and physician groups. However, several respondents reported that private practice physicians provided challenges for IT integration. In some cases, the private practice physicians were limited by time constraints to use EHRs; in other cases, private practice physicians simply had different EHRs that could not currently interface with the hospital EHR system:

> *A lot of these guys are dealing with private practice physicians, and even 5–10 minutes of slowing private practices down with IT, they are not going to like that.* (Subcommittee member, Year 2)

> *Where we'll get challenged is sharing info across private practice to hospital organizations. They don't have to, and we need to create a vision that's compelling and have an infrastructure in place to address their concerns.* (Subcommittee member, Year 2)

> *One example is that you have all the data to put in, but we don't have the data from disparate private practice offices.* (Subcommittee member, Year 2)

> *We are in the process of transitioning private practices to electronic records. It is more cumbersome than anyone would suppose. We have an age range for physicians from 60 to 80 who aren't adopters. There is not a great medical office system out there. To have it useful in the future, you have to have extractable data. It's not just scanning a chart. You can scan it, but it's not interactive and you can't run reports that help you look at trends or practice patterns. They are expensive tools and labor intensive.* (Key physician, Year 2)

> *One of the challenges is to bring all of [the private practice physicians] together as one. The medical oncologists use one system with separate databases and separate patient numbers.* (Subcommittee member, Year 2)

Although this problem is not unique to NCCCP sites and corresponds with overall funding limitations, it can be considered a substantial barrier to IT implementation.

12.4.3 Challenges due to Patient Confidentiality Requirements

Compounding the existing private practice physician challenges are patient confidentiality requirements, both from constraints imposed by Institutional Review Boards (IRBs) and from the Health Insurance Portability and Accountability Act (HIPAA), which limit patient data sharing between hospitals and private practice physicians:

> *Embracing caBIG and creating cross-talks between the EHRs is going to be challenging. One practice won't give us access to their EHR. One private practice said we could see anything we want because we're a health care partner so the HIPAA laws aren't being violated, but the other practice won't let us look at anything. They're worried about sharing stuff with big brother.* (Cancer center/program staff, Year 2)

> *There's the issue of being HIPAA compliant, the issue of being a private practice model, and our physicians having their own medical records and they don't always have access to ours.* (Subcommittee member, Year 2)

In one case, private practice physicians were initially willing to share their patient data, but then HIPAA requirements were violated, which caused the physicians to be more conservative in their willingness to share patient data:

> *In some ways, the EHR made things easier and in others it made it more complex with HIPAA—not so much with me, because my group is a single-specialty practice, but the other group is a multispecialty practice. At least initially, when you had access to their records, you all of a sudden had access to their general medicine patients, cardiology patients, endocrinology, etc., so the means by which someone could limit access had to be worked out. That's what caused some of the foot dragging for a period of time there.* (Subcommittee member, Year 2)

> *There were a lot of roadblocks on our own and concerns about confidentiality, and it took a long time to work out and it seems to have been worked out, but people have limited access that I hope could be broadened.* (Key physician, Year 2)

12.4.4 Priority of Linking to caBIG

Several respondents indicated that the focus on caBIG was a potential barrier to IT integration. Although having a conduit through which IT personnel can focus their activities

may be beneficial to some sites, respondents at other sites indicated that they have no plans to incorporate caBIG; thus, the emphasis on caBIG tools and interfaces actually detracted from their overall IT strategy:

> *IT has been a challenge. We want to be good citizens, but it's really not clear that caBIG meets our needs. We need software and hardware solutions, but I'm not sure those are the right ones. I think from the beginning there wasn't an expectation that we would adopt caBIG but [rather that we would] examine it. [Our IT subcommittee member] is really good because she's a nurse and has continually looked at their solutions, and there may be some areas that meet our needs but many that don't. Even some of the NCI-designated centers that work with us don't use caBIG.* (PI, Year 2)

Some sites are willing to incorporate caBIG but reported having existing IT systems that were not compatible with caBIG:

> *When we wrote our goals document for the pilot, we committed to deploying caTissue and we have a clinical trials management system here, but it's not caBIG compatible.* (Subcommittee member, Year 2)

12.4.5 Requirement of Extensive Hospital Resources

IT implementation requires a great deal of financial resources, including allocation of additional staffing. This is particularly the case in community hospital settings, given the barriers associated with the existing EHR data management systems, the need for system integration, and private practice physicians' time constraints. However, some respondents indicated that current dedicated IT resources were insufficient to meet the needs of the NCCCP:

> *The IT pieces are a pretty significant issue. It's a moving target for us. Projects are coming our way, and we don't have a good system for knowing what is in what system. Doing data collection manually is costly and overwhelming and could bury us. That is a really big barrier. Data management is a really big barrier.* (Cancer center/program staff, Year 2)

> *When it comes to IT, because of the capital limitations, there is a system-wide constraint. Around the IT piece, we have decided not to do caBIG. That decision was made by our IT folks. I am not sure what they are thinking. The NCCCP is not high priority because of all the other things that they are tasked to do. If anything has been hard, it is the IT component. There is no funding for technology, which is one of the bigger struggles for us.* (PI, Year 3)

Respondents also indicated difficulty with allocating personnel to conduct IT-related activities:

> *NCCCP is also increasing the [patient] volume, and doing so without the computer resources will put [our IT personnel] over the edge.* (Subcommittee member, Year 2)

> *It's not hard to say "have a fellow to fill it out or a resident," but we don't have those. We don't have nurse practitioners. Patients see the physician. Most of the deliverables are reasonable and make sense, but there are creep-arounds when they want data on 600 people when we don't have EHRs to pull from.* (PI, Year 2)

> *It is slow and it is one of these things that is an elephant and it is very huge and it is baby steps with regard to IT, and that is one [component] that is extremely labor intensive. It has been a lot more than we initially expected. The goals and everything are great, but making these things operational is much more labor intensive.* (Cancer center/program staff, Year 2)

> *Everyone has IT issues. The demand for IT services goes [up] exponential[ly].* (Subcommittee member, Year 2)

> *Another challenge is that we don't have a team of IT resources to apply to this. We have a very large IT operation, but they're very largely deployed and a lot of time [is] spent on EHR. We don't have a specific group focused on oncology.* (Subcommittee member, Year 2)

Specifically, respondents indicated a need for IT personnel with medical training who could understand both the practitioner perspective and oncology-specific language:

> *Everything we ask [IT staff] has never been done, and no one knows how to do it, can it be done, etc. Everything is enormous when the request is not that big. I don't know if they have any medical IT experience.* (Cancer center/program staff, Year 2)

Respondents noted that IT was a factor involved in integrating all of the NCCCP components. However, the sites did not have the IT staff to support all of the NCCCP components, attend the subcommittee meetings, and identify common needs across the cancer center:

> *It is a problem here to have IT staff to support all the pillars. I don't know if it's a problem at other sites, but I would assume so.* (Subcommittee member, Year 2)

> *It would be good to have an IT resource on all these committees, but if that person existed, we couldn't afford it. The problem is that it takes multiple IT [people], all of whom have different projects and resources. Being able to allocate time to do this is a challenge.* (Key physician, Year 2)

> *It's painful and very labor intensive. It takes a lot of mapping about where this data is coming from and how can it be transmitted. We're putting the resources into it,*

> *and it's costing a lot. We have the resources, but it's very labor intensive.* (Subcommittee member, Year 2)

> *[We] have a 50% FTE dedicated to NCCCP but could probably use one or two additional people. [We] bought node for caTissue and purchased a server for it, but [the 50% FTE staff member] has no time to work on [the] interface for that. We have a tracking tool in Velos (clinical trials software) but haven't gotten that linked to EHR yet; [the] interface has to be written.* (PI, Year 3)

12.5 Summary

The majority of sites indicated that IT was an integral aspect of their hospital's strategic plan. This finding is further supported by the amount of financial and personnel resources dedicated to building IT infrastructure within several of the sites. However, even sites that were fully funded and supported by their top management faced IT implementation barriers that were difficult to overcome, particularly during the first 2 years of the NCCCP. Sites reported similar types of barriers during Year 3 site visits, most notably challenges with linking multiple EHRs. Although full IT integration may not have been plausible by the end of the pilot, conducting inventories and developing a plan were useful activities toward expanding IT capabilities.

13. QUALITY OF CARE

Overview

The NCCCP was designed to improve the quality of care (QOC) by building the infrastructure for quality improvement and improving adherence to evidence-based guidelines. For the purposes of this evaluation, success in QOC implementation encompasses achievements in the following areas: establishing and expanding MDC conferences, improving coordination of care, improving adherence to evidence-based guidelines, and developing conditions of participation for medical staff.

Establishing and Expanding MDC conferences

Overall, the sites made marked progress in establishing or expanding MDC conferences; by Year 3, 7 out of the 16 sites increased the number of multidisciplinary care (MDC) conferences from what was in place at baseline. The value of MDC was recognized by all sites. Sites also reported increased physician participation, more cohesiveness within MDC teams, better integration of patient navigators, genetic counselors, and research staff. Physician leadership and patient navigator involvement seem to be key to the success of MDC conferences and clinics.

Improving Adherence to Evidence-based Guidelines

To assess adherence to evidence-based guidelines for cancer, we examined rates of non-concordance (proportion of patients who did not receive guideline-based treatment of those eligible for the treatment) with five RQRS quality measures for breast and colon cancer care. For all measures, almost all sites decreased non-concordance over the course of the pilot, indicating improvements in adherence to evidence-based guidelines for breast and colon cancer care.

Implementing Conditions of Participation

There have been mixed results in terms of the use of conditions of participation for physicians to meet in order to be considered formally affiliated with the cancer center. Most sites have begun the process of review and implementation, but only seven sites reported full implementation by Year 3 (including two that already had conditions in place at baseline). Adopting the conditions of participation requires buy-in at multiple levels, and there are sensitivities about the impact of these conditions on different physicians and how the conditions of participation relate to hospital credentialing requirements.

Barriers and Facilitators

In many institutions, implementation of the QOC component represents a cultural shift that requires some physicians to change their practice model and an institutional culture that supports innovation and change. Engaging some physicians, particularly those in private practice, is challenging due to time constraints and concerns about loss of revenue. "Champions," particularly leadership among physicians, can help facilitate these changes. Making participation in MDC conferences and other QOC initiatives as easy as possible for physicians and providing navigation support are also critical.

One goal of the NCCCP is to enhance infrastructure for sustained and ongoing quality improvement to support clinical and patient-centered performance and to tailor patient education and support programs in order to improve patient experience and quality of life. This goal to improve cancer patients' quality of care was one of the top reasons cited by the cancer centers for participating in the NCCCP pilot (see Chapter 6). Although there was no

dedicated funding for this component, quality of care (QOC) was an active area within the NCCCP.

The cancer centers have focused their quality of care activities on the following areas:

- increasing multidisciplinary care (MDC) disease-site-specific conferences and clinics;
- developing cancer center–specific medical staff "conditions of participation" for cancer center medical staff;
- increasing the use of evidence-based guidelines, standards, and protocols (e.g., National Comprehensive Cancer Network [NCCN], American College of Surgeons [ACOS]);
- participating in a disease-specific QOC study; and
- expanding genetic counseling and molecular testing.

In addition to these activities, the QOC component through leadership from NCI staff, worked to establish partnerships with two key national organizations: the Commission on Cancer (CoC) and the American Society of Clinical Oncologists (ASCO). CoC was a critical partner that led the implementation of the RQRS in multiple hospitals across the country, including all NCCCP hospitals. NCI also worked with ASCO to encourage sites to participate in their quality initiatives (e.g., Quality Oncology Practice Initiative [QOPI]). We explored the sites' implementation of QOC-related activities primarily during the Year 2 site visits, although some data were collected in other years as well.

13.1 NCCCP QOC Subcommittee Priorities and Strategies

The NCCCP established a QOC subcommittee to provide oversight and guidance for QOC activities across the pilot sites. This subcommittee identified priority needs for improving QOC as follows:

- quality improvement initiatives and increasing use of evidence-based guidelines,
- enhanced care coordination through MDC conferences and/or clinics and patient navigation services; and
- developing conditions of participation for medical staff.

The following sections provide an overview of the subcommittee strategies to address each of the priority areas.

13.1.1 Priority 1: Quality Improvement Initiatives and Increasing Use of Evidence-Based Guidelines

The QOC subcommittee focused on several quality improvement initiatives and on increasing using of evidence-based guidelines such as NCCN, ASCO, and ACOS guidelines. Evidence suggests that adherence to practice guidelines in the community oncology setting is uneven (Smith & Hilner, 2001). A recent survey conducted by the Association of Community Cancer Centers (ACCC, 2010) found that providers encounter a variety of

barriers to following guidelines, including that guidelines are too rigid, are difficult to locate, require significant change of practice, and providers do not have enough time to refer to them.

13.1.1.1 The Electronic Quality Improvement Program (e-QuIP) for Breast and Colorectal Cancer

The Commission on Cancer (CoC) developed a system of measurements and outcomes reporting on basic components of clinical care that are required for formal CoC approval of programs in the field. These web-based applications provide individual-level case summary reports for breast and colorectal cancers diagnosed in 2003 and 2004, as transmitted to the National Cancer Data Base (NCDB) by each CoC-approved program cancer registry. In addition, this and future e-QuIPs, are designed specifically to promote quality improvement activities that can assist facilities in the fulfillment of CoC approvals standards requirements. As of the 2008 Interim Assessment Survey (IAS), all 16 sites were using the e-QuIP quality indicators, representing a 46% increase from the Baseline Assessment Survey (BAS) data reported.

13.1.1.2 The CoC Rapid Quality Reporting System (RQRS)

To facilitate quality improvement and timely evidence-based care, the RQRS was developed through a partnership between many national cancer research partners and coordinated through the CoC. The system provides real-time surveillance and feedback to sites on the status of patients who meet criteria for one or more of six quality of care guidelines: three for breast cancer, two for colon cancer, and one for rectal cancer. Data are reported directly from the hospitals' cancer registries, a new approach that makes the information available in a few weeks—instead of years—enabling closer monitoring and intervention if needed. All 16 of the pilot sites are part of a national pilot test of the RQRS, enabling NCI to compare the performance of NCCCP sites with that of other community cancer centers. To assess adherence to evidence-based guidelines, we examined non-concordance with five RQRS measures (see Section 13.4.3).

13.1.1.3 The ASCO Quality Oncology Practice Initiative (QOPI)

The QOC subcommittee encouraged physician participation in QOPI, which involves monitoring physician adherence to evidence-based guidelines. Developed by ASCO, QOPI is an oncologist-led, practice-based quality improvement initiative. QOPI includes a set of quality measures, a specified chart selection strategy, a secure system for data entry, automated data analysis and reporting, and a network of resources for improvement. As participants in QOPI, NCCCP sites' local physician practices are sharing data that are compared to ASCO QOC guidelines and help identify areas for improvement. This voluntary initiative exceeds the pilot requirements and demonstrates the sites' efforts to work with private practice oncologists to improve QOC.

13.1.2 Priority 2: Enhanced Care Coordination through Multidisciplinary Care Conferences and/or Clinics and Patient Navigation Services

With a growing emphasis on multi-modal cancer therapies, there is increasing attention to the development of MDC teams to provide high-quality care. MDC teams allow for collaborative consultation continuously along the treatment pathway. According to a recent review of MDC cancer care, "The team concept is integral to the effective functioning of multidisciplinary cancer care, given the need to communicate and collaborate among the clinical and other affiliated disciplines" (Fennell et al., 2010, p. 74). Early in the pilot, the QOC subcommittee focused on developing a model of integrated MDC, which involved establishing or expanding MDC conferences and/or clinics and patient navigation programs. A workgroup was tasked with establishing a framework for each site to use to develop and/or assess their current capabilities to deliver comprehensive and integrated services utilizing an MDC model. The workgroup developed the following definition of MDC: "Multidisciplinary cancer care includes prospective and/or concurrent review of patient care, multidisciplinary physician specialists, review and development of a treatment plan based on evidence-based guidelines, communication among physicians, and a written treatment plan that is updated as necessary and reviewed with the MDC team" (NCCCP Quality of Care Subcommittee, 2010). This definition is consistent with the CoC accreditation standards, which emphasize prospective case presentation (CoC, 2011).

At baseline, all NCCCP sites had tumor boards that typically met at least once per month and reviewed patient cases largely on a retrospective basis. This model is typical of traditional tumor boards, which generally review cases following diagnosis and primary treatment (Fennell et al., 2010). NCI required that participating sites establish at least one new disease-site-specific MDC conference during the pilot.

In addition, a deliverable for the sites was to enhance their patient navigation services to improve care coordination for patients throughout the cancer continuum. The role of the patient navigator is to help guide the patients and families through the health care system, to act as the central contact for patients and families, to assist patients in scheduling tests and consultations, and to provide information, address questions and ensure that patients and families understand the diagnosis and the treatment plan. Patient navigation is a key component of the disparities program to ensure that underserved populations have access to timely care. The sites' implementation of patient navigation and evaluation findings are presented in Chapter 9.

13.1.3 Priority 3: Developing Conditions of Participation for Medical Staff

NCI worked with the NCCCP Executive subcommittee, which includes all NCCCP principal investigator (PIs), to develop "conditions of participation" for medical staff (see Appendix R). Most NCCCP sites rely heavily on private practice physicians to support their cancer programs, and NCI recognized the need to encourage their more active involvement

to improve the community cancer centers' abilities to offer state-of-the-art cancer care and to promote research. The goal was to increase physician commitment to the cancer center and improve collaborative efforts across disciplines. The conditions of participation aim to set the baseline for clinical experience and performance requirements for physicians to be considered as formally affiliated with the cancer center. The "conditions" support QOC, for example, through the requirement that physicians participate in MDC conferences, follow evidence-based guidelines, and work with patient navigators (see Section 13.2.4).

13.2 QOC Subcommittee Tools

The QOC subcommittee, through several workgroups, developed tools to support the sites' QOC activities: MDC assessment tool, genetic counseling assessment tool, and chemotherapy consent form. In addition, as discussed above, the NCCCP Executive Subcommittee developed the conditions of participation tool. In the following sections, we discuss each of these tools and the sites' experiences with implementing them.

13.2.1 MDC Assessment Tool

The MDC assessment tool allows sites to assess themselves in terms of patient care integration and to identify gaps and areas to focus improvement efforts. Sites assess themselves on a scale from 1 to 5 (with 5 representing the highest level of patient care integration) based on the following dimensions: case planning, physician engagement, treatment team integration, integration of care coordinators (e.g., nurse navigators), infrastructure, financial, screening for clinical trials, and adherence to quality guidelines. Sites generally thought that the tool was helpful for self-assessment and benchmarking the sites' MDC:

> *Where the MDC matrix has helped [is] surgeons usually think they do better than they actually do. We were looking back at our MDC [conferences] to get a feel for how they were working, but I think the MDC matrix has allowed [us] to do that in a little more detail. Although we were established with MDC and thought they were running well, this has helped.* (PI, Year 2)

> *We looked at the MDC [assessment tool] as far as our breast and lung and GI programs are on the matrix. It was helpful to see where we were compared to what all 5s might be. The matrix tool is good for us to know where we stand and where others out there in the NCCCP got to the next level. (*Subcommittee member, Year 2)

Several sites reported that the MDC assessment tool generated discussion among the key cancer physicians about what constitutes best practices in MDC, what is feasible for cancer centers, and how to address barriers to MDC. However, not all respondents were in complete agreement with the rankings:

> *It's generated a lot of discussion among us in terms of talking to physicians and talking with the resources that we have. In fact, we scored [the MDC assessment tool] independently and then came together to discuss how we each scored it.* (PI, Year 2)

> *I brought that to [the physicians] and we got a lot of heated discussion. How can you say that face to face is the standard? Shouldn't you look at the outcomes? What are the outcomes? Is the outcome that the patient had a comprehensive MDC [plan] that is signed and written? It was only me asking questions and challenging them in the cancer action teams, and there was a lot of discussion. (*PI, Year 2)

> *We've kind of self-assessed ourselves with the tool, and the tool isn't perfect. I think we all embrace MDC and our feeling in this environment, because we don't have the space, is that the virtual world works pretty nicely. If you look at the tool going from left to right, it implies that 5 is better than 4, but the argument I've made with the PI group…is that the effort to strive toward embracing prospective management, guideline utilization, access to trials, access to all the disciplines—all the communications, coordination, all the things that we talk about that foster excellence in cancer care, we believe—all those things can be embraced using variations on the model.* (PI, Year 2)

13.2.2 Genetic Counseling Assessment Tool

The genetic counseling assessment tool is intended to help the sites evaluate and improve their genetic counseling services. The tool allows sites to rank themselves on a scale from 1 to 5 (with 5 representing comprehensive service provision) according to 7 dimensions: patient identification, physician referrals, services provided, pre-test counseling, post-test counseling, documentation of cancer genetics consult in the patient's medical record, and financial services. Respondents generally gave positive feedback about the tool, indicating that it was useful for following in the development and adaptation of genetic counseling protocols.

Some sites indicated that the genetics counseling assessment tool reflected what they were already doing and they gave themselves a high ranking:

> *The genetics one, we're on the other side of the scale, level 4 or 5. We have two genetic counselors, [a] high-risk assessment program, and [a] well-defined program.* (Cancer center/program staff, Year 2)

> *One of the things we did on the quality of care subcommittee is the [genetics counseling assessment tool], and we actually follow it as part of the care [our genetics counselor] provides.* (Program coordinator, Year 2)

In other sites, use of the genetic counseling assessment tool highlighted areas for growth and improvement:

> *One of the things we're using the genetic counseling matrix tool for is assessing our referrals. We realized we weren't getting a lot of referrals from endocrinologists and dermatologists. So we sent out a pilot fax referral form to an endocrinologist's office just to see how it works with one office, and if it wasn't working well then we didn't need to go to 100 offices.* (Cancer center/program staff, Year 2)

> *We determined from these efforts that we needed more visits, so we increased our genetic counselor's availability to three times per month.* (PI, Year 2)

> *What we are trying now is to just follow the suggestions within that tool. The genetic counseling assessment tool assesses who referred the patient to you and that part has been helpful for us.* (PI, Year 2)

One PI thought the site provided access to genetic counseling services although their approach was not exactly the same as the ideal model presented in the tool:

> *We had more of a distributed model whereas some people embrace more of the classic genetics counselor model. So, again, it's this kind of model that's pieces of the various models—hybrids I guess you would call it—that reflect level 2, level 4 in row A, B, and C—that don't necessarily reflect moving all the way to maturity but is working in our system. So of our patients have access to the services, which I think is the important thing, and it's done by their own practitioners [and] in some cases by people to whom they're referred.* (PI, Year 2)

13.2.3 Chemotherapy Consent Form

The chemotherapy consent form provides a uniform template for patient chemotherapy consent that sites can modify according to their institutional needs and requirements. The QOC subcommittee identified this quality improvement initiative based on findings from the NCCCP QOPI aggregate results, indicating a performance gap in the measures related to chemotherapy consent signature and documentation. Several sites noted that they were not able to use the form because of legal constraints in their state on the required language on consent forms. Some adopted the form; others said the form was consistent with what they were already doing:

> *I'm presenting [the chemotherapy consent form] at our section meeting coming up because we want to use that in our chemotherapy outpatient setting for our indigent population because we don't have a chemo consent [form] there.* (Cancer center/program staff, Year 2)

> *We already had a chemotherapy consent form. The manager of our infusion center became very involved in those subcommittee meetings. She used to sit in on the*

> *calls and review them, and the final document is quite modeled after what we're doing. To date, we have not changed our tool.* (PI, Year 2)

13.2.4 Conditions of Participation

The conditions of participation define required and "strongly encouraged" conditions for medical staff to participate in the cancer center in the following areas:

- professional affiliations (e.g., membership in oncologic societies, leadership roles in local, state, and national community cancer activities),
- cancer expertise and continuing education (e.g., conference attendance, dedicated commitment to a specific disease area),
- research and clinical trials (e.g., participation in clinical trials, involvement in national oncology research activities),
- commitment to a philosophy of cancer care (e.g., embracing MDC, participating with patient navigators), and
- cancer program obligations (e.g., following evidence-based guidelines, participating in MDC conferences).

The conditions of participation can be put in place with existing "hospital privileges." Sites' progress in implementing conditions of participation is presented in Section 13.3.4.

13.3 QOC Implementation

In the Year 2 and 3 site visits, sites described their QOC activities and implementation progress. Sites reported the following activities:

- establishing or expanding MDC conferences and clinics,
- improving standards of care by using evidence-based guidelines,
- tracking QOC outcome measures,
- implementing the conditions of participation, and
- hiring and/or training staff to support QOC activities.

In the following sections, we discuss the sites' implementation of these QOC activities.

13.3.1 Establishing or Expanding MDC Conferences and Clinics

Sites determined which MDC teams and conferences to introduce or expand based on patient volume and the readiness of physicians to assume leadership. Sites have developed structures for MDC teams, including regular strategic planning meetings and charters:

> *We chose to start with lung because we felt it was our most critical one. We take care of almost 200 lung cancers a year.* (Cancer center/program staff, Year 2)

> *Our decisions are based on what the volume is.* (PI, Year 3)

> *We have a dedicated breast MDC conference once per week, and combined with this is a conference that deals with other organ systems that may be GI or thoracic. Because of the volume and interest in thoracic, we separated that out.* (Key physician, Year 2)

Many sites described the maturation of the MDC approach over the course of the pilot, with greater physician participation in MDC conferences, more cohesiveness within MDC teams, and better integration of patient navigators, genetic counselors, and research staff. In most sites, the level of development varied across different MDC teams, based in part on when they were established and on physician leadership.

> *They [MDC teams] are all like children that you watched grow up and mature. The breast cancer team is the most mature. The lung cancer team is a very mature tumor board staffed by all different specialists.* (Key physician, Year 3)

> *Getting all the [specialists] in the room together was new here…This is the first time all the physicians have all been together because usually they spend all of their time with their own specialty.* (Program coordinator, Year 3)

> *MDC conferences have evolved. When they started it was almost 100% retrospective and attendance was mediocre. Now they're outgrowing the auditorium for MDC breast conference which is almost 100% prospective now.* (Subcommittee member, Year 3)

> *'We've been able to get a critical mass of all the parties involved, so it hasn't been an issue where there is non-involvement. I think we've had a commitment to people making things work. What we've attempted to do is have physicians recognize that their patients really value this type of opportunity, so this helps their practice.* (PI, Year 2)

> *I can't see things going back to the way they were. Everyone sees the benefits of the MDC [conferences] and that it helps them manage their patients better.* (Subcommittee member, Year 3)

Several sites noted that some physicians who had initially been uninterested or resistant to the MDC model of care at the start of the pilot were coming around to the idea by Year 3:

> *This has been a year where it's getting better. Urologists were very averse to participating and they're starting to participate more. We've had two or three conferences, once every few months. They're bringing cases…they're participating, and that's a start, anyway.* (Key physician, Year 3)

> *The GU guys are more on board than they were a year ago. Our breast and GI, as far as surgeons go, is pretty strong. Others are coming along. It's just keeping on them to show up.* (Key physician, Year 3)

> *Medical oncologists, radiation oncologists, and surgeons are now on board with MDC conferences. More so than last year, particularly the surgeons are seeing the value of the conferences.* (PI, Year 3)

13.3.1.1 Experience with MDC Clinics

Two sites had MDC clinics, a form of integrated care wherein all of the patient care planning at the time of first diagnosis is conducted in 1 day while the patient is in the physicians' offices. Often, this requires all of the core cancer center physicians (e.g., medical oncologists, radiation oncologists, surgeons, specialty physicians) as well as other key staff (e.g., social workers, nutritionist) to see the patient on the same day:

> *Each Thursday morning we have patients scheduled who will see all of the different specialists. Then we have our conference in the afternoon to discuss the patients.* (Key physician, Year 3)

> *We have a separate multidisciplinary clinic where the patient is present. This accounts for 10%–15% of our actual multidisciplinary conferences. The patient goes into a clinical meeting space and doctors meet with the patient and the family, so by the end of the day the patient has a treatment plan. The hard part is to get a surgeon or subspecialist involved.* (PI, Year 3)

A third site had developed an MDC clinic specifically focused on the underserved. Respondents at this site described how they sought physician buy-in and provided support for the clinic:

> *One of the things about the multidisciplinary care low-income clinic is it's the first example of our MDC clinic. It's not in the office like the rest of our practice. It works pretty well, and we use it to address our disparities and QOC issues. We hope that sometime in the future we can expand it to how we practice care in general.* (Key physician, Year 3)

> *The wheels turn slowly at [site], and physicians didn't understand why they'd come down and see patients when they could see them in their offices. But this is something where doctors agree to give of themselves, while we give them the infrastructure: we schedule, we provide staff.* (Cancer center/program staff, Year 3)

"Virtual" MDC Teams

Some sites described their cancer centers as having "virtual" MDC teams (with some referring to them as "virtual *clinics*"). Virtual teams refer to situations where team members do not meet face-to-face (or do so infrequently) but coordinate in order to see the patient over a short period of time and develop a treatment plan (Fennell et al., 2010). Some sites thought that establishing what they viewed as a virtual clinic was a more feasible approach

than a "bricks and mortar" MDC clinic. The "virtual team" approach provides an opportunity to test the MDC clinic model and make incremental changes:

> *We do the virtual MDC clinic by having the patients link to surgical oncologists and medical oncologists via video and teleconference. The remote physicians want to try virtual MDC. Surgical oncologists aren't here, so we need to figure out how to do telemedicine. We have done a number of MDC [conferences] via [tele]conferencing. So it is like a clinic with the patient there.* (PI, Year 2)

> *The MDC specialty virtual clinic approach to colorectal cancer is a great segue into seeing how people can get along better when you dilute the people that are in competition by having the surgeons, pathologists, [and] tumor registry working together to do something for the patients. You have better behavior when you have that group together.* (Key physician, Year 2)

Two respondents indicated that patient navigators are integral to the virtual MDC team approach:

> *The patient navigator will arrange all the patient's multiple appointments in the virtual clinic. The patient gets their direct line and can call them at any time. They're in constant contact. That is such an integral role. It's a mixture between a case manager and a social worker.* (Program coordinator, Year 2)

> *It means that, ideally, the patient is there, and the doctors all come to that patient. The reason it's called a virtual clinic is because we really can't manage that type of coordination at this point with surgeons, radiation, pulmonary medicine, and medical oncology. We can't get everyone in the same place. We have a navigator through lung cancer who will take the patient and walk with them to every appointment. You'll basically accomplish the same thing, but there's someone helping them every step of the way. So they'll get all the tests and they'll be reviewed and they'll get an opinion on how to proceed. It takes usually 1 day to 1.5 days. (*Key physician, Year 2)

> *In the MDC for lung, the patient is funneled in a variety of ways. We hand the patient off to the navigator, arrange for testing on arrival at the clinic, prepare a standardized sheet of what needs to be done for that patient, try to coordinate all of those visits ahead of time so it's done in 2 days…When they leave, hopefully they have an answer and a plan, that may already have started.* (Key physician, Year 3)

13.3.2 Improving Standards of Care by Using Evidence-Based Guidelines

As indicated in Section 13.1.2, one of the NCCCP priorities is to increase use of evidence-based guidelines, standards, and protocols, such as NCCN, ASCO, and ACOS. Many sites commented that one of the main benefits of the NCCCP is that participation had improved

the cancer center's standard of care. One physician commented about NCCCP participation and the focus on evidence-based guidelines: "It keeps us on our toes to meet the scrutiny of our discipline. It also creates better outcomes for our patients." Several sites described how evidence-based guidelines guide treatment planning in the context of the MDC conferences:

> *At each of those meetings, we decided to discuss NCCN guidelines. We're looking at each tumor board meeting. Each chair will record certain things that we'll report to the American College of Accreditation. The research nurses and genetics counselors are at the meetings. They can tell us if we have protocols for things. Everybody has an input, and it's become much more effective in caring for a patient.* (Key physician, Year 3)

> *Now during every tumor board the guidelines have to be reviewed for each patient discussed. The patient is staged, staging is discussed, and each specialty is asked what their role is. The moderator will go around the room and say, "Role of radiation? Role of chemo? Role of therapy?" And, basically, there is a check that each has been considered.* (Key physician, Year 3)

> *90%–95% of cases presented at tumor boards are prospective. They can be before surgery or after staging is done (after surgery). Every discipline is represented there, including non-oncology disciplines like pulmonary and GI. The patient is treated according to NCCN guidelines.* (PI, Year 3)

13.3.3 Tracking QOC Outcome Measures

To understand current practices in comparison to standards of care, several sites reported tracking hospital, cancer center, and patient-level data. However, much of the discussion in the Year 2 site visits was fairly general and did not reference specific guidelines for cancer care:

> *In terms of the hospital dashboard overall, we look at falls rates, Centers for Medicaid & Medicaid Services core measures, patient satisfaction rates, cost per equivalent patient day, associate satisfaction, and quality to safety to financial to satisfaction.* (System/hospital senior executive, Year 2)

> *We are tracking the palliative care consults. Some are tracked by our financial person to determine if we are seeing patients longer than the diagnosis-related group. We could already identify that they needed more support. We track drug costs and all of that is done with claims data. My partner and I also track what happens to patients: How many days did they stay in the hospital? Where did they go after they left the hospital? How often did they get readmitted to the hospital for similar symptoms?* (Subcommittee member, Year 2)

> *We're pretty good at producing quality information and metrics. I'm less worried about that. Pulling the data is not that hard once it's defined. If it's captured electronically, it's easy. If not, it's harder, but there are solutions to making that happen. Teaching the process isn't the hard part. It's getting people to change their behavior that's hard.* (Subcommittee member, Year 2)

> *Then we have a quality dashboard in the hospital with 30 measures that used to get submitted quarterly, but now [get submitted] every 6 months. Items include budget, patient experience, safety, and team (BEST model). Then we have a project we do every year through the cancer committee. For the NCCCP, the patient care coordinators are putting in stuff, other people are putting in stuff, and we put in stuff.* (PI, Year 2)

In the Year 3 site visits, one site described their use of RQRS to track QOC outcomes measures:

> *We have RQRS. Our registry coordinator has worked with the Commission on Cancer and NCI to better understand data transmission. We have used the cancer committee to educate physicians about the variables that can impact the time for treatment. With RQRS, you can obtain needed metrics and data in a timely manner to share with colleagues and impact care. We are still in the process of integrating our work with the registrars.* (Program coordinator, Year 3)

13.3.4 Implementing Conditions of Participation

As previously discussed, the conditions of participation define conditions—either required or strongly encouraged—for physicians to meet in order to be considered formally affiliated with the cancer center. Sites discussed some of the considerations and concerns associated with implementing the conditions of participation, including the need for physician buy-in and flexibility to adapt the conditions to the specific needs of the site:

> *We have been careful because we have 50% employed and 50% private practice…we want [conditions of participation] to come from the cancer committee and want to adopt [them] and make [doing so] a grassroots decision so that it doesn't come from the cancer center director and we will have physicians buy into it. We want [the decision] to come from the medical staff as opposed to the medical director.* (PI, Year 2)

> *There is also the backdrop that the hospital is looking at credentialing or competency measurement. So private practice physicians are anxious about any practice that might limit their scope. We have older people that have privileges and say they are going to do what they want to do. It puts some strain on people being able to have control over the practice.* (Subcommittee member, Year 2)

Sites that had implemented the conditions of participation described how the conditions were part of the MDC team structure:

> *"Program" means breast program, liver program, "melanoma, colorectal, head and neck, and lung. Each has a nurse navigator and a tumor board or conference, and they each have conditions of participation.* (Key physician, Year 3)

> *Most of the people going to those conferences are people who meet conditions of participation. At each of those meetings, we decided to discuss NCCN guidelines. We're looking at each tumor board meeting. Each chair will record certain things that we'll report to the American College of Accreditation. The research nurses and genetics counselors are at the meetings. They can tell us if we have protocols for things. Everybody has an input and it's become much more effective in caring for a patient.* (Key physician, Year 3)

Some sites thought some of the conditions were unreasonable and they suggested flexibility in implementing conditions of participation:

> *The wording will be "strongly encouraged" vs. "never" or "required"; 100% attendance all the time is a hard benchmark. The fellowship, anywhere where it's feasible, you should have [as] a requirement. But some of the training fellowship requirements aren't feasible, specifically for general surgeons. It is strongly encouraged to have fellowships, but many of our surgeons can't sustain themselves on breast surgery alone. If this is going to be sustained, you have to have some reasonable requirements.* (Key physician, Year 2)

> *It goes back to credentialing and how detailed we get. If we have a surgical oncologist or a general surgeon that does two to three colon resections each year, would that fit the requirements? That will be one of the difficult issues we have to work through to get to that level we want to be.* (Subcommittee member, Year 2)

> *There are some challenges with that, and part of it is because there's such a small medical staff and they're having a hard time understanding the need for that. [To overcome that, I think we need to] try to make something that's easy, not perceived as threatening, and have their buy-in as we move forward with ideas. It'll be a challenge.* (Cancer center/program staff, Year 2)

The conditions of participation were modified in some sites, for example, to allow an "affiliate" level of participation with less stringent requirements:

> *We modified them [conditions of participation] a little bit, but it was not as big a deal here as in some places. It scared some of the physicians, but it was stuff we already do and the physicians did not react poorly to it at all.* (PI, Year 3)

> *There are two levels: full, in which there are specific requirements about the number of boards you attend each year and the number of cases you present. But, you can be an affiliate [condition of participation] in which case you only have to show up once each year.* (Key physician, Year 3)

Some sites questioned whether their existing privileging and credentialing systems were sufficient and whether the conditions of participation were needed in addition to these systems:

> *I'm just not sure we're going to use the conditions of participation. In this environment, other than a couple of items that are not in our privileging and credentialing, it just isn't applicable. We already require it as a medical staff and do it as a medical program.* (Cancer center/program staff, Year 2)

Several PIs discussed resistance to the conditions of participation among some physicians and how they tried to address these concerns:

> *I'd prefer to implement [the conditions of participation], but our surgeons aren't inclined. We think that certain people shouldn't be taking care of breast cancer. It turns out that 90% of breast surgeries are dealt with through three physicians. This is something that could direct people to the right surgeon.* (PI, Year 2)

> *We have had to get conditions of participation into play. The incentive for physicians was that they were assured their assigned cases and their referral patterns would not change.* (PI, Year 3)

In one site that reported full implementation of the conditions of participation, the view of one site was that adherence to the conditions was not monitored:

> *The conditions of participation were not ever implemented. No one is monitoring the multidisciplinary conferences. Some practices divide up the workload of attending the MDC [conferences].* (Key physician, Year 3)

13.3.5 Hiring Staff and/or Training Staff to Support QOC Activities

To achieve the QOC goals, a number of sites hired genetics counselors (or extended their hours) and patient navigators. Sites also undertook staff training in genetics counseling and standards of care:

> *We hired a genetic counselor last May, and that's really taken off. She specializes in it, and it's been great for the patients.* (Program coordinator, Year 2)

> *We've hired since last year an advance practice nurse who divides her time now between the inpatient unit and the cancer center and is now receiving her education in genetics counseling. She will spend 1 or 2 days a week in the cancer center, again, doing more routine genetics counseling and testing. When we have complex*

cases, we need a genetics counselor and a geneticist, and you have to have access to them. (PI, Year 2)

We are the inpatient unit, so I am going to see the patients at the bedside and follow pathways that are protocols or written for us for the standard of care. I will be doing the training for nurses with the designated nurse educator and make sure that all of the nurses understand the importance of the standards within these protocols. (Cancer center/program staff, Year 2)

13.4 Overall Success in QOC Implementation

For the purposes of the evaluation, success in QOC implementation encompasses achievements in the following areas:

- establishing and expanding MDC conferences,
- improving coordination of care,
- improving adherence to evidence-based guidelines, and
- implementing the conditions of participation.

In addition, we examined patients' overall experience with care and with their communication with providers. Although improving patient-provider communication was not a specific goal of the pilot, it is an important aspects of high-quality and patient-centered care (Epstein & Street, 2007).

13.4.1 Establishing and Expanding MDC Conferences

One of the major priorities of the NCCCP is to expand MDC disease-site-specific conferences and to increase participation among physicians and other key staff, including genetic counselors, patient navigators, and clinical research nurses and other research staff. Table 13-1 presents the number of MDC conferences[1] and the level of physician attendance for each site in Years 1 and 3. Overall, the sites made marked progress in establishing or expanding MDC conferences: four sites established MDC conferences for the first time, eight sites increased their number of MDC conferences, and one site had no change. Just two sites—both developmental —had not implemented any MDC conferences by Year 3. Both of these hospitals were located in small communities and had relatively low total cancer patient volume and a low number of physicians to engage in these conferences.

Sites reported average physician attendance (across all subspecialties) across all MDC conferences, from "none" to "all" (see Table 13-1). Nine sites reported that "most" (61%–

[1] The SAIC-F Outcomes Worksheets asks about MDC "meetings" defined as "prospective treatment planning i.e., discussions taking place on a case by case basis at the point of a definitive cancer diagnosis and before any treatment modalities have been initiated including surgery with multiple disciplines present. The patient may be invited to attend." It is possible that sites with MDC clinics responded in terms of clinics and/or conferences.

99%) physicians attended MDC conferences, and three sites reported that "some" (26%–60%) attended. In reviewing these findings, it is important to keep in mind that most sites increased the number of MDC conferences from Year 1 to Year 3; thus, even if the reported level of physician attendance remained the same in Year 3, the actual number of physician hours devoted to MDC conferences would have increased.

The sites also reported the types of physicians and other staff roles (e.g., clinical research nurse, social worker, genetic counselor) represented at most or all MDC conferences, for which their expertise was relevant (see **Table 13-2. Types of Roles Represented at MDC Conferences: Year 3[a]**

Site	Cancer Site Specialist	General Surgeon	Primary Care Physician	Pathologist	Radiologist	Clinical Trials Research Nurse	Social Worker	Patient Navigator	Genetics Counselor	Number of Roles Represented
Data Source:					**Outcomes Worksheet**					
Ascension										
St. Vincent (Indianapolis, IN)	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8
Brackenridge (Austin, TX)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Columbia St. Mary's (Milwaukee, WI)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Catholic Health Initiatives										
St. Joseph/Towson (Towson, MD)	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8
Penrose-St. Francis (Colorado Springs, CO)	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing
Good Samaritan (Kearney, NE)	No	Yes	No	Yes	Yes	Yes	No	No	Yes	5
St. Elizabeth RMC (Lincoln, NE)	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	7
St. Francis Medical Center (Grand Island, NE)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Non-system Sites										
Billings Clinic (Billings, MT)	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	6
Christiana (Newark, DE)	Yes	Yes	No	No	Yes	Yes	No	Missing	No	4
Hartford Hospital (Hartford, CT)	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	7
Our Lady of the Lake (Baton Rouge, LA)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	8
St. Joseph/Orange (Orange County, CA)	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	8
St. Joseph's/Candler (Savannah, GA)	Yes	Yes	Yes	Yes	Yes	yes	Yes	Yes	No	8
Sanford Clinic (Sioux Falls, SD)	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	7
Spartanburg RMC (Spartanburg, SC)	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8

[a] The SAIC-F Outcomes Worksheet asks about MDC "meetings." It is possible that sites which have MDC clinics responded in terms of clinics and/or conferences. Sites self-reported which of these 10 roles are represented at most or all of their MDC conferences (i.e., for which their expertise is relevant). Sites indicated as N/A did not have an MDC conference in place.

). In Year 3, of the 14 sites that had MDC conferences, general surgeons and clinical research nurses were generally represented at MDC conferences in all sites, and cancer site specialists, pathologists, and radiologists were generally represented in all but one site. Patient navigators usually attended MDC conferences in 11 sites, and genetics counselors usually attended in 10 sites.

13.4.2 Improving Coordination of Care

The patient survey included questions to assess patients' experiences related to coordination of care. Respondents were asked how frequently members of their cancer care team seemed to be well informed and up to date about their care and how often the team seemed to work together to help them get the care they needed. Table 13-3 presents the percentage of respondents who answered "always" to these questions for Years 1 and 3 (response options ranged from "never" to "always" on a 5-point scale).

Respondents rated coordination of care highly in both Years 1 and 3, and there were no significant changes for all sites combined over the pilot period. In both Years 1 and 3, about 80% of respondents said that members of their cancer care team are always well informed and up to date about their care, and about 82% said that their cancer care team always worked together. At the site level, we found just two significant improvements: respondents from Site 3 were more likely to report that members of their cancer care team were well informed and up to date about the care, and respondents from Site 10 were more likely to report that members of their team seemed to work together to help them get the care they needed. In interpreting the patient survey findings, it is important to note that the survey sample was designed to detect changes over time for the all sites combined, not at the site level.

13.4.3 Improving Adherence to Evidence-based Guidelines

To assess adherence to evidence-based guidelines for cancer, we examined rates of non-concordance with five RQRS quality measures for breast and colon cancer care. We used non-concordance rather than concordance in order to avoid potential ceiling effects (i.e., when a site has near 100% concordance to begin with, there would not be much room for improvement). We compared non-concordance at two time points relevant to the NCCCP pilot period. The first time point included patients diagnosed between January 1, 2006 and December 31, 2007; the second time point included patients diagnosed between January 1, 2008 and May 31, 2010. For this section of the report, we examined these findings specific to the NCCCP hospitals. The RQRS initiative was being implemented in hospitals across the country, both those participating in the NCCCP and those that were not. Although the

changes we report on adherence to guidelines are specific to NCCCP hospitals (de-identified for this section), in general all hospitals reported positive changes primarily because RQRS provided the sites with a system for real-time reporting of treatment indicators.

The five quality measures were as follows (the one measure specific to rectal cancer did not include enough cases to allow a comparison between sites):

- breast conservation surgery and radiation,
- hormone therapy for breast cancer,
- multiagent chemotherapy for breast cancer,
- 12 regional lymph nodes for colon resections, and
- adjuvant chemotherapy for stage III colon cancers.

For all five measures, almost all sites decreased non-concordance from time 1 to time 2 (see Table 13-4). All sites (for which there was complete data) improved in terms of the breast conservation surgery and radiation and hormone therapy measures for breast cancer care. For multiagent chemotherapy, all but two sites improved. Although Site 4 had an increase in non-concordance of 17.4%, at time 1, their non-concordance rate was 3.7, the lowest rate of all sites. For Site 6, the rate of non-concordance remained essentially the same (increase of 0.3%).

For one of the colon cancer measures (12 regional lymph nodes for colon resection), 13 sites decreased their non-concordance rates and three increased non-concordance. For the second colon cancer measure (adjuvant chemotherapy for stage III cancers), non-concordance rates decreased in 13 sites and increased in two sites, and data were missing for 1 site.

These findings suggest significant improvements overall in adherence to these five evidence-based guidelines. However, for the most accurate interpretation of these findings, it is important to consider change over time in adherence to RQRS guidelines in non-NCCCP sites, as reported in the separate *Comparative Health Outcomes Analysis for the NCCCP Evaluation Report*.

13.4.4 Implementing the Conditions of Participation

Sites' progress in implementing the conditions of participation is summarized in Table 13-5. By Year 3, 11 sites reported progress toward implementation of the conditions of participation, with 7 sites reporting full implementation, meaning that all members of the cancer center met the conditions. Note that two sites had fully implemented conditions as of the program's start, so only five progressed to this point over the course of the pilot. In the two sites that reported fully implemented conditions of participation at baseline, although the conditions were developed independently of the NCCCP, they covered all the required conditions in one site and all but one in the second site. Four additional sites reported

partial implementation, meaning that the conditions of participation have been approved and the site is in the process of implementing the conditions with the cancer center staff. Of the 11 sites that had conditions of participation partially or fully implemented by Year 3, 10 included all 5 required conditions, which are that the physician must (1) be an active member of the hospital medical staff, (2) be board-eligible with certification or recertification, (3) have membership in oncologic societies (if available for their specialty), (4) participate in clinical trials, and (5) complete the Human Protection Education for Research Teams training.

13.4.5 Overall Experience with Care and Patient-Provider Communication

The patient survey also examined patients' overall satisfaction with their care at the cancer center and their experiences with patient-centered communication, both of which are important components of how patients perceive the quality of care they received at the cancer center.

Patients were asked to rate the care they received at the cancer center on a scale of 1 (worst possible care) to 10 (best possible care). Patients rated their care very highly in both Years 1 and 3, with scores of 9.2 and 9.1, respectively for all sites combined (see Table 13-6). There were no significant differences at the site level in patients' overall ratings of care in Years 1 and 3.

The NCCCP did not have a specific goal of improving patient-provider communication, but communication is an important component of patient-centered care. The patient navigation program in particular could be expected to improve patients' experience with communication because the role of patient navigator is a central point of contact for patients and includes patient education (see Section 9.3.2). The patient survey included the following items to assess different aspects of patient provider communication over the past 12 months:

- Rate how well members of your cancer care team explained the plans for your treatment.
- How often did your cancer care team pay enough attention to your feelings and emotions?
- How often did your cancer care team talk in terms you could understand?
- How often did your cancer care team check to be sure that you understood everything?
- How often did your cancer care team encourage you to ask questions?

We created a communication scale score based on the number of items for which respondents provided an "always" or "excellent" response.[2] We found no change in patient-

[2] All items had high factor loadings (> 0.4) and IRT slopes (> 1), indicating they group together into one factor.

provider communication across all sites; the mean scale scores were 3.16 in Year 1 and 3.15 in Year 3 (see Table 13-6). There were also no significant differences from Years 1 to 3 in any of the individual sites.

The survey question instructed patients to think about communication "with your cancer care team overall." It is possible that respondents would have answered differently if asked specifically about communication with patient navigators. In the NCCCP patient focus groups, patients described patient navigators as important sources of information and emotional support (Treiman et al, 2011).

13.4.6 Overview of Success in QOC Implementation

To provide a more comprehensive understanding of the QOC activities at each site, it is important to look across all of the indicators. Table 13-7 summarizes the findings for different indicators of success for each site in Year 3. Each of the indicators has strengths and limitations, as discussed in the previous sections, and not all data are available for all sites.

Based on the indicators related to MDC conferences, we found that a number of sites made significant progress: 7 out of the 16 sites increased the number of MDC conferences and reported that across all MDC conferences "most" (61%–99%) physicians participated. In each of these sites, the key roles in the cancer care team (i.e., key physicians, patient navigators, research nurses) were usually represented at MDC conferences.

Implementation of the conditions of participation is an important indicator of physician commitment to the cancer center and collaborative efforts among disciplines. The conditions of participation address (1) establishing cancer medical staff practice pattern standards and promoting research, (2) advancing physicians' involvement in the community cancer centers, and (3) engaging physicians in multidisciplinary teams. By Year 3, 6 of the 16 sites reported full implementation of the conditions of participation with all 5 required conditions; one additional site reported full implementation with 4 of the 5 required conditions. Barriers to implementing the conditions of participation are discussed in Section 13-6.

For coordination of care, the indicators included reflect patients' perceptions of the extent to which different members of their cancer care team were up to date and informed about their care and whether the team seemed to work together. Across all sites, there was no significant improvement in coordination of care as measured in this way. This finding is disappointing given the development or expansion of patient navigation programs in most sites and the role of patient navigators in coordinating care (see Section 9.4.6). During our site visits, we noted that physicians and cancer center staff generally believe their site had made improvements in coordination of care over the course of the pilot program. In general, they reported that the MDC approach and establishment or expansion of patient

navigation programs improved coordination of care. However, we do not have a quantitative indicator of coordination of care from the physicians' perspective.

Overall, sites made marked progress in terms of adherence to RQRS quality guidelines for breast and colon cancer care. Rates of non-concordance with these quality guidelines decreased across most sites.

13.5 Facilitators to QOC Implementation

We explored facilitators to implementation of the various QOC activities primarily in the Year 2 site visits; however, sites also shared their experiences with factors that facilitated implementation in Year 3. Several sites said that participation in the NCCCP had been a catalyst for improving QOC. One PI said, "We've done it for patient care purposes, but to expand it, the impetus came from [the] NCCCP." The specific factors that facilitated improved QOC are

- recognition of the value of MDC conferences and other QOC initiatives,
- an MDC infrastructure prior to the NCCCP,
- provision of support for physician participation,
- presence of a physician "champion," and
- an active hospital cancer committee.

13.5.1 Recognition of the Value of MDC Conferences and Other QOC Initiatives

Many sites commented that over time they had become more convinced of the value of a multidisciplinary approach and the QOC initiatives. This growing recognition of the value of MDC conferences and other QOC initiatives facilitated further changes. One subcommittee member said that initially there had been resistance to some of the QOC initiatives, but that over time "people are coming along, not only out of obligation but with enthusiasm." Other sites also discussed the turnaround among some physicians who had initially been skeptical of MDC conferences and other QOC initiatives:

> *I think since the last year, there's been a lot of growth in certain physicians seeing the value of MDC—before we started our breast programs, [physician] told me that this is a waste of time, and in the last year that same physician stands up and says, "Why aren't we presenting 100% of our patients?" and "This is the best type of care," so there has been some recognition that MDC is of value.* (PI, Year 2)

> *The first couple of years, people were a little cynical or didn't understand what a more comprehensive type program would bring to the table for themselves and their patient. There are still some physicians who feel this way. In this last year, especially, I found that I don't hear those things anymore. People are excited to*

> *bring their cases to conferences. They hear about these trials more, even if we're not accruing. It's just a lot more momentum. They're proud that we're a center that's been designated as an NCCCP site. I think, more and more, as time goes on, they're seeing that it's better for the patients they have. I think they're actually learning something from the conference.* (Key physician, Year 3)

Physicians discussed the benefits of MDC conferences, increased focus on adherence to evidence-based guidelines, and other QOC initiatives as "keeping them on their toes" and "on top of their game" and resulting in improved patient care:

> *The cancer center members believe in the MDC model of care. It keeps us on our toes and able to meet the scrutiny of our discipline. It also creates better outcomes for patients. Most of us have a certain level of eagerness [about the approach].* (Key physician, Year 3)

> *You can see how much it improves patient care. [The MDC conferences] help me plan where the radiation is going to go. I got the physician to change his notes to describe where the organs are to help me with the stereotactic surgery. Once you come [to MDC conference], you realize that siloed care is less effective.* (Key physician, Year 3)

> *I think the people who are participating realize it's good for them and their practice to participate [in MDC conference]. We've managed to convince a critical number of people that it's beneficial for them to come and do things in a standardized and recognized way. …Because of the atmosphere and all the opinions there, they can come back to their patient with more options. I think they are learning to practice better.* (Key physician, Year 3)

> *The MDC [conference] helps you stay on top of your game and makes sure you are considering the NCCN guidelines and other people's opinions. We don't know what is going to be presented beforehand, so it is a didactic conference. [Our medical director] tries to identify the issues ahead of time and use the Socratic method to get people thinking. The surgeons will speak, then the radiation oncologists, and then the medical oncologists. We are able to identify controversial issues and make sure that everyone agrees on a prospective case.* (Key physician, Year 2)

> *Conferences work really well where you have really very positive MDC discussion with relationships among all the specialties. So that process is working very well.* (Key physician, Year 2)

> *In the first 6 months, we caught 15 things that changed therapy; that's quite a few. Something as simple as staging, or knowing exactly where the disease is. When people start seeing that, they start seeing the benefit for the patient too.* (Key physician, Year 3)

Sites noted that having the patient navigators involved with the MDC conferences improves coordination and timeliness of care, and the participation of genetic counselors, nutritionists, research nurses, and others on the cancer care team also improves patient care:

> *The patient navigators are now part of the process, so when we identify a new patient, that patient rapidly gets access to every specialist. It used to take weeks, and now it gets done in 2 days* (Key physician, Year 3)

> *For neck and breast MDC conferences, it has been beneficial to include genetics and dietetics. When we talk about MDC here, we talk about everyone involved with the patient.* (Subcommittee member, Year 3)

> *The research nurses and genetic counselors are at the meetings. They can tell us if there are protocols for things. Everybody has input, and it's become much more effective in caring for patients.* (Key physician, Year 3)

A few physicians commented that although MDC conferences require a time commitment, they are actually time savers because they provide an opportunity to consult with other specialists in one sitting:

> *We've always discussed and corroborated [our plans] with other disciplines, but now it is enhanced communication across specialties. I think [MDC conferences] are a time saver, so I know patients are on track with their care.* (Key physician, Year 3)

> *If you know you are going to see the same physicians at the conference each week, it facilitates a timely dialogue about your patients.* (Key physician, Year 3)

One physician contrasted the current MDC conferences with the conferences prior to the NCCCP:

> *I am surprised at how well it's functioning, especially in a private practice environment where people donate their time. And I've seen conferences in the past; they used to be lame. It used to be more of a documentation activity and now it's more interactive and interesting.* (Key physician, Year 3)

13.5.2 MDC Infrastructure Prior to the NCCCP

The differences across sites on some QOC indicators, such as MDC infrastructure, are striking. For example, at start-up, all sites had "tumor boards," as required for all CoC accredited hospitals, that met at least once a month as their MDC work, while other sites had full conferences and/or clinics to provide MDC. For those few sites in which MDC-related structures were already in place (e.g., disease-site-specific conferences, MDC clinics), implementing additional MDC conferences came with fewer challenges than for sites without

as much of a history. Sites' described the benefits of having existing QOC measures in place for reaching NCCCP pilot goals:

> *We don't experience the same kind of barriers as other freestanding hospitals in creating a cancer center. Cancer has been the first significant service line that uses the multidisciplinary approach and works horizontally within the organization, with surgeons and primary care and dermatologists…. These physicians already value their collective setting and the value it brings to patient care. We're doing a marketing campaign, and the focus is multiple specialists working together for the correct diagnosis for you, and cancer is one service line for that.* (System/hospital senior executive, Year 2)

> *It isn't like this is a new invention—physicians have always worked together in this community. There's always been a multidisciplinary care approach—having things at the [cancer center] makes things a little easier…we are in one place working together.* (Key physician, Year 2)

> *A lot of what you see here originated from what we called "hit teams" and "intervention teams" that were the forerunner to MDC bringing together different physicians of different disciplines around best treatments/protocols to treat cancers that arose from specific organ systems.* (System/hospital senior executive, Year 2)

13.5.3 Provision of Support for Physician Participation

Participation in MDC conferences and other QOC initiatives requires an investment of time by the participating physicians, so it is important to underscore the benefits in terms of the physicians' professional needs and the needs of their patients. Sites indicated that it is important to make participation as easy as possible for physicians and to provide benefits in the form of patient navigation and research support:

> *The single most important strategy is making specialists aware of the MDC conferences...and they [need to] realize they will have access to the patient coordinator. The coordinator figures out the stage of cancer, whether the patient should see a medical oncologist, and if they should be discussed at the conference.* (PI, Year 3)

> *You have to figure out ways for [physicians] to be compensated through nurse navigation.…The surprise is to see how many physicians want to be involved.* (PI, Year 3)

> *[The value added for physicians] has been a combination of additional admin support for the MDC conferences and being able to turn to somebody and say, "This needs to be implemented" and the navigation services.* (Key physician, Year 3)

> *There are new physicians coming to the multidisciplinary conferences. As the cancer center becomes more popular, other people want to come and see. Then they see what happens and they ask, "'How do I present a patient?'" We do everything for them, we get the lab results, we show all of the x-rays, the pathology. We make it easy for them.* (PI, Year 3)

> *The institution makes attending MDC [conferences] nice and easy. There's a nice meal at tumor board. It's fairly painless. In the past we had to pull our own films. Now there's infrastructure support, things are prepared. Everything's ready.* (Key physician, Year 3)

Sites described the critical role patient navigators play in coordinating MDC and supporting physicians. One PI commented that "navigators are really our best shot at being successful":

> *Having the support of the institution has helped with the MDC conferences. A lot of it is cultural, the idea that "We're all going to get together, and it's going to be fun and interesting." And funding from the institution for nurse navigators to coordinate MDCs is essential. It doesn't work without them.* (Key physician, Year 3)

> *Navigators have been essential to supporting MDC [conferences], so physicians don't have to do a lot of work. They help in doing prep work and making sure people are there.* (Key physician, Year 3)

13.5.4 Presence of a Physician Champion for Quality of Care

Leadership at different levels of an organization increases the likelihood of learning, innovation, and change. For the QOC program area, physician leadership in particular seems to be key. Physician "champions" have motivated and led the establishment or strengthening of MDC teams and other QOC initiatives. Sites described physician champions who are committed to MDC and QOC, have "a vision," and successfully engage their colleagues. As one site described, "we needed the leadership to bring everything together":

> *You have to have a physician champion—[Physician name] is our champion. We also have one neurosurgeon who is extremely committed and believes this [the NCCCP and MDC] is a great thing for patients to have.* (Cancer center/program staff, Year 2)

> *[Physician name] is in charge of standardized breast cancer care across all three campuses and he's the champion on all that…. Under his direction, every woman that gets diagnosed gets reviewed in real time. [I] think that's all thanks to [physician name] who has taken us to the next level.* (Subcommittee member, Year 2)

> *[Physician name] had this vision and head/neck [cancer care] lends itself nicely to multidisciplinary care, and we had all of the players in place but we needed*

> *leadership to bring everything together. [Physician name] has done that.* (Key physician, Year 2)

> *[Physician name] draws other physicians out. He personally invites other physicians to come to the MDC [conferences]. He started the lung MDC [conferences], and then other physicians started hearing about it and wanted to come. [Physician name] is engaging and encourages the physicians and makes them speak up during conferences.* (System/hospital senior executive, Year 3)

> *We developed our breast MDC conference and our GU and GI conferences. We work with a champion physician and understand what he wants to do and how that configures with the rest of the physicians and obtain engagement.* (Program coordinator, Year 3)

> *Medical oncologists, radiation oncologists, and surgeons are now on board with MDC conferences more over the last year, particularly the surgeons in seeing the value of the conferences. [Physician] has been the MDC leader in this change.* (PI, Year 3)

13.5.5 An Active Hospital Cancer Committee

As part of its accreditation process, CoC requires that hospitals establish local cancer committees to ensure excellence in cancer care through continuous coordinated cancer care. The committee may consist of senior executives, physicians, pharmacists, cancer center program staff, and other staff involved in the coordinated care of cancer patients. The cancer committee leads the cancer program through setting goals, monitoring activity, evaluating patient outcomes, and improving care. Several sites cited their involvement on their respective cancer committees as an important factor in advancing the QOC for their patients:

> *The cancer committee has grown stronger. The direction we are getting from [physician leaders] has been exceptional.* (Key physician, Year 2)

> *The cancer committee is the best attended committee for physicians. It's all voluntary. Through the committee, I can approach physicians in partnership.* (Key physician, Year 2)

> *We need to continue to work that through the cancer committee. [For] the sorts of things that we do in the cancer committee, looking at the ACOS data and working to bring that around, I think one of us should try to be involved in that as well.* (Key physician, Year 2)

The sites are committed to paying very close attention to ACOS standards through their participation on the cancer committees. As one cancer center program staff member acknowledged, "our [cancer committee] agendas are specific to those [ACOS] guidelines."

One physician mentioned that ACOS evaluation of the MDC conferences and other aspects of QOC facilitated implementation because physicians want a positive evaluation.

> *The American College of Surgeons came through to evaluate our program and the MDC [p conferences]; they really pushed [MDC conferences] too. They evaluated the MDC [conferences] based on an "engine" where you get green, yellow or red lights"…If physicians know they are getting evaluated, they don't like getting a bad score. The college is coming out with things that definitely have to be done with cancer care, like quality check points…all of that is being entered by our registrar and you get printout and nobody likes to get bad printouts.* (Key physician, Year 3)

13.6 Barriers to QOC Implementation

Sites reported a variety of barriers to implementing MDC conferences and/or clinics and other QOC initiatives. Barriers encountered across multiple sites included

- lack of physician participation and engagement,
- the institutional and practice culture,
- inadequate electronic health record (EHR) systems.

13.6.1 Lack of Physician Participation and Engagement

One of the main challenges mentioned was the lack of physician participation and engagement due to time constraints, inconvenience, and concerns about loss of revenue. Getting physicians to "buy in" to an MDC model that is new to many has been difficult in some cases, although there has been progress over time (as discussed in Section 13.3.1).

13.6.1.1 Time Constraints, Inconvenience, and Concerns about Loss of Revenue

For private practice physicians in particular, attending MDC conferences and participating in other NCCCP activities means taking time away from patient care and revenue generation. The convenience of the location also makes a difference:

> *The challenge in private practice engagement is getting people to commit the time.* (PI, Year 3)

> *MDC conferences are a great opportunity to bring docs together to discuss cases prospectively, discuss new data, and stay current. A challenge, though, is to do it within a community context. Private practice docs don't have the time. There's always a concern that someone may lose a patient to another doc.* (Key physician, Year 2)

> *The challenge at the private practice level is: how do you financially make it work? MDC conferences take away from the physicians' patient volume.* (PI, Year 2)

> *I think it's hard to find time outside of your daily work and keeping your office going. Oncologists are hit the worst because they do oncology for all organ systems. So they have to go to breast, liver, head and neck MDC conferences, and then CME, and then journal clubs. Those are all great things, but when you're doing them you're not seeing a patient in your office or doing surgery, you're not doing stuff to generate revenue and keep your office going. If we could have a system that reimburses for everything that needs to be done for patient care—not just the surgery but everything that goes into the thought process—that would be great*. (Key physician, Year 3)

> *I think you need to have at least two docs from the same specialty to have a good MDC. This is challenging because there's no reimbursement for docs, and MDC takes away from private practice docs' time they could be seeing patients.* (Key physician, Year 2)

> *We are private practice physicians…It is hard for me to take time out of my practice to go to conferences and take part in this program…right now we do it pro bono.* (Key physician, Year 3)

> *Now that we've moved [to new cancer center], general surgeons don't come by as much because it's out of their way. So, we've taken a hit [in their MDC conference attendance] in the past 4 months.* (PI, Year 3)

> *One of the challenges is how do you find space for the conferences and have a critical mass of people who have the time because there's a certain number of meeting times and a certain number of meeting rooms, and how do you find a time that the [gastroenterologist], surgeons, [radiation oncology], pathology [medical oncologist] and radiologist can all attend?* (PI, Year 2)

A radiologist said that the demands on their practice were overwhelming because they should attend all MDC conferences:

> *For us as radiologists, [MDC conferences] are daily; it's almost more than at an academic center. We're a general radiology practice, so we have to be present at every tumor board.* (Key physician, Year 3)

13.6.1.2 Challenges in Engaging Some Specialists and Primary Care Providers

Even for sites with well-established MDC conferences, there has been an ongoing challenge to getting certain medical specialists to participate, including surgeons and urologists. Primary care providers do not regularly attend MDC conferences:

> *We already have multidisciplinary care here. We could expand it if we could recruit missing specialists for example pulmonology, oncologic surgery, and thoracic surgery.* (Key physician, Year 2)

> *The hospital tried to do a prostate MDC in a similar fashion several years ago and it stagnated. The urologists have certain ideas about how they do things.* (Key physician, Year 2)

> *The GI MDC has had a hard time getting off the ground. To get the surgeons to the table, that has been challenging.* (Program coordinator, Year 3)

> *We invite them all the time. Primary care attendance at any tumor board is generally limited, unfortunately. We've tried a number of different tactics to encourage their attendance.* (Key physician, Year 2)

> *Our [primary care physicians] don't participate physically in the MDC conferences; it's mainly the major specialists with other support staff.* (PI, Year 2)

13.6.2 Institutional and Practice Culture

In some sites, sites said that their institutions "did not adopt new ways of doing things quickly." Other sites discussed the challenge of getting physicians who are accustomed to practicing in a certain way to adopt new approaches such as MDC:

> *Our doctors are still very much, "this is the way I was trained [and] the way I am going to do it." The only way they move along is if we push them. We are behind the times in changes in health care. So getting people to buy into [an MDC approach] has been difficult.* (PI, Year 3)

> *We've run into some naysayers among the pulmonary doctors. They want to do it the old way, the way they have always been doing it.* (PI, Year 3)

> *There has been some pushback from surgeons and radiation oncologists.… They don't want to be told what to do, and there are time barriers.* (Key physician, Year 3)

> *I think that the stumbling block with quality is getting people interested in doing things differently.…I think that bringing the younger guys is good and that change is difficult for people. And we have to introduce and reintroduce [new ideas] and get the buy-in. [System/hospital senior executive] has been instrumental in doing this. This is challenging because of the private practice environment.* (Subcommittee member, Year 2)

Some sites described the slow process of change in their institutions, requiring buy-in at multiple levels. In one site, the physicians were interested in making changes to improve the QOC, but the institution was "slow moving" due to politics.

> *[Site name] is a very slow-moving organization, and the surgeons are frustrated by it. Here at [site name] politics just take forever.* (PI, Year 3)

> *We are looking to more formally establish an MDC breast clinic (as we have for thoracic). The patient flow is that if they are told by the surgeon that they have cancer, they will come to see us on a different day. We want to streamline this more closely, but we can't do this quickly; we need to get buy-in from everyone involved and get them involved in planning. We can't do this quickly.* (Cancer center/program staff, Year 2)

13.6.3 Inadequate EHR Systems

Another impediment to the progress of QOC implementation has been the lack of adequate EHR systems. The lack of integration of hospital and private physician patient records has been a struggle across many sites in coordinating patient care:

> *I think that is one of the major obstacles to getting timely care. Getting x-rays, getting a report, figuring out what are the oncologists doing, when should we start chemotherapy, when should we start the surgery? So if we could get all of those records in one place that is accessible to everybody, that would be huge. Right now, we only share this information by presenting cases in conferences. The EHR will have to include the private offices, so they can have access to the data.* (Subcommittee member, Year 2)

> *A lot of problems in medicine could be solved with a single EHR, but that doesn't happen in the real world. Hospitals have one set of contracts, and docs have another set of contracts. So we may not be able to integrate that patient into a coordinated system if for reasons of contracts/insurance, they have to be referred out elsewhere. It is hard sometimes to accrue those patients on trials. [We] may have these stipulations that get in the way of providing MDC.* (Subcommittee member, Year 2)

> *We are not participating in QOPI because of the EHR; the time and effort just don't seem justified. The goal is once we're up on the EHR that the discussion will begin again about whether we will participate [in QOPI].* (PI, Year 3)

Some sites experienced staffing and resource barriers when attempting to obtain data for quality outcome measures:

> *At this point we are at a level of integration with our [EHR system] that not everything is available to us in that codable, extractable way. It may be available in written form. That's always a barrier for us: where and how are we going to resource that?* (Subcommittee member, Year 2)

13.7 Summary

Many sites made marked progress in establishing or expanding multidisciplinary care—conferences and, in a few cases, clinics—and implementing other QOC initiatives. Individuals in all different roles—system/hospital senior executives, PIs, program

coordinators, subcommittee members, and physicians—expressed strong support for an MDC approach to care as beneficial not only to the patient but also to physicians (both private and hospital-based) and their institutions. Many of the sites made significant progress in terms of establishing or expanding an MDC approach, and sites said that physician buy-in and participation has improved. Over the course of the pilot, more physicians have come to recognize the value of the MDC model of care. However, there were still significant barriers to engaging physicians, and it is critical that sites provide adequate support and benefits, including the support of patient navigators. It was clear from micro-cost study findings that many sites were investing in these types of supports in order to enhance their quality of care activities. Sites invested nearly 19% of their total matching funds in quality of care activities across all 3 years of the pilot, for a total of $6.9 million. There have been mixed results in terms of the use of conditions of participation for physicians to meet in order to be considered formally affiliated with the cancer center. Most sites have begun the process of review and implementation, but only seven sites reported full implementation by Year 3. Adopting the conditions of participation requires buy-in at multiple levels, and there are sensitivities about the impact of these conditions on different physicians and how the conditions of participation relate to hospital credentialing systems. Committing to conditions of participation requires an investment of time by the physicians, so it was important for the cancer centers to highlight to physicians the benefits of participation in terms of meeting their own professional needs and improving patient care. Given these considerations, the process of review and adoption of the conditions of participation takes time.

Although the growth of patient navigation programs and improved communication and coordination among physicians and others through the MDC conferences would be expected to enhance coordination of care, patients did not report improvement in this area. This finding may reflect the fact that only a portion of patients benefit from patient navigation assistance (see Chapter 9).

The majority of sites improved adherence to evidence-based cancer care guidelines as indicated by significantly reduced rates of non-concordance for five RQRS quality measures for breast and colon cancer care. In addition to greater adherence to evidence-based cancer care guidelines, these finding also reflect sites' commitment to ongoing quality of care assessment through their continued participation in systematic data collection and reporting.

In many institutions, implementation of the QOC component of the NCCCP represents a cultural shift which requires some physicians to change their practice model and an institutional culture that supports innovation and change. Champions, particularly leadership among physicians, can help facilitate these changes.

Table 13-1. Number of Types of MDC Conferences and Level of Physician Attendance

Site	Year 1		Year 3		Change	
	Number of MDC Conference Types[a]	Level of Physician Attendance to MDC Conferences[b]	Number of MDC Conference Types[a]	Level of Physician Attendance to MDC Conferences[b]	Number of MDC Conference Types[a]	Increased Level of Physician Attendance to MDC Conferences[b] (Y/N)
Data Source:			**Outcomes W/S**			
Site 4	0	N/A	6	3	6	Yes
Site 6	16	3	19	3	3	No
Site 10	6	3	9	3	3	No
Site 3	0	N/A	3	1	3	Yes
Site 12	6	2	9	2	3	No
Site 1	5	4	5	3	0	No
Site 9	2	3	4	3	2	No
Site 16	3	3	7	3	4	No
Site 15	2	3	8	3	6	No
Site 11	0	N/A	0	N/A	0	N/A
Site 8	0	N/A	1	3	1	Yes
Site 7	2	2	6	2	4	No
Site 2[c]	2	Missing	5	Missing	3	Missing
Site 13	0	N/A	1	2	1	Yes
Site 5	4	3	4	3	0	No
Site 14	0	N/A	0	N/A	0	N/A

[a] Sites self-reported the proportion of physicians attending based on the following categories: 0 = None, 1 = Few (1%–25%), 2 = Some (26%–60%), 3 = Most (61%–99%), or 4 = All. Sites with "N/A" did not have any MDC conferences operating within that time period.

[b] Types of MDC conferences included breast, thoracic, GI, head and neck, gynecologic, GU, neurologic, general, and "other" types (e.g., lymphoma, hematologic).

[c] Site 2 did not complete this section of the Outcomes Worksheet.

Table 13-2. Types of Roles Represented at MDC Conferences: Year 3[a]

Site	Cancer Site Specialist	General Surgeon	Primary Care Physician	Pathologist	Radiologist	Clinical Trials Research Nurse	Social Worker	Patient Navigator	Genetics Counselor	Number of Roles Represented
Data Source:					**Outcomes Worksheet**					
Ascension										
St. Vincent (Indianapolis, IN)	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8
Brackenridge (Austin, TX)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Columbia St. Mary's (Milwaukee, WI)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Catholic Health Initiatives										
St. Joseph/Towson (Towson, MD)	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8
Penrose-St. Francis (Colorado Springs, CO)	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing
Good Samaritan (Kearney, NE)	No	Yes	No	Yes	Yes	Yes	No	No	Yes	5
St. Elizabeth RMC (Lincoln, NE)	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	7
St. Francis Medical Center (Grand Island, NE)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Non-system Sites										
Billings Clinic (Billings, MT)	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	6
Christiana (Newark, DE)	Yes	Yes	No	No	Yes	Yes	No	Missing	No	4
Hartford Hospital (Hartford, CT)	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	7
Our Lady of the Lake (Baton Rouge, LA)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	8
St. Joseph/Orange (Orange County, CA)	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	8
St. Joseph's/Candler (Savannah, GA)	Yes	Yes	Yes	Yes	Yes	yes	Yes	Yes	No	8
Sanford Clinic (Sioux Falls, SD)	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	7
Spartanburg RMC (Spartanburg, SC)	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8

[a] The SAIC-F Outcomes Worksheet asks about MDC "meetings." It is possible that sites which have MDC clinics responded in terms of clinics and/or conferences. Sites self-reported which of these 10 roles are represented at most or all of their MDC conferences (i.e., for which their expertise is relevant). Sites indicated as N/A did not have an MDC conference in place.

Table 13-3. Coordination of Care: Members of Cancer Care Team Well-Informed and Up to Date about Patient's Care and Team Works Together: Years 1 and 3

	Members of Cancer Care Team Well-Informed and Up to Date about Patient's Care			Cancer Care Team Works Together ("Always")		
	Year 1 (N=2,009	Year 3 (N=1,946)	p-value	Year 1 (N=2,009)	Year 3 (N=1,946)	p-value
Data Source: Patient Survey[a]						
All Sites	77.9%	80.0%	0.139	81.9%	81.6%	0.824
Site 4	80.1%	77.2%	0.478	81.0%	79.9%	0.791
Site 6	77.0%	84.0%	0.087	82.8%	78.8%	0.342
Site 10	74.9%	81.4%	0.133	77.7%	87.9%	**0.012**
Site 3	79.7%	88.0%	**0.049**	83.8%	88.5%	0.241
Site 12	76.4%	69.0%	0.161	88.1%	81.2%	**0.042**
Site 1	83.9%	83.9%	1.000	85.9%	84.8%	0.801
Site 9	71.2%	76.0%	0.240	75.3%	78.3%	0.455
Site 16	83.3%	86.4%	0.401	86.3%	86.7%	0.921
Site 15	70.2%	73.8%	0.451	78.5%	78.9%	0.922
Site 7	83.7%	81.7%	0.585	79.6%	73.1%	0.204

Bold indicates a statistically significant difference between Years 1 and 3.

[a] The patient survey was conducted in the 10 lead sites only. Data are unweighted.

Table 13-4. Rates of Nonconcordance with Five RQRS Quality Measures[a]

	Breast Conservation Surgery and Radiation			Hormone Therapy for Breast Cancer			Multiagent Chemotherapy for Breast Cancer			12 Regional Lymph Nodes for Colon Resection			Adjuvant Chemotherapy for Stage III Colon Cancers		
Site[b]	**Time 1**	**Time 2**	**Percent Change[c]**	**Time 1**	**Time 2**	**Percent Change[b]**	**Time 1**	**Time 2**	**Percent Change[d]**	**Time 1**	**Time 2**	**Percent Change[b]**	**Time 1**	**Time 2**	**Percent Change[b]**
Data Source:	**RQRS data (Time 1= Patients diagnosed from January 1, 2006- December 31, 2007; Time 2= Patients diagnosed from January 1, 2008 through May 31, 2010)**														
Site 1	17.0	15.9	-6.4	51.7	21.9	-57.7	17.6	16.2	-8.1	24.5	25.6	4.6	28.6	15.0	-47.5
Site 2	30.8	16.7	-45.8	72.8	29.4	-59.6	34.8	5.6	-84.0	25.0	27.8	11.1	69.6	25.0	-64.1
Site 3	70.0	6.3	-91.1	0.0	75.0	n/a[c]	40.0	18.2	-54.5	28.0	6.6	-76.3	59.0	10.0	-83.0
Site 4	26.7	7.1	-73.5	26.4	14.3	-45.8	3.7	4.3	17.4	27.5	12.9	-53.0	0.0	12.5	n/a[c]
Site 5	17.6	3.9	-77.6	45.4	10.6	-76.6	14.8	6.5	-56.5	17.8	11.6	-34.7	21.4	9.4	-56.3
Site 6	21.2	14.5	-31.8	60.1	36.0	-40.1	20.8	20.9	0.3[c]	13.6	7.7	-43.7	33.3	16.7	-50.0
Site 7	41.1	3.6	-91.4	56.8	5.8	-89.8	40.7	16.7	-59.1	34.3	21.6	-36.9	28.6	15.6	-45.3
Site 8	5.2	4.2	-19.3	34.5	5.4	-84.5	11.4	3.3	-70.8	25.9	18.2	-29.9	10.3	0.0	-100.0
Site 9	30.2	1.1	-96.4	32.8	8.2	-75.0	13.3	6.5	-51.6	31.7	13.0	-59.0	5.6	0.0	-100.0
Site 10	22.6	5.6	-75.5	49.2	9.2	-81.2	45.2	10.7	-76.3	22.7	6.9	-69.7	43.5	8.6	-80.3
Site 11	73.6	30.8	-58.2	83.4	36.6	-56.1	45.2	26.1	-42.3	29.4	34.6	17.9	43.8	14.3	-67.3
Site 12	26.5	16.7	-36.8	92.8	39.0	-58.0	60.0	14.3	-76.2	7.1	2.2	-69.8	70.8	20.0	-71.8
Site 13	8.6	0.0	-100.0	35.2	6.8	-80.5	18.2	4.8	-73.8	55.1	37.9	-31.2	20.0	10.0	-50.0
Site 14	29.7	11.9	-60.0	47.6	18.4	-61.3	28.6	7.1	-75.0	17.5	7.8	-55.5	20.0	0.0	-100.0
Site 15	20.9	6.9	-67.0	18.8	3.1	-83.3	33.3	14.9	-55.3	21.3	10.4	-50.9	2.6	24.4	826.8
Site 16	28.5	5.6	-80.3	48.4	11.0	-77.3	19.1	4.3	-77.8	29.2	6.9	-76.4	5.9	11.8	100.0

[a] Percent Change is the relative change in non-concordance rate between time 1 and time 2, computed as (non-concordance rate in time 2 − non-concordance rate in time 1)/non-concordance rate in time 1). All relative changes in the rates of non-concordance between time 1 and time 2 were significant unless otherwise noted.

[b] Sites have been de-identified in this table and the corresponding section of the report.

[c] Unable to compute with time 1 non-concordance rate of 0%.

[d] Not a significant change.

Table 13-5. Conditions of Participation Implementation: Years 1 and 3

	Implementation Status		Required Conditions[a]						
Site	Year 1	Year 3	Site Made Progress Toward Implementation from Year 1 to Year 3	Active Member of Hospital Medical Staff	Board Eligible, Certification and Re-Certification	Membership in Oncologic Societies, if Available for Specialty	Participation in Clinical Trials Accrual Coordination, Referrals or Support for Trials	Completion of Human Protection Education for Research Teams Online Course[b]	Total Required Conditions Included by Year 3
Data Source:			**Outcomes Worksheet**						
Site 4	Limited Activity	Partially Implemented	Yes	Yes	Yes	Yes	Yes	Yes	5
Site 6	Fully Implemented	Fully Implemented	No	Yes	Yes	Yes	Yes	Yes	5
Site 10	Missing	Partially Implemented	Unknown	Yes	Yes	Yes	Yes	Yes	5
Site 3	No Activity	Partially Implemented	Yes	Yes	Yes	Yes	Yes	Yes	5
Site 12	Partially Implemented	Fully Implemented	Yes	Yes	Yes	Yes	Yes	Yes	5
Site 1	Approved, but not Implemented	Partially Implemented	Yes	Yes	Yes	Yes	Yes	Yes	5
Site 9	No Activity	Approved, but not Implemented	Yes	N/A	N/A	N/A	N/A	N/A	N/A
Site 16	No Activity	Fully Implemented	Yes	Yes	Yes	Yes	Yes	Yes	5
Site 15	No Activity	Fully Implemented	Yes	Yes	Yes	Yes	Yes	Yes	5
Site 11	Limited Activity	Limited Activity	No	N/A	N/A	N/A	N/A	N/A	N/A
Site 8	No Activity	Fully Implemented	Yes	Yes	Yes	Yes	Yes	Yes	5

(continued)

Table 13-5. Conditions of Participation Implementation: Years 1 and 3 (continued)

Site	Implementation Status		Required Conditions[a]						Total Required Conditions Included by Year 3
	Year 1	Year 3	Site Made Progress Toward Implementation from Year 1 to Year 3	Active Member of Hospital Medical Staff	Board Eligible, Certification and Re-Certification as	Membership in Oncologic Societies, if Available for Specialty	Participation in Clinical Trials Accrual Coordination, Referrals or Support For Trials	Completion of Human Protection Education for Research Teams Online Course[b]	
Site 7	No Activity	Fully Implemented	Yes	Yes	Yes	Yes	Yes	Yes	5
Site 2	Missing	Approved, but not Implemented	Unknown	N/A	N/A	N/A	N/A	N/A	N/A
Site 13	No Activity	Limited Activity	Yes	N/A	N/A	N/A	N/A	N/A	N/A
Site 5	No Activity	Limited Activity	Yes	N/A	N/A	N/A	N/A	N/A	N/A
Site 14	Fully Implemented	Fully Implemented	No	Yes	Yes	Yes	No	Yes	4

N/A = Site did not have partially or fully implemented conditions of participation by Year 3.
Missing = Site did not complete this item on the Outcomes Worksheet.
Unknown = Unable to determine change because of missing data in Year 1.

[a] Sites were required to include these conditions in their conditions of participation.

[b] Online training course required by NIH to be an investigator for cooperative group or NCI studies.

Table 13-6. Overall Experience with Care and Patient-Centered Communication[a]

	Overall Experience With Care (Scale of 1–10)[b]			Communication with Provider[c]		
Site	**Year 1 (N = 2,009)**	**Year 3 (M = 1,946)**	**p**	**Year 1 (N = 2,009)**	**Year 3 (N = 1,946)**	**p**
All sites	9.2	9.1	0.06	3.16	3.15	0.860
Site 4	9	9	0.848	3.07	3.03	0.824
Site 6	9.2	9.1	0.4390	3.16	3.26	0.624
Site 10	9	9	0.902	3	3.16	0.393
Site 3	9.4	9.4	0.869	3.2	3.56	0.085
Site 12	9.2	8.9	0.051	3.05	2.81	0.290
Site 1	9.5	9.2	0.180	3.42	3.22	0.391
Site 9	9	9	0.950	2.91	2.79	0.497
Site 16	9.4	9.4	0.880	3.43	3.40	0.903
Site 15	8.8	8.6	0.301	2.79	2.81	0.930
Site 7	9.3	9.2	0.641	3.59	3.52	0.671

[a] Data presented are unweighted. The patient survey was conducted in the 10 lead sites only. Significance determined at $p < 0.05$.

[b] 1 = worst possible care to 10 = best possible care

[c] The communication scale score is based on five items that assess different aspects of patient-provider communication over the past 4 months: how well members of cancer care team explain plans for treatment; how often cancer care team pays enough attention to your feelings and emotions; how often the cancer care team talks in terms you can understand; how often the cancer care team checks to be sure you understand everything; and how often the cancer care team encourages you to ask questions. The scale score is based on the number of items for which respondents provided an "always" or "excellent" response; a higher score indicates more positive patient-provider communication.

Table 13-7. Overall Success with Quality of Care Implementation

Site[a]	Increase in Number of MDC Conferences[b]	Physician Attendance[c]: Average Proportion of Physicians Attending MDC Conferences in Year 3	Physician Attendance[c]: Increase in Proportion of physicians Attending MDC Conferences (Y/N)	Total Number of Roles at Most or All MDC Conferences[d]	Conditions of Participation: Implementation Status, Year 3	Conditions of Participation: Number of Required Conditions Included, Year 3[e]	Conditions of Participation: Patients' Perceived Coordination of Care (Significant Change Year 1 to Year 3)[f]	Non-concordance Rates of RQRS Quality Measures[i]: Average Change in Non-concordance Rates for 3 Breast Cancer Quality Measures[g]	Non-concordance Rates of RQRS Quality Measures[i]: Average Change in Non-concordance Rate for 2 Colon Cancer Quality Measures[h]
Data Source		**Outcomes Worksheet**			**Outcomes Worksheet**		**Patient Survey**	**RQRS**	
Site 1	No	Most	No	8	Partially Implemented	5	No	-6.2	-10.8
Site 2	Yes	Missing	No	Missing	Approved, but not Implemented	N/A	Data not collected	-20.9	-28.9
Site 3	Yes	Few	Yes	8	Partially Implemented	5	Yes	-35.2	-3.5
Site 4	Yes	Most	No	6	Partially Implemented	5	No	-1.1	-10.4
Site 5	No	Most	No	7	Limited Activity	N/A	Data not collected	-9.1	-18.9
Site 6	Yes	Most	No	4	Fully Implemented[j]	5	No	-11.3	-10.3
Site 7	Yes	Some	No	8	Fully Implemented	5	Yes	-12.8	-37.5
Site 8	Yes	Most	Yes	9	Fully Implemented	5	Data not collected	-9.0	-12.8
Site 9	Yes	Most	No	7	Approved, but not Implemented	N/A	No	-12.1	-20.2
Site 10	Yes	Most	No	7	Partially Implemented	5	Yes	-25.4	-30.5
Site 11	N/A	N/A	N/A	N/A	Limited Activity	N/A	Data not collected	-12.1	-36.3
Site 12	Yes	Some	No	8	Fully Implemented	5	Yes	-27.9	-36.4
Site 13	Yes	Some	Yes	5	Limited Activity	N/A	Data not collected	-13.6	-16.8
Site 14	N/A	N/A	N/A	N/A	Fully Implemented[j]	4	Data not collected	-14.9	-22.8
Site 15	Yes	Most	No	8	Fully Implemented	5	No	5.5	-16.0
Site 16	Yes	Most	No	8	Fully Implemented	5	No	-8.2	-25.1

(continued)

Table 13-7. Overall Success with Quality of Care Implementation (continued)

[a] Sites have been de-identified in this table.

[b] See Table 13-1 for total number of MDC conferences by site in Years 1 and Year 3. N/A if site did not have any MDC conferences.

[c] Sites were coded as "Yes" if the average proportion of physicians across all subspecialties increased from Year 1 to Year 3. According to the Outcomes Worksheet, the data source for this indicator, Few = 1%–25%; Some = 26%–60%; Most = 61%–99%; All = 100%. N/A if site did not have any MDC conferences.

[d] See Table 13-2 for specific roles represented at each site. A total of nine roles were possible: cancer site specialists, general surgeons, primary care physicians, pathologists, radiologists, research nurses, social workers, patient navigators, and genetics counselors. N/A if site did not have any MDC conferences.

[e] Applicable only for sites that achieved partial or full implementation status of conditions of participation by Year 3. N/A if site did not achieve partial or full implementation status by Year 3.

[f] Sites were coded as "Yes" if there was a significant change from Year 1 to Year 3 in the percentage of patient survey respondents who reported that their cancer care team was "always" well informed and up to date about their care or "always" seem to work together as a team. See Table 13-3 for responses to each question by site.

[g] The average change in non-concordance rates was calculated as the difference between the average non-concordance rate in Year 3 minus the average non-concordance rate in Year 1 for three breast cancer quality measures: (1) breast conservation surgery and radiation, (2) hormone therapy for breast cancer, and (3) multiagent chemotherapy for breast cancer.

[h] The average change in non-concordance rates was calculated as the difference between the average non-concordance rate in Year 3 minus the average non-concordance rate in Year 1 for two colon cancer quality measures: (1) 12 regional lymph nodes for colon resections, and (2) adjuvant chemotherapy for stage III colon cancers.

[i] Non-concordance Rate = the proportion of cases who did not receive guideline-based treatment (of those eligible for the treatment).

[j] This site had fully implemented conditions of participation at baseline.

14. SURVIVORSHIP/PALLIATIVE CARE

Overview

A goal of the NCCCP was for pilot sites to build cancer survivorship and palliative care services and to incorporate such services into standard treatment programs at the community cancer centers. However, survivorship/palliative care was not a major focus area of the NCCCP, and funds were not specifically allocated for this program area. The evaluation assessed the sites' capabilities and progress in the following areas:

- development or expansion of psychosocial and palliative care initiatives,
- development of a treatment summary for cancer patients completing active therapy along with a post-treatment care plan,
- increased training of health care professionals in survivorship/palliative care, and
- increased awareness of and referrals to palliative care and hospice programs.

Survivorship/Palliative Care Tools

The survivorship/palliative care subcommittee developed several tools to guide the sites' work in this program component, including a Breast Treatment Summary Tool and two tools for self-assessment of capacity to deliver high-quality supportive care, one focusing on psychosocial care and one on palliative care. The response to these self-assessment tools was favorable, with respondents saying that the matrices helped them identify areas for development. The sites faced significant barriers to implementing the Breast Treatment Summary Tool because of IT issues, and some sites tried alternate "manual" approaches.

Accomplishments Specific to Survivorship/Palliative Care

Survivorship/palliative care was generally less well developed than other NCCCP program components, and for this reason we did not attempt to evaluate "success." However, most sites achieved positive change in at least several areas of survivorship/palliative care, including providing educational programs for physicians and other staff about survivorship/ palliative care, routine screening of patients for psychosocial distress, and referring patients to hospice. Patient Survey data aggregated from all sites showed a significant increase in the proportion of patients who reported receiving a written treatment summary from Year 1 to Year 3.

Facilitators and Barriers

Respondents noted several factors that facilitated survivorship/palliative care implementation and patient care at each site, including adding staff (e.g., palliative care specialists), relationships with community organizations, and connections with other NCCCP sites to share challenges and strategies. Lack of physician engagement was a barrier to improving survivorship/palliative care, as physicians are responsible for referrals to palliative and hospice care. Sites also identified the need for additional staff to focus on survivorship/palliative care activities.

The cohort of cancer survivors will continue to grow as the population continues to age, cancer screening becomes more widely adopted, and cancer treatments become more successful. With approximately 10 million Americans living with a personal history of cancer (Hewitt, Greenfield, & Stovall, 2006), researchers and health care providers have begun to address patients' long-term needs following completion of cancer treatment. Researchers have identified a number of needs and issues, including inadequate documentation of the

care they received or recommended follow-up care, lack of knowledge and understanding of late effects of cancer treatment, and lack of psychosocial assistance and support (Adler, Page, & Institute of Medicine Committee on Psychosocial Services to Cancer Patients, 2008; Hewitt, Greenfield, & Stovall, 2006; Hewitt, Weiner, & Simone, 2003; President's Cancer Panel, 2004). A goal of the NCCCP was for pilot sites to build cancer survivorship/palliative care services and to incorporate such services into standard treatment programs at the community cancer centers. The evaluation assessed the sites' capabilities and progress in the following areas:

- development or expansion of psychosocial and palliative care initiatives,
- development of a treatment summary for cancer patients completing active therapy along with a post-treatment care plan,
- incorporation of survivorship plans into a model of care,
- provision of appropriate follow-up care and monitoring for cancer patients,
- increased training of health care professionals in survivorship/palliative care, and
- increased awareness of and referrals to palliative care and hospice programs (U.S. National Institutes of Health, 2009b).

During the site visit interviews, members of the survivorship/palliative care subcommittee and others described their survivorship/palliative care activities and discussed the facilitators and barriers to implementing this program component. In the Year 2 site visits in particular, the interviews focused on implementation of tools created through the subcommittee (see Appendix C).

14.1 NCCCP Survivorship/Palliative Care Subcommittee Priorities and Strategies

At the beginning of the NCCCP pilot, sites were asked to identify key personnel to act as members of each subcommittee. The purpose of the survivorship/palliative care subcommittee was to help guide the 16 NCCCP sites in their efforts to enhance survivorship/palliative care services. The survivorship/palliative care subcommittee included members from each lead and developmental site. Throughout the NCCCP pilot, the survivorship/palliative care subcommittee divided into workgroups to develop a series of tools. The workgroup tools were designed to help sites to assess their current survivorship/palliative care and to determine guidelines or standards for patient care in these areas. The following sections provide a description of the tools along with sites' experiences with using the tools.

14.1.1 Breast Treatment Summary Tool

The Breast Treatment Summary Tool was developed based on the American Society of Clinical Oncology's (ASCO's) treatment summary forms and incorporates the Institute of Medicine recommendations for treatment summaries (Appendix N). The purpose of the

Breast Treatment Summary Tool is to provide a brief record of each patient's disease characteristics as well as information regarding major aspects of the patient's treatment and those who provided their care (U.S. National Institutes of Health, 2009b). Sites varied in terms of their ability to implement the Breast Treatment Summary Tool. Full implementation of the tool involves accessing tumor registry data and recording patient treatment data from various sources (e.g., surgery, radiation, medical oncology) using an electronic medical record (EHR) and providing a copy of the treatment summary form to patients at completion of treatment.

Sites were asked to rate their implementation of the Breast Treatment Summary Tool using the following categories:

- **Level 1:** reviewed the form but not yet worked to figure out how to implement it or how to identify data to populate the form.
- **Level 2:** completed Level 1 and begun to work to see what it will take to implement the form in your cancer program. This includes meeting with providers to see what is kept in their record that could be used to fill out the form, identifying staff who could be responsible for the form, meeting with IT staff to understand the data elements that are accessible to you to populate the form and what is missing—but not yet giving the form to any patients.
- **Level 3:** completed all of Levels 1 and 2 plus you've started using a hard copy form to get some of the information filled in for patients.
- **Level 4:** completed Levels 1, 2, and 3 plus developed an IT infrastructure to populate the treatment summary form for patients.

At baseline, only four sites reported having reached Level 1, and one site reported having reached Level 2 (see Table 14-1). By the end of Year 3 (by July 1, 2010), most sites had made progress in implementing the tool: nine sites had reached Level 3, and one site had fully implemented the tool (Level 4). However, six sites had not progressed beyond Level 2 by Year 3.

Several sites reported using modified versions of the tool that better meet their needs:

> *In terms of survivorship, I put together a summary of care tool because the summary of care stuff they put together was by disease site. You need a generic tool so that the program care coordinator can fill in the blanks. We went live with it with a new patient. We are using it across three sites.* (Subcommittee member, Year 2)

> *The survivorship tool we are using is a revised, shorter version. It was taking about 45 minutes. As long as we are paper based, we will use a shorter version. If we go electronic, we may employ one with more detail. We are actually doing a software preview tomorrow.* (Cancer center/program staff, Year 2)

Moreover, several sites reported that they were unable to implement the Breast Treatment Summary Tool or used a manual approach because of IT barriers:

> *We've implemented the breast tracking tool, but it's manual. It's an Excel sheet, so trying to pull data points out of it is hard. The issue with implementing the summary is getting the data from all the different sources. I have been meeting with [our nurse navigator] and tumor registrar. It is not real-time data, it is 3 to 4 months out. It requires contracting with people to learn how to do it. A lot of it is reported in the tumor registry as a code, and they have to decipher the code to put it into the treatment summary. You need someone who can do that on a contractual part-time basis. Then [our nurse navigator] is going to help us get the data from the medical oncologists because we can get the information from the registrar. We may pilot it with the colorectal patients because they are going through [multidisciplinary care], and [our nurse navigator] can say at the end of treatment, "Here is your follow-up care plan."* (Subcommittee member, Year 2)

> *We struggle with that a little bit just because it's so time-intensive to get the data for it. We spent over a year with our [information systems] developing the form in our EHR, and it still cannot pull data electronically. It's a manual entry. [Site] presented back in December that they were pulling a summary from the tumor registry, and I pulled the same form and was surprised they're giving this to patients because it's so clinically documented. They just posted a message out last week asking, "Does anyone else use NPACC because we're trying to get a patient summary sheet?" I told them, "Absolutely, we would lend support to that because the information is already there in the registry, so we just need to find a way to get it out." Our tumor registry is usually 3 to 5 months behind, so by the time someone gets done with their treatment, their chart is usually abstracted by then.* (Subcommittee member, Year 2)

> *There is no ASCO treatment summary because there is no electronic chart. I have never gotten a med onc summary. We have communication; it is just not written and summarized.* (Key physician, Year 3)

> *[For] our survivorship treatment plans, we did a lot of work initially but we've not been able to computerize them.* (Cancer center/program staff, Year 3)

One respondent noted that staff resources are required not only to complete the treatment summary, but also clinician time is required to talk with the patient about the treatment summary.

> *The other tool is the treatment summary and I think that was the primary goal of the survivorship committee at the beginning, and there have been a lot of barriers to that. The form's been developed in many different iterations, but there isn't a good answer to the question, "How do you get it filled out and who's going to sit with the patient to go over it?"* (Subcommittee member, Year 2)

To overcome barriers to implementation, one site switched to using software other than the cancer registry:

> *Last year they were still using the cancer registry. Now [they] are working with Cogent, and it simplifies things tremendously.* (Cancer center/program staff, Year 3)

One staff member provided recommendations to NCI for the process for tool development:

> *On survivorship, we are struggling with the treatment summary. Why not have a call on how we can streamline the process? ASCO had one [treatment summary], and we kept tweaking it. ASCO has a one-page summary, and ours is two pages, and we have conversations where other sites are saying that they get the info from the tumor registry. We should have identified what was common to every site. Let's design a tool based on what is already there. We should have done an assessment. All of our physicians are private practice, and we can't just go in and get the data from them. As opposed to designing a tool around what you have available, we did the opposite. I think it is a great idea to have a treatment summary plan and follow-up care, but how are we doing this with multiple specialties?* (Subcommittee member, Year 2)

One respondent noted that the lack of standardization for both treatment summaries and follow-up care plans was a challenge for implementing these tools:

> *[The] other major barrier is lack of standardization for treatment summary and treatment care plan. With [the] NCCCP, they've been able to look at best practices and other [electronic health records]. There is so much ownership and proprietary issues.* (Subcommittee member, Year 3)

During the Year 3 site visits, respondents from three different sites indicated that they plan to continue working on implementing a Breast Treatment Summary Tool using additional funding:

> *[We] haven't made much progress on [the] treatment summary but will be working on [it] with ARRA [American Recovery & Reinvestment Act of 2009] funds.* (PI, Year 3)

> *I think we're moving closer to the treatment summary here. There was a little pushback on that, and I think it was a manpower issue here. [We] got ARRA funding for that. Without NCCCP we couldn't have moved toward that.* (NCCCP program coordinator, Year 3)

> *We're excited about Project 18 (ARRA funds) and another project to improve the information systems. We also have Project 14 on survivorship care and treatment summaries.* (Cancer center/program staff, Year 3)

14.1.2 Breast Cancer Survivorship Care Plan

The Breast Cancer Survivorship Care Plan was adapted from the ASCO Breast Cancer Treatment Summary and includes recommendations based on ASCO practice guidelines for breast cancer follow-up and management. In the Year 2 and Year 3 site visits there was only limited discussion of the Breast Cancer Survivorship Care Plan, although a few spoke of the Breast Treatment Summary tool interchangeably with the Breast Cancer Survivorship Care Plan. Based on the limited discussion of this tool, it appears that sites are still developing approaches for implementing the Breast Cancer Survivorship Care Plan, for example determining patients' priority needs and concerns and the most appropriate timing for sharing the Care Plan with patients.

> *[We used the] ASCO template for treatment summaries and care plans [to] summarize the patient's treatment through diagnosis. [Patient navigator] fills them out and then sets up a time…She continues with end of treatment classes.* (Program coordinator, Year 3)

> *[We are] in middle of purchasing [a] flash drive to store [the] treatment summary and plan; patients will get a copy electronically and on paper. We're also developing a "wallet card" and tracking system within the hospital to monitor survivorship outcomes. We used a satisfaction survey and sampled 250 patients to see if their needs mimicked those nationally, and fear of recurrence and fatigue were major factors. What was surprising was they wanted more written information, so we're thinking of developing a patient newsletter. [We also found that] patients weren't engaging in tools until it addressed patient fears.* (Subcommittee member, Year 3)

> *Most patients don't want [a treatment summary or care plan] initially, but usually it's a year out. We should be proactive in asking patients about it because I think patients are not comfortable asking for it.* (Key physician, Year 3)

14.1.3 Psychosocial Matrix

The psychosocial matrix is designed for community cancer programs to use as a self-assessment tool in evaluating and improving their capacity to deliver high-quality, comprehensive psychosocial care. The tool provides guidance for ensuring that the psychosocial needs of cancer patients are met. Psychosocial health services psychological and social services that enable cancer survivors, their families, and health care providers to optimize health care and manage the psychological/behavioral and social aspects of cancer and its consequences in order to promote better health. A multidimensional, culturally informed psychosocial health needs screening includes emotional/mental health needs (anxiety, depression, coping, sexuality), practical problems (financial, transportation, housing), social problems (lack of social support/resources, vocational impact, insurance), and support needs (personal, social, medical, spiritual) (U.S. National Institutes of Health,

2009b). The psychosocial matrix allows cancer centers to rate activities that they conduct on a continuum from 1 to 5, with 5 representing the highest possible level of integrated care.

Respondents indicated that the psychosocial matrix was a useful tool that helped sites understand their current practices and set strategic goals for future care:

> *We went through and scored ourselves and, considering we are fairly new in this, we were on the mid to high scale but found that education for physicians and staff was something we could improve on.* (Subcommittee member, Year 2)

> *[The] psychosocial matrix helped us to see where we are now and what we could achieve.* (Subcommittee member, Year 3)

Although the psychosocial matrix was perceived as a useful tool, participants noted that to achieve the highest level of psychosocial care (i.e., scoring a 5 on the matrix) would require sufficient funding and staffing resources:

> *The matrix we just completed. The information is good. I am into the money thing, to implement and get to level 5 it is going to cost money, and in these economic times I am not sure that we are going to get funding.* (Subcommittee member, Year 2)

> *Psychosocial matrix: We're working on getting approval, but in talking with our medical director that's going to be our blueprint and we're going to implement it right away, trying to get to all 5s across the board. Something like this doesn't even exist with [the National Comprehensive Cancer Network]. I think the biggest thing where we can still stand to improve is on systematic screening of all patients at various timelines. The biggest obstacle to doing that is simply patient volume, and then there are some process issues in how we implement this. We have two full-time psychologists, two full-time outpatient social workers, and two life coaches, and we're all busy as it is.* (Subcommittee member, Year 2)

14.1.4 Palliative Care Matrix

The palliative care matrix is designed for community cancer programs to use as a self-assessment tool in evaluating and improving their capacity to deliver high-quality, comprehensive palliative care (also sometimes referred to as "supportive care" or "symptom management") (U.S. National Institutes of Health, 2009b).

Similar to the psychosocial matrix, several sites indicated that the palliative care matrix was a useful tool that assisted them in conducting self-assessment, setting goals, and guiding standards of care:

I think with the palliative matrix, one benefit of developing [it is] that [it is] really helping me envision how concretely to move our program forward. It helps really identify quality steps and keep on us for how we're going to grow and how to do it right so that the education piece is in place for physician staff, and care coordination and infrastructure is in place. (Subcommittee member, Year 2)

It's a fabulous tool that will give an objective/independent standard where hospitals can place themselves. It helps you compare yourselves to an independent standard and identifies area for improvement. We think the matrix has a lot of potential. (Subcommittee member, Year 2)

14.2 Survivorship/Palliative Care Implementation

Survivorship/palliative care was generally less well developed than other NCCCP program components. For this reason, we have not attempted to assess whether sites were "successful" in implementing this component, as we did for the three major program components of disparities (Chapter 9), clinical trials (Chapter 10), and quality of care (Chapter 13). The limited overall accomplishments for sites in survivorship/palliative care may be because of the lower priority given to this aspect of care prior to the NCCCP. Activities for which sites were assessed included

- the status of implementation of the Breast Treatment Summary Tool,
- whether sites have a distinct palliative care program,
- whether sites have a distinct survivorship program or clinic,
- the number of education programs for physicians and staff specific to survivorship/palliative care,
- the number of patients screened for psychosocial distress, and
- the number of patients referred to hospice care.

Table 14-2 provides an overview of sites' accomplishment in these different areas. Most sites achieved positive change in four or more of the survivorship/palliative care indicators. Five sites (Site 6, Site 3, Site 15, Site 2, and Site 14) made progress in fewer areas. In the sections below, we summarize the sites' progress (or lack thereof) in each area.

14.2.1 Palliative Care Program

At the start of the NCCCP, 12 of the 16 sites reported that they had a distinct palliative care program (Table 14-2). By Year 3, three sites had added a palliative care program (Site 4, Site 8, Site 13). However, two sites had discontinued the palliative program, and the total number of sites with a distinct palliative care program remained at 12 in Year 3 (data were missing for one site in Year 3).

14.2.2 Survivorship Clinic or Program

At the beginning of the NCCCP, 7 of 16 sites reported having a distinct survivorship clinic or program, such as wellness or follow-up clinic or health education and promotion programs for patients who have completed treatment (Table 14-2). By Year 3, six sites had added a survivorship clinic or program, and two sites no longer maintained such a program. Overall, the number of sites with dedicated survivorship clinics or programs increased over the course of the pilot from 7 to 10 (data were missing for one site in Year 3).

14.2.3 Physician and Medical Staff Education/Communication

At the beginning of the NCCCP pilot, sites reported offering an average of four programs to educate cancer center staff about psychosocial, survivorship, palliative, or end-of-life care, and most sites had offered five or fewer programs. By Year 3, seven sites had increased the number of educational programs in this area. Site 12 and Site 5 reported the largest number of educational programs for physicians and other medical staff focusing on survivorship/palliative care (16 and 17 programs, respectively). During the Year 2 site visit interviews, participants were asked to describe how they communicate survivorship information to cancer center staff. Two respondents referred to newsletters and meetings:

> *We use a variety of ways. For example, newsletters [and] committee meetings.* (Subcommittee member, Year 2)

> *Quarterly we do a palliative care newsletter, in which we take topics that are relevant to palliative care, that is distributed to physicians/staff. So this is another way to help with the education piece.* (Subcommittee member, Year 2)

14.2.4 Psychosocial Distress Screening

Screening for psychosocial distress is an important aspect of survivorship/palliative care that was added to the NCCCP pilot in response to a pivotal report from the Institute of Medicine on the psychosocial health needs of cancer survivors (Adler, Page, & Institute of Medicine Committee on Psychosocial Services to Cancer Patients, 2008). Sites reported the frequency of routine screening for psychosocial distress, using a 5-point scale from *never* to *always*. In Year 1, only one site (Site 12) reported that they always screened patients for psychosocial distress. An additional five sites reported that they screened patients *most of the time.* Over the course of the pilot eight sites had increased the frequency with which patients were routinely screened for psychosocial distress; four sites reported that they *always* screened patients for psychosocial distress and another five sites reported that they do so *most of the time*. However, in three sites the frequency of routine screening decreased and in five sites there was no change (Year 3 data were missing for one site).

14.2.5 Referrals to Hospice

End-of-life care is an essential component of any cancer survivorship program to address care across the continuum. Sites reported how many patients they had referred during the prior year (see Table 14-2). A number of sites did not report the numbers of patients referred to hospice for Year 1 and/or Year 3.[1] For those sites for which data are complete, findings were mixed. In six sites, the number of patients referred to hospice care increased from Years 1 to 3; in five sites, the number decreased. Increases were marked in several sites; for example, in Site 2 the number of patients referred to hospice increased from 4 in Year 1 to more than 350 in Year 3. Several factors not related to the NCCCP could contribute to changes in referrals to hospice care, including changes in patient volume or profile (e.g., proportion who could benefit from hospice), and to changes in the availability of hospice care services in the community. Increases in hospice referrals could also be a result of the efforts to increase awareness and understanding of the importance of hospice for end-of-life care.

14.3 Survivorship/Palliative Care Implementation: Patients' Perspectives

The Patient Survey included three items related to survivorship/palliative care, answered by respondents who indicated that had completed their cancer treatment:

- whether patients received a written treatment summary,
- whether patients were provided an explanation of their follow-up care plan, and
- whether patients received written information about their follow-up care plan.

Across all sites, there was a significant increase in the proportion of patients who reported receiving a written treatment summary (Table 14-3). By Year 3, about 39% of patients who had completed treatment said they had a received a written treatment summary, up from 33% in Year 1. At the site level, there were significant increases in just two sites: Site 6 and Site 16. However, it is important to note that the Patient Survey was not designed to detect site-level differences. About 90% of patients in Year 1 reported that someone on their cancer care team had explained plans for their follow-up care, and this percentage did not increase significantly over the course of the pilot. Similarly, there was no significant increase in the proportion of patients who reported receiving written information about follow-up care plans (40% in Year 1 and 42% in Year 3).

14.4 Facilitators to Survivorship/Palliative Care

Respondents discussed factors that facilitated implementation of the survivorship/palliative care program:

[1] Two sites reported that they refer patients to hospice care, but they could only provide numbers for all hospice referrals (cancer patients and other patients).

- survivorship/palliative care personnel,
- patient navigation,
- relationships with community groups and hospices, and
- linkages with other NCCCP sites.

This section provides a description of these facilitators, along with examples from the Year 2 and Year 3 site visit interviews.

14.4.1 Survivorship/Palliative Care Personnel

Respondents discussed the importance of palliative care nurses and other personnel for providing high-quality survivorship/palliative care. Several respondents noted that they had hired additional personnel. As NCI increased the priority of survivorship/palliative care in the pilot (in Year 2 thru Year 3), sites recognized the need to build capacity in this area, and some had hired (or planned to hire) additional staff:

> *We've added a palliative care events practice nurse to our unit. She talks with the patients and reviews their cases. [We] all work together and screen every one of the patients for palliative care treatment. All of the hospitals are on board with us doing that palliative care consult. I think it has been a tremendous asset.* (Cancer center/program staff, Year 2)

> *We have made a new effort to bring forward palliative care. We are hiring one palliative care physician and a palliative care nurse practitioner, which will be part of the hospitals program, but we finally have approval, after 4 years, to start doing interviews.* (Cancer center/program staff, Year 2)

> *For inpatients, they've been able to establish a palliative care consulting service. Another way is to go through non-physician routes [e.g., nurses, case management] to help begin the process for palliative care. We think they've been able to be available to physicians. This has helped break down some barriers. With regards to hospice, there's a very active nurse liaison working with the palliative care team and case managers to help patients transition to hospice. So the palliative care team and hospice liaison nurse are major facilitators.* (Subcommittee member, Year 2)

> *Survivorship is a beautiful concept. In survivorship, what I think is the breast cancer part, those patients have the luxury with the peace of mind of thinking they're disease free. Survivorship is more so in full swing with the breast part. Full swing because they have a [staff] person there.* (Key physician, Year 3)

14.4.2 Patient Navigation

One activity of particular importance for survivorship/palliative care is patient navigation to ensure that patients receive appropriate follow-up care and connect to appropriate

physicians and services. Patient navigators described their approach to navigating patients from treatment to survivorship care:

> *Then nurse navigator goes through the system as to what is going to happen next and continues to follow the patient and answer any questions [e.g., finances, transportation, counseling] until they don't need us anymore, and ultimately we would graduate them into our survivorship program that is headed by our health psychologist. On that team is actually the [health psychologist], a clinical nurse, and a social worker. With survivorship, you're looking at a whole set of different issues like with reoccurrence, having good nutrition and an exercise program, [and concerns about] "How do I talk to my friends and family and people at work once I'm done with my treatment?" etc.* (Subcommittee member, Year 2)

> *With lung [cancer], our goal is any patient with Stage 3B or 4 gets a palliative care consult. So we're trying to segue into palliative care to help them, but we're trying to help people live better no matter how much longer they have. As far as survivorship, my goal [as a patient navigator] is to get them to the medical oncologist who is going to provide that support or back to their family physician so they can hopefully stay ahead of the game. And we have their plan of care so they should always know when their next appointment is, if it's a scan, and to come in if anything changes.* (Cancer center/program staff, Year 2)

14.4.3 Relationships with Community Groups and Hospices

Affiliations with community survivorship groups and hospices provide the cancer centers with external resources that help to expand the capacity for providing survivorship/palliative care. Respondents discussed relationships with local partners to increase survivorship care:

> *The palliative care—we do a very good job of working with the other care resources in town, hospices in town.* (System/hospital senior executive, Year 2)

One respondent described a partnership with the closest NCI-designated cancer center to provide palliative care:

> *As far as [neighboring NCI-designated cancer center], we have a good relationship with them for survivorship. I work together with two of their nurses on palliative care.* (Cancer center/program staff, Year 3)

14.4.4 Linkages with Other NCCCP sites

The NCCCP helped to link cancer center staff, either through the formal subcommittees or informally through direct contacts (across) sites, creating a learning collaborative where sites share ideas, experiences, and challenges related to the survivorship/palliative care program. Respondents found these collaboration beneficial in terms of sharing challenges, program ideas, and helping them consider ways to develop their program:

> *I did collaborate with [another NCCCP pilot site] to present at [the Oncology Nursing Society] last month. That's been the biggest collaboration around survivorship. We talked about how things have their own set of challenges in the rural areas. Not only is this a new concept to people, but you also have the distance barriers and a very diverse population. We also shared some of the challenges and some of the evidence-based literature that's out there for other ways to offer people support, and some of our unique programs.* (Subcommittee member, Year 2)

> *On survivorship, we went to the [NCCCP pilot] sites, and they have similar rural populations as us, so we got ideas from there.* (Subcommittee member, Year 2)

> *I've been part of the survivorship/palliative care calls. I'm part of the palliative care taskforce through that. Over the past year, we've been developing a palliative care matrix, and I've done a lot of the work in developing that. Those conference calls and subgroup calls have taken up some time and thinking. It's been a very good process and has helped me think programmatically where I want this program to go because we don't have all the components perfect either.* (Key physician, Year 2)

14.5 Barriers to Survivorship/Palliative Care

Respondents reported several factors that impeded the site's ability to implement survivorship/palliative care activities:

- low physician engagement,
- Lack of guidance about standards for survivorship/palliative care, and
- staffing needs.

This section provides a description of these barriers, along with examples from the site visit interviews.

14.5.1 Low Physician Engagement

Physician engagement is essential to the success of survivorship/palliative care because physicians are primarily responsible for referring patients to hospice or palliative care. Several respondents described physician resistance, and two noted that there were financial disincentives for physicians to refer their patients for hospice or palliative care.

> *I wanted to have a survivor clinic. I wanted it to be nurse practitioner–run. None of the physicians are willing to give up the revenue of a follow-up appointment to put these patients in a survivor clinic. I am hoping our new executive director will see that and maybe push a little harder for it. Part of the problem is that we are bringing in two new medical oncologists who are going to have zero patients. To give their patient to someone else to bill, that is taking money away from them. If people could put away their wallets and look at the patient for a little while…. If [a survivor clinic]*

> *was run by a nurse practitioner, the patient would get VERY different information about what to expect and what is to come in the next year.* (Cancer center/program staff, Year 2)

> *[Physicians] are seeing so many patients with the same resources they have had in the past years. The growth is limited based on the resources dedicated to it. It's a non-billable service that becomes a disservice to patients.* (PI, Year 2)

> *There are times when our palliative care folks have experienced physician resistance.* (Key physician, Year 3)

One physician said that the NCCCP had brought attention to the topic of survivorship care and helped to educate physicians:

> *Now, we actually have more than just physician involvement, which extends out into what [the] NCCCP is all about. Before [the] NCCCP, survivorship? But now there's a push for what happens after the treatment. It never filtered down to the doctors before. It's helped educate us as physicians about the bigger picture.* (Key physician, Year 3)

14.5.2 Lack of Guidance about Standards of Survivorship/Palliative Care

Identifying the stage at which patients should receive survivorship/palliative care was an issue of concern for several participants. Specifically, they wanted guidance on when survivorship or palliative care should be initiated.

> *One of the major challenges is that we don't clearly stage our patients as to where they are with the progression of their illness.* (Subcommittee member, Year 2)

> *[It] would be nice if the survivorship/palliative committee could come out with recommendations about when survivorship/palliative care should be offered to patients.* (Key physician, Year 3)

14.5.3 Staffing Needs

Nurses and patient navigators play an integral role in conducting survivorship programs, implementing the survivorship tools, and identifying patient survivorship/palliative care needs. With the increased survivorship activity associated with the NCCCP, several sites identified the need for additional staff and programs:

> *That would be my barrier. The palliative care person has told me that they could have a full-time person who would stay busy. It would be awesome if I could get a same-day referral to palliative care. It's been difficult to get palliative care to the clinic to help us with that. They do have a nurse practitioner who is so busy with inpatient [care] that she doesn't have the time for outpatient referrals. I don't think*

> *they've gotten to the point where they'd have a palliative care outpatient person.* (Cancer center/program staff, Year 2)

> *Up until 6 months ago, there was not a lot of staffing to pull things off…a lot of people were putting in part-time efforts.* (Subcommittee member, Year 3)

14.6 Summary

Overall, survivorship/palliative care appeared to receive less attention from sites than other program components. Compared with other program components, such as disparities and clinical trials, survivorship/palliative care was generally a less developed program component across the sites. No funding was allocated to this program component at the start of NCCCP, and sites had no invoiced costs specific to survivorship/palliative care activities.

Although survivorship/palliative care subcommittee members and others were dedicated to improving survivorship/palliative care, they encountered a number of barriers. IT issues were a significant challenge for implementing the treatment summary and also the follow-up care plan. Some sites were creating treatment summaries "manually" (e.g., populating an Excel spreadsheet with data from various sources), which is a very time- and staff-intensive approach. Only one site had fully implemented the breast care treatment summary by Year 3. Lack of physician engagement and staffing needs (e.g., for palliative care specialists) also limited accomplishments in survivorship/palliative care. However, despite these challenges, many sites had made progress in providing educational opportunities for physicians and other clinicians about survivorship/palliative care, routinely screening patients for psychosocial distress, and referring patients to hospice care. Patient Survey data aggregated from all sites showed a significant increase in the proportion of patients who reported receiving a written treatment summary from Year 1 to Year 3.

The need for survivorship/palliative care will continue to grow as advances are made in screening, diagnosis, and treatment of cancer. To strengthen the survivorship/palliative program, the NCCCP may consider additional ways to incorporate survivorship/palliative care into higher-priority or better-funded aspects of cancer care, such as multidisciplinary care and patient navigation. Given that survivorship/palliative care is generally not revenue producing, another suggestion would be for the survivorship/palliative care subcommittee to tackle the issue of how to make what they do "value added" to clinicians, senior executives, and cancer center leadership. ASCO recommends delivery of treatment summaries and assessment of psychological distress, and the inclusion of these recommendations as part of the Quality Oncology Practice Initiative rating scales provides an impetus for sites to focus on these activities.

Table 14-1. Implementation Level of Breast Treatment Summary Tool[a]

Level of Implementation	Year 1	Year 3
Number of sites not yet at level 1	11	1
Number of sites at Level 1	4	1
Number of sites at Level 2	1	4
Number of sites at Level 3	0	9
Number of sites at Level 4	0	1

[a] 0 = site has not implemented the treatment summary form; 1= site has reviewed the form but not yet worked to figure out how to implement it or how to identify data to populate the form; 2 = site has completed Level 1 and begun to work to see what it will take to implement the form in their cancer program; 3 = site has completed all of Levels 1 and 2 and started using a hardcopy form to get some of the information filled in for patients; 4 = site has completed Levels 1, 2, and 3 plus developed an IT infrastructure to populate the treatment summary form for patients.

Table 14-2. Overall Success in Survivorship/Palliative Care

	Implementation Status of Breast Treatment Summary Tool (0-4)[a]		Distinct Palliative Care Program (Yes/No)		Special Cancer Survivorship Program or Clinic (Yes/No)		Number of Educational Programs for Cancer Center Physicians and Staff[b]			Frequency of Screening Patients for Psychosocial Distress (0-4)[c]		Number of Patients Referred to Hospice Care from Cancer Center[d]		
	Year 1	Year 3	Year 1	Year 3	Year 1	Year 3	Year 1	Year 3	Change	Year 1	Year 3	Year 1	Year 3	Change
Data Source:	Outcomes Worksheet – SAIC-F		BAS	FAS	BAS	FAS	BAS	FAS		BAS	FAS	BAS	FAS	
Site 4	1	2	No	Yes	Yes	Yes	9	9	0	2	3	94	64	-30
Site 6	1	2	Yes	Missing	Yes	Missing	3	Missing	Unknown	1	Missing	308	Missing	Unknown
Site 10	0	4	Yes	Yes	Yes	Yes	11	8	-3	2	3	126	209	83
Site 3[e]	1	3	Yes	No	Yes	No	10	2	-8	2	3	Missing	242	Unknown
Sote 12[e]	0	2	Yes	Yes	No	Yes	5	16	11	4	1	Missing	131	Unknown
Site 1	0	3	Yes	Yes	No	Yes	3	7	4	2	2	398	377	-21
Site 9	0	1	Yes	Yes	No	Yes	0	9	9	2	4	62	84	22
Site 16	0	3	Yes	Yes	No	Yes	1	4	3	3	2	413	375	-38
Site 15	0	0	Yes	Yes	No	No	3	6	3	2	2	479	529	50
Site 11	0	3	Yes	Yes	No	No	2	2	0	3	2	45	200	155
Site 8	0	3	No	Yes	Yes	No	3	3	0	3	4	Unknown	92	Unknown
Site 7	0	3	Yes	No	Yes	Yes	3	2	-1	1	2	60	262	202
Site 2	0	3	No	No	No	Yes	5	4	-1	3	3	4	356	352
Site 13	1	3	No	Yes	No	Yes	2	3	1	2	4	123	70	-53
Site 5	0	2	Yes	Yes	No	No	1	17	16	1	4	142	100	-42
Site 14	2	3	Yes	Yes	Yes	Yes	4	1	-3	3	3	Missing	Missing	Unknown

[a] 0 = site has not implemented the treatment summary form; 1= site has reviewed the form but not yet worked to figure out how to implement it or how to identify data to populate the form; 2 = site has completed Level 1 and begun to work to see what it will take to implement the form in their cancer program; 3 = site has completed all of Levels 1 and 2 and started using a hardcopy form to get some of the information filled in for patients; 4 = site has completed Levels 1, 2, and 3 plus developed an IT infrastructure to populate the treatment summary form for patients.

[b] Types of educational programs include psychosocial, survivorship, personalized care medicine, and/or end-of-life care.

[c] Scale: 0 = Never; 1 = Rarely, 2 = Sometimes; 3 = Most of the time; 4 = Always.

[d] Refers to the number of patients referred in the prior year (2006 for Year 1 and 2009 for Year 2).

[e] Sites refer patients to hospice care, but unable to provide numbers of referrals for cancer patients specifically.

N/A = Data not collected for this site.
Missing = Data missing for this site.
Unknown = Unable to calculate change because of missing data in Year 1 and/or Year 3.

Table 14-3. Treatment Summaries and Follow-up Care[a] Information

	Received Written Treatment Summary (%)[b]			Follow-Up Care Plan Explained (%)[b]			Receiving Written Information about Follow-Up Care Plan (%)[c]		
	Year 1	**Year 3**	**p-Value**	**Year 1**	**Year 3**	**p-Value**	**Year 1**	**Year 3**	**p-Value**
Data Source:					**Patient Survey**				
All Sites	33.4%	38.9%	**0.00**	89.5%	89.7%	0.92	39.8%	42.2%	0.23
Site 4	37.1%	35.0%	0.71	89.0%	90.7%	0.63	47.4%	45.8%	0.79
Site 6	28.0%	39.2%	**0.04**	89.5%	89.1%	0.92	39.9%	43.9%	0.51
Site 10	32.7%	41.1%	0.13	94.3%	89.5%	0.13	39.5%	40.2%	0.91
Site 3	41.5%	48.4%	0.27	95.6%	91.9%	0.22	46.1%	39.5%	0.30
Site 12	26.9%	37.8%	0.07	84.6%	87.2%	0.56	31.0%	39.8%	0.19
Site 1	35.1%	32.6%	0.72	86.1%	82.2%	0.46	34.1%	30.6%	0.63
Site 9	34.1%	33.7%	0.94	89.0%	88.7%	0.93	42.5%	41.6%	0.87
Site 16	34.4%	46.3%	**0.04**	88.3%	90.7%	0.49	41.0%	51.1%	0.10
Site 15	35.3%	34.6%	0.91	88.6%	89.2%	0.87	35.0%	40.9%	0.33
Site 7	30.5%	39.9%	0.07	89.2%	93.2%	0.20	37.9%	41.9%	0.47

Note: Bold indicates change between Years 1 and 3 was statistically significant at $p < 0.05$.

[a] Data presented are unweighted. The Patient Survey was conducted in the 10 lead sites only. The six developmental sites are therefore not listed in this table.

[b] Proportion is among respondents who answered this question.

[c] Proportion is among respondents who answered this question.

Part IV: Conclusions and Recommendations

15. EXPERIENCE WITH THE NCCCP NETWORK AND OTHER NCI PROGRAMS

Overview

Benefits of the NCCCP Network

Overall, respondents found participation in the NCCCP network and specifically in the subcommittees and working groups, to be very beneficial in terms of receiving technical assistance, learning other sites' experiences and best practices, and conducting collaborative work in areas of common interest. Respondents valued the noncompetitive nature of the relationships among NCCCP sites, which allowed them to assist one another and share best practices and resources (e.g., tools, funding information). Respondents also valued the connections with NCI staff who could provide technical assistance.

Respondents offered suggestions for strengthening the NCCCP network, including reducing the administrative burden on sites and sharing evaluation findings, which they can use for quality improvement.

Collaborations with NCI Research Programs

By Year 3, all but one site had established new relationships with one or more NCI-designated cancer centers and seven sites had developed relationships with Community Network Programs (CNPs). In many cases, respondents felt that the NCCCP had "opened the door" for these relationships by increasing the center's visibility and stature.

The benefits of these collaborations included access to expertise, funding opportunities, and expansion of research activities, specifically of early phase clinical trials. A major barrier to collaboration with both NCI-designated cancer centers and CCOPs was their lack of understanding about the NCCCP and a perception of the NCCCP as a competitor. Some respondents noted that these concerns had diminished over time and they reported "breakthroughs" with NCI-designated cancer centers. Some sites had actively reached out to educate the NCI-designated cancer centers about the NCCCP and to highlight the mutual benefits of collaboration.

In this chapter, we address sites' experiences with the NCCCP network, which refers to the network of 16 pilot sites and the NCI staff working with the sites. We also discuss sites' experiences with developing or strengthening relationships with NCI-designated cancer centers and Community Network Programs (CNPs). We explored sites' experiences with the NCCCP network primarily during the Year 2 site visits. In the Year 3 site visits, sites shared updates on their progress in developing or strengthening relationships with NCI-designated cancer centers and CNPs.

NCI and its prime contractor, SAIC-F, through their programmatic or contract administration responsibilities and activities, are essentially providing technical assistance (TA) and running a learning collaborative: the NCCCP network. NCI staff responsible for the NCCCP and specific program components provide information about the overarching aims of the program and mechanisms that might be used by all sites to achieve these aims; they also provide input and advice to participating NCCCP sites on their own specific program goals

and potential mechanisms for achieving them. In addition, NCI and SAIC-F work to foster peer-to-peer learning through a variety of mechanisms, including establishing and supporting the subcommittees for each program component (as described in Chapters 8 through 14) to encourage the NCCCP sites to interact with each other and with other cancer research institutions and NCI programs. Previous research suggests that several aspects of TA and learning collaboratives may influence whether and how rapidly organizations like community cancer centers will be able to innovate, to adopt/assimilate innovations developed elsewhere, or to implement well-defined elements of the NCCCP. These aspects include the type and quality of the interactions and information shared among NCI, SAIC-F, and the NCCCP sites, as well as information shared between the NCCCP sites and other cancer research institutions and programs.

We addressed sites' experience in working with the NCCCP network through a number of questions in our semi-structured interviews and discussion groups (see sample interview questions in Table 15-1). Staff involved in the day-to-day operation of the NCCCP (e.g., principal investigators [PIs], program coordinators) was asked all or most of these types of questions. System/hospital senior executives and key physicians were not asked about contact with other sites and product development because of time constraints and lack of relevance to their role. However, they sometimes commented on these topics without being prompted, and their responses were then coded appropriately.

In Section 15.1, we examine the sites' experiences with NCI subcommittees and workgroups for each program component. These groups provided significant support to and benefits for NCCCP sites. In Section 15.2, we discuss the benefits of TA from the perspective of the sites. It is important to note that we did not evaluate the impact of TA directly, but rather the sites' perceptions of how helpful it was to receive this TA. In Section 15.3, we detail respondents' recommendations for improvement. In Section 15.4, we describe the linkages that NCCCP sites have established or have tried to establish with NCI-designated cancer centers and CCOPs.

15.1 Sites' Experience with NCCCP Subcommittees and Workgroups

In this section, we discuss the ways NCCCP sites collaborated with one another and the benefits of such collaboration. The types of collaboration consisted of both formal and informal linkages. Formal linkages included participation in subcommittee conference calls and webinars. These linkages often generated discussion and led to informal connections, such as phone or e-mail exchanges and visits to other sites. For example, one subcommittee member explained, "You hear something on one of those calls and you reach out to that person." Another subcommittee member added, "A lot happens on the call, and then we e-mail after."

Sites engaged in team learning: staff thought insightfully about their sites' problems and those of other sites', synergized all sites' knowledge and skills, and worked together to resolve problems. The team-learning approach supports successful collaborations for quality improvement. As Ayers and colleagues note: "Organizations' mutual need to work together serves as the impetus for collaboration and depends on recognition of, and appreciation for, the interdependence of members in seeking solutions to shared problems. Members must have an appreciation for the perspectives of other members, feel that their needs are being met through collaboration, and accept collective responsibility for the future of the partnership" (Ayers et al., 2005, p.235).

By learning as a team, sites provided one another other moral and material support. They created a sense of "we," defining their work as a group challenge and working together to solve the problems of individual sites and common problems. In Section 15.1.1, we discuss how sites provided professional support to one another; this support was a benefit for sites dealing with implementation of a complex program. In Section 15.1.2, we examine the material support sites shared with one another. Sometimes this took the form of collaborating on a common interest, grant, or project; other times, it meant providing guidance and sharing tools.

15.1.1 Provision of Professional Support

A handful of respondents discussed receiving professional support from other sites. For these respondents, professional support was a resource that generated an *esprit de corps* and provided reassurance that others shared in their challenges. For example, one cancer center/program staff member said that she appreciated "having someone to whine to."

> *[The calls] are helpful because we're all in it together; you hear that it's not just you. When you hear that others struggle with the implementation plan, [you feel better because] so are you.* (Subcommittee member, Year 2)

Sharing common struggles proved useful for some sites as they learned about potential challenges and felt reassured that they were on the right path:

> *One of the things that I think is helpful on the calls is the presentations from the other sites. It was good to hear how others are dealing with similar situations as we are and how they are handling that.* (Subcommittee member, Year 2)

> *The most useful calls I've attended for the conference calls are when other sites have presented what they're doing. For example, [a call featuring another NCCCP site]…was reassuring to me because they had some of the other challenges, and we're going in a direction that was their direction.* (Subcommittee member, Year 2)

> *That's been a real advantage of [the] NCCCP: that connection to another cancer program that is similar to ours in terms of the challenges that they face. The issues*

> *that we face have been similar, and [the] NCCCP has helped to facilitate that communication.* (System/hospital senior executive, Year 2)

As sites embarked on implementing this complex program, subcommittee and workgroup conference calls among sites built camaraderie and confidence. Such confidence likely enabled sites to progress in their implementation plans and, as one respondent noted, enabled them to frame possible challenges as merely part of a process that others have experienced, rather than as a shortcoming of their individual site.

15.1.2 Provision of Material Support

As a result of team learning, the overwhelming majority of site respondents found the linkages they made with other sites to be helpful. Site respondents noted how learning from other sites helped them to address their local implementation concerns. For instance, one respondent commented generally on the support that linkages with other sites provided:

> *To be able to pick up the phone and talk with someone through [the] NCCCP, it helps us improve our practices. We have learned and shared what works.* (Subcommittee member, Year 2)

This sharing among sites constitutes material support, which respondents said took multiple forms, including collaborations based on a common interest and sharing guidance and tools.

15.1.2.1 Collaborations Based on a Common Interest

Respondents discussed working with other sites when they shared a common interest or goal. Collaborating on a shared interest suggests that information exchange is reciprocal, with each participant in a discussion offering insight and information to the others. Respondents from the majority of sites spoke of collaborating with other sites based on a shared issue. When asked if his site had informal contacts with other sites, one PI explained:

> *It's not the site as much as the common interest. If another site has a common interest, we collaborate with them. I haven't found any site that was not open, except maybe one.* (PI, Year 2)

Having a common interest was a driver for several discussions and special projects, such as the relationship with the H. Lee Moffitt Cancer Center and Research Institute (Moffitt), outreach to specialized populations, and smoking cessation counselors:

> *We did a lot the first year with [another NCCCP site] because we're similar facilities in that we service a large regional area with Native Americans and rural residents.* (Cancer center/program staff, Year 2)

> *I think exchanging information with other sites has been helpful, particularly [with] those that are also participating in the Moffitt partnership. We've been talking to those sites to see how they are doing this.* (Subcommittee member, Year 2)

> *Now, in the second half of the year, I've had more contact with [three NCCCP sites]. It seems like you reach [out] to people when you're doing something [in] common. I sent out an e-mail when we were looking to do something on smoking cessation counselors.* (Subcommittee member, Year 2)

Similarly, respondents collaborated on developing standard benchmarks for aspects of their programs:

> *What we're really trying to do is work with the other sites to come up with a uniform way of approaching clinical trials in a way [that] we can measure baseline, outcomes, and accrual, and reaching disparate populations.* (Cancer center/program staff, Year 2)

> *We've had several interactions with other NCCCP sites. We've grown a lot over the course of the year, and the program has been beneficial to us in allowing [us] to grow our programs and learn something to modify them and make them work. One of the fun things about it has been the opportunity to collaborate and benchmark with the other sites.* (PI, Year 2)

Having standard—and eventually pilot-tested—benchmarks can ultimately benefit all of the NCCCP sites. These benchmarks can help sites gauge their progress and, when appropriate, make adjustments.

Sites have also collaborated to leverage other resources. Having worked together over the past 3 years, several sites had built relationships that helped them coordinate funding applications:

> *One of the other helpful things when we talk to the other NCCCP sites is [asking] "How do you fund things?" Almost everyone has tapped into Susan G. Komen for funding. It's beneficial to find out how other resources are available.* (Subcommittee member, Year 2)

> *On the executive call last week, [one NCCCP site] was working with another NCI site with regards to evaluating [the] NCCCP from a certain perspective. Whatever NCI sent her they shared with us. It's also a P30 grant. So we would link up through that P30 grant. These P30 grants are competitive and are $750,000, and five sites will be chosen. The site leading this effort—I think it's [another NCCCP site]—will partner with as many NCCCP sites as possible.* (Cancer center/program staff, Year 2)

Interestingly, sites could have defined one another as competitors for funds, such as Komen Foundation or other NCI funds, and refused to share information about opportunities. However, the data illustrate that sites helped each other to find and apply for funding.

15.1.2.2 Sharing Guidance and Tools

Respondents shared guidance and tools, for example about particular programmatic challenges. Every site had at least one respondent who mentioned learning from another site. For example, multiple respondents described a specific tool or piece of advice they gained from another site:

> *[We asked another site,] "Should we do this or not?" We're using the patient assessment tool they developed, the data collection tool. We're waiting for an update on that. We may or may not implement the updated version.* (Cancer center/program staff, Year 2)

> *I think there are ideas we've gained.…We have an advisory board of cancer survivors here, and one of the things they want us to do is have more offerings for children—whether it's children with cancer or children whose parents or relatives have cancer. [One NCCCP site] did a presentation on a backpacking program for kids that was helpful to look at. So definitely we gain ideas from them.* (Subcommittee member, Year 2)

> *[One NCCCP site] had good information about going out to physicians—and they actually get dermatology referrals—so hopefully we'll be able to work with them to see if they have a fax form or [determine] what info they send out to the dermatologists to get interest in referring.* (Subcommittee member, Year 2)

> *I have a great relationship with [another NCCCP site]. They have a nurse navigator and documentation tool that assists in data gathering that has been very helpful.* (Subcommittee member, Year 2)

As mentioned in these examples, respondents, upon hearing about tools during presentations, often sought additional information for specific tools. Some respondents identified other sites as more advanced or models in particular areas and turned to those experts for in-depth guidance. The in-depth guidance often involved respondents going on a site visit to another site and spending more time with their counterparts at the "expert" site. Two cancer center/program staff members described how they have sought advice from leaders:

> *For [one NCCCP site], when our navigators spoke with them, it was nice to connect with someone who already had an established program, because we were brand new. It was nice to get some initial questions answered, and we are hoping to do a site visit out there this summer. When I have contacted [an NCCCP site], it has been*

> *for research questions [and] logistical issues like capacity of research coordinators. It helped with programmatic questions. There were a few people that went on a site visit to [an NCCCP site] to take a look at what they have established and the tools they have to help us get our program established this summer. Three people went, and the rest of us did it via teleconference. The sites we have contacted for what we needed have been so much more advanced, so it's been good information. The information that they shared that has helped us the most is how they overcame different problems.* (Cancer center/program staff, Year 2)

> *Since it is a new initiative, we have been reaching out. We didn't have a navigator at the time, but we were able to send someone to [an NCCCP site] and that was very helpful. [One NCCCP site] has at least half a dozen [multidisciplinary care conferences] already. [One staff member] went to [another NCCCP site] to work with their outreach coordinator.* (Cancer center/program staff, Year 2)

As they implemented aspects of their programs, respondents drew on the knowledge and expertise of other NCCCP sites that they saw as more established. The more established sites provided a model for how to implement programmatic components, but they also told their implementation stories, including the challenges they faced and their strategies for managing these challenges. In this way, they informally offered TA to other sites.

Respondents from two sites noticed that other sites often sought their advice. These respondents commented that they felt that they were leaders among the NCCCP sites:

> *I consider us to be in a leadership role in helping to assist and drive other institutions that aren't as familiar with the clinical trials process, so I think that's been something that's been our primary goal—not that we've gained a lot from it, but [we have been] providing leadership to other sites.* (Subcommittee member, Year 2)

> *It's been a great collaboration because we've actually shared our standard operating procedures, our evaluation materials, our orientation checklist, and a lot of our materials with the other sites; and we have also had a few site visits here. [One NCCCP site] came and [a subcommittee member] from [another NCCCP site] came and spent the day here. We're a resource. We get calls and e-mails from other NCCCP sites asking for guidance.* (System/hospital senior executive, Year 2)

Although these two sites identified themselves as leaders and resources for other sites, both also had respondents who mentioned soliciting advice from or collaborating with other NCCCP sites. Thus, assuming a leadership position did not preclude a site learning from others.

The sharing of lessons learned among NCCCP sites helped sites solve problems and head off possible troubles:

> *You're exposed to new ideas and different ways of doing things. Things [other sites have] learned from implementation [have helped], so we don't make the same blunders*. (Cancer center/program staff, Year 2)

Two subcommittee members discussed how the information they gained from a workgroup call caused them to modify their staffing model:

> *I know a couple of us had discussions offline about the staffing models that we discussed on the best practices workgroup, and we decided that it didn't make sense.* (Subcommittee member, Year 2)

> *They actually decided to abandon that [staffing model] because it was too difficult to do, and it wasn't getting useful information.* (Subcommittee member, Year 2)

The ability to get advice from other sites quickly via the listserv proved beneficial for another site. A subcommittee member described posting a question and receiving multiple responses:

> *I posted one [message to the listserv] yesterday. We're trying to figure out how to bill and get good reimbursement for genetic counseling. So I threw an e-mail out there, and I've gotten three replies from three different NCCCP sites.* (Subcommittee member, Year 2)

The varied forums that the NCCCP offers have supported implementation processes among the NCCCP sites. Sites have learned valuable information and strategies for managing their local concerns. This knowledge, in turn, may have conserved resources (financial and emotional) by allowing sites to implement components strategically and appropriately and by helping sites to avoid ill-fated paths.

Overwhelmingly, sites appreciated this sharing. What is most telling is sites' commitment and willingness to provide guidance and share stories, including failures, so that others could learn and grow. In this sense, these sites exemplify the goal of improving cancer care across the nation, and their attitude toward sharing speaks volumes about the collaborative environment that NCI has fostered through the NCCCP.

15.2 Experiences with Technical Assistance

Throughout the pilot program, NCI has provided TA to the sites. Unlike other models of TA provision in which the grantor provides TA to the grantee, sites shared with NCI the responsibility for developing ideas for guidance and TA. This model was by design: NCI conceived of the NCCCP as a private-public partnership, which placed the sites as collaborators in program development rather than only as recipients of funding.

NCI played a critical and lead role in the provision of TA, and the sites generally found this TA to be helpful. When describing their experiences with NCI, respondents often acknowledged specific individuals at NCI:

> *[NCI staff member] is on the CT phone call. Her input is important because she is right on the cutting edge.* (Subcommittee member, Year 2)

> *[NCI staff member] at NCI and [PI] at [our hospital] have both been so supportive—I even have their cell phone numbers.* (Subcommittee member, Year 2)

> *[NCI staff member] has given a lot of resources, and you can go on to the Web site and order supplies as needed.* (Subcommittee member, Year 2)

> *NCI has made [TA] available and it's up to you. For example, [NCI staff member] is coming to visit [our site] and speak, [NCI staff member] has been willing to have phone calls, and I've talked with [NCI staff member] about the CHESS [Comprehensive Health Enhancement Support System] potential project. I think [NCI staff member] set that stage upfront that they're a valuable resource. [Staff members] at SAIC-F have been helpful, but [SAIC-F staff member] in particular is an excellent puller-together of ideas and stimulating individual [with] unique, creative thinking. She's done the conditions of participation, some of the [multidisciplinary care] and genetics work, and is a good resource for the project.* (Subcommittee member, Year 2)

> *I know [TA] has happened from an IT perspective. [NCI staff member] has been extremely helpful, and I believe that's occurred with biospecimens as well.* (Subcommittee member, Year 2)

Although respondents resoundingly affirmed the value of the NCI staff and the TA provided, most respondents did not emphasize particular outcomes or address specific applications of the TA received. (The one exception was a subcommittee member who commented that NCI "facilitate[d] rapid attainment and [Rapid Quality Reporting System])." Instead, respondents spoke in generalities about the usefulness of the TA:

> *I think it's been beneficial in part because the conference calls are like a lecture on a given topic. [NCI facilitators] give a topic, and someone just talks about something that might be of interest to everyone that works on the topic.* (Subcommittee member, Year 2)

Generalities in the interviews may have arisen, in part, because respondents typically characterized the TA in terms of addressing broad goals rather than as specific TA to the site:

> *I don't really think of the things from NCI as TA. Their value to us is getting people from different sites together to solve the problem. I don't see NCI saying, "Here's*

> *how you get caBIG to work with your computer." But this is a new program; maybe they don't know. I see them as setting goals and guidelines and letting us, as a group, solve problems.* (PI, Year 2)

> *I don't see it as technical. Listening to what they provide on the phone, I wouldn't call it technical assistance. It's really updates, rather than how would you solve this problem.* (Subcommittee member, Year 2)

> *TA depends on the subcommittee. The committees are like general oversight, best practices, and getting perspective from other pilots.* (Subcommittee member, Year 2)

One respondent suggested that the youth of the program means that NCI may not have all the answers. Thus, NCI has played a coordinating role so that program participants could resolve problems through collaborating with other sites:

> *It's hard for me to find any fault with the support. We knew all along that this was going to be a new venture and we'd be in discovery mode together, but the NCI leads have been present on the calls and have been receptive when I've had questions. [NCI staff members] and SAIC-F has been responsive. In situations where we wanted more information on how to do something, the onus is really on us to create a methodology and work with the other grantees and work with the subcontractors. NCI has been supportive. Sometimes they answer a question with a vague response only because there's not clear information on that [issue]. I think they've been absolutely fine.* (PI)

Only two respondents, representing two sites, had any complaints about TA. The first respondent commented that the committee chair needed to be stronger:

> *I guess you could call it TA, but it's not working that well.… They need a stronger resource in the committee chair role and probably they just don't have enough hands/people working the projects.* (Subcommittee member, Year 2)

The second respondent felt that the TA could be better tailored to the site and commented that the existing TA was based on an older understanding of their implementation plan:

> *For technical assistance, if NCI leads had come to the sites it would have helped for them to see the program in action. They are basing their information on reporting on a 3-year-old proposal. The best way to see something and how well it is working is to see it in action, but until you go and see if for yourself, you don't have the appreciation for it.* (Subcommittee member, Year 2)

The sites were generally very positive about the TA they received. Although respondents did not discuss specific outcomes or changes in practices resulting from the TA, they did find the process and information useful. Moreover, they discussed soliciting information from the

NCI experts when they had questions, which suggests that they were receiving tailored guidance that would be taken into consideration and possibly enacted in their sites.

15.3 Recommendations for Improvement

As discussed in the previous sections, respondents were overwhelmingly positive about the NCCCP, their relationships with other sites, and the guidance they have received. They did, however, offer a few suggestions for improving the program. Their recommendations included

- reducing administrative burden,
- sharing evaluation and survey findings, and
- developing a better understanding of sites' challenges.

For the first recommendation, respondents requested that NCI minimize and prioritize NCCCP deliverables and reporting requirements. For the second recommendation, respondents hoped to learn more and get feedback from NCI on all of the data they have submitted thus far, which could support local program improvement and revision. For the third recommendation, respondents asked NCI to take into consideration sites' capabilities and capacities, especially with regards to implementing caBIG and caTissue. We address each of these recommendations in the following sections.

15.3.1 Reduce Administrative Burden

The majority of respondents requested that NCI reduce administrative burden. Respondents explained that the reporting requirements consume a lot of time, detract from research and clinical care, and sometimes apparently do not add value:

> *Sites would say that there's definitely scope creep, and it is not insignificant in terms of workload.* (System/hospital senior executive, Year 2)

> *NCI has made strides in the right direction, but the reporting mechanism is still burdensome. We're creating Joint Commission-level documentation in terms of detail. What are the outcomes: number of CTs, number of doctors? That's a one-page report. It takes our staff a lot of time that could be spent on research and clinical care. It's not for regulatory purposes.* (Subcommittee member, Year 2)

> *NCI needs to cut down administrative burden. It sounds way too burdensome…. There are way too many conference calls. There was some correct attention paid to the fact that a lot of the cost of the contract was being absorbed that I could dump this on the assistant, but then they had three more forms for us to fill out. At least 50% of the time is spent on administrative work. It is a burden, and they have got to be sensitive to that. If they make the NCCCP painful enough, good places won't want to do it. If you could, take the non–value added work and reduce it. I went to the*

> *meeting in Dallas, and half of it was something that we didn't end up using. At the highest level, every deliverable has to be considered; you can't have some doctor under some small subcommittee add on deliverables.* (PI, Year 2)

In addition to the amount of information required, respondents commented that collecting large quantities of data in short timeframes was difficult because of how cancer centers are organized:

> *Hindsight is 20/20 with a lot of this. The timing with reporting requirements has often been intense; the due dates have been very short. In a cancer center, getting something done in a week is very hard to do.* (Program coordinator, Year 2)

> *It takes me a long time to fill out the quarterly report. What we aren't doing well enough yet is [determining] how do we keep track of screenings because we do so many screenings in the clinics, and I just found out that there's somebody in the clinic who could help with that. And to get the numbers from the laboratory is difficult because we don't own them, and then to figure out where the clinics send their pathology to if they don't send it to [local vendor] pathology [is difficult]. I can't collect the information right now because it's in too many different poles. I think the other thing I've struggled with is the patient survey. When they told us they wanted 70% return, we told them they were crazy, and we hand-addressed our envelopes. We got 31% on the first go-round, which I thought was pretty good. I think they were expecting too much. It wasn't a horrible burden to send out the surveys. I know some of the other sites complained that sending out over 475 surveys was a lot.* (Program coordinator, Year 2)

As the second quote illustrates, sites have not historically collected and centralized particular kinds of data. Amassing these data for the NCCCP requires multiple steps and actors. Coordinating these activities and gathering data from "many different poles" is not easy to accomplish and requires a lot of administrative time.

Respondents involved in the IT subcommittee found the implementation plan burdensome. According to these respondents, the implementation plan asked for too many details at an inappropriate time:

> *The implementation plan was premature. We had just done that goals document, and my perspective was that this should be done from an implementation standpoint. Other sites had the same experience, and we were told the NCI-designated sites had to do it as well.… Knowing what they know now, people probably would not do this program again. Do we really need so much specific detail around implementation right up front? No. It's a waste of resources. I believe there's good in the project. It was good that we went with this project because we're offering our patients things we never had before.* (Subcommittee member, Year 2)

In short, respondents asked that the NCCCP minimize reporting requirements and relax deadlines, especially for sites where no central repository for cancer data exists. More generally, as the PI above commented, "take the non–value added work and reduce it." This recommendation proposes that NCI examine each deliverable with an eye toward how it fits into larger program goals and how it can benefit sites. Sites could then learn from NCI the value each deliverable adds and have a better understanding of how each fits into the big picture.

15.3.2 Share Evaluation and Survey Findings

During each of the site visits, the evaluation team routinely heard requests for feedback on findings. As one subcommittee member succinctly put it, "Will we ever hear anything from this? I don't even know what they're looking for." The sites dutifully collect data, but as this subcommittee member expressed, some sites do not understand the purpose of the data. Similarly, respondents wanted to know how well they are doing and hoped to use findings to improve their programs:

> *The program focuses you clearly on the six pillars and the data. We don't have data back to tell others about the benefits [of NCCCP]. I'm hungry to get the data back, enrollment numbers, etc. I think it could be a strong shot in the arm. What does this look like across pilot sites, and how can it feed us back in? It would help identify the challenge areas, and the same old issues are right there.* (System/hospital senior executive, Year 2)

> *It would be nice to have a summary on how all the sites are doing: common themes, how all the sites are doing, what we're all doing, and what we're not doing.* (Program coordinator, Year 2)

> *You never really get that feedback from NCI if you're on the right track.* (Program coordinator, Year 2)

> *I guess I'd like to see data on how we're doing on [the] number of trials and accruals. For example, have we enrolled more patients as a whole and have we accrued more minorities? It would help to know across sites best practices for clinical trials accruals and what RTI learns from other sites as to what has worked well.* (Subcommittee member, Year 2)

In addition to having a short-term interest in receiving feedback, several respondents—all hospital senior executives—elaborated on how feedback has long-term implications for cancer center planning:

> *This is a high level/systems kind of thought: at the end of this period, that NCI will wrap up this work and make it known what worked and what it learned. Here's what worked, here's what didn't. I would love to hear that back from NCI. People are*

> *always concerned about government entities, and reports don't come out [until] years later. Everyone hopes that enough good comes from this that another opportunity arises. Sitting several steps removed, I see different things. I assume NCI, several layers removed, can see other things.* (System/hospital senior executive, Year 2)

> *First, it's really demanding to pull reports together; and second, they can see the value in it once it's done. I think the third thing is "What happens at the end of the program?" We're making a multimillion dollar commitment to becoming a major cancer center in the region, but we don't know what is going to happen with the program.* (System/hospital senior executive, Year 2)

As illustrated by the last quote, the findings from the NCCCP could shape the direction the cancer centers pursue in the future. In this way, by sharing the findings and lessons learned, NCI has an opportunity to have an impact on the trajectory of the participating cancer centers.

15.3.3 Develop a Better Understanding of Sites' Challenges

A minority of respondents commented that NCI needs to have a better understanding of the sites' challenges. By and large, these respondents focused on the IT component. They shared that caBIG did not align well with how CCCs work. As one subcommittee member said, "caBIG is designed for NCI cancer centers. NCI has a hard time understanding how we work." Other subcommittee members made similar comments:

> *I'm a listener on the [subcommittee conference] call for the most part. My opinion was that they didn't really understand what the role of a community cancer program's business is and how technology plays with that. If we were fully rolled out with all our core business technology—and we're looking at now what do we do specific to research or specific to these parts of our business—then we could look at some of the tools to see if we [are going] down that path, but it seemed like the tools were the drivers of the IT committee [with regards to] caBIG, and the whole implementation plan was to tell us how you're going to use caBIG even though that's not a requirement of the plan, and [caBIG's systems are] not appropriate for us at this time.* (Subcommittee member, Year 2)

> *Because we're not technically an education institution, we don't have bench research. We're just more of you-bring-a-tissue-down-and-we-make-a-diagnosis pathologists. So some of that goes right over our head. There are other entities, like [NCCCP site], that are involved in this and have a more vested interest than we do. It would serve us a purpose if we were doing more bench research at the clinic, but because we don't, it's not something that's high on our priority list.* (Subcommittee member, Year 2)

In spite of these concerns, one respondent, not focused on IT, offered a possible solution. He recommended that NCI should incorporate the perspectives of non-research staff into the design and implementation of the NCCCP:

> *One way would be a key informant process, and they [NCI] should meet the frontline nursing staff, doctors, meet the people who aren't doing research. They need an advisory panel they really listen to, people who aren't big investigators. Invite people who have gone through grants. NCI and NIH are behemoths, and I don't know who to go to if I had an issue. I know where CTs are on the Web, but it's a cumbersome process.* (Subcommittee member, Year 2)

As the NCCCP progresses, NCI may wish to examine how to integrate the perspective of the CCC end-users into the development and refinement of caBIG. Doing so may also support collaboration across the typical caBIG users (e.g., academic medical centers) and CCCs. CCCs might then be better able to provide information that is useful for larger trials centered in NCI-designated cancer centers.

First, reducing reporting requirements and prioritizing NCCCP deliverables would help sites to conserve resources and mobilize them more appropriately. Second, sites hoped to get feedback from NCI, which would help sites to measure their progress and determine areas for local program improvement and revision. Finally, especially with regards to IT, sites asked that NCI take into consideration the needs, capabilities, and capacities of community hospitals and cancer centers.

15.4 Collaborations with NCI-Designated Cancer Centers

This section deals with the collaborations sites (i.e., formal and informal working relationships) have established (or been unable to establish) with NCI-designated cancer centers. The active collaborations have enriched sites in a number of ways. However, developing relationships has not always been a smooth process: in building such relationships, sites have encountered barriers. These barriers have centered on perceived competition between NCCCP sites and NCI-designated cancer centers and on administrative challenges.

With one exception (Site 14), all sites reported having formal or informal relationships with one or more NCI-designated cancer center by Year 3 (see Table 15-2). Note that the numbers in Table 15-2 do not include relationships that involve referral of cases for clinical trials only. From baseline to Year 3, six sites reported an increase in the number of NCI-designated cancer centers with which they had relationships; five sites reported no change, and five sites reported a decrease. In addition to relationships with NCI-designated cancer centers, sites also developed relationships with Community Network Programs. According to data collected by SAIC-F, seven sites had developed such relationships by Year 3 (none had relationships with CNPs at baseline) (see Table 15-2). In Year 3, the sites identified the specific NCI-designated cancer centers in **Table 15-3. Collaborations[a] with NCI-Designated Cancer Centers: Year 3**

Site	**NCI-Designated Cancer Centers**
Data Source	**FAS**
Ascension Health	
St. Vincent (Indianapolis, IN)	H. Lee Moffitt Cancer Center and Research Institute Melvin & Bren Simon Cancer Center, Indiana University
Brackenridge (Indianapolis, IN)	—
Columbia St. Mary's (Milwaukee, WI)	UW Paul P. Carbone Comprehensive Cancer Center, Univeristy of Wisconsin
Catholic Health Initiatives	
St. Joseph/Towson (Towson, MD)	Greenebaum Cancer Center, University of Maryland University of Chicago Comprehensive Cancer Center Wake Forest Comprehensive Cancer Center, Wake Forest University
Penrose-St. Francis (Colorado Springs, CO)	University of Colorado Cancer Center
Good Samaritan (Kearney, NE)	Mayo Clinic Cancer Center
St. Elizabeth RMC (Lincoln, NE)	Eppley Cancer Center, University of Nebraska Medical Center
St. Francis Medical Center (Grand Island, NE)	Eppley Cancer Center, University of Nebraska Medical Center
Non-system Sites	
Billings Clinic (Billings, MT)	H. Lee Moffitt Cancer Center and Research Institute Mayo Clinic Cancer Center Siteman Cancer Center, Washington University Medical Center University of Colorado Cancer Center
Christiana (Newark, DE)	Kimmel Cancer Center, Thomas Jefferson University
Hartford Hospital (Hartford, CT)	Dana Farber Cancer Center, Harvard University H. Lee Moffitt Cancer Center and Research Institute University of North Carolina Lineberger Comprehensive Cancer Center Paul P Carbone Comprehensive Cancer Center, University of Wisconsin Yale Cancer Center, Yale University School of Medicine
Our Lady of the Lake (Baton Rouge, LA)	H. Lee Moffitt Cancer Center and Research Institute University of North Carolina Lineberger Comprehensive Cancer Center The Vanderbilt Ingram Cancer Center, Vanderbilt University Wake Forest Comprehensive Cancer Center, Wake Forest University

St. Joseph/Orange (Orange County, CA)	City of Hope National Medical Center
St. Joseph's/Candler (Savannah, GA)	H. Lee Moffitt Cancer Center and Research Institute Hollings Cancer Center, Medical University of South Carolina
Sanford Clinic (Sioux Falls, SD)	Mayo Clinic Cancer Center University of Colorado Cancer Center Paul P. Carbone Comprehensive Cancer Center, University of Wisconsin

as partners for their NCCCP-related activities.

Four sites[1] were participating with Moffitt as part of the Total Cancer Care program for biospecimens collection (see Section 15.4.1.3). According to respondents, receiving an NCCCP award helped to "open the door" for developing new relationships with NCI-designated cancer centers or strengthening existing ones. Receiving an NCCCP award raised the cancer center's stature and visibility and changed perceptions about it. One physician said, "They [three NCI-designated cancer centers] are beating at our door. They want us because of our accruals and [the] NCCCP." Another respondent said that opportunities with NCI-designated cancer centers had snowballed; NCCCP involvement led to the opportunity with Moffitt, and success with biospecimens collection in turn opened the door to collaboration with another NCI-designated cancer center:

> *It sets up the fact that we're not "just [a cancer center]". When people come to look at these NCCCP sites, they see a little bit of themselves; they see a desire by doctors who want to get better.* (Key physician, Year 3)

> *[The] NCCCP has changed how we work with [NCI-designated cancer center]. Because of our success with Moffitt, they are more interested in us.* (Cancer center/ program staff, Year 3)

One PI listed five collaborations that have arisen or are in process because of the NCCCP. He said, "We've stepped up our collaboration with [NCI-designated cancer center] as a result of [the] NCCCP. [Without the NCCCP], I'm not sure we would've done it." Another PI commented, "The NCCCP has helped with improving our linkage with [NCI-designated cancer centers]…. I think that this is an important part of [the] NCCCP: Getting community hospitals hooked up with the NCI centers." The types of collaborations included clinical trials, outreach and screening, survivorship programs, bioethics, multidisciplinary care, and (with Moffitt) biospecimens collection.

15.4.1.1 Benefits of Collaboration

These linkages have afforded several advantages for the cancer centers: access to expertise and guidance, expansion of research activities, and opportunities for funding or other resources. We address each of these advantages in turn.

[1] Hartford Hospital, Our Lady of the Lake, St. Joseph's/Candler, and St. Vincent.

Access to Expertise and Guidance

Developing collaborations with NCI-designated cancer centers has given sites opportunities to learn from other organizations with different approaches to cancer care:

> *We've had a research affiliation with [NCI-designated cancer center] for several years, and we continue to work with them. Over the last year, we've increased programmatic relationships with them. In disparities, we've now done several site visits to their mobile mammography and outreach programs in [local city] to learn about their programs. We've also done survivorship visits to their [center]. Outside of clinical trials, it's mainly been survivorship and disparities. In terms of mobile mammography, they've just gone digital, and we're looking at that. They've been very, very helpful.* (PI, Year 2)

> *We also started talking with the [NCI-designated cancer center] because of caTissue and caArray. They have a lot of intellectual capital, so when you go out to them, the flow of information is from high to low. When it comes to caBIG applications, they've been at it longer than we have, so it is helpful for navigating and sharing knowledge.* (PI, Year 2)

The collaborations with NCI-designated cancer centers have introduced NCCCP sites to innovations in cancer care and helped respondents begin thinking about how they might implement similar programs in a community hospital setting.

Expansion of Research Activities

Collaborating with NCI-designated cancer centers also expanded sites' participation in research and strengthened their research capacities. Extension of research capacities included collaborating with NCI-designated cancer centers on grants; sharing physician staff (i.e., joint appointments); and increasing the number, type, and quality of clinical trials. In particular, partnerships with NCI-designated cancer centers allowed sites to open early phase clinical trials. Respondents discussed these various activities:

> *We work with [NCI-designated cancer center], so we have some grants in common with them, so we work with them quite often. We're in the process of applying for other grants. Our physicians have joint appointments with them. We interact with [another NCI-designated cancer center] by participating in some of their research grants. We have a network agreement that we would participate in some of their studies with [NCI-designated cancer center]. With [NCI-designated cancer center], we're usually designated as one of the co-PIs. They allow us to see the patient here and enroll the patient in the study and send the data to [NCI-designated cancer center].* (Subcommittee member, Year 2)

> *We are an affiliate site of [NCI-designated cancer center], which entails that we are able to participate in their NCI-based trials, and our physicians could be PIs and work on investigator-based trials with them.* (Cancer center/program staff, Year 2)

> *The main relationship we have with [NCI-designated cancer center] is referrals to Phase I trials. We will soon have Phase I [trials] with [an NCI-designated cancer center]. The secondary relationship with [NCI-designated cancer center] is that we have breast cancer and prostate cancer tissue and biospecimens research study, and they will become more important once the biospecimens repository is open. It will be [a] mutual exchange of specimens. This will be the first time that a community cancer center is doing research for an NCI-designated cancer center. It's exciting that we are doing it with our grant.* (PI, Year 2)

> *One of the limitations with [the Gynecology Oncology Group] is we don't have access to Phase I trials because you have to be a member. Now we have the opportunity to do this through [two NCI-designated cancer centers].* (Key physician, Year 3)

> *Being able to have clinical trials support from other academic centers and allowing us to partner with other comprehensive centers in our immediate vicinity, like [NCI-designated cancer center] is beneficial.* (Key physician, Year 3)

Collaborations with NCI-designated cancer centers helped sites to expand their research efforts and capacities. Sites that could not historically manage certain types of trials single-handedly could pair with cancer centers accustomed to such activities. Strikingly, respondents also spoke of the relationships as truly collaborative (e.g., "our physicians could be PIs and work on investigator-based trials with them"). This suggests a high degree of collegiality between the NCCCP sites and relevant NCI-designated cancer centers. Section 16.1.4 provides further discussion of sites' research capacity as it relates to overall success.

Opportunities for Funding or Resources

Finally, respondents discussed how their relationships with NCI-designated cancer centers have allowed them to leverage other sources of funding or resources. Respondents typically spoke of working with NCI-designated cancer centers on grants, such as R01, P30, U54, and Clinical and Translational Science Award grants:

> *I've got high-quality people here that are dealing with high-quality people there. We have an R01 program with [cancer center staff member] who heads the prevention up at [NCI-designated cancer center]. [One of our staff] has part of that with colorectal cancer screening. We would've never had that [program] without [the NCCCP]. We have an R01 with [hospital staff member] who heads the clinical pharmacology program at [NCI-designated cancer center] related to colorectal cancer. We would've never had that program.* (PI, Year 2)

> *We have a formalized relationship with [NCI-designated cancer center] to participate in [their] cancer network using cancer restitution funds. In addition to that, we have a relationship with the PI, so we have been involved through a U54 NIH Disparities Research grant, and we are the recipient of the Impact of Improving Disparities Participation in CT grant. There is a collaboration we are doing directly with [NCI-designated cancer center]. We have [two staff members, one of whom] is a community outreach coordinator, and have been able to fund [this] position through the grant with [university].* (PI, Year 2)

> *We were also called by [NCI-designated cancer center] a couple of weeks ago to partner with them and another NCCCP site to get the supplemental P30 grant. It's not very much money, but we're excited about that grant. It's focused on clinical trials, survivorship, and health disparities. We told [the grant organizer that] we are there. He just needs to find one more site. We've recommended [two other NCCCP sites]. So he's making those contacts.* (Cancer center/program staff, Year 3)

> *We got hooked up with [key physician] and brought in one of his clinical trials. We got him lots of patients, we gave him his own nurse, and got him everything on time. Ever since then, he's been singing our praises. He came here and presented four new studies, NCI grants that he wants to write us into. In one of our [American Recovery and Reinvestment Act] projects, they submitted a letter of support for us.* (Program coordinator, Year 3)

Overall, the collaborations with NCI-designated cancer centers have proved beneficial for NCCCP sites. They have gained valuable knowledge, the ability to conduct more research, and additional funding opportunities. However, the sites did not uniformly have an easy time developing such relationships, and sites continued to address barriers in Year 3.

15.4.1.2 Barriers to Collaboration

Sites encountered some obstacles to establishing or strengthening linkages with NCI-designated cancer centers. In some cases, the most logical collaborator, the local NCI-designated cancer center, was a direct competitor in a given market. In other cases, the NCI-designated cancer centers did not understand the role of the NCCCP and were wary of embracing the NCCCP sites. Lastly, some sites faced internal challenges as hospital administrators, trying to manage the effects of the economic downturn, slowed the process of developing relationships with NCI-designated cancer centers.

Competition

A few sites with an NCI-designated cancer center in their market discovered that a likely collaborator was not always a willing partner. In each case, the NCI-designated cancer center was reluctant to develop a partnership because of the market competition between

them and the NCCCP site. Respondents from these centers were disappointed in the lack of progress with the local NCI-designated cancer centers:

> *What is a brick wall is our local NCI center. We talked to part of [the local NCI-designated cancer center and another local competitor]. We offered face-to-face to take some of the charity care. Uniformly, when it gets to the level of the cancer center, they don't want to have anything to do with us. We're competition.* (PI, Year 2)

> *[An NCI-designated cancer center] is active in our market, and they are kind of a competitor, and in the areas where we can collaborate, we are open to it. I don't think we get the same response from their side.* (Cancer center/program staff, Year 2)

> *I think NCI-designated cancer centers might think of us as a threat. There has to be a better way to collaborate, particularly for clinical trials, because that's why people leave.* (Key physician, Year 3)

Some sites said that NCI-designated cancer centers' concerns about competition had subsided over time as they learned more about the NCCCP and realized that collaboration could be a "win-win." One PI observed, "In our early days, there was all this animosity from the director of the comprehensive cancer [center] that money was being taken away from them and given to us." However, this PI reported that collaboration had improved as the NCI-designated cancer center recognized the benefits of collaboration: "We've got the volume, so let's create a win-win."

NCI certainly cannot change market conditions, but if creating partnerships in local markets becomes a priority, then NCI may consider other forms of incentives to promote such linkages.

Administrative Barriers

Respondents from two sites discussed administrative and organizational barriers to developing collaborations with NCI-designated cancer centers. The first explained that they want to move forward but that the administration was concerned about the economic implications of such a relationship:

> *As far as NCI-designated cancer centers, we really want to get our [NCI-designated cancer center]. We've had some struggles with that. They did give us an agreement to become involved with them, and it's been sitting up in administration. Administration doesn't really have a desire to move forward with it. The only concern I had was it was of course heavily involved with clinical trials; however, there was no mention about any funds to assist. Even if we would enroll any patients through their facility, we wouldn't be getting anything.… [Another NCCCP site] did go ahead and*

> *sign up with that agreement. [NCI-designated cancer center] has a really nice cancer registry—one for pancreatic, breast, etc. These are Web-based systems where the patients can also access that information. We'd really like to get involved with that. We're hoping by the end of this year to have some kind of agreement set up.* (Cancer center/program staff, Year 2)

Another respondent commented on the difficulty of creating a collaboration and negotiating the needs of multiple system sites.

> *Most recently, we're participating through [NCCCP site] and [NCI-designated cancer center] for a CHESS protocol, which is a computer-based information system for patients. With [NCI-designated cancer center] we are still in a holding pattern there. [A physician leader] does have contact with them, but we are just not pursuing that right now because at the [system] level we still talk about the [other system] sites affiliated with one of the NCI sites. We have come to the realization recently that we really need to make our own venture, and if something happens at the [system] level we can still participate in that.* (Cancer center/program staff, Year 2)

Misunderstandings about the NCCCP

Related to the local market competition barrier was the misunderstanding people outside the NCCCP had of the intent of the program. Initially, the NCI-designated cancer centers saw NCCCP sites as rivals for funding rather than as potential partners. For instance, several respondents commented on the chilly reception they received from NCI-designated cancer centers:

> *We have gotten some feedback that the CCCs weren't thrilled about community cancer centers, so we had to communicate with them directly.* (Cancer center/program staff, Year 2)

> *We don't hear a lot from PIs that comprehensive cancer centers welcome them with open arms. [Community cancer centers] see [the NCCCP] as competitive. The head of the comprehensive center at [NCI-designated cancer center] was particularly belligerent with [NCI staff member] at the CCOPs medical directors meeting last year.* (PI, Year 2)

To correct misunderstandings and address concerns, it may be useful for representatives from NCCCP sites and NCI-designated cancer centers to have a good discussion explaining the NCCCP, identifying areas for possible collaboration, and delineating roles. However, NCI can play a role in minimizing or eliminating barriers by sharing the unique goals of the NCCCP and the place for both academic medical centers and the NCCCP in NCI's broad vision and strategic plan.

Addressing Barriers

A number of sites have successfully addressed some of these barriers and developed new relationships or strengthened existing relationships with NCI-designated cancer centers. Several respondents described such "breakthroughs" and attributed this success to their concerted efforts to reach out to and educate the NCI-designated cancer centers about the NCCCP. These sites had hosted visits, held meetings and retreats, and otherwise reached out to NCI-designated cancer centers. For example, one administrative director described the following efforts to build a relationship: "We had two members from [NCI-designated cancer center] come down last fall in 2009 and we did a retreat with them so they could see all the things we're engaged in related to [the] NCCCP, so they could get educated."

In their discussions with the NCI-designated cancer centers, the sites tried to allay concerns about competition and highlight the benefits of collaboration, especially the opportunity to enhance clinical trials accrual by working together:

> *We set the tone that we weren't there to compete. We have different patient populations. We kind of complement each other. We can give them patients for research and make their studies more successful. I think convincing them of that has helped.* (Program coordinator, Year 3)

> *We needed to communicate that we are not competing for the same federal dollars, not competing for the same patients even. When this was seen on paper, they started to see that [NCCCP site] was not a competitor and that they could contribute.* (Subcommittee member, Year 3)

> *Our relationships with our local NCI-designated cancer care have been strengthened by [the NCCCP]. There's been a competitive atmosphere between these two organizations for a long time. We're starting to do things differently with [NCI-designated cancer center] that are very encouraging and for the benefit of the program*. (System/hospital senior executive, Year 3)

> *We broke down some barriers and misunderstandings to show that we want to augment what [the NCI-designated cancer center] is doing rather than compete, and they believed this. For example, we were able to get access to a clinical trial through [the NCI-designated cancer center]. We have talked with [the NCI-designated cancer center] about a shared fellowship. We hope to start participating in their general surgery residency.* (Subcommittee member, Year 3)

> *You have comprehensive [cancer] centers that may not have access to [the] patient population, and this is something [our site] can offer….. Also, it will help comprehensive centers with their CT accrual.* (PI)

15.4.1.3 Specific Linkages with Moffitt

As previously noted, several of the NCCCP sites were approached by Moffitt to become collaborating sites for the Total Cancer Care program. At the time of the Year 3 site visits, four sites had contracts in place. Although these relationships with Moffitt as part of the Total Cancer Care program are beyond the scope of our evaluation, we briefly describe the sites' experiences with this program below.

The purpose of the Total Cancer Care program is to systematically collect biospecimens and provide them to Moffitt for storage and research. The NCCCP sites were eager to participate because the program allows them to develop their biomedical research capabilities and provides them with the infrastructure, including staff, to facilitate this growth. However, there are also challenges involved as the sites have had to quickly expand certain aspects of their operations (e.g., IT systems, linkages across departments that may not already be working together). Some of these requirements will help them build capacity but are not included in their contract with Moffitt; thus, the hospital has had to allocate resources. One CEO expressed the benefits of this partnership, including that it would strengthen the site's relationships with the local NCI-designated cancer center:

> *We're getting ready to embark on [a] biospecimens repository, and I think that's going to be huge. Tying our center to a network of others centers around the country, either through caBIG or sharing of information, is a huge benefit to us. Our relationships with our local NCI-designated center has been strengthened by this.* (System/hospital senior executive, Year 3)

Sites experienced several other challenges, which centered primarily on resource and data requirements. One subcommittee member said, "It's requiring significant resources." Other respondents commented on the challenge of learning how to work with Moffitt and educating Moffitt about community hospitals:

> *With [biospecimens], we have Total Cancer Care from Moffitt. At first, we were figuring out how to communicate workflows, how to communicate with patients, the logistics and workflow of how to get the specimens, how to work with EHR, surgery, etc. Now the next step is sharing with Moffitt. That's what we were referring to when we were talking about the data elements. We have to pull data from different sources to build the dataset to give to Moffitt.* (Subcommittee member, Year 2)

> *We are still figuring out our work with Moffitt. We had 283 data elements and had to halve that. We signed a contract, started in July, and collected specimens from 400-plus patients. The challenge came [when] we thought data would be from that original admission, and now they want us to follow them through radiation and so forth. Moffitt understands that this is a big challenge. We have a system to send data blinded to Moffitt. We can identify them so that if we identify a potential trial for*

> *them, we can go back. Just getting to send them the data, we're at the point where we're looking to do this in the next few weeks.… Moffitt is still learning how to deal with community organizations, and we're learning how to work with them.* (Subcommittee member, Year 2)

> *They have not been good about consents in other languages. We have to pay out of pocket. We have spent $50K on IT work to get the information to them electronically so we don't have people doing it by hand or faxing forms all the time.* (PI, Year 3)

One PI contrasted participation in the Total Cancer Care program with participation in the NCCCP network, observing that Moffitt is "not as much relationship driven" and that sharing of information and best practices was more challenging compared to within the NCCCP network. This PI commented, "Moffitt was reluctant to share information, and we had to network on our own to do that."

Although there have been some challenges with implementing the Total Cancer Care program, respondents believed the collaboration with Moffitt was very beneficial. Working with Moffitt gave the sites access to expertise, which enabled them to advance their biospecimens programs. Respondents from two different sites explained the benefits of having a formal structure provided by Moffitt:

> *We knew what we would need operationally to pull it off, and the Moffitt program helped give us the structure.* (Subcommittee member, Year 2)

> *With biospecimens, our personnel are filling out the GAFAT, and our participation in Moffitt is actually implementing the gaps.* (Cancer center/program staff, Year 2)

The relationship with Moffitt also gave participating sites additional resources to conduct their biospecimens work. As one key physician said, "For Total Cancer Care, [Moffitt funds] four or five people." For some sites, the biospecimens component would not have been realized without Moffitt. One cancer center/program staff member explained that they would not have pursued biospecimens without Moffitt because the site did not have the capacity or local resources to do so:

> *FTEs will be supported by Moffitt. The pathology department is excited to participate. Because we don't have a med school or med students, we are not interested in doing a biospecimens repository in the future. I can tell you that unless a medical school came down the street, [our site] is not interested. We are interested in the greater good of research, and having someone like Moffitt to send our specimens to is great.* (Cancer center/program leader, Year 2)

15.4.1.4 Sustainability of Relationships with NCI-designated Cancer Centers

Several respondents said that although their participation in the NCCCP was what initially opened the door to new or strengthened linkages with NCI-designated cancer centers, they

believe that once the relationships had been established the collaboration would be sustained regardless of their NCCCP status. The NCI-designated cancer centers were now more knowledgeable about the sites, had a greater appreciation for the benefits of collaboration, and thus sought continued opportunities for collaboration:

> *Moffitt came looking for us because we were part of [the] NCCCP, but the ongoing relationship has nothing to do with [the] NCCCP. The initial overture might not have happened without [the] NCCCP.* (Subcommittee member, Year 3)

> *I think [the relationship with NCI-designated cancer center] will be sustained here. Even if [the] NCCCP went away at the end of next year, the ball is rolling.* (PI, Year 3)

> *[Name] from Moffitt will contact us on anything that comes up. For example, they're writing a grant and putting us as a PI to use our African American community. Having her aware of everything we're doing has made a big difference.* (Cancer center/program staff, Year 3)

The collaborations with NCI-designated cancer centers in general, and Moffitt in particular, were both challenging and rewarding. The rewards of these collaborations enhance the NCCCP sites and the program in general. Addressing misperceptions about competition between the NCCCP sites and the NCI-designated cancer centers has been the greatest challenge.

15.5 Summary

Overall, the NCCCP network has enriched the sites as they have learned from each other and benefited from the TA provided by NCI. Sites have applied guidance and lessons learned from other sites in the NCCCP network. Respondents appreciate the noncompetitive relationships among NCCCP sites, which allow them to learn from one another and share resources and information (e.g., about funding opportunities).

Many of the respondents say that the NCCCP has helped to "open doors" for building relationships with NCI-designated cancer centers because it has raised the stature of the cancer center. Over the pilot period, six sites reported an increase in the number of NCI-designated cancer centers with which they have established formal or informal relationships. However, other sites reported no change or a decrease in the number of collaborative relationships, and barriers remain, including a lack of understanding about the NCCCP and perceptions that the NCCCP sites are competitors. The sites have worked hard to increase understanding of the NCCCP and to stress the mutual benefits of collaboration.

Respondents appreciated the expertise and guidance available from NCI and through the NCCCP network. Maintaining an effective network requires substantial support and would likely not be feasible in the absence of continued funding.

Table 15-1. Themes and Corresponding Interview Questions

Theme (Section of Report Specific to Theme)	Sample Question
Benefits of sites' involvement/ experiences in NCI subcommittees and workgroups (Section 15.1)	▪ Please describe the contact you have had with other NCCCP sites, outside of the NCCCP calls and annual meeting. ▪ What other NCCCP sites have you been in contact with? ▪ How have you been in contact (e.g., by phone, videoconference, in-person visit, other)? ▪ About how often have you been in contact with each (e.g., once a month or over every few months by phone, one in-person visit)? ▪ What has been the focus of your discussions or activities? ▪ Has your site created any formal partnerships with other sites (i.e., Memoranda of Understanding [MOUs])? ▪ What has been the value of this contact or partnership to you, if anything?
Benefits of TA (Section 15.2)	▪ We would now like to ask you about your overall impressions with the level and types of TA your site has received from NCI. I would like to start by asking you about specific technical assistance your site has received individually (i.e., not via the subcommittees but in one-to-one contact with NCI staff lead). ▪ Has your site received any individualized TA? – Was this assistance been specifically requested by you or someone at this site? – What topics or issues did it address? – To what extent do you feel NCI has been responsive to any requests you have made for advice or assistance? – What do you see as the barriers to NCI providing the support and assistance that you need?
Recommendations for improvement (Section 15.3)	▪ What recommendations would you make to NCI about how to improve the NCCCP network and/or coordinate across pilot sites (both in general and specific to the survivorship and palliative care program component)? ▪ Is there anything else about the NCCCP, your cancer center/hospital/system, or your interactions with the NCI national program staff that you think would be important for us to know? If so, please describe (for hospital senior executives).
Partnerships with NCI-designated cancer centers (15.4.1) and with CCOPs (15.4.2)	▪ Now, I would like to know about external linkages, meaning those contacts or relationships that you have had with other NCI cancer institutions, including NCI-designated cancer centers, CCOPs, Community Network Programs, or any others. ▪ Please describe any contact or relationship you have developed since our last visit with other NCI cancer research programs. ▪ Please describe the nature of your contact or relationship with these other NCI cancer research programs. ▪ In what ways has participation in the NCCCP facilitated these relationships? ▪ In what ways have these relationships impacted your operations or cancer service delivery? ▪ What have been the benefits of these relationships? What have been the costs or unanticipated pitfalls you have encountered through these relationships?

Table 15-2. Relationships (Formal and Informal) with NCI-Designated Cancer Centers and Community Network Programs at Baseline and Year 3

	NCI-Designated Cancer Centers		Community Network Programs	
Site	**Baseline**	**Year 3**	**Baseline**	**Year 3**
Data Source	**BAS**	**Outcome Worksheets**	**BAS**	**Outcome Worksheets**
Site 4	5	5	0	0
Site 6	2	2	0	1
Site 10	3	4	0	1
Site 3	3	2	0	0
Site 12	5	9	0	2
Site 1	1	2	0	0
Site 9	1	3	0	1
Site 16	4	4	0	1
Site 15	3	1	0	0
Site 11	4	4	0	0
Site 8	0	1	0	0
Site 7	2	2	0	1
Site 2	3	1	0	1
Site 13	3	1	0	0
Site 5	2	3	0	0
Site 14	2	0	0	0

Table 15-3. Collaborations[a] with NCI-Designated Cancer Centers: Year 3

Site	NCI-Designated Cancer Centers
Data Source	**FAS**
Ascension Health	
St. Vincent (Indianapolis, IN)	H. Lee Moffitt Cancer Center and Research Institute Melvin & Bren Simon Cancer Center, Indiana University
Brackenridge (Indianapolis, IN)	—
Columbia St. Mary's (Milwaukee, WI)	UW Paul P. Carbone Comprehensive Cancer Center, Univeristy of Wisconsin
Catholic Health Initiatives	
St. Joseph/Towson (Towson, MD)	Greenebaum Cancer Center, University of Maryland University of Chicago Comprehensive Cancer Center Wake Forest Comprehensive Cancer Center, Wake Forest University
Penrose-St. Francis (Colorado Springs, CO)	University of Colorado Cancer Center
Good Samaritan (Kearney, NE)	Mayo Clinic Cancer Center
St. Elizabeth RMC (Lincoln, NE)	Eppley Cancer Center, University of Nebraska Medical Center
St. Francis Medical Center (Grand Island, NE)	Eppley Cancer Center, University of Nebraska Medical Center
Non-system Sites	
Billings Clinic (Billings, MT)	H. Lee Moffitt Cancer Center and Research Institute Mayo Clinic Cancer Center Siteman Cancer Center, Washington University Medical Center University of Colorado Cancer Center
Christiana (Newark, DE)	Kimmel Cancer Center, Thomas Jefferson University
Hartford Hospital (Hartford, CT)	Dana Farber Cancer Center, Harvard University H. Lee Moffitt Cancer Center and Research Institute University of North Carolina Lineberger Comprehensive Cancer Center Paul P Carbone Comprehensive Cancer Center, University of Wisconsin Yale Cancer Center, Yale University School of Medicine
Our Lady of the Lake (Baton Rouge, LA)	H. Lee Moffitt Cancer Center and Research Institute University of North Carolina Lineberger Comprehensive Cancer Center The Vanderbilt Ingram Cancer Center, Vanderbilt University Wake Forest Comprehensive Cancer Center, Wake Forest University
St. Joseph/Orange (Orange County, CA)	City of Hope National Medical Center
St. Joseph's/Candler (Savannah, GA)	H. Lee Moffitt Cancer Center and Research Institute Hollings Cancer Center, Medical University of South Carolina
Sanford Clinic (Sioux Falls, SD)	Mayo Clinic Cancer Center University of Colorado Cancer Center Paul P. Carbone Comprehensive Cancer Center, University of Wisconsin

[a] Formal and/or informal working relationships

16. OVERALL ACCOMPLISHMENTS WITH NCCCP IMPLEMENTATION

Overview

A theory-driven, comprehensive evaluation was conducted of the NCCCP pilot, examining five levels of implementation—network (across the sites), organizational, programmatic, for each of six program component areas, and patient—using a multi-method, multi-year approach to assessing implementation for the program overall and for each of the program component areas. Through the evaluation, we learned a great deal about the extent to which sites reported being able to achieve key outcomes and the structures and processes that seemed to facilitate NCCCP implementation.

Overall Accomplishments of NCCCP Outcomes

In terms of accomplishments, many sites were able to

- enhance research capacity in key areas, particularly in trial capacity and infrastructure (e.g., staff);
- improve their quality of care for key indicators of breast and colon cancer treatment;
- leverage a high level of matching funds for implementing NCCCP activities;
- establish stronger relationships with their key cancer physicians (e.g., more involved in MDC conferences);
- implement new initiatives that they may have otherwise not have known about (e.g., NCCCP tools).

Areas where sites made fewer accomplishments (i.e., evident at fewer sites or unable to be assessed due to lack of data) included building formal partnerships or linkages both with agencies in their community and with NCI-designated cancer centers and increasing their knowledge and skills with respect to the entire continuum of cancer care (e.g., survivorship had minimal measurable growth).

In terms of accomplishments specific to the cancer program at the sites, sites that had more outreach workers seemed to be able to achieve more in the disparities program component. This finding is likely to be because outreach workers tend to focus on establishing new and/or more formalized partnerships with local agencies and use those relationships to provide more screenings to people living in low-income areas. For clinical trials, sites were able to increase the number of physicians accruing to clinical trials and were able to demonstrate accruals to trials that were twice as high as the national average as measured through CTEP data (16% increase compared to 8%, respectively, in accruals to Phase 3 open trials) (reported separately in an analysis completed by Duke's Cancer Care Research Program). The extent to which individual sites were able to increase accruals varied overall and for disparate populations. This finding could be a result of the short timeline for the NCCCP in that within the 3-year pilot period, sites had only enough time to build more trial capacity and work at their relationships with physicians, and not enough time to actually increase their accrual numbers. Although nearly all of the sites were able to increase the number of MDC conferences and the involvement of physicians in them, we were unable to identify organizational factors to explain this accomplishment (i.e., those that we did examine quantitatively do not seem to explain this change). Of the three sites that demonstrated the highest overall improvement in the reduction to their nonconcordance rates as assessed through the RQRS, two had a physician director of their cancer program, as did one of the sites with the lowest level of overall improvements.

Facilitators of Program Accomplishments

Organizational factors that seem to be at least somewhat associated with overall achievements included having a physician director of the cancer program and a program coordinator (specific to the NCCCP) and having a direct reporting relationship between the cancer program and hospital senior executives. Baseline capacity was associated with clinical trials outcomes. Local market as we assessed it was not associated with any outcomes, although the environmental factor of whether the state within which a site is located mandates coverage of clinical trials was associated with accomplishments in this area.

Barriers to Program Accomplishments

Common community hospitals characteristics (e.g., a heavy reliance on private practice physicians, limited capacity and/or infrastructure for increasing clinical trials, limited access to key cancer physicians (e.g., specialists) posed challenges to implementation.

Sustainability

Sustaining a program such as the NCCCP beyond the funding from NCI required a great deal of investment from each of the participating hospitals, and the belief that their ongoing work in the six program areas would help them enhance their cancer research and care. We asked respondents during the Year 3 site visits if they had plans for sustaining the NCCCP beyond the pilot (assuming NCI funding ends) and which components, if any, would be the most or least likely to be maintained through the hospital's investments. Nearly all respondents shared that they believed a few components of the NCCCP (i.e., clinical trials, quality of care, IT) would certainly be continued, even without federal funding, but that others (i.e., disparities, biospecimens) would be far less likely to survive a lack of external funding. Sites noted that they would continue to provide palliative care and some services to cancer survivors but the growth of these programs would be less likely without external funds.

This report presents findings from the overall evaluation of the NCCCP over the course of the 3-year pilot implementation. As described in detail in Chapter 2, the overall evaluation was designed to address key evaluation questions at five possible levels of intervention: (1) network, across the NCCCP sites or learning collaborative developed by NCI to administer the NCCCP; (2) organizational, within the systems and hospitals where the program is being implemented; (3) programmatic, for the influence of the NCCCP activities on delivery of the cancer service line; (4) program component, for each area of activities conducted for the NCCCP; and (5) individual, in terms of the association with patients' perceptions of the quality of care they are receiving within each participating hospital. Three overarching questions guided this evaluation:

1. What changes in each program component, and for the cancer service line overall, seem to be facilitated by the NCCCP?

2. What organizational requirements seem important to effectively manage/implement the NCCCP?

3. What changes and elements are sustainable and potentially replicable?

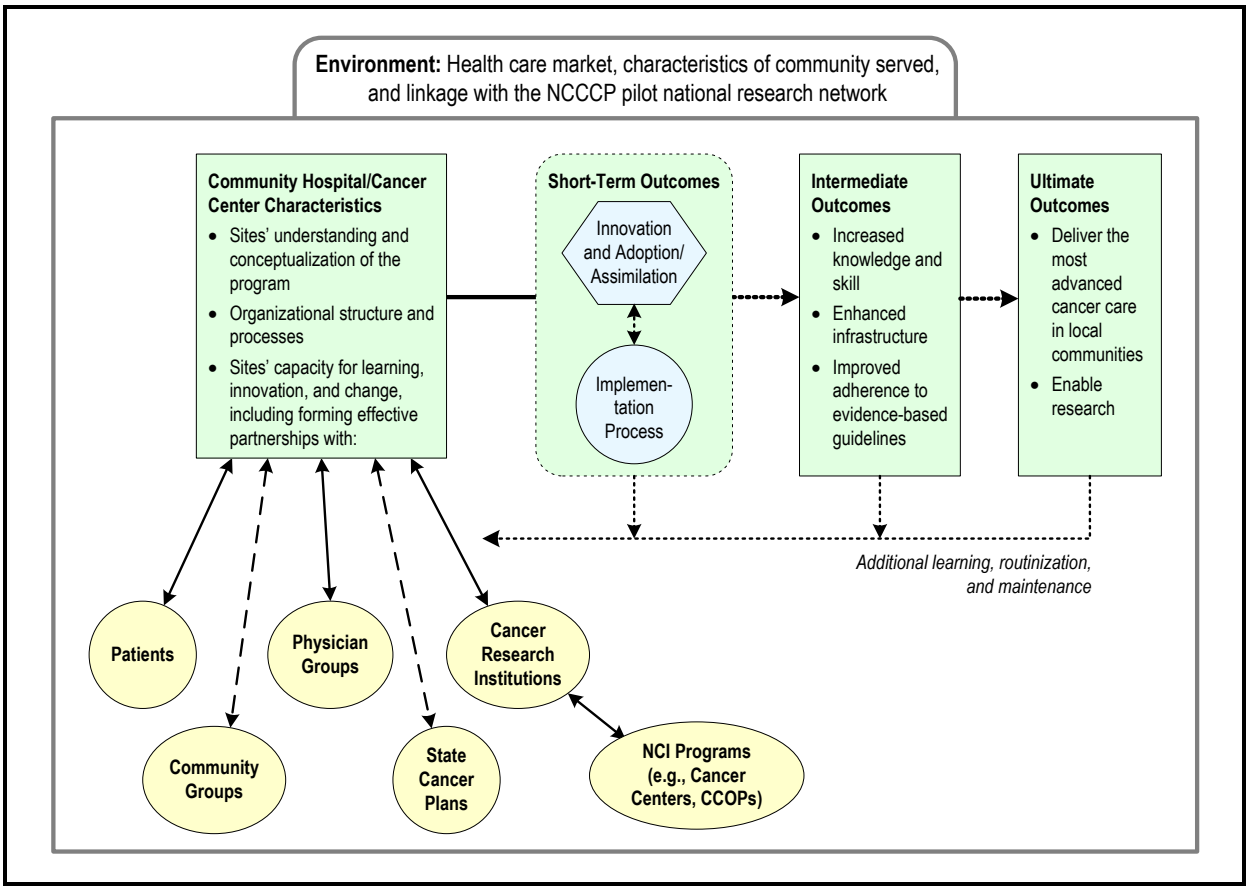
In examining the accomplishments of sites in implementing the NCCCP, it is important to keep in mind the context within which they were working. The NCCCP was a pilot program such that it was a new initiative implemented on a relatively small scale (i.e., 16 hospitals) in order to test the feasibility of the concept of the NCCCP and to improve the design of the program. Therefore, this evaluation was intended to provide a formative evaluation of what seemed to work well and what should be improved upon in order to enhance the NCCCP model moving forward. In this way, the evaluation findings, along with the program, had to evolve over time because so many lessons were being learned during each phase of implementation. The implementation of the NCCCP also occurred within the context of the worst economic downturn since the Great Depression, adding stress on the hospitals for investing in this public-private partnership when many noted their capital reserves were dwindling.

As part of the formative process for understanding the NCCCP, the RTI team worked with the NCI and NCCCP Evaluation Oversight Committee (EOC) to develop a conceptual framework that was then used to guide the evaluation design (Figure 16-1). It was hypothesized that some features of the participating sites would be critical to making accomplishments for the NCCCP. For example, features of the hospital itself were expected to be important in NCCCP implementation, such as its leadership and the key departments that provide services related to the NCCCP pilot components (e.g., pathology for biospecimens research, IT housed within the hospital structure, inpatient cancer services) as well as the hospital's cancer center or program (e.g., the physician leaders directing NCCCP implementation, the outpatient cancer services involved in delivering care). These departments were to work closely together on behalf of the NCCCP, and sites worked with NCI to gradually form the NCCCP network. This network consisted of key staff at all 16 participating hospitals and members of the NCI staff who together made up the NCCCP Program Advisory Committee (NPAC). Members of this network met with each other on a monthly basis and then held separate meetings (usually also monthly) with a number of subcommittees and workgroups in which representatives from the NCCCP sites participate. These various groups identified approaches and specific activities that would help achieve the overall objectives of the pilot. Although we were unable to quantify each site's level of involvement in the NCCCP network, we present findings (Chapter 15) to illustrate how important the network proved to be to how the sites implemented program components. In order to most effectively implement NCCCP pilot strategies and ultimately achieve the major program aims, the NCCCP sites were also expected to partner with

- local community groups (particularly for enhancing their outreach and cancer screening activities to disparate populations),
- key physicians providing cancer care, and
- other NCI cancer research programs (e.g., NCI-designated cancer centers).

The goal was for these entities to work together toward outcomes in each of the six program component areas as shown in the right-hand boxes of Figure 16-1.

Figure 16-1. NCCCP Evaluation Conceptual Framework



Throughout Chapters 4 through 15, we have presented findings for different aspects of the overall evaluation, including the extent to which sites were able to understand and conceptualize the program (Chapter 5); what their organizational structures and processes were and how they changed over time (Chapter 7); whether the sites seemed to be able to learn, innovate, and change with regard to the delivery of cancer care or their coordination and communication among key entities (Chapters 6, 8, and 15); and for which of the NCCCP components they seemed to meet their overarching goals (Chapters 9 through 14). In this chapter, we integrate all of the evaluation findings in order to assess the extent to which the NCCCP pilot helped sites to achieve the short-term, intermediate, and ultimate outcomes as specified in our evaluation conceptual framework (Figure 16-1) and summarized in Table 16-1.

To assess accomplishments in the overall program and for each program component, we developed four sets of composite measures: (1) baseline capacity for sites to implement the

NCCCP (Chapter 4); (2) baseline indicators related to the local context for the hospitals (i.e., market competition, poverty rate of the local population [Chapter 4]); (3) accomplishments in implementing each of three program components (i.e., disparities, clinical trials, and quality of care, presented in Chapters 9, 10, and 13, respectively); and (4) overall accomplishments of the program (Section 16.1). These scores were derived from data elements described in the corresponding chapters. For example, we developed a composite score specific to clinical trials that includes all indicators of accomplishments (e.g., number and type of trials, number of patients, and number of providers involved) and ranked each site based on their level of achievement in each as of the end of the pilot (June 2010). We then assessed these accomplishments relative to their baseline capacity to implement the NCCCP. The final step was to assess which organizational factors may be associated with what each site was able to achieve in clinical trials (Section 16.2). Because we are now presenting findings relative to an assessment of each site's performance, we have de-identified the sites. Random numbers have been assigned to each of the 16 sites, and no names or locations for sites are used in this chapter or in the remainder of this report. The following sections provide an overview of the findings for overall accomplishments, followed by an examination of organizational and environmental factors that may be associated with accomplishments for the three major program components.

16.1 Overall Accomplishments with NCCCP Implementation

Our conceptual framework (Figure 16-1) is a key component to how this evaluation was conducted. It provided the theoretical basis for the evaluation and the measures that we used in each of our methods. It also provides us with a framework through which to understand the evolution of the NCCCP. Sites started the program with specific characteristics at baseline that influenced the extent to which they were able to implement program activities and meet contract deliverables. We start our discussion of overall accomplishments by summarizing the findings for the community hospital and cancer center characteristics that describe their understanding of the NCCCP, related organizational structures and processes, capacity for learning and innovation, and relationships they exhibited with key groups (left side of Figure 16-1).

Much has been learned in this and other areas over the course of the pilot, but only a portion of it was measured through metrics because the outcomes and the concepts to be assessed during the 3-year period were often difficult to quantify. For these reasons, in this chapter we present qualitative findings to illustrate how sites believe the NCCCP benefited them in each of the outcome areas. Where possible, findings are presented in tables, using coded interview data from site visits to help elucidate the patterns. We also present relevant details for interpretation of the overall findings. In several cases, the data presented here were presented in other chapters but are combined with different data variables in this chapter to demonstrate patterns in the findings.

16.1.1 Site Characteristics Relevant to NCCCP Implementation

As noted in Figure 16-1, six specific types of characteristics were important to assess for NCCCP implementation to understand their relationships with short-term, intermediate, and ultimate outcomes:

- baseline capacity of the hospitals and cancer programs for implementing the NCCCP and the local environment within which they are operating;
- sites' understanding and conceptualization of the NCCCP;
- sites' organizational structures and processes;
- sites' capacity for learning, innovation, and change; and
- sites' ability to form effective partnerships with key groups (i.e., community groups, physician groups, NCI Cancer Research programs).

The following sections provide a summary of our findings in each of these areas across all of the sites during all 3 years of the pilot program.

16.1.1.1 Baseline Characteristics of Sites and their Local Environment

As described in detail in Chapter 4, the hospitals selected to participate in the NCCCP pilot were quite varied in terms of their baseline capacity and infrastructure for implementing key aspects of the program. Overarching findings specific to baseline characteristics include the following:

- Sixteen hospitals were selected for participation in the NCCCP pilot, 10 were considered "lead" sites (for the evaluation, 11 were termed "lead" sites by NCI) in that they met key benchmarks (e.g., at least 25 patients accrued to clinical trials, at least 1,000 new cancer patients in 2006), while another 6 were categorized as "developmental" sites (for the evaluation, 5 were categorized as such by NCI), meeting fewer benchmarks at baseline and participating as part of larger health systems.
- Selected hospitals ranged in size from having as few as approximately 9,000 total inpatient discharges in 2006 to as many as 78,000. The proportion of inpatient cases that were cancer-related discharges ranged from 1.9% to 6.9%.
- Eight of the 10 lead sites had a physician director for the cancer center or program, with varying degrees of time devoted to this role.
- All but 2 of the 16 hospitals relied primarily on cancer physicians working in private practices.
- Using a composite measure for baseline capacity (i.e., number of new cancer patients, cancer patients accrued to clinical trials, and percent time of a physician director of the cancer program as of 2006), seven sites were identified as having "high" baseline capacity, and nine had "low" baseline capacity (see Chapter 4).
- Sites varied in terms of their capacity to address disparities at baseline, such that a few sites had no staff specifically working on this issue and others had multiple staff (e.g., outreach workers, staff identified as leaders of these activities).

- Experience with conducting clinical trials was also varied across sites, ranging from several sites identified as lead Community Clinical Oncology Program (CCOP) sites that accrue many patients to clinical trials to those accruing very small numbers of patients (e.g., one site accrued six patients to clinical trials in 2006).
- Although all hospitals were certified by the Commission on Cancer (CoC) at baseline, their capacity to implement aspects of the quality of care (QOC) program component differed such that for MDC conferences, many sites had some conferences on a monthly or weekly basis, while others ranged from none to very few, as well as one site that had numerous MDC clinics and conferences at the start of the NCCCP.
- Baseline environmental factors assessed to create a composite for local market competition (i.e., Medicare market share as well as number of hospitals with cancer programs certified by CoC and number of cancer specialists per 100,000 of local residents) indicated that most of the participating hospitals (n = 11) were operating within a highly competitive market for cancer care.
- Assessing sites for local community context, we found that just as many sites were located in areas with high levels of poverty as were located in areas with low levels (i.e., eight in each category).

16.1.1.2 Sites' Understanding and Conceptualization of the NCCCP

Because the NCCCP was a pilot program, a focus of the first year or two of program implementation was in understanding what the NCCCP model was and how to apply it to each of the participating hospitals' cancer program. As reported in Chapter 5, sites struggled during Year 1 in understanding what the NCI strived for sites to accomplish through the NCCCP and how to implement the different program components within their cancer programs. In an attempt to increase their understanding of the NCCCP, sites had large numbers of staff involved in the NCCCP network subcommittees, with many sites establishing internal structures such that, for each subcommittee of the network, there was a corresponding subcommittee at the site. Also during the first year, several sites struggled with how to explain the NCCCP model to their key cancer physicians in order to engage them in program activities. Over time, as the core staff within each site grew to understand the NCCCP model, they were better able to effectively communicate how they hoped to apply the program to their cancer service line. By Year 3, we were able to measure increases in the number of respondents who could express an understanding of the comprehensiveness and application of the NCCCP to their cancer program. Although this finding was not detected for all sites, there was a marked improvement over time across most sites.

16.1.1.3 Sites' Organizational Structure and Processes

From the start of the NCCCP, the participating hospitals were quite diverse, having a wide array of strengths and weaknesses of their existing cancer programs (Chapter 7). Strengths included the cancer programs' relationship with the hospital and the extent to which the NCCCP, through the principal investigator (PI), could access hospital support and resources. Weaknesses included cancer program that were so small that they had no medical directors

and were relying solely on private practice physicians to implement NCCCP activities. Hospital management across all the sites expressed support for the NCCCP, and most gave tangible examples of how they allocated resources to demonstrate this support (e.g., hiring new staff, buying equipment). Organizational structures that seemed to facilitate implementation of NCCCP activities included having physician leadership of the cancer program and, for half of the sites, having a direct reporting relationship between the physician leader of the cancer program and hospital management. Processes that were key to NCCCP implementation involved those that were best able to engage physician participation. Over the 3 years of the pilot, sites implemented three key strategies for engaging physicians, including engaging them early and often in program activities, using their growth in research and quality of care initiatives to attract physicians' attention and interest in how this work could benefit their practices, and incorporating incentives (e.g., marketing, staff support, patient referrals) into the process of NCCCP participation.

16.1.1.4 Sites' Capacity for Learning, Innovation, and Change

Cancer centers with formal mechanisms for incorporating hospital management in their program's infrastructure, such as through direct reporting relationships between the hospital and cancer program, and those with a physician director for the cancer program seem better equipped to innovate, change, and implement a large-scale program such as the NCCCP (see Chapter 6). The rates of change across sites varied and seemed to be associated with how well senior executives were able to work through issues such as eliminating bureaucratic barriers to staff hiring and able to engage their key physicians in program-related activities.

16.1.1.5 Sites' Relationships with Key Groups

As noted in our conceptual framework, in order for sites to effectively implement the NCCCP, they needed to create or strengthen their relationships with their key cancer physicians and establish and/or maintain linkages with cancer research institutions. The following provides an overview of their accomplishments in these two relationship areas; details are presented in Table 16-2.

Relationships with Key Cancer Physicians

One of the major priorities of the NCCCP was to expand physician involvement in the cancer center, specifically in MDC conferences and/or clinics and in clinical trials accrual. Overall, the sites made marked progress in establishing or expanding MDC conferences and increasing physician participation (see Chapters 7 and 13 for more details). In Year 3, nine sites reported on the outcomes worksheets that "most" (61%–99%) physicians attended MDC conferences (averaged across all MDC conferences and all physicians), and three sites reported that "some" (26%–60%) attended (see Table 16-2). It is important to keep in mind that most sites increased the number of MDC conferences from Year 1 to Year 3 (see

Section 13.3.1); thus, even if the reported level of physician attendance was unchanged, the actual number of physician hours devoted to MDC conferences would have increased.

The sites' implementation of the conditions of participation also provides a measure of physician involvement. By agreeing to the conditions of participation, physicians are more formally affiliated with the cancer center and agree to active involvement, including participation in clinical trials recruitment. Progress in implementation of the conditions of participation has been mixed. Most sites had begun the process of review and implementation, but only seven sites reported full implementation by Year 3 (see Table 16-2; note that two sites started the NCCCP with full implementation, so only five sites achieved it during the pilot). Adopting the conditions of participation requires buy-in at multiple levels, and there are sensitivities about the impact of these conditions on different physicians and how the conditions of participation relate to other hospital credentialing.

Participating in the NCCCP has helped sites in hiring physicians and in establishing or strengthening relationships with private practice physicians. Many physicians want to be part of a more "academic" cancer center that is involved in research:

> *The connection to NCI is very important. [It] helps us recruit new physicians and helps us recruit excellent nurses. People want to be a part of a special program. The linkage is pretty compelling.* (System/hospital senior executive, Year 3)

> *I liked that even though they were a community hospital, they wanted to do clinical trials. It was nice finding a community hospital that was so academic. They have a very good research program here.* (Key physician, Year 3)

Strong leadership at both the hospital and cancer center levels is key to building relationships with physicians and getting them on board for MDC conferences and/or clinics and signing on to the conditions of participation. In some sites, hospital top management was active in bringing private practice physicians on board. Strong physician leaders—as PIs and/or in other leadership roles in the cancer center—also draw in other physicians. In Year 3, one physician commented, "Sometimes you get more done if told by a physician rather than an administrator."

> *Our PI is credible with the surgeons and he understands the needs of the medical oncologists because [he] gets what all the stakeholders bring to the table.* (Program coordinator, Year 3)

> *[Dr. name] has been important to [the] NCCCP. He really gets it. You don't have to sell him on the benefits of NCCCP work. He's willing to participate and contribute, and he's very research-oriented, and he brings his partners along from that same perspective.* (PI, Year 3)

Linkages with Other NCI Programs and/or Research

In Chapter 15, we examined the extent to which the sites were able to develop linkages to either NCI-designated cancer centers or other NCI programs. According to respondents, participation in the NCCCP helped to "open the door" for such relationships; for example, the H. Lee Moffitt Cancer Center and Research Institute (Moffitt) reached out to the sites about participation in the Total Cancer Care (TCC) biospecimens program. However, progress was uneven across sites, and barriers to collaboration remain. From baseline to Year 3, six sites reported an increase in the number of NCI-designated cancer centers with which they had linkages, five sites reported no change, and five sites reported a decrease (see Table 16-2). In addition to linkages with NCI-designated cancer centers, seven sites had developed relationships with Community Network Programs (CNPs) by Year 3 (none had relationships with CNPs at baseline). Other linkages may have been established between NCCCP sites and existing programs but were not assessed in this evaluation.

16.1.2 Innovation and Adoption/Assimilation/Implementation Process

As described in Chapter 2, in order for the sites to effectively implement the NCCCP, each needed to adapt the program to the structures and processes within their hospital and, in some cases, develop relatively new structures and processes related to the delivery of innovative cancer care (e.g., MDC conferences, establishing community partnerships).

16.1.2.1 New Initiatives and/or Approaches

During site visits, respondents often shared how much they believed their cancer program had gained from being involved with the NCCCP (Table 16-3), as best exemplified by the following quotes from senior executives:

> *Prestige is huge, and we try to take advantage of that as much as we can. If you go through the six pillars, we've made great strides in every one of them. If you zero in on cancer, the efforts that have gone on in every pillar line up with our mission and our service to our patients in the community. Our ability to offer clinical trials that we haven't been able to do before. We're getting ready to roll out EHRs and tie it into our cancer physicians. Survivorship has had a lot of strides. The work in disparities has been great. It's all advancing our mission in the world of cancer in a way we haven't been able to do before. Before the RFP came out, we wanted to grow our enrollment in clinical trials. Before this cancer center was built, we were kind of like a virtual cancer program with most of the care happening in physicians' offices. I imagine that's the state at most places. To get access to NCI-sponsored trials has been huge for us as an organization and for our private practice physicians who can now enroll their patients in these trials that they wouldn't have otherwise had access to.* (System/hospital senior executive, Year3)

> *We're attracting patients beyond the traditional service area. We've pulled patients from the competitors, gained market share: 3 to 4 years ago, the market share was*

> *at 40%; 18 months ago, 48%–49%; now, 60+%.... We are providing services and technology that was previously not available.* (System/hospital senior executive, Year 3)

Table 16-4 provides an overview of some of the new initiatives and specific activities facilitated by the NCCCP. For outreach, sites were able to establish new partnerships and presumably learn from these relationships. Specific to cancer care, sites established more MDC efforts and the role of a patient navigator (if they did not already have one). For research, they increased their skills in opening new trials and learning how to use data to better monitor their activities.

16.1.2.2 Communication and Coordination Across Program Components

As described in Chapter 2, in order to facilitate innovation, organizations have to develop or adapt ways for enhancing their communication and coordination across functions and departments. As discussed in Chapter 8, effective communication has been an important aspect of achieving coordination across program components operating from different decision-making units within the NCCCP. Site visit interview data gave some support to the notion that sites that develop effective NCCCP teams that can communicate and coordinate key departments/units/teams through the community cancer center are more likely to implement the program components. Specifically, these data illuminated our understanding of

- the communication systems developed to engage core program staff, hospital senior executives, cancer center leadership, and key cancer physicians;
- the extent to which the NCCCP has been effectively managed at each site (i.e., identification of a program coordinator); and
- the mechanisms in place for the ongoing coordination across the various program components.

Overall, sites have made great improvements in their communication networks, facilitating coordination across program components. From trying to make sense of the NCCCP and its applicability within the cancer program to creating a blueprint for program implementation, there was ongoing consensus across sites on the need for regular communication among program staff. These communication channels ranged from a combination of monthly (or more frequent) program meetings among core program staff, one-on-one meetings among hospital management and core program staff, and meetings with both internal and external physicians. These all have been critical for engaging key program stakeholders, defining roles and processes, and ensuring that all involved are working toward the same strategic goals:

> *Everyone in the cost center for [the] NCCCP meets every Monday morning. A couple of things have happened in the last few years. We have better mechanisms of communication to ensure that information flows from me to other personnel. We*

> *have also increased our screenings, our patient volume, our navigators, and the number of people accrued to clinical trials.* (Program coordinator, Year 3)

As sites have grown in their understanding of the NCCCP and the complexity of its implementation, so has the need for a more centralized system for coordinating across the program components. For 10 sites, one method used to enhance this coordination has included the assignment of key staff (e.g., a program coordinator) to oversee the different program pieces, thus ensuring an efficient overall program structure. For those lacking a program coordinator, the value of having an individual in this role was crucial:

> *We do not have a program coordinator [for our NCCCP], and there definitely needs to be someone like that. We have no administrator and then we had one interim administrator for a couple of months. Then we had [staff name] who has been with us for a couple of months. We need someone who can help us juggle the balls.* (PI, Year 3)

The focus on coordination of program activities has also been propelled by some sites' need to integrate elements of the NCCCP "model" into existing organizational structures and processes. During the Year 3 site visits, we explored which sites had established an NCCCP-specific committee that had developed into a cancer program committee to coordinate work across the program components. Two sites (Sites 4 and 10) had integrated their NCCCP committee into a larger cancer program committee, as a means of helping sustain the cross-program component activities even after the NCCCP ends. Some sites have seen this integrative approach as critical for streamlining organizational operations and engaging physician participation:

> *We have some opportunities to better integrate and involve, probably more so some of our surgeons. I think they know the concepts of what we support in [the] NCCCP. In [multidisciplinary care meetings], we have leads that are wedded to the conference, but if you said, "What is [the] NCCCP?" they would not necessarily know what I am referring to. [So we also take] an opportunity to integrate [the] NCCCP's goals in our usual meetings with them when we discuss our cancer program initiatives.* (Program coordinator, Year 3)

16.1.3 Increased Program-Related Knowledge and Skills

In order to achieve long-term outcomes for the NCCCP, sites needed to increase program-related knowledge and skills that would be associated with enhanced cancer care across the continuum. This was a difficult aspect of NCCCP implementation to assess. From our site visits, we know that the various subcommittees were creating new tools that the sites often implemented, including an MDC matrix, a genetics counseling matrix, and survivorship-specific tools. For each of these tools—previously described in separate chapters for the six program components—we can assume that the sites learned aspects of care that they had

not used before. We could assess only certain aspects of increased knowledge and skills, including how the NCCCP may have helped improve adherence to cancer care guidelines, implementation of conditions of participation, and the development of new partnerships.

As described in Chapter 9, the majority of sites made progress with establishing new community partnerships, although the increase in informal relationships was considerably higher than the increase in formal relationships. Many sites made great strides in reporting race and ethnicity data for their patients using the Office of Management and Budget (OMB) categories. The majority of sites also made progress implementing conditions of participation and in adhering to evidence-based cancer care guidelines (see Section 13.4.3).

16.1.4 Enhanced Infrastructure and Capacity

As described in Chapter 2, sites had to enhance their infrastructure in order to fully implement many aspects of the NCCCP. Because the NCCCP provided a unique opportunity for establishing a public-private partnership between NCI and the 16 hospitals, sites knew they had to invest in their cancer programs in order to participate. Some sites started the program at higher levels of related capacity than others, but because of the comprehensiveness of the NCCCP, no one site had all of the necessary infrastructure and capacity needed to implement the program. For the purposes of this aspect of the conceptual framework, we focused on infrastructure and capacity in the following areas:

- **commitment of hospital management to the NCCCP:** whether senior executives (i.e., CEOs, COOs, CMOs) demonstrate commitment to the NCCCP through participation in committees or dedication of resources, representing the NCCCP within the institution and in the community, and in other ways; and
- **allocation of adequate resources to the program:** investment in NCCCP-related costs, specifically matching costs for the NCCCP program components and infrastructure: biospecimens, clinical trials, disparities, information technology (IT), quality of care, and survivorship.

Although hospital top management all expressed support for the NCCCP, active involvement in the program was limited to a few sites, and allocation of resources to support NCCCP activities spanned a wide range.

16.1.4.1 Commitment of Top Management to the NCCCP

As one way to assess top management support of in the NCCCP, we determined whether the CEO, COO, or other senior executive was part of the NCCCP organizational structure, such as whether they were part of the Executive Subcommittee or other committees. In three sites—Sites 1, 10, and 16—senior executives were involved in NCCCP subcommittees or otherwise represented in the NCCCP structure from the start of the pilot. For example, in Site 16, the CEO and COO were active in securing buy-in for MDC conferences and conditions of participation through their site's Cancer Committee. At other sites (Sites 3 and

14) leadership involvement increased over the course of the pilot. In several sites, the senior executives were instrumental from the initial decision to apply for the NCCCP:

> *It's the hospital administration who had the vision and made it happen.* (PI, Year 3)

The site visit interviews provide more in-depth understanding of leadership commitment to the NCCCP. Across all sites and years, respondents described hospital CEOs or COOs as supportive. However, CEO and COO involvement varied from sites in which they were only periodically or peripherally involved to others where they attended NCCCP-related meetings, provided visibility to the program (e.g., making presentations to hospital boards, representing the program to potential funders and in the community), negotiated with physician groups to increase their involvement, and allocated financial and nonfinancial resources (e.g., office space, new staff positions, equipment purchases) to support the program's efforts:

> *I serve on the Executive Subcommittee of the NCCCP, and we have conference calls with the hospital presidents once every other month. The PI and administrator lead [the call] and set the agenda. From the [hospital] perspective, it allows us to see all the moving parts.* (System/hospital senior executive, Year 3)

> *I have reached out to local community leaders and legislators to ensure that their constituents will receive funding because the NCCCP is in line with the Health Care Reform Act. At [system] national and local levels, we are reaching out to the legislators. There is an important reliance on grants and foundation support and not just the funding for patients.* (System/hospital senior executive, Year 3)

> *I meet with the program coordinator and PI regularly and get updates. I get newsletters. Other than hearing about the project reports, all I can do is allocate resources or knock down barriers. Mostly I just sit back and watch what happens.* (System/hospital senior executive, Year 3)

16.1.4.2 Allocation of Adequate Resources to the Program

The NCCCP was designed to garner matching fiscal support from the participating sites. The range of matching support varied across sites, from just over $100,000 in two sites (Sites 4 and 6) to about $1 million in Site 10 and almost $2 million in Site 16.[1] Both Sites 10 and 16 had strong leadership support for the cancer service line and the NCCCP in particular:

> *Support starts from the top with [CEO] and [COO], and also bringing in [Vice President of the cancer program], who has made this her priority… [Her] role brings legitimacy.* (Key physician, Year 3)

[1] For CHI and Ascension individual sites, matching fund amounts are available at only the system level. Developmental sites did not have the requirement to provide matching funds for the NCCCP.

Allocation of adequate space for the cancer center is also critical. With the staffing and program activities added through the NCCCP—and subsequently with American Recovery and Reinvestment Act (ARRA) funding and other new funding sources—the cancer centers' spacing needs have increased. Two sites completed new cancer center buildings during the pilot, and during the height of the recession they experienced the advantages of consolidation under one roof. In Sites 1 and 10, as well as a few other sites, space limitations were barriers to hiring staff as quickly as the staff would have liked and/or integrating physician practices, and this also made coordination across program activities more challenging:

> *If we expand our current building, it will be physician office space. We have physicians wanting to come into the building and they can't get in. They recognize the advantage of being linked under the brand of [hospital] and want to tell patients that they are in our building.* (CEO, Year 3)

Sites have finite resources, and the cancer centers have to compete with other institutional priorities. As one physician said in Year 3, "We don't control the money here, and there are a lot of people that have their own agenda; cancer is only one agenda." Some respondents described "pushback" and "infighting" from other service lines if the cancer center was allocated substantial resources. Several factors have helped the cancer centers secure resources in this competitive environment, including the increased visibility and stature as a result of the NCCCP (and subsequent ARRA and other funding), increased patient volume, and demonstrated accomplishments in clinical trials or other areas:

> *The support has been more during the last year, which is due to the higher visibility of both [PI] and me in different forums and being able to share very concrete metrics. For clinical trials, we have a clinical trials performance council represented by each department staff, and cancer presents twice a year. We used data that reflected our NCCCP mission and goals, so we showed the growth of clinical trials from 2006 to 2009, both in number of trials opened and in follow-up and accruals. The other [way hospital management has shown support] is having more staff involved that aren't necessarily NCCCP funded in our conference calls and meetings. We decided a year ago, when I realized that staff support the NCCCP mission, regardless of funding stream.* (Program coordinator, Year 3)

16.1.5 Enhanced Research Capacity

A major goal of the NCCCP was to enhance the research capacity among the participating sites mostly in their clinical trials capacity but also in their biospecimens collection and reporting and in their linkages among their IT systems. As presented in Chapter 10, positive changes in patient accrual were better than the national average (based on CTEP data from 2007–2010) (Abernethy & Locke, 2011) and there are promising patterns of enhanced overall cancer research capacity among several of the NCCCP sites. Table 16-4 presents the

findings related to whether sites had enhanced various aspects of their cancer research capacity by the end of Year 3. In defining cancer research capacity, we used the following variables:

- **research staffing:** whether the sites had a research director whose responsibilities included oversight of their research department, and changes in the full-time equivalent (FTE) employees who were either clinical research nurses (CRNs) or clinical research associates (CRAs);
- **clinical trials capacity:** whether sites had improved in any of three possible areas of trial capacity, including the number of open trials at the site, the types of trials available to patients (i.e., prevention, treatment, symptom amelioration, survivorship), and/or whether early phase trials were available to patients;
- **linkages:** whether sites were part of the NCI's CCOP and how many cooperative trials groups they were associated with; and
- **other organizational factors:** such as whether they required physicians to accrue patients to clinical trials as part of their conditions of participation with their cancer center, whether they were a site that had been selected by Moffitt for their TCC program (http://www.moffitt.org/totalcancercare), and/or whether they have an Institutional Review Board (IRB) accessible to them on site.

Although sites' IT capacity could feasibly be related to their ability to conduct cancer research, the data collected on this specific program component were problematic. From the Final Assessment Survey (FAS), all but one site reported that they were able to access electronic health records (EHRs) such that they could access radiology and pathology reports within their cancer center. Because the site without this access could obtain the information only via paper records and all the other sites reported having electronic access to this information, there was insufficient variation across the sites to include that measure in our analysis for enhanced research capacity. Information on whether private practices could access the hospital's and/or cancer program's EHRs from their offices was less consistent (e.g., one hospital indicated they could at baseline but could not 3 years later) and thus is not included in this section. Note that site-specific findings reported in this section and the remaining sections of this chapter are identified by a randomly assigned number for each site to protect their identity.

Although the findings specific to enhanced research capacity are mixed, respondents at most sites felt that their capacity had increased:

> *With clinical research infrastructure, we have increased staff, conducted research, increased the number of research protocols (trials), and have more physicians who are coming to us. That is significant. As we have more trials, we can put the resources behind them.* (System/hospital senior executive, Year 3)

However, as shown in Table 16-4, the NCCCP sites varied in whether they achieved clinical trials outcomes such as the number of positive changes in trial capacity and in patient accrual to clinical trials (see Chapter 10 for more details). Three sites—Sites 5, 10, and 14—

achieved all three changes in trial capacity by the end of Year 3. Site 10 was also successful in being a member of eight cooperative trials groups, being selected for a TCC site, having a research director, and experiencing high increases in staffing by a total of nine FTEs. Although these increases in staffing were likely related to their work as a TCC site (which included hiring staff for biospecimens collection and reporting), sites that were part of TCC shared their impression that they were selected for TCC partly because they were an NCCCP site:

> *I think some of the other things that have happened relationship-wise are here to stay. I think the Moffitt one is here to stay. Moffitt came looking for us because we were a part of [the] NCCCP. Their ongoing relationship has nothing to do with [the] NCCCP. The initial overture might not have happened without [the] NCCCP.* (Subcommittee member, Year 3)

> *Another thing we did was we got the TCC with Moffitt in January 2009…. Within a year we were up and running with TCC. [This] allowed me to hire a biospecimens coordinator…. That was just a result of the whole program.* (Cancer center/program staff, Year 3)

16.1.5.1 Enhanced Research Capacity Relative to Baseline Capacity

As shown in Table 16-4, we have included the baseline capacity for sites to provide a comparison of this measure relative to what they accomplished in enhancing their research capacity. In examining the patterns of baseline capacity to enhanced research capacity, sites that were assessed as having lower baseline capacity were likely to implement fewer changes in trial capacity (0 or 1 change for 4 sites) when compared to sites rated as having higher capacity (n = 2 with 0 or 1 change). However, this pattern did not remain when comparing sites on whether they made 2 or 3 changes in trial capacity and were rated as lower or higher capacity at baseline (n = 5 and 6, respectively). Sites self-reported total patient accrual during Year 3 does not seem to be associated with their baseline capacity.

16.1.5.2 Resource Allocation Relative to Enhanced Research Capacity

We wanted to assess enhanced research capacity scores relative to the matching funds each site had allocated to each of the components and activities specific to cancer research in order to examine whether increased resources within each site seemed to be associated with enhancements in research. As described in the micro-cost study (Section 3.1.2), sites provided data on the matching funds for each program component and related activities (Table 16-5). Table 16-4 also presents the Year 3 matching costs for any research-related investments excluding fixed institutional overhead (if indicated by the pilot sites). These costs cover the following: salaries and benefits; contracted services; materials, supplies, and equipment; space-related costs; and other miscellaneous costs such as travel and software only if they resulted from participation in the NCCCP. In examining these findings,

some interesting patterns emerged. Sites reported matching costs ranging from as low as $115,903 Site 4) to as high as just over $2.1 million (Site 16), with a mean of $862,783. Site 9, the other lead site with a low ranking for cancer research capacity, reported the sixth highest amount in matching funds, spending well below average on research-related activities. Site 16, a lead CCOP, reported a relatively high level of matching costs compared to the other sites. Three developmental sites were able to improve capacity (from their baseline) based on these indicators (Sites 2, 5, and 14). Overall, the sites with the three highest total scores for enhanced cancer research capacity (Sites 1, 5, and 15), reported quite varied levels of matching funds, resulting in few clear patterns in enhanced research relative to the investments.

16.1.6 Delivery of Advanced Cancer Care in Local Communities

Delivery of more advanced cancer care was the ultimate aim of the NCCCP. We assessed this outcome through two constructs: (1) patients' reported overall satisfaction with their care and (2) results from the study involving data from the Rapid Quality Reporting System (RQRS) (Table 16-1). Because sites were guaranteed confidentiality in the presentation of these indicators, descriptions in the text and the tables are de-identified with randomly assigned numbers to the sites in replace of their names.

16.1.6.1 Patients' Perspective of Overall Satisfaction with Cancer Care

We present the patients' reported overall satisfaction with their care based on the patient survey collected during 2009 and 2011. We calculated the overall satisfaction of care and tested the significance of any changes over time for the 10 lead sites (data were not collected for the developmental sites). Overall, patient satisfaction was rated fairly high across all 10 sites, ranging from 8.6 to 9.4 on a 10-point scale. Patients at only one center (12) reported significantly lower levels of satisfaction with their care as of Year 1 (9.2) compared to Year 3 (8.9), although rates at this site were relatively high at both time periods ($p < 0.05$).

During site visits, we heard from respondents that participating in the NCCCP had been critical to enhancing their care because it provided them with a mechanism to learn about what other hospitals are doing and provided benchmarks for their performance. During the Year 3 site visits, respondents were asked about the "value added" of the NCCCP, and many responses mirrored those below:

> *[The] NCCCP is a benchmarking for us…being in this group helps us find out what others are doing and [we] can get information about best practices that would be harder without being part of the program.* (System/hospital senior executive, Year 3)

> *[The] NCCCP has helped make us accountable and establish benchmarks and standards for delivering high-quality cancer care* (PI, Year 3)

16.1.6.2 Improved Quality of Care

In terms of the quality of care measures that we could assess (Chapter 3), the Commission on Cancer (CoC), in collaboration with NCI, developed a comparative evaluation of the NCCCP using data from the pilot test of the RQRS. As described in Chapter 13, the primary purpose of the RQRS was to obtain real-time data from participating hospitals on key quality of care indicators from the National Comprehensive Cancer Network (NCCN). The RQRS is being implemented for six specific indicators, including three for breast cancer care, two for colon cancer, and one for rectal cancer. Hospitals could volunteer to participate in the pilot of the RQRS. All 16 NCCCP sites, as well as several non-NCCCP community hospitals, have been actively reporting data in the RQRS since 2009. RTI, in collaboration with CoC, conducted an analysis of these data to compare the progress made by NCCCP hospitals compared to other, similar hospitals (presented in Chapter 13 and a separate report).

In assessing overall accomplishments for NCCCP-related goals, we incorporated the RQRS into this analysis to assess the organizational factors that may be associated with improvements in these indicators. All of the sites showed improvements in the percentage of nonconcordance in all five measures (the one measure for rectal cancer treatment could not be assessed between sites due to low sample sizes) assessed from time 1 (January 1, 2006, to December 31, 2007) and time 2 (January 1, 2008, to May 1, 2010). Assessing nonconcordance over time is important because it captures the reduction in the proportion of patient cases meeting each evidence-based criteria without also meeting the stated guideline, such that the higher a site′s negative number (i.e., reduction in nonconcordance), the more the site is improving (i.e., following the recommended guidelines). The range of relative change in nonconcordance ranged from -6.4 (Site 1) all the way to +100 (Site 16).

Changes in RQRS Indicators Relative to Key Organizational and Environmental Factors

To further assess the reported changes in the five RQRS measures across the 16 NCCCP sites, we created composite scores on their performance first for the three breast cancer treatment indicators (Table 16-6), then for the two colon cancer treatment indicators (Table 16-7), and finally a combined score to assess overall improvements across the sites (Table 16-8). Tables 16-9 and 16-10 provide a summary of those findings specific to key organizational factors at each of the sites that may be expected to be associated with a site′s ability to make changes for the breast and colon cancer guidelines, respectively. We first describe our hypotheses of organizational factors that could be associated with changes in breast cancer treatment RQRS indicators, followed by those specific to colorectal cancer (CRC) RQRS indicators. We then examine whether there were any such associations between the combined score to assess overall improvements and specific organizational factors.

Findings Specific to Breast Cancer Treatment RQRS Indicators and Organizational Factors

Table 16-6 presents the composite scores for breast cancer treatment indicators. Sites are listed in the order of their ranking on this composite score. As previously noted, there are three indicators for breast cancer treatments such that the higher the negative value for each of them, the more the site improved in reducing their nonconcordance rates. Values presented in Table 16-6 are the changes in the nonconcordance rates from time 1 to time 2. If a site changed by -100 (e.g., Site 13 on Breast Cancer Measure 1), this finding indicates that the site improved such that all of the cases meeting the criteria for that measure had their treatment provided (and reported) according to NCCN guidelines (http://www.nccn.org/professionals/physician_gls/f_guidelines.asp). To create a composite score for breast cancer treatment indicators, we averaged the reduction in nonconcordance rates within each site and then ranked them by quartiles (i.e., one-fourth of sites per quartile ranking). Of the sites with the highest average reduction in nonconcordance rates, two were developmental sites (Sites 12 and 13). Surprisingly, of the four sites with the lowest composite scores, three were lead sites and one was the site with the highest capacity at baseline for implementing the NCCCP (Site 6). To understand any patterns, we hypothesized that these scores specific to breast cancer nonconcordance rates could be associated with organizational factors or patients' perceptions as of Year 3, such as whether or not the site has

- an MDC conference specific to breast cancer,
- patient navigators who provide care for breast cancer patients,
- been rated as significantly improved for their care coordination by the patients in their surveys, and/or
- a higher number of radiation oncologists (i.e., more capacity to address Breast Cancer Measure 1).

Overall, none of these measures for organizational factors seemed to be associated with improved breast cancer treatment indicators such that

- all but four of the sites had breast cancer MDC conferences as of Year 3 and there did not seem to be a pattern in the findings specific to this indicator;
- three different sites had no patient navigators to provide services specifically to breast cancer patients, but this factor did not seem consistently associate increased reductions in nonconcordance rates;
- only two sites achieved a statistically significant improvement in their patients' perception of care coordination, and both of these were among the four sites with the highest reductions in nonconcordance rates; and
- the number of radiation oncologists at sites ranged from 0 to 9 but did not seem to be associated with the level of reductions in nonconcordance reported at each site.

We also considered elements of their organizational structure as possible variables of interest (i.e., whether they have a physician director of their cancer center/program, whether they rely primarily on private practice physicians) and found no patterns in the findings.

Findings Specific to CRC Treatment RQRS Indicators and Organizational Factors

Table 16-7 presents similar findings for the two colon cancer treatment indicators. Sites are again listed in the order of their composite score ranking. Of the four sites that improved the most in reducing their nonconcordance rates, three were lead sites and two were sites with relatively low capacity at baseline for implementing NCCCP (Sites 3 and 9). The site with the highest level for reducing nonconcordance rates (i.e., the best rate) is a site that focused almost exclusively on building their capacity for CRC care because they have key cancer physicians at their hospital who provide that type of care (Site 3). That site, along with 11 others, reported having a CRC MDC conference by Year 3.

As with breast cancer care, we hypothesized that sites with the following organizational characteristics would be more likely to reduce their nonconcordance rates than other NCCCP hospitals:

- patient navigators dedicated to CRC patient care, and
- surgical oncologists and pathologists who attend the CRC MDC conference to potentially enhance coordination of care across the specialties.

We again found no associations between these organizational factors and changes in nonconcordance rates such that

- six sites did not provide patient navigation specific to CRC patients, and these six were among the nine sites with the least improvements in reducing nonconcordance;
- five sites reported having surgical oncologists at their sites, and each of these had varying levels of reductions in nonconcordance rates (i.e., two had high levels, one had medium/high levels, and two had low levels); and
- all but three sites reported that pathologists regularly attend their MDC conferences, and these sites had varying levels of nonconcordance such that this variable does not seem to be associated with their RQRS rates.

Other factors we considered to determine the association with the reductions in nonconcordance composite scores for breast and/or CRC cancer RQRS indicators included whether or not these sites had an EHR, whether they use employed or private practice physician models, or whether they have physician medical directors of their cancer program. None of these variables seemed to be associated with scores for the reduction in nonconcordance rates.

Findings Specific to the Total Composite Score for Improvements in RQRS Indicators and Organizational Factors

Table 16-8 presents the composite scores for the two types of indicators with the overall rankings across the sites. The sites are presented in order by their total ranking for reducing nonconcordance rates. Site 10 ranked the highest with a score of 8, indicating that it was in the top quartile for both the breast and the colon cancer composite scores. Sites 3 and 9 each had a score of 7, and each was in the top quartile for colon cancer measures and in the third quartile for the breast cancer measures. Sites 1 and 11 were in the lowest quartiles for both colon and breast cancer composite scores, and these sites are the lowest overall.

We incorporated into this analysis any organizational variables that may be associated with overall changes in reducing nonconcordance rates. We hypothesized that sites with the following organizational characteristics demonstrate greater improvements in reductions of nonconcordance rates:

- a greater level of effort (i.e., FTE) for their physician director to address issues involving the process for improving these rates,
- a higher number of certified tumor registrars (CTRs) to enhance data entry efforts, and
- a greater number of medical oncologists affiliated with their cancer program to facilitate faster referrals of newly diagnosed cancer patients.

Once again, none of these organizational factors seemed to be associated with reductions in nonconcordance rates. The FTE of the physician director (if they had one) seemed to have no relationship to reducing nonconcordance. However, two of the three sites with the greatest improvement in nonconcordance rates had either a full-time medical director of their cancer program (Site 3) or a half-time one (Site 10) as of Year 3. The number of CTRs ranged from 1 to 5 (with one site not reporting). Interestingly, sites with both the highest and lowest reductions in nonconcordance rates had the highest number of CTRs (n = 5), indicating no relationship between these variables for NCCCP sites.

Sites ranged from having no medical oncologists associated with their cancer program (as reported in the SAR) to as many as 17 as of Year 3. This indicator also seemed to have no association with reductions in nonconcordance rates.

Changes Relative to Baseline Capacity

For each of the outcomes of greatest interest to NCI, including enhanced cancer care, we assessed the progress each site made in relation to where they started at baseline (Section 4.1.5). As described in Chapter 4, based on three key indicators (i.e., patient volume, number of patients accrued to clinical trials, and FTE of a physician director for the cancer program), we rated sites as having either high (n = 7 sites) or low (n = 9 sites) baseline capacity for implementing the NCCCP. Table 16-9 provides a summary of the

findings for sites' baseline capacity relative to their improvements in RQRS indicators. Sites that were rated as having low baseline capacity were actually slightly more likely to have high improvements in their RQRS indicators, perhaps indicating that there is little relationship between the variables used to create the baseline capacity rates and the improvements in RQRS indicators or that the relationship is not a simple linear one.

Changes Relative to Environmental Factors

We also examined the extent to which each site's local market competition rate (described in Section 4.1.5.3) may be associated with whether they improved on their RQRS. One hypothesis is that hospitals operating in a highly competitive market could be more likely to address their quality of care issues so that they can better compete for local patient care. As shown in Table 16-10, we found a slight relationship between these two indicators such that sites operating in highly competitive areas were among those more likely to improve on their RQRS indicators. We also examined the extent to which the local poverty rate (Section 4.1.5.4) might be associated with improvements in RQRS indicators and found no relationship (i.e., the seven sites with low poverty rates and the seven with high poverty rates were each as likely to obtain high improvements in RQRS indicators).

16.1.7 Sustainability

One of the overarching evaluation questions involves the extent to which components of the NCCCP will be sustainable at the participating sites once pilot funding has ended. As a pilot program, NCCCP presents several challenges when addressing sustainability, particularly due to the wide variability in sites' baseline capacity, leadership commitment, funding sources, patient mix, and local competition. Sustainability factors for a site with high baseline capacity, committed leadership, and limited competition may differ from sustainability for sites starting from scratch to build infrastructure and struggling with a growing percentage of uninsured patients. Across all sites, the changing political and economic environment, as well as health care reform, also make sustainability a challenge.

Sustainability has been defined as the "capacity to maintain program services at a level that will provide ongoing prevention and treatment for a health problem after termination of major financial, managerial, and technical assistance from an external donor" (LaPelle, Zapka, & Ockene, 2006, p.1363). The primary process of sustainability has been called "routinization" (Pluye et al., 2004; Shediac-Rizkallah & Bone, 1998; Steckler & Goodman, 1989; Weber, 1995; Yin, 1981), which is described in more detail in Section 16.1.6. Other important factors influencing the extent of sustainability include (1) the ability of a program to be modified over time, (2) the presence of a program "champion," (3) the degree to which a program "fits" with its organization's mission and procedures, (4) how well the program's benefits are readily perceived by staff members and/or clients, and (5) whether stakeholders in other organizations provide support (Scheirer, 2005). Resource investment is also viewed as a likely factor to predict sustainability of a pilot initiative. We begin by

describing what sites reported as their plans for sustainability and how they were working to achieve ongoing NCCCP implementation, even if NCI funding were to be discontinued. To address sustainability as part of the overall evaluation of the NCCCP, we focused on resource investment based on cost study data and potential factors of long-term sustainability, as suggested through the strategic case study (interviews with CFOs) and site visit interviews.

16.1.7.1 Sites' Plan for Sustainability

In Year 3 of the pilot, respondents were asked about their plans for sustaining NCCCP activities even if NCI funding were to be eliminated. Most sites had solid plans for sustaining most of the NCCCP-related activities, particularly the multidisciplinary care (MDC) conferences, patient navigator services, and clinical trials research. Nearly all sites reported that if NCCCP funding were to be eliminated, the first set of activities that would suffer at their hospital would be those related to disparities because prior to the NCCCP none of the sites had a focus on this health issue:

> *Research would keep going but a little differently. No biospecimens. Outreach would probably go away.* (PI, Year 3)

> *The keys will be navigators, survivorship, clinical trials, and some portion of the community outreach. In order for us to continue building on the relationships that we started with, we have to have the people to go out and support the programs.* (Program coordinator, Year 3)

> *What is at risk is biospecimens and commitment to disparities. The MDC [conferences] and nurse navigators are here to stay because the institution sees the value. The one most at risk logically is disparities because you can't put a [return on investment] on it. The primary person doing disparities work is funded through [the] NCCCP.* (PI, Year 3)

> *[It] may be challenging to sustain [the] outreach coordinator position. I imagine if I was at the executive table arguing about what to keep, that one would be a little harder to keep than the patient navigators because we hear the value of that from the patients.* (System/hospital senior executive, Year 3)

Some sites reported having adopted (or planning to adopt) systems and/or processes for sustaining NCCCP elements, such as by obtaining other financial support, aligning staffing plans with the changing health care environment, and increasing related infrastructure.

Obtaining Additional Financial Support

For several sites, the acquisition of funding external to NCI will be critical for sustaining NCCCP efforts. Respondents during Year 3 described how the additional ARRA funding that NCI provided in 2010 to extend the program another year and to enhance efforts in

prioritized areas (e.g., survivorship, IT) had provided them with a lifeline for continuing their efforts and working over the coming year to obtain additional external or internal support. Many respondents reported that the external funds they would seek would be in the form of grant opportunities, community-wide support, and internal support at the institution level:

> *We have to figure out how to position ourselves to encompass what is being done or to have a good mechanism for prioritizing. We are in a better position to compete for grant funding to support. We are looking at all of those things, grants, biorepository grants; the NCCCP funding was only a portion of the NCCCP investment.* (PI, Year 3)

> *Our goal is to keep going after different grants. We have to work with other entities and come up with other models to have a sustained funding. We have every intention of doing that.* (System/hospital senior executive, Year 3)

A few sites also had mechanisms for seeking funds internally through endowments and other sources of funding. Respondents from these sites believed that the achievements they had made as part of the NCCCP would make them more competitive for these types of awards:

> *We are starting to develop a framework for the strategic plan. I think one of the most important strategic items is to look at the philanthropic support. The option for us to grow a program like this where there may or may not be funding is philanthropy. We have a new foundation executive coming on board, and bringing them on board will be a key strategy for us.…At a political level, I have reached out to local community leaders and legislators to ensure that their constituents will receive funding because the NCCCP is in line with the health care reform act.* (System/hospital senior executive, Year 3)

Examining Staffing Plans Relative to NCCCP Funding

With the funding period ending, sites have been forced to make key personnel decisions for sustaining NCCCP efforts. Over the years, sites have found ways to support staff for implementing current NCCCP activities, but during Year 3, because of the external pressures brought on by the national economic downturn and strategic planning around health care reform, sites described how they were having to rethink their staffing plans in order to align themselves with both their continuing NCCCP efforts and to their changing external environments:

> *[The] care coordinator will be initiated, but at a level where that person can do care coordinator stuff for 75% of the time and 25% [of the time] see patients. We'll try using a nurse practitioner instead of a nurse so a small amount of it can be billed. [We will] still keep a navigator role but have her do some billable activities.* (Key physician, Year 3)

> *For us, sustainability of what the grant has funded is obviously very pertinent. Should funding come to a conclusion, or when it does, the thing we have to fully understand here is how is what the grant has funded specifically contributing in a meaningful way to our ability to provide care—provide access to care—in a way we couldn't do without the program.* (System/hospital senior executive, Year 3)

Many sites reported having an increasing focus on maintaining staff positions that would be more likely to result in long-term financial support (e.g., patient navigators, care coordinators).

Increasing the infrastructure for the NCCCP

Given the uncertainty of continued funding, several sites have made significant efforts in building the infrastructure related to NCCCP activities within their current systems in hopes of being able to maintain these structures with internal support from their hospital management. Most respondents felt that this was probably the most critical strategy in sustaining the NCCCP at their individual site. Adapting the NCCCP model has allowed for more streamlined efforts at program implementation, including the integration of cancer programs and services:

> *The NCCCP components are what we live and breathe now, and if NCCCP were gone tomorrow, those are the activities we would still live and breathe. We have the six components and we each have our goals and we are trying to figure out how to have one business plan.* (PI, Year 3)

> *The one cool thing is the infrastructure that [the] NCCCP afforded us was one that we were headed to anyway. [The] NCCCP just got us there a lot faster. It's got to be a substantial return on investment.* (Program coordinator, Year 3)

> *Well, the hard thing for us is that we did not receive much external funding. We have done it through existing mechanisms. If [the] NCCCP left tomorrow, we would lose very little in terms of the infrastructure. We would have to show that the investment is worth it. We can make a pretty good case for most of them.* (PI, Year 3)

Establishing Partnerships to Facilitate Sustained Activities

Partnership building has been an important aspect for sites in not only implementing current activities but also creating synergies that could influence continued program development. For such activities as clinical trials accrual and biospecimens, the partnerships created with academic medical centers (e.g., the H. Lee Moffitt Cancer Center and Research Institute) are believed by many to be long term:

> *If the support ended, our partnerships and relationships with other NCCCP sites would sustain. We have developed relationships and seeing each other at annual meetings, and the monthly calls.* (Program coordinator, Year 3)

> *Really, what we have tried to focus on is how we can sustain this if this [NCCCP funding] all goes away in 10 more months. How can we sustain the energy and excitement around oncology and continuing to look outside the front doors at the community and how can we continue to reach underserved populations? How can we continue to get our oncology message out there and not forget about the underserved? We aren't counting on this continuing, but we want to continue our work.* (PI, Year 3)

16.1.7.2 Resource Investment

Researchers have found that the "incorporation of program activity financing in the 'core funding' of an organization encourages the routinization of a program" (Goodman et al., 1993). Conversely, loss of resources hinders the routinization of a program, particularly when financial resources previously committed to program-related activities are lost (Brach et al., 1994; Pluye et al., 2004; Goodman & Steckler, 1998; Shediac-Riskallah & Bone, 1998). Part of the success at routinization is driven by an organization's leadership and their willingness to advocate for ongoing investments in a program or effort, as was noted by respondents from NCCCP sites in Year 3:

> *When I stepped in, my role was really to advocate at the executive level for this program, and, to the point of sustainability, this has been a really important year for me to understand the program.* (System/hospital senior executive, Year 3)

> *As of July 1, we received renewal for Year 4 [an extension brought about through ARRA funds], but the amount of funding [the hospital] could spend depleted. [The hospital] offered to shoulder the burden of [the] NCCCP while we are waiting for the ARRA grant. With [multiple] existing NCCCP sites, CEOs have taken over combined, the $350,000 (for salaries). The programmatic growth justifies the investment from senior executives.* (PI, Year 3)

> *Any grant has a time limit. It effects sustainability and effects recruiting of people based on funding. That was hard. We have lost time. People who were good candidates may feel reticent to engage. We leverage grants from one entity to other grants. Longevity of cancer affiliation grants (Komen). We have implemented [the] NCCCP and will continue to sustain through other grants. Leadership has recognized how we have leveraged.* (PI, Year 3)

Many cancer center and hospital leaders view the primary role of hospital leaders as one of advocate and financial supporter. To that end, as a key component of sustainability and routinization, we addressed resource investment using matching costs (excluding fixed institutional overhead costs) as these suggest sites' willingness to invest in infrastructure related to the NCCCP. During the collection of micro-cost data in Year 1, 10 activities were selected based on interactions with the PIs for the program in terms of how they allocated

and captured costs for each program component. We then worked with NCI and the Evaluation Oversight Committee to determine which of the matching costs for Year 3 could be potential indicators for ongoing resource investments in their cancer program. The activities included in assessing the potential for sustainability were selected based on the following criteria:

- activities are associated with existing staff (e.g., genetic counseling) and infrastructure (e.g., storage and processing of biospecimens);
- activities include services provided directly to patients (e.g., patient-level activities for survivorship);
- activities include ongoing implementation of the efforts sites either told us they planned to continue even without NCI funds (e.g., care coordination/navigation) or that they were unlikely to cancel (e.g., implementation of IT, administration for clinical trials).

The Year 3 matching costs of the 10 activities are presented in Table 16-11, organized by program component and activity. These costs cover salaries and benefits; contracted services; materials, supplies, and equipment; space-related costs; and other miscellaneous costs such as travel and software only if they resulted from participation in the NCCCP.

Based on Table 16-12, sites had an average matching cost of $767,902 across the 10 activities (n = 10; system sites counted as 1 site each), ranging from $104,445 to $1,969,004. On average, in Year 3 sites spent the most on clinical trials enrollment activities (average cost: $153,540) and the least on IT implementation (average cost: $20,155). Sites did not spend much on genetic counseling either, with an average Year 3 matching cost of $20,243. Other activities with high average matching costs for Year 3 included MDC (average cost: $143,609), care coordination and navigation (average cost: $104,884), and quality improvement (QI) program development (average cost: $96,478). Based on these values, we ranked the sites from the "highest" to "lowest" in terms of their resource investments in these related NCCCP activities. We then used these rankings to assess how baseline capacity and local market competition may be associated with resource investments.

Resource Investment Relative to Baseline Capacity

The wide range of matching costs across sites and activities is open to multiple interpretations. The data may reflect a site's baseline capacity, including their financial resources at the start of the NCCCP pilot, a receipt of additional sources of funding, or perhaps a new focus on cancer care as a priority of the overall hospital system. Lower matching costs may also indicate the limited need for start-up funds, particularly if a specific activity was already in place and routinized within a site. Using our assessment presented in Chapter 4, we compared sites that had a "low" overall baseline capacity to

those that had a "high" level of capacity at baseline to see if this indicator is associated with their level of resource investments. Table 16-13 presents a comparison of these findings. A limitation of this comparison is that the baseline capacity indicator takes into account the hospital's size, research capacity, and a characteristics of their infrastructure (i.e., FTE for a physician director of the cancer program), which may not be associated with their matching investments in one of the NCCCP program components (e.g., quality of care). However, it is likely that hospitals that have a relatively high patient volume and patient accrual to clinical trials are more likely to have a higher level of infrastructure that the hospital has already invested in prior to the NCCCP. Sites with limited or no infrastructure at baseline may incur a greater amount of matching costs compared to sites with preexisting infrastructure. Overall, sites that were rated as having high baseline capacity were likely to invest a high amount of resources when compared to other sites. No sites that were rated with high baseline capacity invested a low level of matching funds. Sites with low baseline capacity were mixed, with three investing a relatively low level of matching funds, and two investing a high level when compared to the other sites.

These costs also provide insight into how NCCCP activities were prioritized during the final year of funding, particularly as sites moved beyond the project start-up phase toward implementation and routinization. Matching costs may have been higher for some activities due to the amount of staffing and resources required (i.e., clinical trials enrollment and MDC conferences), but also viewed by site leaders as providing the greatest return on investment in the long term (i.e., directly associated with key program components, such as research or improving quality of care). Although commonly described as an important aspect of the NCCCP, IT implementation had the lowest average matching cost for Year 3, possibly due to the numerous barriers sites encountered during the first few years of the NCCCP and the realization that their IT goals would require funding well beyond the amount provided by the NCCCP.

As previously noted, financial investment is only one component of sustainability. Other factors of sustainability include whether the program or innovation is modifiable over time, has a "champion," "fits" with its organization's mission and procedures, is viewed by staff or clients as beneficial, and has the support of external stakeholders (Scheirer, 2005). Pluye and colleagues suggest that the processes of implementation and sustainability are "concomitant," with the "process of sustainability beginning as soon as programs are implemented" (Pluye et al., 2004). Thus, facilitators and barriers of program implementation, as discussed in earlier chapters, may play a significant role in ensuring that the NCCCP, or at least some NCCCP activities, continues at sites beyond the pilot period.

Resource Investment Relative to Local Market Competition

As with other outcomes, we examined the extent to which a site's market competition may be associated with its level of investment in NCCCP-related activities during Year 3. One

hypothesis could be that sites that are in more highly competitive markets are more likely to invest in a program like the NCCCP that gives them national recognition and potentially influences their patient care. Whether or not a hospital could compete in the changing economic and political environment was central to their strategic plan:

> *Ultimate sustainability is your financial sustainability. Can you compete and attract from another market? So not just the potential for a designation but how it hardwires how we do things*. (PI, Year 3)

As shown in Table 16-14, we found that hospitals were evenly divided such that those with high local market competition were just as likely to invest either a high or low level of matching funds. Because we could include only 10 sites (as opposed to 16) for these comparisons, any patterns that may be evident are difficult to identify.

16.2 Organizational and Environmental Factors Associated with Accomplishments in the Three Major Program Components

In Chapters 9, 10, and 13, we presented the findings specific to each of the three major program components for which we could potentially assess "success" (disparities, clinical trials, quality of care). In this section, we attempt to differentiate the sites that had some measure of success for each of the three major program components based on their variation in key organizational and environmental factors. Working with NCI and the EOC, we identified a number of such factors that we hypothesized could be associated with accomplishments in each of these areas (see Section 3.2). The following sections provide the overall findings for disparities, clinical trials, and quality of care relative to their level of success presented in previous chapters. Because we are presenting information that could be interpreted as performance measures for each hospital, we have again de-identified the sites using random assignments of numbers.

16.2.1 Organizational and Environmental Factors Associated with Accomplishments in Reducing Disparities

Chapter 9 presents a thorough overview of what activities were pursued by the NCCCP sites with regard to cancer disparities and their ultimate accomplishments in each aspect of this component. As shown in Table 16-15 only one site (Site 4) achieved positive change in all of the measures associated with disparities (e.g., number of outreach workers, patient navigator services). Excluding RQRS measures, there were eight indicators for which sites were assessed with regard to disparities, examining changes from Year 1 to Year 3 in

- the number of systems for which race/ethnicity is tracked using OMB categories,
- the number of formal community partners that represent an underserved population,

- the number of cancer screenings,[2]
- the number of cancer screening events,
- patients' perceived access to care,
- the number of patients navigated for cancer treatment,
- patients' reported awareness of patient navigation services, and
- the number of minority (non-white)[3] patients accrued to clinical trials.

The total scores (i.e., the number each site achieved out of 8) ranged from 3 to 8. (Note that the three sites that were scored as 3 were developmental sites, which could only score as high as a 6 because patient survey data were not collected from these sites.) For this reason, we discuss these findings in terms of the ratio of positive changes each site made with regard to cancer disparities (out of those they could feasibly achieve). Table 16-15 presents the total number of sites for each ratio.

In the following sections, we examine the relationship of these ratios to sites' existing organizational factors that have been hypothesized to be associated with their ability to achieve more in this area. Organizational and environmental factors that could potentially influence accomplishments in the disparities area include

- leadership support for disparities,
- physician involvement in disparities,
- sufficient infrastructure for addressing a variety of patients' needs,
- baseline capacity as of the launch of the program (Section 4.1.5), and
- baseline environmental factors (market competition, poverty rate) (Section 4.1.5).

16.2.1.1 Leadership Support for Disparities

Overall, hospital leaders were generally supportive of the cancer centers' disparities work and thought that improving outreach and services to underserved populations was consistent with the mission of their institutions. However, many respondents acknowledged that without NCCCP funding, they would not be able to do as much in the area of disparities. Many believed that if NCCCP funding were to end this would be the first program area that their hospital would discontinue. As discussed previously, respondents questioned the sustainability of outreach activities because sites relied largely on NCCCP support for outreach staff (see Section 9.7):

[2] Sites provided counts on the number of actual screening tests provided, not the number of patients screened.
[3] Sites only indicated if a patient was "non-white" in the available data source.

> *The culture and mission of the organization support the drive for excellence along with compassion for and consideration of the underserved: It's part of us, it's not something we have to focus on.* (PI, Year 3)

> *Disparities we're proud to do, but we wouldn't have been able to do it as much without the NCCCP funding.* (PI, Year 3)

> *Outreach is integrated, and that is our mission here. [We] want to be able to go out into the community and screen even if people are undocumented.* (Cancer center/ program staff, Year 3)

16.2.1.2 Physician Involvement in Disparities

In sites that rely primarily on a private practice model (14 of the 16 sites), getting physicians involved in outreach activities and committed to providing follow-up care for uninsured patients can be challenging. We noted that reluctance to accept a greater number of uninsured patients was rarely an issue among physicians because all of the sites had a history of providing charity care. By Year 3, many respondents believed the issue to have been resolved through arrangements most hospitals had with their private practice physician practices:

> *For patients without insurance, we only have one neurosurgeon physician group which will say "no," but if it is something I can reach out to them one-on-one about, they will usually take [the uninsured patients].* (PI, Year 1)

> *If someone comes to our office and they don't have any resources, we can't do anything with them because no one will do the tests if they don't have any money.* (Key physician, Year 2)

> *We have a lot of rural areas, and my partner and I travel and go on the road to outlying clinics to provide access and outreach for patients who might not otherwise have access. We don't worry about charitable care, because we are hospital employed. I don't even look.* (Key physician, Year 1)

16.2.1.3 Sufficient Infrastructure for Addressing a Variety of Patients' Needs

Staffing for the disparities program component is discussed in Section 9.4.4. Most sites increased the number of patient navigators (an NCCCP deliverable) and the number of outreach workers over the course of the pilot (see Chapter 9). Some sites had not had any staff members in these roles at the start of the program. Patient navigators are important for addressing disparities because they are intended to ensure that all patients, regardless of their insurance status, receive timely and adequate cancer care. In several sites, patient navigators were hired explicitly to address disparities through outreach to specific patient

groups,[4] such as with Native Americans (Billings Clinics) or Hispanics (St. Joseph/Orange). Chapter 9 provides findings specific to how patients' perceptions of patient navigation changed over the course of the pilot relative to the sites' patient navigator programs.

Some site visit respondents said that the addition of dedicated outreach staff as part of the NCCCP had allowed them to make significant progress in developing partnerships and relationships with underserved communities. As shown in Table 16-16 when the number of outreach workers is compared to a site's ratio to successes in reducing disparities, there were only four sites with five or more outreach workers, but all of those had higher ratios of success than the sites with fewer outreach workers. Because we do not know the adequate number of outreach workers to have in hospitals of varying sizes, if we were to allow that hospitals with four or more outreach workers were rated as high with regard to that variable, then Site 4, the site with the highest ratio of successes for disparities, would be the fifth site in that column, and Site 16 would be the only site in the cell for high number of outreach workers and low ratio of successes (Table 16-16). Based on our small number of sites, there seems to be a slight pattern such that if a site invests in more outreach workers, they will have a higher rate of accomplishments on other domains of cancer disparities. This finding seems reliable because we know that outreach workers are also likely to create more community partners and facilitate screening events, typically in organizations or regions where disparate populations are likely to reside.

16.2.1.4 Baseline Capacity Relative to Ratio of Successes in Reducing Disparities

As described in Section 4.1.5, we rated sites either low or high with regard to their baseline capacity to implement the NCCCP and have compared it to their ratio of successes in reducing disparities. As shown in Table 16-17, there seems to be little relationship between these two variables.

16.2.1.5 Environmental Factors Relative to Ratio of Successes in Reducing Disparities

We also rated the local markets within which each site was operating at baseline and ranked them as either in high or low competitive markets. We then compared those ratings to the ratio of successes in reducing disparities (Table 16-18) and found a slightly negative association such that those sites in highly competitive markets were slightly less likely to achieve a greater number of accomplishments in reducing disparities (six sites in highly competitive markets achieved fewer accomplishments in reducing disparities than the four sites in less competitive markets).

We also examined the relationship between the local poverty rate at the time of the NCCCP launch compared to the ratio of successes in reducing disparities. One hypothesis could be

[4] Although we recognize that patient navigators are usually staff who coordinate the care of cancer patients, we use the terms provided to us by the sites for the roles they had allocated to the NCCCP.

that the greater the level of local poverty, the greater the number of local people a site could recruit to their cancer services. A counter-hypothesis could be that hospitals in areas with high poverty rates are already serving a large share of the uninsured population and have fewer resources to devote to this area of growth. As shown in Table 16-19, however, there seems to be no relationship between poverty rates and the ratio of successes in reducing disparities.

16.2.2 Organizational and Environmental Factors Associated with Success in Clinical Trials

A primary goal of the NCCCP was to help sites build capacity and research infrastructure to implement clinical trials. Overall success in clinical trials is described in Section 10.4 and is defined as achievements in the following areas:

- overall clinical trials capacity as measured by three variables (types of clinical trials offered, number of open clinical trials, and phases of clinical trials);
- total patient accrual to clinical trials;
- minority (non-white) accrual to clinical trials;
- proportion of eligible physicians who are actually enrolling patients; and
- two variables from the patient survey (patients' awareness and understanding of clinical trials).

These indicators resulted in eight possible measures that were then added in order to create a composite scores (with each receiving equal weight). Across all sites, positive change was achieved in a median of five overall success indicators. Using these indicators, there were nine high-change sites that achieved positive change in five or more of the overall success indicators, and seven low-change sites that achieved positive change in fewer than five of the overall success indicators.

Based on discussions with NCI and the EOC, we hypothesized that the organizational and environmental factors that could be associated with overall accomplishments in clinical trials include the following:

- leadership support for research;
- physician engagement in clinical trials and research;
- linkages with other NCI research programs (e.g., CCOP, Cancer Trials Support Unit [CTSU]);
- increased environmental support for clinical trials research (e.g., insurance coverage for trials);
- baseline capacity; and
- local market competition and poverty rate.

We also hypothesized that accomplishments in clinical trials would be associated with overall enhanced research capacity, as described in Section 16.1.4.

16.2.2.1 Leadership Support for Research

Leadership support for research, especially having a director of research who is a physician, is an important element of implementing and sustaining clinical trials activity (Table 16-20). Only one of the nine sites that did not have a physician director of research at baseline hired one by Year 3, meaning that eight sites still did not have a director of research by the end of the pilot period. Among the sites that did have a director of research, it is difficult to determine the degree to which having a director who is a physician influenced overall accomplishments in clinical trials (Table 16-21). Four of the high-change sites and four of the low-change sites had a director of research who was a physician, which indicates that, at least within the context of this study, having a physician director of research was not associated with accomplishments in the selected clinical trials indicators.

Sites subjectively rated leadership support for clinical trials on a scale from zero to 10 on the Baseline Assessment Survey (BAS) and FAS (see Table 16-20). Compared to the sites that were able to make fewer changes, high-change sites on average rated leadership support for clinical trials one point higher than low-change sites at baseline (Table 16-20). Seven sites rated their leadership support at baseline as a 10; 6 of these sites were high-change sites. However, by Year 3, all sites achieved the same mean rating of 9. This suggests that, although the low-change sites made fewer positive changes in clinical trials outcomes, they generally perceived an increase in leadership support for clinical trials over the course of the pilot. Note that we do not know if the same person completed the survey for each response.

16.2.2.2 Physician Engagement in Clinical Trials and Research

As discussed in Chapters 7, 10, and 13, an important aspect of engaging private practice physicians was including clinical trials enrollment as a condition of implemented conditions of participation (Table 16-22). Sites tended to include a minimum rate of patient accrual in their conditions if they had partially or fully implemented the conditions of participation. Table 16-22 presents data on whether sites included clinical trials enrollment in their conditions of participation, the number of physicians eligible to enroll patients, and the number and proportion of eligible physicians actually enrolling patients. There seems to be a pattern that greater physician involvement is associated with more positive outcomes in clinical trials; more high-change sites required clinical trials enrollment as part of their conditions of participation and also increased the number and proportion of physicians actually accruing patients to clinical trials compared to low-change sites. Of the nine private-practice sites that required clinical trials enrollment as a condition, seven were high-change sites. Of the 12 sites that increased the number of physicians actually enrolling

patients, seven were high-change sites. Of the six sites that increased the proportion of physicians actually enrolling patients, five were high-change sites.

Table 16-22 also presents the percent change in accruals in total and for underserved populations as reported in the CTEP data analyzed by Duke's Cancer Care Research Program. For these data, we found that six sites that were rated as high in overall accomplishments were likely to have the highest level of percent change in underserved accrual, while five that were rated as low in overall accomplishments were likely to have the lowest levels of percent change in accrual among underserved populations. This pattern does not hold for sites rated as high or low and whether they were reported as having a high or low percent change in total accruals. When further examining the data in Table 16-22, the four sites with higher percent change in the number of physicians eligible to accrue patients were also those with the highest percent change in total accrual (Sites 3, 10, 12, and 16). This pattern is also inconsistent in that those sites with a relatively high increase in the number of physicians eligible to accrue did not necessarily also report an increase in the number of physicians actually accruing to trials.

Table 16-23 presents the findings for ratio of success (higher/lower) to the proportion of eligible physicians enrolling patients in clinical trials. Note that we set 66% of eligible physicians as the benchmark for defining high and low levels of participation. With further analysis, we noted that 9 of the sites had 12 or fewer physicians who were eligible to enroll patients in clinical trials. Of these 9, 6 were sites rated as having a low degree of change in these indicators. Although having more physicians available to accrue patients increases patient accruals, it is also true that in several of these sites having just a few onsite physicians who are strong advocates of clinical research can greatly enhance overall clinical trials implementation. Anecdotally, for example, we know that there is a strong advocate for clinical trials who is also the PI for the NCCCP at Site 14. As of Year 3, this site had only four physicians who could enroll patients in clinical trials, yet they still were ranked as a site making a high level of overall change in clinical trials, largely because of how whole-heartedly this one physician pushed for clinical trials research.

16.2.2.3 Linkages with NCI Research Programs

Establishing linkages with NCI research programs was another way for sites to enhance their capacity to implement clinical trials. This is discussed in detail in Sections 10.3.4 and 16.1.4. It is difficult to determine which linkages had the greatest influence on accomplishments in clinical trials; there were minimal differences between the high- and low-change sites in CCOP status, participation in CTSU trials, and the number of cooperative group trials activated through CTSU. High-change sites seemed to have more accomplishments increasing the number of cooperative groups they participated in over the course of the pilot. Eight out of nine high-change sites increased the number of cooperative groups they were participating in, whereas only four low-change sites increased this

number. The most salient difference between the high-change and low-change sites was that all four of the Moffitt TCC sites were high-change sites.

16.2.2.4 Increased Environmental Support for Clinical Trials

As discussed in Section 10.6.3, a critical aspect of environmental support for clinical trials accrual is whether a site resides in a state that has passed legislation requiring insurance coverage of clinical trials participation (Table 16-24). In Year 1, seven sites were in states that required insurance coverage of clinical trials; five of these were high-change sites. By Year 3, 14 sites were in states that mandated insurance coverage of clinical trials. Sites 4 and 9, the two sites with the least change in clinical trials, were the only two sites located in states that still did not mandate insurance coverage of clinical trials.

16.2.2.5 Baseline Capacity Relative to Overall Success in Clinical Trials

Baseline capacity seems particularly important to achieving success in clinical trials because one of the indicators for creating that variable is the baseline patient accrual to trials (Section 4.1.4). Table 16-25 provides a summary of the findings for baseline capacity relative to overall success in clinical trials. We found a fairly strong relationship between the baseline capacity measure and their ratio of successes in clinical trials. The majority of sites that achieved fewer successes in clinical trials were more likely to have low baseline capacity, and those achieving more by the end of the pilot were more likely to have been rated as having high baseline capacity. This finding is perhaps confounded by the fact that baseline capacity was assessed using the total patient accrual in 2006 for each site, thereby building clinical trials capacity into this measure.

16.2.2.6 Local Market Competition and Poverty Rate

As with other NCCCP outcomes, we hypothesized that the local competition for cancer care would drive what the sites would be able to accomplish during the course of the pilot (Section 4.1.4). Empirically, however, there seemed to be no relationship between these variables and the extent to which sites succeeded in clinical trials (Table 16-26). We also examined the relationship between the local poverty rate and accomplishments with clinical trials and found no relationship (i.e., sites with low poverty rates locally were just as likely to have had high-changes or low-changes in clinical trials accomplishments).

16.2.3 Organizational and Environmental Factors Associated with Accomplishments in Quality of Care

One of the ultimate goals of the NCCCP was to influence the quality of cancer care accessible to patients in their local communities. Although no funds were specifically allocated to support the quality of care activities, QOC was always a key component of the NCCCP pilot. In Chapter 13 and Section 16.1.5, we have provided an assessment of which sites seemed to have some measure of accomplishments with regard to improved quality of care. As described in Section 16.1.5, all of the sites were able to significantly improve nearly

all of the their nonconcordance rates for the five measures captured in the RQRS study.[5] Using data from RQRS and other outcomes specified for quality of care, we assessed whether organizational and environmental factors seem to be associated with sites' changes in the RQRS indicators; these findings are summarized in Section 16.1.5.

16.3 Summary

Defining success, overall and for the program components, required time and experience with the NCCCP sites. Through monthly phone conferences with NPAC and NCI leaders in each programmatic area, site participants worked with each other on numerous subcommittees and workgroups developing specific activities for each of the program component committees (e.g., developing tools for psychosocial assessments and MDC assessments). Beyond the monthly subcommittee and workgroup meetings, we also know that sites were actively seeking out one another to develop projects and collaborations. From what they learned, we were able to quantify that most had strengthened their relationships with their key cancer physicians, enhanced their cancer research capacity, and built an infrastructure to address ongoing growth in cancer services in the coming years. The next chapter provides overarching themes of conclusions from the program overall as well as for the three major program components.

[5] As previously described, we report nonconcordance rates because doing so helps to control for ceiling effects (as opposed to presenting concordance rates).

Table 16-1. Accomplishments at the Overall Program Level: Key Outcome Measures and Data Variables

Evaluation Outcomes from Conceptual Framework	Evaluation Indicators	Available Data Variables (and Data Sources)
Innovation and adoption/assimilation/ implementation process (Short-term Outcome)	▪ New initiatives and/or approaches to outreach, providing cancer care, conducting research developed at the site	▪ Changes in approach with disparate populations (site visits)
	▪ Communication and coordination across the program components	▪ Mechanisms in place for ongoing coordination across components (site visits)
Increased program-related knowledge and skill (Intermediate Outcome)	▪ Increased adherence to breast and colorectal evidence-based guidelines	▪ Change in adherence to guidelines over time (RQRS)
	▪ Implementation of a physician credentialing program	▪ Conditions of participation implementation (Outcomes Worksheets)
	▪ Development of additional partnerships	▪ Changes in community partners (Outcomes Worksheets)
Enhanced infrastructure/ capacity (Intermediate Outcome)	▪ Establishment of relationships with key physicians	▪ Proportion of physicians who have signed conditions of participation, an indication of whether physicians are "active" members of hospital (Outcomes Worksheets)
	▪ Development of staffing to support the NCCCP	▪ Physician leader of cancer program and FTEs specific to the NCCCP (organizational charts)
	▪ Commitment of leadership to the program	▪ Participation of hospital leader in NCCCP meetings
	▪ Allocation of adequate resources to the program	▪ Level of total and matching funds (micro-cost study)
	▪ Linkages with other NCI programs and/or research	▪ Number of relationships with NCI-designated cancer centers and/or Community Network Programs (site visits)
Enable research (Ultimate Outcome)	▪ Infrastructure in place for conducting research (added biospecimens capacity, increase in clinical trials work)	▪ Clinical trials outcomes (Outcomes Worksheets; CTEP data analyzed by Duke's Cancer Care Research Program)
		▪ Biospecimens capacity (Total Cancer Care sites, biorepository) (SAIC-F)

(continued)

Table 16-1. Accomplishments at the Overall Program Level: Key Outcome Measures and Data Variables (continued)

Evaluation Outcomes from Conceptual Framework	Evaluation Indicators	Available Data Variables (and Data Sources)
Deliver advanced cancer care in local communities (Ultimate Outcome)	▪ Outcomes met for each program component	▪ Composite scores on quality of care, clinical trials, and disparities
	▪ Increased levels of improved experience of care at aggregate levels	▪ Perceived satisfaction with care (patient survey)
	▪ Improved quality of care	▪ Breast and colorectal cancer quality indicators (RQRS)
Routinization and spread (Feedback Loop)	▪ Site's plan for sustainability	▪ Specific plans to continue NCCCP-related efforts (site visits, strategic case interviews)
	▪ Extent to which the NCCCP has become their strategic plan for cancer care	▪ Alignment of the NCCCP with future goals for cancer care (site visits)
	▪ Application of the NCCCP to other hospital service lines (e.g., cardiology)	▪ Whether site was using the NCCCP model for other service areas (site visits)

Table 16-2. Relationships with Key Cancer Physicians and NCI Programs and Research

		Establishment of Relationships with Key Physicians			Linkages with Other NCI Programs and Research[b]			
					Number of Relationships with NCI			
					Designated Cancer Centers			
Site	Baseline Capacity[a]	COP Status Year 3	COP Site Made Progress	Physician Participation in MDC[d] Year 3	Year 1	Year 3	NCI CNPs[e] Year 3	Change in Number of Relationships
Data Source		Outcomes WS		Outcomes WS	BAS and SAIC (quarterly reports) for Year 3			
Site 1	H	Partially Implemented	Yes	3	1	2	0	+1
Site 2	L	Approved, but not Implemented	N/A	3	3	1	1	-1
Site 3	L	Partially Implemented	Yes	1	3	2	0	-1
Site 4	L	Partially Implemented	Yes	3	5	5	0	0
Site 5	L	Limited Activity	Yes	Missing	2	3	0	+1
Site 6	H	Fully Implemented	No	3	2	2	1	+1
Site 7	H	Fully Implemented	Yes	N/A	2	2	1	+1
Site 8	L	Fully Implemented	Yes	3	N/A	1	0	+1
Site 9	L	Approved, but not Implemented	Yes	3	1	3	1	+3
Site 10	H	Partially Implemented	N/A	3	3	4	1	+2
Site 11	L	Limited Activity	No	N/A	3	4	0	0
Site 12	H	Fully Implemented	Yes	2	5	9	2	+6
Site 13	L	Limited Activity	Yes	2	3	1	0	-2
Site 14	L	Fully Implemented	No	2	2	0	0	-2
Site 15	H	Fully Implemented	Yes	3	3	1	0	-2
Site 16	H	Fully Implemented	Yes	3	4	4	1	+1

[a] Derived from Total cancer patient volume, patients accrued to clinical trials, and FTE for Physician Directors at baseline (see Chapter 4).

[b] Formal and informal relationships with NCI designated cancer centers and community network programs

[c] Whether CEO or COO is a member of NCCCP committees and/or referred to in charts as someone with somewhat of a relationship with NCCCP staff; 0= no, 1=yes

[d] Sites self-reported the proportion of physicians attending based on the following categories: 0 = None, 1 = Few (1%–25%), 2 = Some (26%–60%), 3 = Most (61%–99%), or 4 = All. Sites with "N/A" did not have any MDC conferences operating within that time period.

[e] CNP= Community Networks Program, no sites had relationships with these program prior to the NCCCP.

Table 16-3. Sites' Participation and Input on New Initiatives and Specific Activities Facilitated by the NCCCP

Types of Initiatives/ Approaches	Specific New Activities Facilitated by the NCCCP	Number of Sites Increasing Activities (from Year 1 to Year 3)	Illustrative Quotes (and Respondent)
Outreach	Establishing new formal partners	10	Originally we were just going to health fairs handing out FOBTs but not getting the returns; what we found was to partner with healthcare providers to focus on follow-through. (Program coordinator, Year 3)
	Hiring/creating outreach worker positions	6	
	Offering more screening events	11	The screening events and being able to offer free services: We originally offered Women's Wellness Programs but those had different eligibility criteria and outreach; now we have new screening events to bring services out (to the community). (Program coordinator, Year 3)
Cancer Care	Establishing MDC conferences (or clinics)	12	The physicians are a lot more participative with us. They take a lot of pride in being involved with this [MDC conference]. (System/hospital senior executive, Year 3)
	Creating/maintaining the role of patient navigators	9	When we first started, we had some experiences with medical services and all. Navigation was new and there was no infrastructure to make [the patient navigator] successful. Now we have built the infrastructure and we are training and supporting them well. These two navigators have seen more patients in 1 month than we would have seen in 3 or 4 months. (PI, Year 3) We never had anyone to help the patient along the way. If the doctor didn't do it, it wasn't done. Having the nurse navigators specific for each group of patients helps them understand the different problems and outlooks that each patient has…When the nurse navigator talks to the patient, she can understand their needs and then tell us in the program what they need. (Key physician, Year 3)
Conducting Research	Building clinical trial capacity	12	To get access to NCI-sponsored trials has been huge for us as an organization and for our private practice physicians who can now enroll their patients in these trials that they wouldn't have otherwise had access to. (System/hospital senior executive, Year 3)
	Learning how to use data to enhance care	—	The nurse navigators and research program staff has grown because of [the] NCCCP. We just got a data person this year specifically funded by [the] NCCCP. That's huge because we never had a statistician where we could go back, look at outcomes, and publish it. (Key physician, Year 3)

Table 16-4. Enhanced Research Capacity

Site	Baseline Capacity[a]	Research Staffing			Trial Capacity[b]	Linkages		Research-Related Matching Costs		Other Research-Related Organizational Factors		
		Director of Research as of Year 3 (Y/N)	CRN, FTEs, (Change from Year 1 to Year 3)	CRA, FTEs, (Change from Year 1 to Year 3)	Number of Positive Changes in Trials Capacity (0-3)	CCOP Status[c] (Lead, Performance, Unaffiliated)[c]	Number of Cooperative Trials Groups as of Year 3	Matching Costs: Direct + Benefits	Rank Order of Matching Costs	Clinical Trials Enrollment Part of Conditions of Participation by Year 3	TCC Site	IRB at the Hospital by Year 3 (+/No)
Data Source		**Org Charts**	**BAS/ FAS**	**BAS/FAS**	**Clinical Trials Worksheet**	**NCI**	**Outcomes Worksheet**	**Micro-cost Study**		**Outcomes Worksheet**	**FAS**	**FAS**
Site 1	H	+	0	1	2	0	4	618,155	7	+	+	+
Site 2	L	No	2	1	3	8	7			N/A	_	+
Site 3	L	_	4	-2.5	2	∞	6	566,696	8	+	+	No
Site 4	L	+	2	-1	0	∞	6	115,903	10	+	_	+
Site 5	L	No	0.8	0	3	∞	8			N/A	-	+
Site 6	H	+	3.75	0	2	+	7	256,945	9	+	0	+
Site 7	H	+	1	0	3	0	3	1,508,776	2	+	_	+
Site 8	L	No	0.7	0	0	0	5			+	_	No
Site 9	L	_	7	-2	0	+	7	625,596	6	N/A	_	+
Site 10	H	+	1	8	3	0	8	1,174,932	3	+	+	+
Site 11	L	+	4.8	-0.2	0	0	2			N/A	_	+
Site 12	H	_	-2.9	1	3	0	4	644,857	5	+	_	+
Site 13	L	+	1	0	3	0	4			N/A	-	+
Site 14	L	No	1.8	0.2	3	0	3			No	-	No
Site 15	H	No	-7.15	-2	2	0	4	949,382	4	+	+	+
Site 16	H	+	-8	2	1	+	14	2,166,589	1	+	_	+

[a] Derived from Total cancer patient volume, patients accrued to clinical trials, and FTE for physician directors at baseline (see Chapter 4).

[b] As measured through increase in number of open trials, type of trials, and early phase trials.

[c] There has been confusion about which sites are considered "Lead" sites (+) versus "Performance" (∞) or Unaffiliated (0) sites. The data in this table reflect the most recent data RTI received from an NCI expert on CCOPs.

Table 16-5. Research-Related Program Components and Activities

Program Components and Activities	Activities Description
Biospecimens	
Planning and Development	Training and procedure development
Storage and Processing	Specimen-specific activities, including storage costs, analysis, and transfer
Clinical Trials	
Trial Administration/Planning	Negotiating for new trial participation, meeting with academic affiliates
Enrollment Activities	Accruals, enrollment, and follow-up
Disparities	
Care Coordination/Navigation	All costs for patient navigators in this group and coordinating post-screening follow-up activities
Information Technology	
Implementation	Installation and testing of new IT
Planning and Development	System planning and development
Training	Staff training

Table 16-6. Reduction in Nonconcordance Rates for Breast Cancer Treatment Indicators Reported for RQRS

	BC Measure			Average Reduction in Noncon-cordance for Breast Cancer Measures		Organizational Factors Specific to Breast Cancer Treatment			
Site Number[a]	1	2	3		Ranking	Does Site Have a Breast Cancer MDC Conference? (Y/N)	Does Site Have a Breast Cancer Patient Navigator? (Y/N)	Number of Radiation Oncologists	Patients' Perceived Coordination of Care (Y/N)
Data Source	RQRS	RQRS	RQRS	RQRS		Quality of Care Worksheet	FAS	FAS	Patient Survey
13	-100.0	-80.5	-73.8	-84.8	H	N	Y	1	N
7	-91.4	-89.8	-59.1	-80.1	H	Y	N	2	Y
16	-80.3	-77.3	-77.8	-78.5	H	Y	Y	4	N
10	-75.5	-81.2	-76.3	-77.7	H	Y	Y	9	Y
9	-96.4	-75.0	-51.6	-74.3	M/H	Y	N	6	N
3	-91.1	.	-54.5	-72.8	M/H	N	Y	9	N
5	-77.6	-76.6	-56.5	-70.2	M/H	Y	N	1	N
15	-67.0	-83.3	-55.3	-68.5	M/H	Y	Y	5	N
14	-60.0	-61.3	-75.0	-65.4	M/L	N	Y	1	N
2	-45.8	-59.6	-84.0	-63.2	M/L	Y	Y	2	N
8	-19.3	-84.5	-70.8	-58.2	M/L	Y	Y	3	N
12	-36.8	-58.0	-76.2	-57.0	M/L	Y	Y	0	N
11	-58.2	-56.1	-42.3	-52.2	L	N	Y	8	N
4	-73.5	-45.8	17.4	-34.0	L	Y	Y	2	N
1	-6.4	-57.7	-8.1	-24.1	L	Y	Y	3	N
6	-31.8	-40.1	0.3	-23.9	L	Y	N	7	N

[a] Sites were guaranteed confidentiality with these data so are therefore de-identified and assigned a number throughout the tables presenting RQRS data. They are presented based on their ranking in reductions in nonconcordance rates, not by their assigned number.

Breast Cancer Measure 1: Radiation therapy for women under age 70 diagnosed with breast cancer who receive breast conserving surgery administered within 1 year (365 days) of diagnosis.

Breast Cancer Measure 2: Combination chemotherapy for women under age 70 with AJCC T1cN0M0, or Stage II or III hormone receptor negative breast cancer recommended/offered or administered within 4 months (120 days) of diagnosis.

Breast Cancer Measure 3: Administration of Tamoxifen or 3rd generation of aromatase inhibitor for women with AJCC T1cN0M0, or Stage II or III hormone receptor positive breast cancer recommended/offered or administered within 1 year (365 days) of diagnosis.

H = highest nonconcordance rate change; M/H = medium to high nonconcordance rate change; M/L = medium to low nonconcordance rate change; L = lowest nonconcordance rate change.

Perceived coordination of care: Yes means the site had a significantly improved difference in all patients' reported perceived coordination of care between survey responses on both time periods.

Y = Yes; N = No; MDC = Multidisciplinary care conference; RQRS= Rapid Quality Reporting System

Table 16-7. Reduction in Nonconcordance Rates for Colon Cancer Treatment Indicators Reported for RQRS[a]

	Colon Cancer Measure				Selected Organizational Factors (Y/N)			
Site Number[b]	1	2	Average Reduction in Nonconcordance for Colon Cancer Measures	Ranking	Does Site Have a Surgical Oncologist?	Does Site Have a CRC MDC Conference?	Do Pathologists Regularly Attend the MDC Conferences?	Does Site Have a PN Focused on Providing Services to CRC Patients?
Data Sources	**RQRS**	**RQRS**	**RQRS**		**FAS**	**O/C Worksheet**	**FAS**	**FAS**
3	-76.3	-83.0	-79.7	H	N	Y	Y	Y
9	-59.0	-100.0	-79.5	H	Y	Y	Y	Y
14	-55.5	-100.0	-77.7	H	N	Y	N	Y
10	-69.7	-80.3	-75.0	H	Y	Y	Y	Y
7	-36.9	-45.3	-41.1	M/L	N	N	Y	N
8	-29.9	-100.0	-64.9	M/H	N	Y	Y	Y
4	-53.0	.	-53.0	M/H	N	Y	Y	Y
6	-43.7	-50.0	-46.9	M/H	Y	Y	N	N
5	-34.7	-56.3	-45.5	M/L	N	Y	Y	N
12	-69.8	-71.8	-70.8	M/H	N	N	Y	Y
13	-31.2	-50.0	-40.6	M/L	N	Y	Y	N
2	11.1	-64.1	-26.5	M/L	N	N	Y	Y
11	17.9	-67.3	-24.7	L	Y	N	N	N
1	4.6	-47.5	-21.4	L	Y	Y	Y	N
16	-76.4	100.0	11.8	L	N	Y	Y	Y
15	-50.9	826.8	388.0	L	N	Y	Y	Y

[a] The sixth RQRS measure specific to rectal cancer was excluded due to small sample sizes.

[b] Sites were guaranteed confidentiality with these data, so they are therefore de-identified and assigned a number throughout the tables presenting RQRS data. They are presented based on their ranking in reductions in nonconcordance rates, not by their assigned number.

Colon Cancer Measure 1: Appropriate adjuvant chemotherapy for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer recommended/offered or administered within 4 months (120 days).

Colon Cancer Measure 2: At least 12 regional lymph nodes removed and pathologically examined for patients undergoing colon cancer resection regardless of age.

H = highest nonconcordance rate change; M/H = medium to high nonconcordance rate change; M/L = medium to low nonconcordance rate change; L = lowest nonconcordance rate change.

Table 16-8. Overall Hospital Ranking in Reduction in Nonconcordance Rates Across All Five Treatment Indicators Captured in the RQRS[a]

Site Number[b]	Composite Cancer Ranking				Total Ranking	Overall Hospital Ranking in Improved Reduction of Nonconcordance Rates
	Colon		Breast			
Data Source		**RQRS**		**RQRS**		
10	high	4	high	4	8	highest
3	high	4	M/H	3	7	2nd highest
9	high	4	M/H	3	7	2nd highest
14	high	4	M/L	2	6	
13	M/L	2	H	4	6	
7	M/L	2	H	4	6	
8	M/H	3	M/L	2	5	
5	M/L	2	M/H	3	5	
12	M/H	3	M/L	2	5	
16	L	1	H	4	5	
15	L	1	M/H	3	4	
4	M/H	3	L	1	4	
2	M/L	2	M/L	2	4	
6	M/H	3	L	1	4	
11	L	1	L	1	2	lowest
1	L	1	L	1	2	lowest

[a] The sixth RQRS measure specific to rectal cancer was excluded due to small sample sizes.

[b] Sites were guaranteed confidentiality with these data, so they are therefore de-identified and assigned a number throughout the tables presenting RQRS data. They are presented based on their ranking in reductions in nonconcordance rates, not by their assigned number.

This assigns values to the quartiles: 4 = highest, 3 = med/high, 2 = med/low, and 1 = low. The "sum" adds the total for the breast and colon composite.

H = highest nonconcordance rate change; M/H = medium to high nonconcordance rate change; M/L = medium to low nonconcordance rate change; L = lowest nonconcordance rate change.

Table 16-9. Baseline Capacity for Implementing the NCCCP Relative to Improvements in RQRS Indicators

	Improvements in RQRS Indicators	
Baseline Capacity	**Lower**	**Higher**
Low	3	6
High	3	4

Table 16-10. Market Competition Relative to Improvements in RQRS Indicators

	Improvements in RQRS Indicators	
Market Competition Rate	**Lower**	**Higher**
Low	2	3
High	4	7

Table 16-11. Matching Costs by Program Component and Activity

Program Component	Activity
Disparities	▪ Care coordination/navigation (specific to treatment, not for outreach and screening)
Clinical Trials	▪ Trial administration/planning ▪ Enrollment activities
Biospecimens	▪ Planning and development ▪ Storage and processing
Information Technology	▪ Implementation
Quality of Care	▪ Multidisciplinary care ▪ QI program development ▪ Genetic counseling
Survivorship	▪ Patient-level activities

Table 16-12. Year 3 Matching Costs Excluding Fixed Institutional Overhead

	Disparities	Clinical Trials		Biospecimens		Information Technology	Quality of Care			Survivor-ship		
Activity	**Care Coordination/ Navigation[e]**	**Trial Administration/ Planning[c]**	**Enrollment Activities[d]**	**Planning and Development[a]**	**Storage and Processing[b]**	**Implementation[f]**	**Multidisciplinary Care[g]**	**QI Program Development[h]**	**Genetic Counseling[i]**	**Patient-Level Activities[j]**	**Total**	**Rank for Level of Investment (1 = Highest, 10 = Lowest)**
Data Source:						**Cost Study**						
Site 4	$4,921	$13,202	$7,783	$18,280	$1,301	$3,760	$23,539	$10,945	$3,338	$17,376	$104,445	10
Site 6	$0	$3,382	94,703	$352	$8,797	$7,042	$0	$0	$0	$0	$114,276	9
Site 10	$115,782	$213,300	$426,600	$63,536	$111,621	$0	$5,342	$5,342	$2,746	$123,728	$1,067,997	3
Site 3	$49,899	$8,896	$0	$51,402	$254,610	$0	$133,630	$24,598	$21,322	$0	$544,356	7
Site 12	$61,078	$85,142	$106,581	$33,107	$60,449	$0	$83,613	$28,474	$89,430	$11,282	$559,156	6
Site 1	$148,278	$85,836	$116,144	$18,818	$21,764	$13,949	$73,280	$44,148	$5,255	$85,443	$612,913	5
Site 9	$42,495	$17,505	$3,024	$267	$0	$93,739	$166,290	$17,561	$4,575	$90,136	$435,590	8
Site 16	$0	$197,700	$0	$56,416	$0	$34,868	$828,952	$778,200	$0	$72,869	$1,969,004	1
Site 15	$166,491	$222,673	$260,037	$18,084	$10,396	$13,199	$84,121	$12,676	$2,572	$114,927	$905,174	4
Site 7	$459,897	$83,437	$520,528	$59,913	$11,514	$34,992	$37,325	$42,834	$73,190	$42,477	$1,366,107	2
Mean Resource Investment for Each Activity	$104,884	$93,107	$153,540	$32,017	$48,045	$20,155	$143,609	$96,478	$20,243	$55,824	$767,902	

[a] Year 3 matching costs for biospecimens planning and development activities, including training and procedure development.

[b] Year 3 matching costs for biospecimens storage and processing activities, including specimen-specific activities such as storage costs, analysis, and transfer.

[c] Year 3 matching costs for clinical trials administration and planning activities, including negotiating for new trial participation and meeting with academic affiliates.

[d] Year 3 matching costs for clinical trials enrollment activities, including accruals, enrollment, and follow-up.

[e] Year 3 matching costs for disparities-related activities, including all costs for patient navigators and coordinating post-screening follow-up activities.

[f] Year 3 matching costs for information technology implementation activities, including installation and testing of new information technology.

[g] Year 3 matching costs for quality of care multidisciplinary care activities, including multidisciplinary clinics, conferences, and planning.

[h] Year 3 matching costs for quality of care QI program development, including activities such as credentialing and guideline development.

[i] Year 3 matching costs for quality of care genetic counseling activities, not including billable time for patient services.

[j] Year 3 matching costs for survivorship patient-level activities, including completing treatment forms and running support groups.

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Table 16-13. Baseline Capacity Relative to Matching Investments in NCCCP-Related Activities

	Baseline Capacity	
Matching Investments from Hospital	**Low**	**High**
Bottom half (sites ranked 6–10 in matching dollars provided by hospital)	3	0
Top half (sites ranked 1–5 in matching dollars provided by hospital)	2	5

Table 16-14. Market Competition Relative to Matching Investments in NCCCP-Related Activities

	Market Competition	
Matching Investments from Hospital	**Low**	**High**
Bottom half (sites ranked 6–10 in matching dollars provided by hospital)	1	4
Top half (sites ranked 1–5 in matching dollars provided by hospital)	1	4

Table 16-15. Total Sites by Ratio of Success for NCCCP Disparities Efforts

Ratio	Total Sites with Ratio
1.0	1
0.75	6
0.6	4
0.5	5

[a] Because lead sites participated in the patient survey, they could achieve a score of 8, while developmental sites (which did not participate in the patient survey) could only achieve a score of 6. We therefore calculated the "ratio of success" each site achieved of the ones they could feasibly accomplish.

Table 16-16. Ratio of Success in Reducing Disparities by Number of Outreach Workers as of Year 3

	Number of Outreach Workers	
Ratio of Success	**Lower**	**Higher**
≤ 0.6	4	1
> 0.6	6	5

Table 16-17. Ratio of Success in Reducing Disparities to Baseline Capacity

	Baseline Capacity	
Ratio of Success	**Lower**	**Higher**
≤ 0.6	5	5
> 0.6	4	2

Table 16-18. Ratio of Success in Reducing Disparities Relative to Local Market Competition

	Market Competition	
Ratio of Success	**Lower**	**Higher**
≤ 0.6	2	6
> 0.6	4	4

Table 16-19. Ratio of Success in Reducing Disparities Relative to the Local Poverty Rate

	Poverty Rate	
Ratio of Success	**Lower**	**Higher**
≤ 0.6	5	4
> 0.6	3	4

Table 16-20. Leadership Support for Clinical Trials and Overall Accomplishments in Clinical Trials Implementation

Site Number[a]	Overall Accomplishments in Clinical Trials[b] (High/Low)	Director of Research (Yes/No) Year 3	Rating of Leadership Support for Clinical Trials[c] (Scale 0 to 10)		
			Year 1	Year 3	Change
Data Source:		**FAS**	**BAS**	**FAS**	
1	High	Yes	10	9	-1
2	Low	No	9	9	0
3	High	No	10	9	-1
4	Low	Yes	9	9	0
5	High	No	10	8	-2
6	High	Yes	10	10	0
7	Low	Yes	10	8	-2
8	Low	No	3	10	7
9	Low	No	9	8	-1
10	High	Yes	9	10	1
11	Low	Yes	8	8	0
12	High	No	10	10	0
13	Low	Yes	5	10	5
14	High	No	5	9	4
15	High	No	10	9	-1
16	High	Yes	10	9	-1
Mean: All Sites	N/A	N/A	8.6	9.0	0.4
Median: All Sites	N/A	N/A	9.5	9.0	-0.5

[a] Sites were guaranteed confidentiality with these data, so they are therefore de-identified and assigned a number throughout the tables presenting performance data.

[b] High success = sites that achieved positive change in 5 or more of the 9 overall success indicators. Data are presented in Table 10-15.
Low success = sites that achieved positive change in 4 or fewer of the 9 overall success indicators. Data are presented in Table 10-15.

[c] Sites were asked to respond to the following question: "Using a scale from 0 to 10, with (0) being no support to (10) being the most support, rate your perception of how well your cancer center's current leadership (e.g., CEO, Executive Leadership) supports conducting clinical trials in your cancer center." We do not know if the same person completed each survey.

Table 16-21. Relationship of Having a Physician Director of Research to the Level of Change in Clinical Trials Outcomes

Ratio of Accomplishments in Clinical Trials	Whether or Not Site Has a Research Director Who Is a Physician (as of Year 3)	
	No	Yes
≤ 4 Clinical Trials Indicators	3	4
≥ 5 Clinical Trials Indicators	5	4

Table 16-22. Physician Engagement and Overall Accomplishments in Clinical Trials Implementation

Site Number[a]	Overall Accomplish-ments in Clinical Trials[b] (High/Low)	Total Patient Accrual[c]	Total Underserved Accrual	Clinical Trials Enrollment Is Part of Conditions of Participation[d] (Yes/No)	Number of Physicians Eligible to Enroll Patients in Clinical Trials[e]			Number of Physicians Actually Accruing Patients to Clinical Trials			Percentage of Eligible Physicians Enrolling Patients in Clinical Trials[f]		
		Year 3- Year 1 Change in Number (% Change)	Year 3- Year 1 Change in Number (% Change)	Year 3	Year 1	Year 3	Change	Year 1	Year 3	Change	Year 1	Year 3	Change
Data Source:		CTEP			Outcomes Worksheet – SAIC-F								
1	High	4 (14%)	-2 (-15%)	Yes	3	12	9	2	9	7	66.7%	75.0%	8.3%
2	Low	7 (23%)	6 (7%)	N/A	12	12	0	11	11	0	91.7%	91.7%	0.0%
3	High	20 (333%)	23 (76%)	Yes	14	30	16	10	7	-3	71.4%	23.3%	-48.1%
4	Low	-4 (-10%)	-4 (-4%)	Yes	7	9	2	7	9	2	100.0%	100.0%	0.0%
5	High	1 (0%)	0 (0%)	N/A	8	11	3	4	10	6	50.0%	90.9%	40.9%
6	High	-5 (-2%)	22 (12%)	Yes	31	32	1	31	31	0	100.0%	96.9%	-3.1%
7	Low	7 (175%)	0 (-64%)	Yes	14	20	6	7	10	3	50.0%	50.0%	0.0%
8	Low	17 (243%)	6 (-36%)	Yes	10	12	2	3	5	2	30.0%	41.7%	11.7%
9	Low	14 (35%)	15 (15%)	N/A	6	7	1	6	7	1	100.0%	100.0%	0.0%
10	High	6 (40%)	-1 (-18%)	Yes	52	83	31	39	62	23	75.0%	74.7%	-0.3%
11	Low	0 (0%)	0 (0%)	N/A	6	12	6	5	5	0	83.3%	41.7%	-41.7%
12	High	15 (125%)	10 (9%)	Yes	25	57	32	5	21	16	20.0%	36.8%	16.8%
13	Low	1 (9%)	-2 (-24%)	N/A	3	4	1	3	4	1	100.0%	100.0%	0.0%
14	High	13 (57%)	17 (42%)	No	3	4	1	2	3	1	66.7%	75.0%	8.3%
15	High	27 (129%)	13 (19%)	Yes	25	28	3	3	9	6	12.0%	32.1%	20.1%
16	High	406 (427%)	405 (38%)	Yes	33	44	11	20	22	2	60.6%	50.0%	-10.6%
Mean: All Sites	N/A			N/A	16	24	8	10	14	4	67.3%	67.5%	0.2%
Mean: High Performing Sites	N/A			N/A	21.6	33.4	11.9	12.9	19.3	6.4	58.0%	61.6%	3.6%
Mean: Low Performing Sites	N/A			N/A	7.7	10.9	3.1	6.0	7.3	1.3	79.3%	75.0%	-4.3%
Median: All Sites	N/A			N/A	11	12	1	6	9	3	69.0%	74.8%	5.8%
Median: High Performing Sites	N/A			N/A	25	30	5	5	10	5	66.7%	74.7%	8.0%
Median: Low Performing Sites	N/A			N/A	7	12	5	6	7	1	91.7%	91.7%	0.0%

[a] Sites were guaranteed confidentiality with these data, so they are therefore de-identified and assigned a number throughout the tables presenting RQRS data. They are presented based on their ranking in reductions in nonconcordance rates, not by their assigned number.

[b] High success = sites that achieved positive change in 5 or more of the 9 overall success indicators
Low success = sites that achieved positive change in 4 or fewer of the 9 overall success indicators

[c] Findings based on 2007–2010 CTEP data presented separately in Abernethy & Locke, 2011. Underserved accruals include non-white patients and those 65 years of age or older.

[d] N/A = Conditions of participation were not partially or fully implemented as of July 1, 2010.

[e] RTI does not have reliable data on the total number of cancer physicians to be able to calculate the proportion of physicians eligible to enroll patients. RTI does have the total number of key cancer physicians, but in many instances sites reported a greater number of physicians eligible to enroll patients than their total number of key cancer physicians.

f Calculated by dividing the number of physicians actually accruing patients to clinical trials by the number of eligible physicians to enroll patients in clinical trials.

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Table 16-23. Relationship of Proportion of Eligible Physicians Enrolling Patients in Clinical Trials to the Level of Change in Clinical Trials Outcomes

Ratio of Accomplishments in Clinical Trials	Proportion of Eligible Physicians Enrolling Patients in Clinical Trials (as of Year 3)	
	Low (≤ 66%)	High (> 66%)
≤ 4 Clinical Trials Indicators	3	4
≥ 5 Clinical Trials Indicators	4	5

Table 16-24. State-Mandated Insurance Coverage of Clinical Trials and Overall Accomplishments in Clinical Trials Implementation

Site Number[a]	Overall Accomplish-ments in Clinical Trials[b]	Total Number of Patients Enrolled in Clinical Trials[c]			State Requires Insurance to Cover Clinical Trials (Yes/No)		
		Year 1	Year 3	Change	Year 1	Year 3	Change
Data Source:		**Clinical Trials Worksheet – SAIC-F**			**Environmental Analysis**		
1	High	6	139	133	Yes	Yes	No
2	Low	101	85	-16	No	Yes	Yes
3	High	118	561	443	Yes	Yes	No
4	Low	154	98	-56	No	No	No
5	High	2	41	39	No	Yes	Yes
6	High	861	484	-377	Yes	Yes	No
7	Low	81	53	-28	Yes	Yes	No
8	Low	4	37	33	Yes	Yes	No
9	Low	142	90	-52	No	No	No
10	High	108	1,574	1466	Yes	Yes	No
11	Low	51	21	-30	No	Yes	Yes
12	High	332	217	-115	Yes	Yes	No
13	Low	29	14	-15	No	Yes	Yes
14	High	58	142	84	No	Yes	Yes
15	High	29	946	917	No	Yes	Yes
16	High	104	510	406	No	Yes	Yes

a Sites were guaranteed confidentiality with these data, so they are therefore de-identified and assigned a number throughout the tables presenting RQRS data. They are presented based on their ranking in reductions in nonconcordance rates, not by their assigned number.

b High success = sites that achieved positive change in 5 or more of the 9 overall success indicators.
Low success = sites that achieved positive change in 4 or fewer of the 9 overall success indicators.

c Includes patients enrolled in NCI-sponsored, industry/pharmaceutical-sponsored, and other-sponsored trials. According to SAIC-F, other-sponsored trials include the following: "Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by the National Institutes of Health or supported by other peer-reviewed funding organizations, such as the American Cancer Society, the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multisite trial initiated by an investigator at another center."

Table 16-25. Ratio of Accomplishments in Clinical Trials Relative to Baseline Capacity

	Baseline Capacity	
Ratio of Accomplishments in Clinical Trials	**Low**	**High**
≤ 4 Clinical Trials Indicators	6	1
≥ 5 Clinical Trials Indicators	3	6

Table 16-26. Ratio of Accomplishments in Clinical Trials Relative to Local Market Competition

	Local Market Competition	
Ratio of Accomplishments in Clinical Trials	**Low**	**High**
≤ 4 Clinical Trials Indicators	2	5
≥ 5 Clinical Trials Indicators	3	6

17. CONCLUSIONS

This report presents findings from the overall evaluation of the NCCCP pilot over the course of the 3-year implementation. As described in detail in Chapter 2, the overall evaluation was ultimately designed to address key evaluation questions at five possible levels of intervention: (1) network, across the hospitals participating in the NCCCP; (2) organizational, within the systems and hospitals where the program is being implemented; (3) programmatic, for the influence of the NCCCP activities on delivery of the cancer service line; (4) program component, for each area of activities conducted for the NCCCP; and (5) individual, in terms of the association with patients' perceptions of the quality of care they are receiving within each participating hospital. Three overarching questions guided this evaluation:

1. What changes in each program component, and for the cancer service line overall, seem to be facilitated by the NCCCP?

2. What organizational requirements seem important to effectively manage/implement the NCCCP?

3. What changes and elements are sustainable and potentially replicable?

To guide the overall evaluation, our team developed a conceptual framework with input from the NCI and NCCCP Evaluation Oversight Committee (EOC). Grounded in current organizational theory and understanding of cancer services, the conceptual framework was used to create the measures and tools for the evaluation. We used the same framework to organize the findings presented in this report and added text boxes at the start of Chapters 4 through 16 to summarize primary findings across sites for each topic area. This report starts by describing the status of the sites and their surrounding environment as of the time of program initiation (Chapter 4). Chapters 5 through 8 then describe the extent to which sites seemed to be able to achieve key aspects of implementation as guided by the theories in our framework (i.e., understanding of the NCCCP, capacity for learning and innovations, organizational structures and processes, and communication and coordination). Chapters 9 through 14 focus on findings for each of the six primary program components (i.e., disparities, clinical trials, biospecimens, information technology [IT], quality of care, and survivorship), followed by Chapter 15, which provides an overview of the partnerships and linkages sites established or maintained during the pilot. Chapter 16 presents the findings, across all of our available data sources, specific to key outcomes of the pilot, including their overall experience with implementation and the organizational and/or environmental factors that seem to be associated with positive changes made during the course of the pilot. Chapter 16 also describes the extent to which sites seem likely to sustain or replicate aspects of the NCCCP. Where possible, we have combined data across

our evaluation methods in order to broadly assess the defined outcomes, thereby presenting an integrated assessment of what NCCCP was able to do for participating sites.

This chapter focuses on our overall conclusions from the pilot evaluation presented first as overarching themes. These themes were identified through analysis of data across all of the years of the pilot implementation; they address two of the three overarching evaluation questions, including the organizational requirements important to NCCCP implementation and the extent to which the program seems to be sustainable. We then summarize findings specific to each program component and the cancer program overall to address the third overarching evaluation question. We conclude this chapter by discussing the limitations of the data with which we were working and a summary of the conclusions.

17.1 Context for Program Implementation

As noted in the Executive Summary and Chapter 2 of this report, the implementation of the NCCCP pilot occurred within a unique context. The creation of the NCCCP was based on the rationale that most cancer care occurs in the community (estimates are that up to 85% of cancer patients are served by community hospitals). The reasoning was that if cancer outcomes are to improve and research is to be expanded, more attention needs to be paid to the locations where the majority of cancer patients are likely to access cancer care in their communities. Several factors could potentially influence whether the NCCCP pilot was successful in reaching its goals and within which types of settings, including the

- multi-modality nature of cancer care and great reliance on different specialists who may or not have effective means for coordinating patient care;
- extent to which each site emphasized the need to enhance coordination of care through such mechanisms as integrated electronic health record (EHR) systems, establishment of MDC conferences, and/or job positions that facilitated this care (e.g., patient navigators);
- emphasis placed on clinical cancer research (e.g., infrastructure in place such as clinical research nurses (CRNs) to facilitate accruals, willingness of private practice physicians to participate in trials, history of opening trials); and
- ability of each hospital to reach out to their local community and engage people in cancer screening services, among other factors.

Thus, implementation of the NCCCP has been quite timely in engaging these selected community hospitals such that, with NCI guidance through the NCCCP, they are able to be leaders in preparing community hospitals for the shift to more personalized medicine. However, the timing of NCCCP implementation has also occurred within the context of a severe economic downturn and amidst significant policy uncertainty due to ensuing discussions of national and state health care reform.

17.2 Overarching Themes

Throughout this report, we have presented a multitude of data, outlining a variety of opinions and perceptions about implementation of the NCCCP pilot as well as factual data on specific achievements that were made. Using qualitative analysis techniques to examine these findings, we then worked to identify cross-cutting themes for organizing high-level conclusions about the program. This process, referred to as clustering, is a tactic that can be applied to many levels of qualitative data, including across sites or cases such as those participating in the same program. By clustering the findings, we are better to understand a phenomenon by grouping and then conceptualizing findings that have similar patterns or characteristics (Miles & Huberman, 1994). Incorporating findings from the now complete evaluation, we have identified 10 overarching themes that are well supported by multiple data sources from across all 3 years of the pilot implementation. The following sections describe each of the overarching themes for conclusions from the NCCCP pilot evaluation.

17.2.1 Theme 1: Baseline Variation in Organizational Characteristics Made it Difficult to Set Benchmarks for Program Implementation

With the NCCCP being a brand new program in late 2006 and targeting community hospitals and cancer centers with whom the NCI had not historically worked closely, selection criteria needed to be developed. The NCI staff responsible for this initiative (and/or their advisors) chose to include a diverse set of hospitals (based on geography, past experience, infrastructure) to assess both the generalizability or transferability of the program to other community hospitals and the time and investment it would take such hospitals to develop the kind of capacity ultimately envisioned. As a result, the programs varied in terms of their baseline capacity and could be considered in three tiers or groups: very advanced in most key areas relative to peers, advanced in some but not all key areas relative to peers, and not advanced in most areas relative to peers but still met criteria. Although this was an important aspect of the pilot program, having this variation made it more difficult to set benchmarks so that all of the sites knew what was expected of them over time.

With the advantage of a pilot program, diversity of sites, and comprehensive evaluation, much has been learned about the types of hospitals that might have the greatest degree of success in implementing the NCCCP in the future. For the reasons described above, the initial 16 hospitals in the NCCCP pilot varied greatly in their capacity and capabilities even though they all met the selection criteria and successfully competed for the award. Even among the 10 lead NCCCP sites (or 11 lead sites as categorized by NCI), capabilities varied. For example, one important area in which the hospitals varied was their physician or medical staff model. Although most participating hospitals operate with private practice physician models, some have physicians who are employed and may therefore differ in what they are able to accomplish for the program. In addition, due to hospital size and their medical staff model, some had a large number of physicians to potentially involve and draw

upon while others had only a few who could spend a portion of their time on NCCCP-related activities. Sites also varied greatly in terms of how their cancer programs were structured and whether they had access to cancer subspecialists (e.g., gynecologic oncologists), with some lacking a distinct service line specific to cancer care. Those with distinct service lines that included formalized physician leadership (i.e., medical director of the cancer program or service line) seemed to have greater ease in obtaining physician support for program-related changes and in obtaining necessary resources from their hospital's top management. Another example of an important area on which participating hospitals varied was whether they were part of a larger system that was participating as a system in the program or whether they were participating as a single site.

Finally, the variation across the communities within which each hospital operates was also quite diverse. Several of the hospitals are in rural communities, with limited access to transportation, while other participating hospitals are located in highly urban, densely populated areas with a greater diversity in the types of patients they serve (e.g., socioeconomically, racially, ethnically). These differences had to be taken into account, especially as NCI worked with sites to develop the disparities-related activities of the program. Based on our findings, organizational requirements that seem important to effectively manage and implement the NCCCP (an overarching evaluation question) include

- baseline capacity of having higher numbers of patients accrued to clinical trials;
- hospital size, such that those with more key cancer physicians and higher patient volume, were more likely to be able to implement program activities (e.g., conditions of participation, MDC conferences) and increase trial capacity;
- physician director of cancer center (specifics on the level of effort from this person are unknown) to facilitate key NCCCP activities, such as engaging physicians in MDC conferences and increasing overall clinical trial capacity;
- program coordinator to facilitate coordination and communication across the program components;
- direct reporting relationship between physician director of cancer center and senior executives may be important for accessing hospital resources;
- institutional history for providing care to disparate populations; and
- distinct cancer service line or structure that enables for faster integration of NCCCP activities into the organizational processes.

17.2.2 Theme 2: The NCCCP Pilot Requires Time for Start-up and Prioritization of Goals

Since this was a pilot program, much of the program itself (e.g., priorities for each year of the 3-year pilot, roles and responsibilities of all key players, evidence-based approaches to achieving the aims) had to be developed during Year 1. This approach where NCI conceptualized and created aspects of the program together with the sites had advantages in that it helped to have the program ultimately reflect the reality of the cancer centers and

takes advantage of the expertise of NCI staff. As noted in Chapter 2 of this report, both NCI and each participating hospital were engaged in "sense-making" to determine more specifically what the NCCCP is and how it should be developed nationally and applied within each hospital. For this reason, significant time was spent during Year 1 on working together to define the program, including the tasks to complete for each component, the roles and responsibilities of the hospitals and NCI staff, and other aspects of program development and implementation. As previously noted, this sense-making process was also taking place in a unique environmental context. As NCI and the sites spent time on this program development, time to actually implement activities for the program became more limited. In actuality, with the first year of the pilot focused on this aspect of work, one could suggest that implementation of the pilot was conducted over only a 2-year period.

Related to the focus on "sense-making" during Year 1, sites were initially confused about three key issues: (a) what their focus should be during the 3-year pilot; (b) how to prioritize the various program pillars/components, since it was difficult to make progress on all fronts simultaneously given the context, length of time, and nature of the program; and (c) who could set these goals and priorities. At first, sites seemed to be waiting for NCI to tell them what to do for each program component, perhaps because this program was established as a subcontract and they were concerned about meeting deliverables. We found that through the activities conducted during Year 1, sites generally did not have specific plans on how they would implement program components within their own hospitals until they were required to develop work plans in the summer of 2008. In this way, specific visions for application of the program to each site were under development in Year 1, but, as sites developed their work plans specific to each program component, the core teams' understanding of the breadth and depth of the NCCCP became clearer.

In terms of the focus of the program, there were four specifically funded "pillars" of the program at the start of the NCCCP (i.e., IT, biospecimens, clinical trials, and disparities) and two unfunded "components" (i.e., quality of care and survivorship). There was a lot of confusion across the sites about how they should work to address every "pillar" and what NCI thought their priorities should be. As NCI clarified the language of the program (e.g., began calling all six areas of effort "components"), they also directed sites to develop work plans for each program component, which helped sites to prioritize their areas of improvement during the course of the pilot. However, there were so many components and ongoing activities that sites often struggled with how to best spend their time and efforts: what to tackle first and what to delay for later. With the six program components, the NCCCP was quite a complex initiative that seemed to overwhelm some sites, particularly those with limited staff. Although the very nature of a pilot project is shared learning, NCI may want to prioritize early on where new sites should initially focus their efforts. It is clear that sites are required to utilize a large portion of their own resources to implement this program, and the more NCI can do to direct how they use their precious time and resources

will make the NCCCP a much more focused and streamlined process. This need to focus was perhaps best evidenced through findings from the analysis conducted by Duke University's Cancer Care Research Program. As noted in their report, sites that were more advanced in clinical trials research (e.g., CCOPs) had potentially reached a ceiling with regards to how many patients they could feasibly accrue to clinical trials, while the sites with less clinical trials experience needed time to organize in order to conduct trials (e.g., establish protocols and procedures, hire staff). Although most sites were able to demonstrate enhancements to their cancer research capacity, they did so for different aspects of research development (e.g., developing infrastructure, setting up protocols, enhancing accruals of underserved populations). One strategy for future program development, should the NCCCP continue, would be to assess sites on their baseline capacity for each of the six program components and have them develop work plans based on their stage of development for each. For example, sites that are advanced in clinical trials can focus on accruing underserved patients to trials and develop in areas where they need more advancement (e.g., IT or QOC).

With the initial focus on sense-making within a rapidly changing environment, many participating hospitals found it difficult to spend time engaging key local stakeholders in program development and implementation. Each site tended to concentrate on working directly with NCI through the NCCCP network to set priorities for the overall program. The sites therefore spent less time obtaining buy-in for the program among key internal stakeholders, and physicians in particular. They focused on understanding the program more among the core staff who would be implementing the NCCCP and less on ensuring that key physicians were onboard with the program. This somewhat closed, hierarchical approach meant that during Year 1, people outside of the core NCCCP staff had limited, if any, understanding of what the program was attempting to achieve, what approaches were being considered, and what it would mean to them in the coming years. Consequently, as the sites progressed from understanding the program to actually implementing tools and/or key priorities, they often faced resistance from these physicians to becoming involved or even participating in efforts such as the "conditions for participation" or MDC activities.

17.2.3 Theme 3: Establishing a Public-Private Partnership between NCI and the Participating Hospitals Provided the NCCCP with Tremendous Benefits

Perhaps one of the most innovative aspects of the NCCCP is the fact that it is a public-private partnership between the federal government and numerous private hospitals. To establish this partnership, NCI provided each selected hospital with a relatively small amount of funding (approximately $500K per year for each of the 10 programs), and any remaining resources needed to meet NCCCP deliverables were required as matching funds from participating hospitals. Micro-cost study findings indicate that by the end of Year 3, for every $1 provided by NCI, each hospital had spent more than $3 on NCCCP implementation

(excluding any imputed cost of donated time). This program therefore represents a significant investment for each hospital.

It is through this partnership that the investments have been made by these hospitals in the context of a new affiliation with NCI. Each hospital agreed to sign a 3-year (now 5-year) contract with SAIC-F, the prime contractor for NCI, to implement the NCCCP. Although each hospital understood that investments would be required to meet the deliverables in the contract, all hospitals indicated during the Year 1 site visits that the funds required were well above their expectations. However, they also still believed there to be a strategic case for participating in this program and aligning their cancer program with NCI. Without this affiliation, the level of investments being made would likely not be as great. As a result, perhaps because this program was implemented as a contract rather than a grant mechanism, with each hospital required to meet set deliverables, the NCCCP has been able to make a great deal of progress within a short period of time.

17.2.4 Theme 4: Support from Hospital's Top Management Facilitates Program Implementation

Given the investment of time and money, and the involvement of a wide array of different hospital departments (e.g., inpatient and outpatient oncology, research, Institutional Review Boards [IRBs], pathology laboratories, IT), top management support is critical. All of the CEOs professed support, but their actual level of involvement and support varied considerably. For example, senior executives varied in terms of their willingness and ability to provide support via such mechanisms as establishing a part-time medical director or principal investigator (PI), or prioritization of NCCCP-related activities within the hospital (e.g., raising IT and other infrastructure improvement in oncology to the top of the list). Even when hospitals were part of large systems, many decisions related to the NCCCP tended to require local attention and buy-in, and many systems had too decentralized a structure to obtain the necessary support. Therefore, it is critical for each specific hospital CEO to be supportive of the NCCCP. We found that sites where senior executives were more directly involved with NCCCP implementation (e.g., providing direct supervision to the physician director of the cancer program, participating in regular meetings that addressed NCCCP activities) faced fewer barriers in obtaining approvals for investments in their cancer program.

17.2.5 Theme 5: NCCCP Activities Require Physician Leadership

For the pilot program, NCI required that the 10 lead NCCCP sites ensure that there would be a "physician director" of their cancer program by the end of the 3-year pilot program. However, it became clear early on in the evaluation that, given the predominance of the private practice model in most participating hospitals, formal physician leadership was critical from the start of program implementation. A formal physician leader who had at least some core, dedicated time (e.g., at least 25%) to focus on the program and who was

respected by his/her peers seemed critical to enlisting support to implement NCCCP activities. This theme was perhaps most obvious at the two hospitals that initially had no physician director for their cancer program; each hired one during the second year of the pilot. By the end of the third year, these programs had achieved an increase in the number of their MDC conferences, improvements in their clinical trial capacity, and physician approval of their conditions of participation. Although this finding was observed in only two sites, the speed with which they began to implement NCCCP activities once the new physician director was hired was dramatic. However, hiring such a director is a substantial financial commitment by the hospital, which may be difficult in the current economic climate. In addition, it may take time to find a well-qualified candidate who is a good fit for the program and potentially willing to relocate.

It is unclear whether the NCCCP PI (who is not always the cancer program director at this point) needs to be this physician, but at the very least this physician leader needs to be a champion for the program. At one site in particular, it was notable that prior to having a physician lead for their MDC development they were getting "nowhere," but once a physician (who is not the PI but someone other physicians respect) stepped up to lead the MDC effort, the site was better able to initiate this aspect of their program.

17.2.6 Theme 6: The NCCCP Requires Involvement from Numerous Cancer Physicians

Physician involvement in the NCCCP activities was an ongoing challenge for sites for which they had varied success. Nearly all of the participating sites rely on cancer physicians in private practice to provide the majority of their cancer care. These relationships pose challenges to NCCCP implementation, including limited access to physicians to initiate new efforts (e.g., convening new MDC conferences, opening new clinical trials), resistance among some physicians to change their relationship with the cancer program (e.g., related to the "conditions for participation" created by the NCCCP Executive Subcommittee to set criteria by which physicians are assessed and considered to be active in the cancer program), and limited infrastructure to coordinate work (e.g., lack of linkages among physician EHR systems with the hospital, lack of staff or resources to assist physicians in accruing patients to clinical trials).

Engaging physicians in the daily work of the cancer program seemed to be facilitated by two factors: (1) whether there was a physician leader of the cancer program and (2) whether the site had accomplished implementation of key NCCCP activities that facilitated physician engagement (e.g., adding MDC conferences, implementing conditions of participation). What was notable was that as the sites worked to implement NCCCP activities the involvement among their key cancer physicians in these activities increased. Activities that seemed to be the greatest facilitators for engaging physicians were increasing their MDC efforts and establishing staff in key roles to support physician involvement in activities such

as clinical trials accrual (e.g., CRNs who could be located within a private practice for enrolling eligible patients). In many cases, the sites that had a larger number of cancer physicians from which to draw were able to facilitate more activities (e.g., sites with only one or two key cancer physicians were much less likely to have the numbers needed to facilitate more than a monthly MDC conference). One example includes one site that did not have a medical director of their cancer program at the initiation of the NCCCP and was able to identify a physician who was willing to serve as the leader of an MDC conference specific to his subspeciality. This was the first conference convened by this particular site and gradually resulted in more physicians becoming involved in the MDC conference in general. Because there was a sufficient number of physicians to involve in these conferences, this site and others were better able to initiate and maintain these types of efforts. In those sites that had fully implemented their conditions of participation (two at baseline, five more over the course of the pilot), involvement from their cancer physicians was particularly evident. Although the process of implementing conditions of participation can be very controversial and difficult, the fact that five sites were able to accomplish full implementation during the last year of the pilot is a substantial achievement.

17.2.7 Theme 7: Communication and Coordination across Program Components Facilitates NCCCP Accomplishments

Because the NCCCP program components span the cancer continuum of care, a great deal of coordination within each hospital must occur in order to best facilitate change. Hospitals and cancer centers that already had a medical director and executive director overseeing either all outpatient cancer care or both inpatient and outpatient care had some advantages in facilitating this coordination. Specifically, these hospitals were already thinking about the entire oncology service line and had some formal authority and responsibility for the program. This includes overseeing budgets, performance, hiring/firing of staff, facilities, and relationships with physicians. These individuals also often had reporting relationships to the CEO or COO. This structure provided a more natural platform for the NCCCP. In the absence of structure and positions like this, it seemed harder for the oncology program to obtain the necessary resources and attention from top management.

Sites recognized early on the need to integrate and coordinate NCCCP-related activities across those working for each program component within both the cancer programs and hospitals (e.g., pathology departments needed to be active participants in implementing biospecimens activities). In addition to developing the partnerships between NCI and each participating hospital, this program also required people to work together who had no prior history of doing so, which in itself can be challenging. Within each hospital, the NCCCP required that people who in some cases barely knew each other work together to "invent" this program. People from one silo of an organization (e.g., IT) needed to work effectively with others in another silo (e.g., pathology lab) to implement aspects of this program; these people often knew little about how best to work with each other. Stakeholders in this

program were engaged in figuring out not only how to implement the NCCCP within each hospital but also how best to work together with unfamiliar people.

For this reason, many sites established "executive committees" or some type of coordinating structure to better manage NCCCP activities. By Year 2, several sites had formalized this activity into a role of "program coordinator," staff primarily responsible for "pulling all the pieces" together for the NCCCP. Sometimes an NCCCP program coordinator was the same person as the cancer program or center executive director. Even if the NCCCP program coordinator was not the cancer center executive director, it seemed to work well if this person worked closely with the PI and other physician leaders. However, the program coordinator needed to be carefully placed in the organizational structure. Individuals who were most effective in guiding program implementation tended to be those with a close structural relationship with the PI and the authority to communicate with top management, garner the resources needed, or make other necessary decisions and changes.

17.2.8 Theme 8: The NCCCP Enhances Cancer Research Capacity

A major goal of the NCCCP was to enhance the research capacity among the participating sites mostly in their clinical trials capacity but also in their biospecimens collection and reporting and in their linkages among their IT systems. As presented in Chapter 10, positive changes in patient accrual were modest over the relatively short pilot implementation period, though the accrual among NCCCP sites was above the national average as reported in CTEP during the same timeframe (Abernethy & Locke, 2011). Overall, there were promising patterns of enhanced overall cancer research capacity among several of the NCCCP sites. Most of the sites had addressed issues with their biospecimens collection and enhanced aspects of how they collected specimens. As noted, many enhanced their clinical trials efforts. Sites struggled with addressing implementation of a linked EHR. Because of their heavy reliance on physicians in private practice, most of the sites were faced with trying to link systems that had no interfaces available to allow the systems across the hospital and practices to "talk" to each other and share patient records.

Many had also added research staff to their organizational structure and had increased the accessibility to their IRB. In terms of their clinical trials capacity, although sites tended to increase their total patient accruals to trials only slightly, most were able to increase their capacity to conduct more trials (i.e., opening more trials, conducting varying phase and/or types of trials), increase the number of physicians accruing patients to trials, and incorporate clinical trial accrual into their draft or fully implemented conditions of participation. Given this development, sites were clearly laying the groundwork for enhancing their cancer research over time so that patient accrual increases would be expected in the next few years. Because the pilot was only a 3-year program, this type of infrastructure development is an area of major accomplishment for ultimately enhancing each site's research capacity.

17.2.9 Theme 9: The NCCCP Network of Sites with NCI Guidance Provided Important Collaborative Learning Opportunities

The NCCCP network included multiple subcommittees and workgroups that the sites worked on together with NCI staff to prioritize and implement program efforts. It was an aspect of the program that clearly evolved over time such that in the first few months there were monthly meetings with NCI and the PIs from the sites and gradually expanded to include subcommittees that addressed each of the six program components as well as other aspects of program development (e.g., advocacy, communications). Across the sites, the efforts and time NCI staff spent on this network were greatly appreciated. All of the sites repeatedly (over the 3-year site visits) described how much they had learned from the network and from the ability to maintain contact with hospitals that were similar in function and capacity. Although most had suggestions for how to improve the network (e.g., allow sites to provide more input into agenda development, create more workgroups to address focused efforts), every person we talked to noted how much they had learned through this collaborative and indicated that they would like to see it continue. Not only had they learned from the direction provided by NCI staff but also from each other. In addition to the formal network meetings, many sites shared how they had called other sites to ask for specific input on their activities or obtain mentoring on addressing issues as they arose. In numerous cases, NCCCP teams from one site arranged to travel to another NCCCP site to observe how they operated around a program component (e.g., setting up new MDC conferences) and obtain guidance on the challenges they would face if they were to implement similar efforts at their site. Sites that are lead Community Clinical Oncology Programs (CCOPs) shared that this type of shared learning was not an aspect of CCOP implementation and they wish it had been. Many sites believed that their relationships with the NCCCP network sites would continue communicating on an ongoing basis even if NCI's involvement ended.

17.2.10 Theme 10: Sustainability Depends on Maintaining a Connection to NCI

When asking sites during the Year 1 site visits about their reasons for participating in the NCCCP, a consistent response was that they wanted a formal relationship with NCI. Over the course of the pilot, this perception was shared time and again from senior executives, including CEOs and CFOs, as well as many of the key cancer physicians we interviewed. The partnership with NCI, a well-respected national leader in cancer research, was a critical aspect of their involvement and their willingness to invest their own funds in meeting program requirements. Benefits provided by this relationship included a stronger local market position and greater creditability among their patients and the community. Many respondents shared that another benefit was enhancing their ability to recruit cancer physicians to their hospital. We know anecdotally that two physicians hired over the course of the pilot agreed to relocate to one of the NCCCP hospitals because of their participation in the program and connection to NCI. When asked about sustainability of the program, a

consistent finding was the emphasis on the connection to NCI; without that, sites were uncertain what aspects of the NCCCP would continue beyond the pilot. Many of the program activities, such as those related to quality of care and clinical trials, would continue without the NCCCP, but areas where respondents believed their site would stop or at least slow down their development included in reducing disparities (e.g., eliminating outreach and community screening events), collecting and reporting biospecimens, and implementing IT activities not required by the national health care reform. Ultimately, it is difficult to assess sustainability. Although sites varied in terms of their level of matching investments, the perception among many respondents was that any investments related to the NCCCP would be difficult to sustain without a formal connection to NCI.

Related to the NCCCP, it is worth noting that connections with entities within the NCI cancer research network have been established through the NCCCP and most will likely continue. Outside of the NCCCP network, sites have increased the number of partnerships they have with NCI-designated cancer centers, other programs funded by NCI, and national cancer organizations such as the American Society of Clinical Oncology, the Commission on Cancer, and the American Cancer Society. These partnerships have helped to improve patient access to Phase I and II clinical trials, to collect and report additional specimens to tissue banks, to measure adherence to evidence-based practice, and to enhance opportunities for partnering on related efforts (e.g., outreach projects).

17.3 Findings for the Three Major NCCCP Program Components

The NCCCP aims included addressing six program components: disparities, clinical trials, biospecimens, IT, quality of care, and survivorship/palliative care. An overarching evaluation question was the extent to which changes in each program component, and for the cancer service line overall, seem to be facilitated by the NCCCP. Across program components, sites focused a great deal of effort in activities specific to disparities (e.g., creating partnerships, collecting racial and ethnic data, providing cancer screenings), clinical trials (e.g., minority accrual in particular), disparities care (e.g., creating partnerships with community agencies, collecting racial and ethnic data, providing cancer screenings), and quality of care (e.g., establishing MDC conferences). Overall, sites had worked to a lesser degree to implement activities specific to survivorship and palliative care, IT, and biospecimens (which was appropriate given their contractual obligations).

17.3.1 Conclusions for Implementation of the Disparities Program Component

In implementing activities to reduce disparities, it is important to consider that this work typically takes a long period of time because the hospital needs to first build trust in their local community and establish partnerships, often for the first time, with underserved communities and organizations representing them. In some cases, the site also has to work

to identify their local disparate populations and how best to access them for outreach and screening efforts. Overall, having disparities as a program component

- made the sites think more about how to reach out to local disparate populations;
- improved upon their existing outreach structures and processes;
- provided them with direction on the know-how for and importance of tracking patients who are screened by the cancer program;
- enhanced their understanding of how to track and report racial and ethnic information such that many hospitals implemented Office of Management and Budget (OMB) reporting in several of their databases;
- increased their level of effort in providing cancer screening events;
- guided hospitals to invest in this area of care (e.g., creating positions for outreach staff that were not necessarily funded by the NCCCP, allocating space, purchasing screening equipment);
- increased the perception among patients (as measured through the patient survey) of greater access to care among less educated respondents; and
- increased their patient navigation services, which were initially designed to address disparities in breast cancer treatment outcomes (Freeman, 2006).

Challenges with this program component included not having a clear vision until later in the program (i.e., mid-2008) about what the sites should be doing to address their local disparities and how they should best use their time. In addition, because of the time it takes to build the local partnerships and because the NCCCP pilot was for only 3 years, there were fewer increases in formal partnerships than will likely be needed to sustain the outreach and screening activities beyond the funding period. Although sites increased their informal partnerships, research has shown that unless partnerships are formalized and the agencies have a positive history of working together, the relationships are far more difficult to maintain (Roussos & Fawcett, 2000). It is important to note, however, that many of the NCCCP sites began the program without knowing much about how to establish any partnerships, so even developing a few over the course of the pilot may represent important lessons learned that they can apply beyond the end of the program.

17.3.2 Conclusions for Implementation of the Clinical Trials Program Component

Building clinical trials capacity can also take a long time because there is a lot of capacity building that is required in order to open the first trial. First, sites need to enhance their research infrastructure by getting organized and establishing the leadership for research, enlisting support from physicians, hiring research staff, meeting regulatory requirements, and establishing IRB and research pharmacy support. As sites begin to open more trials, they need to learn efficient and effective ways to monitor and maintain the regulatory requirements, set up contracting agreements, develop procedures, and enhance their

knowledge of the types of trials their patients would most benefit from and the process for setting each up. Over the course of the NCCCP, sites clearly

- increased infrastructure and capacity (e.g., greater number of open trials, phases of trials opened, better access to IRBs, increased number of physician accruing patients);
- established processes to enhance patient accrual such as incorporating clinical trials into review of each case presented at MDC conferences; and
- increased accrual of underserved populations for racial/ethnic minorities, rural populations, and the over-65 population (site reported and Cancer Therapy Evaluation Program [CTEP] data).

NCCCP sites were implementing the clinical trials program component in a national context that included large trials being closed and an overall decline in patient accruals across cancer centers. The fact that an increase in capacity and infrastructure was present across the sites indicates that over time the number of patients accrued to trials will increase. Most notable improvements in patient accruals were among sites that were less developed in clinical trials at the time of the launch. Because of the time and effort required to build the capacity to open just one trial and enroll the first patient, it is perhaps a greater achievement for those sites to increase from zero to only a very few patients accrued than it is for other sites with well-established accrual rates to increase beyond their baseline numbers. Some sites with established accrual rates may have reached ceilings in the proportion of patients who could reasonably be enrolled in clinical trials.

17.3.3 Conclusions for Implementation of the Quality of Care Program Component

Delivery of more advanced cancer care was the ultimate aim of the NCCCP. From analysis of the Rapid Quality Reporting System (RQRS) data described in Chapters 13 and 16, evidence was presented that the NCCCP sites were able to increase the reduction in their nonconcordance rates for guidelines around breast and colon cancer treatment (Halpern, Spain, & Holden, 2011). Other areas addressed by the quality of care component included enhancing MDC conferences and/or clinics, implementing the conditions of participation previously described, and working with sites to build their capacity to provide genetics counseling. Over the course of the pilot, most sites increased the number of MDC conferences, but a few had no changes. This aspect of program implementation took time because of the time physicians needed to be willing to devote to additional meetings. As with the clinical trials component, it seemed that it was a more significant accomplishment for a site to go from having no MDC conferences to one MDC conference by the end of the pilot than it was for a site to add one additional MDC conference to an already full calendar. Building the infrastructure to convene the meetings and the staff and physician engagement to attend them regularly were major barriers to this aspect of program implementation. We found that over time there seemed to be growing recognition of the value of MDC

conferences among physicians, and in many sites this approach was really beginning to take hold. Key aspects of MDC conference implementation that sites achieved included the following:

- four of the six sites that had no MDC conferences at baseline managed to add some by the end of Year 3;
- increasing numbers of physicians and staff were reported as regularly attending MDC conferences;
- four sites were able to get primary care physicians to participate in their MDC conferences;
- all sites reported that CRNs attend their MDC conferences;
- patient navigators were also attending most MDC conferences, potentially enhancing the sites' ability to improve care coordination; and
- several sites were pushing to establish procedures so that all newly diagnosed cancer patients would be presented prospectively at MDC conferences in order to develop their treatment plan.

However, challenges remained at some of the sites in terms of engaging their general surgeons in MDC efforts or in the cancer program overall. Only 7 of the 16 hospitals had been able to fully implement the conditions of participation over the course of the pilot, primarily because of barriers they faced in enlisting the support of their key cancer physicians in the "conditions" under consideration. We observed that a few sites were unable to recruit cancer subspecialists to their cancer centers because of the resistance among their existing physicians to potentially "losing" patients to these new specialists. One site shared how they were unable to gain the support from their senior executives to open a position for a surgical oncologist because of the resistance from their general surgeons. Sites were finding that have physicians be board-certified as a requirement of their conditions of participation was challenging for these reasons.

17.4 Limitations

The NCCCP evaluation was a comprehensive, multi-method design to which few federally funded programs are ever subjected. As a pilot designed and implemented out of NCI's Office of the Director, it was important that a rigorous evaluation be conducted by an independent party in order to provide findings that could guide decision making about the future of the program. We relied on multiple data sources, collected through a variety of sources, such that we were able to triangulate many of our findings from more than one source (Patton, 2002). As a longitudinal evaluation, we were able to track and monitor changes over time and obtain input from the sites on what they felt was being driven by the NCCCP and what changes would have happened without the program. In preparing this integrated overall evaluation, we were able to examine each issue through multiple

perspectives, a process rarely afforded program evaluators who are often working with only one or two sources of data in order to interpret the impact of an initiative.

Our approach to conducting the evaluation was state-of-the-art in that we started by developing a theoretically grounded framework, informed by current literature, for how we thought the program should work in an ideal situation. We used the framework to then guide each aspect of the evaluation plan, including the development of measures for each evaluation component, and to aid in the interpretation of findings as we have done in this report. However, as with any evaluation, there are limitations to the data used for the analyses that should be kept in mind. Obvious challenges, such as the limited number of sites that started the program at varying levels of capacity, have been addressed as best we can through our analysis approach (e.g., by assessing sites' success relative to their capacity at baseline). Other major limitations include the timing of the data collected; the completeness, accuracy, and specificity of the data collected; the focus of the data being collected by others; and time constraints on the final analysis.

In terms of the timing of the data collected, many of the time periods for which data were requested from sites differ across data sources. Responses to the BAS/IAS/FAS included some items that asked for progress in the past calendar year and some items that were specific to the last program or fiscal year. The site visits were all conducted in the spring and summer of 2008 and 2009 and the summer and fall of 2010; individuals were generally asked to provide responses over the "past year." Although most of these variations in the time periods for the available data were unavoidable simply because of when the sites provided the data, when the site visits could be conducted, or when findings were available, they do present challenges in determining specifically when changes occurred and which factors seem to be associated with the changes. We have attempted to control for these variations where we could by presenting more than one source of data, when available, or estimating that a change occurred "during Year 1" and not being more specific than that period of time. We carefully reviewed findings specific to these details to ensure that we reported changes relative to the correct points in time (e.g., the end of the program) as best we can given these constraints.

The completeness, accuracy, and specificity of the data also presented challenges. Many data sources were collected for program-monitoring purposes rather than for research; thus, the requirements of these data differed. In some cases, such as in the collection of the BAS, there was insufficient time to test the questions because data collection had to occur very quickly after the program launch. As we examined each source, we identified issues with missing variables and responses that were obviously erroneous, did not match when compared to a second data source, and/or were lacking specificity. To address these issues, we imposed data abstraction rules such that two sources of data were reviewed for each data element and, when there was disagreement across the sources, a second analyst reviewed the data to identify a validated data source. In many cases, we reviewed the data

as a group to resolve issues. However, for several indicators that we examined to include in this analysis, we were ultimately unable to use them due to concerns over the validity of the available data.

Since much of the data we used for the evaluation was collected for program monitoring purposes, we were often reliant on others to collect data and ask questions that we eventually had to rely upon for our analysis. In this way, we sometimes had limited input, usually due to a lack of time, as to what questions were asked, how they were asked, and of whom they were asked. Because the NCCCP was implemented through a subcontractor, there was a great deal of coordination that had to happen in order for the data to be collected from the sites. This coordination was happening within an already busy schedule such that there was often insufficient time to provide review and comment on the questions to be asked. Some data elements eventually had to be dropped because of this process and our not knowing how to interpret the responses.

Ultimately, this was a very comprehensive evaluation that provides assessment of a program during the pilot phase such that findings can be used to guide program development and make decisions about the future of program funding. Thus, this is a formative evaluation, meant to inform the development and implementation of a new pilot program, the NCCCP.

17.5 Summary

Overall, the implementation of the NCCCP seems quite timely given the growing national emphasis on personalized medicine and the increasing need for diverse populations to participate in clinical research. Research also shows the national urgency to better address the quality of patient care among different disparate populations, which the NCCCP endeavors to accomplish through the participating hospitals. Ultimately, NCI′s hope is that by having these hospitals participate in programs for personalized medicine (IT and biospecimens), they are being brought into the new cancer research network (e.g., caBIG, The Cancer Genome Atlas [TCGA]) in their own right. Even with the environmental context of the economic downturn and uncertainty with regard to health care reform, the participating hospitals seemed to have embraced the opportunity to be part of a new initiative with NCI and to do what was necessary to bring their hospitals′ patient care to a higher level. Although challenges to program implementation remain, such as the continued engagement of physicians in each aspect of program development and maintaining the support of senior executives in the program′s efforts, the NCCCP leaders at each site seem enthusiastic to learn from each other and apply proven strategies to enhance the program within their site. This evaluation facilitates the documentation of all the lessons learned and provides a means for ensuring that information gained through implementation can be applied to ongoing program improvements.

18. RECOMMENDATIONS

This report presents findings from the overall evaluation of the National Cancer Institute's (NCI) Community Cancer Centers Program (NCCCP) pilot, which was implemented from July 2007 to June 2010. The evaluation addresses findings during the period of initiation through implementation of the pilot. The ultimate aim of the NCCCP was to expand cancer research and deliver the latest, most advanced cancer care to a greater number of Americans in the communities in which they live. To achieve the program's stated aims, NCI established a public-private partnership with a selected group of participating hospitals and systems and their cancer centers, with a focus on six program components:

- reducing **disparities** across the cancer continuum;
- enhancing **clinical trials** research;
- increasing capacity to collect **biospecimens** per NCI's best practices;
- improving the use of **information technology (IT)** and electronic health records (EHR) to support improvements in research and care delivery;
- improving access to and **quality of cancer care** and related areas, such as the development of integrated, multidisciplinary care (MDC) teams; and
- placing greater emphasis on **survivorship** and palliative care.

NCI awarded a contract to RTI International in 2007 to conduct an independent evaluation of the NCCCP pilot program. The comprehensive evaluation included a multimethod, longitudinal design that addressed the following overarching evaluation questions:

- What changes in each program component and for the cancer program overall seem to be facilitated by the NCCCP?
- What organizational requirements seem important to effectively manage/implement the NCCCP?
- What changes and elements are sustainable and potentially replicable in other community hospitals?

Although this was a very short program, implemented from 2007 to 2010, the evaluation yielded massive amounts of information and lessons learned from this important pilot effort. In Chapter 17, we presented our overarching conclusions around 10 themes of findings and described findings for each of the overarching evaluation questions. We have now grouped these themes into two areas of recommendations for the future of the NCCCP should the program move forward: (1) the aspects of the model (i.e., the way the NCCCP is designed) that are supported or should be considered for changes based on findings from the evaluation and (2) the organizational requirements that are supported as being important to facilitating NCCCP implementation. Table 18-1 provides an overview of the overarching recommendations aligned with conclusions and specific recommendations.

18.1 Recommendations Specific to the NCCCP Model

As described in Chapter 2, the NCCCP model encompassed a number of concepts that were based on the rationale that most cancer care occurs in the community (estimates are that up to 85% of cancer patients are served by community hospitals). This reasoning was grounded in the thinking that if cancer outcomes are to improve and research is to be expanded, there needs to be more attention paid to the locations where the majority of cancer patients are likely to access cancer care in their communities. As the federal government's principal agency for cancer research, NCI's mission centers around advancing cancer research and training (www.cancer.gov), so development of the NCCCP to enhance research capacity among community hospitals—which would ultimately extend the reach of research to a broader population of patients—was well aligned with the agency's mission. Hence, the need to focus efforts on care provided through community cancer centers.

18.1.1 Aspects of the NCCCP Model Supported by Evaluation Findings

The NCCCP model incorporated the six key program components that were designed to address cancer care across the continuum and influence the participating hospitals to build their cancer research capacity. Although the primary focus on enhancing research was through conducting clinical trials, sites were also to identify ways to improve collection and reporting of high-quality biospecimens. These research components combined with enhancing aspects of cancer care by improving both access to and quality of care, as well as increasing survivorship and palliative care services, established a model for the program that was quite broad and complex. Overall evaluation findings strongly support that the model should continue to be

- conducted through a public-private partnership between NCI and selected hospitals,
- focused on addressing cancer health disparities and cancer research, and
- supported by the NCCCP network and ongoing involvement from NCI staff.

By maintaining these three aspects of the NCCCP model or design, NCI will continue to leverage their capital in expanding cancer research to a broader array of communities. Hospitals welcomed the opportunity to partner with NCI and wanted to continue this relationship. Sites that involved senior executives as collaborating partners in their daily NCCCP activities were more likely to obtain the necessary resources for implementing NCCCP components compared to sites that did not involve top management. Some hospitals stated they were even willing to "pay for the privilege" of having a formal connection to NCI. The power of this partnership cannot be overstated. Our findings from all of the studies demonstrated that developing the NCCCP through a network of hospitals that received ongoing technical assistance from NCI staff was invaluable to the participants and provided them with a mechanism to more quickly and efficiently expand their cancer services and enhance their cancer research. It was also clear that without the focus of the NCCCP on

cancer disparities, many of these hospitals would not be expanding in these areas of care. Most of the hospitals held community cancer screening events on a limited basis prior to the NCCCP, but most had fairly limited knowledge about their local disparate populations and had not developed effective strategies for reaching out to those residents. The NCCCP provided them with mentoring and guidance on how best to conduct outreach in key communities and engage disparate populations in their services.

Finally, our findings strongly support the value of the NCCCP network and the mentoring sites received from each other and from NCI staff. Most respondents believed they had learned a great deal from each other and they would not have received that type of opportunity in any other type of program. Sustaining the NCCCP network beyond the pilot will be a challenge. Plans could be made now for how to make the NCCCP network more self-sustaining (i.e., procedures for sites to operate the network without a contractor's help). Sustainability will also be enhanced if NCI infrastructure is established to support this program. Most NCI staff guiding the NCCCP sites seemed to already be very busy with their current positions and were adding the NCCCP work onto their schedules. Therefore, the extent to which the NCCCP could continue without investment from NCI into staffing for the program is uncertain.

18.1.2 New Aspects to Consider for the NCCCP Model

Additional aspects of the NCCCP that would benefit the future development of the program include

- Establishing explicitly defined phases of the program so that sites can better set priorities and direct their efforts over time, and
- highlighting the need for formal collaboration between NCI research programs and the NCCCP.

As noted in the conclusions, the NCCCP pilot required a great deal of time for sites to first understand what was expected of them and then apply it to their cancer program (i.e., most sites took at least 1 year for this process). Some of the sites started out as very strong in many of the program components, but no one site was a leader in all six areas of the NCCCP. Because sites were relying mostly on physicians and others who were implementing aspects of the NCCCP in addition to their otherwise full-time positions (and not necessarily for the benefit of their private practice, when applicable), it may have helped sites to achieve more measurable outcomes if they had first prioritized where they wanted to focus their efforts and developed work plans that involved phasing or staging the components into their program over a specific period of time. For each phase, the programs would be required to meet specific deliverables. For example, NCI may determine that sites should first focus on both making sure they have their key physicians on board with the program and their infrastructure in place to implement the program (e.g., a clinical research department where there are staff who can focus on cancer clinical trials, a well-functioning

Institutional Review Board [IRB], adequate EHR capability, sufficient MDC conferences or a platform for accomplishing MDC conferences). For the pilot hospitals, so much had to happen so quickly that the sites became somewhat frustrated with the program, not knowing where best to spend their efforts. The more NCI can work with future sites to set the priorities early on and help them "phase" their work, the more sites will be able to deliver on specific outcomes of the program. An illustration of how the program could be phased is by establishing that the first 6 months of the program is to focus on capacity building such that sites are to

- conduct a needs assessment (i.e., similar to the gaps assessments conducted for biospecimens and IT at baseline) to identify gaps and areas of greatest need for improvement;
- identify a minimum number of program components of focus, perhaps a core set of priorities in that one must be addressing disparities, with another area of focus on some aspect of cancer research capacity (e.g., trial capacity) and develop work plans for each with measurable objectives;
- identify (and/or hire) key staff and physician leaders for the selected focus areas; and
- meet with top management to review work plans and enlist their support for key areas of investment (e.g., space needed for new staff, opening of new positions).

At the end of the first 6 months, each site would have a draft work plan that could be reviewed by NCI and revised accordingly so that each site has specific but tailored deliverables based on their areas of focus. Each site would also potentially be assigned to work on specific subcommittees of the NCCCP network (that correspond with their work plans) to receive guidance and mentoring from other sites and NCI staff. As the sites evolve, they could then be prioritizing where to spend their energy for a sustained effort. In this way, NCI could have sites, for example, that are fairly advanced in clinical trials research serve as mentors to other sites that are developing that area, while these mentoring sites focus their efforts on disparities, an area they need to develop further.

In terms of collaborations with other NCI-funded programs, it was clear early in program implementation that NCCCP sites were experiencing numerous barriers in establishing linkages with NCI-designated cancer centers, although they experienced success in developing relationships with the local Community Network Programs (CNP). We often heard during interviews how sites were struggling with these relationships, and many had come to believe, rightly or wrongly, that other NCI-funded programs felt threatened by the existence of this new program and the potential that it brought in reducing their own funds from NCI. It was clear that the sites struggled with articulating the value they brought to these other programs such that the benefit to collaborating with them was made clear. One consideration in moving forward would be to establish the requirement that other NCI-funded programs, such as an academic medical center, be strongly encouraged (or even required) to collaborate with NCCCP sites so that they can each build capacity. For academic

medical centers, the "value added" of a partnership with the NCCCP could be access to cancer patients they would otherwise not be able to enroll in clinical trials (particularly patients from disparate populations) or obtain their biospecimens. For the NCCCP sites, the value added would be to build their research capacity by partnering on grant applications or providing access to their local population to test interventions. These types of requirements would highlight the complementary nature of the programs to the work of existing NCI programs and the positive contributions this program can make to enhancing overall cancer patient care.

18.2 Recommendations Specific to Organizational Requirements for Future NCCCP Sites

As NCI decisions are made about whether to expand the NCCCP, consideration should be given to the variation of future sites. Although it was important to have a broad diversity of sites participating in the pilot in order to learn about the variables to consider in selecting sites, these lessons learned can now be applied to the selection of future sites. There are key aspects of cancer care related to NCCCP participation that NCI may want to consider as benchmarks for selection of future hospitals. From our evaluation findings, we would recommend that a more similar set of hospitals with key characteristics be selected for participation and that NCI start by setting benchmarks from which each hospital needs to start in order to be selected. Program requirements for sites should emphasize the following:

- **Alignment of fit** between the NCCCP aims and the hospital's mission, including
  - **History of programs related to providing charity care** to their local community and having this as part of their hospital's mission; and
  - **Demonstrated top management support** that is assessed through more than a letter of commitment from the CEO but requires details on specific ways in which senior executives will provide ongoing support and visibility for the program and its staff;
- **Capacity for conducting clinical trials research** such that there is at least 1 clinical research nurse on staff, an NCI trial has been opened at the site within the past 2–3 years, and the site is a member of at least a small number of cooperative trial groups to ensure they have ready access to trials; although the number of patients accrued in the year prior to the NCCCP was used as the benchmark for clinical trials capacity (n = 25 or more for lead sites), setting the bar higher with more specific indicators of capacity, yet not so high that the sites have potentially reached a ceiling in patient accruals, would ensure greater accomplishments;
- **Hospitals with specific organizational characteristics**, including
  - **Larger hospitals** with a greater patient volume and access to a broader array of subspecialists (e.g., require that they have at least a minimum number of medical and radiation oncologists collocated in their cancer center, have at least one type of surgical specialist, and do not rely only on general surgeons);

  - **A physician director of their cancer program** with a set minimum proportion of their time allocated to this position (e.g., 25% or greater); although lead sites were required to have this physician in place at the end of the pilot period, the leadership this role brings to the program is essential to facilitating many of the key activities (e.g., engaging physicians in attending MDC conferences, implementing conditions of participation); thus, a physician director is needed from the start;

  - **Direct reporting relationship** between the cancer program's physician director and one of the senior executives (i.e., CEO, COO) to provide ongoing access to hospital resources and support;

  - **Distinct cancer service line**, although not necessarily a standalone cancer center, but an organized set of activities and staff, under the leadership of the physician director, that demonstrates coordination across key areas of cancer care;

  - **A program coordinator** specific to the NCCCP whose primary role includes coordinating activities across the program components; and

  - **NCCCP principal investigator with direct access to the physician director** of the cancer program and perhaps to top management and who is not otherwise embedded in the hospital's structure or far removed from the cancer program that he/she will have little impact on influencing peers to participate in activities; and

- **A core set of physicians willing to commit time** to the NCCCP, perhaps as identified leaders at baseline for each program component the site is to address. These physicians need to include more than the principal investigator and/or the cancer program medical director, perhaps including one from each of the treatment modality specialties (i.e., clinical and radiation oncology, and surgery) and together one can serve as the lead, while the others are co-leads or in some designated role from the start. Their role can include facilitating involvement in NCCCP activities among their peers.

In terms of alignment of fit between the NCCCP and hospital's mission, it was important that all of the participating hospitals in the pilot program had a history of programs related to providing charity care to their local community and saw that as a core part of their mission. Many of the hospitals already had a strategic plan in place or were developing one that specified areas of growth that matched those in the NCCCP aims. Because of this fit between the NCCCP and each hospital, they were willing to invest their own money into this initiative since they saw it as supporting their strategic goals as an organization. In addition, with new sites, NCI could consider requesting that the CEO or COO not only provide letters of support for the program (with any future applications for funding) but also list specific ways they plan to support the program (e.g., attendance at program meetings in the first 3 to 4 months, presentation of program at upcoming hospital board meetings, allocation of direct resources such as staff hirings). This would make much more tangible the expectations for top management, and would give them concrete ideas about what they can do to advance the NCCCP.

For cancer research, as a core mission for NCI, the NCCCP has to address this area in order to remain a viable addition to the research network. It seemed as though setting a minimum of 25 patients accrued to clinical trials as of 2006 as a benchmark for selecting lead sites did little to capture the extent to which sites truly had the foundation from which to build their cancer research. Most of the sites were able to build their research infrastructure over the course of the pilot (e.g., increase in clinical research nurses and access to an onsite IRB) such that it is likely patient accrual will start to increase in the next few years. However, NCI may want to select sites with these aspects of their infrastructure in place (at some minimum level) so that increases in accruals can be detected more quickly. For this reason, NCI should consider whether there are other metrics, perhaps informed from the analysis conducted by Duke University's Cancer Care Research Program, that could be used in selecting sites for future participation.

Other aspects of the organizational requirements are specific to the hospital's structure and staffing. As NCI selects new NCCCP sites, it will be important to examine their organizational structure and assess the extent to which the cancer services are aligned with each other. We believe it is important for medium- to larger-sized hospitals, as opposed to small ones, to be considered for future NCCCP sites. These hospitals will have a higher patient volume and will likely have access to a greater number of cancer physicians, including perhaps subspecialists. However, in order to maintain the link to communities, so that this program can help to reach people across the country, it will be important not to set the size requirements so high that only hospitals in urban areas can meet the criteria. In addition, we believe that selected hospitals should have a physician director of their cancer program from the state and have a cancer service line that is organized in such a way as to distinguish it from other functions in the hospitals. We also found it to be fairly critical that this physician director has direct access to the top management in order to access resources and support. Finally, in many structures, it may be necessary to require programs to allocate funds to establishing the role of a program coordinator who can facilitate the necessary linkages and coordination required for program implementation. In addition to this leadership, sites need to have access to and involvement from other key medical staff. There has to be at least a strong core of private practice or employed physicians interested in clinical trials, biospecimens, and/or improving the quality of care in each of the core oncology disciplines (hematology/oncology, surgical oncology, radiation oncology) in order to implement key aspects of the NCCCP.

This pilot was set up to examine the extent to which it was beneficial to NCI to fund system-level sites as opposed to individual hospitals, with the hope of improved dissemination of the program. From our findings, we know that one of the two systems was very centralized in its management structure while the other was more decentralized. It was clear from our findings that if system sites are selected in the future, those that are more centralized will be able to access resources on behalf of the program and coordinate activities across the

participating hospitals. Overall, however, the individual hospitals did seem to be able to better focus their efforts and make changes more efficiently because they were operating within only one bureaucratic structure.

18.3 Summary on the Future of the NCCCP

A comprehensive evaluation design was implemented to assess the NCCCP pilot. The design included multiple methods used to collect data across all sites during the 3-year pilot period. We have presented an integrated report of the findings across all of the evaluation methods. By following our conceptual framework in presenting the findings, we have presented results across the years from baseline (Chapter 4), through the focus on Year 1 (Chapter 5−7), and for Years 2 and 3 (Chapters 8−15). With each chapter, we have presented the details of findings specific to different concepts underlying the NCCCP model or for each of the program components. After presenting the findings for the details of the program, in Chapter 16 we began the process of synthesizing the findings to the major themes from across the findings, as presented in Chapter 17. From those themes, we have focused our recommendations on two areas of change: to the NCCCP model and to the sites selected to participate in the program should it continue. Although this pilot was very short, only 3 years, which did not allow sites to make a great deal of change in that timeframe, we found that much was accomplished nonetheless. This evaluation provides important insights into factors that contribute to success and can be considered for continuation or expansion of the program.

Table 18-1. Overarching Recommendations Mapped to Supporting Conclusions and Specific Recommendations

Overarching Recommendation	Supporting Conclusions	Specific Recommendations
Changes to the NCCCP model	The NCCCP pilot requires time for start-up and prioritization of goals.	▪ Establish phases of the program (e.g., sites can focus on capacity building during the first 6 months and identify focus areas). ▪ Allow sites to focus on 2–3 program component areas at a time, rather than all 6 (or more). ▪ Assign "mentors" to new sites such that those that have been implementing the NCCCP can provide specific guidance and orient new awardees.
	Establishing a public-private partnership between NCI and the participating hospitals provided the NCCCP with tremendous benefits.	▪ Federal government funding often requires a specific matching of funds for each dollar of an award. Given findings from the cost study, NCI could establish a 1:3 match such that for every $1 from NCI, the site has to demonstrate matching funds of $3.
	The NCCCP enhances cancer research capacity.	▪ Provide direction for integration of the NCI cancer research programs: – Highlight the value the NCCCP can bring to NCI-designated cancer centers and their research portfolio. – Establish the expectation that NCI-designated cancer centers have to create a formal linkage with at least one NCCCP site that involves more than patient accrual to trials.
	The NCCCP network, with NCI guidance, provided important collaborative learning opportunities. Sustainability depends on maintaining a connection to NCI.	▪ Create a plan for sustaining the collaboration across NCCCP sites: – Establish procedures for the network to become operationally self-sustaining. – Establish internal infrastructure within NCI that allocates staff to work on the program as part of their job responsibilities (e.g., a program coordinator at NCI similar to the role that several sites established).

(continued)

Table 18-1. Overarching Recommendations Mapped to Supporting Conclusions and Specific Recommendations (continued)

Overarching Recommendation	Supporting Conclusions	Specific Recommendations
Organizational requirements important to NCCCP implementation	Baseline variation in organizational characteristics made it difficult to set benchmarks for program implementation.	▪ Establish criteria that all hospitals must meet to ensure that those identified as NCCCP sites have at least a minimum set of characteristics at baseline (e.g., specific capacity for conducting clinical cancer research).
	Support from senior executives facilitates program implementation.	▪ Ensure that the NCCCP mission aligns with the strategic plan for the hospital's cancer program, including a history of providing charity care, and hospital's top management provides specific ways for which they will support the program.
	NCCCP activities require physician leadership. NCCCP activities require involvement from numerous cancer physicians.	▪ Select only those sites with a physician director of the cancer program already in place. Ensure support from other physician leaders by assigning responsibilities or roles at the start of the program, or somehow assess their commitment to NCCCP activities. Consider as a benchmark that hospitals have to have a minimum number of cancer physicians who are willing to take on leadership roles within the program (e.g., two cancer physicians with a minimal percentage of time available to devote to NCCCP activities, such as one to lead enhancing research capacity and another to focus on developing new MDC conferences; or consider only hospitals with at least one radiation oncology practice located in their cancer center since this was a key physician several had difficulty accessing).
	Communication and coordination across program components facilitates NCCCP accomplishments.	▪ Encourage sites to institute an NCCCP coordinating committee that works internally to effectively communicate and integrate program activities ▪ Select sites with a distinct cancer service line or with clear plans for integrating services during the program period ▪ Select sites that demonstrate that physician director of the cancer program has direct communication channels with senior executives

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GLOSSARY

All trials: includes therapeutic, prevention, and symptom management/cancer control trials that are sponsored by NCI, industry/pharmaceutical sponsors, and "other" sponsors. SAIC-F defines "other-sponsored" trials as "Externally Peer-Reviewed Trials: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc. and Institutional Trials: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center."

Cancer center: refers to the cancer center or cancer program within a site; some sites have a standalone cancer center while others do not.

Cancer center/program leadership: refers to the senior leaders of the cancer center or program in each hospital. For some hospitals, there are medical directors (i.e., physicians) who serve as the cancer center/program medical director, but for other programs the leadership could include the executive director when there is no cancer program medical director or one that serves only in a related role for a small proportion of their time.

Cancer center/program staff: these individuals include all cancer center medical directors, cancer center administrative staff, and staff who have been assigned with specific roles on the NCCCP (not including principal investigators or program coordinators). It is an all-encompassing term to identify quotes from interviewers considered to be part of the cancer program at each hospital.

Cancer program: refers to the cancer center or cancer program within a site; because many of the NCCCP sites have cancer services that are fairly fragmented throughout their hospital (i.e., not a well-defined service line) and may or may not have a standalone cancer center, the term "cancer program" is used to encompass all cancer services.

Cancer service line: well-defined, mutually exclusive category or grouping of individual services or interventions focused on the delivery of cancer care in a hospital.

Clinical research studies: includes research activities that are not classified as clinical trials: screening, early detection, diagnostic, epidemiologic, observational, outcome, ancillary, and correlative studies.

Clinical trials: includes trials categorized as therapeutic, prevention, and symptom management/cancer control.

Developmental sites: refers to the six pilot sites that were selected to participate as part of a system of hospitals. These sites were termed "developmental" because they did not meet the baseline measures (e.g., cancer patient volume of 1,000 or more in 2006) to qualify as "lead" sites for the NCCCP. The health systems participating in the NCCCP pilot were Ascension Health and Catholic Health Initiatives (CHI). Ascension Health had one lead site (St. Vincent) and two developmental sites (Brackenridge and Columbia St. Mary's). CHI designated two of their sites as their lead sites (Penrose-St. Francis and St. Joseph Medical

Center). CHI then established a regional network of hospitals in Nebraska to work as their developmental sites, including Good Samaritan (Kearney), St. Elizabeth Regional Medical Center (Lincoln), and St. Francis Medical Center (Grand Island).

Early-phase trials: includes clinical trials categorized as Phase I, I/II, and II.

Environment: includes the health care market, local health care policy, characteristics of community served, and linkage with the NCCCP network.

Hospital: refers specifically to the hospital at a site as a separate entity from the cancer center or program; this does not include the cancer center.

Key physicians: these individuals include any key cancer physicians who provide care to patients served by a participating cancer center.

Lead Community Clinical Oncology Program (CCOP) site: the awardees/lead institutions of record on the CCOP NIH U-10 Cooperative Agreement. These sites receive the funds as a CCOP site and are responsible for administering the program. The NCCCP pilot sites categorized as lead CCOPs are Christiana, Sanford Clinic, and Spartanburg Regional Medical Center.

Lead sites: refers to the 10 pilot sites (8 individual sites and 2 system sites) that received NCCCP funding: Billings Clinic, Christiana, Hartford Hospital, Our Lady of the Lake, St. Joseph Hospital, Sanford Clinic, Spartanburg Regional Medical Center, St. Vincent, and St. Joseph Medical Center.

Medicare market share: the total number of Medicare inpatients at the hospital divided by the total Medicare cases in the market.

Meta-matrix: a master chart that assembles descriptive data from each of several cases/data sources into a standard format (Miles & Huberman, 2003).

Minority (non-white) accrual to clinical trials: minority accruals were tallied for the following types of trials: "therapeutic, symptom management/cancer control, and prevention." Other trials are classified as anything other than "therapeutic, symptom management/cancer control, and prevention"; minority accruals were not collected for these types of trials. According to SAIC-F, sites were asked to report "minority accrual" as a single number with all races/ethnicities combined. For the majority of the data, sites were asked to report "minority accrual" without any differentiation between race and ethnicity. The quarterly report instructions were as follows: "Minority Accrual: Provide the number of minority patients accrued to each protocol for the period of this quarterly report." However, in Year 3, Quarter 4 (and for all of Spartanburg's NCI-sponsored trial data), a few began reporting this information by the Office of Management and Budget (OMB) race and ethnicity categories; "minority accruals" include American Indian, Native Hawaiian, Asian, Black and More than one race. Thus, for Year 3, Quarter 4 and Spartanburg's NCI sponsored trial data, we did *not* include each accrual entered into one of the following categories: White, Not reported/patient refused, Not reported/data not available. Also, we did *not* count any accruals in the "ethnic minorities" category.

NCCCP core team: includes the principal investigator, program coordinator, cancer leadership staff, and representatives from each program component.

NCCCP linkages: describes sites' relationships with other NCI research programs (e.g., cooperative trials groups, NCI-designated cancer centers, Moffitt Total Cancer Care Initiative).

NCCCP network: a formal collaborative that includes representatives from the 16 pilot sites as well as NCI staff working with the sites. The NCCCP network consists of an Executive Subcommittee, made up of the principal investigators and lead NCI staff as well as numerous other subcommittees and workgroups. Members of the network meet at least monthly on conference calls to develop activities specific to NCCCP program components.

NCI-sponsored trials: includes only therapeutic, prevention, and symptom management/cancer control clinical trials that are sponsored by NCI.

Non-concordance: captures the reductions in the proportion of patient cases meeting each evidence-based criteria without also meeting the stated guideline, such that the higher a site's negative number (i.e., reduction in nonconcordance), the more the site is improving (i.e., following the recommended guidelines).

Organizational culture: a set of basic tacit assumptions about how the world is and out to be that is shared by a set of people and determines their perceptions, thoughts, and feelings, and, to some degree, their behavior (Schein, 1985).

Organizational learning: the process of improving actions through better knowledge and understanding (Fiol & Lyles, 1985, p. 803).

Other-sponsored trials: externally peer-reviewed trials: R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc.; institutional trials: in-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center.

Performance Community Clinical Oncology Program (CCOP) sites: organizations and institutions supported on the CCOP NIH U-10 Cooperative Agreement that are not lead institutions of record. The NCCCP pilot sites categorized as performance CCOPs are Billings Clinic, Penrose-St. Francis, St. Elizabeth Regional Medical Center, and Our Lady of the Lake.

Pilot program: small-scale preliminary study to test the feasibility or improve the design of a program.

Principal investigators: these individuals were the ones assigned to lead the NCCCP program subcontract at each site. In several cases, the principal investigator was also the cancer center/program medical director, but sometimes this person served in more of an administrative role for the cancer center or was a key cancer physician (but not the medical director) at the site.

Program components: the six areas of focus for which all the sites were required to develop activities: disparities, clinical trials, information technology, biospecimens, quality of care, and survivorship and palliative care.

Program coordinators: these individuals were identified by the sites as having the role (formal or informal) of coordinating the program.

Senior executives (of the hospital or the system): includes executive-level managers of the hospital, like chief executive officers, chief operating officers, chief medical officers, chief information officers, and chief financial officers. As top management, these senior executives prioritize or sponsor an NCCCP-related initiative and direct the necessary resources to support program implementation at their facility. Top management and senior executives are used interchangeably in the overall report.

Site: includes both the hospital and cancer center; references to "sites" are not specific to either the hospital or cancer center. Some sites participated as part of a larger health system.

Subcommittee members: these individuals participated in the NCCCP network and included physicians, nurses, administrators, social workers, and any other individuals identified by sites as being critical to our understanding of their implementation of each specific program component.

System sites: refers to the pilot sites that operate as part of a system, including Ascension Health (St. Vincent Hospital, Brackenridge, and Columbia St. Mary's) and Catholic Health Initiatives (St. Joseph Medical Center, Penrose-St. Francis, Good Samaritan, St. Elizabeth Regional Medical Center, and St. Francis Medical Center).

Top management: includes executive-level managers of the hospital, like chief executive officers, chief operating officers, chief medical officers, chief information officers, and chief financial officers. As top management, these senior executives prioritize or sponsor an NCCCP-related initiative and direct the necessary resources to support program implementation at their facility. Top management and senior executives are used interchangeably in the overall report.

Underserved: refers to racial and ethnic minorities; rural populations; low-income, underinsured, and uninsured populations; and older adults who typically experience greater disparities and cancer screening, diagnosis, treatment, and outcomes.

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