February 2009

Evaluation Design Report for the National Cancer Institute's Community Cancer Centers Program (NCCCP)

Final Report

Prepared for

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ACRONYMS

ACoS	American College of Surgeons
AMC	Academic Medical Centers
ASCO	American Society of Clinical Oncology
BAS	Baseline Assessment Survey
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
CHI	Catholic Health Initiatives
CI	Confidence Interval
CMS	Centers for Medicare and Medicaid Services
CNP	Community Network Program
COC	Commission on Cancer
CPT	Current Procedural Terminology
CT	Clinical Trials
CV	Curriculum Vitae
ECOG	Eastern Cooperative Oncology Group
EHR	Electronic Health Record
EOC	Evaluation Oversight Committee
EPM	Evaluation Planning Matrix
FAS	Final Assessment Survey
GEM	Generalized Exponential Models
GOG	Gynecology Oncology Group
IAS	Interim Assessment Survey
ICD	International Classification of Diseases
IOM	Institute of Medicine
IRB	Internal Review Board
IRT	Item Response Theory
IT	Information Technology
MDC	Multidisciplinary Care
MPH	Masters of Public Health
NCCCP	NCI's Community Cancer Centers Program
NCCN	National Cancer Care Network
NCDB	National Cancer Database
NCI	National Cancer Institute
NIH	National Institutes of Health
NPAC	NCI Program Advisory Committee
NSABP	National Surgical Adjuvant Breast and Bowel Project
OMB	Office of Management and Budget
PCC	Patient-Centered Care
PDSA	Plan-Do-Study-Act

PI	Principal Investigator
QCA	Qualitative Comparative Analysis
QI	Quality Improvement
ROI	Return on Investment
RQRS	Rapid Quality Reporting System
RTI	RTI International (trade name for Research Triangle Institute)
RTOG	Radiation Therapy Oncology Group
SAIC	Science Applications International Corporation
SES	Socioeconomic Status
SID	Sequential ID Number
SQL	Structured Query Language
SSL	Secure Sockets Layer
SWOG	Southwest Oncology Group
TA	Technical Assistance
TBD	To Be Determined
USPSTF	United States Preventive Services Task Force

EXECUTIVE SUMMARY

RTI International (RTI) has been selected by the National Cancer Institute (NCI) to evaluate the NCI 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 has been designed to address key evaluation questions at five possible levels of intervention: (1) national, through the network or learning collaborative being developed by NCI to administer the NCCCP; (2) organizational, within the systems and hospitals that the program is being implemented; (3) programmatic, for the impact on delivery of the cancer service line; (4) individual, in terms of the impact on patients' perceptions of the quality of care they are receiving within each participating hospital; and (5) with regard to each program component of the NCCCP. Three overarching questions guide this 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 manage/implement the NCCCP?

What changes and elements are sustainable and potentially replicable?

This plan will be used to guide the development of metrics and methods to assess the program over the course of the 3-year pilot. RTI will be responsible for conducting a case study, an economic study, and a patient survey and for providing ongoing feedback on overall program development.

For the case study, RTI will conduct site visits during each of the 3 years of program implementation to obtain in-depth information about aspects of program design, development, and implementation. During the first year of site visits, RTI focused on understanding the processes and structures at three of the four levels of evaluation: national, organizational, and programmatic. Patient-level and program component outcomes will be addressed in future years, as well as through other evaluation methods. The primary evaluation outcomes specific to the case study include

understanding NCCCP implementation,

assessing change in site performance over time, and

determining NCCCP structures and processes associated with successful performance.

To prepare for the site visits, RTI will draft new protocols each year based on the evaluation plan in order to collect data from four (or five, for systems-based sites) primary groups of individuals:

- hospital leaders and management staff (and system staff if a systems-based site),
- NCCCP leaders (including leads for each component, such as the information technology expert) and cancer program staff,
- key physician leaders (e.g., surgeons, department chiefs), and
- patients (and possibly caregivers).

Prior to each site visit, RTI will review documents available from each site (e.g., applications, progress reports) and abstract information into a qualitative database for coding and analysis over the 3 years. Each year, RTI will develop individual site reports and incorporate findings from the case study into an annual cross-site evaluation report in Years 2 and 3.

The overall purpose of the patient experience survey is to gain an understanding of the patients' perspective on the NCCCP pilot study and to assess how well patients' health care and informational needs are being met. Through the survey, we will assess 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. For the survey, RTI is developing an instrument that will include existing, tested items for each construct incorporated into the evaluation plan, and newly developed questions as needed. The draft survey has been tested through cognitive interviews in both English and Spanish. Once the survey has been finalized and institutional review board (IRB) approvals have been obtained, RTI will provide sites with complete packages for mailing the survey to eligible respondents. The survey will be designed to be completed on paper, over the phone, or via the Web. The initial survey will be administered in early 2009 and repeated approximately 15 months later to obtain the best possible feedback from patients during the NCCCP pilot.

The economic study is designed to assess sustainability and potential for replicability of the pilot programs. This part of the evaluation will include both a micro-cost study of program activities and a strategic case analysis to identify the financial or other motivations for organizational participation in the NCCCP. For the micro-cost study, RTI has developed a data collection tool that will identify the funded and unfunded costs of activities attributable to participation in the pilot. RTI will use the core components of the NCCCP as the underlying structure to estimate activity-based costs. The primary questions to address through the micro-cost study include:

- What are the total implementation costs for the sites?

What are the costs of operating the NCCCP annually?

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 will analyze program cost structure by activity and source of funding and will include the findings in our annual evaluation report. We will also identify core program activities that are associated with outcomes that can be consistently measured across all sites and used to compute incremental costs per additional outcome unit. For these activities, RTI will analyze site-level variation in cost-effectiveness and consider differences by type of organization and by level of readiness prior to the start of the pilot.

The strategic case study will integrate original data gathered from executive interviews with secondary data on organizational, financial, and local market conditions. RTI will conduct telephone interviews with chief financial officers at each site 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. Follow-up interviews at the end of the third year will probe leadership perceptions of success or failure with respect to initial expectations.

These data, in addition to secondary data analysis from the baseline assessment survey and other sources, will be analyzed and reported in the annual evaluation report to be provided to NCI at the end of the second and third years. Protocols for the site visits will be adapted at the beginning of each calendar year to incorporate knowledge gained during the previous visits and to address additional evaluation specified in the 3-year evaluation plan. As data are collected through the site visits, coding and analysis will be completed in order to provide cross-site, longitudinal findings for the NCCCP and to inform future program development. A list of manuscripts is being developed to ensure proper dissemination of the findings by informing ongoing evaluation research innovations and organizational theory and management research.

1. INTRODUCTION[1]

1.1 Overview of the NCCCP

The NCCCP is a 3-year pilot program to test the concept of a national network of community Cancer Centers 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.

The pilot program is designed to encourage the collaboration of private-practice medical, surgical, and radiation oncologists, with close links to the NCI research and to the network of 64 NCI-designated Cancer Centers principally based at large research universities.

The NCCCP seeks to

bring more Americans into a system of high-quality cancer care,

increase participation in clinical trials,

reduce cancer health care disparities, and

improve information sharing among community Cancer Centers.

This evaluation design report outlines a comprehensive, yet feasible, evaluation plan for the NCCCP.

1.2 Summary of the NCCCP Sites

NCI selected sites for participation in the NCCCP based on a number of selection criteria, including

hospital dedication to a cancer service line (e.g., free-standing Cancer Center building);

delivery of care to at least 1,000 new cancer cases per year;

plans for implementation of an electronic health record (EHR) system within the 3-year pilot program;

accrual of at least 25 patients (at least 50 was preferred) into clinical trials annually;

assurance that their hospital offers treatment to all patients diagnosed with cancer, regardless of insurance status; and

variation in sites, such as geographic region served and whether the site was a Community Clinical Oncology Program (CCOP) site.

Based on these criteria, a total of 10 programs were funded: eight individual hospitals and two system sites, which altogether includes 16 hospitals. The two system sites, Catholic Health Initiatives (CHI) and Ascension Health Systems (Ascension), each selected a "lead" site to facilitate the implementation within their system of the NCCCP to select other "developmental" sites. These developmental sites could include hospitals that did not meet the selection criteria above but had the potential to do so by the end of the pilot. CHI

[1] Elizabeth Adams contributed to the writing of this section.

selected two lead sites that met the selection criteria: St. Joseph Medical Center in Towson, Maryland, and Penrose-St. Francis Health Services, in Penrose, Colorado. CHI added a developmental site that is regionally based in Nebraska and encompasses three hospitals: Good Samaritan Hospital in Kearney, St. Elizabeth Regional Medical Center in Lincoln, and St. Francis Medical Center in Grand Island. Ascension selected St. Vincent Indianapolis Hospital in Indianapolis, Indiana, as the lead site and two additional hospitals as developmental sites: Columbia St. Mary's in Milwaukee, Wisconsin; and Brackenridge Hospital in Austin, Texas. Table 1-1 provides an overview of selected NCCCP site characteristics.

Table 1-1. NCCCP Site Overview

Funded Programs	Name of Participating System/Hospital	Location	Type of Site (Individual or System Site; Lead or Developmental Site)	Description of Geographic Region	Local Disparate Populations (listed in order of population size)	CCOP Site	# of New Cancer Cases (Cancer Center only) in 2006	# of New Cancer Cases (hospital and Cancer Center combined) in 2006
1	Hartford Hospital	Hartford, CT	Individual	Urban	African Americans; Hispanics	No	no data	2595
2	St. Joseph's/Candler Hospital	Savannah, GA	Individual	Urban	African Americans; Hispanics	No	586	1,057
3	Spartanburg Regional Hospital	Spartanburg, SC	Individual	Urban/Rural	African Americans; Hispanics	Yes	1,379	1,379
4	St. Joseph Hospital	Orange, CA	Individual	Urban	Asians; Hispanics; African Americans	No	315	1,527
5	Sanford Clinic	Sioux Falls, SD	Individual	Rural	Rural elderly; Native Americans	Part of Regional Site	1,236	1,236
6	Our Lady of the Lake Regional Medical Center	Baton Rouge, LA	Individual	Urban/Rural	African Americans; Hispanics	Yes	1,299	2,591
7	Billings Clinic	Billings, MT	Individual	Rural	Rural elderly; Native Americans	Part of Regional Site	1,429	1,429
8	Christiana Health Care	Newark, DE	Individual	Urban	African Americans; Hispanics	Yes	2,863	2,863

(continued)

Table 1-1. NCCCP Site Overview (continued)

Funded Programs	Name of Participating System/Hospital	Location	Type of Site (Individual or System Site; Lead or Developmental Site)	Description of Geographic Region	Local Disparate Populations (listed in order of population size)	CCOP Site	# of New Cancer Cases (Cancer Center only) in 2006	# of New Cancer Cases (hospital and Cancer Center combined) in 2006
9	Ascension Health Systems	Indianapolis, IN	Lead System Site	Urban	African Americans; Hispanics	Yes	2,713	3,195

		Austin, TX	Developing System Site	Urban	Hispanics; African Americans	No	149	2,032
		Milwaukee, WI	Developing System Site	Urban	African Americans; Hispanics	No	no data	1,662
10	Catholic Health Initiatives	Penrose, CO	Lead System Site	Urban/Rural	Hispanics	Part of Regional Site	no data	1,223
		Towson, MD	Lead System Site	Urban	African Americans; Hispanics	No	1,078	1078
		Kearney, NE	Developing Regional System Site	Rural	Rural elderly; Native Americans	No	175	553
		Lincoln, NE	Developing Regional System Site	Urban/Rural	Rural elderly	Yes	210	772
		Grand Island, NE	Developing Regional System Site	Rural	Rural elderly; Native Americans	No	150	559

1.3 Process Completed for an Evaluability Assessment

A great deal of work has been accomplished in the first year of the evaluation assessment and implementation. The following provides an overview of the steps completed to date in designing the overall evaluation. As described more thoroughly in Section 2.1, RTI, with input from NCI and others, has developed a conceptual framework for the NCCCP pilot using knowledge of the settings in which they will be implemented and current prominent theoretical constructs. Using these and other theoretical constructs to provide a foundation for the evaluation design, a multimethod (qualitative and quantitative) and multilayered (managerial to direct service providers) approach will be used to fully respond to the evaluation questions and activity areas described in Section 2.2. The evaluation questions have been prioritized through the process outlined below.

1.3.1 Step 1: Pilot Site Evaluability Assessment (September 2007–June 2008)

The first task for the NCCCP pilot evaluation focused on conducting an evaluability assessment. Evaluability assessment is an analysis of the feasibility and utility of the evaluation (Wholey, 1978). This process was created to determine the extent to which an effectiveness evaluation was feasible for a particular program (Smith, 1989). The evaluator must clarify what the program is intended to accomplish and determine the measurements of program performance that are feasible and relevant for the goals of the evaluation. This

involves a review of program documents, such as program plans, meeting minutes, proposals, progress reports, attendance records, and other archival information related to the program. Evaluability assessment also requires evaluators to familiarize themselves with the current literature on the issue under study. The goal is to help the evaluator understand the work that has already been done, the stage of development of the program, and the major objectives and activities that are discussed in the program documents.

During this process, the evaluator "clarifies the logic of the programs (resources, activities, objectives and causal links between activity and objectives); identifies those portions of the program which are ready for useful evaluation (well-defined objectives; plausible, testable causal links between activities and objectives; well-defined uses for evaluation information); and identifies feasible evaluation and management alternatives" (Wholey, 1978, p. 54). For this process, RTI completed several tasks to methodically determine the aspects of the NCCCP that could be evaluated in order to propose the most rigorous evaluation plan possible. These tasks included:

- review of all program documents to understand the activities and plans of each,
- participating in meetings and interviews with NCI staff and key stakeholders (i.e., members of the NCCCP Evaluation Oversight Committee [EOC]),
- specifying key evaluation questions to address during Year 1 site visits, and
- exploring with site staff (during visits, subcommittee meetings, etc.) feasible ways to collect priority outcomes for the evaluation.

As we followed this process, we began to create an evaluation planning matrix (EPM) that incorporates these key evaluation questions and matches them to process and impact measures appropriate to each level of inquiry (Section 2.2). As the NCCCP evolves, we plan to revisit these matrices to ensure that our measures are capturing the prioritized outcomes and that we are reporting on the findings of greatest importance to NCI.

1.3.2 Step 2: Engage Stakeholders (September 2007–September 2008)

RTI's approach has emphasized the need to facilitate evaluation planning with careful consideration of the many potential stakeholders and the array of possible uses for the evaluation (Holden & Zimmerman, 2009). For the NCCCP pilot, stakeholders include the NCCCP Evaluation Project Officer, Dr. Steve Clauser; the NCCCP Program Officer, Dr. Maureen Johnson; key consultants, Dr. Arnie Kaluzny and Ms. Donna O'Brien; the NCCCP EOC and the NCI Program Advisory Committee (NPAC) (lists of NPAC and EOC members appear in Appendix A); Science Applications International Corporation (SAIC) staff, including Joy Beveridge and Deb Hill (i.e., the contractor working directly with NCCCP sites); and others as requested. This evaluation design has been created in full collaboration between RTI and all the identified stakeholders.

We first met with the Program Officer for the evaluation, Dr. Steve Clauser, and for the program, Dr. Maureen Johnson, the EOC, NPAC, and others at the kickoff meeting in Maryland on September 17, 2007. We then worked with NCI and SAIC to review and advise the development of baseline assessment surveys (BAS) that were to collect measures across all the pillars and components (henceforth referred to as components, including biospecimens, clinical trials, disparities, information technology, quality of care, and survivorship). The BAS were administered in November and December 2007. During that time, we began participating in conference calls with NCI and the EOC at least monthly to discuss the theoretical underpinnings for the NCCCP pilot evaluation and the research design for each component of the study. These discussions helped inform the development of the NCCCP evaluation conceptual framework (Section 2.1) and the protocols for conducting site visits to all the sites from February to June 2008 (Appendix B). As we planned to conduct the site visits, stakeholders were involved with initial planning calls with each site; they advised us on whom to meet with during each visit and the priority questions to address. As we returned from site visits, we participated in debriefing conference calls with these stakeholders to share preliminary impressions and discuss ways to incorporate lessons learned into the ultimate evaluation plan.

1.3.3 Step 3: Describe the NCCCP Pilot Program (October 2007–June 2008)

Through this evaluation planning process, RTI has thoroughly described how the sites are setting up their programs and what they plan to accomplish. Tools that RTI created to describe the NCCCP evaluation include two conceptual frameworks and two comprehensive EPMs (Section 2). As part of the evaluability assessment, RTI developed "topline" summary reports for each of the 16 NCCCP sites based on documents reviewed and site visits conducted between February and June 2008. The first set of site visits were considered to be an important step toward completing the evaluability assessment of the NCCCP and developing a feasible set of metrics and measures to be collected over the 3-year pilot. At the same time, we have worked with sites to understand the economic data they currently have available and to create the templates for collection of cost data. We have also established the methods and criteria for drawing the patient sample and administering the survey through the use of each site's registry. We now thoroughly understand the systems the sites have in place that can be used to provide evaluation data, and we have incorporated this information into this design report as feasible.

1.3.4 Step 4: Focus and Finalize Evaluation Plan (March 2008–November 2008)

Once all of the details were gathered through the document reviews, site visits, and other steps outlined above, a final important step to complete planning is to focus the evaluation. A final step in consensus building for the proposed evaluation plan was to obtain

stakeholder feedback and recommendations on the list of priority evaluation questions to be answered through the combined methodologies of the evaluation. Evaluation planning is most effective when it involves a process of consensus building among the key players who will be using the evaluation findings (Patton, 2008). On July 28, 2008, RTI convened a key stakeholder meeting to review outcomes in each of the four levels of the evaluation and make decisions about the priority questions to address in the overall evaluation plan. Evaluation questions were then reviewed and revised through e-mail exchanges with a core group of EOC members and NCI staff. Through iterations of each section of this design report, the evaluation plan has now been finalized with NCI and is presented in the remainder of this report. It is important to note that this evaluation plan will be revisited each year to ensure that it remains current in describing all the methods being implemented to assess the NCCCP pilot.

1.4 Overview of this Report

This report contains an overview of the evaluation and the overarching questions to be addressed in our final analysis. In Section 2, we describe the development of the NCCCP evaluation conceptual framework and present literature used to support the development of the evaluation's constructs and themes. We then describe the overarching evaluation questions for each of the five levels of inquiry and identify the methods for assessing each. This overview section is followed by a detailed summary of each of the three types of studies or methods being conducted for the NCCCP evaluation, including a case study (Section 3), methods for assessing patient outcomes (i.e., the patient survey and patient/caregiver focus groups) (Section 4), and the economic study (Section 5). We conclude the report with a description of our overall analysis plan to be completed in the final few months of this project (Section 6) and the timeline for completing each deliverable (Section 7).

2. EVALUATION OVERVIEW

2.1 Overview of the NCCCP Evaluation Conceptual Framework

As described in Section 1.1, the ultimate aim of the NCCCP is 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 has established a national network of participating community hospitals and systems and their Cancer Centers and is focusing on six program components where specific deliverables are required from the sites:

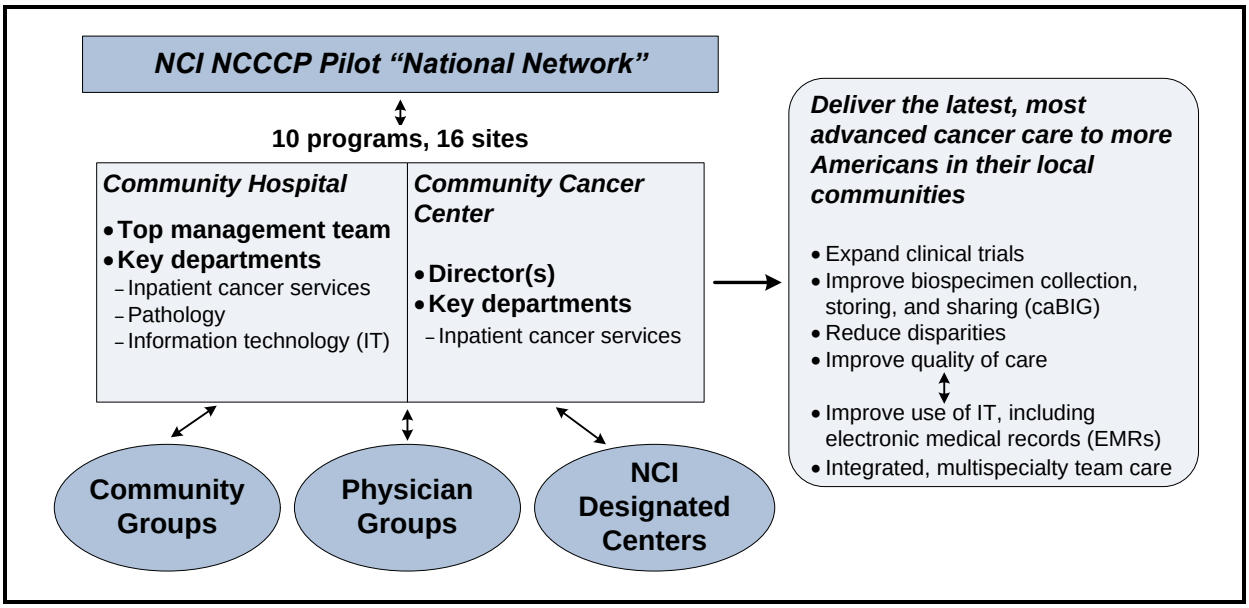
- increasing capacity to collect **biospecimens** per NCI's best practices;
- enhancing **clinical trials (CT)** research;
- reducing **disparities** across the cancer continuum;
- improving the use of **information technology (IT)** and EHRs to support improvements in research and care delivery;
- improving **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.

The six program components have differing levels of importance with respect to the NCCCP evaluation. Disparities is perhaps the most important program component since 40% of the funding for the NCCCP came from NCI's Center to Reduce Cancer Health Disparities. CT, quality of care, and survivorship are important as well because of their overall impact on direct patient care. Because the NCCCP sites are new in conducting biospecimens research and/or developing IT systems, NCI is focusing on having the sites assess their capacity for each and address gaps as they can during the 3-year pilot program. For this reason, these two components are of lower priority importance to the overall program evaluation.

Figure 2-1 illustrates how the NCCCP is structured as a national program. In the center box, features of the sites themselves are noted as being critical to the success of the NCCCP. These include aspects of the hospital itself, such as its leadership and the key departments that provide services specific to the NCCCP (e.g., pathology for biospecimens research, IT housed within the hospital structure, inpatient cancer services), and of the Community Cancer Center (CCC) or program (e.g., the physician leaders directing NCCCP implementation, the outpatient cancer services involved in delivering care). These entities will work closely with and be informed by NCI's National Network specific to the NCCCP. This Network consists of key staff at all 16 participating hospitals and members of NPAC, who are NCI leadership staff involved in guiding sites through implementation for each of the six program components. Together, this Network meets on a regular basis, through a number of subcommittees that include staff from across the NCCCP sites, to determine activities and approaches to implement across the sites and for each component. In addition to the

National Network, the NCCCP sites also need to be prepared to partner with local community groups, key physicians providing cancer care, and NCI cancer research programs to most effectively implement NCCCP strategies. Together, these entities will work toward achievements in each of the six program component areas as shown in the right-hand box of Figure 2-1.

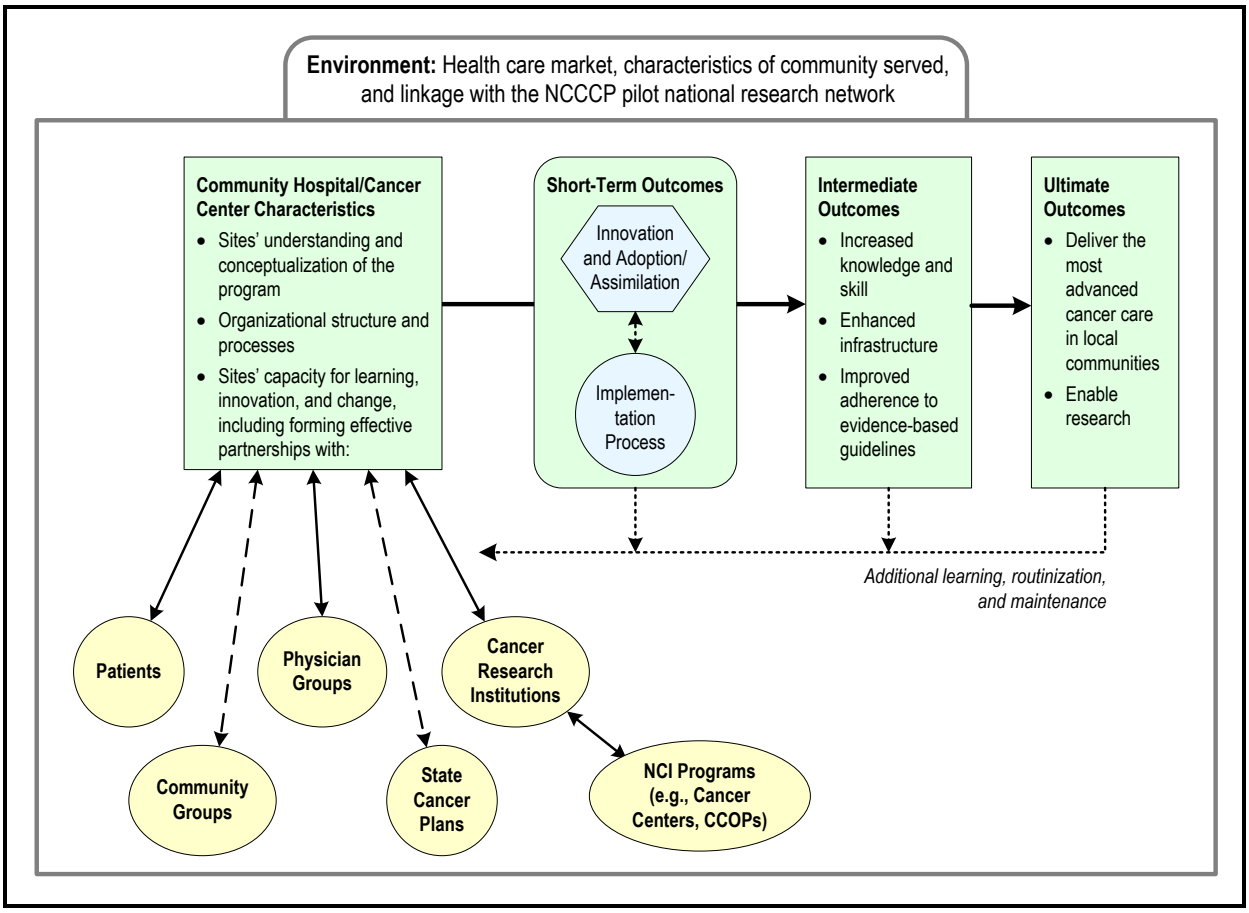
Figure 2-1. NCCCP Pilot Program Model



This initial model served as a basis for developing an understanding of the NCCCP sites and what they were being asked to achieve. We recognized that developing and implementing the NCCCP requires substantial learning, innovation, and change by participating sites and by NCI and its program staff who oversee the program. This is particularly true for three reasons. First, no single NCI program has ever identified these specific and ambitious overarching goals, particularly the emphasis on delivering the latest, most advanced cancer care to more Americans in their local community and combining the six program components into a single, unified program. Although there are potential synergies among the program components, it is challenging to develop a comprehensive yet practical NCCCP that accomplishes these major aims and for which the whole is truly greater than the sum of its parts. Second, participating hospitals (selected because of their identification as "community hospitals") have historically not been as involved as academic medical centers (AMCs) in national efforts to advance cancer care and research. These hospitals have different competencies and constraints. Thus, they may face some unique challenges and have a relatively steep learning curve in some areas. Finally, due to advances in cancer care and research, as well as the unique nature of the NCCCP and the community hospital setting, there are fewer well-established strategies for making progress in some program

components to achieve the program goals. Rather, community hospitals and the NCCCP National Network must collectively invent many elements of the program required to achieve the NCCCP aims. The following sections describe our evolving understanding of the NCCCP, which led to the development of our evaluation conceptual framework (Figure 2-2).

Figure 2-2. NCCCP Evaluation Conceptual Framework



2.1.1 NCCCP Requires Organizational Learning

Organizational learning has been defined as "the detection and correction of errors" (broadly conceived, as in gaps between actual and desired performance) (Argyris & Schön, 1978, pp. 2–3) or "the process of improving actions through better knowledge and understanding" (Fiol and Lyles, 1985, p. 803). 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 means 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., improve 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 centered care. Across organizations or within wider professional communities, approaches like collaboratives of various kinds can be established and used. Finally, various approaches have been used to develop partnerships with community-based organizations and coalitions that share an interest in reducing disparities and improving the quality of care and research.

Given the nature of the NCCCP, the conceptual framework used for the evaluation primarily draws on the theoretical literature and applied research on learning, innovation, and change. We also draw on related theoretical literatures and applied research in health care, including quality improvement, process re-engineering or redesign, patient-focused or centered care, implementation research, learning collaboratives, diffusion and dissemination of innovations, 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 but cursory literature review and relied on key experts in

organizational learning and management, 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, several theories needed to be drawn upon to understand and evaluate different aspects of the program. For example, some theories were more helpful than others in informing the measures and outcomes to incorporate into the evaluation, depending on the unit of analysis (e.g., network, organization or site, program, patients), the specific program component and related tasks (e.g., invent new strategies and tactics or implement those that are more well-established), and the specific evaluation question (e.g., how to accelerate implementation, how to disseminate proven or promising practices).

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. The major domains are

- the local and national environment in which each hospital operates, including linkages with the NCCCP staff and National Network;
- characteristics of each hospital and CCC and "fit" between characteristics of the CCC 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 CCCs 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 CCC's characteristics, and the *process* of implementing the NCCCP both at the National Network level and by CCCs.

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 CCCs' ability to make greater progress toward achieving intermediate goals and ultimately the desired program outcomes—for example, how key aspects of the environment or CCCs' characteristics may affect their ability to innovate, adopt and assimilate innovations made by others, or implement changes required by the NCCCP. These hypotheses are discussed in Section 6.

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

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 CCCs are dependent on other organizations (e.g., insurers) for key resources for which they must compete with other organizations (e.g., other CCCs). 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 health care policy and market, the characteristics of the community served, and the linkage with the NCCCP National Network. The adage that "all health care is local" applies to the first two aspects of environment. As described in Section 1.3, the NCCCP includes 16 sites, which operate in 14 states. While 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 health 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 CCCs' 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 CCC relative to insurance plans and competitors (e.g., other CCCs, physician groups, and possibly AMCs). For example, some states and markets have relatively low rates of uninsured and populations with relatively comprehensive health insurance benefit packages. As such, they 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 not yet typically applied to cancer care, these activities give CCCs incentives to develop the infrastructure necessary to improve quality. Finally, the power of the participating CCC relative to other hospital systems and physician groups is often important. On the one hand, greater competition and less market power may stimulate CCCs to work harder to learn,

innovate, and improve. On the other hand, too much competition and not enough market power may result in CCCs 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 CCCs' strategic case for the NCCCP, described in Section 5.3 of this evaluation report. Other influences from the environment that might impact NCCCP implementation include the hospital's financial viability and operating profit margin, relative to competitors in the local community. Sites will need to perceive that NCCCP can provide them with benefits, beyond the funding provided by NCI, that are more valuable than the anticipated costs of implementing the program. This profitability of the hospital and how NCCCP may impact it are measures to be incorporated into the evaluation at both the environmental (i.e., fiscal health of the NCCCP sites relative to others in the community) and the organizational (i.e., operating margins and profitability of oncology services) levels.

Community Characteristics. Two key aspects of the characteristics of the communities in which CCCs 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 CCC 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 will provide unique opportunities and challenges for CCCs or sites, as they work to achieve the ultimate aims of the NCCCP.

NCCCP National Network. NCI and its support contractor, SAIC, through their programmatic or contract administration responsibilities and activities, are essentially providing technical assistance and running a learning collaborative, or the NCCCP National Network. To date, the "Network" includes the NCCCP sites themselves, NCI staff involved in NCCCP implementation, and institutions funded through the NCI cancer research network: NCI-designated Cancer Centers, CCOPs, and Community Network Programs (CNPs). In addition, the "Network" may include linkages among the NCCCP sites and the American College of Surgeons (ACOS), and other oncology-specific national organizations, but these are not currently included in the evaluation measures to be collected for the NCCCP National Network. Those organizations currently identified as part of this Network are important to include in the evaluation plan because of the impact they may have on how the program implements aspects of the program. For example, 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 to achieve them by all CCCs, but they also

provide input and advice to participating CCCs on their own specific program goals and potential mechanisms for achieving them. In addition, NCI and its support contractor work to foster peer-to-peer learning through a variety of mechanisms, including encouraging CCCs to interact with each other and other cancer research institutions and NCI programs. Previous research suggests that several aspects of technical assistance and learning collaboratives may influence whether and how rapidly organizations like CCCs 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, and CCCs, and between CCCs and other cancer research institutions and programs.

2.1.2.2 Community Cancer Center (CCC) Characteristics

As shown in Figure 2-2, the next major domain included in our conceptual framework is the characteristics of the CCC) which includes characteristics of the hospital within which each operates. Each CCC 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 CCC or NCCCP site would impact its ability to learn, innovate, change, and succeed in the NCCCP. But what specific aspects of the CCC'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 CCC or NCCCP site to learn, innovate, change, and succeed in the NCCCP. These include the CCC'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 CCCs or NCCCP sites to understand what they need to do to succeed in the NCCCP, they have to 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. As noted, 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 or have not been a major focus (e.g., quality of care, multidisciplinary teams, IT/EHRs). In addition, community hospitals are central to this effort, and to date they have not been as involved in activities of this nature. Finally, the NCCCP is a pilot and, as such, is a work in progress.

Given the uncertainty associated with any new program pilot like the NCCCP, the NCI National Network and individual CCCs and NCCCP sites will engage 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 and 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 and vision, culture), professional values and beliefs, or technical issues. Theories of organizational learning, innovation, and change suggest that sense-making will improve 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 (or group and 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. As such, it has been said that they often resemble a “professional’s repertoire.” However, people are often not aware of these models and their impact on their behavior. Therefore, a 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.

At a concrete level, current mental models that may shape participants' understanding and conceptualization of the NCCCP include traditional images of community hospitals, other NCI programs, and high quality cancer programs. For example, some NCCCP sites might conceptualize a CCC participating in the NCCCP as becoming a "super community hospital cancer program," a "CCOP plus," or a "junior academic medical center or NCI designated center." Still others have different or complementary images, such as a "community cancer care and research organizer" or a "crucial link or hub" between local communities, NCI, and the national cancer research communities. Although each of these images suggests the desire to be an elite group of community hospital cancer programs based on some criteria or benchmark, they may rest on slightly different assumptions about the NCCCP, what it is trying to achieve, how best to move forward, how success might be defined, and how long it may take for success to be achieved.

Organizational Structure and Processes. Building on the work of Donabedien (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 organizational outcomes (e.g., efficiency, effectiveness) and patient outcomes (e.g., mortality, morbidity, patient experience). In this evaluation, the CCCs' general structures comprise the internal environment or 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 CCCs or NCCCP sites to achieve the program's aims: the organization of the hospital within a health system or as its own entity, the hospital relative to its cancer services, the cancer services structure relative to that of the NCCCP, and the size of the system or hospital within which NCCCP is being implemented.

Organizational Structure: Hospital's Relationship to a Health System: The first important aspect of structure is whether the participating CCC or NCCCP site is a member of a larger health system and, if so, what kind of system. Some CCCs 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., forthcoming).

Organizational Structure: Hospital's Relationship to its CCC: 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 (i.e., functional, divisional, matrix, parallel, and service line or program), which 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, information technology) 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 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.

Organizational Structure: CCC's Relationship to the NCCCP: Within these general structures, each CCC will develop a unique NCCCP structure. Depending on the overall organization and oncology program design, top management and NCCCP leaders will determine which structure might work best for the NCCCP.

Organizational Structure: Organizational Size: A structural characteristic related to these other three structural features (system, CCC, and NCCCP) is size. Generally speaking, as organizational size increases, coordination and communication become more difficult. Thus, CCCs and cancer programs that are larger may have a greater challenge understanding and conceptualizing the NCCCP and getting all the pieces in place to move the program forward rapidly.

Organizatio nal 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 information technologies.

For further information, see IOM (2001), Ferlie & 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.

Organizational Processes: Leadership Qualities and Processes: There are many definitions of leadership, but one of the most useful descriptions of the concept is to think of leadership as an ongoing conversation among people who care deeply about something of

great importance (Ferlie & Shortell, 2001). In addition, leadership at all levels of an organization or CCC increases the likelihood of learning, innovation, and change. Therefore, it should be exhibited by different types of people (e.g., top managers, physicians, nurses) and in different forms (e.g., formal or informal opinion leaders or champions). Examples of leadership at different levels of the CCC 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 formation of ties with key external organizations.

Related to the issue of organizational learning, innovation, and change, Burns makes an important distinction between transactional and transformational leadership (1978): Transactional leadership works within the status quo and existing rule structures. It tends to emphasize incremental change by focusing on symptoms of problems and "single-loop learning." In contrast, transformational leadership works to upset the status quo and existing rule structures, replacing them with a "new order" or "new way of doing things." Transformational leadership focuses on breakthrough changes and represents "double-loop learning." In this way, leadership is both a structural feature and a process within each organization.

Organizational Processes: 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, CCC, NCCCP) increases the likelihood of learning, innovation, and change, in addition to more rapid movement and 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 CCCs' 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 CCC is willing to invest or that can be secured from other funders (e.g., local governments and foundations) may or may not be sufficient to achieve the aims of the NCCCP in the time desired. 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 Section 5.

Organizational Processes: 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 emphasizing 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 re-codify new knowledge; to link it with its own 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, and some of the other structural features described in this section.

Organizational Processes: Effective Team Building: In order to develop effective teams, it is important to first 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; share responsibility for tasks and outcomes; and 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).

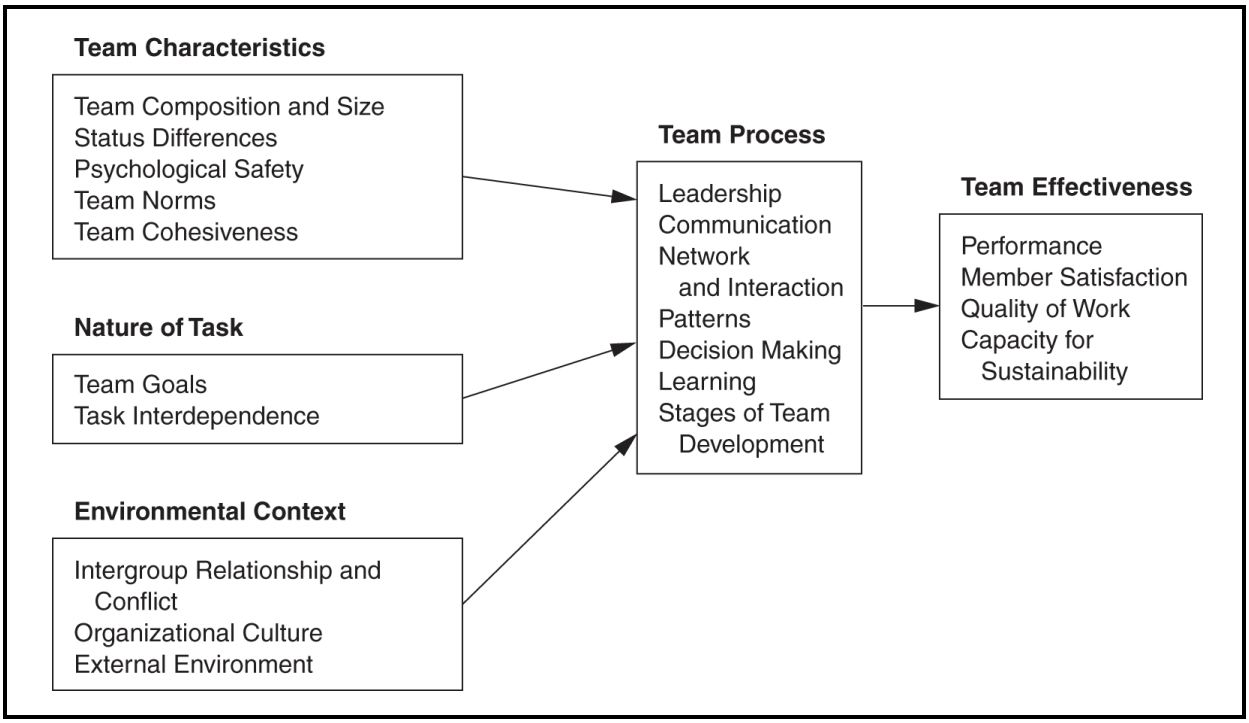
Project teams are time-limited teams that produce one-time outputs such as a new product or service.

Management teams are teams that coordinate and provide direction to the subunits under their jurisdiction.

A program like the NCCCP will certainly involve oncology work teams, but may also result in the development of parallel and/or management teams.

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 environmental context may all affect team processes and ultimately team performance (see Figure 2-3).

Figure 2-3. Model of Team Effectiveness



Source: Fried, Topping, & Edmondson, 2006

With regard to developing effective teams, it is worth noting that a great deal of recent literature and research in health care has referred to "micro-systems," so clarifying the similarities and differences between teams and micro-systems may be helpful. Teams can be thought of as the basic building blocks of micro-systems. The essential elements of a health care micro-system include (1) a core team of health professionals; (2) a defined population that they care for; (3) an information environment to support the caregivers and patients; and (4) support staff, equipment, and facilities (Nelson, Batalden, & Mohr, 1998). Some have described the job of the micro-system as standardizing care based on the best current evidence; stratifying patients based on medical need, and providing the best evidence-based care within each stratum; and customizing care to meet individual needs for patients with complex health problems.

Donaldson and Mohr (2001) discuss why the IOM uses the term micro-system rather than team:

> "The reason for this choice requires some explanation of both the origin of the term *micro-unit* or *micro-system* and the place of systems thinking in health care. Although the term *micro-system* is new to health care and may at first seem abstract and foreign, it was chosen carefully. The prefix *micro-* emphasizes its focus on small systems that are often embedded in larger *macro*-systems. The term *system* emphasizes that success in achieving

> clinical purposes requires the conscious development of *systems* to guide care processes. The committee adopted the term *micro-system* in contrast to more traditional terms, such as *team*, *practice*, or *panel* to emphasize the idea that a micro-system encompasses not just the practitioners but also the patients, technologies (including information technologies), and processes of care that are integral to their work. It also emphasizes *systemness* as a feature that can be purposefully advanced using regular, ongoing information about the outcomes of care that indicate how well the micro-system processes meet patients' needs" (p. 2).

Based on this description, one could view the micro-system concept as an attempt to incorporate a number of other important organizational structures and processes into a single integrated construct. Although research on micro-systems uses different language and focuses on a number of processes more specific to improvement in health care (e.g., Plan-Do-Study-Act [PDSA]), many of them overlap with constructs already in the literature For example, Donaldson and Mohr (2001) identified eight themes, or features, of highly functioning micro-systems: integration of information, measurement, interdependence of the care team, supportiveness of the larger system, constancy of purpose, connection to the community, investment in improvement, and alignment of roles and training. Many of these features are similar to the features identified and described above (e.g., information technology, leadership at all levels, alignment across all organizational levels, culture of learning and absorptive capacity, the importance of teams). Similarly, Batalden et al. (2003) focused on processes that teams can use to achieve peak performance (e.g., creating an awareness of work as a micro-system, developing micro-system thinking, and general quality improvement techniques such as PDSA).

Organizational Processes: Use of Information Technology: Finally, IT is an important structural feature of participating CCCs and health systems. Improving CCC 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 research and to connect patients and provider teams for a variety of purposes.

Capacity for Learning, Innovation, and Change. In addition to some of the structural issues outlined in the previous section, we discuss four organizational characteristics 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 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 not sufficient to stimulate innovation and deep and lasting change. Rather, internal sources of change (e.g., intrinsic motivation, organizational goals) must complement these external sources in order to not only create but also 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 not acceptable 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 either directly or indirectly cause a change in the behavior and/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 also exist with the NCCCP—such as the need for structural changes, the need to increase inter-department coordination, changes in managerial or leaders' roles, and resources allocation and budgeting—are often associated with increased power and politics in organizations.

There are a number of traditional sources of power within an organization and ways of increasing that power. The latter includes

- taking responsibility for areas of relative uncertainty and complexity (e.g., quality improvement initiatives, EHR implementation);
- satisfying strategic contingencies (e.g., dealing with activities and events, both inside and outside the organization, that are essential for attaining organizational goals);
- providing key resources (e.g., revenue, national visibility) to the organization or other key departments or units;

- creating greater dependencies or increasing the level of non-substitutability (i.e., difficulty of replacing the group);
- participating in and controlling, to the extent possible, information flows and decision-making processes; and
- expanding social networks and building coalitions.

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. Information may not be acted upon unless internal goals, incentives, and accountability mechanisms are utilized within the CCC (which relates to the issues of leadership, culture, and alignment described above.)

Fit or Match between Organization and NCCCP: A final factor that influences the capacity of CCCs 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 NCCCP pilot includes the perceived advantages relative to current practice (e.g., NCCCP results in superior quality of cancer care and research); compatibility with values, beliefs, and mission/vision; complexity (e.g., whether the innovation is relatively easy to understand and use); 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 are observable to key groups and stakeholders). We have already discussed the characteristics of CCCs (e.g., structures and processes, such as leadership, absorptive capacity, and readiness to change) and the NCCCP National 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.

Ability to Form Effective Partnerships with Key Groups in the Community. As Figure 2-2 shows, CCCs 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 CCCs, including those related to the NCCCP, but there may be some goals and interests that are not fully shared and seem to conflict; or various groups or stakeholders may disagree on the means for moving forward. The evaluation design for the NCCCP currently 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 2-2) but not for the community groups or state cancer plans (i.e., relationships depicted by the dotted lines in Figure 2-2).

For example, much has been written recently about the high degree of conflict in hospital-physician relationships, the reasons for it (e.g., conflicting incentives), and potential solutions, including working together to counterbalance the interests of insurers or competing CCCs and physician groups; having more physician input on boards; or specific arrangements involving employment, joint ventures, and contracts (see, e.g., Berenson, Ginsburg, & May, 2007; Goldsmith, 2007; Lake et al., 2003; Pham et al., 2004). Similarly, there may be challenges with successfully engaging patients or with forming effective partnerships with cancer research institutions and NCI programs that will need to be explored through 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 install an innovation developed by another organization into their own, 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 things (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 results have 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, and large-scale, transformational change is likely to occur through emerging, nonlinear and nonsequential, 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 process.

Despite these challenges, several models are helpful for thinking about these processes. They include Roger's (2003) Model of the Innovation Process, Lewin's (1951) classic three-stage change process and variants of it (e.g., Weick and Quinn, 1999), and Kotter's (1996) Transformational Model.

Roger (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, where 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). In the fourth stage, the innovation is clarified. More people gain experience with it, 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 where information about the innovation is initially absorbed and acted upon by a small body of highly motivated recipients. Dissemination is a more active process, where special efforts are made to ensure that intended users become aware of the innovation, then receive, accept, and use it.

Finally, in the routinization stage, the innovation loses its identity as being something new and is 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. These include 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 as it requires organizational members to accept new ideas and alter existing attitudes and behavior. Finally, 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).

A more recent model by Weick and Quinn (1999) turns this process on its head, proposing that change occurs through a three stage process that involves freezing, re-balancing, and unfreezing. The central premise is that organizations are already in flux and exist in an increasingly complex and unpredictable environment. Therefore, an organization must first freeze in order to create some stability and assess where it is and where it should go. Managers can facilitate freezing, sense-making, and the creation of mental models by sharing stories and examples of activities that illustrate the ideals or core assumptions and developing a clear vision of where the organization wants to go. Then managers can facilitate re-balancing: communicating core organizational goals and values by linking them to strategic alternatives. Once equipped with this unified vision and strategic direction, the organization can unfreeze, allowing various departments/units, teams, and individuals to resume their semi-autonomous activities.

Finally, Kotter's (1996) model of Transformational Change provides more guidance to managers attempting to engage in large-scale change. He proposes an eight-stage model, which includes 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 aspects of the CCCs, 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 CCCs 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 (see Section 3 on the case study). Ultimate outcomes will be assessed through the overall analysis described in Section 6.

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). As previously noted, 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 are 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 we propose the NCCCP will work and the conditions under which it will likely work best. Based on this framework (Figure 2-2) and our understanding of the NCCCP, in order to address each of the overarching questions, the evaluation will need to collect and analyze data at five possible levels of intervention:

- Network level (i.e., across the programs and within the National Network),
- organizational level (i.e., within the systems and/or hospitals) (see Figure 2-1),
- program level (i.e., within the CCC or cancer service line),
- patient level, and
- program component level (i.e., biospecimens, clinical trials, disparities, IT, quality of care, and survivorship).

Through work completed during Year 1 of the evaluation, we have developed primary and secondary questions (matched to key words) for each of the NCCCP's first four levels of potential impact listed in Table 2-1. Each of the key words are described in detail after Table 2-1. We then discuss the primary and secondary questions specific to the program components in the remainder of this section.

2.2.1 Evaluation Questions for the National Network

The primary goals of the NCCCP National Network are to provide formal and informal linkages between key entities involved in cancer research, including

- NCCCP participating sites,
- NCI (i.e., Project Officers, Consultants, NPAC), and

NCI cancer research programs (i.e., NCI-designated Cancer Centers, Community Clinical Oncology Programs [CCOPs]).

The formal Network was created specifically for the benefit of NCCCP and involves monthly conference calls for NCI staff and all 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 are co-led by staff members from the NCCCP sites, and an NPAC member with relevant expertise serves on each. A primary evaluation question at the network level is 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 encourages the sites to create formal "external" linkages with other cancer research programs, including NCI-designated Cancer Centers and CCOPs. Because several of the NCCCP sites are also CCOP sites or participate in regional CCOPs, the evaluation plan includes questions specific to how CCOP sites may differ in what they are able to accomplish relative to non-CCOP sites. These external linkages are critical to the NCCCP's establishment of credible research efforts since these outside entities are the national leaders in conducting this research. Many argue that much of the work to be attempted by the NCCCP cannot be effectively accomplished at the community level due to a lack of expertise in conducting this type of research or limited infrastructure within these settings. Much of the evaluation will focus on answering the question of whether the NCCCP is a feasible way to improve cancer research at the community level. Therefore, linkages between sites not

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Four Levels of Program Intervention

Level of Analysis and Domain from Conceptual Framework	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
Network Level (i.e., across the programs and within the National Network)—*Environment* in Figure 2-2	NCCCP linkages (internal)	How well has the 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 Network impacted how individual sites operate/ provide care	Case Study[a]
	NCCCP linkages (external)	How well has the Network facilitated sites to establish linkages with other NCI cancer research programs (e.g., NCI-designated Cancer Centers, CCOPs)?	What are the relationships of 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 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 didn't have prior to NCCCP involvement?	What is the impact of the Network and resulting products on the NCCCP sites and their cancer service line? What did they learn through Network connections that has helped them improve relationships with MDs, etc.? How have products been used (from the Network) at each site? 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., COC, ASCO)?	Specific examples of partnerships with NCI staff, NCI cancer research programs, other NCCCP sites Assessment of products and how used at each site	Case Study; Economic Study

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Four Levels of Program Intervention (continued)

Level of Analysis	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
	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 is the nature (e.g., frequency, mechanisms like phone or site visits) of the collaboration between NCI and the pilot sites? 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
Organizational Level (i.e., within the systems and/or hospitals)— *Community Hospital Characteristics (see Figure 2-2)*	Effective management practices	What are the organizational requirements necessary to effectively manage/implement NCCCP?	What are the key measures of readiness to implement NCCCP at any one site (for replication)? How much time does the physician director, if there is one, dedicate to the NCCCP? What are his/her responsibilities specific to 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 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 is the impact of the structure on the implementation of the NCCCP?	Role/priority of cancer services in overall hospital/system strategy Organization of cancer services within hospitals/systems	Case Study

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Four Levels of Program Intervention (continued)

Level of Analysis	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
	Physician practice models	What are the physician practice models through which 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? What are the necessary skills to effectively manage these relationships?	Organizational charts of relationships between leaders Barriers to each model and how that differs across sites	Case Study Economic Study Multimethod analysis
	Infrastructure	What infrastructure has the site developed (i.e., staff, data, program related) in order to implement NCCCP? What lessons did the organizations learn on the infrastructure required to implement NCCCP successfully?	What was the "human and physical capital" in place and how has that changed as a result of NCCCP? What institutional support for the NCCCP has been provided by which offices (CEO, board, etc.) within the hospital or system? What has the organization learned from the pilot about their approach to addressing health care disparities and if they have improved their ability to track their efforts?	Linkages between cancer program and other hospital departments (e.g., pathology, surgery, etc.) Assessment in changes in infrastructure over time and 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 NCCCP Increased infrastructure for NCCCP Investments relative to NCCCP (i.e., matching costs)	Case Study Micro-Cost Study Multimethod Analysis

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Four Levels of Program Intervention (continued)

Level of Analysis	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
	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 does the overall system structure and support impact 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
Program Level (i.e., within the Cancer Center or service line)- Cancer Center Characteristics (Figure 2-2)	Cancer service line changes	How has the NCCCP helped them 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 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 uninsured? How does NCCCP facilitate development of a 'seamless delivery system' to the patient?	Changes in scope and use of care/services provided during pilot study and extent to which related to NCCCP efforts (and not what they would have otherwise done) Patient's perceptions of coordination of their care	Case Study; Patient Survey and Patient Focus Groups
	Value added (of NCCCP)	What is the "value added" of the NCCCP to the cancer services provided?	For CCOP sites, what does NCCCP add to what they were already doing? Does being a CCOP sites make it "easier" to address barriers and implement NCCCP? What are sites doing as a result of NCCCP that they would not otherwise be doing? How is their "baseline" of activities related to their ultimate accomplishments?	Differences in barriers/ facilitators of NCCCP implementation between (lead) CCOPs and non-CCOP sites Extent to which both types of sites are able to implement other program components	Case Study;

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Four Levels of Program Intervention (continued)

Level of Analysis	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
	Economic indicators	What financial commitments do sites need to make to implement NCCCP relative to key outcomes (e.g., patients accrued to clinical trials, etc.)?[c] Do sites believe 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 NCCCP?	Labor/time commitments both invoiced and matched Opportunity costs of MDs Outcomes of interest relative to costs Profitability (or not) of cancer service line; staff perceived NCCCP impact on profitability	Micro-Cost Study (combined with other data elements from Patient Survey, etc., for cost-effectiveness)
Patient Level – Ultimate Outcomes in Figure 2-2	Population served	How does the population of patients served by the sites change during the time that they are an NCCCP pilot site?	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;
	Health disparities	In what ways do the sites reduce cancer health disparities (specific to screening only or across the continuum)? Are there differences in how patient subgroups (racial/ethnic minorities, low-income, uninsured) are provided treatment or access clinical research (i.e., CT accrual) when compared to those who are insured?	How do patient navigation services help to address cancer disparities at each site? How does access to care across the continuum differ for patient groups (e.g., MDC, screening, survivorship services)? How has the organization increased its effort in outreach to the underserved in its community?	Increase in minority/disparate groups served by cancer service line Increase in screening programs offered Percent change of patients by race/ethnicity served by cancer program	Patient Focus Groups and Patient Survey Case Study

(continued)

Table 2-1. Prioritized Primary and Secondary Evaluation Questions across the First Four Levels of Program Intervention (continued)

Level of Analysis	Key Words	Primary Evaluation Questions	Secondary Questions	Sample Outcomes	Methods
	Patient experience	What are the patients' reports of the quality of care they receive, including satisfaction with MDC and communication, emotional support, financial assistance, timely access to appointments, referrals, waiting times, and overall satisfaction with care?	How "patient-centered" does the care seem to be and how does that change over time? How well do patients believe their care is coordinated? To what extent have sites established services for patients to facilitate access to care (e.g., financial, transportation, child care)?	Perceptions of care received Knowledge of and access to services	Patient Survey Patient Focus Groups

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

[b]Relevant only to the NCCCP system sites.

[c]For key outcomes to be incorporated in the cost-effectiveness analysis, see Section 5.

already doing this work (i.e., NCCCP sites for the most part) and those that are leaders in it (i.e., NCI cancer research programs) are essential to building this local capacity. Possible linkages that could occur between the NCCCP sites and other NCI cancer research programs include

- 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 national level will focus on the linkages that are created as a result of the NCCCP (both internal and external), the benefits these linkages bring to the NCCCP sites, and the impact of the technical assistance (TA) they provide each other as well as what they receive from NCI.

2.2.2 Evaluation Questions for the Organizational Level

As described in Section 2.1, organizational-level factors (e.g., the sponsoring hospital's management and leadership) will likely have a huge impact on 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,
- physician practice models,
- infrastructure,
- plans for sustainability, and
- systems-based effects (when applicable).

In terms of effective management practices, as informed by Dr. Mary Fennell, the Chair of the EOC, this involves several management subtasks: (1) aligning goals and defining the NCCCP (i.e., early implementation), (2) building the infrastructure (e.g., hiring staff, building a data system, consolidating needed resources), (3) building the long-term structures/resources needed to support institutionalization of the program over time, (4) enhancing replicability (i.e., building the site so that it can be used as a model for other community hospitals or cancer programs), and (5) integrating with community physicians (both the existing physician practice models in the area and "freestanding" or independent MDs involved in cancer care). It will be important to understand both the processes and structures of the management styles at each site in order to better know which styles seem to lead to more effective implementation of the NCCCP (i.e., whether established program goals are met in the 3-year time period). Since NCI hopes to expand this program after the pilot, if outcomes are achieved, the evaluation needs to be able to identify the key features

of the organizational processes and structures that seem to be related to each site's readiness to implement the NCCCP. These readiness features can be used to better identify potential NCCCP sites in the future.

During the evaluability assessment, a key finding was the extent to which the NCCCP sites rely on private practice physician models for their cancer service line and how these practice models (and others) seem to be impacting the initiation of the NCCCP. In the private practice models, physicians have various forms of legal agreements with the hospital (e.g., lease space only, serve in an administrative role for a stipend or as a volunteer) that 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 work specific to the NCCCP. This "free" time commitment is often in addition to other responsibilities for the physicians that go well beyond a typical 40-hour work week. For this reason, primary evaluation questions will need to address how the sites are engaging these physicians within the medical model in which they operate, and which strategies seem to be the most effective in obtaining physicians' ongoing involvement.

Infrastructure is another key factor to include in the evaluation plan. This includes the extent to which sites already have 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 changes over time as a result of NCCCP participation. As noted in Section 2.1, changes will occur in part because of the leadership's support and allocation of funds to make the changes happen. Such changes include how the hospital addresses care to their local disparate populations and what lessons they learn from the NCCCP with regards to how to better meet the needs of these individuals.

One of the overarching evaluation questions involves the extent to which the NCCCP is sustainable at the participating sites. This question will be particularly important to address at the organizational level, which is why it is included here. It will be important to measure the factors that are 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 at the end of the pilot we can specify those factors that seem to be most strongly associated with whether a site has specific plans to institutionalize the changes brought about by the NCCCP.

The last primary question included under the organizational level is only specific to the two system sites participating in the NCCCP (Ascension and CHI). 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 that are not necessarily NCCCP sites. Information specific to this question will be primarily descriptive in understanding what the relationships are between the lead and developing system sites, what developing sites are able to accomplish relative to where they started, and how the system works 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 will be 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 in 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. While NCI does not expect these sites to become AMCs providing comprehensive care within the time of the 3-year pilot, there is the expectation that more and better services will be provided to patients over time. The evaluation is designed to assess the types of services provided to patients, how those services change or are enhanced over time, and the extent to which these services are provided in a seamless, patient-centered way to enhance the patients' experience.

The concept of value added is difficult to define, and some aspects of it will be impossible to measure during the NCCCP pilot. However, it is important to specify the extent to which these NCCCP sites are building and improving their cancer services in ways that they would have not done, or known how to do, had it not been for the program. This issue is particularly important to address for CCOP sites, since some argue that these sites should have been the ones selected as NCCCP sites (i.e., some say that being a CCOP should have been a selection criteria for the NCCCP). Because several of the participating sites are CCOP sites and the rest are not, the evaluation design provides the opportunity to assess whether this designation seems to influence how well sites are able to implement the NCCCP.

Another key evaluation question addresses the economic indicators for sites to become involved in the NCCCP. As described in Section 5, a specific component of the evaluation is an economic study that collects micro-cost data on the implementation of the NCCCP over the 3-year pilot, as well as evidence of the strategic case for implementing the NCCCP. We already know that implementation of the NCCCP required sites to provide $3 in matching

funds for every $1 received from NCI. Based on feedback during the first year of implementation, it is estimated that sites are investing far more than this baseline requirement in order to build their cancer service lines specific to the NCCCP. This evaluation will measure the incremental costs of implementing the program over time, and whether there remains a strategic case for participating in the NCCCP by the end of the pilot.

2.2.4 Evaluation Questions for the Patient Level

Priorities at the patient level are to enhance the quality of care patients receive and to ensure that all patients are able to access that care, regardless of insurance status, racial or ethnic background, or other potential barriers to care. The following three issues are 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 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 has 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 addresses 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 obtained through the disparities research program, 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 have varying levels of expertise in knowing how to conduct outreach to special populations and recruit them for services. Therefore, the evaluation will focus on how sites are able to better address care to these disparate groups. Unfortunately, because few sites collected these data at the baseline, the evaluation will not be able to provide findings at the patient level in terms of how outcomes of care vary for different groups. However, two methods are in place for the evaluation that will obtain data directly from patients through a survey and/or focus groups (Section 4). The focus of this second patient-level evaluation question is on what the organization is 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 patient survey and focus groups will be used to measure patients' overall impressions of their quality of care. Aspects of care that the patient survey will address 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 will also address these issues but will be used as a means to explore barriers and facilitators to patients accessing care and will enable probing of specific responses to obtain more details about patients' experiences.

2.2.5 Evaluation at the Program Component Level

In addition to the four levels described in Sections 2.2.1 through 2.2.4, because of the complexity of the NCCCP, there is a fifth level at the program component level such that outcomes for each of the components (i.e., biospecimens, clinical trials, disparities, IT, quality of care, and survivorship) will need to be tracked and measured over time. Through the processes described in Section 1.3, a set of prioritized questions for each program component has been developed (see Table 2-2).

2.2.6 Detailed Evaluation Planning Matrices

Once all of these overarching questions were agreed upon with key stakeholders, the lead evaluator developed an EPM to facilitate the development of the evaluation plan at each of the corresponding levels of intervention. The EPM is an organizational tool for evaluation planning and is organized by the five levels of intervention in the NCCCP evaluation. As a tool, the EPM helps to focus the evaluation by specifying the elements of the evaluation plan. We have developed two EPMs to span each level of analysis (Appendices C and D).

For each primary evaluation question, the EPM specifies its corresponding secondary (and in some cases tertiary) evaluation questions, short-term and intermediate outcomes of interest, data sources, and data elements. Each of these categories is briefly described below.

Primary evaluation questions: These are the evaluation questions developed for each of the five levels of intervention (Tables 2-1 and 2-2).

Secondary (and tertiary) evaluation questions: For each primary evaluation question, there are additional questions that need to be addressed through the NCCCP evaluation. These questions often specify in more detail the underlying processes, structures, or outcomes that will need to be incorporated into the evaluation methods and measures.

Short-term outcomes (less than 1 year): These are measures specific to each evaluation question assessed within the first year of program implementation. These measures are typically formative and focus on program implementation. The short-term outcomes are likely to inform ongoing program improvement. In the matrix,

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	Eval
Disparities	1. To what extent do sites enhance awareness, communication, and use of services (e.g., CTs, continuum of cancer care) for identified disparate populations? 2. What strategies do sites use to outreach to disparate populations in their region? What are the characteristics (e.g., partner involvement, approach used) of the strategies that seem to work best (i.e., greatest increases in screening activities)? 3. What are the organizational characteristics of sites that are best able to increase the proportion of patients in identified disparate groups for each service provided (e.g., screening, CTs, patient navigation, MDC)?	1. Changes in baseline and repeat of patient survey 2. Descriptions from staff during site visits of the strategies used that they consider to be a success in reaching disparate groups 3. Assessment of organizational characteristics from all data in case study	1. Increase identifie race/eth awarene cancer s 2. Lessons seem to increasi populati 3. Key fea structure to enhar groups
Clinical Trials	1. What organizational factors are related to increases in the types of CTs implemented at each site (e.g., Phase 2), changes in patient accrual (e.g., by race/ethnicity), or number of physicians accruing patients?	1. Assessment among staff during site visits of the level of support and infrastructure available to increase all aspects of CTs research	1. Facilitat adminis model) t increasi 2. Patient
Quality of Care	1. To what extent do sites increase multidisciplinary care for their patients? 2. How is patient-centeredness of care increased across sites? 3. How does quality of care (for key quality indicators) change at NCCCP sites when compared to other, similar hospitals?	1. Collect MDC specific data through baseline, interim, and final assessment survey of sites and case study 2. Survey and focus groups of patients early in the program and at the end of the pilot 3. Track performance based on RQRS reporting, within NCCCP program and compare (potentially) to similar non-NCCCP RQRS Community Cancer Centers	1. Improve decrease treatmer with car 2. Increase about co physicia 3. Evidenc on key M endorse cancer c

(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	Eval
Survivorship	1. To what extent do sites provide treatment summaries and follow-up care plans to all patients? 2. How comprehensive is survivorship care by the end of the pilot (e.g., support services, health promotion)?	1. Track distribution of treatment summaries through baseline and subsequent site surveys 2. Assess changes in types of care/services survivors are aware of and/or using through the patient surveys and focus groups	1. Increase receivin follow-u 2. Enhance treatmer
Biospecimens	1. 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?	1. Assessments by staff at sites of the progress made in addressing gaps in biospecimen collection and reporting through site visit interviews	1. Lessons implem and repo commun
IT	1. What factors influence the extent to which sites choose to or are able to implement (either in part or in whole) of caBIG? 2. What is the status of EHR implementation within the Cancer	1. Perception among key staff during site visits on advantages and disadvantages to implementing	1. Lessons caBIG t applicab

Center and related hospital departments and linkages with the Cancer Center-affiliated private practice physicians? How does that change over time?	components of caBIG 2. Assessment of progress made with EHR implementation through baseline and subsequent site surveys	hospital 2. Facilitat among l and spe by the u

short-term outcomes have been specified for each of the evaluation and/or supplemental questions.

Intermediate outcomes (1–3 years): These are measures specific to each evaluation and/or supplemental question assessed over the course of the 3-year pilot program to determine the extent to which the activities have resulted in change.

Data sources: For the matrix, we have specified the data sources from which specific data elements will be derived. Data sources reflect the methods with which data elements will be collected; they are addressed in the next section.

Data elements: The data elements reflect the actual data variables or indicators used to assess the corresponding outcome.

It is through the development of tools like the EPM that the evaluation can become more focused and feasible. For the NCCCP, that has been a challenging process because it is a very complex program being implemented in relatively diverse organizations. The following section describes the major challenges to providing definitive evaluation findings for the NCCCP.

2.3 Design Challenges

By now, the complexity and dynamics of the NCCCP are clear. There are numerous interrelationships and interchanges at varying stages of development such that the evaluation design has to be flexible and account for variability as much as possible. For that reason, the design includes collection of qualitative and quantitative data that allows for triangulation of findings at the end of the pilot. The evaluation plan described in this report is comprehensive and will yield a huge amount of data to be analyzed and interpreted. Even though the pilot is to be implemented over only a 3-year period, it will measure many important findings through this design. Each individual component of the evaluation design is described in Sections 3 through 5, while our overall analysis plan is described in Section 6. For the overall evaluation, there are three primary challenges that impact the extent to which final results can be used to inform future program development.

First and foremost, the NCCCP sites were selected based on a set of criteria that were used to define a community-based Cancer Center. At this point in the evaluation planning, only NCCCP sites are included in the design. No comparisons are possible between NCCCP sites and similar hospitals that are not participating in the program. The design accounts for this limitation by including a case study to better understand the context within which the program is being implemented and identify key features of these sites that seem to be related to specific outcomes of the program. However, we will not be able to determine whether the NCCCP being implemented in similar sites will have the same results or what ultimately the NCCCP allows sites to accomplish that other similar sites were not able to accomplish in the same period of time. Thus, we will not be able to attribute any changes measured to the NCCCP, but we should be able to assess the contribution the NCCCP makes in advancing these sites as Cancer Centers.

The second major challenge, particularly in assessing changes specific to some of the program components, is that sites are starting at different stages of development and each will need to be assessed based on their individual starting points. For example, several of the sites had little experience enrolling patients in clinical trials, while others have highly successful clinical trials research programs. In contrast, most of the sites had little experience developing outreach programs to reach special populations and most admitted to struggling to find strategies that work in their community. Thus, some of the activities underway at different sites are quite varied and do not lend themselves to comparisons across sites. In addition, for some of the program components, there are not specific activities or interventions that every site is supposed to implement. Therefore, identifying consistent measures to track over time is challenging particularly since the differences across sites on some indicators are striking (e.g., some sites have "tumor boards" that meet once or twice a month as their MDC work, while other sites have full clinics to provide MDC care). In reporting of all evaluation findings, we will need to develop a composite measure (see Section 6) to assess sites on their level of development by each program component at baseline to compare to their status on each at the end of the program. For some program component activities, each site will need to be assessed based on its own level of progress, as opposed to drawing comparisons across the sites.

The third major challenge is the current lack of patient-level outcome data. While a patient survey is being collected during Years 2 and 3 of the program, these data will not provide true baseline measures from patients on their experience with care prior to the NCCCP. This design does, however, provide for assessment of changes in patient's perceptions at the initiation of the NCCCP, compared to at the end of the program. Otherwise, there is currently no means of knowing how quality of care, use of services, timeliness of care, and other important indicators changed for patients over the course of the pilot.

3. CASE STUDY

3.1 Overview of Case Study Methodology and Related Evaluation Questions

The outcomes of interest in the NCCCP pilot are uniquely suited for measure using qualitative research methods. Key characteristics of qualitative research include the following: it is aimed at understanding and description; it focuses on process and context; its design is emergent and flexible in nature; its design, data collection, and analysis are iterative processes; and its analysis is inductive rather than deductive, that is, interpretations are derived from the data (Janesick, 2000; Creswell, 1998; Denzin and Lincoln, 2000; Glesne and Peshkin, 1992). These features of qualitative research make it well suited for "studying naturally occurring, ordinary events in natural settings" (Stake, 2006, p. 10).

One qualitative research method, the case study, has been used increasingly in public health (Ulin et al., 2005) as a comprehensive program evaluation strategy. As defined by Robert Yin (2003), a primary contributor to the developing methodology of case study research, a case study "investigates a contemporary phenomenon within its real-life context; when the boundaries between phenomenon and context are not clearly evident; and in which multiple sources of evidence are used" (p. 23). Using a case study methodology in evaluation is largely driven by research questions related to how and why programs do or do not influence participants and is based on the premise that participants' actions are best understood within the specific contexts in which they occur (Yin, 2003). With regard to the NCCCP evaluation, the case study is designed to focus on measuring the structures and processes that sites use to effectively implement the NCCCP and the factors that seem to be related to how well they succeed. As shown in Table 3-1, many of the overarching evaluation questions (Section 2.2) at the national, organizational, and program levels will be addressed through the data collection techniques incorporated in the case study design. Questions to address change for each of these levels of NCCCP implementation will be addressed during the case study over the course of the 3-year pilot (e.g., questions specific to these will be asked during site visits in Years 1-3).

These questions tend to be more explanatory and likely to deal with the "operational links needed to be traced over time, rather than mere frequencies and incidence" (Yin, 2003, p. 18). Therefore, case studies are particularly valuable when the evaluation aims to capture individual differences or unique variations from one program setting to another or from one program experience to another (Patton, 2008). As such, the case study relies on many of the same techniques as a "history," but it "adds two sources of evidence not usually included in the historian's repertoire: direct observation and systematic interviewing" (Yin, 2003, p. 19). In fact, the case study's unique strength is its ability to deal with a broad range of data from documents, artifacts, interviews, and observations.

Table 3-1. Primary Purposes of the Case Study and Corresponding Levels of NCCCP Implementation and Primary Evaluation Questions

Purpose of the Case Study	Level of NCCCP Implementation and Primary Evaluation Questions			
	National Network	Organizational	Program	Patient
Understand NCCCP implementation	What is the impact of TA provided by NCI on the sites' ability to reach NCCCP goals and objectives?	What are the organizational requirements necessary to effectively manage/ implement NCCCP? What are the physician practice models through which NCCCP is being implemented? What factors of each model seem to impede or facilitate NCCCP implementation? What infrastructure has the site developed (i.e., staff, data, program related) to implement NCCCP? What lessons did the organizations learn on the infrastructure required to implement NCCCP successfully?		
Assess change in site performance over time	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 didn't have prior to NCCCP involvement?		How has the NCCCP helped them redefine or revise their cancer service line?	How does the population of patients served by the sites change during the time that they are an NCCCP pilot site?

(continued)

Table 3-1. Primary Purposes of the Case Study and Corresponding Levels of NCCCP Implementation and Primary Evaluation Questions (continued)

Purpose of the Case Study	Level of NCCCP Implementation and Primary Evaluation Questions			
	National Network	Organizational	Program	Patient
Determine NCCCP structures and processes associated with successful performance	How well has the "Network" facilitated sites to establish linkages with each other (i.e., NCCCP sites connecting to each other)? How well has the "Network" facilitated sites to establish linkages with other NCI cancer research programs (e.g., NCI-designated Cancer Centers, CCOPs)?	What characteristics and/or features of the system-funded sites impede/facilitate achieving system goals (i.e., dissemination of program activities) and program goals (i.e., within each site)? What program-related changes are likely to be sustained or institutionalized within the existing sites?	What is the "value added" of the NCCCP to the cancer services provided?	In what ways do the sites reduce cancer health disparities (specific to screening only or across the continuum)? Are there differences in how patient subgroups (racial/ethnic minorities, low-income, uninsured) are provided treatment or access clinical research (e.g., CT accrual) when compared to those who are insured? What are the patients' reports of the quality of care they receive, including satisfaction with MDC and communication, emotional support, financial assistance, timely access to appointments, referrals, waiting times, and overall satisfaction with care?

In conducting a case study, the first obligation is to define the "case" (Yin, 2003; Stake, 2006; Miles and Huberman, 1994). Miles and Huberman (1994) define the case as "some phenomenon occurring in a bounded system," which is, in effect, the unit of analysis (p. 25). As a general guide, the unit of analysis in a case study is revealed when the research or evaluation questions are clearly specified (Yin, 2003). The overall effort in evaluating the implementation experiences of NCCCP pilot sites, including best practices to support cancer research and improved cancer care delivery, makes the organization the case or unit of analysis.

Case studies can be either single- or multi-case designs. Single cases are used to confirm or challenge a theory, or to represent a unique or extreme case (Yin, 2003). The case may be chosen for an unusual quality, it may be of interest by itself (i.e., an "intrinsic case"), or it may illustrate the issue on which the researcher is focused (an "instrumental case") (Miller and Salkind, 2002). If more than one case is to be included in a study, as in a multi-case study or "collective case study," the cases are described and compared. Stake (2006) asserts that an important reason for doing a multi-case study is to understand how the program or phenomenon performs across different contexts and environments (p. 23). Multi-case studies, such as the one proposed for the NCCCP, are particularly valuable because similar patterns linking program processes to outcomes across sites increase confidence in the results. A multi-case study approach will provide an in-depth study and analysis of the NCCCP pilot sites and can be used to more thoroughly assess the central evaluation question of feasibility by considering the experience of all pilot sites together (Stake, 2006). In addition, any similar patterns linking program processes to outcomes across sites increase confidence in the results. All of these aspects of case study research support its use as an evaluation strategy for the NCCCP pilot study.

A key strength of the case study method involves using multiple sources and techniques in the data-gathering process. For this reason, it has often been described as a triangulated research strategy that can occur with data, investigators, theory, and methods (Denzin, 1978; Ryan et al., 2002). The need for triangulation arises from the ethical need to confirm the validity of the processes. As noted by Patton, one important way to strengthen a study design, particularly one relying heavily on qualitative data, is through triangulation, or "the combination of methodologies in the study of the same phenomena or programs" (2008, p. 187). A goal in this pilot study is to achieve triangulation in the data collection and analysis. For the NCCCP case study, our analysis will include a "between (or across) methods" triangulation where "two or more distinct methods are found to be congruent and yield comparable data … [and] provide a more certain portrayal" of the phenomenon under study (Creswell and Clark, 2006, p. 108). Building in these different approaches helps strengthen the conclusions and recommendations drawn from the data.

3.2 Case Study Data Collection

As noted by Denzin (1978) and above, 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 the data sources (Jick, 1979). For the NCCCP case study, three primary types of data sources will be used for analysis:

site visits (e.g., key informant interviews, patient focus groups, observations),

document review (e.g., progress reports), and

secondary data (e.g., site surveys).

Sample data variables for each of these data sources are presented in Table 3-2, and each data source is described in more detail in the following sections.

Table 3-2. 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
	Hospital leadership support for the NCCCP
	Processes followed in program implementation and accomplishments within each program component
Document review	Applications for funding
	Quarterly progress reports
	Subcommittee minutes and documents created by Work Groups
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 Commission on Cancer

3.2.1 Site Visits

Site visits provide a unique opportunity for researchers to collect in-depth information about the processes, activities, and barriers experienced by NCCCP Cancer Centers. Annual site visits will be conducted each of the 3 years at the NCCCP sites. Prior to each round of site visits, RTI will implement a process to obtain input from key stakeholders on the topics to cover during the visits and the people with whom to interview. Since each visit is limited to a 2- or 3-day trip, we need to prioritize the issues to address during each visit. The selection of domains, topics, and the primary and secondary evaluation questions to address during each visit will be drawn directly from the EPMs (Appendices C and D). Table 3-3 provides a summary of the level of evaluation and corresponding key words (see Table 2-1) to be addressed during the site visits in Years 1-3.

Table 3-3. Key Words or Domains for Each Level of Evaluation to Cover for Each Year of Site Visits

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

During the site visits, we will collect two types of data: observational data and in-depth interviews with individuals or small groups of key people at each site. During the third year of site visits, we will also conduct patient focus groups, which are described in detail in Section 4.2. The following provides an overview of the planning process for the site visits, including how interviewees were or will be identified and recruited, and the design of the interviews and protocol for conducting the site visits during Year 1, as well as observational data we planned to collect while on site. We will follow a similar process in planning for the site visits during Years 2 and 3; however, the primary purpose of data collection will differ across the years.

3.2.1.1 Year 1 Site Visits

Beginning in February 2008, RTI planned and conducted site visits to the 10 NCCCP programs, located within 16 hospitals, which include both lead and developmental sites (see Table 1-1). 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 within their organization, 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 2-2):

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 moderator to follow up on various views or statements that may have been unanticipated in either the design of the interviewer's 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, could only provide us with a short period of time to talk to them and many of the topics of interest would be site-specific, we knew we needed a more flexible approach than a standardized interview format would allow. We also realized the constraints imposed by the government's Office of Management and Budget (OMB), which requires that any questions to be asked of more than nine people undergo a lengthy review (which typically takes 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 semistructured. For these types of interviews, the issues and questions to be explored are outlined, but the order and wording of the questions does not have to be 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 study's overarching constructs, as described in Section 2.1, RTI and NCI worked together to develop eight interview discussion guides (Appendix B), 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 domains or factors listed above:

individuals' roles and responsibilities both within the hospital 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 hospital leadership 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 that allow the researchers to increase the depth of information addressed and modify the interview based on the respondents' availability and knowledge. Based on these domains of questions, we determined who within each site would be the most appropriate to ask the related questions and planned for the site visits accordingly. RTI and NCI worked together to identify two groups of individuals as essential to meet with during the first site visit: hospital leaders and management staff, and key Cancer Center program staff. The interviews varied in length depending on the respondents' availability and role in the program. Table 3-4 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 site visit (Appendix E). 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.

Table 3-4. Requested Interviewees for Year 1 Site Visits by Organizational Role and Suggested Interview Length

Organizational Role	Suggested Interview Length
Hospital Leaders and Management Staff	
Principal Investigator	90 minutes
Chief Executive Officer or Chief Operating Officer	45–60 minutes
Medical Director	45–60 minutes
Key Cancer Program Staff	
Physician Director of Cancer Center if not PI	60 minutes
Administrative Director of Cancer Center	60 minutes
Members of NCCCP subcommittees (group meeting—no more than nine)	90 minutes
Chief of Radiation Oncology	45–60 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	Allow up to 90 minutes

For the NCCCP evaluation, a team of 2 or 3 researchers attends each site visit so that one can focus on conducting interviews and the other can observe the nuances of the situation

and serve as notetaker. During Year 1, it was imperative that senior researchers lead each site visit because so much was unknown about how the sites were implementing the NCCCP. The lead interviewer needed to be knowledgeable of 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. We also retained the expertise of three medical oncologists to travel with our teams during the first four site visits in order to provide expertise about the 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 notetaker and lead interviewer during the interviews (e.g., interactions between staff members and the tone and mannerisms of the interviewee).

Throughout the day during each visit and in the evenings over dinner, we set aside time 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 topline report.

3.2.1.2 Year 2 Site Visits

Planning for the second year of site visits began in January 2009 so that visits can be conducted from March through June. The planning process for protocol development and scheduling of site visits will closely mirror the one described for the Year 1 site visits. Beginning in March 2009, RTI will conduct site visits to 10 locations across the country, limiting the site visits to only lead system sites during Year 2. We will conduct telephone

interviews with key staff at the six hospitals that are considered the "developing" sites for the two systems (i.e., Austin, TX, and Milwaukee, WI, for Ascension; and Penrose, CO, and the three Nebraska hospitals for CHI). Whether all 16 hospitals or just the 10 lead sites will be visited in Year 3 is yet to be determined, but the plan at this time is to visit all sites for the final year of the evaluation. As shown in Table 3-3, the focus on Year 2 will be on thoroughly understanding 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. Since that time, they have developed work plans that are guiding their implementation for each component. Year 2 questions will focus on what they have worked on in each area, what they have accomplished, and the barriers and facilitators for each step. We will also obtain updates from the sites on topics addressed during Year 1 visits, such as interactions with the NCCCP National Network; changes in their organizational structure and staffing, physician relationships and/or leadership support; and changes in their cancer service line and delivery of care. Development of the protocols for these site visits will be completed in March 2009, with site visits to begin by the end of March. As we work to refine the questions to address during the visits, we will also identify the people we need to interview. At this point, we plan to meet with the following people:

the principal investigator,

the cancer center director (if 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 will also be requesting a brief meeting with each CEO for about 10-15 minutes to touch base with them about the program. The site visit teams will include Year 1 lead interviewers (Debbie Holden, Kelly Devers, Lauren McCormack, Katherine Treiman, and Amy Roussel) and notetakers (Sonya Green, Karen Isenberg, Nikie Sarris, Heather Kane, and Elizabeth Adams). Since the primary focus for Year 2 will be on how the sites are addressing cancer care (e.g., disparities, screening, outreach, navigation) and updates on organizational issues, the teams will need to be paired again so that their areas of expertise complement each other. We will however ensure that at least one team member who visited a site in Year 1 will return to that site in order to provide consistency in our knowledge of the site. Prior to each site visit, the RTI team members will be reviewing all program materials (e.g., progress reports, work plans, IAS responses, subcommittee minutes) and also listening in on upcoming NCCCP Subcommittee calls so that we are up to speed with all the work that is underway.

3.2.1.3 Year 3 Site Visits

Year 3 site visits will be conducted in spring 2010, as the sites are preparing for the end of the NCCCP. Much of the focus during Year 3 visits will be on similar issues addressed during Year 1, such as

- individuals' roles and responsibilities both within the hospital 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 leadership for NCCCP implementation,
- strategies for implementing the NCCCP in the coming year, and
- mechanisms for coordinating NCCCP efforts within the site.

We will be particularly interested in how sites have effectively managed the program and what the staff's general impression of the NCCCP is at the end of the pilot. Year 3 will be the only year in which we will ask interviewees about their plans for sustaining the program, specifically which NCCCP components they plan to sustain, and where they will obtain the resources to do so. As with Years 1 and 2, we will plan for the 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 will also propose the people with whom to meet during each site visit and then work with the sites to create schedules. We will again be conducting 2- to 3-day site visits with teams of two staff. It has yet to be determined whether all 16 hospitals will be visited during this final year of the evaluation. If they are not, and only the 10 lead sites are visited as in Year 2, we will conduct telephone interviews again with each of the sites we are unable to visit.

Patient focus groups will be a unique component of Year 3 visits. This aspect of the evaluation design is under development (see Section 4.2) since so many issues need to be resolved before patient recruitment can begin. It is our plan to conduct approximately 20 focus groups (2 per site at the 10 lead sites) among patients and perhaps caregivers. The primary purpose of the focus groups will be to expand on findings from the patient survey such that the questions to be used in the protocol will be organized around the domains covered in the survey (e.g., clinical trials participation, receipt of patient navigation). To finalize the process for conducting the focus groups, we are organizing an ongoing group of advisors to help address the issues so that by fall 2009, RTI can work with the sites to begin patient recruitment. A document is under development to describe every aspect of the focus groups and will be added to Section 4.2 of this report by the end of September 2009.

3.2.2 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), quarterly progress reports, and subcommittee minutes, 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 will code data from these sources and incorporate them into our data files as described in Section 3.3.

3.2.3 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 the following:

- 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 and Medicaid (CMS) files;
- Survey Application Record data from the Commission on Cancer.

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 will be identified and incorporated into the overall analysis in Year 3, and for each of the cross-site reports to be completed in Years 2 and 3.

3.3 Analysis Plan for Case Study Data

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 and 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).

For the NCCCP evaluation, we use 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 and Huberman, 1994). The following sections describe how we prepare the case study data for analysis and track inter-rater reliability, and how we will use the coded data to conduct a cross-site analysis during Years 2 and 3.

3.3.1 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 and 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 Section 2.1 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 (Appendix F). For each year of data collected, we will start our coding process by building on the codes in Appendix F. Upon completion of each set of site visits (i.e., summer of 2009 and 2010), we will work as a team to refine and add to the list of codes. We will then follow the process described below to ensure the reliability of coding. In this way, we will develop an initial list of codes that are comprehensive in scope and that will potentially provide NCI with ad hoc findings around key topics (e.g., activities around each program component, staffing changes).

3.3.1.2 Assessing Inter-rater Reliability

Once the codes are defined, we convene a meeting with coders to review the codes and ensure that all have a common understanding of the meaning of each. Two coders are then assigned to work independently and concurrently on a subset of interviews in order to assure reliability of codes assigned to the text. As noted by Miles and Huberman, "definitions get sharper when two researchers code the same data set and discuss their initial difficulties" (1994, p. 60). This double-coding not only aids definition clarity but is also a good reliability check. During the first stages of data coding, we test and refine the codes through debriefings among the coders. Because two different people are coding the data,

they have the opportunity to check their impressions and interpretations with each other, thereby increasing the extent to which the data are reliably analyzed. At this stage, some codes are likely to change. Through initial testing of the codes, some codes will likely be identified as inappropriate or inadequate in describing particular phenomena that the text is conveying. Ultimately, it is expected that the data analysis will follow the Miles and Huberman (1994) interactive model of qualitative data review, where we simultaneously collect, display, and reduce data; draw conclusions; and verify our assertions.

3.3.1.3 Coding and Interpreting the Data

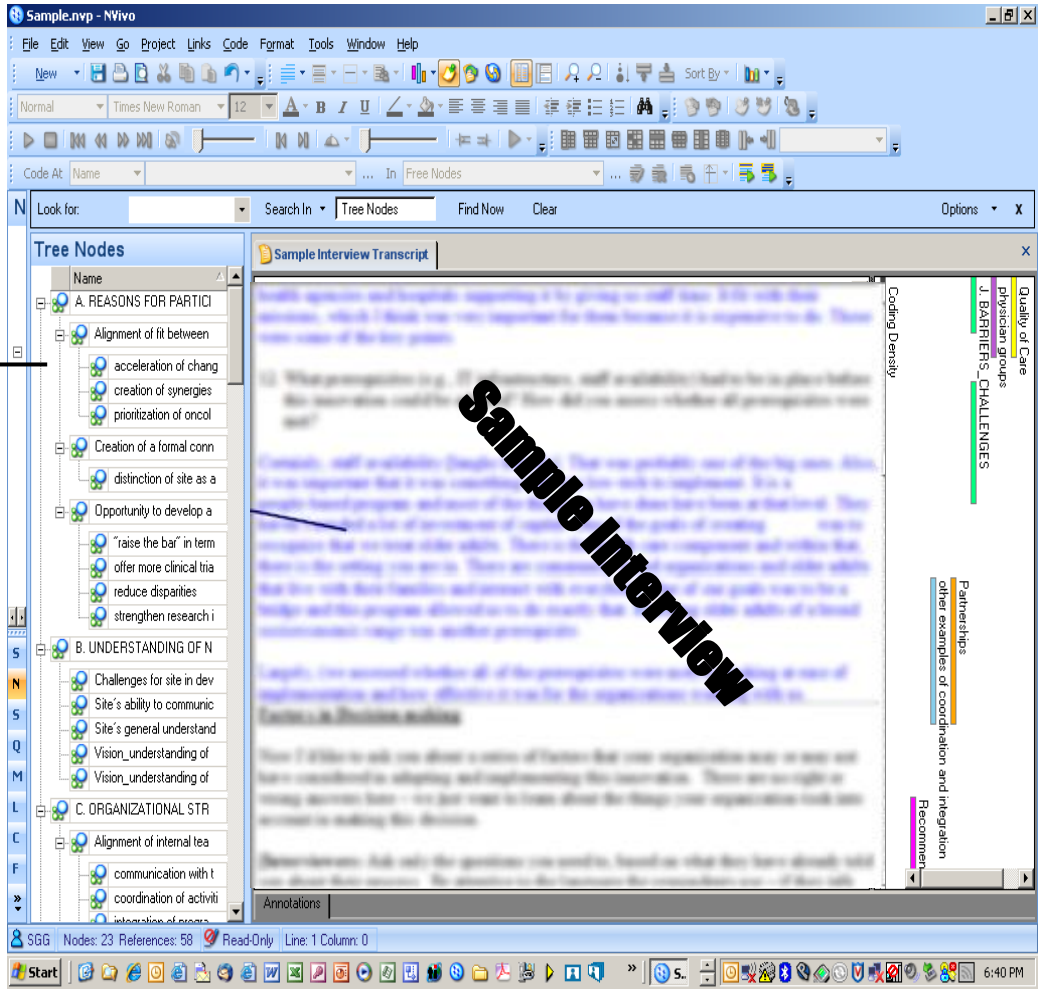
Once the codes are finalized and all of the analysts are trained on their use and meaning, we begin the coding process. To facilitate the coding, we use NVivo, a qualitative analysis software program. Data from the various sources (e.g., notes from interviews, progress reports) are imported into NVivo and assigned as a "source document" that will include site visit field notes and observations, focus group notes, organizational charts, and other secondary data files to be 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 are coded, the findings can be compiled based on the codes and organized by the node and/or respondents within and across sites. This facilitates interpretation and reporting of the findings, particularly for a cross-site analysis, as explained in the following section. Figure 3-1 provides a screenshot of how NVivo may be used to organize qualitative data for analysis. Once we have developed the codes and ensured that all coders are in agreement on what each means, we then code all qualitative data (e.g., progress reports, notes from site visits, subcommittee minutes) that may provide input on our findings. Coding of Year 1 data was completed in fall 2008 so that those data are ready for cross-site analysis once the Year 2 data are coded. We plan to code Years 2 and 3 data in the summers and falls of 2009 and 2010.

3.3.2 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 and Huberman, 1994, p. 79). For this evaluation, the analysis of individual cases will produce rich descriptions of each site's processes, barriers, and facilitators in implementing the NCCCP. After the site visits for Year 1, we developed a

Figure 3-1. NVivo Screenshot

This is a list of all the codes created by the researcher. In this example, they are categorized by theme/topic area.



These colored bars (called Coding Stripes) illustrate how the content of the interview notes/ transcript has been classified (or labeled) using the codes on the far left.

"topline report" specific to each site and shared them with NCI for comments. We created a report for each of the 16 hospitals, with the outline organized around the key themes or domains of the conceptual framework (Figure 2-2). At the end of Years 2 and 3, additional text will be added to these reports to build on the description of the sites and highlight changes over time. The contents of these topline reports were written by the teams who visited each site and then reviewed for accuracy against the notes from the visits.

A cross-site analysis will allow 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 multi-case, multi-site design and a focus on understanding common processes or patterns that occur across many sites. Because common elements are being assessed for each case (e.g., NCCCP implementation processes, change in performance over time, and structures/processes associated with success), it will also be 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 will facilitate a cross-site analysis by allowing for data to be coded and analyzed across all respondents, and several codes could be combined for further analysis. In this study, the identification of commonalities, as well as contradictions, across the pilot sites will contribute to answering the overall evaluation questions. For example, respondents' discussions of the cancer Biomedical Informatics Grid (caBIG) may be combined to gain a better understanding of the extent to which sites are able to implement it into their daily workflow. Similarly, cross-site discussions may provide valuable information about key organizational factors related to success in clinical trial accrual.

For the NCCCP case study, the first cross-site analysis will occur in fall 2009, after completion of coding of the data from Years 1 and 2. We have begun to examine our cross-site findings specific to Year 1 to ensure that our codes are adequately addressing the evaluation questions and hypotheses contained in this design report. As Year 2 findings are coded and added to the data set, we will begin to analyze our findings across our themes (e.g., sites' understanding and conceptualization of the program; comparison of organizational structures across sites). Ultimately, we will prepare a cross-site report that includes analyses and interpretations of findings from Years 2 and 3 combined. This report will be organized into sections that cover our themes, much like the topline reports prepared at the end of Year 1. A second cross-site report will be developed at the end of the evaluation. While it may be organized around themes, it could also be presented by level of evaluation. We will work with NCI to determine the best way to organize and present the findings in the final evaluation report.

3.4 Timeline for Case Study Reports

As described in Section 7, each year RTI will provide an annual evaluation report that includes sections for each of the separate studies described in this document (i.e., case study, economic study, patient survey, and patient focus groups). Table 3-5 provides a detailed timeline of the activities and reporting specific to the case study for the NCCCP evaluation.

Table 3-5. Detailed Timeline of Case Study Activities and Reporting

	Y1				Y2				Y3[a]			
Case Study Activities	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Develop site visit discussion guides	•					•				•		
Work with sites to plan visits	•	•				•	•			•	•	
Conduct site visits		•	•			•	•			•	•	
Prepare notes from visits			•	•			•	•			•	•
Specify codes for data analysis and train coders				•			•	•			•	•
Draft individual site topline reports (in Years 2 and 3, we will update existing reports)		•	•	•			•				•	
Identify data sources for coding			•			•	•			•	•	
Code all qualitative data			•	•			•	•			•	•
Draft cross-site report based on overarching evaluation questions and themes									•			•

[a] The third year of the evaluation (Y3) will end in summer 2010, so final reports, while under production in the fourth quarter, will not be due until the end of the contract period.

4. PATIENT OUTCOMES[2]

4.1 Patient Survey

4.1.1 Survey Objectives

The primary purpose of the NCI Community Cancer Centers Program (NCCCP) patient survey is to gain an understanding of the patients' perspective on the NCCCP pilot by assessing how well patients' health care and informational needs are being met. We will collect 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 period. The first survey will collect 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 will provide the baseline data. The second group of survey participants will have received treatment after the pilot program has been operational for approximately 2 years. Thus, we will be able to examine changes over time in patient experiences as the pilot program develops and becomes more established in the sites.

The patient survey is 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 instrument also requests some sociodemographic and health status data. Limited information from cancer registries will be merged into the data set. Together with the patient focus groups, the patient survey complements other elements of the NCCCP evaluation by providing the patient perspective.

4.1.2 Data Collection

RTI will administer the patient survey using three modes (i.e., mail, telephone, and Web-based) to increase the survey response rate. Ten Cancer Centers are participating in the patient survey:

1. Hartford Hospital, Hartford, CT
2. St. Joseph's/Candler Hospital, Savannah, GA
3. Spartanburg Regional Hospital, Spartanburg, SC
4. St. Joseph Hospital, Orange, CA
5. Sanford Clinic, Sioux Falls, SD
6. Our Lady of the Lake Regional Medical Center, Baton Rouge, LA
7. Billings Clinic, Billings, MT
8. Christiana Health Care, Newark, DE
9. Ascension Health Systems—St. Vincent, Indianapolis, IN

[2] Connie Hobbs, Shelton Jones, David Harris, and Mai Nyguen contributed to the writing of this section.

10. Catholic Health Initiatives—St. Joseph's Medical Center, Towson, MD

On September 11, 2008, RTI completed a training session with the Cancer Centers in which we outlined the patient selection criteria and de-identified the data file submission process. Each of the 10 participating Centers will provide RTI with a password-protected, de-identified list of all patients who meet the study criteria. To qualify for the study, a patient must (1) have had one or more outpatient cancer treatment visits at the Cancer Center since July 1, 2007, (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. RTI has requested that the following variables be included for each eligible participant:

sequential ID number (SID), created by each site as a unique identifier for each patient,

gender,

year of birth,

race (up to five different race variables are allowed to match the cancer registry race variables),

Spanish origin/Hispanic ethnicity,

year of diagnosis,

collaborative cancer stage,

cancer type,

ICD code, and

treatment modality.

The Centers may send up to two distinct cancer diagnoses per patient, where applicable; therefore, the variables year of diagnosis, collaborative cancer stage, cancer type, ICD code, and treatment modality may appear twice for some patients. Each of the cancer diagnoses must independently meet the study criteria listed above. RTI conducted a training via a conference call on January 27, 2009 to walk sites through the process of mailing out the survey packets.

4.1.2.1 Sample Size and Power

The target sample is designed to provide adequate statistical power to detect differences in specific survey response variables between specific analysis domains or comparison groups. For example, the sample design should accommodate the detection of significant gender differences over all the study sites. It will be possible to generate defensible estimates for the four major cancer types of interest (breast, lung, prostate, and colon), up to four age groups, and four stages of cancer. We expect age group and cancer stage to be more limited depending on the distribution of the sample across these domains. Overall, site-specific estimation will be possible.

The intent is to minimize the sample sizes necessary to achieve the desired levels of statistical power with certain constraints imposed by the logistics of survey data collection. Table 4-1 illustrates the sample sizes needed to achieve acceptable levels of statistical power at a significance level of 5%. For completeness, both one- and two-tailed test computations are provided for a typical effect size of 0.10. These counts are the minimum number of completed patient interviews needed per comparison group. As shown in Table 4-1, the sample sizes will increase as the proportions approach 0.50.

Table 4-1. Number of Completed Interviews Necessary to Achieve Acceptable Power for a Significance Level of 5%

			One-Tailed Test Power			Two-Tailed Test Power		
Difference	**P1**	**P2**	**80%**	**85%**	**90%**	**80%**	**85%**	**90%**
0.10	0.15	0.25	197	229	272	250	286	334
	0.20	0.30	231	268	319	293	335	392
	0.25	0.35	259	301	358	328	376	439
	0.30	0.40	280	326	388	356	407	476
	0.35	0.45	296	344	409	376	429	502
	0.40	0.50	305	354	422	387	443	518
	0.45	0.55	308	358	426	391	447	523

A sample of 300 completed patient interviews per comparison group will allow for at least 85% power using a two-tailed test to detect 10% differences for the smallest proportions. Similarly, 250 completed surveys will yield 80% power. Given a sample of 300 completions and assuming a patient response rate of 70%, a total of 430 patients would need to be selected from each Cancer Center. To account for issues such as incomplete surveys and deaths among potential participants since the time of treatment, we recommend sampling 475 individuals per site, for a total of 4,750 patients across the 10 participating Cancer Centers.

4.1.2.2 Randomization

RTI will randomly select 475 patients from each Center from the de-identified and password-protected list of eligible patients submitted by the Centers via e-mail attachment to the RTI statistician. RTI will return the master list to the Centers indicating which patients were selected for the study using a flag (a variable indicating whether patient was selected). At no time will RTI will not have participants' personally identifiable information, such as name, address, or social security number (with the exception of patients who volunteer their names when calling to complete the telephone survey [see 4.1.2.3]).

RTI will supply the Centers with survey packets to send to potential participants. Each of the 10 Centers will be responsible for mailing the survey packet to the 475 randomly selected patients from each Center. Center staff will refer to the randomization list provided by RTI and will match the SID with the corresponding SID on the patient packet. RTI will hold a training session with the Centers to outline the proper procedures for matching patients, mailing the packets, and ensuring the confidentiality of potential study participants.

4.1.2.3 Survey Materials

The packets that patients receive will include an invitation to participate in the survey, a hard copy of the survey instrument, and instructions for completing the survey. Each patient may choose to complete the survey in one of three ways: (1) by completing the hard copy of the survey and returning it to RTI using the pre-stamped and pre-addressed envelope provided in their packet; (2) by calling RTI's Call Center using a toll-free phone number included in the patient notification letter and completing the survey with an RTI interviewer; or (3) by following the instructions on the Web survey information sheet and completing the survey via the Internet on a secure RTI Web site. The survey will be available in both English and Spanish.

A complete survey packet will contain the following items:

- a prepaid envelope to house the items below;
- an address label for the prepaid packet envelope (Center staff will generate name and address labels);
- a patient notification letter, which each Center will personalize, print on Center letterhead, and have signed by the Center's director (this is the only item that will need to be inserted into the patient packet by Center staff and will have information regarding the three different ways to respond to the survey);
- a hard copy of the survey instrument with a consent form printed on the inside cover of the survey booklet;
- A Web survey information sheet (for those who respond by accessing the RTI Web site);
- A Spanish survey request card (for patients who prefer to receive a Spanish-language version of the survey);
- a prepaid and pre-addressed tear-proof envelope used by participants to return the completed survey to RTI (for those who respond by mail);
- a permission-to-be-contacted form, which pertains to being part of the focus group (this is not directly related to the survey, and granting permission is not required to complete the survey); and
- a small, prepaid and pre-addressed envelope to return the permission-to-be-contacted form.

Patients who choose to complete the survey by telephone will call the RTI Call Center, as instructed in their notification letter, and either complete the interview at that time or leave

a message for an interviewer to call them back, in which case the patient would provide a telephone number. Patients will identify themselves by their assigned RTI study identification number, although some may voluntarily provide their name. In no case will the interview ask the respondent's name; if the respondent voluntarily provides his or her name, that information is *not* recorded or retained.

4.1.2.4 Follow-up with Nonrespondents

Approximately 4 to 8 weeks after the initial mailings, RTI will generate a list of people, using their SID, who have yet to complete the patient survey by any mode. RTI will carefully monitor the response rate and determine the appropriate timing for the second mailing. Once the list is verified by the Centers, RTI will create packets identical to those described above and ship them to the Centers to mail to nonrespondents. Patients not interested in participating in the survey may choose to contact their Cancer Center or RTI to express this preference after receiving the first packet. Those patients will not be mailed a second survey packet.

4.1.2.5 Data Security

RTI will house the master database of survey responses and has procedures in place to ensure the confidentiality of the data. RTI has implemented an information security program based on the Defense in Depth concept. This strategy combines the capabilities of people, operations, and technology. The first layer of protection is RTI's Internet firewall. All traffic between the RTI network and the Internet passes through this single connection point, providing a high level of protection and monitoring to all systems within the RTI network.

The firewall is used to create two RTI network domains with different levels of accessibility from the Internet. These domains are often called the "private network" and the "public network," although the public network is not actually open to the public. The private network is the main RTI network, on which most systems are located. Access to this network from the Internet is very restricted, using a limited set of protocols to access specific systems. For example, incoming e-mail is only permitted to specific mail servers. The public network is configured to provide services that require access from the Internet such as Web servers. Servers on the public network must be registered with IT and must specify which services they run.

Web surveys hosted on RTI Web servers are placed behind load-balancing devices, which are configured to deny all traffic not specifically allowed according to their configuration. They are required to implement secure sockets layer (SSL) encryption, and all users are required to enter a personalized user name and password before they can access the site. Data collected from the Web survey are stored in an RTI structured query language (SQL) server database within the RTI secure network.

The RTI Call Center, which will conduct the phone surveys, is located in a separate network domain for additional isolation. The Call Center network meets all security standards of RTI's main internal network. To perform the telephone interview for this project, Call Center staff will access the same Web survey found on the Web site. Data from completed paper questionnaires will be entered into the system by authorized RTI staff using the same Web survey instrument; therefore, the same data security imposed on the Web survey will also be applicable to the telephone interview data and the data entry process.

All collected data will be maintained in internal databases as needed until the close of the contract. Access to the internal databases is available only to RTI staff with the proper authorizations. Project staff with access to stored data can do so only from workstations that meet RTI's security standards. Each workstation is protected from computer viruses by regularly updated anti-virus software. Data files are not stored on workstation hard drives, except as transient files during an active process, after which files are deleted immediately. Workstations are locked and password-protected when unattended and are located within key-card access buildings.

4.1.3 Analysis Plan

The survey analysis will focus on the following outcomes of interest:

- awareness and utilization of Cancer Center services and resources,
- access to care (i.e., patients' ability to get appointments as soon as they want or get tests and procedures without delay),
- coordination of care (i.e., the perception that members of the cancer care team are informed about patient's care and work together to provide appropriate care),
- patient navigation assistance (e.g., assistance with transportation and financial issues, obtaining medications),
- patient-centered communication (e.g., whether providers spend enough time, pay attention, and provide clear explanations),
- sufficient information about clinical trials provided by member of cancer care team,
- knowledge and attitudes related to clinical trials,
- appropriate survivorship care (e.g., whether staff provide treatment summary or explain follow-up care plan), and
- overall satisfaction with care at the Cancer Center.

4.1.3.1 Dependent and Independent Variables

Table 4-2 provides a summary of the dependent and independent variables, all of which are drawn from the survey except where noted. Some patient-level measures (e.g., gender, age, stage at diagnosis) will be obtained from the sites' cancer registries as these measures are available and defined for each patient. We will also explore how data from the site visits and other sources (e.g., quarterly reports from the sites, interim assessment survey) can be

Table 4-2. Summary of Dependent and Independent Variables

Dependent Measures	Independent Measures
Cancer Center services and resources Awareness of services and resources (e.g., support groups, psychological counseling, palliative and hospice care) Utilization of services and resources[a]	*Site-Level Measures*
Patient navigation assistance Awareness of patient navigation program Utilization of patient navigation program[a] Patient navigation assistance (e.g., assistance with transportation, financial issues, obtaining medications and medical supplies)	**Site and type of site** Site (10-19) System/non-system Urban/suburban/rural Physician practice model Market competitiveness[b]
Patient-centered communication (e.g., providers treated patient with respect, paid attention, encouraged questions, spent enough time; patient involvement in decision-making)	**Program Development** Overall level of program development Level of development—Disparities program component Level of development—Clinical trials program component Level of development—Survivorship program component Level of development—Quality of care program component
Clinical trials Attitudes toward clinical trials Knowledge of clinical trials Likelihood of participating	*Individual-Level Measures*
Appropriate survivorship care (e.g., provided treatment summary, explained plan for follow-up care)	**Background characteristics** Demographics (race/ethnicity, marital status, live with others, employment, education, income, and number of people supported [age and gender from cancer registry]) Health insurance coverage Survey language (Spanish or English)
Overall rating of care	**Health Status** Overall health Mental health Other health conditions
	Cancer type and history Cancer type(s) (survey and cancer registry) Cancer stage (cancer registry) When first diagnosed (survey and cancer registry)

(continued)

Table 4-2. Summary of Dependent and Independent Variables (continued)

Dependent Measures	Independent Measures
Overall rating of care (continued)	**Treatment status and types of treatment** Types of treatment received (survey and cancer registry) Whether finished treatment
	Self-efficacy related to communication with health professional
	Social support (proxy measure) Marital status Live alone or with others
	Level of exposure to the NCCCP Proportion of cancer care received at Cancer Center Utilization of patient navigation program[a] Utilization of various Cancer Center services and resources[a]
	Completed survey alone or with assistance

[a] Utilization of Cancer Center services and resources and utilization of patient navigation program may be used as both dependent and independent measures. Depending on the analysis, other measures may also be used as both dependent and independent measures.

[b] Based on data about the catchment area (metropolitan statistical area, counties), such as proportion of cancer admissions that are to the Cancer Center, proportion of medical oncologists and radiation oncologists practicing at the Cancer Center, and number of public and/or private hospitals.

used to develop measure for analysis, particularly those that reflect the extent of program development.

4.1.3.2 Program Development Variables

To examine how the extent of program development (or program intensity) influences different outcomes, we will develop a measure of the extent to which the NCCCP overall has been implemented at the site, and measures of the extent to which different program components have been implemented. Specifically, we are interested in the disparities, clinical trials, survivorship, and quality of care program components because these are likely to have the greatest effect on the outcomes of interest.

Our recommended approach for developing these program development measures is to rate the four program components on a scale of 1 to 3, with 1 being a low level of development, 2 being a moderate level of development, and 3 being a high level of development (see Table 4-3). We would calculate the mean of these individual program component scores for an overall rating of program development for each site. In this approach, we will work with NCI to define criteria for scoring each program component. For example, for the clinical trials program component, scores may be based on the numbers of open trials, the percentage of patients enrolled in trials, and similar factors. RTI and NCI will score the sites

independently and then compare results to assess inter-rater reliability. If there are differences, the two groups would meet to make a final determination of an appropriate score.

Table 4-3. Scoring for Program Development Variables

Program Component	Score 1–3
Disparities	
Clinical Trials	
Quality of Care	
Survivorship	
Overall Rating (mean)	

These variables will measure the *relative* level of program development (and development of specific program components) in different sites. They will be used for analytic purposes only and are not intended as an evaluation of the specific sites.

Hypotheses

Our major hypotheses about change in outcomes from baseline to follow-up and relationships between independent measures and outcomes are presented below. Table 4-4 also illustrates the expected relationships between independent measures and outcomes.

Cross-sectional hypotheses:

1. There will be a positive relationship between the proportion of cancer care patients receive at the Cancer Center and most outcome measures (i.e., patients who receive all of their care at the Cancer Center will experience better outcomes relative to those who only received part of their care at the Cancer Center).
2. There will be a positive relationship between the level of overall program development and most outcome measures (i.e., patients at sites with a higher overall program development score will have greater awareness of services and resource and report a higher overall rating of care).
3. There will be a positive relationship between the level of development of specific program components and selected outcomes (e.g., a positive relationship between the clinical trials program component level of development and clinical trials knowledge and attitudes; a positive relationship between the survivorship program component level of development and appropriate survivorship care).

Longitudinal hypotheses:

4. There will be positive changes over time (from baseline to follow-up) for most of the outcome measures as the pilot programs develop and become established at the sites.

5. There will be improvement in outcomes over time within subgroups that traditionally experience health care disparities (e.g., those with lower incomes, racial/ethnic minorities).

Table 4-4 illustrates expectations about relationships between independent and dependent variables. For example, the table indicates that a higher level of exposure to the NCCCP (proportion of cancer care received at the Cancer Center and utilization of the patient navigation program) will be positively associated with patients' overall rating of care and other outcomes.

Table 4-4. NCCCP Patient Survey: Hypotheses about Relationships between Independent and Outcome Variables at Baseline

	Outcome Variables												
	Cancer Center Services & Resources				Patient Navigation				Clinical Trials				
	Aware-ness	Utiliza-tion	Access to Care	Coordi-nation of Care	Aware-ness	Utiliza-tion	Naviga-tion assist-ance	PCC	Informed	Attitudes	Knowl-edge	Post-Treat-ment Care	Overall Rating of Care
Exposure to the NCCCP													
Most/all care at Cancer Center (ref: most/some care elsewhere)	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Utilized patient navigation program (ref: did not utilize)	↑	↑	↑	↑	NA	NA	↑	↑	↑	↑	↑	↑	↑
Site-level measures													
Higher level development—overall program	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Higher level development—disparities component	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Higher level development—clinical trials component									↑	↑	↑		
Higher level development—survivorship component												↑	
Higher level development—quality of care component			↑	↑					↑	↑	↑		↑

(continued)

Table 4-4. NCCCP Patient Survey: Hypotheses about Relationships between Independent and Outcome Variables at Baseline (continued)

	Outcome Variables												
	Cancer Center Services & Resources				Patient Navigation				Clinical Trials				
	Aware-ness	Utiliza-tion	Access to Care	Coordi-nation of Care	Aware-ness	Utiliza-tion	Naviga-tion assist-ance	PCC	Informed	Attitudes	Knowl-edge	Post-Treat-ment Care	Overall Rating of Care
Patient-level measures													
Minority race/ethnicity (ref: White)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
SES (income, education) (ref: lowest)	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Insured (ref: no coverage)	↑	↑	↑	↑					↑			↑	↑
Survey language—Spanish (ref: English)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Longer time since diagnosis	↑	↑			↑	↑	↑		↑				
Finished treatment	↑	↑			↑	↑	↑		↑			NA	
Greater communication self-efficacy	↑		↑		↑	↑	↑	↑	↑			↑	↑
Greater social support (marital status, live with others)	↑	↑	↑		↑	↑	↑	↑	↑			↑	↑

(continued)

Table 4-4. NCCCP Patient Survey: Hypotheses about Relationships between Independent and Outcome Variables at Baseline (continued)

	Outcome Variables												
	Cancer Center Services & Resources				Patient Navigation				Clinical Trials				
	Aware-ness	Utiliza-tion	Access to Care	Coordi-nation of Care	Aware-ness	Utiliza-tion	Naviga-tion assist-ance	PCC	Informed	Attitudes	Knowl-edge	Post-Treat-ment Care	Overall Rating of Care
Exposure to the NCCCP													
Most/all care at Cancer Center (ref: most/some care elsewhere)	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Utilized patient navigation program	↑	↑	↑	↑	NA	NA	↑	↑	↑	↑	↑	↑	↑

Notes:

↑ Positive effect on outcome measure; ↓ negative effect on outcome measure.

A blank cell indicates no hypothesized relationship. These independent variables may be utilized as control variables for analysis.

Not applicable (na) indicates that we will not examine the relationship between these sets of independent and outcome variables.

"Ref" refers to the reference category for multivariate analysis.

4.1.3.3 Data Editing and Imputations

We anticipate that not all patients will agree to participate in the survey. Of those who do participate, we anticipate some item nonresponse. Because sampling unit (or patient) nonresponse and item nonresponse can both bias survey estimates, we will implement logical editing and statistical imputation procedures to reduce nonresponse bias.

Item nonresponse will be addressed through logic editing by ensuring that data values are within the ranges expected. For example, if gender is missing or out of range, we will use other questionnaire items such as cancer type to determine the correct gender when possible. Because statistical imputations can be labor intensive, we will only impute key domain and analysis variables.

Hot-deck imputation methods are some of the most cost-effective methods. These methods use item respondents in the current data file as response "donors" for the item nonrespondents (which become the "receptors"). For each receptor, a donor is identified either by ordering the database on various characteristics and selecting the donor most similar to the receptor or by randomly selecting a donor from a pool of donors with similar characteristics. For example, some characteristics that could be used to determine similarity between donors and receptors are gender, cancer type, and cancer stage. We will use a weighted sequential hot-deck procedure developed by Iannacchione (1982). This procedure selects a donor from a receptor pool of donors using the sampling weights of donors and probability minimal replacement sequential sampling (Chromy, 1979).

4.1.3.4 Nonresponse Bias Analysis

Virtually all survey data are subject to potential nonresponse bias. RTI has developed and implemented effective methodology for measuring and reducing bias due to nonresponse, which has been used in several large-scale studies such as those conducted in surveys of students and instructional staff for the Department of Education.[3] When a subset of sample units does not respond, estimates developed based on the responding units could be subject to nonresponse bias. For instance, when estimating a mean based on respondents only($\bar{y}_R$) the incurred bias is the difference between this estimate and the target parameter (μ), which is the mean that would result if a complete census of the target population was conducted and all units responded. This bias can be expressed as follows:

$$B(\bar{y}_R) = \bar{y}_R - \mu \, .$$

However, for variables that are available from the sampling frame, μ can be estimated by $\hat{\mu}$ without sampling error, in which case the bias in $\bar{y}_R$ can then be estimated as follows:

$$\hat{B}(\bar{y}_R) = \bar{y}_R - \hat{\mu}.$$

[3] National Postsecondary Student Aid Study (NPSAS) (http://nces.ed.gov/surveys/npsas).

For this survey, these variables could include demographic, geographic, and health-related indicators that are available on the roster of patients. Moreover, an estimate of the population mean based on respondents and nonrespondents can be obtained by

$$\hat{\mu}=(1-\hat{\eta})\,\bar{y}_R+\hat{\eta}\,\bar{y}_{NR},$$

where $\hat{\eta}$ is the weighted unit nonresponse rate, based on design weights prior to nonresponse adjustment. Consequently, the bias in $\bar{y}_R$ can then be estimated by the following:

$$\hat{B}(\bar{y}_R)=\bar{y}_R-\hat{\mu}=\bar{y}_R-\left[(1-\hat{\eta})\,\bar{y}_R+\hat{\eta}\bar{y}_{NR}\right]=\hat{\eta}\left(\bar{y}_R-\bar{y}_{NR}\right).$$

That is, the estimate of the nonresponse bias is the difference between the mean for respondents and nonrespondents multiplied by the weighted nonresponse rate, using the design weights prior to the nonresponse adjustment. This is the basic approach that will be used to measure bias in key estimates for the patient survey.

4.1.3.5 Sample Weighting

To reduce the possibility of bias due to nonresponse, patient design weights will be adjusted within cells indexed by variables that are deemed predictors of response status, such as the implicit stratification variables that implicitly partitions the patients into homogenous segments. The variables must be defined for both respondents and nonrespondents, so the cancer registries are the most complete information source. These variables include cancer location, cancer type (based on ICD codes), cancer stage, type of treatment, and patient age.

The sample design weights for responding patients will be adjusted upward to compensate for those who do not respond. These adjustments will be implemented within each site by the stratification variables. Sample weight adjustments, including those for nonresponse and poststratification, will be calculated using RTI's generalized exponential models (GEM) software (Folsom and Singh, 2000). GEM is a raking procedure that is a generalization of the logic-type model, which has been proven to produce weights with less variability than what is achievable via traditional methods. GEM is superior to standard raking methods in two regards. First, it allows a much larger set of variables and their interactions to be used during the model development for nonresponse and raking adjustments, thus enabling the weighted data to mimic the distribution of the target universe with respect to a more comprehensive set of indices. Second, this desirable property will be achieved while preventing the adjusted weights from becoming too extreme, thus producing study estimates that better represent the target universe without significantly increasing variance of estimates, which will reduce the power of statistical tests.

4.1.3.6 Planned Analyses

Development of Composite Measures

In some cases, it may be appropriate to combine individual survey items into composite measures. For example, we may develop an overall measure of attitudes towards clinical trials based on patients' responses to items on the potential benefits and drawbacks of clinical trials. Other possible composite measures include patient-centered communication, access to care, and awareness of services and resources. As a first step in developing the composite measures, we will compute basic descriptive statistics for each item, including the percentage of respondents endorsing each response option and the number of missing responses. Items with little variability in responses may not be effective at distinguishing among patients. Next, we will use factor analyses to examine the dimensionality of each measure. We will conduct confirmatory factor analyses using the Mplus software (Muthén and Muthén, 1998–2007) when a specific factor structure is hypothesized or when analyzing previously validated scales such as the adapted Makoul Communication Assessment Tool (Makoul et al., 2007) included in the survey as a measure of patient-centered communication. We will assess model fit using several fit indices, such as the comparative fit index, Tucker-Lewis Index, and standardized root mean square residual. For newly developed scales, we will conduct exploratory factor analyses to determine the most appropriate factor structure.

Next, we will conduct item response theory (IRT) analyses to explore the properties of the items included in the scales. We will select an IRT model that matches the type of item and the number of response options. Dichotomous items will be analyzed using the 1-parameter logistic (1PL or Rasch), 2PL, and 3PL IRT models. We will compare the fit of these models using likelihood ratio tests for nested models. Items with more than two response options will be analyzed using Samejima's graded response model or Bock's nominal model, depending on whether the items include ordered response options. Ideally, the measures should include items with high IRT slope parameters and a range of threshold parameters.

Finally, we will examine the internal consistency of the composite measures using Cronbach's alpha. To assess construct validity, we will examine correlations between the measures and compare scores for groups that should vary on the construct being measured. For example, we may expect more educated respondents to have a greater understanding of clinical trials. Significantly different scores among these groups will provide evidence for the construct validity of the scales.

Descriptive Statistics

For both the baseline and follow-up surveys, the first step will be to examine the variables using univariate and bivariate analyses. Then we will assess differences in outcome measures by site and site-level characteristics and also across patient subgroups of interest (e.g., by cancer type, race/ethnicity, other demographic characteristics, level of exposure to

the NCCCP). We will use appropriate tests of significance (e.g., *t*-tests, chi-square) to examine whether there are statistically significant differences across subgroups.

Comparison of Findings from Baseline and Follow-up Surveys

We will examine respondent characteristics at baseline and follow-up and adjust the samples as necessary for comparison purposes. Then we will explore differences in outcome measures between baseline and follow-up to examine whether and how the patient experience has changed over time. To the extent possible, we will also investigate differences in outcome measures over time by site and site-level characteristics and among patient subgroups of interest (our ability to conduct this level of analysis will depend on the sample sizes for specific subgroups). For example, we may explore whether there was more likely to be a positive change in outcomes for patients with specific cancer types or with different sociodemographic profiles (depending on sample sizes for each type of cancer).

Correlation Analyses and Model Testing

We will conduct correlation analyses to assess the strength of relationships hypothesized between independent measures (e.g., cancer type, cancer stage, type of treatment) and dependent measures (e.g., patient overall rating of care). The choice of variables will be similar to those used as stratification or predictors of patient nonresponse. In addition, we will develop and test models to determine site and individual-level predictors of various outcomes and of changes over time in outcomes. These models will be developed based on theoretical considerations and relevant findings from prior research.

Below is the conventional linear regression model for an infinite population of cancer patients:

$$Y = X\beta + e,$$

where

- X = the matrix of independent variables in the patient population (namely, background characteristics, health status, cancer type and history, treatment status and types of treatment, self-efficacy, social support, level of exposure to the NCCCP, indicator for completing survey alone or with assistance, site-level measures, site and type of site, and site characteristics) and
- Y = the vector of dependent variables in the patient population (namely, Cancer Center services and resources, patient navigation assistance, patient-centered communication, clinical trials, appropriate survivorship care, and overall rating of care).

The vector β = the vector of regression coefficients to be estimated, and e is the vector of random errors.

Since our probability sample is a finite population of cancer patients, we will estimate

$$\beta = \left[X'X\right]^{-1} X'Y .$$

The Horvitz-Thompson estimators (Horvitz and Thompson, 1952) will be used in our regression models to capture the nonresponse adjusted design-based weights and to properly compute design consistent variance estimates. These estimators are as follows:

$$x'wx = \sum_{i=1}^{n} x_i' x_i w_i \text{ = Horvitz-Thompson estimator for } X'X \qquad (4.1)$$

and

$$x'wy = \sum_{i=1}^{n} x_i' y_i w_i \text{ = Horvitz-Thompson estimator for } X'Y \qquad (4.2)$$

where

x_i = row vector of independent variable values from the cancer registries and from survey results for the sample patient (i),

w_i = the nonresponse adjusted analysis weight for the sample patient (i), and

y_i = the dependent variable values for the sample patient (i).

Our regression coefficients will be estimated by b as follows:

$$b = (x'wx)^{-1}(x'wy) \qquad (4.3)$$

We will test our hypothesis that the regression coefficient associated with each variable in the model is equal to zero, namely,

$$H_o : b_i = 0 \text{ vs.}$$

$$H_A : b_i \neq 0$$

The test for overall model significance will also be computed as

$$H_o : b = 0$$

vs.

$$H_A : b \neq 0 .$$

Linear regression will be used to model continuous outcome variables. This procedure is found in SUDAAN (software developed by RTI for statistical analyses of cluster-correlated data).

Logistic regression, also found in SUDAAN, will be used to model binary outcome variables. The model is provided below:

$$\log(p/1-p) = X'\beta$$

$$p = prob(Y=1/X)$$

To predict whether a patient was informed about clinical trials, we will define Y as follows:

Y = a vector set to 1 if response is yes, 0 if no.

Table 4-5 is an example for estimating the cross-site regression coefficients using a selected list of independent variables to model two major outcomes: (1) overall rating of care, and (2) the probability that a cancer patient was informed about clinical trials. Across-time regression models will also be investigated, using a time variable as a regressor. We will also interact time with the overall program development variable. Both cross-site and across-time modeling will be mindful of potential characteristics of program participants that may violate the assumption that the error structure has the same variance. Within-site models using a subset of the independent variables shown will also be tested provided there is sufficient sample size to warrant including these variables in the models. We will explore appropriate model specification for each outcome variable.

As with any survey, it will not be feasible to ask all questions of possible interest because of constraints on the survey length. Also, we will not have access to respondents' medical records or utilization data. We will rely on self-report and cancer registry data to obtain information about the respondent's cancer (type, stage at diagnosis, time since diagnosis), type(s) of treatment, and health status. Thus, in interpreting the survey findings, it will be important to bear in mind potential omitted variable bias.

4.1.3.7 Data Summaries for Sites

We will provide summary site-level findings to each of the participating sites using baseline data. "Data books" for each site will include a profile of respondents from the site and frequencies for key variables for the site and for all other sites combined. In addition, we will present selected cross-tabulations (e.g., outcome measures by respondent characteristics and other key independent variables). However, sample sizes will be too small to conduct statistical tests of differences among subgroups of respondents at a single site. The table shells in Appendix G illustrate the types of cross-tabulations that we may provide to the sites.

Table 4-5 Selected Independent Variables to Model Overall Rating of Care or to Predict the Probability of Being Informed about a Clinical Trial (Sample Table)

Independent Variables (x_i)	Beta Coefficients (b_i)	SE Beta	Lower 95% CI	Upper 95% CI	T-Test B=0	P-Value
Intercept						
Site						
Program development						
Gender						
Male						
Female						
Ethnicity						
Hispanic						
Non-Hispanic						
Race						
White						
Black						
American Indian/Alaska Native						
Native Hawaiian/other Pacific Islander						
Asian						
Other						
Marital Status						
Married/living as married						
Divorced/separated						
Widowed						
Single (never married)						

(continued)

Table 4-5. Selected Independent Variables to Model Overall Rating of Care or to Predict the Probability of Being Informed about a Clinical Trial (Sample Table) (continued)

Independent Variables (x_i)	Beta Coefficients (b_i)	SE Beta	Lower 95% CI	Upper 95% CI	T-Test B=0	P-Value
Age						
21–30						
31–40						
41–50						
51–60						
61–70						
71–80						
81 or older						
Income						
Less than $20,000						
$20,000–$39,000						
$40,000–$59,000						
$60,000–$79,000						
$80,000–$99,999						
$100,000 or more						
Education						
No school						
Grades 1–8						
Grade 9–11 (less than high school graduate)						
High school graduate or GED						
College 1–3 years (some college)						
College 4 years or more (college graduate)						

(continued)

Table 4-5. Selected Independent Variables to Model Overall Rating of Care or to Predict the Probability of Being Informed about a Clinical Trial (Sample Table) (continued)

Independent Variables (x_i)	Beta Coefficients (b_i)	SE Beta	Lower 95% CI	Upper 95% CI	T-Test B=0	P-Value
Employment						
Working full-time						
Working part-time						
Homemaker/family caregiver						
Retired						
Unemployed						
Student						
Other						
Cancer Type						
Bladder						
Breast						
Colorectal						
Endometrial						
Kidney (renal)						
Leukemia						
Lung						
Melanoma						
Non-Hodgkin lymphoma						
Pancreatic						
Prostate						
Skin (not including melanoma)						
Other						
Don’t know						

(continued)

Table 4-5. Selected Independent Variables to Model Overall Rating of Care or to Predict the Probability of Being Informed about a Clinical Trial (Sample Table) (continued)

Independent Variables (x_i)	Beta Coefficients (b_i)	SE Beta	Lower 95% CI	Upper 95% CI	T-Test B=0	P-Value
Stage at Diagnosis						
0						
I						
II						
III						
IV						

4.2 Patient (and Caregiver) Focus Groups

Focus groups are to be conducted among patients (and possibly caregivers) at the NCCCP sites during site visits. This component of the evaluation is designed to provide an in-depth understanding of patients' (and possibly caregivers') perspectives about their care at the Cancer Centers. The qualitative findings will complement the patient survey data, exploring topics in greater depth.

A decision has been made to conduct focus groups only during the third year of site visits (i.e., spring 2010). A document is under development that will specify the segmentation strategy, recruitment procedures, and protocol for these groups. Focus groups plans will be finalized during summer 2009 and added to this section of the design report.

5. ECONOMIC STUDY

5.1 Overview

The NCCCP economic study is designed to assess the sustainability, effectiveness, and potential replicability of the NCCCP concept. The following economic questions are most important to the program evaluation:

- How effective were the sites in targeting resources to achieve measurable program goals?
- How much would it cost to sustain program operations beyond the pilot period?
- How many similar community-based clinical sites exist around the country, and how much could they expect to spend if they chose to institute similar programs?

What sort of return on investment—whether monetary or nonmonetary—could motivate other community hospitals to engage in the types of organized research and outreach that the NCCCP represents?

This part of the RTI evaluation will include 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 need to be answered in order to address the four study questions listed above:

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?

What sort of return on investment (monetary or other) was initially expected by executive management for participating in the NCCCP?

At the close of the program, what is management's perception of success or failure of the NCCCP in meeting these expectations?

We will address the first three questions through the micro-cost study, with data collected using the Cost Assessment Tool (CAT), as detailed in Section 5.2. The last two questions will be addressed through a separate study of the "strategic case study" which is a variation of the traditional business case found in organizational literature, extended to include both monetary and nonmonetary returns. The strategic case will rely on information gathered from a set of initial and follow-up telephone interviews with the financial executives of the participating hospitals or system organizations. Findings from these interviews will be integrated with other executive interview data that have been collected during site visits and at annual meetings, with an analysis of the organizational component of the BAS, and with analysis of other secondary data relevant to the organizations and their markets. Within the framework of this evaluation, RTI's goal for the strategic case study is not to "make the case" for participation by directly measuring expected returns but to identify the financial and other strategic motivations for organizational participation. Section 5.3 briefly describes RTI's technical approach for this portion of the economic study. Additional information on the strategic case study is provided in Appendix H ("Concept Paper for Addressing the Strategic Case for Site Participation in NCCCP").

5.2 Micro-Cost Study

5.2.1 Types of Data Collected

During the first contract year, the RTI team met several times by teleconference with the Project Officer and members of EOC to clarify the objectives of the micro-cost study and come to an agreement on the types of cost data that should be collected. Key decisions that

needed to be made included whether to track average costs for NCCCP-type activities or just incremental costs associated with pilot participation; whether and how to include allocated fixed overhead costs, including time spent by the Chief Executive Officer (CEO)/Chief Financial Officer (CFO) on planning or oversight; and how much focus to place on cost-effectiveness measures. Input on these issues was also sought from site PIs at the annual meeting in June 2008. From these meetings, we arrived at a consensus that the micro-cost study should focus on incremental rather than average costs. By incremental costs, we mean costs related to core component activities that would not have been incurred if the organization was not part of the NCCCP pilot project. We recognize that some of the participating organizations might already have had programs in place that carried out similar activities (e.g., community screenings, tumor boards, multidisciplinary care committees). In these cases, it may be difficult for NCCCP staff to distinguish between newly incurred NCCCP costs and ongoing NCCCP-like operations. However, our primary goal in stressing incremental project-related costs is to avoid loading the study with the costs of cancer care and research programs that were already in place at the sponsoring hospitals before the NCCCP pilot.

By extension of this same argument, we decided not to document details for allocated fixed overhead.[4] However, expenditures for rent, facility maintenance, or equipment that are directly attributable to NCCCP participation could be identified as part of that site's matching costs.

RTI's study design originally included separate analyses of start-up (i.e., initial implementation) costs and annual operating costs. Although this is a clear accounting distinction in theory, input from site staff at the annual meeting indicated that most, if not all, sites already had aspects of each NCCCP program components in place prior to the NCCCP and that most of the first year NCCCP-funded outlays were expected to be recurring costs throughout the pilot. Based on this input, RTI no longer plans to collect these costs separately. We expect that some sites may have initial outlays for recruiting, equipment purchases, or IT design that are nonrecurring, and we will examine differences in cost structure between the first and subsequent years of the project to identify these.

5.2.2 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 source of funding. The workbook is "pre-loaded" with previously invoiced costs that were covered by the NCCCP contract, but it will require additional input from site administrators or budget analysts to allocate these costs across specific activities and to load other costs related to the project.

[4] Fixed overhead costs are generally allocated to patient care and research areas based on set formulas. This is typically done to assign costs for items such as building depreciation and administrative support services (e.g., payroll, personnel, legal, financial management, executive office).

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

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

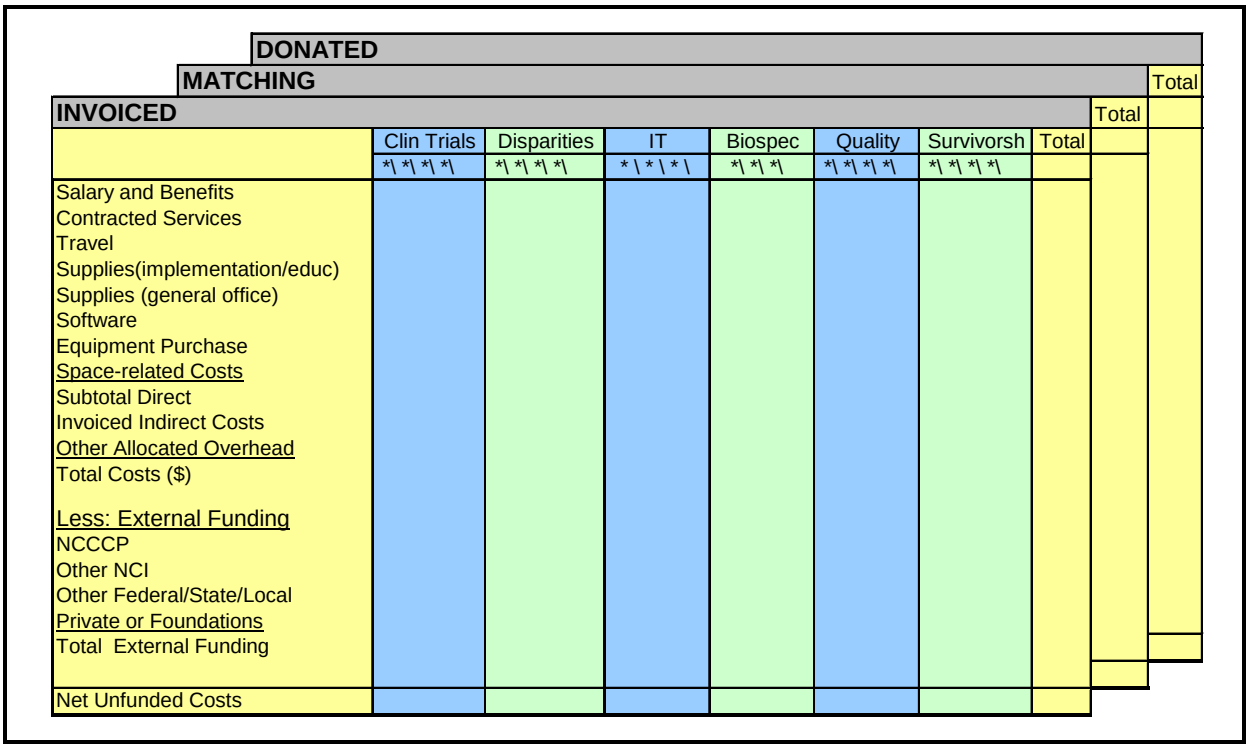
- total implementation and operating costs by type (e.g., salary, materials, contract services, travel);
- distribution of costs across activities within the core component;
- share of costs funded by the NCCCP contract, by other external sources, and by the sponsoring organizations; and
- contribution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

Data collection is separated into three worksheets representing three cost "domains." These distinguish costs that are (1) covered under the NCCCP contract (Invoiced) from (2) those that are incurred by the sponsoring hospital 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 will be imputed 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.[5]

Figure 5-1 presents a schematic representation of CAT as modified for 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.

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

Figure 5-1. Schematic of the Cost Assessment Tool



The validity of our cross-site comparisons and any related cost-effectiveness measures depends heavily on the accuracy of the activity-based cost allocations within each core component. To develop these allocations, RTI's cost study team reviewed the sites' submitted quarterly reports to identify commonly defined activities across sites. An ad hoc group of site administrators and program directors reviewed the column descriptions and cost types (rows) over several iterations to suggest additions, deletions, and refinements. The resulting draft was then reviewed by the Project Officer, members of the EOC, and members of NPAC, who made additional suggestions, resulting in the activity column headings shown in Table 5-1 (for reference, copies of each input worksheet are also provided in Appendix B). As a final review, CAT is being pilot-tested by administrative personnel in two sites to check for reasonableness and feasibility.

Table 5-1. CAT Activity-Based Cost Allocations within Program Components

CAT Input Columns	Activity Explanation/Example (hyperlinked from column headings within CAT)
Activities Common to all Core Components	
Cross-site communication	Contact with other sites regarding NCCCP-related goals
NCCCP administration	Tasks related to deliverables to NCI
Symposia/conferences	Attending or sponsoring conferences

Activities Specific to Clinical Trials	
Trial administration/planning	Negotiating for new trial participation, meeting with academic affiliates
Enrollment activities	Accruals, enrollment, follow-up
Activities Specific to Disparities	
Screening	Costs related to new screening activities
Community outreach	Activities designed to increase visibility and awareness in the community
Partnership activities	Meeting with local organizations (e.g., American Cancer Society, local community organizations, political representatives, other professional organizations)
Care coordination/navigation	Includes all costs for patient navigators in this group; also includes coordinating post-screening follow-up activities
Activities Specific to Information Technology	
Planning and development	Includes strategic planning for new IT and meeting with vendors
Implementation	Installation and testing of new IT
Training	Instructing staff on the use of new IT

(continued)

Table 5-1. CAT Activity-Based Cost Allocations within Program Components (continued)

CAT Input Columns	Activity Explanation/Example (hyperlinked from column headings within CAT)
Activities Specific to Biospecimens	
Planning and development	Includes training and procedure development
Storage and processing	Specimen-specific activities, including storage costs, analysis, and transfer
Activities Specific to Survivorship	
Program development	Planning, development, and administration of new or expanded programs
Patient-level activities	Includes activities such as completing treatment forms and running support groups
Activities Specific to Quality Of Care	
Multidisciplinary care	Does not include patient navigator costs (see Disparities), includes multidisciplinary committees, conferences, and planning activities
Quality improvement (QI) program development	Includes activities such as credentialing and guideline development
QI initiatives	Includes data analysis, monitoring, and other implementation costs for new QI programs

NOTE: Column 1 corresponds to column headings. Information in Column 2 is included in a separate sheet with further descriptions and instructions and can be accessed by CAT users by right-clicking any of the column headers.

5.2.3 Data Collection Logistics

5.2.3.1 General

CAT will be forwarded electronically to each pilot site administrator, who can forward it to the most appropriate person(s) for completion. Although we use the terms "pilot site" throughout this chapter, single NCCCP contracts made to a system head office (such as CHI) but covering expenditures at multiple hospitals are considered one site for purposes of completing the forms.

5.2.3.2 Invoiced Costs

For the invoiced cost domain worksheet, information data by core component are loaded directly to the CAT worksheets from electronic files that are transferred quarterly from SAIC to RTI. At each site, the designated administrative person will be responsible for allocating invoiced costs to the individual activity columns using percentage estimates, from which the worksheet will compute allocated amounts. The first round of cost allocations will incorporate all invoiced costs from the first year of the contract (July 1, 2007–June 30, 2008) and will be distributed in November 2008, for completion by February 2009. For

Years 2 and 3 of the pilot project, RTI will distribute the updated CAT worksheets to sites within 2 weeks of receiving the final (June 30) contract invoices and will request turnaround from the sites within 4 weeks.

While working with the sites to gain a better understanding of how they defined specific invoiced costs, RTI learned that some sites included institutional indirect cost rates in their billed amounts and others did not.[6] To develop consistently defined direct costs versus overhead costs, RTI requested confirmation from each site on their use of indirect cost add-ons. We have embedded columns in the CAT worksheet incorporating formulas that strip any invoiced indirect costs from the direct cost rows within CAT, separately identify these amounts, and transfer them to another row. For comparability, sites that do not include indirect costs in the rates used for contract invoices can compute them based on similar formulas and report them on a line in the Matching worksheet. RTI's analyses will separate direct from indirect costs. Table 5-2 provides an example of invoiced costs currently provided by sites to SAIC on a quarterly basis.

Table 5-2. Summary of Year 1 Invoiced Costs, by Type of Expenditure and Core Component Activity

	Salaries and Benefits			Other Direct Costs	Invoiced Allocated Indirect Costs (if applicable)	Total	
	Medical Director/PI	Administrative Director/ Program Coordinator	All Other				
Total Contract Awards	$388,166	$2,606,358	$145,459	$166,545	N/A	$3,306,529	100%
By Component:							
Clinical Trials	$67,265	$641,425	$73,755	$18,600		$801,045	24%
Disparities	$182,339	$1,047,343	$42,636	$18,667		$1,290,986	39%
Information Technology	$53,886	$351,740	$10,472	$67,000	TBD (still getting information from sites)	$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 will work with sites to reassign to appropriate core component.

[6] Applicants for pilot program funding were instructed to use "fully loaded hourly rates" in their financial proposals, so indirect costs were expected to be included in the budgets. Some applicants chose to use direct hourly rates only, or direct hourly rates plus an indirect add-on for benefits only, to leverage the fixed contract amounts of $500,000 per site per year.

5.2.3.3 Matching Costs

Sites are given some leeway in identifying and quantifying matching costs related to NCCCP activities, as long as they are incremental. CAT instructions (which are accessed by right-clicking the cell containing the domain worksheet description) explicitly instruct users to exclude any costs that were part of the organization's operations prior to participating in the pilot project, even if they directly overlap with newly funded NCCCP activities. RTI recognizes, however, that such distinctions are difficult to operationalize and that there is some potential for overstatement. As with the invoiced costs, sites are asked to allocate matching cost amounts 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 can be entered by specific activity within the core components.

Sites will be asked to document first-year matching costs in one worksheet. After that, RTI will request matching costs information on the same quarterly update schedule as is used for invoiced costs.

5.2.3.4 Donated Costs

From conversations with site administrators and medical directors, we expect the majority of donated services documentation to relate to uncompensated time from community physicians and their staff. From discussions with site staff, we expect most of this time to relate to trial enrollments and multidisciplinary care committees. Site personnel are only asked to estimate the number of hours spent on NCCCP activities, by type of professional as listed on the specific lines for this worksheet (see Appendix B).

5.2.4 Output Measures for Cost-Effectiveness

Some resources captured in CAT can be used in cost-effectiveness measures comparing performance across pilot sites. Because this phase of the NCCCP evaluation does not include analysis of claims, medical records, or registry data, it does not document outcomes such as changes in treatment choice, service utilization, morbidity, or mortality. The denominators used in the cost-effectiveness component of our economic evaluation will therefore be unit changes in specific intermediate output measures, and comparisons will be limited to core area activities for which we have pre- and post-pilot output measures.

Outputs can be directly measured activities, such as total screenings and treatments or enrolled patients, minority screenings, treatments, or enrolled patients; or they can be intermediate process measures, such as number of cases coordinated by patient navigators or cases under the review or management of multidisciplinary care committees. RTI also

plans to adapt results from the two patient surveys for use as denominators, specifically the change in responses from questions capturing overall patient satisfaction and levels of provider communication.

5.2.5 Analysis Plan

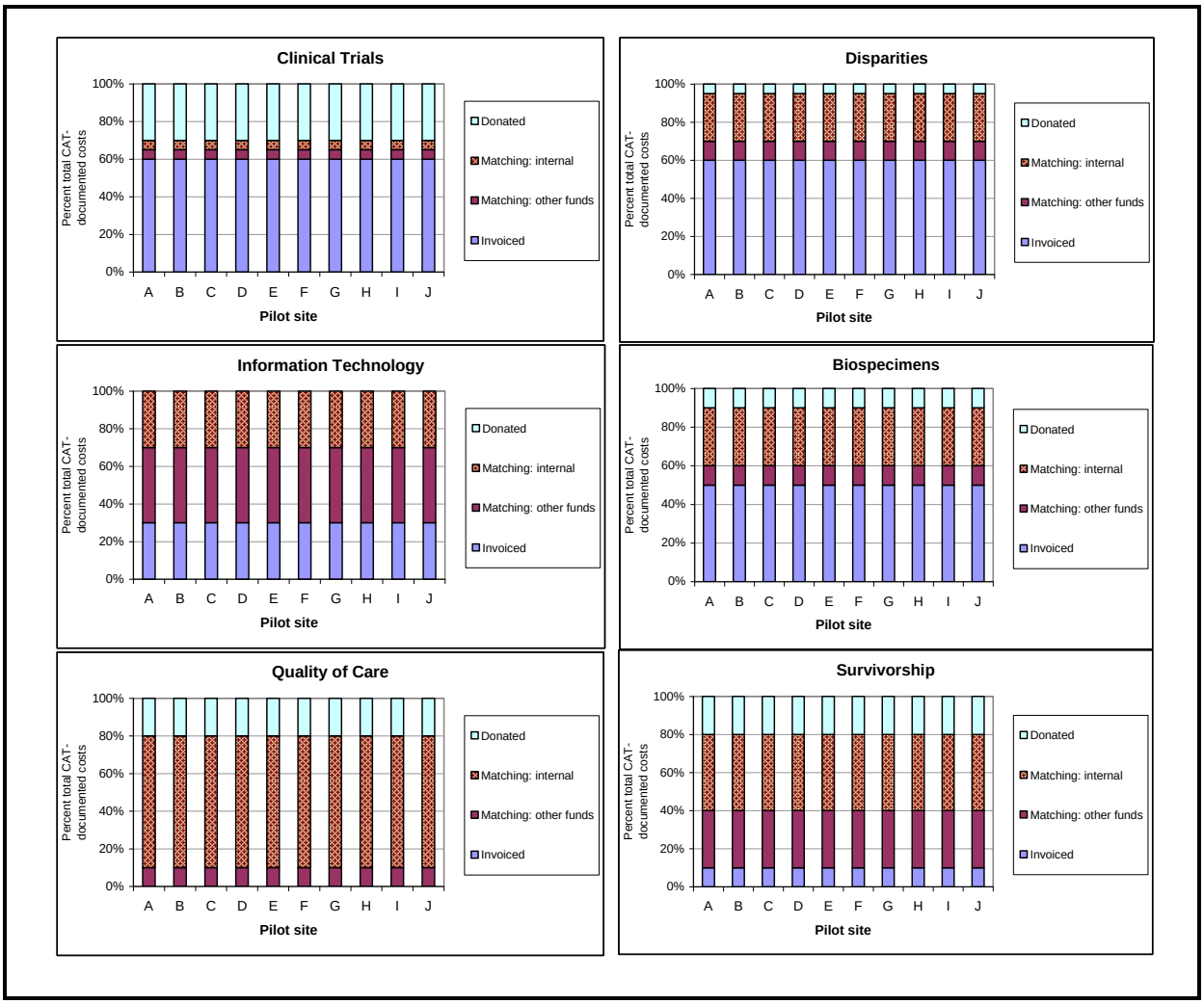
5.2.5.1 Total Project Costs

RTI will analyze each site's program cost structure by type of activity and by source of funding for each of the major types of costs (salaries, materials, overhead). We will analyze variation in activity-based expenditures across sites and investigate patterns in the differences by type of organization, market characteristics, or level of readiness and/or prior experience in NCCCP-type activities. Findings will be included in our annual cross-site evaluation report. Table 5-3 presents an example of a cost summary table that will be included in the report, using data from the invoices forwarded by SAIC for the first year. The final data will include more detail on types of activities and will be expanded to include matching costs and donated time. Table 5-3 and Figure 5-2 provide additional examples of how the reported data can be presented to convey site-level variation in cost structure and focus.

Table 5-3. Sample Presentation: Shell Table for Documented Costs Attributable to NCCCP Implementation, by Core Component and Funding Source

	Invoiced Costs	Matching Costs: Other Funding	Matching Costs: Internally Funded	Donated Time	Total
All Reported Costs					
All Sites:	$	$	$	$	$
Percent	%	%	%	%	100%
Site A	$	$	$	$	$
Site B	$	$	$	$	$
Site C	$	$	$	$	$
Site D	$	$	$	$	$
Site E	$	$	$	$	$
Site F	$	$	$	$	$
Site G	$	$	$	$	$
Site H	$	$	$	$	$
Site I	$	$	$	$	$
Site J	$	$	$	$	$
Direct Costs Only (Excludes Allocated Indirect Costs)					
All Sites:	$	$	$	$	$
Percent	%	%	%	%	100%
Site A	$	$	$	$	$
Site B	$	$	$	$	$
Site C	$	$	$	$	$
Site D	$	$	$	$	$
Site E	$	$	$	$	$
Site F	$	$	$	$	$
Site G	$	$	$	$	$
Site H	$	$	$	$	$
Site I	$	$	$	$	$
Site J	$	$	$	$	$

Figure 5-2. Sample Presentation: Shell Figure for Distribution of Core Component Expenditures, by Site and Funding Source



5.2.5.2 Cost-Effectiveness

RTI will identify a set of core program activities to be associated with the agreed-upon output measures gathered before and after pilot participation and gathered across all sites. Incremental costs for these activities will be used as the numerators for cost-effectiveness ratios, which we define as incremental costs per incremental outcome unit. Multiple cost aggregates may be appropriate as numerators for specific output measures; a provisional list of these ratios is presented in Table 5-4. As with the analysis of total costs, we will investigate site-level variation in cost-effectiveness to consider patterns in the differences by key organizational and market characteristics.

Table 5-4. Examples of Cost-Effectiveness Ratios for Consideration

Area/Description	Variables	Analytic Framework
Clinical Trials	Enrollment planning $ / new trials Enrollment activity $ / Δ new accruals Enrollment activity $ / Δ completed accruals	Compare across sites and examine differences by prior experience and CCOP participation
Disparities	Total outreach $ / Δ # screenings Screening activity $ / Δ # screenings	Compare across sites and examine differences by community demographics and type of hospital ownership
	Total disparities $ / Δ market share from locally underserved ZIP codes	
	Navigator $ / Δ survey-measured outcomes re provider communication and/or patient satisfaction or understanding	Compare across sites and examine differences by prior experience community demographics
Quality of Care	Multidisciplinary care $ / Δ MDC committee caseload	Compare across sites and examine differences by prior experience and physician practice organization

5.2.6 Timing

Data from the Year 1 micro-cost study are expected to be returned to the RTI team in February 2009, with preliminary analyses available for review by March 2009 and a draft report submitted by RTI by May 2009. The CAT for Year 2 is expected to be distributed in early August 2009 and returned to RTI within 4 weeks. Results from Year 1 and either preliminary or final analyses from Year 2 cost data will be incorporated into the second-year NCCCP evaluation report, depending on the submission date of that report.

5.3 Strategic Case Study

Final approval of RTI's technical approach to the strategic case study has not been received. Our proposed approach is outlined below and detailed in the concept paper included in Appendix J.

The strategic case study will integrate original data gathered from executive interviews with secondary data on organizational, financial, and local market conditions. RTI will conduct telephone interviews with chief financial officers at each site 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. Follow-up interviews at the end of the third year can probe leadership perceptions of

success or failure with respect to initial expectations. We are particularly interested in the metrics employed by executive leaders in defining success or failure for nonmonetary returns.

Interview data will be supplemented by analysis of the organizational component of the BAS and with analysis of other information on the overall financial performance of the sponsoring organization, its market share, the numbers and types of its competitors, the local physician supply, and local patient demographics.

6. OVERALL ANALYSIS PLAN

The final analysis of the evaluation data at the end of Year 3 will consist of separate analyses for each study component (i.e., case study, patient outcomes, and economic study) as described in Sections 3, 4, and 5, respectively, as well as a comparative analysis to answer each of the overarching evaluation questions presented in Section 2.2. Even though the NCCCP evaluation will provide huge quantities of data from multiple sources, the overall analysis will be at the organizational level (i.e., n=10 programs or 16 hospitals). Even when looking at patient-level data and other contextual and environmental factors, questions to be addressed for the overall analysis will be site-specific in that patients responding from a specific site will be aggregated to assess how outcomes from the survey are associated with various environmental, organizational, or program components.

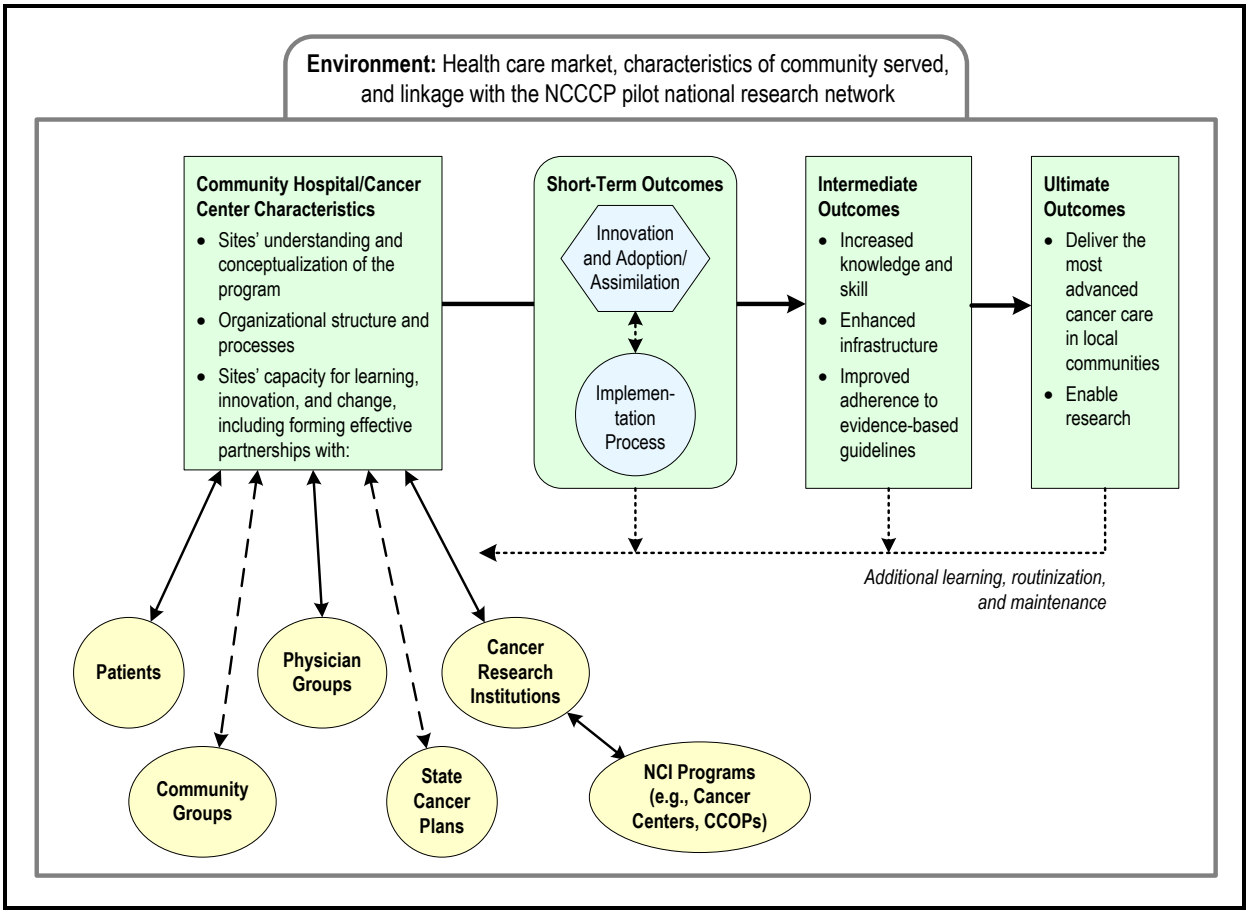
This section focuses on the final overall qualitative comparative analysis to address the questions presented in Section 2.2 and the corresponding hypotheses. There are three overarching evaluation questions and numerous hypotheses to answer with regard to NCCCP implementation, and each will require a comparative analysis. For this final analysis, the most sophisticated type of triangulation will be performed, which combines data from quantitative sources (i.e., patient survey, cost study) with qualitative data (i.e., case study, focus groups). This triangulation will be done in order to capture a "more complete, holistic, and contextual portrayal of the unit(s) under study. This is, beyond the analysis of overlapping variance, the use of multiple measures may also uncover some unique variance which otherwise may have been neglected by single methods.…In this sense, triangulation may be used not only to examine the same phenomenon from multiple perspectives but also to enrich our understanding by allowing for new or deeper dimensions to emerge" (Jick, 1979, in Creswell and Clark, 2006, p. 109). Using techniques from Ragin (1987) for qualitative comparative analysis, we will test each of the following hypotheses, using the dependent and independent measures described in the sections that follow.

6.1 Statement of Hypotheses

This section is organized into each of the two major levels that will likely impact the implementation of the NCCCP: environmental and organizational (i.e., the box in Figure 6-1 titled "Community Cancer Center Characteristics") and the third level that will likely be impacted by the NCCCP: the patient (i.e., impacts on patient care as described in the intermediate and ultimate outcomes). Since the hypotheses presented in this section are derived directly from the NCCCP evaluation conceptual framework, it is repeated here to help guide the reader. As shown in Figure 6-1 (and Figure 2-2) and described in Section 2.1, these three levels are key to understanding the factors that will influence whether the NCCCP works well and reaches the achievements NCI has specified and whether these achievements impact patients' perceptions of care. We start by stating the hypotheses for the environmental, organizational, and patient levels. These include hypotheses illustrated

in Figure 6-1 (and described in Section 2.1) that lend themselves to mixed methods analysis. Note that only those hypotheses that can be addressed through mixed methods are included in this section (e.g., "national level" analysis will be addressed through the case study analysis only). In stating each hypothesis, the dependent variables have been underlined and the independent variables are presented in italics. The measures and operationalization of each of these variables is under development through the course of the second year of the evaluation. Once they are finalized, they will be added here.

Figure 6-1. NCCCP Evaluation Conceptual Framework



6.1.1 Environmental-Level Hypotheses

As described in Section 2.1.2.1, there are numerous factors at the environmental level that are expected to impact a site's ability to successfully implement the NCCCP. There are three factors of particular relevance to the NCCCP, including local health policy and market, community characteristics, and the NCCCP National Network (pages 2-7 and 2-8). As can be seen with the current evaluation design, there is a limited number of data sources that assess environmental factors specific to the NCCCP. For that reason, variables for only one

of the following hypotheses are part of this design report. The hypothesis that will be tested with existing measures or ones to be created is the following:

CCCs that *more frequently and proactively engage* with NCI's NCCCP National Network are more likely to successfully implement the NCCCP.

In addition to this hypothesis, six hypotheses will be tested if data sources can be identified to address them. These data sources are currently being gathered to assess existing measures that may be used to test each hypothesis and determine whether they can be incorporated into the evaluation design. For now, these hypotheses are not included in the evaluation design but will hopefully be added at a later date:

CCCs in states that *mandate private insurance coverage of clinical trials* will be more likely to improve their clinical trial accrual rate than CCCs in state that do not.

CCCs that are *located in more competitive markets* are less likely to achieve NCCCP goals than CCCs in less competitive markets.

CCCs in states with *more robust cancer plans and resources* will be more likely to secure outside resources to support NCCCP-related activities and successfully implement the NCCCP.

CCCs in states that have *more generous Medicaid coverage of clinical trials* will be more likely to improve their clinical trial accrual rate than CCCs in states with less generous coverage.

CCCs in health care markets with *relatively low levels of uninsured and generous payer mix* (e.g., private coverage with comprehensive benefit package) will be more likely to improve their clinical trial accrual rate than CCCs in health care markets with relatively high levels of uninsured and less generous payer mix (e.g., Medicare, Medicaid).

CCCs located in markets with *more community groups* that are well organized are more likely to successfully engage in outreach and reduce disparities.

6.1.2 Organizational-Level Hypotheses

As shown in Figure 6-1 and described in Section 2.1.2.2, there are four major subdomains within an organization that are likely to impact its ability to learn, change, and succeed in the NCCCP. These include each site's understanding and conceptualization of the NCCCP; existing structures and processes; its capacity for learning, innovation, and change; and its ability to form effective partnership with key groups in the communities. Based on the literature and knowledge about how NCCCP is intended to function, the following hypotheses will be tested with the final analysis:

CCCs whose *reasons or impetus for participating* in the NCCCP are driven by their mission/vision and desire to distinguish themselves regionally and nationally are more likely to successfully implement the NCCCP.

CCCs that perceive that there is a *good "fit " between their organization and the nature of NCCCP* are more likely to successfully implement the NCCCP.

CCCs whose *hospital leadership (managerial and clinical) is very committed to and supportive of the NCCCP* aims are more likely to successfully implement the NCCCP.

CCCs that develop *effective NCCCP teams that can communicate and coordinate* key departments/units/teams through the CCC are more likely to successfully implement the NCCCP.

CCCs with relatively *greater profit margins and resources* to dedicate to the oncology program are more likely to successfully implement the NCCCP.

CCCs that have had *greater experience with multidisciplinary teams* are more likely to successfully implement the NCCCP.

CCCs that have a *matrix, parallel, or service line structure* are more likely to successfully implement the NCCCP.

CCCs that have *more robust information systems*, specifically in the area of cancer care, are more likely to successfully implement the NCCCP.

CCCs and NCCCP programs that have a *full-time medical director, NCCCP-capable cancer center administrator, and/or "champion "* (formal or informal) are more likely to successfully implement the NCCCP.

CCCs that have *rich communication networks* (i.e., many different forums for exchanging ideas and information about the NCCCP) are more likely to better understand the program and what it means to their organization.

CCCs that have a *greater portion of employed physicians or stronger participation agreements* with private practice oncologists are more likely to successfully implement the NCCCP.

CCCs that *involve physicians and other key departments/staff* early and often in program development are more likely to successfully implement the NCCCP.

CCCs that are *part of centralized health systems* are more likely to successfully implement the NCCCP. They will also be better able than non-centralized system sites to disseminate the NCCCP elements to other CCCs in their system.

CCCs that have a *full-time medical director at the systems level* are more likely to successfully implement the NCCCP. They will also be better able than non-centralized system sites to disseminate the NCCCP elements to other CCCs in their system.

CCCs that *make and celebrate tangible improvements or progress*, even if incremental or small, are more likely to maintain momentum and successfully implement NCCCP.

CCCs that *perceive that the overall benefits of the NCCCP have been and will continue to be greater than the overall costs are more like*ly to have specific plans for sustaining the program beyond the pilot period.

CCCs that are better able to *routinize* successful NCCCP strategies and elements, through a variety of mechanisms likely formal and informal policies and practices and ongoing education and training, are more likely to have specific plans for sustaining the program beyond the pilot period.

6.1.3 Patient-Level Hypotheses

An ultimate outcome of the NCCCP is to "deliver the most advanced cancer care in local communities." At this point, the quality of care provided to patients is not incorporated into this evaluation design, but measures will be collected directly from patients (via the survey and focus groups) in terms of their experiences with the care they received from each of the 10 programs. Primary indicators assessed through the survey and focus groups include patients' awareness of the different types of services offered (i.e., more comprehensive services across the continuum of cancer care will be offered to more patients in NCCCP sites over time) and their use of or satisfaction with each type of service. With the composite measure on the "successful implementation of the NCCCP" (see Section 6.2.1), we will analyze findings from the survey and focus groups, in addition to data from the case study, to test the following hypotheses:

CCCs that are able to demonstrate *successful implementation of the NCCCP* will have a greater proportion of patients report higher levels of awareness of services.

CCCs that are able to demonstrate *successful implementation of the NCCCP* will have a greater proportion of patients report higher levels of access to and satisfaction with the services they received (e.g., patient navigation, clinical trials).

6.2 Measures Development

In stating the hypotheses, it is important to determine the dependent variables that will be incorporated into the final analysis. Many of the dependent variables will be determined by the factors used to define "success" for the program. These variables, along with the independent variables to be used to test each hypothesis, are described in the following sections.

6.2.1 Dependent Measures Development

As noted in the hypotheses, the primary outcomes variable is whether or not the sites achieve NCCCP accomplishments or are "likely to successfully implement" the NCCCP. Development of composite measures to assess "success" and each of these other complex measures will continue during Year 2 of the evaluation in preparation for the final analysis at the end of the fourth year of the evaluation (note: the evaluation is funded for approximately one year beyond the programs in order to allow for time to analyze data). These composite measures or scores will be derived from two primary sources: an assessment of the deliverables that sites provide for each program component, and supplemental assessments that incorporate additional (to be determined) elements of implementing each component. The deliverables for each of the program components are shown in Table 6-1, followed by the deliverables for the overall program in Table 6-2.

Table 6-1. NCCCP Deliverables and Metrics for Each Program Component

Area	Deliverable	Metrics
Clinical Trials	Increase clinical trial accrual, including a specific focus on accrual of underrepresented and disadvantaged patients; accrual to all clinical trials, including treatment, prevention, and behavioral trials with specific focus to increase accrual to multi-modality trials and NCI-sponsored trials; and the capability to offer phase II trials and develop protocols for appropriate referral of patients for phase I trials to NCI-designated Cancer Centers or academic medical research institutes.	Track accrual overall and for underrepresented patients NCI trials, early phase trials, linkages with other NCI, programs (e.g., CCOPs), and referrals to NCI-designated Cancer Centers. Track participation in activities such as: CALGB, ECOG, SWOG, RTOG, NSABP, and GOG.
Health Care Disparities	Demonstrate a documented improvement in health screening activities and outreach to community members, including a specific focus on underrepresented and disadvantaged populations, implementation of a policy that all patients who are screened will be treated with appropriate follow-up care, and linkages with NCI programs (e.g., Community Networks Program, Cancer Information Service).	Track screening activities by disease site (e.g., breast, colon). Confirm adherence to screening and treatment policy. Track linkages.
	Increase partnering with local, state, and national community organizations, both governmental and nongovernmental.	Track the number, type, and goals of partnerships.
	Expand patient navigation.	Track expanded staff and resources for navigation.
Information Technology	Recommend IT infrastructure requirements, necessary interfaces, and applicability of specific components of caBIG for community hospital settings.	Complete individual detailed analysis and report.
	Implement and integrate electronic health records [EHR].	Track implementation of EHRs.
Biospecimens	Recommend the necessary infrastructure requirements, policies and procedures, cost, and other implementation issues for biospecimen collection and storage, required for implementation enabling community hospitals to participate in biospecimen initiatives.	Complete individual detailed analysis and report.
Quality of Care	Increase MDC disease-site-specific committees and clinics.	Track the number and type of MDCs.
	Increase use of evidence-based guidelines, standards, and protocols (e.g., NCCN, ASCO).	Track the number and type of guidelines. Document improved compliance with guidelines
	Participate in a disease-specific quality of care study.	Participate in NCCCP pilot Commission on Cancer quality of care study to measure improvements in breast and colon cancer treatment.
	Expand genetics and molecular testing.	Track components of the genetics program that are offered on site or through referral over time.
		Adopt and implement "conditions of participation."
	Develop a Cancer Center–specific medical staff "conditions of participation" to support the patient care, quality research, and community outreach goals of the Cancer Center.	
Survivorship	Expand survivorship and palliative care programs.	Implement Patient Treatment Summary; track new or expanded survivorship and palliative care programs/activities.

Table 6-2. NCCCP Deliverables for the Overall Program

Additional Program Deliverables	Metrics
A physician program director with cancer expertise with the program under an administrative/medical structure	A position description and CV of physician program director that demonstrates that the physician program director has a broad scope of authority to oversee all aspects of the program and that the director shall dedicate most of his or her time to the cancer program (including patient care responsibilities); a description of his or her time commitment, and an organizational chart showing the reporting relationships and span of authority
Ongoing support and regular meetings for at least four multidisciplinary, organ-site specific planning committees (e.g., lung, head and neck); a colorectal cancer multidisciplinary planning committee may be a priority if one does not exist, since this will be the focus of evaluation during the pilot	Minutes of multidisciplinary meetings, quarterly reports, and final report of process improvements, accomplishments, and issues resolved
Increased use of evidence-based guidelines, standards and protocols (e.g., NCCN, ASCO, USPSTF, ACoS)	Documentation of use of guidelines and reports on improved compliance with guidelines
The development of a Cancer Center–specific medical staff credentialing program to support the patient care, quality research, and community outreach goals of the Cancer Center.	A process for credentialing of medical staff for the Cancer Center shall be approved by the organization and its medical staff and implemented
Expanded patient navigation support	Documentation of expansion of patient navigation program, and how it meets the needs of the patients served by the cancer center; description of the patient navigation staff, including educational background and experience; quarterly progress reports will include an update and report on patient navigation, including the type of staff dedicated to these efforts (e.g., nursing, social work)
Increased outreach infrastructure, expanded programs/linkages for cancer screening and treatment, and evidence of sustainability for outreach programs to address health care disparities	Documentation of increased services, partnerships, and a description of effective methods that led to success; participation in the formal program evaluation

Table 6-2. NCCCP Deliverables for the Overall Program (continued)

Additional Program Deliverables	Metrics
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; implementation of electronic health record [EHR] and tumor registry; participation in the development of a group report with recommendations	Individual and group report to be completed. Implementation of electronic health record and tumor registry.
A detailed report with recommendations on the necessary infrastructure requirements, policies and procedures, cost, and other implementation issues such as collaborations necessary for biospecimen collection and storage, required for implementation enabling community hospitals to participate in biospecimen initiatives that will advance the research agenda of NCI; participation in the development of a group report with recommendations	Individual and group report completed
Linkages with NCI-designated Cancer Centers or academic medical research institutions appropriate to meet the objectives for the NCCCP pilot; exploration of the resources and assistance of the developing Cancer Expert Corps program and/or linkages with expertise at NCI-designated Cancer Centers for more specialized training or access to more specialized services with a special focus on reducing health care disparities	All relevant relationships will be noted and described, including how these relationships assist the NCCCP pilot in the achievement of pilot goals; new or expanded relationships established during the pilot will be included in quarterly progress reports
Demonstration of increased accrual rates to clinical trials, particularly in earlier phase trials, and a detailed report with a description of the methods/programs/strategies utilized to accomplish increased accruals; accruals for NCI trials and minority recruitment will be tracked specifically	Documentation of an increase in accruals to NCI-sponsored clinical trials and for minority recruitment; a report on effective methods that led to success; participation in the formal program evaluation
Genetic and molecular testing on site or through a formal specimen referral to approved labs	A description of the in-house program with the credentials of the staff person or a copy of an affiliation agreement or contract with a description of the service
Increased referrals to hospice	An increased number of referrals based on volume and baseline and an increase in patients receiving hospice program benefits with an increased length of stay in primary hospice receiving program referrals

(continued)

Table 6-2. NCCCP Deliverables for the Overall Program (continued)

Additional Program Deliverables	Metrics
Expansion of palliative care initiatives into the cancer program	A full description of the palliative care plan, program, and staffing
Incorporation or expansion of *survivorship plans* into model-of-care to ensure that an appropriate plan is developed for patients (from initial diagnosis to discharge) and to ensure appropriate follow-up and monitoring for cancer patients	A description of the program integrating survivorship plans and a report on the status of implementation
Results of a quality of care study, such as for colorectal cancer	Full compliance with study and results reported
NCCCP National Network recommendations for incorporation into the future program	Participation in the network development activities over the course of the pilot (see F.2.e.)
For Health Systems	For developmental locations, each location will have achieved all baseline and subcontract deliverables, such as distinct location; provision of a "tool kit" for effective strategies and methods for successful knowledge transfer of cancer program key components; if applicable, transfer of knowledge to rural settings; participation in the formal program evaluation.

A combination of these deliverables (Tables 6-1 and 6-2), along with the outcomes in the conceptual framework (Figure 6-1), will be used to develop a composite score across the sites that defines "successful implementation of the NCCCP." The outcomes specific to the conceptual framework are listed in Table 6-3.

Table 6-3. Evaluation Outcomes from the Conceptual Framework with Corresponding Evaluation Data Elements

Evaluation Outcomes	Evaluation Data Elements
Deliver the most advanced cancer care in local communities (Ultimate Outcome)	▪ Deliverables for each program component are met ▪ Patients report improvements in their care experience
Enable research (Ultimate Outcome)	▪ Pilot sites produce deliverables specific to clinical trials and biospecimens
Increased program-related knowledge and skill (Intermediate Outcome)	▪ Increased adherence to breast and colorectal evidence-based guidelines ▪ Implementation of a physician credentialing program ▪ Administration of patient navigation training programs ▪ Development and implementation of strategies to address disparities ▪ Development of additional partnerships and strategies for working with partners (e.g., patients, community groups, physician groups, state cancer plans, cancer research institutions)
Enhanced infrastructure/capacity (Intermediate Outcome)	▪ Establishment of relationships with key physician groups ▪ Development of staffing to support the NCCCP ▪ Commitment of leadership to the program ▪ Enhanced MDC program ▪ Allocation of adequate resources to the program
Innovation and adoption/assimilation/ implementation process (Short-term Outcomes)	▪ Communication and coordination across the program components ▪ Application of the NCCCP to cancer service line
Routinization (Feedback Loop)	▪ Sites' plan for sustainability ▪ Extent to which the program is affordable for sites to sustain

Data for each variable used to develop the composite score will be compiled into a qualitative comparative analysis matrix to assess the relationships between environmental and organizational characteristics on the "success" of the NCCCP. The following section describes the operationalization of the independent variables to assess with regards to their impact on the overall success of NCCCP implementation, followed by a description of how the overall comparative analysis will be conducted.

6.2.2 Independent Measures Development

As noted in Section 6.1, there are numerous independent variables that need to be operationalized in order to prepare for data coding, preparation, and analysis. Table 6-4 provides operational definitions for each of the independent variables stated in the hypotheses; however, these definitions may be refined and edited in the coming year as we learn more from the programs and add to our data library.

Table 6-4. Operational Definitions for Each Independent Variable from Hypotheses Statements

Independent Variable	Operational Definition
Organizational Level	

Reason or impetus for participating in the NCCCP	Perceived fit with hospital's mission/vision and desire of hospital staff to distinguish themselves regionally and nationally in the cancer care field
Good fit between organization and the nature of the NCCCP	• Perceived advantages relative to current practice (i.e., the NCCCP results in superior cancer care and research) • Compatibility with values, beliefs, and mission/vision • Trialability, or the ability to experiment with the NCCCP on a limited basis rather than an all-or-nothing approach • Complexity, or ease with which sites can understand and use NCCCP activities • 5- Observability, or the extent to which the results are observable to key groups and stakeholders
Commitment from and support of hospital leaders (both managerial and clinical)	Demonstrated support from hospital leaders, including allocation of resources for new equipment/facilities, creation of new staff positions, ensuring visibility of the NCCCP among hospital staff and important decision makers (e.g., boards), presence of key leaders at NCCCP events and/or meetings, and visible support for NCCCP initiatives (e.g., announcements and policies specific to new "participating physician" criteria)
Effective NCCCP teams	• Representativeness of the team of members who should be included • Evidence of division of labor • Functionality of team (e.g., how often they meet, how they are functioning) • 4- Existence of entity to coordinate/integrate all components and activities
Relatively greater profit margins and resources to dedicate to the oncology program	Assessment of hospital's reported profit margin and funding allocated to oncology services and how both change over the period of the pilot
Existence of multidisciplinary teams	Number and types of meetings and team sites assembled, disease sites that are of focus, level of participation from key physicians
Organizational structure	Description of the structure to indicate whether sites operate as a matrix, parallel, or service line, or some other structure
More robust information systems	NCCCP-related departments and practices are connected via IT either through built interfaces or comparable systems; more robust systems would include those that are linked with pathology, operating rooms, and private practices of key oncology physicians
Existence of full-time medical director, NCCCP-capable Cancer Center administrator, and/or "champion"	Percentage of time medical directors (and relevant others) estimates devoting to the NCCCP
Rich communication networks	Number and types of forums for exchanging ideas; information dissemination specific to the NCCCP

(continued)

Table 6-4. Operational Definitions for Each Independent Variable from Hypotheses Statements (continued)

Independent Variable	Operational Definition
Greater portion of employed physicians or stronger participation agreements with private practice physicians	Number of sites implementing participation agreements developed by the Network; indication of whether a site relies on employed physicians primarily or those in private practice
Involvement of key physicians and other departments/staff	Assessment of level of involvement of key physicians and departments
Establishment and celebration of tangible improvements or progress	Number and types of observable improvements specific to the NCCCP
Overall benefits of the NCCCP are perceived as greater than its overall costs	Assessment by hospital leaders of the specific costs and benefits of participating in the NCCCP
System Level	
Centralized health systems	Indication of whether the system is centralized
Full-time medical director at the systems level	Indication of whether a medical director exists at the system level and the percentage of time they spend working on the NCCCP
Patient Level	
Higher level of awareness	Aggregated measure of the awareness level for each type of service among respondents to the patient survey
Higher levels of access to or satisfaction with services	Aggregated measure (within each site) of the levels of access to or satisfaction with services as derived from the responses to the patient survey

6.3 Data Analysis Overview

The overall comparative analysis will include two major steps: (1) the development of composite measures that quantify or categorize the dependent and independent variables, and (2) the analysis of these variables and their relationship to one another through the use of qualitative comparative analysis (Ragin, 1987). The composite measures are under development and will be finalized during the second year of the evaluation. This section describes the process of developing these measures, along with a sample, and provides an overview of how qualitative comparative analysis (QCA) will be conducted to answer each hypothesis.

6.3.1 Development of Composite Measures

For the overall program and for each program component, we propose developing a ranking or score to assess *each site's* level of development at baseline, or during the Year 1 site visits in spring 2008, and how they compare to those rankings during the Year 3 site visits. These scores will be derived from data elements in the deliverables required from each site (Tables 6-1 and 6-2) and the overall evaluation variables (Tables 6-3 and 6-4). For example, we would develop a composite score specific to "clinical trials" that includes all five indicators of success (i.e., number and type of trials, number and characteristics 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. Table 6-5 provides a draft matrix for the baseline year as an example of how these rankings would be used to guide assessment of each site with regards to their improvement in clinical trials research.

Table 6-5. Sample of Variables to Use in Development of a Composite Score for Clinical Trials Work across the NCCCP Sites

	Number Patients Accrued		Number of Active NCI Trials		Types of Trials		Proportion of Minority Patients		Number of Providers Enrolling Patients
Site Name	2006[7]	2009	2006	2009	2006	2009	2006	2009	2009

We would then repeat the ranking process for each site after the Year 3 site visits. In preparation for the qualitative comparative analysis described in the following section, each site will be scored based on the above criteria and assessed for activities or work in each program component and across the overall program, both before and at the end of NCCCP implementation.

6.3.2 Qualitative Comparative Analysis

Over the years, social scientists have been challenged by the ability to conduct statistical analyses when examining issues at macro levels of society. Whether analyzing findings across societies or countries, or across organizations, researchers often do not have a large enough sample to conduct many of the multivariable analyses required to detect significant findings. As the number of observations decreases, the possibility of subjecting hypotheses to rigorous statistical testing diminishes (Ragin, 1987). For the NCCCP evaluation, the unit of analysis for the overarching questions is at the organizational level, where the sample

[7] Timeframes to be determined. Since a full year of work both prior to NCCCP implementation and at the end of the program would be ideal, we will likely use July 2006 to June 2007 as the baseline timeframe and July 2009 to June 2010 as the end point. However, this will be determined by the timeframe for which each variable within a composite score was collected (based on responses in the baseline assessment survey for the program components and in the site visit data for overall program scores).

size is limited to either 10 programs or 16 hospitals—a sample size too small for conducting logistical regression analysis or similar statistical procedures. For this reason, we will follow a process for conducting a systematic comparative illustration across the NCCCP programs in the final analysis for this evaluation. Using principles described by Ragin (1987) that incorporate Boolean algebraic processes into a rigorous analysis of qualitative findings, we will conduct a QCA for each stated hypotheses in this study. Ragin describes case-oriented comparative analysis as "designed to uncover patterns of invariance and constant association" (1987, p. 51). With this approach, "cases" (i.e., for the NCCCP, hospitals or organizations) are examined as a whole: "as a total situation resulting from a combination of conditions, and cases are compared with each other as wholes" (1987, p. 49). This design makes it possible to examine the "conjunctures in time and space" (p. 49) that produce important changes. This approach fits well with the NCCCP evaluation design in that it requires that researchers "suspend assumptions about the equivalences of cases and conditions" (p. 49) and accounts for those variations in the analysis. As Ragin notes, "it is not assumed at the outset of an investigation that all the cases are drawn from roughly the same population or that the meaning of various measurements (including presence/absence [of] variables) are the same from one case to the next. This flexibility, which is the hallmark of the case-oriented approach, enriches the dialogue between ideas and evidence" (p. 49). For this reason, the analysis focuses on the variety of meaningful patterns of causes and effects that exist, as opposed to the relative frequency of the patterns.

Using principles from Boolean algebra, data are entered into "truth tables." The raw data are first converted into nominal-scale variables and represented in binary form (as ones or zeroes). Values for both the independent and dependent variables are then sorted into a truth table so that the patterns and relationships can be closely examined. For example, to test the hypothesis that "CCCs that develop *effective NCCCP teams that can communicate and coordinate* key departments/units/teams through the CCC are more likely to successfully implement the NCCCP," a truth table would be generated and then populated with nominal data to describe each site (see Table 6-6).

Table 6-6. Sample Truth Table for Team Effectiveness in Relation to Successful NCCCP Implementation

Condition				Success[8]	Number of Instances (n=10 mutually exclusive categories)
A	B	C	D		
0	0	0	0	0	1
0	0	0	1	0	2
0	0	1	1	1	0
0	1	1	1	1	0
1	0	0	0	0	0
1	1	1	0	1	1
1	1	0	0	1	0
0	1	0	0	0	0
0	1	1	0	1	0
0	0	1	0	0	1
0	1	0	1	1	0
1	0	0	1	1	0
1	0	1	0	1	0
1	0	1	1	1	1
1	1	0	1	1	1
1	1	1	1	1	3

A= representative of the team of members who should be included
B= evidence of division of labor
C= functionality of team (e.g., how often they meet, how they are functioning)
D= existence of entity to coordinate/integrate all the components and activities

As can be seen in Table 6-6, the "conditions" represent all possible combinations. In this example, since there are four variables for assessing "team effectiveness," there are four possible "conditions" that can exist (2^4= 16). The determination of the value for success in this example would need to be made as to which and how many conditions need to exist in order for the site to be considered "successful" at having an effective team. In this particular example, the data are arrayed to demonstrate this level of success, which would then need to be used to analyze the overall relationship of "effective teams" to the "success" in implementation of the NCCCP.

Ultimately, the change in each composite score from Year 1 to Year 3 would be analyzed to determine characteristics of the sites that seem to impede or facilitate the greatest degrees of

[8] Note that success is calculated in this example as any instance where two or more of the conditions are met. It may be determined that all four (or perhaps three or more) of the conditions of "effective teams" need to be met in order to assess the relationship of this independent variable to "success" of the NCCCP.

change. During Year 2, much work needs to be done to specify all of the included variables and agree upon the conditions that constitute success in each instance.

6.4 Finalizing the Overall Analysis Plan

Since the variables to compare are at the site level, we are limited to analysis across the 10 programs or 16 hospitals, depending on the question under review. Therefore, we will rely on QCA. QCA is designed for data analysis with small sample sizes and is based on Boolean algebra. Because it is not feasible to use traditional quantitative statistical techniques with only a few cases, QCA provides methods for making inferences from these data as long as the analysis maximizes the number of comparisons made across cases. These comparisons (usually comprised of dichotomous variables) can then be simplified into truth tables that illustrate the different combinations of conditions that produce a certain outcome. Since introducing this method, Ragin has expanded this technique beyond binary indicators (i.e., whether or not a case exhibits a certain characteristic). Since there will likely be variables from the NCCCP evaluation that will not be easily converted into dichotomous variables, we plan to use this expanded approach to draw conclusions about the answers to the three overarching questions and hypotheses. We will use an available software package for QCA to conduct the analysis for each of the hypotheses stated in Section 6.1.

While this design report provides a thorough overview of the NCCCP evaluation, there is continuing work to be done to refine and specify the variables to use in the overall analysis. In this section, we have begun to specify what the final analysis will include by presenting a set of hypotheses statements at the environmental, organizational, and patient levels of influence. A primary activity for the coming year of the evaluation is to fully operationalize the "successful implementation of the NCCCP" and develop composite measures that can be assessed over time. This work will involve ongoing input from the stakeholders and experts described in Section 1 of this report. Our hope is to finalize this overall analysis plan within a year so that our key stakeholders agree on the operational definition of each key variable, particularly of the dependent measures, and RTI can ensure that our data coding and preparation incorporates these definitions.

7. DELIVERABLES AND TIMELINES

In the fall of 2009 and 2010, RTI will provide NCI with an overall evaluation report. This report will summarize activities during the year and include separate reports for each study component (i.e., case study, economic study, and patient survey). These reports will be reviewed separately and then incorporated into the final annual evaluation report. RTI will also provide the NCCCP sites with individualized reports of findings from their patient surveys and focus groups. During the final year of the evaluation (by the end of RTI's contract in March 2011), RTI will provide NCI with an overall evaluation report that includes findings from the analysis described in Section 6 and analysis of all the data sources outlined in Table 7-1.

Table 7-1. Timeline for Evaluation Methods and Written Reports of Findings

Evaluation Methods and Data Sources	Y1 (September 2007–September 2008)	Y2 (September 2008–September 2009)	Y3 (September 2009–September 2010	Y4 (September 2010–March 2011)
Programmatic Data				
Site surveys	Baseline	Interim	Final	
Quarterly progress reports	Quarterly	Quarterly	Quarterly	
Network meeting minutes and projects	Monthly	Monthly	Monthly	
Subcontract deliverables			●	
Evaluation Data				
Site visits (i.e., interviews with program staff, key stakeholders)	●	●	●	
Patients focus groups			●	
Patient survey		●	●	
Micro-cost study	●	●	●	
Strategic case interviews		●	●	
Assessment of secondary data (e.g., Commission on Cancer [CoC] annual reports from sites)	●	●	●	
Evaluation Reports				
Final and revised evaluation design report		●	●	
Individual site reports (based on visits)	●			
Individual site reports (based on patient surveys)		●		●
Individual site reports (based on patient focus groups)				●
Micro-cost study reports		●	●	●
Strategic case study report				●
Cross-site reports (based on case study)			●	●
Annual evaluation reports			●	●

● = one data collection point or report

In addition to the deliverables outlined in Table 7-1, RTI will work with NCI to report findings to NCI leadership and advisory boards as needed. This support may include presentations (or help with presentations) as follows:

evaluation design report (fall 2008),
cross-site case study report (fall 2009 and 2010),
patient survey reports (falls of 2009 and 2010), and
micro-cost study reports (falls of 2009 and 2010).

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APPENDIX B: SITE VISIT INTERVIEW DISCUSSION GUIDES

(8 GUIDES ~ AVAILABLE UPON REQUEST)

APPENDIX C: EVALUATION PLANNING MATRIX BY INTERVENTION LEVELS

Table C-1. Network

Key Words	Primary Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
NCCCP linkages (internal)	How well has the "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?	Extent to which sites are collaborating with each other on specific activities	Site visits; subcommittee minutes	Types of collaborations; expectations of collaborations	Changes in collaborations across sites	Site visits; subcommittee meetings; quarterly reports	Types of collaborations; expectations of collaborations
		What did these linkages contribute to NCCCP implementation within each site?	N/A			Specific ways Network impacted how individual sites operate/provide care	Site visits; subcommittee meetings; quarterly reports	Sample projects sites worked on together; staff perceptions of collaborations on their cancer care operations
NCCCP linkages (external)	How well has the "Network" facilitated sites to establish linkages with other NCI cancer research programs (e.g., NCI-designated Cancer Centers, CCOPs)?	What are the relationships of the NCCCP sites to other NCI cancer research programs and which were created as a result of NCCCP?	Description of linkages/ partnerships	BAS/IAS/FAS; quarterly reports; site visits	# and types of linkages with NCI research facilities, barriers and challenges to establishing linkages	Description of linkages/ partnerships; what worked well and less well, and why?	BAS/IAS/FAS; quarterly reports; site visits	Increases in # and types of linkages with NCI CCs and how they change over time; degree to which relationships met NCCCP site expectations

(continued)

Table C-1. Network (continued)

Key Words	Primary Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		What new linkages between sites and other NCI cancer research programs have been created as a result of NCCCP?	Process for initiating linkages	BAS/IAS/ FAS; quarterly reports; site visits	Types of linkages attempted; facilitators and barriers	Proportion of linkages made (to those attempted) with NCI cancer research programs	BAS/IAS/FAS; quarterly reports; site visits	Degree to which linkages met NCCCP site expectations;
Benefits of 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 didn't have prior to NCCCP involvement?	What is the impact of the "Network" and resulting products on the NCCCP sites and their cancer service line?	N/A			Specific ways products have been implemented at each site	Site visits; quarterly reports	# of products applied to each site; staff perceptions of the usefulness of each product; changes made to the cancer service line as a result of specific products
		What did they learn through Network connections that has helped them to improve relationships with MDs, etc.?	N/A			Strategies for working effectively with private practice providers	Site visits	Types of strategies used and those that seem to successful

(continued)

Table C-1. Network (continued)

Key Words	Primary Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		How have products been used (from the Network) at each site and disseminated to other sites (in their system, if applicable)?	N/A			Tracking of how products were disseminated beyond the "lead" NCCCP sites	Site visits; quarterly reports	Dissemination strategies used; NCCCP staff perceptions on how well products were received by other sites
		What is the impact of participation in the NCCCP program on the site's abilities to collaborate with other NCI cancer research programs?	Description of initial linkages attempted	Site visits; subcommittee minutes	Process for initiating linkages; facilitators and barriers	Accomplishments made as a result of linkages with NCI cancer research programs	Site visits; FAS	Lessons learned from linkages; staff perceptions of accomplish-ments made via linkages that NCCCP facilitated
Impact of TA	What is the impact of TA provided by NCI on the sites' ability to reach NCCCP goals and objectives?	What is the nature (e.g., frequency, mechanisms like phone or site visits) of the collaboration between NCI and the pilot sites?	Extent to which a knowledge network is in place	Site visits; subcommittee minutes	Examples of how information is shared; identification of specific strategies used to share information and how it has been used at non-NCCCP sites	Extent to which a knowledge network is in place	Site visits; provision of a "tool kit" for effective strategies and methods of knowledge transfer (RFQ for sites)	Examples of how information is shared; identification of specific strategies used to share information and how it has been used at non-NCCCP sites over time

(continued)

Table C-1. Network (continued)

Key Words	Primary Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		What do sites believe they have gained from direct TA from NCI and each other?	N/A			Specific examples of ways sites have benefitted from both NCI and each other's TA	Site visits	Perceptions of usefulness of TA; examples of how activities with subcommittees have been implemented at each site

Table C-2. Organization

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
Effective Manage-ment	What are the organizational requirements necessary to effectively manage/ implement NCCCP?	What are the key measures of readiness to implement NCCCP at any one site (for replication)?	What is the volume of patients for the NCCCP pilot programs? What is the relationship between volume of cancer patients and various outcomes? Is there a certain volume of cancer patients required to achieve aims of NCCCP pilot?	Describe volume levels	BAS/IAS/ FAS	# of new cancer cases by type; # of cancer cases in hospital and cancer center; # of cancer cases receiving each type of care (medical, radiation, surgery)	Description of any changes in volume, and examine linkages between volume and outcomes	BAS; site visits	Change in volume, association between volume and outcomes
			What are the characteristics of the hospital in which the NCCCP pilot is located (e.g., religious affiliation, size, teaching status) and how do these characteristics facilitate or impede improvement, and achievement of NCCCP objectives?	Describe hospital characteristics and examine initial performance in four areas, and overall	Site visits	Hospital market area; teaching status; religious affiliation; number of years in location; volume of people served; overall strength of the hospital's balance sheet	Examine association between organization type and improvement in four areas, and overall	AHA survey, site visits, out-comes data	Hospital market area; teaching status; religious affiliation; number of years in location; volume of people served

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Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
			How are cancer services organized and managed in the hospital overall? For example, does the hospital have a service line structure, with one person accountable for all aspects of cancer care (across various department lines) and single budget?	Description of cancer service organization	Site visits	Reporting and communication lines allow direct access of NCCCP to hospital leadership and between CC director and NCCCP leadership (e.g., reporting is regularly scheduled, includes annual updates for the hospital/ system board)	Description of cancer service organization; any changes over time	Site visits	Changes in relationship of cancer center to hospital; staff responsible for cancer center reporting to hospital; manage-ment of budget
			How do cancer services fit into the hospital's overall mission/vision and strategy? What is the hospital's long and short term goals with respect to cancer services?	Descriptions of short and long term goals	Site visits; applica-tions; any secondary documents	Role/priority of cancer services in overall hospital/ system strategy; organization of cancer services within hospitals/ systems	Achievement of goals with regard to cancer services	Sites visits	Written mission statements; perceived priority of cancer services

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Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		How are the NCCCP pilot sites managing their programs?		Description of management styles; evidence of realistic short and long term program objectives	Site visits	Program goals and objectives; processes in place to address each program component; evidence objectives are attainable in specified period of time	Evidence of realistic short and long term program objectives	Site visits	Program goals and objectives; processes in place to address each program component; evidence objectives are attainable in specified period of time
		How much time does the physician director, if there is one, dedicate to the NCCCP? What are his/her responsibilities specific to NCCCP? How do both the time commitment and responsibilities change over time?		Description of roles and responsibilities specific to NCCCP	Site visits; Cost Assess-ment Tool (CAT)	Time commitment to NCCCP during initiation; time expected to spend on NCCCP vs. what was actually required; lessons learned	Changes in roles and responsibilities for NCCCP	Site visits; CAT	Job description of NCCCP physician director (for replication); percent time required of director during initiation and implementa-tion

(continued)

Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		What are the roles and responsibilities of the program coordinator at each site? Is this position essential to effective management of NCCC? How should it complement the role of the lead physician?		Description of program coordinator role and relation to physician director	Site visits	Distinction between MD and coordinator role; staff perceptions of usefulness of program coordinator role	Changes in roles and responsibilities for NCCCP	Site visits; CAT	Job description of program coordinator; lessons learned in terms of useful roles for this person to assume
		What is the "location" of the NCCCP program within the hospital's/ system's organizational structure and associated reporting structures? How does this change over time?		Description of programs location in hospital organizational structure and associated reporting relationships	Applications, topline org charts, site visits	Location of NCCCP within hospital structure; reporting relationships of NCCCP staff to hospital	Description of programs location in hospital organizational structure and associated reporting relationships; any changes over time	Site visits	Location of NCCCP within hospital structure; reporting relationships of NCCCP staff to hospital; changes in structure over time

(continued)

Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		What is the impact of the structure on the implementation of NCCCP?	What are the critical roles and functions that seem related to reaching their goals (or lack thereof)?	Descriptions of NCCCP organizational structure	Applica-tions, topline org chart, site visits	# of FTEs; type and number of clinicians involved; type and number of other staff; roles and responsibili-ties of key players	Descriptions of NCCCP organizational structure; any changes over time	Site visits	Changes in FTEs; type and number of clinicians and other staff involved over time; roles and response-bilities and how they change over time
Physician Practice Models	What are the physician practice models through which 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 is the history of hospital-physician relationships? Has the hospital and physicians (cancer specialists, primary care physicians) historically had good working relationships or contentious relationships? Are physicians and the hospital collaborating?	Description of history of hospital-physician relationships	Site visits, some from BAS	Examples of previous working relationship; identification of areas where they collaborate, compete, etc.; perceptions of relationships	N/A		

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Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
			What is the medical staff model for the NCCCP pilot? For example, how many physician groups are involved? What mix of employed, contract, joint venture, or other types of relationships with private practice physicians (e.g., conditions of participation)?	Description of medical staff model	BAS, site visits	# of FTEs; type and number of clinicians involved; roles and responsibili-ties of key players; facilitators and barriers of models	Description of medical staff model; changes over time; medical staff model that supports the program	IAS/FAS, site visits	Changes in FTEs; type and number of clinicians involved over time; roles and responsi-bilities and how they change over time
		What strategies do sites use to effectively engage physicians in the NCCCP program components?		Descriptions of incentives to provide physicians for participation	Site visits	Benefits to physicians for participation; lessons learned in terms of what works well	Process for how sites implemented criteria for participating physicians; assessment of change in physician participation	Site visit; physician participa-tion criteria	Changes in #s of physicians involved in site subcom-mittees, MDCs, etc; lessons learned in terms of what worked well
		What are the necessary skills to effectively manage these relationships?		N/A			Description of management styles and tools used by those who increased physician participation	Site visits; progress reports	Changes in physician participa-tion relative to tools used by sites

(continued)

Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
Infrastructure	What infrastructure has the site developed (i.e., staff, data, program related) in order to implement NCCCP? What lessons did the organizations learn on the infrastructure required to implement NCCCP successfully?	What was the "human and physical capital" in place and how has that changed as a result of NCCCP?		Descriptions of programs and services in place at baseline	Site visits; applications; any secondary documents	Assessment of comprehen-siveness of cancer care; review of capital in place	Changes in human and/or physical capital of benefit to NCCCP activities	Site visits; IAS/FAS; progress reports	Equipment purchased to benefit NCCCP (e.g., new mammo-graphy machine, etc.); lessons learned in terms of required infrastructure; linkages between cancer program and other hospital departments (e.g., pathology, surgery)
		What institutional support for the NCCCP program has been provided by which offices (CEO, Board, etc.) within the hospital or system?	What is the structure and role of NCCCP leadership/ management?	Description of NCCCP leadership roles and management involvement; evidence of support for NCCCP	Applications, BAS, site visits	Hospital executive managements' role, and level of support, and perspectives on its implications for implementa-tion and outcomes	Increased hospital executive management support required to improve cancer care and clinical research	Site visits; topline org chart; quarterly reports	Changes in FTEs; percent time involved and changes over time; roles and responsibilities and how they change over time

(continued)

Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		What has the organization learned from the pilot about their approach to addressing healthcare disparities and if they have improved their ability to track their efforts?		Description of how disparities were addressed prior to NCCCP	Applications; BAS; site visits	Proportion of patients for which race/ethnicity is known; organizational philosophy of addressing disparities; related infrastructure in place	Changes in how disparate care is prioritized within hospital/ cancer service line	Site visits	Collection of race/ ethnicity from patients (and other related measures); assessment of increase of disparate care as a priority for hospital
Plans for Sustainability	What program-related changes are likely to be sustained or institution-alized within the existing sites?	What factors seem to be associated with (i.e., facilitate or impede) the likelihood of institutional-ization (or routinization per framework)?	What are the key measures of "likely to institutionalize" over time?	Description of NCCCP fit with cancer service line activities/ plans underway prior to program initiation	Site visits	Leadership support for NCCCP as a long-term goal; assessment of NCCCP fit with ongoing hospital activities	Plans for sustaining NCCCP activities after program end date	Site visits; CAT; strategic case	Staff hiring for key roles related to NCCCP; increased infrastruct-ure for NCCCP; investments relative to NCCCP (i.e., matching costs); fit of cancer service line within hospital's mission

(continued)

Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
System-level Effects	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 kind of system is each hospital a member of (e.g., local/regional or national, centralized or decentralized, degree of "systemness")? How do the sites within a system interact with each others?	Description of the nature of the system where hospital is housed; communication systems	Applica-tions, BAS, site visits	Relationship of hospital to rest of system and home office; evidence of knowledge networks in place and how info is shared; examples of ways hospitals work together and/or could work together better	Description of the nature of the system where hospital is housed; communication systems	IAS/ FAS, site visits	Relationship of hospital to rest of system and home office; evidence of knowledge networks in place and how info is shared; examples of ways hospitals work together and/or could work together better
		How does the overall system structure impact NCCCP implementation?	What kind of system support is provided for sites in the NCCCP? Does the system provide other kinds of financial and non-financial resources to support the NCCCP pilot?	Description of system support	Applica-tions, BAS, site visits	Resources (e.g., QI, IT) provided by system for cancer services; system-level staff (i.e., physician director) dedicated to cancer care	Description of system support	IAS/ FAS, site visits	Changes in resources (e.g., QI, IT) provided by system for cancer services; system-level staff (i.e., physician director) dedicated to cancer care

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Table C-2. Organization (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
			What is the evidence of system-wide knowledge transfer (i.e., to what extent do they replicate NCCCP within the system)? Are system-affiliated hospitals able to accelerate the pace of improvement and/or are they more likely to achieve the NCCCP pilot program?	Extent to which a knowledge network is in place	Site visits	Examples of how information is shared; identification of specific strategies used to share information and how it has been used at non-NCCCP sites	Extent to which a knowledge network is in place	Site visits	Examples of how information is shared; identification of specific strategies used to share information and how it has been used at non-NCCCP sites over time

Table C-3. Program

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
Cancer Service Line	How has the NCCCP helped the 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 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 uninsured?	Availability of care at the cancer center; identify-cation of gaps in services	BAS, site visits	Types of services provided; services where referrals are required; assessment of types of services available across cancer continuum	Availability of care at the cancer center and patient knowledge of the availability of care; identification of gaps in services	Site visits; IAS/FAS; patient survey and focus groups	Changes in scope and use of care/ services provided during pilot study and extent to which related to NCCCP efforts (and not what they would have otherwise done); patient awareness of available services
		How does NCCCP facilitate development of a "seamless delivery system" to the patient?		Description of site-s built structure and how well patients should be able to locate services	Site visits (via tours)	Types of services available to patients; assessment of how well these services can be located and how well patients could navigate the built environment	Ease with which patients are able to locate services	Site visits; patient survey and focus groups	Assessment of site's coordination of care and how patients are able to find their way to needed services; patient perceptions of care coordination (Survey, Section B)

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Table C-3. Program (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
Value Added	What is the "value added" of the NCCCP to the cancer services provided?	For CCOP sites, what does NCCCP add to what they are already doing?	Does being a CCOP site make it "easier" to address barriers and implement NCCCP?	Description of staff's under-standing of NCCCP and how it differs from NCCCP	Site visits	Extent to which key staff understand what NCCCP adds to CCOP sites; clarify of NCCCP mission among CCOP and non-CCOP sites	Variation in how CCOP sites are able to achieve key outcomes relative to other sites	Site visits; IAS/FAS; patient survey and focus groups	Access to CTs among CCOP vs. non-CCOP sites; extent to which both types of sites are able to implement other program components; staff perceptions of what CCOP added to their NCCCP implementation
		What are sites doing as a result of NCCCP that they would not otherwise be doing? How is their "baseline" of activities related to their ultimate accomplishments?		Description of cancer service line activities at baseline	Applica-tions; BAS; site visits	Perceptions of how NCCCP adds to/ complements ongoing cancer work	Assessment of site achievements relative to their plans prior to NCCCP	Applica-tions; site visits	Perception among staff of work they accomplished as a direct result of NCCCP; plans written in applications compared to what they implemented

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Table C-3. Program (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
Economic Indicators	What financial commitments do sites need to make to implement NCCCP relative to key outcomes (e.g., patients accrued to clinical trials)? Do sites believe NCCCP is a worthwhile investment in advancing their cancer service line?	What are the incremental costs of NCCCP?	What are the direct costs of implementing and operating NCCCP OVERALL and the requirements needed to sustain existing sites?	Total costs for all of NCCCP related activities during Year 1	CAT; internal financial documents	Cost of NCCCP overall during start-up (i.e., labor costs, supplies, equipment, consulting or contract costs associated with the four core funded areas)	Total costs of all of NCCCP related activities/year	CAT	Cost of NCCCP overall by year; total activity-based costs and costs per FTE; index-adjusted for social wages
			What are the costs of operating each program component (i.e., CT, disparities, biospecimen, IT)?	Total costs (direct and indirect) by program component during Year 1	CAT; internal financial documents	Cost per major program component during start-up (Year 1)	Total costs by program component/year	CAT	Cost per major program component by year

(continued)

Table C-3. Program (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
			What are the indirect institutional costs associated with operation of NCCCP?	Total costs by program component/year	CAT; internal accounting records (and/or Medicare cost reports)	Allocated fixed costs, including rent, facility support, personnel & admin support	Total costs by program component/ year	CAT; internal accounting records (and/or Medicare cost reports)	Allocated fixed costs, including rent, facility support, personnel & admin support
			What are the costs associated with physician and other in-kind time spent on NCCCP program activities?	Proportion of time spent on NCCCP activities/ year	Site visits	Estimated hours or % effort by type of physician, converted to standard dollars using standardized national income stats	Proportion of time spent on NCCCP activities/year	Site visits; CAT	Estimated hours or % effort by type of physician, converted to standard dollars using standardized national income stats
		What is the "strategic case" for involvement in NCCCP?	How profitable or unprofitable is the provision of cancer services for the hospital?	Description of profitability or losses attributable to the provision of cancer care	Site visits, any secondary documents	Staff perceptions of whether cancer is profitable; rationale for cancer focus	Description of profitability or losses attributable to the provision of cancer care; extent to which NCCCP is perceived to be worth the costs	Strategic case study	Profitability (or not) of cancer service line; staff perceived NCCCP impact on profitability; outcomes of interest relative to costs

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Table C-3. Program (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
			What financial resources does the hospital have to invest in achieving NCCCP Pilot goals? What is the financial status of the hospital? What are the hospitals margins and how stable is the hospital financially?	Description of hospitals financial status	BAS, financial reports	$ profit prior to NCCCP; hospital margins and financial stability; $ profit specific to cancer care	Description of hospitals financial status	CAT; IAS/FAS; strategic case study	$ profit prior to NCCCP; hospital margins and financial stability; $ profit specific to cancer care

Table C-4. Patient

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
Population Served	How does the population of patients served by the sites change during the time that they are a NCCCP pilot site?	How well are sites able to identify their minority patients?		Extent to which sites can report race/ethnicity data	BAS	# of patients by race/ ethnicity	Extent to which sites can report race/ethnicity data	IAS/FAS	Improved tracking of patient race/ ethnicity
		Are sites able to increase the proportion of minority/ disparate patients served?		N/A			Changes in patients served by race/ethnicity (other disparate measures)	IAS/FAS	Increase in patients served by specific groupings
		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)?		N/A			Assessment of organizational support, structures to increase access of disparate groups to comprehensive care	Site visits; patient survey	Evidence of support for increasing care to disparate groups (i.e., more services to improve access, programmatic efforts to identify and track patients through care)

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Table C-4. Patient (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
Health Disparities	In what ways do the sites reduce cancer health disparities (specific to screening only or across the continuum)? Are there differences in how patient subgroups (racial/ethnic minorities, low-income, uninsured) are provided treatment or access clinical research (i.e., CT accrual) when compared to those who are insured?	How do patient navigation services help to address cancer disparities at each site?	Are there differences in how patient subgroups are provided treatment or access clinical research when compared to those who are insured?	N/A			Access to patient navigation services for patient groups	Patient survey and focus groups	Patient awareness of patient navigation (PN) services; patient perceptions of usefulness of PN care
		How does access to care across the continuum differ for patient groups (e.g., CT accrual, MDC care, screening, survivorship services)?		Availability of services at baseline	BAS; limited info from Y1 site visits	Types of services provided; # of patients accessing in 2006	Access to all cancer services for patient groups	Patient survey and focus groups; IAS/FAS	Patient awareness of available services; reported counts of patients accessing each type of care; types of available services
		How has the organization increased its effort in outreach to the underserved in its community?	Do sites offer a broader range of services at the end of the pilot (e.g., more survivor services, navigation)?	Description of outreach services at baseline	BAS; limited info from Y1 site visits	Types of community partners; screening provided at baseline	Changes in outreach services provided in community	IAS/FAS; site visits; quarterly reports	# of screening events; # of cancer screenings provided/year; # of patients screened (by race/ethnicity)

(continued)

Table C-4. Patient (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
Patient Experience	What are patient's reports of the quality of care they receive, including satisfaction with multi-disciplinary care team care and communication; emotional support; financial assistance; timely access to appointments, referrals; waiting times; and overall satisfaction with care?			N/A			Patients overall impression of the quality of their care	Patient survey and focus groups	Patient's evaluation of their care (Section G of survey); feedback from patients on overall quality of care
		How well do patients believe their care is coordinated?		Patient reports of communication of care	Patient survey and focus groups	Baseline items on patient survey to assess extent to which patients feel site communicated effectively (Section D of survey)	Improvements in patient reports of communication of care	Patient survey and focus groups	Repeated items on patient survey to assess extent to which patients feel site communicated effectively (Section D of survey)

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Table C-4. Patient (continued)

Key Words	Primary Evaluation Questions	Secondary Evaluation Questions	Tertiary Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		To what extent have sites established services for patients to facilitate access to care (e.g., financial, transportation, child care)?		Description of services available to address access	BAS; limited info from Y1 site visits	Assessment on extent to which services are available to address access issues	Changes in available services to address access	Site visits; FAS	Assessment on extent to which services are available to address access issues

APPENDIX D: EVALUATION PLANNING MATRIX BY PROGRAM COMPONENTS

Table D-1. Biospecimens

Overarching Evaluation Questions Specific to Biospecimens	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
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?	What aspects of NCI's best practices are sites able to implement?	N/A			Assessment of the feasibility of implementing specific best practices	Final report from sites on recommendations of the necessary infrastructure requirements	Specific aspects of best practices that seem feasible to implement at community hospitals
	What organizational activities and support seem related to changes made in their biospecimen work?	Description of challenges with implementing possible biospecimen changes	Site visits	Staff perceptions of organizational support and barriers to biospecimen changes	Ease with which sites were able to implement (or not) best practices	Economic study; site visits; biospecimen gap analysis	Lessons learned in terms of implementing biospecimen collection and reporting (per best practice) in community-based hospital settings

Table D-2. Clinical Trials

Overarching Evaluation Questions Specific to Clinical Trials (CT)	Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
What organizational factors are related to increased implementation of more and different types of CTs?	What is the level of organizational support for increasing CTs? And implementing earlier phase trials?		Description of organizational support in increasing CT accrual	Site visits	Facilitators and barriers (e.g., administrative, financial) to begin earlier phase CTs and increasing CT accrual	Change in organizational support over time	Site visits; final report	Facilitators and barriers (e.g., administrative, financial) to begin earlier phase CTs and increasing CT accrual
	What is the infrastructure necessary to increase CT participation across the sites?	Are CCOP sites better able to increase the number and type of CTs implemented than non-CCOP sites?	Description of infrastructure in place to facilitate CT conduct	BAS	Structures in place in support of CTs; equipment/ supplies, etc.	Changes in infrastructure support over time	Site visits	Increased structures in place in support of CTs
			Capacity and availability of sites to offer clinical trials	Quarterly reports; site visits; monthly subcommittee reports	Number and type of clinical trials offered	Increased capability to offer Phase II trials (RFQ for sites)	Quarterly reports; site visits; monthly subcom-mittee reports: final reports	# of days/weeks from start of CT until enrollment of first patient; # of patients/race enrolled by time from initiation

(continued)

Table D-2. Clinical Trials (continued)

Overarching Evaluation Questions Specific to Clinical Trials (CT)	Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	What is the level of support among key physicians in increasing CT accrual?	What factors seem to be related to whether a physician increases CT accrual among his/her patients? Among minority patients?	Community-based clinical researchers/ physicians' knowledge, attitudes, and practice (KAP) of cancer CT research; patient knowledge of CTs	Patient survey; site visits	# physicians trained in CT practices; patient barriers to CT participation	Increase in community-based clinical researchers/ physicians' KAP of cancer CT research; increase in patient knowledge of CTs	Patient survey; site visits	# physicians trained in CT practices; patient barriers to CT participation
	What type of CTs is each site involved in implementing and how does this change over time? *(In RFQ for sites, stated goals are to "increase enrollment in CTs by community hospital-based cancer centers" and to "increase enrollment in CTs of minority population" (p. 5)*		Description of trials involved in during the first year	RFA applica-tion; site visits; quarterly progress reports	Number and type of clinical trials offered	Evidence of an increase in treatment, prevention, behavioral trials with specific focus on multi-modality trials and NCI-sponsored trials (RFQ for sites)	RFA applica-tion; site visits; quarterly progress reports; final report from sites; SAR	Facilitators and barriers (e.g., administrative, financial, medical care model) to begin earlier phase CTs and increasing CT accrual; change in number and types of clinical trials implemented over time by type and funding source

(continued)

Table D-2. Clinical Trials (continued)

Overarching Evaluation Questions Specific to Clinical Trials (CT)	Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	What are the demographic characteristics of patients enrolled in CTs and how does that change over time?		Description of enrolled patients	RFA application; site visits; quarterly progress reports	Number of people/race and ethnicity enrolled in Phase I, II, and III CTs; number of people/age enrolled in Phase I, II, and III CTs (RFQ for eval)	Increase in number of people/race and ethnicity enrolled in Phase I, II, and III CTs; increase in number of people/age enrolled in Phase I, II, and III CTs (RFQ for eval)	RFA applica-tion; site visits; quarterly progress reports; final progress reports from sites; patient survey	Number of people/race and ethnicity enrolled in Phase I, II, and III CTs; number of people/age enrolled in Phase I, II, and III CTs (RFQ for eval)
	What is the history of CT research at each site? What processes do site follow that seem to be related to how well they increase CT research (i.e., more trials, more patients, and/or more physicians involved)?	What process do sites go through to initiate a new CT? Which processes seem to lead to a more efficient initiation? How does this change over time?	Description of initiation process; decision-making process for determine which trials to start	BAS; site visits	Facilitators and barriers to initiation of any trial; period of time to start of enrollment	Changes in processes over time	FAS; site visits	Facilitators and barriers to initiation of any trial; period of time to start of enrollment

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Table D-2. Clinical Trials (continued)

Overarching Evaluation Questions Specific to Clinical Trials (CT)	Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
		What is the history of each site in CT implementa-tion? How does history seem to impact their ability to implement CTs?	Experience of key staff in implementation of Phase I, II, and III CTs	RFA applica-tion; site visits	# of years and types of CTs implemented prior to award (# of years as a CCOP or MB-CCOP if applicable)	N/A		
		What process do sites go through to try and increase earlier phase CTs? A. What factors seem to be related to whether a site can begin earlier phase trials? B. What factors seem to be related to whether sites can implement virtual Phase I sites?	Development of protocols for appropriate referral of patients for Phase I trials to NCI-CCs (RFQs for sites)	Quarterly reports; site visits; monthly subcom-mittee reports: final reports	# of patients referred; # of patients accepted into CT	Appropriate referrals of patients for Phase I CTs	Quarterly reports; site visits; monthly subcom-mittee reports: final reports	# of patients referred; # of patients accepted into CT

Table D-3. Disparities

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
To what extent do sites enhance access, awareness, communication, and use of services (e.g., CTs, continuum of cancer care) for identified disparate populations?	What priority population is proposed to be reached by each site?	Description of populations being prioritized	Applica-tions; BAS; site visits; quarterly reports; monthly subcom-mittee reports	Race/ethnicity; geographic location (e.g.,rural vs. urban); insurance status (i.e., insured vs. uninsured vs. underinsured)	Description of changes in priority populations proposed to be reached over time	Site visits; site-specific quarterly reports; monthly subcommittee reports	Age, race/ethnicity, income, geographic location (i.e., rural vs. urban), insurance status (i.e., insured vs. uninsured vs. underinsured)
		Description of local population (e.g., % of minority population) and region (e.g., poverty rates, uninsured)	Applica-tions; Census data	Race/ethnicity; region; poverty rates; insurance status	Description of changes in local population (e.g., % of minority population) and region (e.g., poverty rates, uninsured)	Census data	Race/ethnicity; region; poverty rates; insurance status
	What is the system of care to reach disparate populations (e.g., clinics in rural settings, MDs working outside hospital)?	Description of proposed or current systems of care in reaching disparate popns	Site visits	Types of systems of care and # minority patients screened from each	Most effective care models in reaching disparate populations; increase in screening rates among disparate groups through these systems of care	Site visits	Types of systems of care and # minority patients screened through each

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Table D-3. Disparities (continued)

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	What types of Patient Navigation (PN) programs are available at each site? What is the purpose of each activity related to cancer?	Description of patient support services provided and what influenced site to provide those types of patient navigation programs	BAS; patient survey; site visits; patient focus groups	Type and purpose of PN service (e.g.,transportation provided; on-site navigator to meet patient at appointment)	Description of factors influencing types of PN services offered over time (e.g.,change in priority population; increase in screening rates; staff turnover)	Patient survey; site visits; patient focus groups	Type of PN services provided over time (e.g.,transportation provided; on-site navigator to meet patient at appointment), impact of PN services on perceived continuity of care
		Accessibility of navigator services to patients	BAS; site visits	Ease with which referrals for navigation are made; diversity of patients served by program; staff perceptions of program accessibility	Accessibility of navigator services to patients	Site visits; patient survey; focus groups	Ease with which referrals for navigation are made; diversity of patients served by program; staff and patient perceptions of program accessibility

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Table D-3. Disparities (continued)

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	To what extent have sites established services for patients to facilitate access to care (e.g., financial assistance, transportation assistance, child care)?	Establishment of services to facilitate access to care	BAS, site visit, document review, progress reports	Scope and quality of services to facilitate access to care	Provision of services to facilitate access to care	BAS, site visit (including tours), document review, progress reports	Scope and quality of services to facilitate access to care; ease with which it appears that patients can find and access services
	To what extent are patients aware of the services available to them?	Reported awareness of available services	Patient survey and focus groups	Overall awareness of services	Reported awareness of available services	Patient survey and focus groups	Increased proportion of patients in identified disparate groups (e.g., by race/ethnicity, age) reporting awareness and usage of specific cancer services
	How well do patients feel providers have communicated with them about their care and available services?	Reported satisfaction with provider communication	Patient survey and focus groups	Overall satisfaction with communication of services	Reported satisfaction with provider communication	Patient survey and focus groups	Changes in satisfaction of communication (disparate populations compared to other patient groups)

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Table D-3. Disparities (continued)

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	How has patient use of services changed during the pilot?	Proportion of patients using available services (e.g., CT, MDCs, PN, education services)	BAS/IAS/ FAS	Counts of patients using each services	Changes in proportion of patients using services	BAS/IAS/FAS	Lessons learned on strategies that seem to yield the best results in increasing services to disparate populations
What strategies do sites use to outreach to disparate populations in their region? What are the characteristics (e.g., partner involvement, approach used) of the strategies that seem to work best (e.g., greatest increases in screening activities)?	What partners do sites develop relationships with in order to increase outreach and screening? What are the lessons learned with regard to these partnerships?	Description of facilitators or factors that have helped make this partnership a success in increasing minority screening rates; description of barriers that have hindered this partnership in increasing minority screening rates	Site visits	Descriptive data of partnership facilitators and barriers	Description of facilitators or factors that have helped make this partnership a success in increasing minority screening rates; description of barriers that have hindered this partnership in increasing minority screening rates; description of what could have been done differently to make this partnership more successful (i.e., areas for improvement)	Site visits	Descriptive data of partnership facilitators and barriers

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Table D-3. Disparities (continued)

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	What is the level of commitment of the cancer center to community outreach?	Description of the staffing and resources available for outreach efforts	BAS; site visits	# of staff working in outreach; funding set aside for outreach efforts; perception among staff of importance of outreach	Description of the staffing and resources available for outreach efforts		# of staff working in outreach; funding set aside for outreach efforts; perception among staff of importance of outreach
	What community outreach methods have sites implemented?	Description of proposed community outreach methods to be implemented and description of actual community outreach methods implemented	Applica-tions; quarterly reports; monthly subcom-mittee reports; site visits	Types of pub ed and outreach methods proposed and implemented	Description of changes in community outreach methods implemented over time	Applications; quarterly reports; monthly subcommittee reports; site visits	Changes in types of pub ed and outreach methods proposed and implemented over time

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Table D-3. Disparities (continued)

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	How successful are sites in improving health screening activities among disparate groups? *(In RFQ to sites, a stated purpose is to "develop additional programs to increase outreach to the underinsured and uninsured for screening AND TREATMENT" [p.5])*	Increase in number of prevention and screening programs and other early detection activities	Site visits; quarterly reports; monthly subcom-mittee reports	Number of prevention and screening programs and other early detection activities for disparate populations	Increase in number of prevention and screening programs and other early detection activities	Report required across sites (a joint report) that is a collection of successful approaches to improve outreach and address disparities; site visits; quarterly reports; monthly subcommittee reports; final reports from sites	Change in number of prevention and screening programs and other early detection activities for disparate populations over time

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Table D-3. Disparities (continued)

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	What community outreach methods seem most effective in recruiting disparate populations targeted for each screening program? For the CTs? For the patient navigation?	Site perceptions of the effectiveness of each community outreach method in recruiting the priority population for screening	Site visits; quarterly progress reports	Number of participants screened by community outreach efforts	Site and participant perceptions of the effectiveness of each community outreach method in recruiting the priority population for screening, etc.	Site visits; quarterly progress reports	Number of participants screened by community outreach efforts over time
		Patients report of how they found out about services	Patient survey and focus groups	Types of methods reported by patients (e.g.,waiting room flyer, brochure; word-of-mouth; physician/nurse; health fair; faith-based org)	Proportion of each community outreach methods reaching participants screened; participant knowledge of program	Site visits; quarterly progress reports; patient survey and focus groups	Change in types of methods used to reach disparate groups over time; number of participants screened by community outreach efforts over time

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Table D-3. Disparities (continued)

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
What are the organizational characteristics of sites that are best able to increase the proportion of patients in identified disparate groups for each service provided (e.g., screening, CTs, patient navigation, MDCs)?	What is the demonstrated commitment to the underserved? How is this changing over time? What are sites doing to ensure "All who are screened for cancer receive treatment for cancer"? How does that change over time?	Description of outreach activities for, services offered to, and funding provided for the underserved	Site visits; site-specific quarterly reports	Funding source; date of activity; # of underserved attending activity; # of underserved participating in service	Description of outreach activities and services offered to the underserved	Site visits; site-specific quarterly reports; final reports from sites	Funding source; date of activity; # of underserved attending activity; # of underserved participating in service
	Who are the partners to the cancer center? How does this change over time?	Description of the partner organizations and the priority populations they represent	Applica-tions; BAS; quarterly progress reports; site visits	Descriptive data about the partner organizations and their priority populations; # with MOU	Description of the partner organizations and changes in the priority populations they represent over time	Applications; quarterly progress reports; site visits	Change in number and types of partners; # of MOUs/formal agreements established

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Table D-3. Disparities (continued)

Overarching Evaluation Questions Specific to Disparities	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	What is the organizational structure and staffing and how does this impact the site's ability to reach underserved populations? What are the site's barriers and facilitators?	Description of site's organizational structure, leadership support, and staffing that seems to influence how well they can increase service to underserved populations	Site visits	Descriptive data about the partner organizations and their priority populations; infrastructure for addressing disparities; involvement of advocacy groups and/or survivors	Description of site's organizational structure, leadership support, and staffing that seems to influence how well they can increase service to underserved populations	Site visits	Key features of organizational structure and support, and partnerships, that seems to lead to enhanced services for disparate groups

Table D-4. Information Technology

Overarching Evaluation Question Specific to Information Technology (IT)	Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
What factors influence the extent to which sites choose to or are able to implement (either in part or in whole) of caBIG?	To what extent are sites able to implement caBIG?	What organizational activities and support seem related to changes made in their IT infrastructure?	Description of challenges with implementing possible caBIG-related changes	Site visits	Staff perceptions of organizational support and barriers to IT changes	Ease with which sites were able to implement (or not) caBIG	Final/joint report with recommendations on IT infrastruc-ture require-ments (RFQ for sites)	Increased knowledge of infrastructure requirements, necessary interfaces, and applicability of specific components of the caBIG (p. 10 of 31)
		What aspects of caBIG do sites choose to and able to implement?	N/A			Assessment of utility of caBIG components with similar community- based hospitals	Site visits	Lessons learned in terms of aspects of caBIG that may or may not be applicable to community-based hospital settings

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Table D-4. Information Technology (continued)

Overarching Evaluation Question specific to Information Technology (IT)	Evaluation Questions	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
What is the status of EMR 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?	To what extent, and how, are NCCCP pilot programs incorporating electronic medical records (EMRs) and other information technology in order to achieve program aims?		Description of EMR capability, plans for improving	Applications, BAS, site visits	Type of system in place; purchases and upgrades made; plans for EMR development/ enhancement	Assessment of progress made with EMR implementa-tion through baseline and subsequent site surveys	Site visits	Facilitators of EMR implementa-tion among hospital staff and physicians and specific benefits to the program by the use of EMRs

Table D-5. Quality of Care

Overarching Evaluation Question Specific to Quality of Care (QOC)	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
To what extent do sites increase multidisciplinary care (MDC) for their patients?	To what extent have sites established MDC teams to ensure coordination and continuity of cancer treatment? Do team members have clearly defined roles and responsibilities, including who will communicate with the results/issues with the patient?	Descriptions of multidisciplinary team structures, processes, and management	BAS, site visit, progress reports	# of committees; committee functioning; types of disciplines represented on each; *could use integration measures from Slovik*	Established at least 4 MDC, organ-site specific planning committees (RFQ to sites p. 10)	BAS/IAS/FAS; site visits; progress reports	# of committees; committee functioning; types of disciplines represented on each; *could use integration measures from Slovik*
	To what extent are patients accessing MDC and navigating the Cancer Center's system seamlessly?	Provision of care by MDC teams	BAS, site visit, patient focus groups, utilization data?	% of cases in which care provided by MDC team	Improved coordination and continuity of cancer treatment from increased use of MDC team (p. 10 of 31 of RFQ for eval)		% of cases in which care provided by MDC team; decreases in time from one point of care to the next
	What is the site's process for increasing MDC? What seems to work well?	Descriptions of MDC teams in place at baseline	Site visits	Planned changes in MDC care	Description of processes used to include MDC	Site visits; progress reports	Lessons learned in changing MDC; barriers and facilitators

(continued)

Table D-5. Quality of Care (continued)

Overarching Evaluation Question specific to Quality of Care (QOC)	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element

Overarching Evaluation Question specific to Quality of Care (QOC)	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
How is patient centeredness of care increased across sites?	What are patients perceptions of how centered their care is at the site?	Perceived patient centeredness of care	Patient survey and focus groups; site visits	Reported satisfaction with care; observed aspects of patient centered care (e.g., location of services at site visits)	Changes in perceived patient centeredness of care	Patient survey and focus groups; site visits	Changes in reported satisfaction and observed care at sites; increased perceptions among patients about communication among physicians involved in their care
	To what extent have the sites used telemedicine to improve research, clinical care, or access? What have they addressed through telemedicine?	Telemedicine infrastructure and policies for telemedicine utilization	BAS, site visit, document review, progress reports, patient focus groups	# of telemedicine uses; ways telemedicine is used; examples of situations in which it was used well; topics discussed during sessions	Telemedicine infrastructure and policies for telemedicine utilization	BAS, site visit, document review, progress reports, patient focus groups	# of telemedicine uses; ways telemedicine is used; examples of situations in which it was used well; topics discussed during sessions
How does quality of care (for key quality indicators) change at NCCCP sites when compared to other, similar hospitals?	*Under development (will be addressed by comparative analysis if that is added to the evaluation plan)*						

Table D-6. Survivorship

Overarching Evaluation Question specific to Survivorship	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
How comprehensive is survivorship care by the end of the pilot (e.g., support services, health promotion)?	What health promotion/education programs are available to patients during treatment, and how does that change over time?	Description of programs available to patients, family, friends	BAS/IAS/FAS	Types of programs available; to whom; # of people attending programs/ year	Changes in programs available to patients/ families/ friends over time; increases in # of people attending programs/year	Site visits	Types of programs available; to whom; # of people attending programs/ year
	What patient education is provided to patients during treatment, and how does that change over time? *(Demonstrated improvement in patient education provided from RFQ for eval)*	Assessment of availability of primary prevention programs/ materials	Educational materials; BAS/IAS/FAS	Types of materials available; # and types of languages materials are provided	Increases in types and #s of materials offered to patients	Educational materials; BAS/IAS/FAS	Types of materials available; # and types of languages materials are provided
		Assessment of availability of secondary prevention programs/ materials	Educational materials; BAS/IAS/FAS	Types of materials available; # and types of languages materials are provided	Increases in types and #s of materials offered to patients	Educational materials; BAS/IAS/FAS	Types of materials available; # and types of languages materials are provided
		Assessment of availability of patient education for diagnosis and treatment	Educational materials; BAS/IAS/FAS	Types of materials available; # and types of languages materials are provided	Increases in appropriate languages in which materials are provided	Educational materials; BAS/IAS/FAS	Types of materials available; # and types of languages materials are provided

(continued)

Table D-6. Survivorship (continued)

Overarching Evaluation Question specific to Survivorship	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element

What psychosocial services are provided to patients and how does that change over time?	Evidence patients are assessed for psychosocial services	BAS/IAS/FAS; site visits	Type of assessment done, # of patients assessed	Increases in the proportion of patients assessed		Type of assessment done, # of patients assessed
	Access of patients to qualified mental health professionals	BAS/IAS/FAS; site visits	Number and type of MH profession-als on staff; process for patients to access care	Improved access of patients to qualified MH professionals	BAS/IAS/FAS; site visits	Changes in # and type of MH professionals on staff; process for patients to access care, turnover of staff
What palliative care services are available to patients?	Access of patients to appropriate palliative care	Patient survey; BAS/IAS/FAS; Education materials available to patients	Availability of specific program; # of patients served	Expansion of palliative care initiatives	Patient survey; education materials available to patients	Availability of specific program; # of patients served
To what extent are hospice services available to patients?	Evidence of appropriate referrals to hospice	BAS/IAS/FAS; site visits	# of referrals to hospice; perceptions of whether hospice is used as needed by patients	Increases in appropriate referrals to hospice	Site visits	# of referrals to hospice; perceptions of whether hospice is used as needed by patients

(continued)

Table D-6. Survivorship (continued)

Overarching Evaluation Question specific to Survivorship	Supplemental Evaluation Questions	Short-term Outcomes (<1 year)	Data Source	Data Element	Intermediate Outcomes (1-3 years)	Data Source	Data Element
	What cancer survivorship programs (i.e., wellness or follow-up clinic for patients who have completed treatment) are available to patients?	Extent to which comprehensive care is available to patients after completion of treatment	BAS/IAS/FAS	Types and #s of programs available to patients; accessi-bility of services to patients	Changes in services/activities provided over time	Site visits	Increases in # of patients attending; increased # of offered programs
	How aware are patients of the services available to them?	Awareness level among patients for specific services	Patient survey and focus groups	Reported awareness levels and use of services	Changes in awareness level among patients for specific services	Patient survey and focus groups	Enhanced awareness and use of post-treatment services among survivors
To what extent do sites provide treatment summaries and follow-up care plans to all patients?		Extent to which sites provide written treatment summaries to patients	BAS/IAS/FAS; sample treatment summaries from sites	# of patients with treatment summaries and frequency they are provided to patients as hard copies	Increases in proportion of patients who receive written treatment summaries to patients	Site visits	Increased proportion of patients receiving treatment summaries and follow-up care plans post treatment

APPENDIX E: PLANNING CALL DISCUSSION GUIDE FOR CASE STUDY SITE VISITS

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I. PURPOSE & SIGNIFICANCE OF THE NCCCP EVALUATION

- The National Cancer Institute (NCI), Science Applications International Corporation-Frederick (SAIC-F), and RTI International (RTI) are all partners involved in the implementation of the NCI Community Cancer Centers Program (NCCCP) pilot and evaluation. While NCI is involved in both the program and evaluation implementation, RTI is conducting the evaluation, and SAIC-F is managing the implementation of the program.
- The purpose of the evaluation is to support a process and impact assessment of the implementation, operations, and performance of the NCCCP pilot sites that are hospital-based cancer programs. The process assessment will evaluate the implementation experience of the specific NCCCP pilot sites, and, through, individual site assessments and comparative research, assess the feasibility, best practices, relationship to NCI-designated Cancer Centers, and other community resources and replicability potential of the NCCCP model (and its program components) to support cancer research and improved cancer care delivery.
- As the evaluation is being designed in collaboration with NCI, RTI must remain objective about the NCCCP in order to ensure validity to the evaluation results. The more RTI is able to maintain independence from the program development and implementation decisions, the more they can objectively measure the process and impact outcomes of the NCCCP and thus improve program decision making. Nonetheless, **the complexity of the program requires collaboration such that key stakeholders in the program are helping to guide the measures to include in the evaluation plan.** Therefore, throughout the evaluation development and implementation, it will be important for RTI to remain separate from the program implementation of NCCCP but informed by the expertise of relevant program staff and partners engaged in that aspect of development.

II. BACKGROUND & PURPOSE OF THE CASE STUDY VISIT

- As the independent evaluation contractor, RTI will design and implement three specific studies as part of the overall evaluation for the NCCCP: a case study, cost study, and a patient survey to be administered as a pre- and post- measure of experiences with the program.
- The case study component of the project involves a visit (i.e., site visit) to all 14 pilot sites. The purposes of the case study visits are as follows:
    - **Enhance our understanding of how the sites have interpreted NCCCP and applied it to their site;**
    - **Describe each site's overall approach to**
        - key aspects of program development, including coordination across departments and units, integration of NCCCP objectives into cancer center strategic planning and hospital operations;
        - capacity building of infrastructure (e.g., staffing, equipment) to address each of the key components of NCCCP;
        - extent to which support and commitment of hospital leadership is demonstrated such that it is clear they are helping to facilitate capacity building to address NCCCP objectives;
        - connectedness between what the Cancer Center and hospital are doing and the extent to which NCCCP staff are able to change their operations (or get leadership support to make the change happen) to support NCCCP components (connections of the clinical model to the program's components? barriers sites are encountering to establishing these connections?).
    - **Inform development of a conceptual framework for NCCCP that can be applied across the sites and to evaluation planning;**
    - **Determine common data elements (e.g., intervention variable, cost data) that can be collected across sites to assess aspects of NCCCP implementation;**
    - **Understand sites' expectations in terms of what NCCCP will provide them over time and whether it is meeting their expectations to date; and**

- **Understand the expectations, experiences, perceived benefits and barriers to working with other NCCCP sites both formally and informally, particular in terms of program development.**

- Please note that the purpose of the site visits is **NOT** to provide technical assistance or consultation or to audit individual programs, but rather to collect in-depth quantitative and qualitative information to describe how sites are setting up their programs and what they plan to accomplish. During February–June 2008, RTI will conduct *initial* site visits to each of the 14 pilot sites and then *annual* site visits in Years 2 and 3 of the pilot study. **We are scheduled to visit your site on <SITE VISIT DATES>.** During the initial site visits, we will focus on understanding each site's management and infrastructure that has been put in place to support the NCCCP. We would like to obtain information for drafting a logic map/model of how the NCCCP is being structured and operationalized at your site. Specific details regarding the site visits are described later.

PLANNING FOR THE CASE STUDY VISIT

A. Purpose of the planning call

To prepare for the visit to your site in **<MONTH>,** we'll conduct a 2-hour "planning call" with the program Principal Investigator (PI) and key staff who may assist RTI in coordinating and scheduling the interviews and other logistics. **The planning call is scheduled for <DATE AND TIME (EST) OF PLANNING CALL>.** We would like your permission to tape-record the discussion for back-up purposes only. This will ensure we have adequately captured key points from the discussion. The purposes of the call are as follows:

- First, we would like to set aside the first hour to clarify who the key staff are at your site, based on your responses to the Baseline Assessment Survey (BAS), and who responded to each section of the BAS. During this discussion, we will also clarify any inconsistencies in responses on the BAS that will be important for our evaluation.

- Second, we would like to discuss with you our plans and purpose for visiting your site. Specifically, during the call, we would like to (1) obtain your assistance in identifying key individuals with whom we can interview one-on-one and/or as a group during the visit (see attached Appendix A, "Worksheet for Identifying Potential Interviewees"), (2) identify a site contact who can assist in scheduling the individual and/or group interviews as well as to assist with other logistics, and (3) identify a person with whom a member of our team can follow-up with by phone to ask questions for the cost-study.

B. Planning Call Agenda

1. Introductions

2. Review Background and Purpose of the Case Study Visit

3. Planning for the case study visit
    a. Planning calls with sites
        i. Clarify BAS responses
        ii. Discuss planning for a case study visit
    b. Identify potential interviewees (see Appendix A)

c. Coordinating visit
    i. Securing room(s) for interviews (with telephone if needed)
    ii. Scheduling site interviews (see Appendix B)
    iii. Identifying any observation opportunities
    iv. Recommendations for accommodations
    v. Available site/campus maps
    vi. Identify contact person to coordinate site visit interviews and assist with logistics
4. Next steps

COMPONENTS OF THE CASE STUDY VISIT

A. Creating the Schedule of Interviews

- We are planning for a **<two-day> or <three-day>** visit to your site. During our visit, we will conduct individual (or group, as schedules allow) interviews. See the worksheet on page 8 for help with scheduling these interviews.
- During the first day of the visit, we can come as early or stay as late as you need in order to accommodate people's schedules. For example, we recognize that the people we hope to meet with while in **<CITY>** are very busy and some will be working in clinics. We will be willing to come early and/or stay late on **<DAY 1 DATE> or <DAY 2 DATE>,** in order to meet with interviewees as needed. We can also come early on **<DAY 2 DATE> or <DAY 3 DATE>,** for interviews but will need to plan to leave by 3:30 p.m. on the last day so that we can catch our flight home.
- During the site visit, RTI will conduct individual or group interviews with key management and program staff and stakeholders involved in the implementation of the NCCCP. It will be important for us to talk to key program staff, hospital leadership and management staff, clinical staff, and others who have been critical to the start-up period of the program. Talking with these individuals will allow the evaluators to

provide a rich, qualitative description of the program initiation process at your site, including (1) details about the varied program models, taking account of innovative strategies and approaches to putting in place the infrastructure to support the program; (2) challenges to-date faced by pilot sites; and (3) unique efforts to overcome program difficulties.

- Interviews will last between 45 and 90 minutes, depending on the person we're meeting with and their level of involvement during start-up. For example, to start off the interviews for our site visit, we would like to meet with the PI for 90 minutes. The purpose of this meeting will be for us to thoroughly understand the NCCCP at your site, what has been accomplished as of our site visit, and who have been the key people to your current accomplishments. Other interviews, with higher management such as your hospital's CEO or with directors of key departments in your hospital will likely last approximately 60 minutes. The draft worksheet in Appendix A provides our suggested list of potential interviewees and the times allotted for each.
- In preparing for the visit, we will work with you to determine who it makes the most sense for us to meet with for longer or shorter periods of time but will rely on your advice in terms of who you think can provide us the broadest understanding of what you've planned for the coming year and the deepest knowledge of what your Cancer Center and NCCCP offers. We can also work with you to determine if it makes sense to combine interviewees. For example, we recommend for this site visit that we interview your hospital's CEO and COO together, or only one of them, instead of both. This interview would only be for approximately 45 to 60 minutes.
- As you can see from our list in Appendix A, we only have **<2> or <3>** days to meet with an array of people. We will be relying on your contact person to schedule these meetings and ask that you plan for us to be located in one room where the interviewees can all plan to meet with us. This arrangement will help us make the most of our time in **<CITY>** so that we can learn as much as possible about your site.

B. Visitors

- The case study is being conducted by RTI International (the independent evaluation contractor). No NCI or government staff will be attending this site visit. Your site will be visited by **<Dr. _____ (lead interviewer), <and> Dr./ Ms. _____ (notetaker), <and Dr. _____, a clinical oncology expert (MD)>, <and Dr. _____, an organizational health researcher>.** We plan to conduct all of the interviews as a **<team> or <group>**, so that **<both> or <all 3>** of us are present for each meeting. **Our oncologist will only be on site during one day of the visit, and we will work with your contact person to determine whom he should meet with while there. Dr. <oncologist's name> will be visiting your site on <date>. Please be advised that the purpose of the oncologist's visit is NOT to provide consultation or technical assistance but to conduct observations and assessments for program evaluation purposes.**

C. Conducting the Site Visits

- To make these visits a success, we need your site's help with the following:
  - identifying appropriate staff and stakeholders for site visit interviews;
  - identifying appropriate staff who can answer questions about the site's financial systems—***an RTI staff member will conduct these by phone following and separate from the in-person site visit;***
  - scheduling site interviews (Appendix B);
  - securing a private room for conducting interviews (with a phone if needed);
  - suggesting hotel accommodations for the team;
  - providing any available site/ campus maps to the team; and
  - identifying a contact person from your program who can help us set up times for interviews.
- We will obtain institutional review board (IRB) approval before going on site visits and each interview will include our obtaining the consent for participants to be interviewed. We will also assure interviewees confidentiality in their responses. We will have a notetaker present during each interview who will be typing up notes as the person speaks and will ask permission to digitally record each interview.
- We request that during our visit, you provide us with a tour of your Cancer Center so that we can get a sense of where clinics are located, etc. Up to an hour's time can be set aside for this tour if you think that much time is necessary for us to obtain a good understanding of your services and what the patient's experience is when they seek care. Based on people's availability, we can tour facilities whenever it seems the most convenient.
- If you think it would be a good use of time, we would be happy to provide an introductory overview of the site visit to staff who are interested. Having conducted numerous site visits like this in the past, we recognize that people often have a lot of questions about the visits, what they are for, and how the information obtained during them will be used. If you would like to schedule a time when we provide this information to a group of people, we'd be happy to offer this service but it is completely up to you whether you want us to spend time doing this. Prior to each interview, we will explain to each interviewee the purpose of our meeting with them and how the information will be used.
- For key staff and personnel who are not available to meet with us during the scheduled site visit, we will conduct follow-up phone calls with some of them to ask additional questions. We will work with you while on site to identify those people and will follow-up with them upon return from the visit to schedule the call.
- Other than your assistance in planning for the visit, you do not need to prepare in any special way for these visits. Please do build in lunch breaks during our visit and just let us know places we can go nearby to eat. We do not need for you to arrange for our meals.

ADDITIONAL FOLLOW-UP

A. Cost-study follow-up call

- In planning for the cost study component of the evaluation, RTI needs to assess the types of financial data currently being collected by sites and the different financial systems used by sites so that we can determine whether there are common data elements already available that do not need to be collected but can inform the cost study. Within a few weeks after the planning call, an RTI team member will conduct a telephone

interview with an appropriate staff member who is knowledgeable about these issues. RTI staff will ask questions of this person about the financial data already available at your site and the extent to which it could be mined for the cost study. This process will help us determine what additional data collection tools need to be developed in order to collect the cost data relevant to the NCCCP evaluation. These calls will last approximately 30 to 45 minutes and be conducted by a staff member at RTI with knowledge of financial data systems within hospitals. During the planning call, we will ask you to identify a contact person for this follow-up call.

DATA ANALYSIS AND REPORTING

Your responses during the site visit interviews will NOT be identified by name. The first evaluation report produced for the NCCCP will summarize data from the first site visit specific to your program. We will code the data collected during Year 1 so that it can be used to provide NCI with cross-site findings during Year 2. We will work with NCI to determine if and when findings will be shared with the sites and will keep you apprised as these decisions are made.

APPENDIX A: Worksheet for Identifying Potential Interviewees

Organization		
Role	**Names**	**Suggested interview length**
Hospital or Systems Leaders & Management Staff		
➢ Principal Investigator		90 minutes
➢ CEO or COO		45–60 minutes
➢ Medical Director		45–60 minutes
Key Cancer Program Staff		
➢ Physician Director of Cancer Center if not PI		60 minutes
➢ Administrative Director of Cancer Center		60 minutes
➢ Members of NCCCP subcommittees (no more than 9)		90 minutes
➢ Chief of Radiation Oncology		45–60 minutes
➢ Lead nurse for NCCCP		45–60 minutes
➢ Key Cancer Center Physicians (number will vary by site), include some key physicians for clinical trials. Site can suggest group or individual meetings		Allow 90 minutes
Tour of Cancer Center		
➢ Staff member of site's choosing		30 minutes

APPENDIX B: Worksheets for Scheduling Site Visit Interviews[9]

Day 1:	**<SITE VISIT DATE>** **Location (i.e., bldg, room#):_____**

Lead Interviewer:
Note-taker:
Oncologist (if traveling):
Organizational Researcher (if traveling):

Morning			**Afternoon**		
Time	**Interviewee(s) & Contact Information**	**Special Notes**	**Time**	**Interviewee(s) & Contact Information**	**Special Notes**
8:00 - 9:30 am	PI		1:00 – 1:30 pm		
9:30 -10:00 am			1:30 – 2:00 pm		
10:00 – 10:30 am			2:00 – 2:30 pm		
10:30 – 11:00 am			2:30 – 3:00 pm		
11:00- 11:30 am			3:00 – 3:30 pm		
11:30 – 1:00 pm	**Lunch: Case study team will have a lunch break alone to debrief.**		3:30 – 4:00 pm		
			4:00 – 4:30 pm		
			4:30 – 5:00 pm		
			5:00 – 6:00 pm		
			6:00 – 6:30 pm		
			6:30 – 7:00 pm		

Day 2:	**<SITE VISIT DATE>** **Location (i.e., bldg, room#):_____**

Lead Interviewer:
Note-taker:
Oncologist (if traveling):
Organizational Researcher (if traveling):

Morning			**Afternoon**		
Time	**Interviewee(s) & Contact Information**	**Special Notes**	**Time**	**Interviewee(s) & Contact Information**	**Special Notes**
7:00 – 7:30 am			1:00 – 1:30 pm		

[9] Note: These worksheets are drafts only and should be adapted to best meet the schedules of people we hope to interview while on site. In other words, you may find that it's best if we meet with someone from 10-11 instead of 10-10:30. Please adapt this worksheet as needed to fill in the time slots.

7:30 – 8:00 am			1:30 – 2:00 pm		
8:00 – 8:30 am			2:00 – 2:30 pm		
8:30 – 9:00 am			2:30 – 3:30 pm		
9:00 - 9:30 am					
9:30 –10:00 am					
10:00 – 10:30 am					
10:30 – 11:00 am					
11:00 – 11:30 am					
11:30 – 1:00 pm	**Lunch: Case study team will have a lunch break alone to debrief.**				

Day 3:	**<SITE VISIT DATE>** **Location (i.e., bldg, room#):_____**				
Lead Interviewer: **Note-taker:** **Oncologist (if traveling):** **Organizational Researcher (if traveling):**					
Morning			**Afternoon**		
Time	**Interviewee(s) & Contact Information**	**Special Notes**	**Time**	**Interviewee(s) & Contact Information**	**Special Notes**
7:00 – 7:30 am			1:00 – 1:30 pm		
7:30 – 8:00 am			1:30 – 2:00 pm		
8:00 – 8:30 am			2:00 – 2:30 pm		
8:30 – 9:00 am			2:30 – 3:30 pm		
9:00 – 9:30 am					
9:30 –10:00 am					
10:00 – 10:30 am					
10:30 – 11:00 am					
11:00 – 11:30 am					
11:30 – 1:00 pm	**Lunch: Case study team will have a lunch break alone to debrief.**				

Use Day 3 schedule for system sites ONLY!

APPENDIX F: QUALITATIVE CODING DICTIONARY FOR SITE VISIT INTERVIEW DATA

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
REASONS FOR PARTICIPATING	Creation of a formal connection with NCI	Distinction of site as a recognized leader in their market	Site's description of how linking with NCI was reason for participating; site's description of the extent to which an NCI connection "legitimizes" their program	"We want to pursue NCI designation, to become a full-blown program. Outside of benchmarking it is a strong differentiator" Orange	
	Opportunity to develop and learn how to improve cancer research and care	Offer more clinical trials	Site's description of their desire/ ability to offer and enroll more patients in clinical trials	"accelerating access to trials and offering hope and maybe coming up with answers" Orange	
		Strengthen research infrastructure	Extent to which the NCCCP adds to/ strengthens the site's research infrastructure	"A lot of the activity we are going through now as part of the deliverables and 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" OLOL	
		"Raise the bar" in terms of quality of cancer care			
		Reduce disparities			
	Alignment of fit between NCCCP and strategic priorities of sites	Prioritization of oncology/ cancer care	Extent to which the NCCCP goals fit with the hospital's/ Cancer Center's (CC's) mission and priorities around cancer care	"It will allow us to fulfill our mission as a hospital (e.g., clinical trials)" CHI Penrose	
		Creation of synergies across pillars and components	Most sites saw NCCCP as an opportunity to accelerate change and realign or strengthen their strategic priorities along the lines of the NCCCP pilot pillars.		
		Acceleration of change	Most sites saw NCCCP as an opportunity to accelerate change and realign or strengthen their strategic priorities along the lines of the NCCCP pilot pillars.		

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
UNDERSTANDING OF NCCCP AND VISION	Site's general understanding of broad vision		Core team's description of their understanding of the broad vision of the NCCCP		
	Vision/understanding of application of program to site		Core team's description of their understanding of how NCCCP goals will be applied to the site; also core team's description of how the different pillars will come alive or interact within their specific organizational structures	"Margaret 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." CHI Penrose	
	Vision/understanding of application of program to individual's role		Respondent's description of their understanding of how NCCCP goals will be applied to their individual role.		
	Site's ability to communicate complexity of NCCCP			Ex: Sites ability to list all of the pillars and how they interact to create one overall program	This could possibly be a subcode of "site's general understanding'—to be explored later
	Challenges for site in developing a common understanding		Barriers/challenges faced by sites in developing a common understanding of the NCCCP goals/vision among key players	ex: busy schedules	
ORGANIZATIONAL STRUCTURE	Structure of oncology services	Structure of NCCCP at site	Insight into how the site's oncology services are structured with the CC and how the NCCCP is structured at the site	ex: NCCCP-specific committees (e.g., executive committees established that are specific to the NCCCP) ex: Cancer Committees; Cancer Program Advisory Committees	Several sites have established an executive committee specific to NCCCP or other coordinating structure in building effective teams that seemed to be helping to coordinate efforts across the pillars and components.
	System structure of oncology services	Barriers: system structure			
	Alignment of internal teams	Integration of program effectively managed			Many sites have established "executive committees" or some type of coordinating structure; sites without this coordinating structure

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
					seemed to be struggling more with integration and coordination
ORGANIZATIONAL STRUCTURE (cont)		Coordination of activities			
		Communication with team members and internal with physicians	Extent of communication among team members, including physicians (i.e., those on org charts)		
		Other examples of coordination and integration		Ex: sharing of staffing resources	
	Role and responsibilities		Individual's role, activities, tasks related to the CC and hospital		
	Relationships with private practice physicians	Barriers: relationships w/ private practice docs	(referring to the private practice docs on the org charts), any insight into how integrally involved private practice docs are with NCCCP, quality of relationship, how much the program relies on the PP docs		Managing their relationships with physicians in order to effectively engage them in NCCCP implementation was a major barrier reported across the sites. Sites with physician directors of their Cancer Center seemed to be having more success in engaging the private practice physicians than those without this leadership (6 of 16 sites had no or vacant Director positions).
	Relationships with hospital physicians	Barriers: relationships w/ hospital docs	(Referring to the hospital docs on the org charts), any insight into how integrally involved these docs are with the NCCCP, quality of relationship, how much the program relies on these docs		
		Description of medical model	Description of type of medical model under which private practice docs operate and/or they relate to the hospital	Ex: private practice; integrated	CHECK WITH DEBBIE TO CLARIFY TYPE OF PRACTICE AT SANFORD AND BILLINGS—They are private practice docs employed by the hospital
		Incentives	Incentives/strategies used to motivate private practice docs to participate		
		Changes being made	Any changes (e.g., operationally, structurally) the site has undergone to increase private practice doc	Ex: Hartford's "purchase" of a local doc's private	

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
			participation	practice?	
CAPACITY	Staffing		Site's account of staffing resources already in place or lacking Can also include site's account of staff expertise/ knowledge in implementing NCCCP goals	Ex: Hiring nurse navigators as a result of the grant	Capacity subcodes can be cross-coded with pillar activities as well
	Infrastructure	Physical space		Ex: inpatient beds located in separate part of hospital within another unit (Billings)	
		Equipment			
		New building	Site's plans to build a new CC		
		Funding	Grants/other funding sources used to supplement NCCCP	Ex: Sanford has endowment fund to support EMR system	
		IT/EMR resources	This code may include: • Hospital/system IT staff • Access to proven systems (hardware and/or software) • Competing priorities and/or lack of time for IT department • All systems and hospitals are working to implement EMR but facing numerous challenges doing so		IT support was present for some sites but a struggle for most, with change coming slowly • Limited staff and resources • Limited access to proven systems • Competing priorities All systems and hospitals are working to implement EMR but facing numerous challenges doing so
		caBIG™	Discussions about caBIG and the IT capabilities required	This is also associated with IT and thus should be double-coded with IT/EMR.	This should be double-coded with IT/EMR.
		Lab resources	Includes discussions about capacity to handle pathology/biospecimens and resources required		
		Surgical services			
		Research			
		Community outreach	Community outreach here refers mainly to existing resources that may (or may not) facilitate community outreach (e.g., satellite offices)		

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
READINESS FOR CHANGE	Leadership support	Hospital leadership support	Discussions regarding overall support received from hospital leadership (e.g., CEO, board) for the NCCCP	Ex: NCCP and oncology is a priority **HOSPITAL/SYSTEM-**wide. Examples of hospital support include placing NCCCP on the hospital agenda; working to raise money and dedicate resources; purchasing equipment that the hospital had delayed before NCCCP; hiring new staff, particularly in key specialty areas (e.g., gynecological oncology, surgical oncology); allocating space that could otherwise be leased	Greater support from hospital leaders seems related to better understanding of and access to resources, fewer barriers to overcome, and stronger staff support.
		CC leadership support	Discussions regarding overall support received from the CC for the NCCCP	Ex: NCCP and oncology is a priority **CC-**wide. Examples of CC support include placing NCCCP on the CC agenda; routinely working with employed and private practice clinicians to achieve NCCCP goals; purchasing equipment that hospital had delayed before NCCCP; hiring new staff, particularly in key specialty areas (e.g., gynecological oncology, surgical oncology); allocating space that could otherwise be leased	

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
READINESS FOR CHANGE (cont)		Program champion	Person who is strategically located to have access to upper management as well as influence on, or control over, day-to-day program operations (can include key physicians and non-MD staff). The champion often enthusiastically advocated for the needs of the program, particularly to help secure resources for its continuation (Scheirer, 2005)	"Dr. Padova, the senior guy around cancer, is kind of the informal leader in medical oncology. We engaged him to serve as a medical advisor to us and he has done so for the last 6.5 yrs and he was kind of an acting role as medical director"	The role of the PI [and others] and that person's position within the Cancer Center seems paramount to how well they are able to foster leadership support
	Dedicated resources/time		What it takes to implement the NCCCP in terms of time and resources; not to be confused with staff (persons) required, but time required of staff and resources needed to implement the program. The notion here is do key staff have the dedicated resources/time to do these new tasks or are they attempting to carry out NCCCP-related activities on top of other responsibilities?		Most hospital leaders interviewed recognized that NCCCP requires more resources than anticipated Sites with obvious (and present) physician leadership of NCCCP seemed to be having greater success garnering resources Lack of time: everyone's plates were already full even before NCCCP In particular, all PIs noted that this program is taking significantly more of their time than they anticipated
	Partnerships	NCI-designated CC	Site's existing (or lack of) relationships with NCI-designed CCs	"Now, in December, brought in GCC, MCC, Moffit and we had external linkages for retreats and built metrics" LCRP	Most sites had established at least one new connection with an NCI-designated CC; some sites have concerns about how to establish mutually beneficial relationships with CCs Relationships being discussed included providing patients access to Phase I and II clinical trials, sites providing specimens for tissue banks, partnering on outreach and other grant projects, and serving as

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
					affiliate sites of CCs
READINESS FOR CHANGE (cont)		CCOP/ minority CCOP	Site's existing (or lack of) relationships with CCOP sites		
		Community groups	Site's existing relationships with community-based organizations	Ex: American Cancer Society	
		Patients		Ex: patient advisory groups; St. Joe Orange has survivorship group that provided input on CC building design	
		Physician groups	Site's perceptions of their relationships with key physicians in hospital and/or private practice (again, this overlaps with the relationship with physicians code)		
		State coalitions			
NATIONAL NETWORK	Recommendations for improvement		Site's recommendations for improving relationship/ communication with the National Network; overall experience with the National Network	• Allow sites to provide agenda items • Provide a structure that allows more sites to participate consistently • Develop a matrix of requests made of sites across the subcommittees • Allow time for discussing "big picture" issues (e.g., future direction of program)	
	Product development and dissemination	Site's use of Network products	Products/ tools developed from the national network; extent to which sites have used (or will use) these products and benefits and barriers experienced	Ex; GAFAT	
ENVIRONMENT	Market share	Competition	Competition among hospitals in general, competition among hospitals to work with private practice physicians, and competition among private practice physicians		

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
	Community characteristics	Disparate population(s) served			
IMPLEMENTATION	Planning process		Site's plans for implementing pillar components; anything related to the planning process	Ex: staff meetings;	
	Activities	Clinical trials	Site-specific activities related to clinical trials	Ex: site assigned PIs Ex: site increased accrual	
		Biospecimens	"	Ex: site engaged pathology to set protocols	
		Information technology	"	Ex: site hired 1 FTE for IT Ex: Site implements caGrid or caBIG Ex: site interfaces registry with cancer center	
		Quality of care	"…Includes multidisciplinary clinics, tumor boards, credentialing, conditions of participating doc.		
		Disparities	"…Includes screening and community outreach	ex: hired outreach coordinator	
		Patient navigation	"	Ex: site develops a patient navigation flow chart; Ex: site hires patient navigators	
		Survivorship/palliative care/hospice	"	Ex: site develops a patient education program	
		Advocacy			
		Communications			
VALUE ADDED		Value added: organization		Ex: change in policy	
		Value added: program		Ex: site enhanced existing services	
BARRIERS/ CHALLENGES					
STRENGTHS/ FACILITATORS/ BENEFITS					
LESSONS LEARNED			Catch-all code for lessons learned from program start-up to implementation		

Overarching Theme	Code	Subcode	Definition	Example	Additional Notes
MISCELLANEOUS			Catch-all code for anything important to capture but not yet assigned a code; relevant text can be reviewed later to develop any necessary codes.		

APPENDIX G: SAMPLE TABLES FOR SITE-LEVEL DATA BOOKS

(AVAILABLE UPON REQUEST)

APPENDIX H: CONCEPT PAPER FOR ADDRESSING THE STRATEGIC CASE FOR SITE PARTICIPATION IN NCCCP

June 2008

Concept Paper for Addressing the Strategic Case for Site Participation in NCCCP

Prepared for

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RTI Project Number 0210903.000.003

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10. INTRODUCTION

As part of its evaluation of the feasibility and sustainability of the National Cancer Institute's (NCI's) Community Cancer Centers Program (NCCCP) pilot, RTI International will gather input from executive and program leadership and interview financial officers to gain insight on (a) their motivations for participating as an NCI pilot site, (b) their expectations for financial or other returns on NCCCP investment, and (c) the conditions under which they would commit to conducting the activities in the future. A key to sustainability for NCCCP may rest with its ability to convince executive leadership of the sponsoring institutions that there is a business case for participating in pilot program activities.

11. A DEFINITION OF "THE BUSINESS CASE"

In 2003, Sheila Leatherman and colleagues published a set of case studies and a seminal analysis of "the business case" for quality improvement in health care. Their purpose was to understand why organizations seem slow to adopt proven approaches to improve safety and efficacy of patient care. They began by defining the business case for health care interventions as a situation where

> *"…the entity that invests in the intervention realizes a financial return on its investment in a reasonable time frame, using a reasonable rate of discounting. This may be realized in 'bankable dollars' (profit), a reduction in losses for a given program or population, or avoided costs. In addition, a business case may exist if the investing entity believes that a positive indirect effect on organizational function and sustainability will accrue within a reasonable time frame"* (Leatherman et al., 2003, p. 18).

The authors make a distinction between the "social case," the "economic case," and the "business case" for institutional quality initiatives. The social case for the activity or intervention exists if it can be shown to improve access to care, health status, quality of life, or community health or result in any other socially desirable outcome related to health care. The economic case exists if discounted financial benefits of the intervention are greater than discounted costs over a foreseeable future. An economic case can be made even if that period is relatively long and even if parties that benefit are not the same as those that incur the cost. In contrast, the business case exists only if there is a positive financial return and if the potential benefits accrue to the same entity that makes the program investment. The benefits must also occur within a time frame that is short enough to be valued by that entity, but the key attribute in making the business case is the alignment of costs and benefits within the same entity.

To summarize, justifications for a given intervention can take three forms:

What is the benefit to patients or the health of the community?

- *The social case*—where you can demonstrate any improvement to health or community health

Is this a good use of my community's scarce resources?

- *The economic case*—where you have a social case AND you can demonstrate positive long-run financial return at the community (or population) level

Is this a good use of my organization's scarce resources?

- *The business case*—where you have an economic case AND you can demonstrate positive short-run financial returns to the same organization that is making the investment ("alignment of financial incentives")

After presenting several case studies, Leatherman et al. (2003) note that while the economic and/or social cases for many interventions are evident, the business cases are not. They conclude that "misalignment of financial incentives creates a formidable obstacle to the adoption of quality interventions" (p. 1). Too frequently, benefits from programs to improve care management or to promote healthier behavior will be felt by the patient, community, or third-party payer but not by the individual organizations that must fund the intervention.

12. NCCCP CONTEXT

The objective of NCCCP is to bring state-of-the-art cancer care to patients in community hospitals by encouraging closer links between local oncology practices and NCI research networks. Specific goals of the pilot project are to increase local enrollment in clinical trials, address health disparities by reaching out to clinically underserved populations with education and improved access to care, explore ways to use health information technology—specifically electronic medical records—to improve information sharing between community-based and academic or other cancer research environments, and expand capacity for collection and storage of biomedical specimens that are needed to support the nation's research agenda. The pilot project has six areas of focus: clinical trials, health disparities, health information technology (IT) (caBIG™), biospecimen collection, quality of care, and survivorship (palliative care is included in this focus area).

While a business case might be made for some of these focus areas, others may be primarily grounded in mission-driven research goals or commitment to community health. Management's commitment to research and motivation for improved specimen collection, for example, would tend to be based on the social case for intervention. The health IT activities funded at this stage of NCCCP are primarily exploratory and might also be justified based primarily on a social or economic case without expectation of immediate financial returns (although there may be an assumption that this activity enhances a facility's reputation and improves its competitive position). Increased clinical trial enrollment and improved access for underserved populations both have the potential to enhance reputation

and increase service volumes and market share; thus, they are likely candidates for an economic case and possible candidates for a business case. In some communities, these activities could have great potential for financial rewards—for example, by attracting new patients or reducing out-referrals. In other communities, they could raise short-term financial risks by adding to uncompensated care burdens.

Leatherman et al.'s (2003) definition for a business case explicitly expands the concept to include nonmonetized benefits, by allowing for circumstances where the entity expects a "positive indirect effect on organizational function and sustainability" even in the absence of financial return. Their expansion is highly relevant for the application of these concepts to NCCCP, where many of the perceived immediate benefits from participation may relate to enhanced reputation. In adopting this expanded concept of the business case, it may be useful to change the terminology from "business case" to "strategic case" to underscore the importance of understanding the short-term, properly aligned, financial and nonfinancial incentives that motivate organizations to choose to partner with NCI in such a project.

13. EVALUATION OBJECTIVES: MAKING THE STRATEGIC CASE

The evaluator's role is not to construct the business case for any of these project activities or to define an overall strategic case for participation in NCCCP. The evaluator's role in this study should be to identify whether top management believes that a strategic or business case for participation can be made and the potential measures to use in assessing it. Reiter et al. (2007) and Kilpatrick et al. (2005) provide in-depth discussions of the data needs for documenting the business case. Both articles describe in detail the types of data required to make a business case for health care program interventions, and both stress that there must be a consensus on the metric for success of the health intervention and the ability to measure the financial returns attributable to that success.

Documenting how institutional leaders assess a strategic or business case, what metrics they use, and what their acceptable time horizons are for recognizing financial or other indirect returns are all critical components to understanding whether this sort of initiative can be rolled out to other communities. A large part of the overall strategic case for NCCCP participation will come from the balance of financial versus mission-driven goals; therefore, we also need to understand how executives view the risk and reward trade-offs between the key focus areas, each of which may have the potential to improve care independent of whether it returns a profit, breaks even, or risks additional losses.

RTI's evaluation will pay attention to variation across sites in how the strategic or business case is perceived. This is important for making study results helpful to NCI, particularly in deciding how to roll NCCCP out to other communities in the most effective manner. There may be systematic differences in how financial and other executives construct or evaluate

the business case for NCCCP activities according to differences in sites' organizational structure. Three key organizational correlates that may affect perceptions of risk, return, and acceptable trade-offs between the social, economic, and business case are (1) the integration of the cancer center into the hospital management structure, (2) the relative mix of physician practice-owned versus hospital-based oncology care, and (3) independent versus system ownership. It is therefore important that site-level background data on organizational structure and finances, physician practice organization, community demographics, and local health care supply be used to inform the analyses of interview data. The evaluation should examine the relationship between the organizational structure of the site, its expectations of and commitments to core NCCCP activities, and its allocation of internal resources to core NCCCP activities. An important question to ask is whether sites of different size and stature necessarily have the same motivations for and returns from participating in the NCCCP pilot. Responses will help NCI better tailor its programs to fit the needs of specific sites and communities in future expansions of the program.

14. APPROACH

RTI will use a mix of telephone interviews and secondary data to carry out this part of the study. Individual telephone interviews for what we will call the strategic case studies will be carried out at the end of the first contract year, targeted for the chief financial officer at each site. Additional input will be collected from NCCCP pilot program leadership as part of pilot meetings and annual site visits. Modified interview protocols may be designed for executives from independent hospitals versus those from systems. Some sites may have already explicitly formulated the strategic case, while at others we may need to probe for insights into the strategic operating and financial goals that implicitly constitute a case for participation. At or near the close of the pilot project, re-interviews will be conducted (where possible with the same staff member) to gather data on whether the project lived up to the early assumptions. In the re-interview, we will allow management a chance to confirm the validity of their original case for participation—specifically, whether they were able to measure success or failure and whether their original conception of monetary and nonmonetary rewards was realistic or accurate—and we will give them a chance to restate that case according to lessons learned.

Where we find substantive differences across sites in the case for participation, we will try to analyze these in the context of other organizational, financial, and community characteristics. We expect the strategic case for participation in NCCCP to be influenced by each site's competitive position, by recent trends in its financial condition, by the contribution of inpatient and outpatient cancer care to that condition, and by the state of physician-hospital relations among oncology specialists. For this reason, we plan to supplement original interviews with comprehensive background information from secondary sources. Such sources may include documents shared by the sites (e.g., financial

statements, management accounting reports), data extracted from the Baseline Assessment Survey (e.g., market share, patient mix, service mix, physician arrangements, competitors), or data compiled by RTI analysts from state or national sources (e.g., national data on profitability by diagnostic research group, inpatient and outpatient cancer service mix from cost reports, charity care from IRS Form 990s). To the extent possible, information from secondary sources should be gathered and summarized by site before conducting specific site interviews.

Concurrently with this study, RTI will be documenting actual program-related expenditures by pilot site based on the micro-cost data collected for NCI-funded and supplemental (i.e., matching) activities. The cost study is a separate but complementary part of RTI's evaluation of NCCCP. It is designed to help NCI document the distribution of spending across key focus areas and, eventually, to help assess the return on program investment relative to specific program outcomes. At the close of the project, RTI expects to integrate findings from the cost study with data from the follow-up interviews on the strategic case for participation, allowing the cost data to inform our conclusions regarding top leadership's perception of success, failure, sustainability, and replicability of this project.

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APPENDIX I

Commission on Cancer

Letter of Support

Commission on Cancer

A multidisciplinary program of the American College of Surgeons

May 18, 2009

Madeleine Wallace, Ph.D.
Acting Chief, Evaluation Branch (EB)
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Dear Dr. Wallace:

I would like to express my enthusiasm for the NCI Community Cancer Centers Program (NCCCP) pilot evaluation that is being proposed by Dr. Irene Prabhu Das of the National Cancer Institute. Dr. Prabhu Das plans to conduct a multi-level, comparative evaluation assessing the effectiveness of the NCCCP. This effort will provide a valuable complement to the work of the National Cancer Data Base (NCDB).

Program staff at the NCDB has collaborated with staff in the Division of Cancer Control & Population Sciences in recent years on a variety of initiatives focusing on the development and implementation strategies for the National Quality Forum endorsed quality of care measures for breast and colorectal cancer. Most recently, our work has focused on the engagement of the NCCCP centers to participate in a rapid reporting system that would bring performance reports on these NQF measures into the clinical setting. Dr. Prabhu Das' proposed work will contribute to our understanding of the stability and viability of these reporting methodologies as they bear on timing and delivery of a variety of clinical services. Ultimately, the NCCCP pilot program evaluation will help us understand how patient, provider, and health care system behavior and performance can be improved to enhance the quality of health care and health outcomes.

I am confident that Dr. Prabhu Das' work will lead to changes and improvements in the NCCCP for the NCI, and that the NCDB will benefit from her findings. I look forward to continued collaboration with the Division of Cancer Control & Population Sciences, particularly as we focus on implementation strategies of quality evaluation report cards in real world medical settings.

Sincerely,

E. Irene Gay

Andrew K. Stewart, MA
Senior Manager – National Cancer Data Base
Commission on Cancer
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