

Towards a Comprehensive Cancer Measure Set: Value-Based Episodes of Care

Washington, DC: May 20, 2008
Workshop Summary

Introduction

Although significant gains have been made in both the prevention and treatment of cancer, many individuals do not receive the evidence-based interventions, such as screenings and adjuvant therapies, known to be effective in the early diagnosis and subsequent management of their disease. Building on the work of public and private driven initiatives, the National Quality Forum (NQF) is working to identify a comprehensive cancer measure set by applying the NQF framework for assessing “episode efficiency” for chronic conditions to the cancer community. Given the longitudinal nature of oncologic disease, with its discreet treatment phases, the complexity and diversity of care-givers, and the vital role of patient empowerment knowledge, cancer emerges as an excellent paradigm for exploring the potential of moving towards this episodic assessment of what constitutes optimal care and how this can be achieved in the most efficient manner.

Project Background

This project built upon prior work at the NQF completed under the Cancer Quality Measures Project (<http://www.qualityforum.org/projects/ongoing/cancer/index.asp>), as well as current work under the auspices of the patient-focused episodes of care project which has developed a measurement framework for evaluating efficiency across episodes of care (<http://www.qualityforum.org/projects/ongoing/episodes/index.asp>).

The aim of this project was to provide the government with recommendations for a path forward for cancer quality measurement, as well as a defined research agenda. The project was guided by a Planning Committee, chaired by Dr. Patricia A. Ganz (UCLA Schools of Medicine and Public Health), and comprised of experts from the cancer community and others with expertise in performance measurement (Appendix A). Primary support for this project was provided by the Agency for Healthcare Research and Quality and the National Cancer Institute.

Specifically for this project, the NQF worked with the full range of stakeholders to:

- Commission a white paper outlining the current state of performance measurement in cancer care and key issues around the development of a comprehensive measurement strategy;
- Plan, support, and implement a workshop to create an action plan for developing the next generation of cancer quality of care measures;

- Map out an action plan for development of the next generation of cancer measures including a gap analysis of needed measures and possible application of the NQF generic framework for evaluating efficiency across episodes of care to cancer; and
- Lay out a future vision for an evolving measurement and monitoring system focused on achieving value across episodes of care.

The following workshop summary is organized by the content prepared for and discussed at the workshop, *Towards a Comprehensive Cancer Measure Set: Value-Based Episodes of Care*, convened May 20, 2008, in Washington, DC (see Appendix B for agenda). The summary will: (1) briefly address the current state of cancer care quality measurement; (2) present one approach for measuring quality care through the episode of care approach and describe the Planning Committee's conceptualization of episodes of care for breast and colorectal cancers; (3) highlight recognized gaps in measures of cancer care quality; and (4) summarize the recommendations offered by the experts at the workshop for a path forward.

Where We Are Today: The Current State of Cancer Care Quality Measurement

Although evidence-based treatment guidelines from the National Cancer Center Network (NCCN) exist, the diagnosis and treatment of cancer is certainly unique. Affecting a broad and diverse population with varying length and severity, treatment for cancer involves multiple care providers and care settings, and thus strong focus on the coordination of care. Additional cross-cutting issues are almost always involved, including patient and family engagement in care (particularly in decision-making around treatment and therapy options); palliative and end-of-life care; pain and symptom management; and psychosocial needs.

For the purpose of this project, a white paper was commissioned to provide a detailed overview of the current state of cancer care quality measurement. Dr. Michael Hassett (Dana-Farber Cancer Institute & Harvard Medical School) and Dr. Peter Bach (Memorial Sloan-Kettering Cancer Center) authored the paper (see Appendix C), which offered not only a retrospective and current look at quality measurement in this area, but also offered context to the complexities involved in closing the existing measure gaps, in getting to a desired state of cancer care quality measurement. The authors specifically addressed what makes assessing the quality of cancer care particularly challenging and what critical aspects in research, policy, and implementation must be considered in order to move forward.

These concepts hold particular importance for cancer patients, given the physical, emotional, cognitive, personal, financial, family and other consequences that develop as a result of a cancer diagnosis....because of the complicated, multi-site, inter-disciplinary and multi-disciplinary nature of cancer care, coordination of care is a vital aspect of care that is insufficiently addressed by cancer quality measures (Hassett & Bach, 2008).

Current cancer care quality measures focus on process (i.e. screening) over outcome and do not encompass measurement of the cross-cutting elements – particularly care coordination and psychosocial and palliative/end-of-life care. Since 2000, NQF has been engaged in endorsement efforts around cancer care quality measurement. Related specifically to cross-cutting areas of symptom management and end-of-life care, NQF in 2007 endorsed for accountability in the hospice setting the Family Evaluation of Hospice Care survey, a standardized instrument designed to assess the quality of hospice care delivery from the perspective of family caregivers and to yield actionable information. More specific to cancer-related symptom management and end-of-life care was NQF's endorsement of measures of overutilization (e.g., chemotherapy in the last 14 days of life) and underutilization (e.g., admission to hospice for less than three days). A table summarizing the most recent NQF-endorsed measures related to cancer care can be found in Appendix D. In late 2006, to address quality of care for patients at end of life, NQF endorsed a National Framework and Preferred Practices for Palliative and Hospice Care Quality (report available at: <http://www.qualityforum.org/pdf/reports/palliative/txPHreportPUBLIC01-29-07.pdf>).

Furthermore, while much work with respect to measurement and quality assessment has been accomplished for several common cancers (e.g., breast and colorectal), much more remains to be done for other types of cancer (e.g., lung, prostate, pancreas, ovarian, lymphoma, etc.). The National Committee for Quality Assurance, National Cancer Institute, Agency for Healthcare Research and Quality, and numerous others have been heavily engaged in measure development for cancer care. A review of past efforts as well as efforts currently underway is outlined in the white paper. Appendix A of the White Paper also offers key stakeholder organizations and groups involved in cancer care quality measurement.

One Approach to Quality Measurement and Performance Improvement: The Patient-Focused Episode of Care Framework

NQF's Measurement Framework for Evaluating Efficiency across Patient-Focused Episodes of Care

Considering the complexity of any cancer, as well as its numerous care settings and care providers, conceptualizing valuable and efficient care for patients and their families can prove challenging. NQF has developed a patient-focused measurement framework through which such complex conditions can be diagnosed, treated, and followed-up. The *Framework for Measuring Efficiency across Patient-Focused Episodes of Care* (<http://www.qualityforum.org/projects/ongoing/episodes/index.asp>) offers an approach to evaluating efficiency across episodes of care while taking into careful consideration not only the various settings and providers of care (and transitions between them), but also specifically the treatment and outcome preferences of the patient. Furthermore, in presenting the opportunity to assess efficiency (as a function of cost and quality of care) from the patient's perspective as well as the provider's, the framework also specifically allows for the assessment of gaps in measurement, care provision, and patient-provider

and provider-provider communication, driving towards a comprehensive set of measures of efficiency in the system and value to the patient.

The episode of care approach offers strengths and limitations with respect to feasibility and measurement among others, especially as they apply to a range of conditions from acute to chronic. But it is by looking at the episode of care approach through the lens of these various conditions, including cancer, which allows for these strengths to be bolstered and limitations addressed moving forward.

Strengths:

1. *Patient-centered* way of evaluating health system performance.
2. Clinical guidelines offer *clear pathways*: The cancer community has explicit advantage over other chronic care treatment communities because detailed and evidence-based guidelines provide for clearer mapping to the episode approach and offer measurable points by which diagnoses, processes, and outcomes can be assessed.
3. A way to shift performance measurement towards assessments that allow judgments to be made about *value* by providing measures of quality, cost of care, and outcomes that can only be interpreted in the light of patients' well-informed preferences.
4. Could foster and enable *new strategies for financing* healthcare that could eliminate current incentives to overuse certain services (i.e., imaging for low back pain) and underuse others (i.e., preventive care such as mammograms), and could facilitate the development of alternate payment models.
5. Allows for *comparisons for conditions over many years*, not simply between clinical encounters: This timing construct provides for linkages with payment and performance reporting systems, and may also provide the opportunity for progress for a chronic condition to be tracked from year to year, thereby extending the larger episode beyond the single year timeframe.

Limitations:

Despite its advantages, the Committee recognizes the limitations associated with attempting to evaluate efficiency across episodes. These stem mainly from the inability of existing commercial episode grouper methodologies to:

1. Address *appropriateness* of care.
2. Adequately *risk-adjust* for different populations.
3. Sort out patients with *multiple chronic conditions and complex comorbidities* (which are especially applicable to cancer care).
4. Facilitate *comparisons among organizations*.
5. Address *complexities associated with Stage 4 cancers*: Care and payment structure complexities exist for stage 4 cancers that do not allow for seamless adaptation to the proposed episode models (need to come to agreement on an

approach or framework by which to encompass this high cost, high resource use component of cancer treatment).

The Framework and White Paper offer further discussion of additional considerations with regards to both the strengths and limitations of the episode of care approach, including: access; limits of 1-year timeframe; difficulty of payment structure; and data needs.

Conceptual Episode of Care Models for Cancer Care

In preparation for the workshop, experts in breast and colorectal cancers worked with NQF staff to conceptualize these specific cancers within the episode of care framework described above. Using cancer treatment guidelines for support, models were created to visually represent these conceptualizations and understand the various pathways that a patient may enter a breast and/or colorectal cancer episode of care. These models are elaborated on below and in corresponding appendices. Covering the full range of severity of cancers and using practice and treatment guidelines, the models of episodes of breast, colon, and rectal cancers demonstrate the complexity of issues (access to care, psychosocial needs, treatment preferences, informed decision making, and symptom assessment among others) to consider both within and beyond the health care system as a patient moves through the episode.

Breast Cancer

The breast cancer episode as proposed by the Planning Committee and further fine-tuned at the workshop (Figure 1) presents several pathways (based on clinical practice and treatment guidelines) by which a patient diagnosed with breast cancer might negotiate his or her diagnosis, treatment, and follow-up with multiple care providers and settings, and includes consideration of several patient-reported and desired outcomes. A brief overview of the various phases of the breast cancer episode is provided below.

Episode phases

Phase 1: Population at Risk

Ideally, in evaluating how well the health care system performs in providing high quality cancer care, it would be important to consider the population at risk and to capture the period preceding diagnosis, when it is conceivable that the cancer—and its diagnosis and subsequent treatment—could have occurred at an earlier stage or optimally could have been prevented altogether through ensuring evidence-based age and sex appropriate screenings.

Phase 2: Evaluation and Initial Management

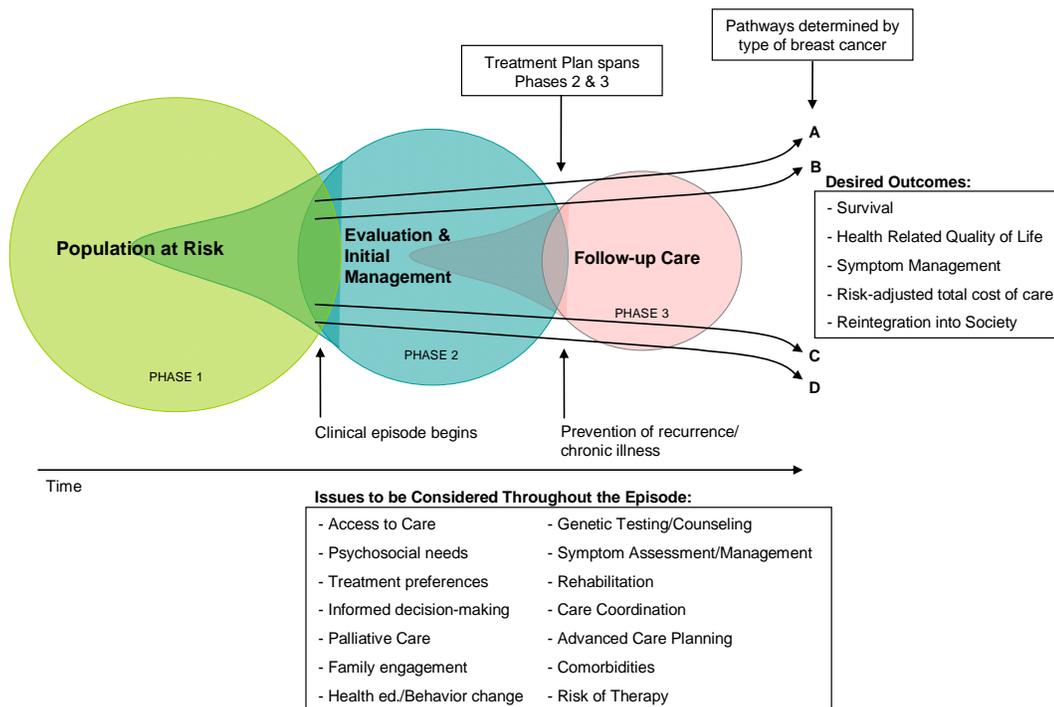
This phase begins with presentation of a patient with cancer-like symptoms or through cancer screening, and includes the diagnosis of

cancer by stage of cancer. Pathways A through D are built upon evidence-based guidelines and offer the various ways (and corresponding timeframes) by which a patient diagnosed with breast cancer navigates the diagnosis, evaluation and management, and treatment and follow-up care specific to the cancer type.

Phase 3: Follow-up Care

The development of a treatment plan and prevention of recurrence transitions a breast cancer patient into the final episode phase of follow-up care. Close monitoring of symptoms and outcomes from therapy (dependent upon the patient’s pathway) that are aligned with the patient’s preferences combine to determine several elements of care: secondary prevention; initiation of palliative care; and/or delivery of hospice care.

Figure 1: Context for Considering a Breast Cancer Episode of Care

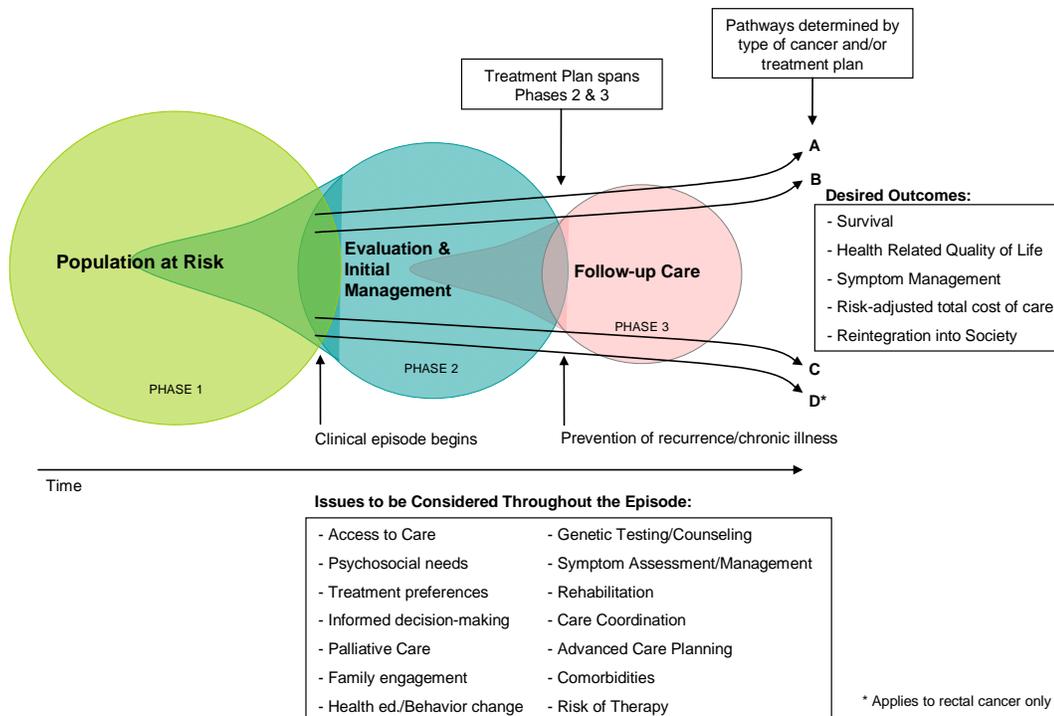


Appendix E serves as a preliminary outline for further operationalizing breast cancer to the episode model. This model and accompanying outline could prove helpful in guiding future work to build a comprehensive measure for set for breast cancer.

Colon and Rectal Cancers

As in the breast cancer model presented above, patient-focused episode of care models for colon and rectal cancers (Figure 2) similarly offer the opportunity to examine the patient's movement through the diagnosis, treatment, and follow-up of his or her cancer.

Figure 2: Context for Considering Colon and Rectal Cancers Episodes of Care



Appendices F and G serve as preliminary outlines for further operationalizing colon and rectal cancers, respectively, to the episode model.

Addressing Measurement Gaps: Driving Toward the Desired State of Cancer Care Quality Measurement

The episode of care approach, described above, provides a useful framework for mapping existing cancer measures as well as for highlighting measure gaps, and thus can inform us about areas in need of measure refinement or development. The Workshop built upon gaps offered in the White Paper and provided an open forum through which experts in cancer care and quality measurement could expand on these identified gaps and dive deeper. A summary is offered below, with further detail and discussion included in the White Paper.

Mapping measurement needs to the proposed episode models for breast and colorectal cancers above highlights previously highlighted gaps:

1. Patient outcomes, care coordination, shared decision-making, patient/family engagement, and other factors intrinsic to the episode framework are not fully captured by current measures.
2. Current measures do not take into consideration the multidisciplinary and interdisciplinary provider teams working across multiple and varied care settings involved in cancer care. These factors must be taken into account in order to report on measures for the full episode of cancer care and to be able to make comparisons between providers and settings.
3. Current measures are focused on the most common cancers and should be broadened to assess quality of care for less common and rare cancers.
4. Measures are needed to assess access to and delivery of appropriate psychosocial and palliative/end-of-life care for cancer patients and their families.

Technical Issues Moving Forward

In addition to these recognized gaps, there are several technical issues that workshop experts suggest must be addressed in order to close these measurement gaps. The technical issues are not limited to the list provided below, but offer information on some of the most significant hurdles that remain with respect to technical needs.

The first of these is that there are still significant data needs required to gain a full understanding of the experience of cancer care diagnosis and treatment. According to the White Paper presentation at the workshop, because there are many different diagnoses, treatments, providers, preferences, etc., cancer quality measurement requires the collection and aggregation of varying data sources. Furthermore, no existing database (e.g., claims, registry, etc.) contains all the needed elements to measure quality, regardless the framework (e.g., traditional, episode-based, or other). Admittedly, gathering all this data would be time consuming, resource intensive, and costly, but is necessary in order to move forward.

A second area of technical issues exists with respect to the real-world testing of measures. While a number of quality measures have been proposed, many have not been tested in routine clinical settings. (There are several notable exceptions – e.g., American Society of Clinical Oncology’s Quality Oncology Practice Initiative, National Hospice and Palliative Care Organization’s end-of-life care efforts). Hassett and Bach suggest that it would help to focus efforts on: (1) establishing a framework for testing the feasibility and reliability of existing measures and (2) better understanding the results of current cancer quality measurement efforts.

Finally, efforts to prioritize the development and implementation of measures to fill the identified gaps will need to consider the measurement burden placed upon providers.

Because there are many different clinical conditions, health care providers, treatment settings, and outcomes that could be measured, the approach to closing the measurement gaps must take into consideration the financial and practical implications of increased measurement. And while prioritizing efforts may help those involved be more sensitive to this burden, questions remain about how best to prioritize which measures, populations, and/or outcomes to target. For example, value-based methods, such as cost-effectiveness, frequently prioritize treatments for common conditions that improve survival above all else. Alternatively, consensus-based methods incorporate other outcomes, but with added costs and complexities. Any and all paths forward should take this into strong consideration.

The Path Forward: Expert Recommendations of Needs and Next Steps

In an effort to fully capture the expertise assembled at the Workshop, a concluding exercise was conducted whereby each attendee offered two concrete recommendations for closing the cancer care quality measurement gaps highlighted above. The recommendations encompass a wide range of issues and have been categorized into major categories, including:

- a. patient-centered measurement;
- b. data and measurement issues;
- c. models of accountability; and
- d. explicit consideration of palliative and psychosocial care needs.

While the recommendations detailed within this workshop summary do not comprehensively capture all that must be achieved to continue to measure and improve the quality of cancer care in the United States, they offer concrete and critical suggestions for a path forward, taking into consideration all aspects of care, complex as they may be.

A. Patient-Centered Measurement

One of the most apparent themes across the suggested recommendation for closing the cancer care quality measurement gap was a call for patient-centered measurement. Experts spent significant time discussing that a focus on outcomes and cross-cutting issues must come first, but also that shared decision-making and clear communication were critical as well.

With respect to the focus on outcomes and cross-cutting issues, experts suggested focusing on broad cross-cutting measures (e.g. symptom management, end of life, communication around transitions, psychosocial distress) rather than specific cancers. As the episode model tries to capture, other experts agreed that including patient-reported outcomes into the system for measuring quality of care would also be necessary moving forward. Additionally, in order to assist any care provider in delivering care that is responsive to patients' needs, discussion of symptom management during initial

development of plan of care should be included in structural measures, perhaps with the development of validated questionnaires for appropriate cancer related symptoms (such as nausea, vomiting, fatigue, pain, etc.) which physicians can use in regular patient follow-up calls.

Shared decision-making and clear communication were also important points to the experts to capture in patient-centered measurement. Specific recommendation within this realm included the need to improve informed decision-making on the part of the patients and their families; patient preferences ought to guide the creation of measures that matter to patients (communication, coordination, shared-informed decision making, palliation/symptom management always, etc.). In fact, some experts suggested that there are multiple domains (e.g. communication, information, continuity) that are currently being measured by hospice (Family Evaluation of Hospice Care Survey, for example, which has been endorsed by NQF) that could be adopted now across all cancer care sites for all patients regardless of point in disease trajectory. Discussing and managing expectations was also highlighted as critical to a patient-centered approach.

B. Data and Measurement Issues

As discussed in the measurement gaps section earlier, significant needs exist around securing the correct and relevant data elements; expanding upon the current guidelines and evidence base; pushing beyond process measures to outcomes measures; and supporting a framework and system for all of the measurement needs.

Specific recommendations with respect to data needs included the need to capture the initial stage of cancer as well as the disease status of the patient, and to specifically do so on claim forms if possible. Data systems ought to be standardized to capture these and various other elements of the episode of care model.

Building upon the strong foundation on NCCN Guidelines, experts called for measures that assessed adherence to these guidelines. Well suited for initial attention may be the common/important problems with good evidence in support of effective interventions, as well as the evidence of wide practice variation. However, many of the experts agreed, as noted earlier, that pushing beyond the current focus on guidelines and process measures toward outcomes measures would present a fuller picture of the quality of cancer care being delivered.

Finally, experts called for the creation of a framework to support quality measurement and public reporting of cancer care, particularly to assist in the prioritization of measure development. The trajectories and aspects of care must be understood by all, and furthermore incorporated through harmonized data elements into strong, capable information technology systems.

C. Models of Accountability

Given the complex, multi-provider and multi-setting nature of cancer care highlighted throughout this summary, next steps clearly point to the need for shared accountability across health professionals and provider organizations. As such, multidisciplinary care coordination emerged as a strong recommendation from the experts.

Cancer care practices and organizations must demonstrate that multi-disciplinary cancer care (including not only the usual providers, but also medical measuring and ancillary specialist) is applied at the time of diagnosis. Multi-disciplinary teams should be incentivized to coordinate and communicate throughout the episode of care. Improving systems of care and care coordination is also of high interest at the health plan level.

D. Psychosocial and Palliative Care Needs

Perhaps one of the strongest set of recommendations to emerge from the group of experts was the call for both psychosocial and palliative care needs to be addressed explicitly and throughout the episode of care.

The important issue to measuring both access to and utilization of these services was a key recommendation. Support for public reporting of NQF-endorsed end-of-life measures was also suggested. The NQF framework for measuring episode efficiency, with specific attention placed on patient-reported outcomes related to quality of life and symptom management, can assist in understanding and encouraging development of such measures, as can the previously mentioned endorsed measures for palliative/end-of-life care. Most importantly, the assessment of psychosocial and palliative care needs of the patient and family were called for much earlier in the episode of care, if not at the very start. NQF's endorsed framework, *A National Framework and Preferred Practices for Palliative and Hospice Care Quality*, offers guidance on these aspects of care as well.

Conclusion: Next Steps

It is clear that barriers exist today that do not allow for providers and communities to offer the best possible care to all cancer patients. Current measures are limited in scope and significant data and research needs exist. Furthermore, as various stakeholders in the continuum of cancer care begin to work to close the measurement gap and achieve more efficient and more valuable care for the patient, the role the patients and their families play will prove critical to any future success, as will the level of coordination between the multiple care providers and settings. Measurement's reach will also need to consider broadening beyond the clinical setting and into communities, where the much-needed psychosocial and palliative care supports can be provided and the cultural and social factors associated with cancer development and treatment (including disparities) addressed.

NQF has been active in taking steps to help close this gap. As the convener and a Partner of the National Priorities Partnership (NPP), NQF has worked with 27 other key stakeholders in health and health care to establish national priorities and goals for performance measurement and public reporting. The Partnership has identified an initial set of six national priorities (patient and family engagement; population health; safety; care coordination; palliative care; overuse), with corresponding goals and actions. Several of these priorities directly relate to the gaps and path forward described in this summary, particularly palliative care, patient and family engagement, and overuse. The full list of priorities and corresponding goals can be found on the NPP web site at www.nationalprioritiespartnership.org.

Taken together, the recognized gaps in cancer care quality measurement and the expert recommendations provided through this NQF workshop provide a better understanding of key measurement gaps and a conceptual framework—patient-focused episodes of care—for moving forward.

Appendix A:

Towards a Comprehensive Cancer Measure Set – Value-Based Episodes of Care: Workshop Planning Committee

Patricia A. Ganz, MD (Chair)

UCLA Schools of Medicine and Public Health, Los Angeles, CA

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Bridges to Excellence, Newton, CT

Paul Jacobsen, PhD

Moffitt Cancer Center, Tampa, FL

Marsha Nelson

American Hospice Foundation, Washington, DC

Lee Newcomer, MD, MHA

United HealthCare, Edina, MN

Louis Potters, MD, FACR

North Shore - Long Island Jewish Health System, New Hyde Park, NY

Karen Stanley, RN, MSN, FAAN

Connecticut Hospice, Wilton, CT

Ellen Stovall

National Coalition for Cancer Survivorship, Silver Spring, MD

Larissa Temple, MD, FACS

Memorial Sloan Kettering Cancer Center, New York, NY

NQF Staff

Karen Adams, PhD

Vice President, National Priorities

Anisha S. Dharshi

Program Director

Appendix B:

**TOWARDS A COMPREHENSIVE CANCER MEASURE SET:
VALUE-BASED EPISODES OF CARE**

**Marriott Metro Center
775 12th Street, NW
Washington, DC 20005**

May 20, 2008

WORKSHOP AGENDA

- 8:30 am Welcome & Opening Comments
Janet Corrigan, PhD, MBA, NQF, President and CEO
*Patricia Ganz, MD, UCLA Schools of Medicine and Public Health
and Planning Committee Chair*
- Message from our Sponsors
Marybeth Farquhar, AHRQ
Steven Clauser, NCI
- 8:45 am **Panel I (A)**
**Current State of Cancer Quality Measurement Field: A Retrospective
and Prospective Approach**
- White Paper Presentation: Overview of Current State of Cancer Quality
Measurement Field (Retrospective)
Peter Bach, MD, MAPP, Memorial Sloan-Kettering Cancer Center
*Michael Hassett, MD, MPH, Dana Farber Cancer Institute and
Harvard Medical School*
- 9:30 am Discussion Period with Invited Participants
- 10:15 am Break
- 10:30 am **Panel I (B)**
**Discussion of Key Gaps in Cancer Care and Necessary Measures:
Prospective Approach**
- Key Gaps in Cancer Care: What Areas of Cancer Quality Need to be
Addressed? (Prospective)
Ellen Stovall, National Coalition for Cancer Survivorship
Lee Newcomer, MD, MHA, UnitedHealthcare

- 11:00 am Planning Committee and Cancer Community Reactants
Louis Potters, MD, North Shore-Long Island Jewish Health System
Linda Lillington, DNSc, RN, Oncology Nursing Society
Carlos Gomez, MD, Georgetown University Hospital
- 11:45 am Discussion Period with Invited Participants
- 12:15 pm Working Lunch
- 1:00 pm **Panel II**
Measurement Framework: Application of Episode of Care Framework to Cancer Care
- Review of Episode of Care Measurement Framework
François de Brantes, MBA, Bridges to Excellence
- 1:30 pm Application of Episode of Care Measurement Framework to Cancer Care: Necessity and Modified Model
Patricia Ganz, MD (breast cancer perspective)
Larissa Temple, MD, Memorial Sloan-Kettering Cancer Center (colorectal cancer perspective)
Paul Jacobsen, PhD, Moffitt Cancer Center (cross-cutting perspective)
- 2:00 pm Discussion Period with Invited Participants
- 2:45 pm Break
- 3:00 pm **Panel III**
Final Cancer Care Recommendations for NQF and Federal Government
- Review of Suggested Measurement and Prioritization Areas and Key Delineation of Next Steps
Paul Jacobsen (summarization)
- 4:15 pm Closing Comments
Janet Corrigan
Patricia Ganz
- 4:30 pm Adjourn

Appendix C:

**The Current State of
Cancer Quality Measurement**

A background research paper for

*Towards a Comprehensive Cancer Measure Set:
Value-Based Episodes of Care*

An NQF workshop convened to guide the development and
endorsement of future cancer quality measures.

Michael J. Hassett, MD, MPH

Instructor of Medicine,
Dana-Farber Cancer Institute & Harvard Medical School,
Boston, MA

Peter B. Bach, MD, MAPP

Associate Attending Physician,
Memorial Sloan-Kettering Cancer Center,
New York, NY

Dedicated to **Dr. Rodger J. Winn** who passed away April 4th, 2007 from esophageal cancer. Through his roles as co-chair of the National Quality Forum's Quality of Cancer Care steering committee and chairman on the National Comprehensive Cancer Network's guidelines steering committee, Dr. Winn played an integral role in efforts to develop practical and rigorous cancer quality measures.¹

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I) Introduction

In 1996 the Institute of Medicine published “Crossing the Quality Chasm”.² The opening of the Executive Summary read:

The American health care delivery system is in need of fundamental change. Many patients, doctors, nurses, and health care leaders are concerned that the care delivered is not, essentially, the care we should receive.

It went on to note that: “Between the health care we have and the care we could have lies not just a gap, but a chasm.” A report from the National Cancer Policy Board of the Institute of Medicine followed shortly thereafter.³ It drew the conclusion that: “for many Americans with cancer, there is a wide gulf between what could be construed as the ideal and the reality of their experience with cancer care.” The report emphasized that:

There is no national cancer care program or system of care in the United States. Like other chronic illnesses, efforts to diagnose and treat cancer are centered on individual physicians, health plans, and cancer care centers. The *ad hoc* and fragmented cancer care system does not ensure access to care, lacks coordination, and is inefficient in its use of resources.

The quality of cancer care

To be sure, these are dire assessments of the quality of healthcare available to Americans both in general, and specifically for those with cancer. Few have questioned the veracity of the Institute’s conclusions. The data suggesting that the healthcare provided to patients in the United States neither parallels long-established best practices nor takes rapid advantage of important biomedical advances are convincing. In cancer, for the vast majority of cancer diagnoses, there are studies showing shortfalls in the quality of care received.⁴ A recent review of treatment in the National Cancer Institute's Patterns of Care study documented that among 7,000 patients diagnosed with one of the 11 most prevalent cancers, fewer than two thirds of patients received care that was consistent with clinical practice guidelines.⁵ Even in those areas where the gains in patients’ outcomes are likely to be the greatest, practice varies and adherence to recommended approaches falls short. The use of adjuvant chemotherapy in patients with node-positive colon cancer is below 75% in multiple studies.^{6,7} Even for common surgical procedures, such as surgery for early stage breast cancer, adoption of the National Institute’s of Health standards has been spotty.⁸ Radiotherapy for rectal cancer and surgery for lung cancer are other services that are definitively underutilized relative to the potential benefits they could deliver.^{9,10}

The quality gaps afflict more than the care given to patients who have just been diagnosed with cancer. For patients at risk of cancer, proven cancer screening tests are underutilized. Nationwide, fewer than 40% of patients are up to date with colon cancer screening recommendations, and 50% of patients have never had any evaluation for colon cancer.¹¹ The “Pap test” for cervical dysplasia and cervical cancer is not yet available in some communities, despite its introduction into medical practice early last century. Today, between 60% and 80% of women who develop cervical cancer in the United

States have not had a Pap smear in the past 5 years. This is despite the fact that it was introduced more than 60 years ago, is stunningly efficacious at preventing death, and is relatively inexpensive. (www.cancer.org)

Cancer survivors are not guaranteed high quality care either. A recent report from the National Cancer Policy Forum – “Lost in Transition” – painted a gloomy picture of the challenges these patients face, noting that:

Barriers facing cancer survivors and their providers in achieving quality survivorship care include (1) a fragmented and poorly coordinated cancer care system; (2) the absence of a locus of responsibility for follow-up care; (3) poor mechanisms for communication; (4) a lack of guidance on the specific tests, examinations, and advice that make up survivorship care; (5) inadequate reimbursement from insurers for some aspects of care; and (6) limited experience on the best way to deliver care.

Empiric research supports these conclusions. Among women who have had breast cancer, only about half receive routine surveillance mammography annually as recommended, even though many receive surveillance mammography too frequently.¹² Moreover, there is evidence that cancer survivors do not always receive other non-cancer preventive services as recommended.¹³

There is a concern that patients who recur or have cancer that is unresponsive to initial treatments may also not be receiving the best care. This is a challenging area to study. What constitutes appropriate care processes is not always well specified, and identifying patients who have recurred is not straightforward, particularly in large administrative data sets. At present, the extent to which these patients receive sub-optimal or over aggressive care is therefore not well known. Nevertheless, there is a sense that many patients who have advanced disease that is refractory to initial treatment receive additional therapies that provide little opportunity for benefit and a higher than acceptable risk of complications and toxicity.¹⁴

Anecdotes about patients receiving multiple different unproven therapies for metastatic disease are frequent. For example, Lee Newcomer MD commented that the 248 patients with pancreatic cancer treated within the UnitedHealthcare network received 188 different chemotherapy regimens. This is all the more alarming when one realizes that only a handful of chemotherapy medications have been shown to prolong survival in such patients, and the survival benefits associated with these medications are extremely modest.^{15, 16} Each additional line of treatment imposes additional burdens on cancer patients, in terms of side effects, time and money. That many patients appear to be receiving chemotherapy into their last days of life, relatively few utilize hospice care, and of those who enroll in hospice many do so for only a few days, are often cited as examples that cancer care is too aggressive.^{17, 18} A more patient-centered approach to cancer care might focus somewhat more on palliation rather than active treatment. End of life care in general is hard to scrutinize, and the normative standards for it are not universally agreed upon. Nevertheless, the abiding sense is that the dying experience for cancer patients is not handled well by the care system.

Another challenge is that quality appears to vary a great deal based on the care provider or care setting, providing another mechanism by which overall cancer care

quality may be sub-optimal. Numerous studies have documented strong “volume-outcome” relationships for major cancer surgeries.¹⁹ The absolute risk difference for 30-day mortality for patients undergoing either pancreatectomy or esophagectomy for cancer differs by around 10% between high and low volume hospitals.²⁰ Similarly, complication rates after commonly performed procedures, such as prostatectomy, vary to a great extent based on experience, and also between surgeons who are experienced.²¹ These surgical “volume-outcome” relationships suggest that a great deal of potential health gain is not captured. The provider-dependent variation in quality affects other services as well. For example, there is evidence that different skill levels between physicians performing colonoscopies leads to substantial differences in the effectiveness of screening colonoscopy.²² And a large literature points to inconsistencies in the interpretation of screening mammograms based on the radiologist’s experience.^{23, 24}

Along with variable quality, there are concerns about the care experience. For diagnosed patients, care is frequently described as uncoordinated or fragmented. Patients easily get lost in a maze of conflicting views, incomprehensible explanations, and confusing guidance, and when they receive treatment recommendations, they often confront substantive financial tradeoffs, where the treatments they are offered are accompanied by co-payments that are many thousands of dollars. An acknowledgement of the extent of care fragmentation and confusion intrinsic to cancer care has prompted the creation of an entire new specialty service for cancer patients – patient navigation.^{25, 26} Patient navigation aims to help individuals negotiate the care maze, with its attendant complexities, multiple specialists and treatment options, and financial challenges. Some research suggests that navigation enhances care quality and patient satisfaction, but its mere existence demonstrates that the current cancer care system has deep shortcomings.

Lastly, no serious deliberation about improving cancer care quality can be undertaken without considering the enormous and rising costs associated with cancer treatment. The last decade has seen the introduction of numerous expensive diagnostics and treatments, such that the major media regularly features stories about cancer patients who are unable to afford the care recommended to them by their physician. Part of the reason is that physicians and hospitals have financial interests that are not aligned with the patients whom they treat. Greater profits are to be had when more services are rendered, and in many cases, the profit margin also increases when the service itself is more expensive. As it is unlikely that greater utilization of more expensive services is *de facto* the route to high quality care, a neutral payment mechanism for hospitals and doctors is much more likely to be an enabler of quality than the current incentive system.

Potential approaches to improving quality

There is relative consensus that quality will not consistently improve throughout the care continuum unless active steps are taken to measure care quality along multiple dimensions. This cancer quality assessment movement is propelled by two assumptions. First, that quality is inconsistent, as outlined above. Second, that quality measurement could improve quality of care.²⁷ These assumptions do not help to clarify the extent to which quality measurement for oncology care is feasible, how measurement should shape care delivery, or whether quality measurement is even acceptable to providers and patients.

Some have suggested that to successfully change care practices, it is necessary to pair evidence-based medicine with evidence-based management.²⁸ Perhaps, quality measurement can only lead to quality improvement when these two components are combined effectively. The use of proven evidence-based management practices for oncology care, particularly integrated quality improvement efforts like disease management programs²⁹⁻³¹, have lagged in part because of the complex nature of cancer care and the challenges associated with coordinating care effectively (discussed in greater detail below).

Moreover, the relative proportion of the quality equation that can and should focus on structure (such as use of Electronic Health Records), process (such as adherence to practice standards), outcomes (such as 30-day mortality or recurrence rates), patient experience of care (such as patient satisfaction), and efficiency remains unsettled. As suggested above, all seem to be appropriate domains to explore. The relative merits of each depend to some extent on the goals of quality measurement as outlined below.

Quality monitoring for internal evaluation

It is routine at this point for institutions and health organizations to implement internal quality assessment and quality improvement programs. In oncology, the National Comprehensive Cancer Network program gathers information on adherence to practice guidelines within its member institutions. These adherence measures are used largely for feedback to the institutions. An advantage of the approach is that the NCCN gathers data from multiple institutions, and as a result, an institution can determine whether or not it is performing below, at, or above the performance of its peers. It is assumed that at a minimum, the targets achieved by the higher performing institutions should be within reach. In general, the member institutions have access to performance statistics for the other member institutions, while reports released to the public provide de-identified data only.

The American Society of Clinical Oncology sponsors a program called the Quality Oncology Practice Initiative. In the program, oncology practices monitor their performance along multiple dimensions of quality through a systematic set of chart reviews. Then, the practices, much like the NCCN institutions, submit their data to a central repository, and thus a set of benchmarks are created. Each practice can view its data and the pooled and anonymized data from other practices. Here again, one principle of the approach is that comparison to one's peers provides a reasonable way of assessing where quality can be feasibly improved. Studies from the QOPI project have suggested that the process has led to quality improvement.³² Reports from ASCO also suggest that the number of practices participating in QOPI is growing steadily.[personal communication, Kristin McNiff]

In other words, efforts to measure quality so that institutions or practices can gauge themselves and identify room for improvement rest largely on the supposition that internal comparisons will motivate improvement, without the public knowing which institutions or practices are higher performing. It is also worth noting that in both the case of NCCN and QOPI, the exercises are occurring among a self-selected group of participants. It remains an open question whether these processes could encompass a substantial proportion of either institutions or practices that provide cancer care.

Quality measurement for public reporting

Unlike quality measurement with confidential feedback, public reporting of quality has the potential to drive quality improvement because it creates an openly competitive framework between practices or institutions. The “penalty” for non-participation is also more severe, in that institutions and practices that are silent about their quality can be made to look questionable when other institutions and practices are transparent about theirs.

Competition between institutions may be further stoked by a fear of losing contracts or patients, or just by a desire to use quality metrics as part of public relations materials. There are relatively few experiences to date in the use of public reporting of cancer quality measures to date. Most experience has been garnered at the hospital level or plan level, and typically the measurement is broad based. For instance, the Department of Health and Human Services maintains a hospital quality comparison website, where general measures of acute care can be compared between hospitals (www.hospitalcompare.hhs.gov). Similarly, plans can be compared based on the HEDIS measures, which include some measures of cancer screening.

The notable exception at this point is the National Commission for Quality Assurance (NCQA) oncology practice recognition program, which makes public the ratings of practices. The number of practices participating, however, remains small relative to the number of practices delivering cancer care. (www.ncqa.org) [Phil Renner personal communication] Despite the nascence of quality reporting as a strategy for improving quality, at least one preliminary report suggests that hospital quality has improved as a result of public reporting of measures.²⁷

Payment for reporting quality measures

The Oncology Demonstration projects run by the Centers for Medicare and Medicaid Services in 2005 and 2006, and the institution of quality measurement through the Physicians Quality Reporting Initiative (PQRI) begun in 2007, are illustrative of the range of approaches a government payer might take to obtain quality measures in oncology. In each of these projects, measures of quality were gathered from physician offices. In the Oncology demonstration projects, physicians were paid directly for submitting ‘measures’. In the 2008 version of PQRI, which primarily focuses on care of non-cancer conditions, there are 13 measures related to the management of cancer (out of 138 total measures). There is no direct payment for reporting, but participation leads to eligibility for bonuses.

The Oncology demonstration projects and PQRI provide some other insights. All used the ‘claim form’ (technically the HCFA 1500 form) to gather quality information. To facilitate reporting using this form CMS created additional billing codes that were unique to the measures for which data were being gathered. In 2005, the focus was on gathering patient symptom data at the time of chemotherapy administration in physicians’ offices. A payment of \$130 accompanied the submission of measures on patient pain, nausea, and fatigue. Participation rates exceeded 90% (OIG report). In 2006, the focus shifted to measuring disease stage and process and the payment was decreased to \$23. Physicians, in the context of Evaluation and Management visits, submitted codes describing the purpose of that visit, the patient’s disease status, and whether their care adhered to established practice guidelines. Participation rates were high in this

demonstration project as well at mid-year 2006 (year end estimates have not been published).

The data from these demonstration projects could hypothetically be used to profile the quality of care received by cancer patients in Medicare, and this information could be made available to the public in a manner comparable to the “hospital compare” project. Such steps have not yet been taken. So, at this point the Demonstration projects should be considered “pay for reporting” without public disclosure. However, several further steps have been contemplated and openly discussed, including public reporting of quality and payment for quality (or “pay for performance”).

Pay for Performance (P4P)

Payment for performance can be thought of as a broad effort by payers to reimburse health care providers when they meet pre-specified performance targets. This general approach may include payment for quality, payment for efficiency, or both. It is fair to characterize payment for quality in oncology more as a concept than a widespread operational reality. There are no large-scale programs where oncologists or institutional cancer care providers receive payments that are somehow indexed to the quality of care they provide. There are, however, scattered anecdotal reports of payers and institutional cancer care providers incorporating P4P quality targets into their reimbursement contracts [Michael Hassett, personal communication].

Several barriers may be functioning to restrict the adoption of P4P in cancer care, including the limited array of validated measures, the challenges with gathering sufficient high-quality data, and the lack of scientific evidence that P4P efforts foster quality improvement. UnitedHealthcare and US Oncology (the largest privately held network of oncology practices in the United States) have announced an initiative designed to explore the feasibility of assessing the quality of systematically delivered care. They are evaluating the care provided to clinically similar cohorts of breast, colon and lung cancer patients treated using the US Oncology Pathways, and comparing them to the care provided in the broader community, where care tends to be more tailored by individual physicians. If the program, involving approximately 2,500 patients, demonstrates that there are advantages to the Pathway-based approach to care, then there will be discussions of alternative payment systems that reward the efforts required to develop and implement standardized approaches to treatment. It is expected that the Pathways program will provide patients with both higher quality and also lower cost care.

Efficiency and Value

In recent years, other concerns about cancer care quality have emerged, including a concern about its high cost, its inefficiencies, and its comparative value. Of course, cancer care is not homogenous. Some services are highly cost-effective, and others are very expensive while providing minimal (or sometimes no) benefit. The rising cost of cancer drugs has drawn some of the spotlight. Many new cancer treatments that have extremely high price tags have been approved in recent years. Most were initially approved for the treatment of patients with refractory metastatic disease – a pattern that may reflect the realities of the regulatory path to approval more than the clinical situations where the drugs have maximal efficacy. This phenomenon has created a scenario in which the most expensive drugs in the armamentarium are being directed at

patients who are expected to experience very marginal benefits and face little or no prospect of cure. Thus, they are oft cited examples of wasteful spending in cancer.³³

Concerns regarding the structure of the cancer care delivery system, including the potential that lack of care coordination leads to redundant or missing services, have also surfaced. These concerns can be linked back to work by the Dartmouth Atlas Healthcare Project, which has shown convincingly that while resource utilization varies across regions of the country, quality and outcomes do not vary similarly.³⁴ In other words, spending more on care does not necessarily yield better outcomes. When one considers 1) the millions of Americans who do not have access to cancer care because they lack health coverage and 2) the resource-constrained nature of our health care system, the inefficient use of health care resources quickly becomes more than just a question of efficiency.

How to operationalize and measure the concepts of value and efficiency and how to improve the allocation of cancer care resources remain unsettled issues. In the most basic terms, both efficiency and value should be conceived of as fractions: the numerator is expressed in units of benefit and the denominator is expressed in units of resource consumption. Under this paradigm, we conceive of them as fundamentally the same construct. The most basic example of a value measure comes from cost-effectiveness analyses, in which a specific unit of benefit (the numerator) is anchored to a finite degree of health gain, and presented relative to a specific unit of resource consumption (the denominator) often characterized in dollars. While there has been some acceptance of this method for deciding between two distinct treatment options, there has been some resistance to using it in situations where resource allocation issues arise.³⁵ This is in part because large scale efforts to allocate resources using incremental cost-effectiveness ratios have met with both societal resistance and methodologic challenges.

The example of cost-effectiveness analysis sheds light on the challenges intrinsic to measuring value and efficiency more broadly. Cost-effectiveness analyses are usually limited to evaluating at most a handful of alternative treatment choices where only one decision between options must be made. The focus on a single outcome as well, such as the gain in quality adjusted life years due to a single treatment, highlights the narrow scope of current value-based assessments. Ideally, the assessment of value would extend beyond this narrow definition to include benefits like patients' experience with care, patients' comprehension and satisfaction with their decisions, and the quality of follow-up and survivorship care. Clearly, this sort of continuum will be hard to capture using binary quality measures focused on specific metrics.

It appears increasingly clear that the most widely accepted paradigm for quality measurement – the process based quality measure – may not marry well to the challenges and goals of measuring efficiency and value. Cancer care presents several particularly challenging aspects on this front. It is intrinsically multi-disciplinary and longitudinal, involving many caregivers working in many care settings who are paid using different mechanisms. It is also not a single disease or even a set of related diseases – it encompasses dozens of different conditions that have different treatment approaches, different prognoses, and different complications. So many conditions with so many treatments suggests that constructing individual quality measures based on care processes would be enormously complex, and their ascertainment and reporting by providers enormously burdensome.

For example, one of the most oft-cited quality measures – the use of adjuvant chemotherapy in patients with node-positive colon cancer - applies to only 5% of all patients at the time of cancer diagnosis. This statistic actually overstates the relevance of this measure to cancer care in general, as it reflects the proportion of patients at initial diagnosis who would be members of the denominator of this measure. When these patients develop recurrent or metastatic disease, or become terminally ill, or enter longitudinal follow-up as survivors, the measure would no longer apply to them, even though these domains are ones that arguably should be a focus of quality measurement.

Quality and Efficiency measurement in Cancer: A way forward

This paper was developed at the behest of the National Quality Forum, as a background on which to base a new quality measurement and reporting effort in cancer. As we have noted, the forum's efforts are justified: there are shortfalls in the care received by patients who are diagnosed with cancer. As we have also noted, there have been some notable steps forward in the quality measurement arena, and thus much to be learned from what has been done already. Lastly, we foresee a set of substantive set of challenges ahead.

In this paper, we endeavor both to summarize where the cancer quality measurement effort has been and where it should go. In doing so, we are trying to condense a tremendous body of work produced by others in many settings and with many purposes. The next section focuses on the unique challenges we face in cancer quality measurement. The third section outlines existing quality measures and key stakeholders who are active in cancer quality measurement. We do not anticipate that our lists will be all encompassing – there could very well be excellent measures in use that we did not identify, and organizations that were left out but should not have been. Some readers will notice that we have not included any measures or other efforts related to cancer screening, despite its public health importance. This was a conscious decision on our part which was motivated by a belief that the endeavor of screening touches fundamentally different parts of the healthcare system.

A final section discusses possible ways forward. This section presented some challenges to us, as we present our opinions and views on the field. In doing so, we acknowledge that our ideas and opinions are just a tapestry of other people's ideas developed and elaborated over the course of the healthcare quality movement. We have endeavored to point readers to other sources that discuss the positions we advance, and thus credit those whose ideas we reiterate.

II) Unique Challenges of Cancer Quality Measurement

There are many unique features to cancer and its treatment that make assessing the quality of cancer care particularly challenging. 1) Cancer therapy often involves multiple different providers functioning simultaneously and/or sequentially. This multidisciplinary team can include a surgical oncologist, a medical oncologist, a radiation oncologist, a radiologist, and at times a palliative care specialist, and in almost all cases involves an interdisciplinary approach to care that incorporates physicians, nurse practitioners, physician assistants, nurses, social workers, psychiatrists/psychologists, primary care physicians, and others. 2) Cancer treatments occur in many different settings, including the hospital, the outpatient clinic, the ambulatory infusion center, the radiation oncology treatment center, the radiology department and the palliative/hospice care facility; in some circumstances treatments in different settings occur concurrently. 3) Cancer care can be acute, sub-acute and chronic, and the change from one type of care to another can be abrupt and unexpected. 4) Cancer is not one medical condition but rather a series of distinct medical conditions defined by cancer type and stage; different measures and benchmarks may be needed to assess quality for different cancer types and stages. 5) Cancer care also incorporates crosscutting issues that apply across a range of different cancer types and stages (e.g., pain/symptom management, end-of-life care, etc.). 6) Cancer care utilizes personalized medicine, including the incorporation of prognostic and predictive variables, more frequently than many other medical specialties. 7) The evidence base that guides cancer treatment is constantly evolving, and the data often come from relatively small phase II clinical trials rather than large phase III randomized controlled trials. 8) Cancer treatments, compared to non-cancer treatments, are more likely to cause serious adverse effects and lead to substantial impairments in quality of life. 9) Cancer treatments sometimes rely on a limited supply of highly specialized personnel or technologies for which there are substantial initial acquisition and continued maintenance costs.

These characteristics confound efforts to measure the quality of cancer care in several ways. First, it is hard to identify a standard of care, because the resources available to treat cancer vary by region, the evidence base is evolving rapidly, experts may not agree what is optimal care, and patient preferences can influence treatment decisions. Second, it can be hard to determine which institution or provider is responsible for a quality measure, because care is often rendered across different providers working in different practice settings, and more than one person or institution may be responsible for any given decision. Third, it can be hard to design a quality measure that yields valid data about the entity being assessed, because once the different cancer types, stages and prognostic/predictive variables are considered, each measure may only apply to a small fraction of patients. Fourth, since cancer treatments are more likely to cause adverse effects, impair quality of life and confer substantial costs, measuring the extent of over-use is a particularly important, but underdeveloped aspect of cancer quality assessment. Fifth, some have argued that patient-reported outcomes (PROs) could be used to help assess the quality of cancer care, because the disease and its treatments can significantly impair quality of life; however, there are no agreed upon standards with regard to which PROs should be used or how they could be used to impact quality.^{36,37} Sixth, while most attempts to measure quality have focused on the acute-care setting (e.g., use of acetylsalicylic acid for acute coronary syndromes) or the

chronic-care setting (e.g., HbA1c targets for patients with diabetes), efforts to assess the quality of cancer care must function across these different care settings. As patients' clinical needs change when they move through the trajectory of disease, so do the components of care that need to be evaluated. Care coordination is an underdeveloped aspect of cancer quality assessment.

The following example elucidates some of the challenges associated with measuring the quality of cancer care. Consider a patient who has just been diagnosed with acute myeloid leukemia (AML). The care this patient receives could be provided in many different settings, including the primary care provider's office (where the condition might be diagnosed and long-term follow-up could occur), the hospital (where initial chemotherapy treatments could be administered), the oncology clinic (where visits with cancer specialists occur), and the infusion center (where treatments are administered). The care could also be provided by a series of different providers, including hematologists, transplant specialists, radiation oncologists, social workers, infusion nurses, psychiatrists and nutritionists. Perhaps the patient receives curative chemotherapy at one hospital, goes into remission and receives follow-up care from an ambulatory oncology practice. Then the patient's cancer relapses, at which point his/her care is transferred to another oncology practice and he/she is subsequently admitted to a different hospital for a bone marrow transplant. The complex nature of this patient's care and the fact that multiple care sites & providers are needed to provide this care confound efforts to assign responsibility for each aspect of care and to collect sufficient high-quality data to accurately measure quality. Since most community-based practices/hospitals are unlikely to see large numbers of patients with AML, it may be hard to generate reliable measures of the care they provide. And because AML is relatively uncommon and the evidence base is evolving, experts may disagree about the standard of care, making it harder to identify true indicators of quality.

The AML example highlights another challenge of cancer quality assessment as well – the fact that standards of care (i.e., indicators of quality) depend not only on the diagnosis but also on the stage. For example, assume the patient with AML develops heart failure from high dose chemotherapy. Does this event reflect poor quality care? If the patient is young and the goal is to cure the AML, then high dose chemotherapy may be appropriate and heart failure, while undesirable, does not necessarily reflect poor quality care. On the other hand, if the cancer progressed despite previous therapy and cure is not an option, then high dose chemotherapy is usually not appropriate and the heart failure may reflect poor quality care. In other words, which treatments should be given and how much tolerance one should have for side effects/adverse events vary by cancer type and stage. When cure is an option more aggressive treatments are administered and some ensuing side effects are expected, whereas when palliation is the goal less aggressive treatments are given and side effects are not tolerated as much. These intricacies make collecting the data needed to assess quality a daunting task. Many data elements are required, including patient variables (age, cancer type, stage, prognostic characteristics, co-morbid medical conditions, etc.), treatment variables (surgery, chemotherapy, radiation therapy, medical therapy, psychotherapy, supportive & palliative therapies), institution & provider variables, patient preferences, etc. Because most medical record, administrative, epidemiologic, and claims data sets do not incorporate all

these data elements, many quality indicators that appear to be valid targets are, unfortunately, not feasible.

Finally, by exploring the AML example further it is possible to envision the potential importance of psychosocial aspects of patient care, and thus appreciate an important potential blind spot for the quality measurement movement. This AML patient may also face anxiety, depression, fatigue, hair loss, nausea, mouth sores, prolonged hospitalizations, separation from family and friends, disability from work, loss of income, infertility, neuropathy, etc. Cancer care is not just about diagnosing and treating the primary disease; these other challenges must be addressed with the same care and sensitivity. Several broad types of psychosocial consequences exist. 1) Many cancer patients experience anxiety and depression, or struggle to cope with their diagnosis and its potential consequences. 2) Since cancer can cause symptoms and cancer treatments sometimes lead to side effects or adverse events, cancer patients frequently experience changes in their quality of life. 3) Many, if not most, patients who have cancer die as a result of their disease; consequently, end-of-life care is an integral aspect of cancer therapy. How well these psychosocial consequences are managed should be as much a focus of quality assessment as the clinical management of the primary diagnosis.

Several organizations have attempted to gather the variables needed to measure the quality of cancer care into one analyzable dataset. Their experiences suggest that doing so is a costly, time consuming and potentially prohibitive task. The National Comprehensive Cancer Network (NCCN) has taken a centralized approach. Since 1997, it has prospectively compiled data for all women with breast cancer treated at participating member institutions.³⁸ The data are collected via patient surveys conducted at each patient's first presentation and medical record reviews conducted by dedicated chart abstractors at regular intervals. The data elements include detailed patient, treatment, and outcomes variables. They are used to assess concordance relative to the NCCN's breast cancer treatment guidelines. Each participating institution enters its data into a central data repository via an internet portal.³⁹ In addition to the data repository and the internet portal, the resources required for this process include the chart abstractors who gather the data and enter it into the database, the programmer who maintains the database, and the analyst who compiles the quality measures.

Through the Quality Oncology Practice Initiative (QOPI), the American Society of Clinical Oncology (ASCO) has also taken a relatively centralized approach to quality assessment. Oncology practices that elect to participate in QOPI choose which quality measures within the QOPI measure set they wish to evaluate. They perform internal chart reviews during predetermined observation periods and enter results into a central database via a common web-based application. Participation requires an average of 1-2 days to identify charts and 15-40 minutes/chart to complete the abstraction & data entry processes. The number of charts sampled varies by the number of providers working at the site and the number/kinds of measures being assessed. Central personnel are required to maintain the database and conduct the analyses. Results are fed back to participating sites via a secure internet portal.

The challenges faced by Bridges to Excellence, in its effort to develop the Prometheus Payment model, further highlight the problems stemming from the lack of available data. The goal of this initiative has been to model evidence-informed case rates (episodes) for colon and breast cancer. Bridges to Excellence has found that claims data

sets simply do not provide enough information to parse out two major data elements: 1) cancer stage and 2) potentially avoidable complications in the outpatient setting. Because of these data gaps, Bridges to Excellence has put a hold on the development of cancer-specific episodes. In an attempt to address data gaps, UnitedHealthcare has started a voluntary program in which they ask oncologists for the initial stage at diagnosis via a fax form, and for an update of each patient's clinical status every six months. They also ask for other clinical parameters that affect treatment selection, such as HER2 and estrogen receptor status for breast cancer patients. So far, UnitedHealthcare has achieved a 55% compliance rate with this voluntary program at 6 months, and is using the clinical status and staging data to cluster patients into clinically similar groups for analysis. Is this the right approach? Can this sort of 'case by case' approach yield quality improvement?

Finally, one of the most significant challenges that stems from the complex nature of cancer quality measurement is with interpreting and using the data. The same complexity that makes the data-gathering process more difficult also confounds efforts to interpret the results of cancer quality measurement initiatives, especially by people who are not cancer specialists. If cancer quality measures are made publicly available how will patients use these data; will they derive benefit from seeing these data? Will institutions be able to use these data to perform surveillance and improve the quality of care? Can and should payers build incentives for performance based on these data? These questions are unanswered now, but will need to be addressed in the future – particularly if one supports the assertion that evidence-based management will be needed to successfully change care practices.²⁸

III) Previous Efforts to Develop and Catalogue Cancer Quality Measures

This section will outline previous major efforts to develop and catalogue cancer quality measures. First, we will outline efforts to summarize existing measures. Such efforts are most commonly coordinated by organizations that have a major interest in quality of care. A few examples include the Institute for Medicine (IOM), the National Quality Forum (NQF), and the Agency for Healthcare Research and Quality (AHRQ). Second, we will describe efforts to develop new cancer-quality measures. Such efforts are commonly sponsored by organizations that are primarily focused on cancer, such as the American Society of Clinical Oncology (ASCO), the American Society of Hematology (ASH), and the National Comprehensive Cancer Network (NCCN). Finally, we will discuss efforts to develop measures sponsored by organizations with a broader mandate, such as the American College of Surgeons (ACS), RAND, the National Hospice and Palliative Care Organization (NHPCO), and the National Health Service of the United Kingdom (NHS). AHRQ previously sponsored three reports designed to comprehensively summarize the quality measures that had been developed for breast cancer, colorectal cancer, and pain/symptom management.³ Rather than simply replicating these results, this review will focus on broad accomplishments with regard to the development of cancer-quality measures for all cancers with an eye toward identifying where future research and resources should be directed.

As proposed by the Agency for Health Care Research and Quality (AHRQ), this review will consider a quality measure to be “a mechanism to assign a quantity to quality of care by comparison to a criterion”⁴⁰. The terminology used to describe quality measures will reflect the naming conventions promulgated by the AHRQ. The focus will be on measures that address the evaluation, treatment and follow-up of patients with cancer. Measures targeting cancer screening will not be addressed herein, for several reasons. First, a relatively comprehensive and mature set of cancer-screening measures already exists. Of the 34-cancer measures cataloged by the National Quality Measures Clearinghouse (NQMC)⁴¹, more than half pertain to the detection of cervical, breast and colorectal cancer (e.g., the percent of women who had a mammogram within the last two years). Moreover, cancer-screening measures have been a part of the Health Effectiveness Data and Information Set (HEDIS) for several years. Finally, while cancer screening is a vital aspect of health care that should be the target of quality assessment efforts, it more accurately pertains to the general population than to the cancer population and the responsibility to coordinate cancer screening generally rests with primary care providers rather than cancer specialists.

The Institute of Medicine (IOM) does not create quality measures, but has contributed substantially to cancer-quality measurement efforts in the United States. First and foremost, it defined what high quality care should be – “the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”⁴² Through a series of publications in the 1990’s, which culminated in the widespread release of “To Err is Human” in 2000^{43,44} and “Crossing the Quality Chasm” in 2001⁴⁵, it helped raise public consciousness regarding the magnitude of the quality problem in the United States.

The Institute of Medicine (IOM) addressed the specific issue of cancer quality measurement in “Ensuring the Quality of Cancer Care”⁴⁶, in which it asserted that a

substantial cancer-quality problem existed, but acknowledged that it was hard to fully characterized the extent of the problem because few high-quality cancer-measures were available. Therefore, the publication made the recommendation to “measure and monitor the quality of care using a core set of quality measures,” and laid the groundwork for how measures should be developed and implemented. It argued that the first step should be to identify effective care through research systems. Then, specific quality measures should be developed to span the continuum of care for all common cancers (e.g., breast, colon, lung & prostate), and all measures should be tested within the health delivery system. Finally, it asserted that systematic improvements in health care quality would only come about if there were collaborative efforts between the public and private sectors to develop measures and coordinate quality improvement efforts.

In 2005, the IOM applied these principles to a specific situation. Together with the Georgia Cancer Coalition, they reported the results of a one-year study to select cancer quality measures that were supported by good quality evidence and could be used to help bolster Georgia’s efforts to assess and improve the quality of care offered to patients with common cancers (e.g., breast, lung, colorectal and prostate).⁴⁷ The project identified 52 measures pertaining to the prevention (10), early detection (5), diagnosis (14), and treatment (23) of cancer.

The Agency for Healthcare Research and Quality (AHRQ), through its National Quality Measures Clearinghouse (NQMC), has catalogued quality measures for many conditions including cancer. The measures are recorded using standardized terminology and a structured format. The goal is to facilitate widespread access to quality measures by interested parties in the health care community. To date, the NQMC has cataloged 34 quality measures pertaining to cancer. Most (almost 60%) pertain to cancer screening and detection. The non-screening measures mostly apply to specific cancers and target processes of care; only one process measure applies broadly across different cancer types (the percentage of patients with cancer who have a review of their case by a primary care practice/provider within six months of their diagnosis). Three measures address the structural domain – the volume of pancreatic resection, the volume of esophageal resection and the ability of a clinic or institution to produce a register of all cancer patients. Only two outcome measures are recorded – the mortality rates associated with pancreatic and esophageal resection.

The AHRQ and the National Cancer Institute (NCI) have worked jointly on the Cancer Quality of Care Measures Project since 2002. The first phase of this project, in which NQF and the RAND Corporation also participated, defined seven priority areas for cancer quality measurement.⁴⁸ Three were cancer-site specific: (1) breast cancer diagnosis and treatment; (2) colorectal cancer diagnosis and treatment; and (3) prostate cancer diagnosis and treatment. Four applied to multiple possible cancer sites: (4) access, including clinical trials and culturally competent care; (5) communications and coordination of care (including information technology uses); (6) prevention and screening (including interventions traditionally within the purview of the health care system); and (7) symptom management & end-of-life care. The second phase of the project reviewed the population of available measures with the goal of identifying those that were ready for use. The steering committee for phase II decided to focus on three topic areas selected from the seven priority areas – breast cancer, colorectal cancer, and symptom / end-of-life care.

First, evidence-based reviews were commissioned for each topic area. The results of these reviews, published as a series of evidence reports, outlined the existing array of quality measures for each area. A 2004 technology assessment titled “Measuring the Quality of Breast Cancer Care in Women⁴⁹,” surveyed the range of measures assessing the quality of breast cancer care in women and characterize the parameters that potentially affected their suitability for wider use. The review was conducted by the University of Ottawa Evidence-based Practice Center, and focused on measures for diagnosis, treatment, follow-up, and reporting/documentation of care. The study identified 143 quality indicators; most focused on processes of care and assessed whether or not women received indicated treatments. In addition to these process-based quality measures, this review notably also identified measures targeting structural aspects of care and care-coordination (e.g., referral to an oncologist for treatment and board certification of medical oncologists), and measures focusing on patient-reported outcomes like quality of life and satisfaction (e.g., overall satisfaction with care, change in quality of life before vs. after treatment; satisfaction with treatment choice, satisfaction with decision making, etc.). The authors concluded that only 12 measures were scientifically validated, and of those almost all were designed to assess the quality-of-life associated with cancer treatments (e.g., the Functional Assessment of Cancer Therapy Scale for breast cancer).

In 2006, “Cancer Care Quality Measures: Diagnosis and Treatment of Colorectal Cancer,” identified measures available to assess the quality of care provided to patients with colorectal cancer and evaluated the extent to which these measures had been tested. The review was conducted by the Duke Evidence-based Practice Center. The study focused on process measures that addressed 5 aspects of colorectal cancer care: 1) diagnosis (17 measures), 2) treatment (32 measures), 3) colonoscopic surveillance (6 measures), 4) pathology, operative & chemotherapy reports (17 measures), and 5) differences in quality of care across patients’ age, race/ethnicity, and/or socioeconomic status (49 measures). It found that coverage of general process measures across the various leverage points in the continuum of care was extensive, but that there was a need to refine some existing measures and to develop more technical measures (e.g., adequate lymph node retrieval and evaluation at the time of surgery). In the end, it concluded that the most important areas for future development were 1) to identify measures for areas in which they were lacking and 2) to better identify/focus on those measures that have the greatest impact on outcomes.

The technology assessment for symptom management and end-of-life care, also published in 2006, identified quality measures pertaining to the palliative care of patients with cancer – with a specific focus on pain, dyspnea, depression and advanced care planning. The analysis, conducted by the Southern California Evidence-based Practice Center, identified 40 operationalized and 19 non-operationalized measures. Most focused on pain (12) and advance care planning (21); a few addressed depression (4) and dyspnea (2). Unfortunately, few measures had been tested specifically in cancer populations. Consequently, the authors argued for 1) more testing of available measures (especially those created for depression) in cancer populations, 2) more research regarding how to measure quality in populations of patients with an impaired ability to self-report, 3) more measures to evaluate the quality of supportive pediatric cancer care, 4) more work to define ‘end-of-life’ patients prospectively, and 5) more research evaluating measures in important sub-populations (e.g., gender, race/ethnicity, and inpatients/outpatients). After

reviewing the results of these three technology assessments, the NCI endorsed 6-breast cancer, 4-colorectal cancer, and 9-symptom management/end-of-life measures.

Since 1999, the National Quality Forum (NQF) has attempted to address the recommendations outlined in “Ensuring Quality Cancer Care.” Through a public-private partnership, it has promoted a common approach to measuring cancer care quality through two initiatives. The goal of the Quality of Cancer Care Performance Measures project has been to identify a standardized set of evidence-based performance measures to be used for public accountability and quality improvement in 3 clinical areas -- breast cancer treatment and diagnosis, colorectal cancer treatment and diagnosis, and symptom management/end-of-life care. It has cataloged 6 breast cancer measures, 4 colorectal cancer measures, and 9 symptom management/end of life cancer care measures - all mainly focus on the institution level (e.g., hospitals, health plans). The goal of the National Voluntary Consensus Standards for Clinician Level Cancer Care project has been to identify and endorse measures for public accountability and quality improvement related to cancer care at the individual clinician level. The project was designed to address the Center for Medicare & Medicaid Services’ (CMS) need to identify quality measures for the Physician Quality Reporting Initiative (PQRI). So far, the NQF has identified 19 candidate consensus standards for this initiative. These measures span a relatively wide range of cancer care types (breast cancer, colorectal cancer, prostate cancer, myeloma and leukemia) and treatments (chemotherapy, hormonal therapy, radiation therapy, supportive therapy). They also include several crosscutting measures that apply to the spectrum of cancer care (e.g., plan of care for pain, cancer stage documentation, etc.).

The American Society of Clinical Oncology (ASCO) has participated in several efforts to develop cancer quality measures. In 2000, it sponsored the National Initiative for Cancer Care Quality (NICCQ) to develop quality measures for breast and colorectal cancer. To that end, NICCQ investigators reviewed scientific literature & pertinent guidelines, and proposed 108 measures for 7 domains of care: diagnosis and staging, initial therapeutic management, management of treatment toxicity, referrals and coordination of care, psychosocial support, patient preferences and inclusion in decision making, and surveillance after initial therapy. NICCQ then designed and implemented a prototypical quality monitoring system, and using data from several sources successfully evaluated practice performance relative to 61 of these measures. In 2002, ASCO introduced the Quality Oncology Practice Initiative (QOPI) to help facilitate practice-based quality improvement. The program provides to participating practices quality measures, automated data entry & reporting services, and quality improvement tools. The measures are derived from existing guidelines & standards, are intended to be consensus-based & clinically relevant, and are updated periodically. The spring 2008 list of QOPI measures includes 73 items that address symptom/toxicity management, end-of-life, clinical trial assessment, breast cancer, colorectal cancer, Non-Hodgkin’s lymphoma, lung cancer, and other core aspects of oncology care that apply generally regardless the diagnosis (e.g., pathology report confirming malignancy available in the chart.”)

The National Comprehensive Cancer Network (NCCN) is an alliance of U.S. cancer centers that has developed a comprehensive set of evidence-based guidelines for all major cancers. It also maintains a prospective database on patterns-of-care at member institutions for patients with breast cancer, colorectal cancer and lymphoma. Using these

two resources, the NCCN generates evidence and consensus-based cancer quality measures. In the past, these have been used mainly for internal reporting purposes, but an analysis of practice performance relative to 30 breast cancer quality measures will appear in press shortly. The breast cancer quality measures generated by the NCCN exclusively target processes of care. They assess both over-use and under-use, and pertain to major aspects of the initial care offered to women with breast cancer – e.g., surgery, chemotherapy, radiation therapy, hormonal therapy, etc. The measures identified by this analysis as having clinical impact, scientific acceptability, usefulness, potential for improvement, reliability and feasibility were used as inputs for consideration by the ASCO/NCCN initiative described above.

The American College of Surgeons was arguably the first organization in the United States to systematically address the issue of cancer care quality when it created the Commission on Cancer (CoC) in 1922.⁴⁹ In 1989, the CoC, together with the American Cancer Society, created the National Cancer Data Base (NCDB). This is an oncology outcomes database that captures institution-level data on 75% of all newly diagnosed cancers in the United States; it serves as a useful tool for patterns-of-care studies⁵⁰ as well as efforts to validate quality measures⁵¹. Each organization that contributes data to the NCDB tumor registry could use the data that it collects for its own internal quality measurement efforts. To our knowledge, there has been no central effort to catalogue these efforts (though such an effort could prove both informative and valuable). Nonetheless, the contribution that the NCDB has made to institutions' quality measurement efforts simply by making data collection a priority and establishing a framework in which it can occur systematically cannot be underrated.

In 2007, the CoC collaborated with ASCO and the NCCN to generate a series of breast and colorectal cancer measures to be submitted to the NQF's Quality of Cancer Care Performance Measures project (discussed above). Each organization contributed candidate measures, and after a review process five measures were approved by all groups. All were designed to assess care at the institution/systems level; none focused on individual provider performance. Four were endorsed by the NQF as accountability measures (to be used for public reporting, payment incentive programs and selecting providers); one was endorsed as a quality improvement measure (to be used for internal performance monitoring).

In an effort to assess the quality of radiation oncology care, The American College of Radiology (ACR) started conducting retrospective surveys of national radiation oncology practices in 1973. This Patterns of Care Study, perhaps one of the earliest efforts to systematically measure the quality of radiation oncology care, involved a series of recurring structure-oriented facility surveys, disease-specific projects in which processes of care were assessed (by comparing practice standards developed through literature review and expert consensus to data abstracted during the review of a stratified random sample of patient charts), and outcomes. While the name of this NCI funded effort has changed to Quality Research in Radiation Oncology (QRRO), its work continues today. In its most recent national process survey, QRRO facilitated the voluntary reporting of quality data at the facility and patient levels for the following cancers in which radiation oncology plays a major role: breast, cervix, lung, prostate and stomach. Process of care measures were defined based on the available evidence and

expert consensus. It is hoped that the survey will provide national benchmarks for numerous quality indicators, including aspects of care not backed by clinical trial data.

Several other organizations have attempted to develop and/or catalogue cancer quality measures. The AQA alliance, a joint effort of the American Academy of Family Physicians, the American College of Physicians, America's Health Insurance Plans, and the Agency for Healthcare Research and Quality, has worked to compile a set of measures that can be used to assess performance at the provider and group levels. As of October 2007, its compendium of approved measures lists 5 prostate cancer, 2 pathology, 8 oncology, 4 melanoma, 2 thoracic surgery, and a series of more general measures that could apply to cancer patients.⁵² The Centers for Medicare & Medicaid Services took a different approach to quality measurement in 2006 when it introduced the oncology demonstration project.⁵³ Rather than defining specific quality measures, it simply asked providers to report three data elements for each established patient encounter: (1) the primary focus of the visit; (2) the current disease state; and (3) whether current management adheres to clinical guidelines. Reporting options for the third category included (1) management adheres to guidelines, (2) management differs from guidelines because of enrollment in a clinical trial, (3) management differs from guidelines because the treating providers disagrees with the guideline recommendations, (4) management differs from guidelines because the patient chose an alternate treatment, (5) management differs from guidelines because of a patient's co-morbid condition or performance status, (6) patient's condition not addressed by available guidelines, and (7) management differs from guidelines for another reason not listed. Results from this program are eagerly awaited.

Cancer Care Ontario (CCO) is the provincial agency responsible for improving cancer services in Ontario, Canada. Since 2005, it has coordinated a relatively unique cancer quality measurement effort called the Cancer System Quality Index (CSQI). Its goals are to evaluate the cancer care system's performance and progress, to identify where improvements can be made, and to make the whole system more accountable. The CSQI includes 30 evidence-based measures spanning five aspects of cancer care: prevention, access, outcomes, evidence, efficiency and measurement. To facilitate quality assessment across the province and across all modalities of cancer care, measures were selected in part based on their feasibility in the absence of medical chart abstraction data and on their ability to have a system-level focus. The system was designed to complement, rather than supplant, the detailed program-level performance already used in Ontario largely for internal management purposes.

Most of the measures discussed above pertain to the care provided by physician providers or at large institutions (e.g., hospitals). While non-physician providers, such as nurses, pharmacists, nutritionists, social workers, etc., play an integral role in the provision of high-quality cancer care, their efforts have been the targets of quality measures relatively less frequently. The Oncology Nursing Society and the American Nurses' Association have worked to develop a framework for quality measurement in oncology nursing⁵⁴, as well as a core set of common data elements and a system for collecting & using these data to promote quality cancer care. Certainly, establishing workflows that ensure high quality care has been a major focus for oncology pharmacists, though efforts to publish systematically derived quality measures for oncology pharmacy care are uncommon.

End-of-life care is widely considered an integrally important aspect of cancer care, but the quality dimension of that care is uniquely hard to measure and often overlooked. Fortunately, there are several notable exceptions to this trend. Earle and colleagues⁵⁵ identified potential indicators of the quality of end-of-life care using administrative data: 1) Institution of new anticancer therapies or continuation of ongoing treatments very near death; 2) A high number of emergency room visits, inpatient hospital admissions, or intensive care unit days near the end of life; and 3) A high proportion of patients never enrolled in hospice, only admitted in the last few days of life, or dying in an acute-care setting. Separately, the PEACE Palliative Care Quality Measures Project⁵⁶, conducted by the Carolinas Center for Medical Excellence, compiled a list of 34 quality measures recommended by experts to be used by individual organizations to improve quality of care. The measures spanned 11 domains, including structure & process, many different aspects of symptom management and quality of life (e.g., pain, dyspnea, other physical symptoms, psychological symptoms, social aspects of care, spiritual aspects of care, and cultural aspects of care), care offered to the imminently dying, ethical and legal aspects of care and adverse events. To assist parties interested in using these measures, the authors also prepared tools to assist with patient selection and data collection.

The National Hospice and Palliative Care Organization (NHPCO) has taken a leadership position in this area, and has developed a series of quality measures that apply to all patients receiving hospice and palliative including cancer patients. For example, it developed the End Result Outcome Measures⁵⁷ to assess how well hospices achieve the goals of managing pain within 48 hours of admission, avoiding unwanted hospitalizations, and avoiding unwanted CPR. It also teamed up with Brown University's Center for Gerontology and Health Care Research to create the Family Evaluation of Hospice Care survey.⁵⁸ The purpose of this survey is to assess the quality of hospice care delivery from the perspective of family caregivers and to yield actionable information. From the perspective of quality measurement, the NHPCO's efforts are noteworthy, because they assess quality of care relative to patients' preferences (a shifting standard) rather than relative to pre-determined benchmarks defined by entities external to and uninvolved in the immediate care encounter (a fixed standard).

The large-scale efforts to develop and catalogue cancer quality measures discussed above are not nearly the only efforts that have been undertaken. Many other organizations have worked to describe cancer quality measures; unfortunately, discussing all of these efforts is beyond the scope of this paper. However, several broad conclusions can be made regarding past efforts to develop cancer quality measures and, particularly, the gaps that are still waiting to be filled:

- 1.) There are few measures available to assess the care offered to patients with some diagnoses and conditions. For example, while many measures have been proposed for some cancers (e.g., breast & colorectal), relatively few measures have been developed for other cancers (e.g., lung, prostate, pancreas, ovarian, lymphoma, etc.). The measures that are available tend to focus on the initial diagnosis and treatment of early stage cancer; fewer measures address follow-up care, the evaluation and treatment of later stage cancer, and end-of life care. Most of the measures that do address these other areas tend to focus on structural aspects (e.g., is

the patient in hospice) and processes that are only weakly linked to high-impact outcomes (e.g., amount of active treatment received prior to death).

2.) The scope of existing cancer quality measures is limited. Measures tend to focus on processes of care, especially those directed by institutions and physicians. While the care provided at **clinics** and by **non-physician providers** (e.g., nutritionists, social workers, nurses, etc.) are not commonly the focus of cancer quality measures, they are integral to ensuring the provision of care for the whole patient. While the measures outlined above frequently address quality of care from the perspective of best medical practice, they often do not address other aspects of cancer care delivery, such as survivorship, the psychosocial needs of cancer patients, the imperative to ensure that communication and respect are integral aspects of care, etc.⁵⁹ These concepts hold particular importance for cancer patients, given the physical, emotional, cognitive, personal, financial, family and other consequences that develop as a result of a cancer diagnosis. Finally, because of the complicated, multi-site, inter-disciplinary and multi-disciplinary nature of cancer care, coordination of care is a vital aspect of care that is insufficiently addressed by cancer quality measures.

3.) There are significant limitations associated with the technical qualities of many existing measures. There can be inconsistency with regard to the level of consensus and/or evidence upon which some measures are based. Not infrequently, measures sound more like clinical practice guidelines in that they lack a clearly defined numerator and denominator. Only rarely are measures updated as new data become available and treatments change. Testing of measures in the real world is uncommon. Benchmarks for most cancer quality measures do not exist.

4.) The goal of widespread implementation of quality measurement standards should be to improve quality of care. It is unclear how to best use quality measures to achieve this goal, and which measures are the best suited to facilitate such improvement.

5.) Despite these limitations, the number and breadth of efforts to develop cancer quality measures undertaken to date demonstrates an impressive willingness to make quality-of-care a high priority. Most importantly, the sincere commitment evidenced by these efforts encourages future attempts to build upon past successes.

IV) Approaching Cancer Quality Measurement

In developing a strategy for improving the quality of cancer care through measurement, reporting, and payment policy, there is value in defining the objectives of the strategy. One might imagine that the objectives are readily apparent: improve the quality of care. But in truth, there are multiple potential objectives, and the relative weight placed on each can influence the adopted strategy. Donabedian outlined a general framework for quality measurement along three dimensions: structure, process, and outcomes.^{60, 61} Undoubtedly, all are relevant. But, an examination of current quality measurement approaches makes it clear that on a relative basis, process measures predominate, structural measures are less common, and outcome measures are virtually non-existent. For instance, in the 2008 CMS PQRI, of the 138 measures that are included, only 2 are structural, while 136 are either process (use of a drug for a condition) or surrogate outcome (maintenance of a particular blood pressure level). Our impression is that this imbalance towards process and surrogate measures, and the relative absence of patient centered outcome measures, reflects current day realities of a quality measurement movement in its infancy.

Outcome measures

It could be argued that assessments of outcome are of greatest relevance to patients, and thus measuring outcomes might be the most appropriate way to enhance quality through measurement, reporting, and payment policy. Yet, the practical obstacles to the measurement of outcomes are multiple. Unlike structural measures, or to a large extent process measures, outcomes must be adequately risk-adjusted to be valid. Very little background work in oncology has been done on this front. There are no models for risk-adjusting disease specific survival, for example, for most cancer types. Beyond just the matter of comorbidity differences and their impact on the frequency of competing risks of death, differences in cancer prognosis are far from being understood, despite the discovery of some prognostic markers in some cancers, and the availability of commercial tests for estimating outcomes in some patient groups.

An additional practical obstacle to the use of outcome measures in cancer lies in the duration they take to develop. An outcome such as disease specific survival can take many years to determine. This means that outcome measures will necessarily reflect the quality of care delivered some time (usually years) before the time of assessment. As a result, outcome measures at the time of assessment are relevant to care delivered some time in the past – not necessarily to care delivered in the present. Physicians and institutions being measured based on their outcomes may resent being unable to demonstrate rapid improvements due to the time lag that outcomes entail.

Payment policy will be hard to marry to outcomes for similar reasons. In general, payments need to be determined relatively quickly. In the case of PQRI, bonus payments that are relatively small in magnitude (i.e. 1.5% of all payments) will be determined by the middle of 2009 for the calendar year 2008. As a practical matter, if the payments were a large proportion of revenues, an average of a one year delay before receipt would create a strain on physician practices, and so one would expect that payments would have to be tried up at the end of each quarter if they were large in size. For this to occur, the outcomes of the patients would have to be observed and measured within a short time frame.

Short term outcomes, such as complications occurring during an admission for a major cancer surgery, or death occurring within close proximity to a major cancer surgery (such as within 30 days) could feasibly meet this logistical requirement for outcome measures. Analyses of complication rates and short term mortality rates suggest that there are large differences in them between hospitals and between providers, and these results appear robust to risk-adjustment.^{19, 62, 63} Thus, it is conceivable that short term outcome assessment could be used as an approach to quality measurement. Standing in the way of such an approach is the reality that sample sizes will tend to be very small for such a purpose, and thus differences in outcomes between providers may be too influenced by chance variations to be acceptable or useful.⁶⁴

Longer term outcomes, such as survival rates, recurrence rates, or other such metrics of cancer treatment success, necessarily take far longer to evolve: multiple years in nearly all cases. So, it would be challenging to link payments directly to outcomes such as these. Whether general outcome statistics could be generated to profile facilities based on these longer term outcomes remains an open question. Such an endeavor has a certain intrinsic appeal, as it would be attractive to have facilities profiled based on their ability to achieve the outcomes that patients value most. But it should also be acknowledged that these types of measures would necessarily reflect performance of several years ago, making them less relevant to decision making in the present, and also harder to improve for facilities that seek to do so. .

In other words, despite the intrinsic appeal of measuring outcomes as a way of improving quality, there are numerous challenges to doing so. Perhaps for this reason, there have been only limited forays into measuring outcomes as a way of assessing care quality, except for research purposes. And so there are few working examples in other disease states on which to base an appropriate strategy.

Structural measures

At the other end of the spectrum lie measures of structure. Structural characteristics, such as staffing ratios, availability of special services like patient navigation, or the use of electronic health records or care pathways, are relatively easy to assess at either the practice or institutional level. Many of the Joint Commission's measures are structural, and measures in ASCO's QOPI project, such as ones determining whether medical records in a practice document a chemotherapy plan or include stage information, are arguable structural in nature.

There are several challenges that structural measures introduce. One is that many structural measures are not well linked to evidence. The use of electronic health records, for instance, has not been shown to improve patient's experience of care, the quality of their care, the continuity of their care, their survival, or the cost of their care in any consistent way. Yet, employing electronic health records has been frequently suggested as an appropriate structural measure to assess the quality of care available in a practice.

The paucity of evidence is not an accident. For many potential structural characteristics, it is very difficult to study the impact of them on care quality for a number of reasons that are beyond the scope of this paper. For many others, the sense that certain structural characteristics are important to care quality is so strong that it is difficult to imagine actually conducting studies to reaffirm these notions. As a result,

even for assumed advantageous characteristics, the extent of the outcome gain from these characteristics will remain unknown, and so the relative importance of them will too.

Changing the structure of a practice or institution, or introducing particular features to the practice or institution, can be an expensive proposition. Requiring oncologists to have electronic health records (EHR's), for instance, will be a tough sell without thorough documentation that quality is improved by having EHR's. Anecdotally, the price of a fully functional EHR to an oncology practice with a handful of physicians can easily exceed \$100,000, and annual maintenance can easily run in to tens of thousands of dollars. Even from a pure business standpoint, oncologists may decide that the additional potential payments they could receive if they purchased EHR's would not offset the costs of buying and maintaining them. That the extent of the possible payment for 'quality' is a moving an unpredictable target makes the business case even dodgier.

Despite these challenges, there is merit in considering some structural measures of cancer care quality, particularly if evidence emerges that some structural characteristics directly influence patient satisfaction or outcome. For instance, it seems reasonable to ensure that cancer patients receive care in practices in which cancer stage is routinely documented and available, where there is access to a care coordinator or some other individual who will aid the patient in navigating a multi-disciplinary care plan, and where a close interdigitation of treatment services with end of life and comfort services exists.

Process measures

As we noted, most work in cancer quality measurement has focused on process measures. We believe this is for three reasons. First, most processes that have been considered or introduced as quality measures are directly linked to high quality evidence from multiple randomized controlled trials. Thus, it can be concluded that when these processes are followed, better outcomes will be achieved. Second, most quality measurement in other conditions has focused on process measurement, and so it was logical to extend the paradigm to cancer. Lastly, the majority of literature on cancer care quality focuses on process deficiencies, and so the most direct approach to these deficits, and to monitor our ability to address them, is to measure these shortfalls.

The CMS Oncology Demonstration project of 2006 is an example of process measurement in oncology. The underlying question focused on whether or not care is being delivered according to evidence based standards. Some of the challenges posed by focusing on process measures we have already noted. In particular, the great deal of heterogeneity of cancer types and treatments means that very little of cancer care can be covered by any single measure. This means that either very little of care will be the object of measurement, or the number of process measures oncologists are asked to report will be voluminous – neither are particularly appealing from an implementation standpoint.

Framework for choosing quality measures: features of appropriate measures

Whether outcome, structure, or process measures, the approach to selecting and implementing particular measures should not be undertaken without consideration of several parameters. Included among these, measures should be those:

- a) Where there is a reasonable possibility that measurement will lead to improvement. There is not much merit in assessing a dimension of quality where

- performance is already very high, and also little merit where there is little likelihood that institutions or practices can achieve higher performance.
- b) That can conceivably have a large clinical impact should be considered in preference to those where the relative impact is likely slight. For instance, some evidence based process measures have a large potential to influence disease specific survival. Measures that enhance the utilization of recommended adjuvant therapy in breast or colon cancer are examples. By contrast, measures that focus on the delivery of only marginally beneficial treatments do not.
 - c) Are feasible to measure in a consistent manner with only minimal burden imposed on providers. Measures that can be generated from existing claims data are therefore highly preferable to measures that can only be obtained through chart review. Measures that focus on structure are also relatively easy to obtain, while measures that require additional coding are more burdensome (in general), and those that require chart review should be incorporated with caution.
 - d) That can be easily understood by consumers and purchasers. This is an important feature, as a movement towards consumer directed healthcare will require quality measures that fairly reflect the quality of providers in a manner that is transparent to patients and purchasers.
 - e) That are scientifically acceptable to the broadest possible degree. This is a key requirement of any quality measure, and often underappreciated in our estimation. Quality measurement, no matter how effortless, necessarily will result in winners and losers among providers and institutions: such is the consequence of comparisons. Therefore the dimensions along which providers are measured must be fully robust and acceptable, else the enterprise itself is threatened. One concern we have is the tempting notion that practice of medicine can be pulled faster forward through the introduction of quality measurements.
 - f) That are valid and reliable, meaning that the measures capture what they are intended to, and that they can be reproducibly recorded in a consistent manner when circumstances are similar.
 - g) That are either adaptable or robust to changes in the scientific evidence. Highly specific process measures can become invalid in the blink of an eye; highly general ones can lack specificity and therefore the power to improve practice.

Framework for choosing quality measures: prioritization

These basic standards for acceptable quality measures in cancer do not give insight into how measures should be prioritized. Here again, one could take the view that such prioritization should be straightforward: as ideal prioritization would reflect the intersection of potential gains through measurement with potential burden of measurement. But even within this framework, there are a number of different perspectives one could adopt, which are not necessarily mutual exclusive. In terms of the potential gain, we'd propose several different viable perspectives:

- a) Survival: traditionally, prolonging survival (or disease specific survival) has been the primary objective of cancer treatment. So even though the general trend in quality measurement is away from this basic endpoint, it would be reasonable to prioritize the selection of quality measures with an express intent of improving survival of patients with cancer.

- b) Quality of life/death: given that many patients afflicted with cancer have incurable conditions, and thus will eventually succumb to their disease, it would be reasonable to prioritize quality measurement approaches around ensuring that the quality of life of patients with cancer is enhanced. Such a focus might put measures of care coordination and comprehension, adequacy of pain relief, and availability of end of life care center stage, even though these measures are unlikely to have large effects on survival.
- c) Value/Efficiency: given that the cost of cancer care is rising, and the out of pocket costs of care are rising exponentially (www.cancer.org), the selection of quality measures could focus on those services and structural characteristics that are most associated with high value care. We discuss this notion in an ensuing section in more detail.
- d) Comprehensibility to consumers: to the extent that quality measurement and reporting has as its aim to make healthcare decision making more transparent, it would be logical to focus on measures that are easily comprehensible to consumers. Measures focused more on experience, or on outcomes that are known to matter to most patients (such as quality of life) would hold sway over technical measures of proficiency that might not be easily interpreted.
- e) Comprehensiveness: to the extent that quality measurement and reporting has the aim of shifting the focus in cancer away from individual treatments and towards the care of the whole patient, it would be logical to construct measures that were inextricably multi-dimensional. By necessity, these measures would have to be composites of individual uni-dimensional measures.

Framework for choosing quality measures: focus and setting

In choosing a focus for quality measurement and reporting, one can also conceive of a number of different frames of reference and setting. One of the challenges is that there is a logical temptation to measure and report on those things that are easiest to capture, while shying away from harder measurement challenges. This bias affects both the targeting of the measurement and its scope.

Focus on hospitalizations

For instance, it is somewhat easier to focus on measuring occurrences during a hospital admission. The “episode” is self contained, and it is generally believed that there is no ambiguity regarding the identity of the accountable provider: in the hospital, the hospital is accountable. Yet, the reality of care delivered in the hospital is more complicated. Within the facility are physicians and other healthcare providers making treatment decisions. Although some hospitals are ‘staff model’, in that the physicians are employed by the hospital, most hospitals are not structured this way; instead, in some places hospitals compete for physicians to bring their patients to them – particularly when they are revenue generating cases such as patients with cancer. So, there could be challenges for hospitals if they are asked to balance their competitive interest in attracting physicians with their competitive interest in performing well on quality measures that are directly affected by those same physicians.

More important, for most patients, only a small fraction of their cancer care is received during an acute hospital admission – far more is received from providers in physician offices, outpatient facilities, and at home. The cancer care episode then, necessarily, crosses provider boundaries and as a result, in only very rare cases is there a single clear provider who is accountable for the quality of care the patient has received.

Focus on episodes

This reality has prompted an interest in measuring quality during ‘episodes of care’, and we believe that undoubtedly this is the way cancer care should be conceived, financed, and measured, even though doing so will be difficult.

A cancer care episode is daunting conceptually. When does it begin? When does it end? Does it begin with the work-up of an abnormality prior to a diagnosis of cancer and end when the patient dies, irrespective of cause, b/c they will either have measurable disease or be a survivor – either way, still a cancer patient? Or, does a particular patient’s cancer treatment pass through many different episodes? Here, some compromise is probably needed, as the latter scenario has practical strengths, and we believe that in most cases it is possible to delineate different episodes of treatment within a particular patient’s cancer experience. Within each episode, coordination is needed, and quality in terms of process, structure, and in some cases outcome could be measured. Payment policy, which is typically fee-for-service, could be modified to marry to the concept of an episode of cancer treatment, and thus payments could be modified based on the quality of care during that episode.

In an example, a patient who undergoes colon cancer surgery, is found to have node positive colon cancer, and then receives adjuvant chemotherapy could be viewed as experiencing an episode of care – diagnosis and initial treatment, for instance. Current payment policy would atomize this care into the payment to the hospital (during the surgery), the payment to the pathologist (for interpreting the biopsy/tissue), the payment to the surgeon (for performing the surgery), the payment to the outpatient physician (an oncologist, perhaps) who counsels the patient on the findings and recommends adjuvant chemotherapy), and then multiple individual payments to the oncologist and physician practice or hospital outpatient department for the administration of chemotherapy. Other medical events that might commonly occur, such as the obtaining of an extra CT scan or PET scan, would be paid individually.

In this example, the entire course of care is what should be of importance to the patient, and thus the quality of that episode overall is what should be measured. Some overall measures that are patient focused would play a role: measures of satisfaction, comprehension, comfort. But individual measures focused on certain evidence based steps within the episode would also be included. For instance:

- 1) Surgical complications or mortality – evidence suggests this varies widely in colon cancer⁶⁵
- 2) The number of nodes dissected and evaluated by the pathologist – although still controversial, some studies suggest that outcomes are affected by this, while others are more neutral⁶³
- 3) The quality of care coordination – some studies suggest that a primary reason for patients not receiving adjuvant chemotherapy is that they

are lost in the transition from hospital discharge to initial evaluation by an oncologist.⁶⁶

- 4) The appropriate counseling regarding adjuvant chemotherapy and its appropriate use (correct drugs, doses, duration). Studies suggest that many patients in Medicare do not receive appropriate adjuvant therapy.^{6,67}
- 5) Appropriate plan of follow-up put in place, with evidence based surveillance recommended. Some studies suggest that surveillance is performed too often in many patients.¹²

A combined measure across these many different processes could pave the way for measuring episodes of cancer care. For patients with other types of cancer, similar episodes could be constructed, and quality measures attached, although we acknowledge that the example presented here is one where both the empiric data suggesting deficiencies and the abundance of medical evidence on what is effective care is unusual. Care for patients with recurrences or incurable conditions could and should also be conceived of in a framework of episodes. For these patients, multiple providers will often be involved, including not only oncologists but palliative care experts and radiation oncologists.

To make episode based measurement work, payment policy will have to line up with it. Otherwise, individual providers within the care continuum will have relatively less incentive to collaborate in the care of the patient, and some may not see the financial benefit of doing so. Therefore, payment should be ‘bundled’ to episodes, not to individual healthcare events. Some type of ‘risk adjusted’ prospective payment for all of the care a patient with a new diagnosis of node positive colon cancer could be determined from payer claims data that are currently available. How these payments should be distributed across multiple providers remains an open question, but the lack of financial integration between different providers is something that will need to be overcome.

Equally important, to make episode based payment work will require vastly more information about individual patient’s disease status at the beginning of an episode, as well as information about changing disease status within an episode. Even basic information about a cancer patient’s stage is not available in claims data. Even within particular stage groups, information is unavailable regarding a patient’s eligibility for particular treatments. Information about receptor status or mutation status, which is critical to treatment decisions and thus linked to large potential costs, is not routinely available in claims. Any move to episode based payment should address the lack of basic clinical information that would be needed to develop case rates.

Overall focus:

There are many challenges ahead in defining the correct measures, and how to group them together into episodes of care so that high quality efficient care can be identified. The ultimate objective is to improve patient care while managing costs. Numerous studies have demonstrated that such improvement and cost containment are both sorely needed. There are many ways that the effort can go wrong. Narrowly focused quality measurement can produce systems that ‘measure to the test’ – meaning that overall quality is not necessarily improved. There is a risk that quality measurement

activities can become added burden without much benefit, particularly if what is being measured is not particularly important to public health. And there is a risk that the quality measurement enterprise itself is used to paper over glaring shortcomings in the healthcare system overall. A few measures, it could be argued, will not fix our highly fragmented, disorganized cancer care system that focuses too much on delivering treatments and not enough on patient's experience or comprehension of their disease.

V) Unanswered Questions

What issues should be addressed by future research efforts? While much has been accomplished with regard to cancer quality measures, much remains to be done. Further research will be required to address a number of important issues.

- 1.) Many of the cancer quality measures that have already been developed need to be **tested in real world settings** to determine whether or not they are feasible and reliable. Furthermore, gathering real world data for existing measures will facilitate efforts to define realistic benchmarks.
- 2.) **Collecting large amounts of high quality data in a reliable and efficient manner** is one of the biggest challenges to comprehensively measuring the quality of cancer care. Future research should define which data elements are needed, how to gather data reliably and accurately, who should be responsible for data collection and what data sources should be used (e.g., claims, tumor registry, medical records, patient surveys, etc.)? Specific questions include...
 - a. How can existing data resources (such as cancer registries) be used most effectively and efficiently? A survey of NCDB-participating institutions to see how they use registry datasets for internal quality monitoring might provide useful information regarding how these datasets can be used moving forward (this effort would not require collecting the actual results of these monitoring efforts). Also, an analysis of the successes, failures, and lessons learned from the CMS's and other organizations' recent quality monitoring efforts – including the demonstration project and PQRI initiative – are eagerly awaited.
 - b. Are new data collection methods needed, and if so, then what should they look like?
 - c. How much will data collection cost and who will pay for it?
 - d. Is it possible to define a minimum set of data elements needed to allow cancer quality measurement? If so then who should be responsible for defining this minimum data set and updating it over time?
- 3.) **Information technology (IT)** systems, such as electronic medical records, computerized provider order entry systems and results reporting systems, are becoming increasingly common among oncology practices. Future research should explore if/how these systems can be used to leverage efforts to measure cancer care quality. Do existing IT systems contain data elements that can be used to measure quality of care, and if so then which ones? Could IT systems be enhanced to include the data elements needed to facilitate quality measurement; if so, then would providers use them? For example, would medical oncologists and pathologists be willing to record stage data using categorical response categories rather than simply dictating text notes?
- 4.) **Quality measures have been developed for some aspects of cancer care, but not others. Future efforts must work to fill in these holes.** Quality measures are needed to evaluate selected cancer types, patients with recurrent/metastatic disease, care provided by non-physician providers (e.g., nurses, pharmacists, social workers, etc.), care coordination, and notably to

assess cross-cutting aspects of care (e.g., psychosocial, follow-up/long-term care/survivorship, patient-reported outcomes, end-of-life care, etc.). More measures are also need to address the structure and outcomes aspects of cancer care.

- 5.) One accepted principle regarding the development of quality measures is that they should be scientifically acceptable. In practice, this usually means that measures target clinical situations where there are high-quality data and/or experts agree. However, in cancer care there are many situations for which no such data are or every will be available. **Is it possible to develop measures of quality for clinical situations in which there are no large, phase III randomized controlled trials and experts do not always** (e.g., should efforts be made to develop quality measures for rare cancers or should efforts focus only on common cancers)?
- 6.) **Patient preferences** play an integral role in cancer care, both for patients with localized and recurrent/metastatic disease. How should patient-preferences be considered when assessing quality of care? Do we assume that patient preferences are largely influenced by providers and ignore them when measuring quality? Or, do we attempt to exclude patients who prefer not to receive recommended treatments from the denominators of quality measures? If we adopt the latter approach, then how do we accurately assess patient preferences in all situations without getting results that are confounded by providers' opinions?
- 7.) **Tools are available to assess patient reported outcomes.** Which tools are the best and most practical ones to use, and how can these tools best be used to improve the quality of cancer care?
- 8.) Accountability measures are used by patients, payers and others to analyze and compare practice performance. **Is public reporting of quality measurement data different for oncology than other specialties?** Does it have different implications? Are specific types of measures more useful to patients than others? Is a focus on 'survival' obligatory, given that the notion of "cure" and "survival" are foremost in the public's mind? Given the relatively prevalent notion that there is a volume-outcome relationship, should cancer quality measures designed for the purposes of accountability address this issue more extensively? Should a focus of future research be on what patients want or need to know?
- 9.) **How are measures interpreted by the parties who use them, such as patients?** Can patients be taught how to use cancer quality measure data? What are the consequences of communicating quality data to patients (and other interested parties)? Do patients understand these data? Do these data influence how patients select providers? Do they make patients more anxious? Do they improve quality of care?
- 10.) Do existing quality measures sufficiently address the issue of **disparities** (whether caused by geography, race/ethnicity, socioeconomic status, etc.), or are other measures needed?
- 11.) The **episode of care** paradigm offers interesting, if untested, potential. For example, it may offer the opportunity to assess the care experienced by a

patient throughout the course of his or her illness. What are the advantages and disadvantages of this approach? To what extent do the 1) multidisciplinary complex nature of cancer care, 2) the need for large amounts of data from different sources when measuring quality, and 3) the need to attribute responsibility in order to target quality improvement efforts confound the adoption of the episodes framework? Are there particular aspects of oncology care for which this framework is an ideal or suboptimal method of quality assessment? More generally, is there a need to rigorously study whether or not (or, to what extent) different types of quality measurement impacts different domains of care?

What practical and policy issues need to be addressed? In addition to the need to learn more about cancer quality measurement, we must make choices regarding the political and practical aspects of cancer quality measurement.

- 1.) **How best can a consensus-based organization like NQF coordinate with cancer specific professional organizations or large provider organizations?** Are there particular types of quality measures on which large national organizations, professional bodies, or local entities should focus that will best serve the larger agenda? If so, then which ones?
- 2.) **How should the responsibility to measure quality-of-care be divided among the interested parties?** In other words, which aspects of quality measurement should occur at / be the responsibility of the various interested parties at the national, state, health-plan, institution, clinic and provider level? How much, if any, of the quality measurement process should be mandated (vs. voluntary), and if so them whose responsibility is it to mandate this?
- 3.) **Who should collect the data and compile the results?** Does this depend on the measure or other factors?
- 4.) While the costs of cancer quality measurement are unknown, they are likely to be significant. **Who will pay for efforts to gather data and measure quality of care?** If IT systems are going to be a part of quality measurement, who will pay to build, implement and maintain these systems (patients, health-plans, purchasers, federal or state agencies)?
- 5.) As a result of the many ongoing clinical trials being conducted for cancer, standard practices change frequently. **How will the health care system ensure that measures are updated regularly,** who will be responsible for updating measures, how frequently should this occur, and what will it cost?
- 6.) Should costs be factored into efforts to measure quality or should costs and quality be considered separately (i.e., **what role should efficiency-based measure play**)? What consequences stem from efforts to integrate quality assessment and cost control? When measurement efforts incorporate distinct concepts that are sometimes at odds with each other, such as outcomes, costs and patient-centeredness, how do measures (or users of measures) balance the relative importance of these distinct priorities?

- 7.) **Is efficiency/value a socially acceptable construct?** To what extent does it function as a way to reduce overuse vs. as a way to allocate resources based on relative values? Historically, this latter construct has met with resistance in the United States.
- 8.) Establishing standard definitions for the data elements used to measure quality would facilitate efforts to assess practice performance and allow the reporting of results that are comparable. **Should data standards be established, and if so then by whom?**
- 9.) Given that most quality and efficiency measurement activity to date has focused on clinical (i.e., doctor-centered) processes, **how can patient centeredness be introduced most effectively into measurement efforts?** What are the strengths and weaknesses of different approaches? How do we emphasize that patient experiences matter in the curative as well as the palliative setting?"
- 10.) **What are the mechanisms by which quality measures most effectively lead to improvements in quality of cancer care?** Given that resources are limited, is it best to focus on accountability measures, pay-for-performance, quality improvement measures, or some combination of each?
- 11.) Given the resource constrained environment within which our health care system operates, it may not be possible to measure quality as broadly and thoroughly as some may like (or as may be optimal). **Choices will have to be made regarding which measures should receive the highest priority.** How will these choices be made? Who should make these decisions? To what extent should this prioritization process be data-driven, consensus-driven, or other? What resources, methods or mechanisms are currently available / need to be developed to assist with this effort?
- 12.) As is clear from this report, many cancer quality measures have been developed. **How can the results of this and other similar projects that identify best quality-measurement practices be disseminated most widely to ensure optimal adoption by all interested and involved parties?**

VI. Conclusions & Recommendations

At the National Quality Forum workshop, “Towards a Comprehensive Measure Set,” several recommendations were made regarding the future direction of cancer quality measurement...

- 1.) Given that quality problems exist now, participants expressed a strong desire to identify not only those areas where research is needed, but also those areas where **immediate improvements** can be made to the quality of care currently being administered (i.e., do not forget to target the ‘low hanging fruit’).
- 2.) **Cross-cutting clinical issues** (e.g., quality-of-life/patient reported outcomes, survivorship, end-of-life care, psychosocial care, etc.), play an important role in the care of many, if not all, cancer patients and should be the focus of greater efforts to develop and implement quality measures.
- 3.) Beyond simply developing new measures, it is important to **find simple and efficient ways to identify high-priority measures**; the current consensus/evidence-based approach involving large committees of interested parties can be overly cumbersome and time-consuming (especially when one considers that cancer treatments are changing relatively rapidly).
- 4.) Participants expressed particular interest in assessing quality for some processes for which there is little evidence linking concordant performance with better outcomes, or for situations where there are significant challenges to producing reliable and valid measurements (e.g., patient-centered outcome measures, documentation of cancer stage, creation of a survivorship care plan, care coordination, etc.). Research is needed to elucidate the role such measures could and should play.
- 5.) **It is important to better understand whether / how measures can be used to improve quality-of-care, and to develop paradigms / frameworks for facilitating the use of quality measures as tools that facilitate quality improvement in real-world clinical practice.** This requires understanding the potential mechanisms by which measurement could impact quality (e.g., pay-for-performance, internal assessment, public reporting, etc.) and developing practical methods for implementing these mechanisms. Several examples of practical methods for implementing quality measures already exist. For example, organizations have created tools for abstracting chart data at clinical sites (e.g., ASCO developed QOPI and the American College of Radiology developed QRRO), practices have developed and started to use disease & stage-specific pathways to guide practice and facilitate measurement (R. Hoverman & T. Smith, personal communication), and investigators/payers have begun to develop real time quality assessment using claims/administrative datasets (L. Newcomer & S. Edge, personal communication). More such efforts are needed, and studies exploring the impact existing efforts have had on quality are warranted.

- 6.) Some providers and payers consider inconsistent care to be an indicator of poor quality care. **More research is needed to define appropriate benchmarks for situations in which care is inconsistent, and to understand when it is appropriate to conclude that consistent care yields more favorable outcomes.** This may have particular importance when establishing benchmarks within the episode framework.
- 7.) **The episode of care framework is a potentially valuable tool for cancer quality assessment and cost containment. However, barriers to implementing this framework exist.** For example, should episodes be defined using cancer type, stage, or a combination of the two? Can non-claims based data sources be used in conjunction with claims datasets to assess quality of care using the episodes framework; if so, then which data sources are available? Should cross-cutting aspects of care, such as end-of-life care, represent unique episodes or be incorporated into cancer-type specific episodes?

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Appendix A: Stakeholders

Entity	Contacts	Activities
Aetna, Chicago, IL	Burton F. VanderLaan, MD Region Medical Director	Member, NQF Quality of Cancer Care Measures Steering Committee
Agency for Healthcare Research and Quality, Rockville, MD	Marybeth Farquhar, RN, MSN Senior Advisor, Quality Indicators Initiative	Member, NQF Quality of Cancer Care Measures Steering Committee
Ambulatory Quality Alliance/Hospital Quality Alliance/Pharmacy Quality Alliance		Consensus building groups on measurement. AQA with 4 cancer specific measures.; HQA with generic surgical quality measure; John Tooker (AQA chair)
American College of Radiology – Quality Research in Radiation Oncology		
American Cancer Society, Atlanta, GA	Harmon Eyre, MD Chief Medical Officer,	Insurance reform, outreach, practice guidelines (in prevention) Member, NQF Quality of Cancer Care Measures Steering Committee
American College of Surgeons Commission on Cancer	Steven Edge, MD	NCDB (with ACS); Quality measures; reporting at hospital level
	Andrew Stewart	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
American Hospice Foundation	Marsh Nelson, ACSWQ, Vice President	Developing a template for a publicly reported hospice report card Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
American Medical Association – Physician Consortium for Performance Improvement	Gregory Wozniak	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
American Nurses Association	Rita Munley Gallagher	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
American Society of Clinical Oncology Health Services Committee, Alexandria, VA	Kristen McNiff & Theresa Mulvey	NICCCQ project ASCO/NCCN quality measures Member, NQF Quality of Cancer Care Measures Steering Committee Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
American Society of Hematology, Lutherville, MD	Eric Seifter, MD, FACP	Member, NQF Clinician Level Cancer Care Steering Committee
American Society for Therapeutic Radiology and Oncology (ASTRO)	David Adler Emily Wilson	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
Blue Cross Blue Shield Association	Carole Redding Flamm	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”

Entity	Contacts	Activities
Bridges to Excellence	Francois de Brantes	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
The Brookings Institution	Joachim Roski	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
California Health Decisions, Orange, CA	Ellen Severoni, RN President	Member, NQF Quality of Cancer Care Measures Steering Committee
Cancer Care	Diane Blum	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
Cancer Quality Alliance, Washington DC	Ellen Stovall (NCCS) Patricia Ganz (ASCO)	
Centers for Disease Control and Prevention, Atlanta, GA	Mary C. White, ScD Chief, Epidemiology and Applied Research Branch	Member, NQF Quality of Cancer Care Measures Steering Committee
Centers for Medicare and Medicaid Services, Washington, DC	Melinda Jones, MS Health Insurance Specialist	Member, NQF Quality of Cancer Care Measures Steering Committee
Connecticut Hospice	Karen Stanley	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
Cox College of Nursing and Health Sciences, Springfield, MO	DeLois Weekes, DNSc, RN President and CEO	Member, NQF Quality of Cancer Care Measures Steering Committee
Dana-Farber Cancer Institute, Boston, MA	Craig Earle, MD, MSc Michael Hassett, MD, MPH	Member, NQF Clinician Level Cancer Care Steering Committee Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
DC Pediatric Palliative Care Collaboration	Carlos Gomez	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
EHR vendors –		Incorporate measures (custom)
Fox Chase Cancer Center, Cheltenham, PA	Suzanne Miller, PhD	Co-Chair, NQF Clinician Level Cancer Care Steering Committee
Gentiva Health Services	Mara Benner	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
George Washington University Medical Center	Gene Colice	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
High Value Healthcare Project/QASC	Mark McClellan, Brookings Institution	Data sharing and aggregation, quality measurement/improvement for cancer and disparities, efficiency in cancer
Hospital Corporation of America	Dennis Martin	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
IPRO, Lake Success, NY	Thomas W. Hartman, BA Director,	Member, NQF Quality of Cancer Care Measures Steering Committee
The Johns Hopkins Kimmel Cancer Center, Baltimore, MD	Antonio Wolff, MD, FACP	Member, NQF Clinician Level Cancer Care Steering Committee

Entity	Contacts	Activities
Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL	Jerod M. Loeb, PhD	Member, NQF Quality of Cancer Care Measures Steering Committee
The Leapfrog Group	Suzanne Delbanco (leaving)	Quality standards for surgical volume
Louisiana State University Medical Center, New Orleans, LA	Vivien W. Chen, PhD Chair, Epidemiology Program and Acting Associate Dean	Member, NQF Quality of Cancer Care Measures Steering Committee
Markey Cancer Center, Lexington, KY	Alfred M. Cohen, MD Director and CEO	Member, NQF Quality of Cancer Care Measures Steering Committee
Medical College of Wisconsin, Milwaukee, WI	Christopher Schulz, MD	Member, NQF Clinician Level Cancer Care Steering Committee
Memorial Sloan-Kettering Cancer Center, New York, NY	Robert E. Wittes, MD Physician-in-Chief	Co-chair, NQF Quality of Cancer Care Measures Steering Committee
	Peter Bach, MD, David Pfister, MD, Larissa Temple, MD	Participant, NQF Workshop "Towards a Comprehensive Cancer Measure Set"
Moffitt Cancer Center	Paul Jacobsen	Participant, NQF Workshop "Towards a Comprehensive Cancer Measure Set"
National Breast Cancer Coalition, Sioux Falls, SD	Patricia Haugen	Member, NQF Clinician Level Cancer Care Steering Committee
National Business Group on Health, Washington, DC	Helen Darling, MA President	Co-chair, NQF Quality of Cancer Care Measures Steering Committee
National Cancer Institute, Bethesda, MD	Steven Clauser, PhD, Senior Scientist for Performance Measurement and Program Evaluation,	Member, NQF Quality of Cancer Care Measures Steering Committee Participant, NQF Workshop "Towards a Comprehensive Cancer Measure Set"
National Cancer Policy Forum of the IOM	Roger Herdman; Hal Moses	Various topics in quality, costs, innovation
National Coalition for Cancer Survivorship, Silver Spring, MD	Ellen Stovall Executive Director	Member, NQF Quality of Cancer Care Measures Steering Committee
National Committee for Quality Assurance, Washington, DC	Greg Pawlson, MD, MPH Executive Vice President	Member, NQF Quality of Cancer Care Measures Steering Committee
National Comprehensive Cancer Network (NCCN)	Bill McGivney	Practice guidelines, compendia, core resource for 2006 CMS demonstration; combined effort with ASCO on quality measures
	Mark Krasna	Participant, NQF Workshop "Towards a Comprehensive Cancer Measure Set"

Entity	Contacts	Activities
National Hospice and Palliative Care Organization (NHPCO)	Carol Spence, MS, RN Director of Research	Development, data collection and comparative reporting poor performance measures related to hospice and palliative care; national initiative to provide tools and resources to assist hospices with quality assessment and performance improvement
North Shore – Long Island Jewish Health System	Louis Potters	
Oncology Nursing Society, Pittsburgh, PA	Gail Mallory, PhD, RN	Member, NQF Clinician Level Cancer Care Steering Committee
	Linda Lillington	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
Partners HealthCare, Boston, MA	Craig C. Earle, MD, MSc	Member, NQF Quality of Cancer Care Measures Steering Committee
Providence St. Joseph Medical Center, Burbank, CA	Christopher Rose, MD Department of Radiologic Oncology	Member, NQF Quality of Cancer Care Measures Steering Committee
Quality Oncology Practice Initiative	Joseph Simone; Peter Eisenberg; ASCO	
Roswell Park Cancer Institute, Buffalo, NY	Michael Kuettel, MBA, MD, PhD	Member, NQF Clinician Level Cancer Care Steering Committee
	Stephen Edge, MD & Boris Kuvshinoff, MD	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
Susan G. Komen for the Cure	Cindy Geoghegan	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
UCLA School of Medicine and Public Health	Patricia Ganz, MD	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
UCSF Comprehensive Cancer Center	Robert A. Hiatt, MD, PhD Director of Population Sciences and Deputy Director	Member, NQF Quality of Cancer Care Measures Steering Committee
United Healthcare, Edina, MN	Lee Newcomer, MD, MHA	Co-Chair, NQF Clinician Level Cancer Care Steering Committee Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
University of Michigan, Ann Arbor, MI	James Montie, MD	Member, NQF Clinician Level Cancer Care Steering Committee
	Arden Morris, MD, MPH	Member, NQF Clinician Level Cancer Care Steering Committee
	James Hayman	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”

Entity	Contacts	Activities
University of Minnesota, Minneapolis, MN	Michelle van Ryn, PhD, MPH Associate Professor,	Member, NQF Quality of Cancer Care Measures Steering Committee
University of Washington School of Medicine	Jesse Fann	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
US Oncology	Lloyd Everson, Russell Hoverman, and others	Practice Guidelines, prospective/capitated payment Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”
Unaffiliated	Joseph Simone, MD Simone Consulting, Dunwoody, GA	Member, NQF Quality of Cancer Care Measures Steering Committee
Unaffiliated	James Mortimer, BA Consultant, Barrington, IL	Member, NQF Quality of Cancer Care Measures Steering Committee
VCU-Massey Cancer Center	Thomas Smith, MD	Participant, NQF Workshop “Towards a Comprehensive Cancer Measure Set”

Appendix D:
**Specifications of the National Voluntary Consensus Standards for
Quality of Cancer Care**

BREAST CANCER

MEASURE	<u>IP OWNER¹</u>	<u>NUMERATOR</u>	DENOMINATOR	INCLUSIONS/EXCLUSIONS/ ADJUSTMENTS	DATA SOURCE/REPORTING
Post-breast conserving surgery irradiation	American College of Surgeons (ACS)	Radiation therapy to the breast initiated within 1 year (365 days) of date of diagnosis.	Include, if <u>all</u> of the following characteristics are identified: <ul style="list-style-type: none"> • Women. • Age 18-69 at time of diagnosis. • Known or assumed to be first or only cancer diagnosis. • Primary tumors of the breast. • Epithelial malignancy only • AJCC Stage I, II, or III. • Surgical treatment by breast conservation surgery (surgical excision less than mastectomy). • All or part of 1st course of treatment performed at the reporting facility.² 	Exclude, if <u>any</u> of the following characteristics are identified: <ul style="list-style-type: none"> • Men. • Under age 18 at time of diagnosis. • Over age 70 at time of diagnosis. • Second or subsequent cancer diagnosis. • Tumor not originating in the breast. • Non-epithelial malignancies. • Stage 0, in-situ tumors. • Stage IV, metastatic tumors • Surgical treatment by 	Data Source: <ul style="list-style-type: none"> • Medical record or tumor registry. • Data item and code definitions available via Facility Oncology Registry Data Standards (FORDS) manual.

¹ Intellectual Property owner. For the most current specifications and supporting information please refer to the IP owner.

MEASURE	IP OWNER ¹	NUMERATOR	DENOMINATOR	INCLUSIONS/EXCLUSIONS/ADJUSTMENTS	DATA SOURCE/REPORTING
			<ul style="list-style-type: none"> Known to be alive within 1 year (365 days) of diagnosis. 	<ul style="list-style-type: none"> subcutaneous, total, modified radical, or radical mastectomy. None of 1st course therapy performed at reporting facility. Died within 1 year (365 days) of diagnosis. 	
Adjuvant chemotherapy	ACS	Consideration or administration of multi-agent chemotherapy initiated within 4 months (120 days) of date of diagnosis.	<p>Include, if <u>all</u> of the following characteristics are identified:</p> <ul style="list-style-type: none"> Women. Age 18-69 at time of diagnosis. Known or assumed to be first or only cancer diagnosis. Primary tumors of the breast. AJCC T1c, Stage II or III. Epithelial malignancy only. Primary tumor is estrogen receptor negative and progesterone receptor 	<p>Exclude, if <u>any</u> of the following characteristics are identified:</p> <ul style="list-style-type: none"> Men. Under age 18 at time of diagnosis. Over age 69 at time of diagnosis. Second or subsequent cancer diagnosis. Tumor not originating in the breast. Non-epithelial malignancies. Stage 0, in-situ tumor. AJCC T1mic, T1a, or T1b tumor. Stage IV, metastatic 	<p>Data Source:</p> <ul style="list-style-type: none"> Medical record or tumor registry. Data item and code definitions available via Facility Oncology Registry Data Standards (FORDS) manual. <p>Reporting: Measure performance rates should be reported as:</p> <ul style="list-style-type: none"> administered

² *Accountable provider facility* is defined as follows: A responsible facility is any institution that provides any component of the primary care for the reported cancer diagnosis, including surgery, radiation, and/or systemic therapy. In essence, this means that several institutions may be responsible for the measure if different elements of care were provided by different institutions.

MEASURE	<u>IP OWNER</u> ¹	<u>NUMERATOR</u>	DENOMINATOR	INCLUSIONS/EXCLUSIONS/ ADJUSTMENTS	DATA SOURCE/REPORTING
			negative. <ul style="list-style-type: none"> • All or part of 1st course of treatment performed at the reporting facility.² • Known to be alive within 4 months (120 days) of diagnosis. 	tumor <ul style="list-style-type: none"> • Primary tumor is estrogen. receptor positive <u>or</u> progesterone receptor positive. • None of 1st course therapy performed at reporting facility. • Died within 4 months (120 days) of diagnosis. 	therapy. <ul style="list-style-type: none"> • considered therapy. • an aggregate rate.

MEASURE	IP OWNER ¹	NUMERATOR	DENOMINATOR	INCLUSIONS/EXCLUSIONS/ ADJUSTMENTS	DATA SOURCE/REPORTING
Adjuvant hormonal therapy	ACS	Consideration or administration of tamoxifen <i>or</i> third generation aromatase inhibitor initiated within 1 year (365 days) of date of diagnosis.	Include if <u>all</u> of the following characteristics are identified: <ul style="list-style-type: none"> • Women. • Age >=18 at time of diagnosis. • Known or assumed to be first or only cancer diagnosis. • Epithelial malignancy only • Primary tumors of the breast. • AJCC T1c or Stage II or III • Primary tumor is estrogen receptor positive <u>or</u> progesterone receptor positive. • All or part of 1st course of treatment performed at the reporting facility² • Known to be alive within 1 year (365 days) of date of diagnosis 	Exclude, if <u>any</u> of the following characteristics are identified: <ul style="list-style-type: none"> • Men. • Under age 18 at time of diagnosis. • Second or subsequent cancer diagnosis. • Tumor not originating in the breast. • Non-epithelial malignancies. • Stage 0, in-situ tumor. • AJCC T1mic, T1a, or T1b tumor. • Stage IV, metastatic tumor • Primary tumor is estrogen receptor negative <u>and</u> progesterone receptor negative. • None of 1st course therapy performed at reporting facility. • Died within 1 year (365 days) of diagnosis. 	Data Source: <ul style="list-style-type: none"> • Medical record or tumor registry. • Data item and code definitions available via Facility Oncology Registry Data Standards (FORDS) manual. <i>Reporting:</i> Measure performance rates should be reported as: <ul style="list-style-type: none"> • administered therapy. • considered therapy. • an aggregate rate.

MEASURE	IP OWNER ¹	NUMERATOR	DENOMINATOR	INCLUSIONS/EXCLUSIONS/ ADJUSTMENTS	DATA SOURCE/REPORTING
College of American Pathologists Breast Cancer Protocol	College of American Pathologists (CAP)	Not applicable.	Not applicable.	None.	See <u>www.cap.org/apps/docs/cancer_protocols/2005/breast05_pw.pdf</u> .
Needle biopsy diagnosis	ACS	Patient whose date of needle biopsy precedes the date of surgery.	Patients presenting with AJCC Stage Group 0, I, II, or III disease who undergo surgical excision/resection of a primary breast tumor.	Exclusions: <ul style="list-style-type: none"> None provided but measure is in development phase as an accountability measure. It is noted that 20-25% of lesions are not amenable to needle biopsy but this is not explicitly an adjustment in the measure. 	Medical record or tumor registry. Definitions available via FORDS manual.
Patients with early stage breast cancer who have evaluation of the axilla	Intermountain Health Care	Number of women in the denominator that received either axillary node dissection or sentinel lymph node biopsy (SLNB) at the time of surgical resection of the primary tumor.	Number of women with diagnosis of stage I-IIb breast cancer that received either lumpectomy or mastectomy.	None.	Standards FORDS registry data.

COLORECTAL CANCER

MEASURE	IP OWNER ¹	NUMERATOR	DENOMINATOR	INCLUSIONS/EXCLUSIONS/ADJUSTMENTS	DATA SOURCE/REPORTING
Adjuvant chemotherapy	ACS	Consideration or administration of chemotherapy initiated within 4 months (120 days) of date of diagnosis.	Include, if <u>all</u> of the following characteristics are identified: <ul style="list-style-type: none"> • Age 18-79 at time of diagnosis. • Known or assumed to be first or only cancer diagnosis. • Primary tumors of the colon. • Epithelial malignancy only. • At least one pathologically examined regional lymph node positive for cancer (AJCC Stage III). • All or part of 1st course of treatment performed at the reporting facility² • Known to be alive within 4 months (120 days) of diagnosis. 	Exclude, if <u>any</u> of the following characteristics are identified: <ul style="list-style-type: none"> • Under age 18 at time of diagnosis. • Over age 79 at time of diagnosis. • Second or subsequent cancer diagnosis. • Tumor not originating in the colon. • Tumor originating in the appendix. • Non-epithelial malignancies. • All pathologically examined regional lymph nodes are negative. • Stage IV, metastatic tumor. • None of 1st course therapy performed at reporting facility. • Died within 4 months (120 days) of diagnosis. 	Data Source: <ul style="list-style-type: none"> • Medical record or tumor registry. • Data item and code definitions available via Facility Oncology Registry Data Standards (FORDS) manual. Reporting: Measure performance rates should be reported as: <ul style="list-style-type: none"> • administered therapy. • considered therapy. • an aggregate rate.

MEASURE	<u>IP OWNER</u> ¹	<u>NUMERATOR</u>	DENOMINATOR	INCLUSIONS/EXCLUSIONS/ ADJUSTMENTS	DATA SOURCE/REPORTING
Completeness of pathology reporting	Cancer Care Ontario	<p>Number of colorectal cancer resection pathology reports containing selected mandatory elements from the College of American Pathologists ("CAP") Cancer Checklist for Colorectal Resections, January 2005 revision.</p> <p>All of the following data elements must be present in a pathology report to be counted as positive in the numerator. The elements to be collected are as follows:</p> <ol style="list-style-type: none"> 1. Specimen type/procedure 2. Tumor site 3. Tumor size 4. Histologic tumor type 5. Histologic grade 6. # nodes examined 7. # nodes involved 8. Proximal margin status 9. Distal margin status 10. Circumferential/radial margin status 11. Lymphatic (small vessel) invasion 12. Venous (large vessel) invasion 13. Staging information (pT) 	All audited colorectal cancer resection pathology reports.	<p>Interpretive Notes:</p> <p>¹ Explicit statement of pN was not required for completeness.</p> <p>² Explicit statement of margin involvement for each of the three margins was required for completeness.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> ▪ Squamous cell cancer (to exclude anal surgeries). 	Pathology reports (for CRC resections).

MEASURE	IP OWNER ¹	NUMERATOR	DENOMINATOR	INCLUSIONS/EXCLUSIONS/ADJUSTMENTS	DATA SOURCE/REPORTING
CAP Colon and Rectum Protocol	CAP	Not applicable.	Not applicable.	None.	See www.cap.org/apps/docs/cancer_protocols/2005/colonrectum05_pw.pdf .
Surgical resection includes at least 12 nodes	ACS	>=12 regional lymph nodes pathologically examined.	<p>Include, if <u>all</u> of the following characteristics are identified:</p> <ul style="list-style-type: none"> • Age >=18 at time of diagnosis. • Known or assumed to be first or only cancer diagnosis. • Primary tumors of the colon. • Epithelial malignancy only. • AJCC Stage I, II, or III. • Surgical resection performed at the reporting facility. 	<p>Exclude, if <u>any</u> of the following characteristics are identified:</p> <ul style="list-style-type: none"> • Under age 18 at time of diagnosis. • Second or subsequent cancer diagnosis. • Tumor not originating in the colon. • Tumor originating in the appendix. • Non-epithelial malignancies. • Stage IV, metastatic tumor. • Surgical procedure was local tumor destruction or excision, anything less than a partial or segmental resection. • Surgical resection not performed at reporting facility. 	<p>Data Source:</p> <ul style="list-style-type: none"> • Medical record or tumor registry. • Data item and code definitions available via Facility Oncology Registry Data Standards (FORDS) manual. <p>Reporting: Measure performance rates should be reported stratified by patient demographic and tumor characteristics.</p>

SYMPTOM MANAGEMENT AND END-OF-LIFE CANCER CARE

MEASURE	IP OWNER ¹	METHODOLOGY		INCLUSIONS/EXCLUSIONS/ ADJUSTMENTS	DATA SOURCE/REPORTING
Family Evaluation of Hospice Care	Brown University	Responses to survey instrument See Figure A-1 - Family Evaluation of Hospice Care Survey and Table A-1 - Administrative Specifications at the end of this appendix.	Family members of all patients enrolled in a hospice program. This tool is only for family members of patients who died following care.	<i>Exclusions:</i> Exclude patients who are not enrolled in a hospice program or have disenrolled from a hospice program. Live discharges are excluded.	Family member of deceased patient (survey responses).
MEASURE	IP OWNER ¹	NUMERATOR	DENOMINATOR	INCLUSIONS AND/OR EXCLUSIONS	DATA SOURCE
Comfortable dying	National Hospice and Palliative Care Organization	Patients who pain was brought under control within 48 hours of admission to hospice.	Patients who were uncomfortable because of pain on admission to hospice.	Inclusions: Patients are eligible if they: <ul style="list-style-type: none"> • Acknowledge they are uncomfortable because of pain at the time of admission; • Communicate and understand the language of the person asking the question; • Are able to self-report; and • Are at least 18 years of age or older. 	Patient self-report.

MEASURE	IP OWNER	NUMERATOR	DENOMINATOR	INCLUSIONS AND/OR EXCLUSIONS	DATA SOURCE
Chemotherapy in the last 14 days of life	Craig Earle, MD, of Dana-Farber Cancer Institute	<p>Patients who died from cancer and received chemotherapy in the last 14 days of life</p> <p>ICD-9: 140 – 239 Chemotherapy administration codes: ICD-9 diagnosis codes: V58.1 <i>OR</i> ICD-9 procedure codes: 99.25 <i>OR</i> CPT codes: 964xx, 965xx <i>OR</i> HCPCS codes: J7150, J85xx, J86xx, J87xx, J8999, J9xxx, Q0083, Q0084, Q0085 <i>OR</i> DRG codes: 410 <i>OR</i> Revenue center codes: 0331, 0332, 0335 <i>OR</i> BETOS codes: O1D <i>OR</i> NDC Brand descriptions: Alkeran, Cytosan, Methotrexate Sodium, Temodar, VePesid, Xeloda.</p>	Patients who died from cancer.	None.	Administrative data; Medicare-SEER + Death Index.

MEASURE	IP OWNER	NUMERATOR	DENOMINATOR	INCLUSIONS AND/OR EXCLUSIONS	DATA SOURCE
<p>More than one emergency room visit in the last 30 days of life</p>	<p>Craig Earle, MD, of Dana-Farber Cancer Institute</p>	<p>Patients who died from cancer and had >1 ER visit in the last 30 days of life.</p> <p>ER visit codes: HCPCS codes: 99281, 99282, 99283, 99284, 99285 <i>OR</i> MEDPAR (Medicare inpatient file) indicator codes:</p> <ul style="list-style-type: none"> • admsrce=7 <p>This is the medpar source inpatient admission code 7=Emergency room - the patient was admitted upon the recommendation of this facility's emergency room physician <i>OR</i></p> <ul style="list-style-type: none"> • admtype=1 <p>This is the medpar inpatient admission type code 1=Emergency - the patient required immediate medical intervention as a result of severe, life threatening, or potentially disabling conditions <i>OR</i> BETOS codes: M3.</p>	<p>Patients who died from cancer.</p>	<p>None.</p>	<p>Administrative data; Medicare-SEER + Death Index.</p>

MEASURE	IP OWNER	NUMERATOR	DENOMINATOR	INCLUSIONS AND/OR EXCLUSIONS	DATA SOURCE
<p>More than one hospitalization in the last 30 days of life</p>	<p>Craig Earle, MD, of Dana-Farber Cancer Institute</p>	<p>Patients who died from cancer and had >1 hospitalization in the last 30 days of life.</p> <p>MEDPAR only:</p> <ul style="list-style-type: none"> • did not include SNF claims • counted number of admissions (using admit date variable) per person during last 30 days before death. <p>No codes used.</p>	<p>Patients who died from cancer.</p>	<p>None.</p>	<p>Administrative data; Medicare-SEER + Death Index.</p>

MEASURE	IP OWNER	NUMERATOR	DENOMINATOR	INCLUSIONS AND/OR EXCLUSIONS	DATA SOURCE
Intensive care unit admission in the last 30 days of life	Craig Earle, MD, of Dana-Farber Cancer Institute	<p>Patients who died from cancer and were admitted to the ICU in the last 30 days of life.</p> <p>MEDPAR only:</p> <ul style="list-style-type: none"> • did not include SNF claims • did not include pediatric, psychiatric, burn or trauma ICUs (MEDPAR variable increment 3,4,7,8) • variable in MEDPAR called <i>incrdays</i>, which is number of ICU days per visit • used hospital admission date variable (<i>admitdate</i>) and then checked if <i>incrdays</i> was >0 for admissions occurring in the last 30 days before death. <p>No codes used.</p>	Patients who died from cancer.	None.	Administrative data; Medicare-SEER + Death Index

MEASURE	IP OWNER	NUMERATOR	DENOMINATOR	INCLUSIONS AND/OR EXCLUSIONS	DATA SOURCE
Dying in an acute care setting	Craig Earle, MD, of Dana-Farber Cancer Institute	<p>Patients who died from cancer in an acute care hospital.</p> <ul style="list-style-type: none"> • No SNF claims. • If death date occurs between hospital admit and discharge OR dschgsta = B OR discdest = 20. <p>The MEDPAR code indicating the status of the beneficiary on the date of discharge from the facility; B = Discharged dead Discdest = The MEDPAR code primarily indicating the destination of the beneficiary upon discharge from a facility; also denotes death or skill nursing facility (snf)/still patient situations.</p> <p>20 = died.</p>	Patients who died from cancer.	<i>None.</i>	Administrative data; Medicare-SEER + Death Index

MEASURE	IP OWNER	NUMERATOR	DENOMINATOR	INCLUSIONS AND/OR EXCLUSIONS	DATA SOURCE
Not admitted to hospice	Craig Earle, MD of Dana-Farber Cancer Institute	<p>Patients who died from cancer without being admitted to hospice.</p> <p>Those without claims in Medicare HOSPICE file.</p>	Patients who died from cancer.	None.	Administrative data; Medicare-SEER + Death Index.
Admitted to hospice for less than 3 days	Craig Earle, MD, of Dana-Farber Cancer Institute	<p>Patients who died from cancer and spent fewer than three days in hospice.</p> <p>Medicare HOSPICE file only:</p> <ul style="list-style-type: none"> Subtracted hospice admission date (admndate) from death date variable to get hospice length of stay. <p>No codes used.</p>	Patients who died from cancer who were admitted to hospice.	None.	Administrative data; Medicare-SEER + Death Index.

Appendix E:

CONTEXT FOR CONSIDERING A BREAST CANCER EPISODE

- I. Introduction
 - a. Brief background on efficiency framework as basis for work
 - b. Context-setting for breast cancer within the health care system
 - i. Wealth of state of the art, evidence-based care
 - ii. Great deal of knowledge re: short/long-term effects
 - iii. Strong influence of patient preferences in care
 - c. Context-setting for breast cancer patient
 - i. Diverse age group with distinct pathological subgroups and varying prognoses that influence treatment decisions
 - ii. Progression through the episode and success with treatment also dependent upon the patient's stage in life and development
 - iii. Psychological and physical response varies
 - d. Episode approach and measurement for breast cancer
 - i. Strengths
 - ii. Limitations
 - iii. Explanation of Pathways A/B/C/D
 - e. Overall principles to guide techniques and treatment of all cancer patients
 - i. Treatment of patient, not just tumor
 - ii. Do not over-treat
 - iii. Do not under-treat
- II. Phase 1 Discussion: Population at risk
 - a. All women over age 21
 - b. Includes women that are “high risk”
 - c. Includes women with strong familial risk
 - d. Includes women with known hereditary mutations
- III. Phase 2 Discussion: Evaluation & Initial Management
 - a. Clinical episode commences
 - b. Presentation of a breast cancer episode
 - i. Description of first phase of clinical episode
 - ii. 3-4 weeks of fury around initial discovery and diagnosis → treatment routine → transition when treatment concludes
 - iii. Screening mammography identifies an abnormality
 - iv. Palpable abnormality identified via self-exam
 - v. Physical exam by a provider detects an abnormality
 - vi. Patient presents with symptoms (i.e. back pain) of metastatic cancer
 - 1. small tumor that grows rapidly
 - 2. tumor ignored in/not detected over time
 - c. “Pathways” discussion (based on NCCN Guidelines)
 - i. Pathway A
 - 1. Small tumor, localized

2. Favorable biological characteristics (e.g., hormone receptor positive)
 3. Lumpectomy, radiation
 4. Endocrine therapy (at least 5 years and may be more)
 5. Acute treatment complete within 3 months → long-term preventive therapy with endocrine therapy, diet, exercise
 6. Discovered via screening
 7. Often limited psychological impact
 8. Low rate of post- treatment morbidity
 9. Also, non-invasive breast cancer (DCIS); 30,000-40,000 cases/year (25% of breast cancer cases)
- ii. Pathway B
1. Larger tumor +/- positive nodes
 2. Favorable biological characteristics (HER 2 neu negative)
 3. Chemotherapy + lump/mastectomy
 4. Depending on recipe: 16 weeks – 6 months of treatment
 5. → radiation (6 weeks)
 6. After initial frenzy, treatment complete within 8-9 months
 7. May/may not go on extended endocrine therapy
 8. More physical and psychological distress
- iii. Pathway C
1. Unfavorable biological characteristics (e.g., large tumor with many positive nodes, poorly differentiated, HER 2 neu positive, triple negative)
 2. Mastectomy (may/may not)
 3. Radiation (may-may not)
 4. Chemotherapy; possible neoadjuvant chemotherapy
 5. 1-1.5 years of targeted biotherapy with trastuzumab (Herceptin); represents 25% of breast cancer cases
 6. Life-saving treatment, but toxic and expensive
 7. More physical and psychological distress
- iv. Pathway D
1. Metastatic disease at presentation
 2. Chemotherapy and hormonal therapy; breast surgery may or may not be done
 3. Patient is symptomatic from start
 4. Treatment aim: manage effects of cancer/treatment
 5. Trade-off: side effects of treatment
 6. Palliative care figures prominently with active cancer management
 7. Increased physical and psychological distress and disability
- d. Treatment options
- i. Lumpectomy (with radiation)
 - ii. Mastectomy (with/without reconstructive surgery)
 - iii. Radiation/Chemotherapy; adjuvant therapy
- e. Value of second opinion

- f. Treatment plan spanning Phases 2 & 3
- g. Treatment summary and Survivorship care plan (per IOM) at transition points when oncologic care is not as intense
- IV. Phase 3 Discussion:
 - a. Intent: prevention of recurrence/chronic illness
 - b. Ongoing endocrine therapy
- V. Issues for Consideration across the Episode once we have tissue diagnosis of cancer
 - a. Access to care
 - b. Genetic testing and counseling
 - c. Psychosocial needs
 - d. Treatment preferences (special cases: older patients)
 - e. Informed decision-making and use of decision aids
 - f. Health education/behavior change
 - g. Palliative care/symptom management
 - h. Family engagement
 - i. Rehabilitation
 - j. Care coordination
 - k. Advanced Care Planning
 - l. Symptom Assessment/Management
 - m. Comorbidities

Appendix F:

CONTEXT FOR CONSIDERING A COLON CANCER EPISODE

- I. Introduction
 - a. Brief background on efficiency framework as basis for work
 - b. Context-setting for colon cancer within the health care system
 1. Prevalence: 108,070 in 2008 www.cancer.gov
 2. Importance of screening
 3. Wealth of data on management of colon cancer with evidence based guidelines from various national organizations
 - a. some variability in recommendations but not significant
 - b. guidelines not always changed with new data
 - c. Context-setting for colon cancer patient
 1. Overall survival ~65%, recurrences usually within 5 yrs
 2. Many RCTs help guide treatment
 3. Patient comorbidities play a role in decision making and outcomes
 4. Limited choices in terms of management - surgical options: open/laparoscopic, chemotherapy: yes/no, all iv vs some iv
 5. Proportion of patients will present with synchronous (~20%) or metachronous metastases (30%)
 - a. Medical co-morbidities and patient preferences play a significant role in decision making
 - b. Chemotherapy mainstay of therapy
 - c. Considerable controversy over role of surgery, particularly in management in asymptomatic patients
 - i. Small subset of patients who may have surgically respectable disease (10%) who may benefit from combined therapy
 - ii. Role for Radiation in subset of patients
 - iii. Individualized with some data to support specific scenarios
 - d. Episode approach and measurement for colon cancer
 1. Strengths
 2. Limitations
 - e. Explanation of Pathways A/B/C
 - f. Overall principles to guide techniques and treatment of all cancer patients
 1. Treatment of patient, not just tumor
 2. Do not over-treat
 3. Do not under-treat
- II. Phase 1 Discussion: Population at risk
 - a. All men and women over age 50

- b. All individuals with “high risk” family history
- c. All patients known hereditary mutations

III. Phase 2 Discussion: Evaluation & Initial Management

- a. Clinical episode commences
- b. Presentation of a colon cancer episode
 - 1. Asymptomatic screening colonoscopy
 - 2. Physical exam by provider identifies guaic +ve stool prompting work-up
 - 3. Radiologic test prompting further workup
 - 4. Symptomatic Presentation: alteration in bowel habit, weight loss, obstipation/obstruction
 - 5. Diagnosis requires colonoscopy for biopsy confirmation and patient referred to surgeon for management
- c. “Pathways” discussion with treatment options (NCCN guidelines)
- d. Pathway A: surgery only (Stage I and some Stage II)
 - 1. Surgery consultation – decision re open vs laparoscopic surgery made
 - 2. Undergo surgery within 4-6 wks of initial visit
 - 3. Pathology demonstrates favorable early tumor and adequate node sampling
 - a. T1/T2, N0 – no consultation with medical oncologist
 - b. T3/T4, NO – consultation with medical oncologist and decision made to not pursue chemotherapy
 - i. Co-morbidities
 - ii. Limited benefit
 - iii. Patient preferences
 - 4. Minimal psychological effect
 - 5. 30% of patients
 - 6. 6-8 weeks post-operative recovery
 - 7. Alteration of bowel habit minimal, minimal long term psychological effects
- ii. Pathway B: surgery plus chemotherapy
 - 1. As above for #1 and #2
 - 2. Pathology demonstrating: unfavorable features in N0 patients, inadequate nodal sampling or nodal involvement -> Consultation with medical oncologist
 - 3. Chemotherapy x 6 months
 - 4. Morbidity of chemotherapy
 - 5. Active treatment 8-10 months
 - 6. More significant long term psychological effect
- iii. Pathway C: Metastatic disease
 - 1. Synchronous
 - a. Symptomatic
 - i. Surgery tailored to extent of disease

- ii. Surgical resection of primary followed by chemotherapy (minimum 6 months)
 - iii. Subsequent surgical therapy for symptoms (ie bowel obstruction) and in a subset for metastatectomy
 - b. Non-symptomatic
 - i. Chemotherapy x 6 months with f/u CT to assess response
 - ii. Small proportion will undergo surgery for symptoms and/or complications (perforation, etc)
 - iii. Small proportion will undergo surgery for metastatectomy
 - c. Transition to palliative care when chemotherapy too toxic and/or tumor progression and/or patient wishes ~ md 21 months from diagnosis
 - 2. Metachronous metastasis
 - a. Resectable
 - i. Neoadjuvant chemotherapy + surgery vs surgery +/- adjuvant chemotherapy
 - ii. 8-12 months of active therapy after resection
 - iii. Cure ~15-25%
 - b. Non resectable
 - i. Chemotherapy
 - ii. Symptomatic surgery
 - c. Transition from active therapy to palliation with treatment toxicity and/or dx progression and/or patient wishes (~21 months post dx)
 - iv. Treatment options
 - 1. Surgical options
 - a. Curative setting - open vs laparoscopic
 - b. High volume vs low volume center
 - c. Resect vs Chemo for asymptomatic stage IV
 - 2. Chemotherapeutic options
 - a. Adjuvant therapy y/n
 - b. All iv vs some iv
 - c. When to stop chemo in stage IV
 - 3. Radiation therapy
 - a. May be used in limited neoadjuvant settings
 - b. Palliation of symptoms
 - e. Value of second opinion
 - f. Treatment plan spanning Phases 2 & 3
 - g. Treatment summary and Survivorship care plan (per IOM)s
- IV. Phase 3 Discussion: Follow-up Care
 - a. Intent: prevention of recurrence/chronic illness
 - b. Pathway A: Surgery Only (NCCN guidelines)
 - c. Stage I/II

1. P/E & BW q3months x 2 yrs, followed by q6months x 3 yrs
 2. CT chest/abd/pelvis for stage I/II qyr x 3 yrs dictated by CEA and/or symptoms and/or pathology (ie adverse features)
 3. colonoscopy at yr 1, then 3 yrs, then at discretion of gastroenterologist
- d. Pathway B: Surgery and Chemotherapy (NCCN guidelines)
 4. P/E & BW q3months x 2 yrs, followed by q6months x 3 yrs
 5. CT chest/abd/pelvis qyr x 3 yrs and/or as dictated by CEA and/or symptoms
 - e. Pathway C: Metastatic Disease
 1. Majority of patients will be actively treated
 2. Patients with metastatectomy will follow Pathway B
 3. Patients transitioned to palliative will be managed symptomatically
- V. Desired Outcomes
- a. Primary: survival
 - i. Disease-free
 - ii. Recurrence-free
 - iii. Stratification based on evaluation of initial management
 - b. HRQOL
 - c. Toxicity of therapy
 - d. Symptom Management
 - e. Risk-adjusted total cost of care
 - f. Reintegration into society
- VI. Issues for Consideration across the Episode once we have tissue diagnosis of cancer
- a. Access to care
 - b. Genetic testing and counseling (applicable to 5-10% of cases)
 - c. Risk of treatment options (i.e. toxicity of care, mortality post-surgery, biopsy)
 - d. Co-morbidities
 - e. Psychosocial needs
 - f. Treatment preferences
 - g. Informed decision-making and use of decision aids
 - h. Health education/behavior change
 - i. Palliative care
 - j. Family engagement
 - k. Rehabilitation
 - l. Care coordination
 - m. Advanced Care Planning
 - n. Symptom Assessment/Management

Appendix G:

CONTEXT FOR CONSIDERING A RECTAL CANCER EPISODE

- I. Introduction
 - a. Brief background on efficiency framework as basis for work
 - b. Context-setting for rectal cancer within the health care system
 - i. Prevalence: 40,740 in 2008 www.cancer.gov
 - ii. Importance of screening
 - iii. Wealth of data on management of rectal cancer and evidence based guideline from various national organizations
 - 1. some variability in recommendations but not significant
 - 2. guidelines not always changed with new data
 - c. Context-setting for rectal cancer patient
 - i. Overall survival ~65%, recurrences usually within 5 yrs
 - ii. Many RCTs help guide treatment
 - iii. Patient comorbidities play a role in decision making and outcomes
 - iv. Patient co-morbidities and preferences play a larger role in decision making
 - v. Patients are stoma adverse, seek options to avoid
 - 1. Sphincter preservation: “low anterior resection +/- diverting stoma”, “transanal excision”
 - 2. Permanent stoma: “abdominal perineal resection”
 - vi. Significantly dysfunction associated with treatment including alterations in bowel, bladder and sexual function
 - vii. Treatment varies by stage
 - 1. Neoadjuvant CT/RT and post op CT
 - 2. Upfront surgery, no additional therapy
 - 3. Surgery + post op CT/RT
 - 4. Upfront chemotherapy vs surgery + Chemotherapy for metastatic patients
 - d. Episode approach and measurement for rectal cancer
 - i. Strengths
 - ii. Limitations
 - iii. Explanation of Pathways A/B/C/D
 - e. Overall principles to guide techniques and treatment of all cancer patients
 - i. Treatment of patient, not just tumor
 - ii. Do not over-treat
 - iii. Do not under-treat
- II. Phase 1 Discussion: Population at risk
 - a. All men and women over age 50
 - b. All individuals with “high risk” family history
 - c. All individuals with known hereditary mutations
 - d. Adherence to screening guidelines
- III. Phase 2 Discussion: Evaluation & Initial Management
 - a. Clinical episode commences
 - b. Presentation of a rectal cancer episode

- i. Asymptomatic screening colonoscopy
- ii. Physical exam by provider identifies mass and/or guaic +ve stool prompting work-up
- iii. Radiologic test prompting further workup
- iv. Symptomatic Presentation: alteration in bowel habit, weight loss, obstipation/obstruction
 - v. Diagnosis requires colonoscopy for biopsy confirmation
 - vi. Gastroenterologist/colonoscopist refers patient for surgical opinion, CT scan arranged
 - vii. Staging of tumor via MRI or endorectal ultrasound
- c. "Pathways" discussion with treatment options (NCCN guidelines)
 - viii. Pathway A: surgery only
 - 1. Subgroup of patients (~10-15%): T1, T2, N0 tumors
 - 2. Transanal excision, Low anterior resection, Abdominal perineal resection
 - 3. pathologic confirmation of T1/T2, N0 status
 - 4. If temporary stoma, reversed 3-6 months after surgery
 - ix. Pathway B: surgery plus neoadjuvant/chemotherapy, possibly followed by more surgery
 - 1. Majority of patients: ultralow T2N0, T3N0, T1-4N1-2
 - 2. 6 weeks CT/RT
 - 3. 6-8 weeks recovery
 - 4. Surgery (Low anterior resection +/- diverting stoma, abdominal perineal resection)
 - 5. 4-8 week recovery
 - 6. 4-6 months additional chemotherapy
 - 7. Ileostomy reversed
 - 8. About 11 months from treatment initiation to completion
 - x. Pathway C: surgery and chemoradiation
 - 1. Preoperatively staged T1,T2: NO
 - 2. Transanal excision, Low anterior resection, Abdominal perineal resection
 - 3. Pathology demonstrates T3 or N1-2 disease
 - 4. 6 months CT with 6 wks of RT sandwiched between
 - 5. If temporary stoma, reversed 1-2 months post treatment
 - xi. Pathway D: metastatic
 - 1. Synchronous Symptomatic
 - a. Surgery: stent/stoma/resection
 - b. Chemotherapy
 - 2. Synchronous Asymptomatic
 - a. Chemotherapy
 - 3. Metachronous
 - a. Chemotherapy
 - 4. Consideration for metastatectomy based upon resectability of metastases and primary during Pathway

- 5. Transition from active therapy to palliation with treatment toxicity and/or dx progression and/or patient wishes (~21 months)
- 6. Significant focus on symptoms in patients with locally recurrent unresectable disease (ie ureteric stents, pain control, RT)
- d. Treatment options
- e. Value of second opinion
- f. Treatment plan spanning Phases 2 & 3
- g. Treatment summary and Survivorship care plan (per IOM)
- IV. Phase 3 Discussion: Follow-up Care
 - a. Intent: prevention of recurrence/chronic illness
 - b. Improve bowel, bladder, sexual function
 - c. NCCN guidelines
 - i. Pathway A-C
 - 1. Physical Exam/CEA q3-6 months x 2 yrs, q6 months x 3 yrs
 - 2. CT chest/abdomen/pelvis q yr
 - 3. Colonoscopy yr 1, then at 3 yrs
 - 4. Flex sigmoidoscopy prn
 - ii. Pathway D
 - 1. Majority of patients will be actively treated until transitioned to palliation
 - 2. Patients with metastatectomy will undergo follow-up through Pathway A-C
 - 3. Patients transitioned to palliative mode will be managed symptomatically
 - d. Desired Outcomes
 - i. Primary: survival
 - 1. Disease-free
 - 2. Recurrence-free
 - ii. HRQOL
 - iii. Colostomy status
 - iv. Functional outcomes
 - v. Toxicity of therapy
 - vi. Symptom Management
 - vii. Risk-adjusted total cost of care
 - viii. Reintegration into society
- V. Issues for Consideration across the Episode once we have tissue diagnosis of cancer
 - a. Access to care
 - b. Genetic testing and counseling (applicable to 5-10% of cases)
 - c. Risk of treatment options (i.e. toxicity of care, mortality post-surgery, biopsy)
 - d. Co-Morbidities
 - e. Psychosocial needs
 - f. Treatment preferences

- g. Informed decision-making and use of decision aids
- h. Health education/behavior change
- i. Palliative care
- j. Family engagement
- k. Rehabilitation
- l. Care coordination
- m. Advanced Care Planning
- n. Symptom Assessment/Management
- o. Comorbidities