

NQF

NATIONAL QUALITY FORUM

**National Voluntary
Consensus Standards
for Quality of
Cancer Care**

A
CONSENSUS
REPORT

This report is dedicated to the memory of Rodger Winn, MD, a devoted medical professional who worked with academic and community-centered oncologists, policymakers, and the public to improve the quality of healthcare for patients with cancer and their families. Today and in the future, hundreds of thousands of patients with cancer will have improved quality of care as a result of Dr. Winn's work.

A widely acknowledged expert in quality of cancer care, Dr. Winn served as co-chair of the National Quality Forum's (NQF's) Quality of Cancer Care Steering Committee from 2002 to 2003, and since 2004 he had been a clinical consultant at NQF, where he directed this project and produced a seminal report to endorse national quality standards for palliative and hospice care. In addition, at NQF he served as a consultant for projects on healthcare-associated infections – in particular surgical site infections – and ambulatory care quality.

In addition to his distinguished clinical and academic career, Dr. Winn served as chair of the National Comprehensive Cancer Network's Guidelines Steering Committee, a group of 45 panels charged with writing more than 100 cancer treatment guidelines. As the first chair of the American Society of Clinical Oncology's (ASCO's) Health Services Research Committee, he initiated the ASCO guidelines program. Dr. Winn also contributed greatly to the Institute of Medicine's (IOM's) work on cancer survivorship, serving with distinction on the committee that wrote the 2005 IOM report on adult survivorship, which served in part as the foundation for legislation pending in the U.S. Congress.

Rodger was generous of spirit and a voice of experience and caring. He is greatly missed.

ACKNOWLEDGMENTS

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Foreword

Few diseases carry the physical or emotional impact that accompanies a diagnosis of cancer. Cancer kills more than half a million Americans annually, with an estimated 1.4 million new cases per year in the United States, and exists in our collective imagination—perhaps more than any other disease—as a scourge to be eliminated. “Curing cancer” is routinely listed by many Americans as a scientific goal to be achieved—and it would indeed be a worthy one. An equally important goal is to provide high-quality care to patients with cancer. Yet currently there exist relatively few commonly accepted measures of performance with respect to its treatments.

This report details 19 standardized performance measures for gauging the quality of cancer care in the areas of breast cancer, colorectal cancer, and symptom management and end-of-life care. They will facilitate the comparison of cancer care providers for purposes of accountability, quality improvement, and surveillance, and can be used by consumers, providers, federal and private purchasers, and researchers, among others. These measures have been carefully reviewed and endorsed by a diverse group of stakeholders pursuant to the National Quality Forum’s (NQF’s) formal Consensus Development Process, giving them the special legal status of voluntary consensus standards.

We thank NQF Members and the Quality of Cancer Care Performance Measures Steering Committee and its Cancer Data and Methods Panel and Technical Panels for their stewardship of this work and for their dedication to improving the quality of cancer care in the United States.



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National Voluntary Consensus Standards for Quality of Cancer Care

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National Voluntary Consensus Standards for Quality of Cancer Care

Executive Summary

In 2006, approximately 565,000 Americans died of cancer, and an estimated 1.4 million Americans developed it. Add to these numbers all those who currently live with cancer, and it becomes clear that millions suffer from this disease and its effects. And although much is known about delivering high-quality cancer care, this evidence is not adhered to often enough. Although advancements have been made in quality accountability for other clinical areas, they have been lacking in cancer care.

To address this need, in 2002, the National Quality Forum (NQF) embarked on the Quality of Cancer Care Performance Measures project at the request of several federal partners. This project had the companion goals of identifying a set of voluntary consensus standards for quality of cancer care for use by the public and private sector and recommending a research agenda for filling gaps in the set.

This NQF report details 19 voluntary consensus standards for cancer care in 3 priority areas: breast cancer, colorectal cancer, and symptom management and end-of-life care. These consensus standards have been evaluated for their importance, scientific evidence, usability, and feasibility. They were scrutinized and vetted through NQF's Consensus Development Process (Version 1.7) and meet the criteria of voluntary consensus standards as detailed in the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119.

This project, as well as the work of many stakeholder groups, is aimed at establishing a comprehensive cancer care quality measurement and reporting system, which includes a set of standardized performance measures. These voluntary consensus standards may be used for purposes of accountability (i.e., for comparisons of entities and in such

activities as public reporting, payment incentive programs, and the selection of providers by consumers, health plans, or purchasers); for quality improvement (i.e., for internal monitoring of performance within an organization or group so that analyses can be performed and remedial

actions instituted); or for surveillance (i.e., for use at the community, regional, and/or national level to monitor patterns and trends of care in order to guide policy-making and resource allocation). They also may be used to facilitate research.

National Voluntary Consensus Standards for Quality of Cancer Care

| PRIORITY AREA | MEASURE |
|---|--|
| Breast Cancer | <ul style="list-style-type: none"> ■ Post breast conserving surgery irradiation ■ Adjuvant chemotherapy ■ Adjuvant hormonal therapy ■ College of American Pathologists Breast Cancer Protocol ■ Needle biopsy diagnosis ■ Patients with early stage breast cancer who have evaluation of the axilla |
| Colorectal Cancer | <ul style="list-style-type: none"> ■ Adjuvant chemotherapy ■ Completeness of pathology reporting ■ College of American Pathologists Colon and Rectum Protocol ■ Surgical resection includes at least 12 nodes |
| Symptom Management and End-of-Life Care | <ul style="list-style-type: none"> ■ Family Evaluation of Hospice Care (FEHC) ■ Comfortable dying ■ Chemotherapy in the last 14 days of life ■ More than one emergency room visit in the last 30 days of life ■ More than one hospitalization in the last 30 days of life ■ Intensive care unit admission in the last 30 days of life ■ Dying in an acute care setting ■ Not admitted to hospice ■ Admitted to hospice for less than three days |

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Chapter 1: National Voluntary Consensus Standards for Quality of Cancer Care

Introduction

In 2006, approximately 565,000 Americans died of cancer, and an estimated 1.4 million Americans developed it.¹ Add to these numbers all those who currently live with cancer, and it becomes clear that millions suffer needlessly from this disease and its effects.

Although much is known about delivering high-quality cancer care, this evidence is not adhered to often enough today. If it were, it would improve outcomes for thousands of patients diagnosed with cancer. While the magnitude of the healthcare system's failure in this regard is unknown, we do know that it is substantial.²

Advancements have been made in quality accountability for other clinical areas, but eight years after the Institute of Medicine (IOM) recommended measuring the quality of cancer care using a core set of performance measures,² no such set has been developed. To address this need, the Agency for Healthcare Research and Quality (AHRQ), the National Cancer Institute (NCI), the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention (collectively referred to as the Federal Partners) have sponsored a multiphase project, the Quality of Cancer Care Performance Measures project, with the following goals:

- identify a National Quality Forum (NQF)-endorsed[®] set of voluntary consensus standards for quality of cancer care in three priority areas for use by the public and private sector for accountability, quality improvement, surveillance, and research, and

¹Jemal A, Siegal R, Ward E, et al., Cancer statistics, 2006, *CA Cancer J Clin*, 2005;56:106-130.

²Hewitt ME, Simone JV, eds., *Ensuring Quality Cancer Care*, Washington, DC: National Academy Press; 1999.

- recommend a research agenda for filling gaps in the set of voluntary consensus standards for cancer care for the three priority areas that could be addressed through additional research and/or testing of existing performance measures considered, but not endorsed, or through the development *de novo* of measures.

This report is organized into three chapters. This chapter summarizes the rationale for the priority areas initially selected and presents the NQF-endorsed purpose of the set, the endorsed framework for assessing the quality of cancer care, and research recommendations, most of which apply to all three priority areas. It also presents an overview of the performance measures endorsed for purposes of surveillance, quality improvement, and public accountability at the hospital-level of measurement in each of the priority areas. Chapter 2 provides more detailed information about the NQF breast and colorectal cancer diagnosis and treatment consensus standards and includes recommendations specific to those areas. Chapter 3 presents the consensus standards and recommendations related to symptom management and end-of-life care for cancer patients.

Establishing the Priorities

In 2002, NQF embarked on the Quality of Cancer Care Performance Measures project. The project's first phase, sponsored by NCI, sought to establish a framework for cancer care quality measurement and a plan to identify, evaluate, and agree upon existing measures that could be assessed

under NQF's Consensus Development Process (Appendix F). A project Steering Committee was appointed (Appendix B), the members of which were selected based on their expertise in oncology and/or performance measurement and their respective stakeholder affiliation, to recommend priorities regarding measures that might be sought. Seven priority areas were identified in the first phase of the project, as follows:

1. diagnosis and treatment of breast cancer;
2. diagnosis and treatment of colorectal cancer;
3. symptom management and end-of-life care;
4. access to care/clinical trials/cultural competence;
5. communication and coordination of care (including information technology issues);
6. diagnosis and treatment of prostate cancer; and
7. prevention and screening.

During the second phase, three of these areas were selected for the consideration of consensus standards and are examined in this report:

1. diagnosis and treatment of breast cancer;
2. diagnosis and treatment of colorectal cancer; and
3. symptom management and end-of-life care.

These three areas were selected based on five criteria: they were to be areas consistent with national goals; be key leverage points; address variation in care; be patient centered; and address disparities in vulnerable

populations. The Steering Committee specifically included both cross-cutting and disease-specific measures in this initial set to achieve as much momentum as possible and also to serve as a model for the future development of both types of measures. The breadth of conditions subsumed under cancer care—ranging from the screening of at-large populations for cancer to the active treatment of patients with the disease to the provision of supportive care for those in the dying phase of their illness—is vast, and the outcomes are varied. The Steering Committee believed that performance measures that would lead to an increase in cancer curability are of the highest priority. At the same time, the Steering Committee stressed that measures addressing symptom management and improved quality of life, even if not directly linked to curability, are of great importance.

The Steering Committee also recognized that the care of a patient with cancer rests not only with oncology specialists, but also with a full array of professionals who manage cancer care as part of their daily practice. For this measure set, the Steering Committee believed that the emphasis should be on cancer-related specialties and generalists' activities that directly relate to cancer care; similarly, skills should be assessed in a cancer-related context—for example, in the context of the communication of cancer-specific information, rather than in the context of general communication skills or areas.

Purpose

The purpose of the cancer care quality measurement and reporting system, including a set of standardized performance measures, is to inform the public, patients, payers, providers, purchasers, and researchers about the quality of cancer prevention and treatment activities, including the patient experience across healthcare delivery systems, and to identify opportunities to improve these activities in order to reduce death, disability, suffering, and the economic burden caused by cancer.

In deriving the purpose statement, the Steering Committee determined that both an increase in survival and a decrease in morbidity both were primary targets for measures. In addition, it was believed that symptom management and quality-of-life issues were of primary interest. The Steering Committee also believed that *patients* represent a unique group distinct from the *public* by virtue of their individual perspectives and needs; thus, both categories of stakeholders were encompassed in the purpose.

A set of ancillary purpose statements for the cancer care quality measurement and reporting system also was derived relating to the benefits to be derived from endorsing a cancer measure set:

- provide consensus standards that can shape the education and training curricula of professionals who will be responsible for managing the care of the cancer patient;
- identify research areas where there is need for development of quality measures;

- provide benchmarks for establishing national and regional priorities and policies;
- hasten the transfer of new modalities into clinical practice;
- provide a foundation for the accreditation of professionals; and
- establish a mechanism for the adoption of quality measures in electronic medical records systems.

The use of quality measures to generate data that could be used for policymaking and allocation of resources is an area of critical importance in developing a cancer measure set. Measures designed to capture patterns of care at the population level or to assess the availability of structural elements fall under the rubric of “surveillance measures.”^{3,4} The latter three bullets relate to the improvement of quality at the professional level and were believed to represent important benefits that would result from deriving an NQF-endorsed measure set.

Scope and Framework

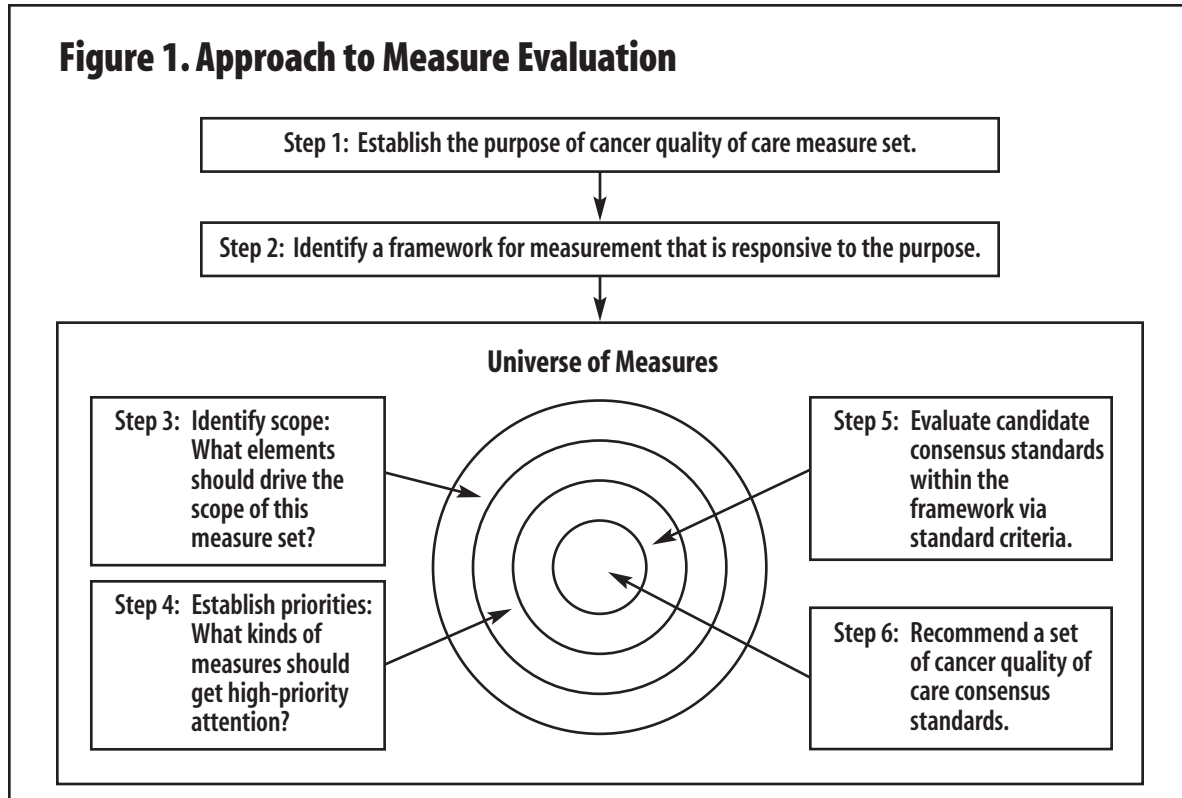
In addition to endorsing a statement of purpose for the quality of cancer care performance measure set—which includes both the measures identified in this report and in work NQF hopes to undertake in the future—NQF also has endorsed a

framework for measuring and reporting the quality of cancer care and an approach to measure selection (see Figure 1). It is recognized that it will take a number of years to fully populate the framework with performance measures, but when fully populated, the portfolio of NQF-endorsed measures for cancer care should encompass:

- a. structure, process, and outcome measures;
- b. screening and the management of pre-malignant conditions or the management of nonmalignant tumors if their management can be linked to a decrease in morbidity or mortality from a neoplastic process;
- c. cancer professionals and facilities in the context of their specific cancer-related activities;
- d. disease-specific measures that focus specifically on diagnosis and treatment, but not screening of normal populations, management of abnormal findings prior to diagnosis, or prevention activities;
- e. measures related to curability;
- f. follow-up and surveillance for second primaries in cancer patients;
- g. communication, coordination, and decisionmaking issues specifically related to cancer-related activities;
- h. measures that are family focused as well as patient focused;

³The definition of a *surveillance measure* that was initially envisioned for this project was in the context of considering populations above the health plan level. The primary aim of such a measure is to identify broad problems and facilitate public policy and resource allocation decisionmaking. The Steering Committee recommended the expansion of the context for the use of surveillance measures to any population level, including hospital and provider office/group levels. The Steering Committee noted that the expanded use of surveillance measures captured areas for which appropriate target levels of performance were poorly defined, and the measures could be used to identify performance outliers and potentially lead to exploratory activities to determine if a problem existed and if remedial activity would be indicated.

⁴Lipscomb J, Donaldson M, Arora N, et al., Cancer outcomes research, *J Natl Cancer Inst Monogr*, 2004;(33):178-197.



- i. measures addressing physical, psychological, spiritual, and social symptoms (for the priority area of symptom management and end-of-life care); and
- j. measures that address all patients (every patient should be covered by a measure).

The fully populated portfolio of measures should include those that apply to various levels of the health system (e.g., community, facility, accredited oncology specialties, other healthcare professionals), and emphasis should be placed on measures of interest to consumers and those that are suitable for accountability purposes. When used for accountability, measures should be under a reasonable degree of control of the healthcare system at the level of the system to which they are applied.

Measures should be evidence based, tested in cancer populations, and associated with interventions that have resulted in demonstrated symptom improvement.

Finally, a comprehensive set of quality of cancer care consensus standards should address the six IOM aims for care: beneficial, patient centered, timely, efficient, safe, and equitable. Because cancer encompasses a heterogeneous array of clinical conditions requiring care from multiple disciplines in many different settings, the six aims must be examined across several domains, as follows:

- surgical, radiological, and oncology services;
- demographic populations;

- disease trajectory and symptom control;
- cancer specialty care (medical oncology, radiation oncology, and surgery); and
- care settings.

Appendix D details specific content areas in each of these domains and presents them in matrices with the six IOM aims; these matrices should facilitate the identification of areas for which measures are needed and should be used to direct research and development initiatives that lead to a comprehensive measure set.

Approach to Measure Evaluation

NQF evaluates candidate consensus standards using four criteria. Not all measures are strong—or equally strong—regarding how they meet each of the four criteria:

1. **Importance.** The extent to which a measure reflects a variation in quality and/or low levels of overall performance, and the extent to which it captures key aspect of the flow of care.
2. **Scientific Acceptability.** The degree to which the measure produces consistent and credible results when implemented.
3. **Usability.** The extent to which intended audiences (e.g., consumers, purchasers) can understand the results of the measure and are likely to find them useful for decisionmaking.
4. **Feasibility.** The way in which data can be obtained within the normal flow of clinical care, the extent to which an

implementation plan can be achieved, and the feasibility of reporting and collecting measures via a manual process and/or automation using electronic systems.

For this project, a Cancer Data and Methods Panel (CDMP) also was convened in August 2004 to advise the project's Steering Committee, Technical Panels, and NQF staff on issues related to the operationalization of the framework. The CDMP reviewed related NQF reports including NQF's Strategic Framework Board publications,⁵ *A National Framework for Healthcare Quality Measurement and Reporting*,⁶ and *A Comprehensive Framework for Hospital Care Performance Evaluation*.⁷ The CDMP's recommendations (Appendix E) were reviewed by the Steering Committee in October 2004 and subsequently led to the provision of additional guidance to NQF staff and to the Technical Panels that were involved in measure evaluation.

The following recommended areas of application were also used to classify the measures: accountability, quality improvement, and surveillance. Accountability measures generally are used in comparing different entities and in support of activities such as public reporting, payment incentive programs, and the selection of providers by consumers, health plans, or purchasers. Quality improvement measures are intended for the internal monitoring of performance within an organization or group so that analyses can be performed and remedial

⁵McGlynn EA, Introduction and overview of the conceptual framework for a national quality measurement and reporting system, *Med Care*, 2003;41(1 Suppl):I1-I7.

⁶NQF, *A National Framework for Healthcare Quality Measurement and Reporting*, Washington, DC: NQF; 2002.

⁷NQF, *A Comprehensive Framework for Hospital Care Performance Evaluation*, Washington, DC: NQF; 2003.

actions instituted. A key attribute of surveillance measures is their potential to create change through public reporting. Public reporting of surveillance measures could influence 1) the allocation of resources to improve access to appropriate end-of-life care and 2) provider and institutional behavior. Aggregation and reporting of macro-level utilization data could be useful for surveillance to identify trends over time; regional health system deficiencies; provider decisionmaking for managing care; and the characteristics of community-level care.

The following criteria were considered by the Steering Committee in identifying the application areas for various measures:

- Accountability measures should have a high level of scientific validity and reliability to ensure that differences are accurately reported.
- There should be no difference between accountability and quality improvement measures in the level and soundness of the scientific evidence of the underlying aspect that is being evaluated – the underlying scientific basis should be sound for both types of measures.
- Sample sizes may differ, with accountability measures requiring large sample sizes to make comparisons statistically significant. Different statistical methodologies may be used in assessing the two types of measures – for example, statistical process control may be used for quality improvement measures.⁸ Additionally, the use of cross-cutting

measures, aggregating measures across time, and “roll-up” measures may provide the necessary sample size to achieve statistical significance.

- The feasibility of collecting data should be considered. Specifically, if data cannot be collected in a consistent manner with standardized coding across institutions, they should not be used as the basis of an accountability measure. In contrast, a quality improvement measure requires merely that the data be collected consistently within the institution, which is easier to achieve. Similarly, coding may be inconsistent across a broad range of providers; thus the measurements will not refer to the same populations or entities. For quality improvement purposes within a single institution or network, this may be acceptable.
- Because cancer – especially if one type is to be evaluated – is a relatively infrequent disease, most measures for accountability may be at the institutional level rather than at the physician level.
- Measures used for accountability should be transparent and understandable to those in all segments of the healthcare system, especially consumers.
- For accountability measures, adequate inclusion and exclusion criteria and risk adjustment should permit a 100 percent inclusion target for the measure. The aim should be that all of the appropriate patients should receive the intervention. The value of accountability measures that have threshold levels of less than 100 percent is difficult to evaluate. For example, if only 75 percent of patients

⁸Care should be taken to balance the benefit of having the statistical stability of large sample sizes with the concerns of small providers who wish to present information about their performance on process measures of care in public forums on an equal footing with larger providers. Responsible public reporting should include information on confidence intervals and data limitations.

could reasonably be expected to meet the criteria, questions of case mix might become paramount. Similarly, rates over 90 percent might raise issues of overuse.

Identifying Cancer Care Measures

Measures were identified through the use of several complementary strategies. In addition to a Call for Measures and active surveillance for appropriate measures, systematic evidence reviews were conducted to identify measures related to the priority areas.

The Call for Measures for breast cancer, colorectal cancer, and symptom management and end-of-life care was issued and in addition, the Steering Committee and Technical Panel members were asked to identify measures and/or sources of potential measures. The breast cancer Call yielded 25 candidate consensus standards. The colorectal cancer Call yielded eight candidate consensus standards, one of which was not considered to be within the scope of the project. The symptom management and end-of-life care Call yielded 11 candidate consensus standards. In addition, the National Quality Measures Clearinghouse, sponsored by AHRQ, was queried to identify candidate consensus standards for these priority areas, although none was identified. Two measures that were submitted to the NQF Ambulatory Care project were considered suitable for the colorectal cancer measure set and were included with the consent of their developers.

Under separate funding from AHRQ, three systematic literature reviews were

performed to identify measures related to breast cancer care, colorectal cancer care, and symptom management and end-of-life cancer care.

Breast Cancer: University of Ottawa Evidence-based Practice Center (EPC)

The University of Ottawa EPC reviewed published and unpublished literature to identify measures related to breast cancer care and to propose areas in which measures were needed. Only 11 validated measures were found, all relating to quality-of-life psychometric studies; 143 potential indicators were found relating to breast cancer diagnosis and treatment. None of the measures identified was considered suitable for NQF review due to lack of scientific development, reliability, and/or validity to sufficiently quantify patterns of breast cancer care.

Colorectal Cancer: Duke University EPC

The Duke University EPC also reviewed published and unpublished literature to identify measures related to colorectal cancer care and to propose areas in which measures were needed. The study noted the difficulty in identifying measures that were reported in the quality improvement context. Areas identified in the EPC report that corresponded to measures submitted to NQF for review were preoperative staging, completeness of pathology reporting, retrieval of adequate lymph nodes at surgery, postoperative colonoscopy surveillance, and adjuvant chemotherapy. Three measure developers identified from the Duke EPC review were approached about submitting their measures, but all declined due to proprietary issues.

Symptom Management and End-of-Life Care: Southern California EPC

The Southern California EPC undertook a systematic literature review to identify the quality of care measures for pain, dyspnea, depression, and advance care planning and to identify gaps in the literature. The EPC noted that many of the measures identified were not ready in the area of accountability because of inadequate specifications and testing, but suggested that they might be useful for quality improvement. No additional measures were identified from this effort.

The NQF-Endorsed Quality of Cancer Care Consensus Standards

The NQF-endorsed cancer care consensus standards titles and purposes are presented below, as are research recommendations in each area. Chapters 2 and 3 provide additional information for each priority area. The measure specifications can be found in Appendix A.

Breast Cancer

Six national voluntary consensus standards are endorsed for breast cancer care:

- **Post breast conserving surgery irradiation** – accountability, quality improvement, surveillance.
- **Adjuvant chemotherapy** – accountability, quality improvement, surveillance.
- **Adjuvant hormonal therapy** – accountability, quality improvement, surveillance.
- **College of American Pathologists Breast Cancer Protocol** – accountability, quality improvement, surveillance.
- **Needle biopsy diagnosis** – quality improvement, surveillance.
- **Patients with early stage breast cancer who have evaluation of the axilla** – quality improvement, surveillance.

Colorectal Cancer

Four national voluntary consensus standards are endorsed for colorectal cancer care:

- **Adjuvant chemotherapy** – accountability, quality improvement, surveillance.
- **Completeness of pathology reporting** – accountability, quality improvement, surveillance.
- **College of American Pathologists Colon and Rectum Protocol** – accountability, quality improvement, surveillance.
- **Surgical resection includes at least 12 nodes** – surveillance.

Symptom Management and End-of-Life Care

Nine national voluntary consensus standards are endorsed for symptom management and end-of-life care:

- **Family Evaluation of Hospice Care (FEHC)** – accountability, quality improvement, surveillance.
- **Comfortable dying** – quality improvement, surveillance.
- **Chemotherapy in the last 14 days of life** – surveillance.
- **More than one emergency room visit in the last 30 days of life** – surveillance.
- **More than one hospitalization in the last 30 days of life** – surveillance.

- **Intensive care unit admission in the last 30 days of life**—surveillance.
- **Dying in an acute care setting**—surveillance.
- **Not admitted to hospice**—surveillance.
- **Admitted to hospice for less than three days**—surveillance.

Relationship to Other NQF-Endorsed Consensus Standards

This report does not reflect the full range of NQF-endorsed performance measures and practices that apply to the delivery of high-quality cancer care. The cancer measures can be used with other NQF-endorsed measures to provide a more complete picture of the quality of care provided.

Research Recommendations

NQF offers the following recommendations for research to improve the evidence base for performance measurement in cancer care and to enhance the implementation of the endorsed measures.

Breast and Colorectal Cancer

Recommendation 1: General Research Agenda

A comprehensive measure set for breast and colorectal cancer care should include measures that address all of the areas detailed in the four content domains—trajectory of the disease, oncology services, oncology care settings, and demographic populations (Appendix D). For each of these areas, the highest level of quality should encompass the IOM aims for

healthcare quality—that is, that healthcare should be safe, beneficial, patient centered, efficient, timely, and equitable. Many of the critical areas in which measures are lacking are not specific to breast or colorectal cancer, but rather are cross-cutting for cancer care in general. For example, pain management in breast cancer should be pursued, as should pain management for all cancer patients. Similarly, many areas transcend multiple domains, which is why we see an absence of safety measures related to both oncology services and oncology care settings. Other high-priority areas that should be pursued include psychosocial issues, metastatic disease, medical oncology office practice, and nursing.

Recommendation 2: Data Availability

An important area that will underlie the success of future research pertains to the availability of data. A major component of a quality research agenda should be directed toward the development of substantially more sophisticated information technology solutions related to the storing and retrieval of data. Although the electronic medical record (EMR) often is proposed as the solution, it appears that EMRs will not be available in a form that is capable of granular data collection across multiple settings for several years. Shared databases and registries should be explored as vehicles for expanding the pool of available data. Additionally, appropriate safeguards should be explored to protect privacy and data security.

Recommendation 3:**Development of Consumer-Oriented Measures**

Another significant deficit is the lack of data about the areas patients find most important. This includes measures of health-related quality of life, patient experience and symptom management, as well as, process measures (e.g., coordination and continuity of care). Focus groups should be held and patient surveys should be undertaken to identify these patient-centered priorities. Current surveys are not cancer specific, and it is not clear whether the results of existing surveys can be extrapolated to the cancer population. Research also should be undertaken to ensure that measures are presented in terms consumers and patients can understand.

Recommendation 4:**Research to Meet Quality Aims**

Specific areas that should shape the research agenda include the following:

Safe

- Safety issues frequently are not addressed in oncology, but should be; this would require having highly granular data to monitor chemotherapy dosing and radiation dosages and portals.
- Surgical safety issues often are addressed in general surgery measures, but their applicability to cancer-specific surgery should be assessed.

Beneficial

- The prime focus should be on measures addressing aspects of care areas that have a direct impact on survival.

- Measures of symptom control, especially at end-of-life and in the metastatic setting, also are very important and should be viewed as a high priority.
- Treatment-specific measures should be reviewed frequently. The dynamic nature of scientific advances may make it difficult to generate treatment-specific measures – that is, by the time the measure is developed, the science will have changed.

Patient Centered

- The identification of patient-centeredness measures, especially in the areas of shared decisionmaking and quality of life, are needed across the entire spectrum of cancer care.
- Some aspects of patient satisfaction surveys address major quality areas, and research should further define these and validate their use as quality measures.
- Patient-centeredness issues may be addressed by discipline-specific measures for all disciplines covering the care of patients – for example, as nursing-sensitive measures.

Efficient

- Efficiency measures should be one of the most important areas of effort, because such a focus could have an enormous impact on costs; the overutilization of diagnostic testing and surveillance testing may be a prime target.

Equitable

- Access to care for all populations and groups across all settings is of critical importance. Disparities related to cancer treatment and outcomes have been well documented, and the development of initiatives to reduce these disparities should be of the highest priority.

- Special attention should be directed to treatment of the over-70 age group.

Timeliness

- Timeliness measures should evaluate whether appropriate tests or treatments are administered in a timeframe that fosters informed decisionmaking but is not delayed to the point where effectiveness of care would be affected.

Recommendation 5: Measure Development

To ensure that all aspects of quality of cancer care are addressed and that the measure sets for breast and colorectal cancer care are comprehensive, measures should be developed in the following areas, which address major processes or outcomes. These areas are grouped under the aims of quality in Table 1, found at the end of this chapter.

Recommendation 6: Future NQF Activities

The development of a comprehensive set of breast and colorectal cancer care measures will continue to evolve over several years. In order to facilitate the development of these measures, ongoing efforts should be made to coordinate the activities of NQF and measure developers. Specifically, efforts that can expedite the recognition of measure deficiencies and the suggestion of appropriate modifications will facilitate rapid re-testing and submission of measures for review and ultimately increase the availability of measures in the breast cancer and colorectal cancer care measure sets.

Symptom Management and End-of-Life Care

The paucity of measures submitted or otherwise identified during this project attests to the need for valid measures related to symptom management and end-of-life care generally and cancer care specifically. There is also limited quality improvement benefit for measures that begin with death and retrospectively assess patient quality of care. A coordinated and well-funded program to address these gaps should become a national priority. The program should emphasize basic conceptual and infrastructure issues that need to be addressed in order to produce a standardized set of quality of cancer care performance measures. These measures should address documenting and reporting cancer care in an efficient and timely manner.

Research Recommendation 1: Database Research

There currently is no standardized database or system for collecting information about symptom management or end-of-life care. A mechanism for standardizing data elements, or deriving interoperability, should be sought through public-private initiatives. In addition, research should be developed to examine the feasibility of collecting and reporting data through manual processes and/or automation using electronic systems.

Research Recommendation 2: Types of Measures

Research is needed to determine the types of measures that meet the needs of various healthcare stakeholders. Studies should be undertaken in consultation with user groups to ensure that these groups consider the

appropriate measures and that the measures in a given area meet the quality assessment needs of the related group. Special consideration should be given to the development of measures that meet the standards for accountability and public reporting, especially in light of current consumer and purchaser interest in these areas.

**Research Recommendation 3:
Modes of Presentation**

For each measure developed, research is needed to find out how the information can best be presented to each stakeholder group so that the data used fulfill the usability criteria.

Research Recommendation 4: Measurement of Symptoms in Cancer Populations Versus General Patient Groups

The management of symptoms such as dyspnea, pain, and depression may be generalizable across many patient populations; thus, information related to the measurement of symptoms in cancer patients could be included in the results of general surveys. Research is needed to demonstrate that the results of measuring symptom control in the general populations are valid as applied to those with cancer-related symptoms.

**Research Recommendation 5:
Health Insurance Portability and Accountability Act of 1996 (HIPAA)-Compliant Patient Data**

Research should be undertaken to determine how patient-specific data could be collected while ensuring privacy in accordance with all HIPAA requirements. Additionally, research into the development of a confidential unique identifier for patients should be pursued.

**Research Recommendation 6:
Stability of Cancer-Related Measures**

Technology management in cancer care is rapidly changing; thus, measures should be constantly assessed to ensure that they are not based on outdated methods and procedures.

**Research Recommendation 7:
Outcomes of Symptom Management**

Research on the adequate management of pain and dyspnea should be of the highest priority with respect to the physical management of symptoms, and depression and anxiety should be the highest priorities in the area of psychosocial symptom management. Other important areas for research include anorexia, nausea, constipation/diarrhea, delirium, and other gastrointestinal conditions.

**Research Recommendation 8:
Intermediate Outcomes of Processes**

In selecting process measures, developers should also focus on the intermediate outcome of those processes, i.e., the direct results of the process. In essence, this will address the dimension of quality, that is, how well the processes were carried out. In the area of radiation therapy, correct dosing and tumor localization are still a critical issue. In surgery, assessment of the pathology specimen can yield valuable quality information about the adequacy of the surgery. Parameters for chemotherapy care are not as clear, for example, relative dose intensity, and further studies will be necessary to delineate that they are the appropriate intermediate outcome measures.

Complication rates, including short-term mortality rates, can also be used to assess intermediate outcomes. This has been studied primarily in surgery; therefore, basic studies in radiation therapy and chemotherapy would have to be performed. Additionally, sophisticated risk-adjustment processes will have to be used to ensure that complications are measured appropriately in incomparable populations.

**Research Recommendation 9:
Patient-Centered Decisionmaking**

With respect to the area of palliation, the development of patient-centered measures should receive the highest priority, especially in assessing the quality of end-of-life care. Research should be conducted to support the development of measures that assess the congruence between the care that is delivered and patient preferences for that care. The overall prevalence of advance care planning currently is unknown, and measures should be devised to ensure that this vital task is performed. Significant emphasis should be placed on assessing the quality of communication between patients and physicians.

**Research Recommendation 10:
Efficiency Measures**

Significant research funding should be directed toward assessing the overuse or misuse of services, problems that will become increasingly important given the economic climate of healthcare. One important issue in the area of misuse is inappropriate testing during work-ups for new or recurrent disease. The overuse of aggressive therapy in the terminal phases of illness is a significant source of inefficient care, and measures should be devised to identify reasonable thresholds. For example, a measure directed at the evaluation of radiotherapy use in the last 14 days of life should be developed.

**Research Recommendation 11:
Pediatric Measures**

The management of pediatric patients may entail factors that may lead to differences in resource utilization as compared with adult patients. Ongoing research is needed to identify these factors. Additional research should be conducted to support the development of measures to evaluate pediatric cancer care.

Table 1 – Recommended Measure Development for Breast Cancer and Colorectal Cancer

(Research areas that apply to both breast and colorectal cancer are designated B/C, while those specific to breast cancer are designated B, and those specific to colorectal cancer C.)

Safe Care. (Safety measures assess whether harm was done to a patient or measure the rate of harmful experiences across patients.)

- Assessment of complications
 - major surgical procedures (B/C)
 - biopsies (B/C)
 - acute and postirradiation sequelae (B/C)
 - acute and postchemotherapy sequelae (B/C)
 - wound infections (B/C)
- Assessment of systems to prevent complications (B/C)

Beneficial Care. (Measures relate to the achievement of clinical benefits, primarily from disease-oriented interventions, and may include processes [was the correct thing done?], outcomes [were optimal results obtained?], and technical performance of interventions [when the right thing was done, was it done correctly?]. Potential areas for beneficial measure development were assessed for the various phases in the trajectory of cancer: diagnosis, work-up, treatment, follow-up, treatment of relapse, and end-of-life care.)

- Diagnosis
 - adequacy of pathology reports (B/C)
 - interpretation of mammograms and other imaging (B)
 - appropriate use of MRI (B)
 - adequacy and completeness of colonoscopy (C)
- Work-up
 - appropriate use of PET scans (B)
 - bilateral mammograms within two months of surgery (B)
 - documentation of complete staging by American Joint Committee on Cancer standards (B/C)
 - accuracy of staging (B/C)
 - appropriate marker studies (B/C)
- Treatment
 - technical quality of chemotherapy (B/C)
 - dose and dose modifications
 - use of appropriate agents
 - timing
 - technical quality of radiation (B/C)
 - dose
 - fields
 - partial breast irradiation (B)
 - technical quality of surgery
 - margin status (B/C)
 - number of nodes (B/C)
 - appropriate breast-conserving surgery (B)
 - rate of sphincter-sparing surgery/appropriate abdominoperineal resections (C)
 - malignant polyp management (C)
 - management of ductal carcinoma in situ (DCIS) and lobular carcinoma in situ (LCIS) (B)
 - total mesorectal excision in rectal cancer (C)
 - monitoring of sentinel node proficiency (B)
 - laparoscopic colon surgery (C)
- Follow-up
 - appropriate testing—mammograms (as defined by sensitivity, specificity, positive predictive value, etc.) (B)
 - inappropriate overtesting (B/C)
 - assessment of primary care surveillance practices (B/C)
 - management of lymphedema (B)
 - adequacy of enterostomal care (C)

(more)

Table 1 – Recommended Measure Development for Breast Cancer and Colorectal Cancer

(Research areas that apply to both breast and colorectal cancer are designated B/C, while those specific to breast cancer are designated B, and those specific to colorectal cancer C.) (continued)

Beneficial Care. (continued)

- Outcome measures
 - 5-year survival (B/C)
 - 30-day mortality (C)
 - assessment of whether 10-year survival is a better measure than 5-year survival (B/C)
 - percentage of early stage disease and stage at diagnosis (for surveillance purposes only and representative of screening, not treatment) (B/C)
 - rates of local recurrence (B/C-rectum)
 - functional status (B/C)
 - time off from work
 - development of new functional measures
 - assessment of comorbidity

Timely Care. (Timeliness measures evaluate whether appropriate tests or treatments are administered in a timeframe that fosters informed decisionmaking but that is not delayed to the point where effectiveness of care would be affected.)

- Delay in biopsy: time between mammogram to pathologic diagnosis (B)
- Delay in time from symptoms to endoscopy (C)
- Initiation of treatment prior to definitive diagnosis (B)
- Time between resolving nondefinitive mammographic findings (B)

Patient-Centered Care. (Patient-centeredness measures relate to the experiences of illness and healthcare of the patient and his or her family. Quality care in this area may be assessed in several dimensions: respect for preferences and values; the provision of information and education; the amelioration of physical and emotional discomfort; the involvement of the family; coordination of care; and support of decisionmaking. These measures reflect the quality of care provided by healthcare professionals as perceived by the patient. Providers also should be aware of the quality of patient-centered care they are rendering. One approach to defining patient-centered care advocated by the National Breast Cancer Coalition has been to ascribe six overlapping core values to this aim: access, information, choice, respect, accountability, and improvement.)

- Coordination and professional communication (B/C)
 - referral for genetic screening when appropriate
 - designation of leader or coordinator of care
- Decision support (B/C)
 - determination of whether the patient wants to be involved in decisionmaking and how patient preference should be accommodated by measure development
 - measurement of time to definitive decisionmaking with a focus on ensuring that patients are not rushed into decisionmaking about type of primary surgical management
 - decisionmaking about whether to undergo chemotherapy in the elderly
 - eliciting patient preferences and degree of shared decisionmaking about major clinical interventions
 - type of surgery
 - radiation therapy
 - adjuvant and palliative chemotherapy
 - reconstruction in conjunction with mastectomy (B)
 - decisionmaking regarding prophylactic mastectomy (B)
- Information/education (B/C)
 - provision of information by providers for all therapies
 - user understanding of clinical reports
 - mammogram reports (B)
 - pathology reports
 - quality of information at time of transition periods (B/C)
 - diagnosis
 - first recurrence
 - second recurrence
 - progression of disease

(more)

Table 1 – Recommended Measure Development for Breast Cancer and Colorectal Cancer

(Research areas that apply to both breast and colorectal cancer are designated B/C, while those specific to breast cancer are designated B, and those specific to colorectal cancer C.) *(continued)*

Patient-Centered Care. *(continued)*

- Emotional support (B/C)
 - communication at end-of-life
 - psychological symptom assessment
 - psychological support at completion of primary and adjuvant treatment
 - type and frequency of counseling
- Respect for preferences and values (B/C)
 - general CAHPS®-like measure ¹
 - development of a cancer module for CAHPS
 - assessment of physical symptoms (B/C)
 - assessment both during and after treatment
 - assessment of all symptoms

Efficient Care. (Most of these measures relate to the overuse of resources with no supporting evidence of effectiveness.)

- Overutilization of staging tests (B/C)
- Over-retesting of mammographic exams (B)
- Mastectomy for Stage IV disease (B)
- Use of serum markers to routinely monitor disease (B)
- Overuse of imaging in follow-up (B/C)
- Overuse of chemotherapy, other treatment modalities and testing in terminal state: may be more difficult in breast and colorectal cancer than lung (B/C)
- Time between last dose of chemotherapy and death (B/C)
- Timeliness of clinical follow-ups (B/C)
- Duplicative follow-up by multiple providers (B/C)

Equitable Care. (Measures of equitability evaluate whether there are disparities in care related to demographic, economic, or environmental factors.)

- Access to care: rural versus urban (B/C)
 - Disparities in outcomes, especially mortality (B/C)
 - geographic variation
 - variation based on demographic and socioeconomic factors
-

¹CAHPS refers to the Consumer Assessment of Health Plans Survey.

NATIONAL QUALITY FORUM

Chapter 2: National Voluntary Consensus Standards for Diagnosis and Treatment of Breast and Colorectal Cancer

Introduction

Although major advances have been made in prevention, screening, and treatment, cancer remains the second largest cause of mortality in the United States, behind heart disease. From a morbidity perspective, patients with uncontrolled tumors may undergo a course marked by suffering and, even if rendered free of disease, experience pervasive physical, psychosocial, and spiritual sequelae. Economically, losses due to the disease include direct costs of \$37 billion and losses due to productivity and mortality of \$11 and \$59 billion, respectively.

The care of cancer patients is complex and requires the seamless integration of care from many professional caregivers, including pathologists, radiologists, primary care physicians, surgeons, radiation oncologists, medical oncologists, nurse oncologists, social workers, and chaplains, to name just a few. Despite intensive training in all of these disciplines, in 1999 the Institute of Medicine (IOM) evaluated the state of U.S. cancer care and concluded "... 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."¹

Because of the heterogeneity and complexity of this care, the development of a comprehensive set of measures gauging the quality of cancer care has been slow in developing, although ongoing activities in many measure development organizations and medical subspecialty

¹Hewitt ME, Simone JV, eds., *Ensuring Quality Cancer Care*, Washington, DC: National Academy Press; 1999.

societies ensure that the array of standards will expand in the near future. This chapter focuses on two of the most common neoplasms—breast and colorectal cancer.

Issues Related to Data for Breast and Colorectal Cancer Standards

During the evaluation of candidate breast cancer and colorectal cancer consensus standards, two broad data-related issues were identified.

Tumor Registry Data as the Data Source

The majority of measures submitted drew on data from hospital-based tumor registries. In the United States, 75 percent of cancer patients receive their care through Commission on Cancer (CoC)-approved programs that mandate that hospitals maintain registries of standardized data, as detailed in the Facility Oncology Registry Data Standards (FORDS).² State tumor registries, under the auspices of the Centers for Disease Control and Prevention (CDC), also collect standardized data. Tumor registry data are considered a reasonable source of data for measures, although the following potential shortcomings must be taken into account:

- Data from tumor registries may not be available for two to three years (following receipt of treatment), which may have substantial impact on the ability to track measures in a timely manner.
- Because only 75 percent of cancer cases are managed in hospitals with CoC approval, the availability of data from tumor registries for the other 25 percent may be problematic.
- The ability to collect data regarding outpatient therapy, for example, adjuvant hormonal or cytotoxic, may vary across registries. Estimates of 8 to 18 percent differences between registry and medical chart data have been reported. The CoC has an audit process in place, and an onsite examiner further evaluates the accuracy of registry data at the time of program approval.

Burden of Data Collection

Data collection for assessing measure performance entails a substantial outlay of resources, both in terms of personnel and funds. The cost of data collection especially will pose a significant burden for cancer measures that require medical record review to capture information not available in registries or administrative databases. An important segment of quality care related to patient-centered issues such as shared decisionmaking may be available only through record review or patient surveys.

Breast Cancer

Breast cancer is the most common cancer in women and the leading cause of cancer-related death for women. In 2005, an estimated 140,000 women were diagnosed with the disease and despite therapeutic

² American College of Surgeons, *FORDS. Facility Oncology Registry Data Standards*. Available at www.facs.org/cancer/coc/fords/errata0605.pdf. Last accessed November 2006.

advances over the last several decades, 33,000 died from the disease.³ Survival is correlated with the stage of the disease at diagnosis. Current five-year survivals are Stage 0 (in-situ disease), 99.6 percent; Stage I, 87.5 percent; Stage II, 76.7 percent; Stage III, 50.7 percent; and Stage IV (metastatic disease at presentation), 15.8 percent.⁴ Breast cancer is a major cause of morbidity, and the psychosocial burden experienced even by women rendered free of their disease exacts a sizeable toll on the health of American women.⁵

The diagnosis and treatment of breast cancer requires a multidisciplinary approach, and optimal care can be achieved only if the efforts of the primary care physician, the breast imager, the pathologist, the surgical, radiation, and medical oncologists, the nurse oncologist, and the plastic surgeon are applied in a manner consistent with high standards. Unfortunately, surveys from many sources and covering many aspects of care demonstrate that not all women receive care of the highest quality.⁶

Examples of less than adequate management exist across the spectrum of breast cancer care. In order to treat breast cancer appropriately, the clinician must begin with an accurate diagnosis and staging of the disease. The pathology elements required for proper management are well documented,⁷ but despite the wide availability of this vital information, a substantial proportion of pathology reports do not contain it.⁸ Similar deficiencies exist in the treatment area, with documented suboptimal use of radiation after breast-conserving surgery⁹ and adjuvant chemotherapy and hormonal treatment¹⁰ after surgery for early-stage disease. In many instances, these disparities are especially important for certain vulnerable groups. Elderly patients are much less likely to be given treatment after surgery,¹¹ despite evidence that they receive the same benefit as others.¹² African American elderly women are less likely to receive radiation therapy than elderly white women.¹³ Rural patients who live a distance from radiation centers

³Jemal A, Murray T, Ward E, et al., Cancer statistics, 2005, *Ca Cancer J Clin*, 2005;55:10-30.

⁴National Cancer Data Base. Available at web.facs.org/ncdbbmr/sas6/surv/GRAPHS/OY96S37XaT00000B.html. Last accessed November 2006.

⁵Ganz PA, Rowland JH, Desmond K, et al., Life after breast cancer: understanding women's health-related quality of life and sexual functioning, *J Clin Oncol*, 1998;16:501-514.

⁶Malin JL, Schuster MA, Kahn KA, et al., Quality of breast cancer care: what do we know? *J Clin Oncol*, 2002;20:4381-4393.

⁷Fitzgibbons PL, Page DL, Weaver D, et al., Prognostic factors in breast cancer. College of American Pathologists Consensus Statement 1999, *Arch Path Lab Med*, 2000;124:966-978.

⁸White J, Morrow M, Moughan J, et al., Compliance with breast-conservation standards for patients with early stage breast cancer, *Cancer*, 2003;97:893-904.

⁹Morrow M, White J, Moughan J, et al., Factors predicting the use of breast conserving surgery therapy in Stage I and Stage II breast cancer, *J Clin Oncol*, 2001;19:2254-2262.

¹⁰Harlan LC, Abrams J, Warren JL, et al., Adjuvant therapy for breast cancer: practice patterns of community physicians, *J Clin Oncol*, 2002;20:1809-1817.

¹¹Du XL, Goodwin JS, Increase of chemotherapy use in older woman with breast carcinoma from 1991-1996, *Cancer*, 2001;92:730-737.

¹²Muss HB, Woolf S, Berry D, et al., Adjuvant chemotherapy in older and younger women with lymph node positive breast cancer, *JAMA*, 2005;293:1073-1081.

¹³Mandelblatt JS, Kerner JF, Hadley J, et al., Variations in breast cancer treatment in older Medicare beneficiaries. is it Black and White? *Cancer*, 2002;95:1401-1414.

are more apt to be treated with mastectomy or are less likely to receive irradiation if they have a breast-conserving procedure.¹⁴

Breast cancer care also can serve as a model for addressing issues of patient empowerment through shared decision-making. Should a woman undergo mastectomy or lumpectomy; should she undergo reconstruction; should she take potentially toxic chemotherapy? Each of these major decisions represents a critical need for shared decisionmaking between patient and physician. Unfortunately, a significant proportion of women do not feel they have been given enough information or the opportunity to discuss their options.¹⁵

Economically, breast cancer has a serious impact on the healthcare system. CDC estimates that \$7 billion a year is spent on the treatment of breast cancer.¹⁶ Since a large part of this expenditure is spent on care for women with advanced disease, optimal care in the initial phases of the disease will save not only lives but also valuable healthcare dollars.

The NQF-Endorsed National Voluntary Consensus Standards for Diagnosis and Treatment of Breast Cancer

The National Quality Forum (NQF)-endorsed[®] consensus standards for breast cancer encompass six measures that will facilitate efforts to improve the quality of

care for patients with a breast cancer diagnosis who are undergoing treatment. Five of these consensus standards are measures, and the sixth is a standard protocol for the reporting of breast cancer pathology. The measures are all considered hospital-level measures.

Four measures are endorsed for accountability, quality improvement purposes, and/or surveillance. Two measures are endorsed for quality improvement and/or surveillance. Table 2 presents the six endorsed consensus standards.

Breast Cancer Measures Identified for Further Development

Of the measures submitted in response to the Call for Measures, two were identified as needing further development in order to be considered for endorsement as a measure of accountability and improvement. It was recommended that the measure developers address certain methodological issues. The measures that were identified in this developmental category included the following:

- 80 percent or more women with breast cancer diagnosed through the National Breast and Cervical Cancer Early Detection Program should have initiated treatment within 60 days, and
- percent of invasive breast cancer patients with estrogen receptor/progesterone receptor status documented.

¹⁴Nattinger AB, Kneusel RT, Hoffmann RG, et al., Relationship of distance from a radiation facility and the initial breast cancer treatment, *J Natl Cancer Inst*, 2001;93:1344-1346.

¹⁵Janz NK, Wren PA, Copeland LA, et al., Patient-physician concordance: preferences, perception, and factors influencing the breast cancer surgical decisions, *J Clin Oncol*, 2004;22:3091-3098.

¹⁶Centers for Disease Control and Prevention, *Prevention and Controlling Cancer: The Nation's Second Leading Cause of Death, At a Glance 2007*. Available at www.cdc.gov/nccdphp/publications/aag/dpcp.htm. Last accessed November 2006.

Table 2 – National Voluntary Consensus Standards for Diagnosis and Treatment of Breast Cancer

(R = Recommended; FD = Further Development)

| CONSENSUS STANDARD | RECOMMENDED USE | | |
|---|-----------------|---------------------|--------------|
| | ACCOUNTABILITY | QUALITY IMPROVEMENT | SURVEILLANCE |
| Post breast conserving surgery irradiation | R | R | R |
| Adjuvant chemotherapy | R | R | R |
| Adjuvant hormonal therapy | R | R | R |
| College of American Pathologists Breast Cancer Protocol | R | R | R |
| Needle biopsy diagnosis | FD | R | R |
| Patients with early stage breast cancer who have evaluation of the axilla | FD | R | R |

Colorectal Cancer

Colorectal cancer represents a major threat to health in the United States, ranking third in incidence for all tumors for both men and women. In 2006, an estimated 148,000 Americans developed cancer of the colon or rectum, and 55,000 died of the disease.¹⁷ Although rates have decreased over the past several years, probably resulting from increased screening for adenomatous polyps,¹⁸ the aging of the population ensures that this tumor will remain a major health concern, since the median age for developing colorectal cancer is 71 years, and 67 percent of these tumors are diagnosed in people over 65 years of age.¹⁹

The overall survival rate at five years for patients developing a colon tumor is 51 percent,²⁰ a rate that is considered problematic. Survival correlates with the stage at diagnosis, with rates of 72.9 percent for Stage I, 62.6 percent for Stage II, 48.1 percent for Stage III, and only 6.2 percent for Stage IV. The low overall survival rate reflects the fact that more than 40 percent of cases present with regional lymph node or distant metastases. Similar rates apply to rectal cancer.

In addition to their impact on survival, these tumors may result in considerable morbidity and have serious implications for a patient's quality of life. For patients who require a colostomy, considerable time must be spent managing side effects and

¹⁷ Jemal A, Siegel R, Ward E, et al., Cancer Statistics 2006, *Ca Cancer J Clin*, 2006;56:106-130.

¹⁸ National Cancer Institute (NCI), Stat bite: declining incidence of colorectal cancer, *J Natl Cancer Inst*, 2006;98:734.

¹⁹ NCI, *SEER Cancer Stat Fact Sheets, 2000-2003*. Available at seer.cancer.gov/statfacts/html/colorect.html?statfacts_page=colorect.html&x=12&y=16. Last accessed November 2006.

²⁰ American College of Surgeons, *Five Year Survival Rates for Colon Cancer Cases Diagnosed in 1998*. Available at web.facs.org/ncdbbmr/sas6/surv/GRAPHS/OY97S14XaT00000B.html. Last accessed November 16, 2006.

preventing complications.²¹ Major bowel dysfunctions may occur in patients who do not require colostomy, greatly affecting their social functioning.²² Evaluation of sexual function in patients undergoing rectal surgery has shown that the procedure made their sexual lives worse in 29 percent of women and 45 percent of men.²³ One year following surgery, colorectal patients still have significant emotional and social functioning deficits,²⁴ including issues such as satisfaction with care, receiving information, and making sense of the cancer experience.²⁵

Despite the prevalence of colorectal tumors, deficiencies have been demonstrated in many aspects of the care of patients. Properly managing colorectal cancer requires accurate staging, which depends on a complete pathology report. Unfortunately, surveys have demonstrated that key elements used to determine staging are left off pathology reports in a

significant number of cases.^{26,27} A major thrust in colorectal quality improvement has been assuring that an adequate number of lymph nodes are included in the surgical specimen, because inadequate resections or pathology assessments decrease survival rates. Studies have shown that a substantial number of cases do not have the requisite number of nodes reported.²⁸ This may correlate with the size of the hospital, with smaller hospitals being less likely to meet the standard.²⁹

Treatment-related parameters reflecting quality care are the colostomy rate (lower is better) and the mortality rates. Inter-hospital comparisons point to possible volume effects, with lower volume centers performing more colostomies³⁰ and demonstrating higher mortality rates^{30,31} and higher local recurrence rates. The effect of hospital size may be especially relevant for the management of elderly patients with their higher mortality rates.³² In the area of

²¹ Doughty D, Principles of ostomy management in the oncology patient, *J Support Oncol*, 2005;3:59-69.

²² Vironen JH, Kairaluoma M, Aalto M, et al., Impact of functional status on quality of life after rectal surgery, *Dis Colon Rectum*, 2006;49:568-578.

²³ Hendren SK, O'Connor BI, Liu M, et al., Prevalence of male and female dysfunction is high following surgery for rectal cancer, *Ann Surg*, 2005;242:212-223.

²⁴ Arndt V, Merx H, Stegmaier C, et al., Quality of life in patient with colorectal cancer 1 year after diagnosis compared with the general population: a population-based study, *J Clin Oncol*, 2004;22:4829-4836.

²⁵ Dunn J, Lynch B, Rinaldis M, et al., Dimensions of quality of life and psychosocial variables most salient to colorectal cancer patients, *Psychooncology*, 2006;15:20-30.

²⁶ Wei JT, Miller EA, Woosley JT, et al., Quality of colon carcinoma reporting: a process of care study, *Cancer*, 2004;100:1262-1267.

²⁷ Stocchi L, Nelson H, Sargent DJ, et al., Impact of surgical and pathological variables in rectal cancer: a United States community and cooperative group report, *J Clin Oncol*, 2001;19:3895-3902.

²⁸ Baxter NN, Virnig DJ, Rothenberger DA, et al., Lymph node evaluation in colorectal cancer patients: a population-based study, *J Natl Cancer Inst*, 2005;97:219-225.

²⁹ Miler EA, Woosley J, Martin CF, et al., Hospital to hospital variation in lymph node detection after colon resection, *Cancer*, 2004;101:1065-1071.

³⁰ Hodgson DC, Zhang W, Zaslavsky AM, et al., Relation of hospital volumes to colostomy rates and survival for patients with rectal cancer, *J Natl Cancer Inst*, 2003;95:708-716.

³¹ Schrag D, Panageas KS, Riedel E, et al., Surgeon volume compared to hospital as a predictor of outcome following primary colon cancer resection, *J Surg Oncol*, 2003;83:68-78.

³² Dimick JB, Cowan JA Jr, Upchurch GR Jr, et al., Hospital volume and surgical outcomes for elderly patients with colorectal cancer in the United States, *J Surg Res*, 2003;114:50-56.

adjuvant therapy – the administration of chemotherapy or radiation therapy in addition to surgery to improve the chances of not having the disease recur – many patients are not receiving appropriate care. In 2002, one-third of patients with Stage III colon cancer did not receive adjuvant chemotherapy.³³ Factors correlating with usage include age,^{33,34,35,36} hospital volume,¹⁹ and ethnicity/race.^{33,34,35,37} The sum total of these findings must be that a substantial number of Americans do not receive treatments that could improve their chances of survival.

A major domain of quality care for the colorectal patient is that it be patient centered. Areas such as communication and coordination of care are of paramount interest to the receiver of care³⁸ and can negate the value of excellent technical competence.³⁹ More than one-third of colorectal patients have reported that communication was either unclear or too sparse to answer their needs.⁴⁰ This may be especially true in sensitive areas such as

sexuality.⁴¹ Problems of providing information and coordination of care are exacerbated when dealing with minority or non-English language groups.⁴²

This combination of a highly prevalent tumor and well-documented disparities in care makes colorectal cancer a very suitable target for quality improvement and public reporting, including the use of a set of voluntary consensus standards. The ultimate goal is to provide the healthcare community at large with a diverse set of performance measures that can be used for public reporting and internal quality improvement initiatives so that all patients eventually will receive optimal care.

The NQF-Endorsed National Voluntary Consensus Standards for Diagnosis and Treatment of Colorectal Cancer

The NQF-endorsed consensus standards for colorectal cancer encompass four measures that will facilitate efforts to improve the quality of care for patients with a

³³ Jessup JM, Stewart A, Greene FL, et al., Adjuvant chemotherapy for Stage III colon cancer: implications of race/ethnicity, age and differentiation, *JAMA*, 2005;294:2703-2711.

³⁴ Hodgson DC, Fuchs CS, Ayanian JZ, Impact of patient and provider characteristics on the treatment and outcomes of colorectal cancer, *J Natl Cancer Inst*, 2001;93:501-515.

³⁵ Schrag D, Cramer LD, Bach PB, et al., Age and adjuvant chemotherapy use after surgery for Stage III colon cancer, *J Natl Cancer Inst*, 2001;93:850-857.

³⁶ Ayanian JZ, Zaslowsky AM, Fuchs CS, et al., Use of adjuvant chemotherapy and radiation therapy for colorectal cancer in a population-based cohort, *J Clin Oncol*, 2003;21:1293-1300.

³⁷ Shavers VL, Brown ML, Racial and ethnic disparities in the receipt of cancer treatment, *J Natl Cancer Inst*, 2002;94:334-357.

³⁸ Schrag D, Communication and coordination: the keys to quality, *J Clin Oncol*, 2005;23:6452-6455.

³⁹ Eisenberg L, Good technical outcome, poor service experience. a verdict on contemporary medical care? *JAMA*, 2001;285:2639-2641.

⁴⁰ Kerr J, Engel J, Schesinger-Raab A, et al., Doctor-patient communication: results of a four year prospective study in rectal cancer patients, *Dis Colon Rectum*, 2003;46:1038-1046.

⁴¹ Papagrigroriadis A, Heyman B, Patients' views on follow-up of colorectal cancer: implications for risk communication and decision making, *Postgrad Med J*, 2003;79:403-407.

⁴² Ayanian JZ, Zaslowsky AM, Guadagnoli E, et al., Patients' perceptions of quality of care for colorectal cancer by race, ethnicity, and language, *J Clin Oncol*, 2005;23:6576-6586.

colorectal cancer diagnosis who are undergoing treatment. Three of these endorsed consensus standards are measures, and the fourth is a standard protocol for the reporting of colon and rectum cancer pathology.

Three of the proposed consensus standards are considered to be appropriate for accountability and quality improvement purposes, and one is endorsed as a quality improvement measure. All four are endorsed for use as surveillance measures. Table 3 presents the four consensus standards.

Colorectal Cancer Measures Identified for Further Development

Three colon measures have merit as accountability measures if revisions can be made to the specifications and parameters of the measures:

- colonoscopy to the ileocecal valve prior to surgical resection;
- postoperative radial margin status; and
- adjuvant radiotherapy administered or considered for patients receiving surgical resection of Stage II or III rectal cancer.

Additionally, the consensus standard Surgical Resection Includes at Least 12 Nodes was recommended for further development as a measure of accountability and quality improvement.

Table 3 – National Voluntary Consensus Standards for Diagnosis and Treatment of Colorectal Cancer

(R = Recommended; FD = Further Development)

| CONSENSUS STANDARD | RECOMMENDED USE | | |
|--|-----------------|---------------------|--------------|
| | ACCOUNTABILITY | QUALITY IMPROVEMENT | SURVEILLANCE |
| Adjuvant chemotherapy | R | R | R |
| Completeness of pathologic reporting | R | R | R |
| College of American Pathologists Colon and Rectum Protocol | R | R | R |
| Surgical resection includes at least 12 nodes | FD | FD | R |

NATIONAL QUALITY FORUM

Chapter 3: National Voluntary Consensus Standards for Symptom Management and End-of-Life Care in Cancer Patients

Introduction

The optimal management of cancer comprises two major aims: first, to obliterate the cancer (or, if this is not possible, to control the growth of the malignant tumor), and second, to ameliorate symptoms in order to improve the patient's quality of life. For some patients, the second aim becomes the solitary goal when the disease no longer responds to therapeutic interventions. In each phase of cancer care—initial diagnosis, primary treatment, survivorship, advanced, and end-of-life—the patient and the oncology team must confront a varying constellation of symptoms related both to the disease and to the therapies being administered. As the end-of-life phase commences, improving the quality of dying becomes the overall objective of care. At this stage, palliative care and hospice¹ specialists may be called on to assume primary management of a patient so that the symptoms that might prevent a “good death”² are effectively managed.

¹NQF has recently endorsed a national framework and preferred practices for palliative and hospice care, which defines palliative care and hospice care. *Palliative care* means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. *Hospice care* is a service delivery system that provides palliative care for patients who have a limited life expectancy and require comprehensive biomedical, psychosocial, and spiritual support as they enter the terminal stage of an illness or condition. It also supports family members coping with the complex consequences of illness, disability, and aging as death nears. Hospice care also addresses the bereavement needs of the family following the patient's death.

²Institute of Medicine, *Approaching Death: Improving Care at the End of Life*, Washington, DC: National Academy Press; 1997.

In addressing symptom management for patients with cancer, particularly in the end-of-life phase, the focus of care must extend far beyond the physical domain. Emotional, psychological, social, and spiritual distress³ – which can vary from normal unpleasant reactions to serious psychological illness – must be addressed; a third of cancer patients experience significant degrees of this distress.⁴ Additionally, 10 to 25 percent of cancer patients may suffer from a major depressive disorder.⁵ To provide high-quality oncology care at the end of life, the caregiver team must include psychologists, social workers, chaplains, and others who provide emotional, psychological, social, and spiritual support.

Many studies demonstrate shortcomings in the management of symptoms in the cancer patient, even for those patients who receive multifaceted care through a care

team. Large-scale, post-death surveys demonstrate that a considerable portion of families felt that the needs of the dying patient were not attended to adequately.⁶ Eighteen percent of hospitalized patients did not consider their pain adequately controlled,⁷ and 42 percent of cancer patients did not receive appropriate levels of analgesia.⁸ Both oncologists⁹ and nurses¹⁰ were found deficient in their recognition of depression; adolescent¹¹ and elderly patients¹² are especially susceptible to having psychological problems that go unrecognized. Social settings (e.g., rural settings) may affect the accessibility of patients to attend support groups,¹³ and some cultural perspectives may hinder effective communication.¹⁴ A frequently unmet area in end-of-life cancer care is that of spiritual needs – needs that when unattended may exacerbate psychological

³Jacobsen PB, Donovan KA, Trask PC, et al., Screening for psychological distress in ambulatory cancer patients, *Cancer*, 2005;103(7):1494-1502.

⁴Zabora J, BrintzenhofeSzoc K, Curbow B, et al., The prevalence of psychological distress by cancer site, *Psychooncology*, 2001;10(1):19-28.

⁵Agency for Healthcare Research and Quality, Management of cancer symptoms: pain depression, and fatigue: summary, *Evidence Report/Technology Assessment*, 2002;61:1-9.

⁶Teno JM, Clarridge BR, Casey V, et al., Family perspectives on end-of-life care at the last place of care, *JAMA*, 2004;291(1):88-93.

⁷Whelan CT, Jin L, Meltzer D, Pain and satisfaction with pain control in hospitalized medical patients, *Arch Intern Med*, 2004;164(2):175-180.

⁸Cleeland CS, Gonin R, Hatfield AK, et al., Pain and its treatment in outpatients with metastatic cancer, *N Eng J Med*, 2004;330(9):592-596.

⁹Passik SD, Dugan W, McDonald MV, et al., Oncologists' recognition of depression in their patients with cancer, *J Clin Oncol*, 1998;16(4):1594-1600.

¹⁰McDonald MV, Passik SD, Dugan W, et al., Nurses' recognition of depression in their patients with cancer, *Oncol Nurs Forum*, 1999;26(3):593-599.

¹¹Hedstrom M, Krueger A, Ljungman G, et al., Accuracy of assessment of distress, anxiety, and depression by physicians and nurses in adolescents recently diagnosed with cancer, *Pediatr Blood Cancer*, 2006;46(7):773-779.

¹²Brown EL, Bruce ML, McAvay GJ, et al., Recognition of late-life depression in home care: accuracy of outcome and assessment information set, *J Am Geriatr Soc*, 2004;52(6):995-999.

¹³Koopman C, Angell K, Turner-Cobb JM, et al., Distress, coping, and social support among rural women recently diagnosed with primary breast cancer, *Breast J*, 2001;7(1):25-33.

¹⁴Harris KA, The informational needs of patients with cancer and their families, *Cancer Pract*, 1998;6(1):39-46.

symptoms.¹⁵ In a survey of primary care physicians, less than half considered themselves able to deal with spiritual issues.¹⁶

High-quality care to ameliorate the symptoms associated with cancer has important ramifications at the systemic level, especially with regard to end-of-life care. There are widely documented deficiencies in the use of Do Not Resuscitate (DNR) orders; one study found that only 52 percent of patients desiring a DNR order actually had one written.¹⁷ Additionally, despite the enactment of the Patient Self-Determination Act of 1990 (P.L. 101-508), only a minority of patients has documented advance directives.¹⁸ A survey of Oncology Nurses Society members found that nurse respondents scored low in confidence and knowledge related to assisting patients with advance directives.¹⁹

Racial disparities in symptom management and end-of-life care are evident for African American women with breast cancer compared to their Caucasian counterparts. These disparities include less optimal management of pain,²⁰ lower family

rating of care received as excellent or very good; more reports of absent or problematic physician communication; and greater concerns about being informed and about family support.²¹

The appropriate management of symptoms and the provision of comprehensive end-of-life care has important implications for the efficiency of the healthcare system. Anticipatory attention to severe symptoms such as pain and nausea and vomiting may prevent the use of other expensive resources such as hospitalizations. Focus is warranted on an increasing overutilization of aggressive treatment in situations where palliation alone is appropriate.²² Analysis of Surveillance, Epidemiology, and End Results (SEER)-Medicare data demonstrate that there is a considerable proportion of outliers for utilization events such as receiving chemotherapy in the last 14 days of life, percent of patients referred to hospice, and number of hospital admissions, emergency room visits, or intensive care unit (ICU) admissions in the last 30 days of life.²³ When comparing only highly

¹⁵Hills J, Paice JA, Cameron JR, et al., Spirituality and distress in palliative care consultation, *J Palliat Med*, 2005;8(4):782-788.

¹⁶Ellis MR, Vinson DC, Ewigman B, Addressing spiritual concerns of patients: physicians' attitudes and practices, *J Fam Pract*, 1999;48(2):105-109.

¹⁷Hakim RB, Teno JM, Harrell FE Jr, et al., Factors associated with do-not-resuscitate orders: patients' preferences, prognoses, and physician judgments. Support Investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment, *Ann Intern Med*, 1996;125(4):284-293.

¹⁸Kish Sk, Martin CG, Price KJ, Advance directives in critically ill cancer patients, *Crit Care Nurs Clin North Am*, 2000;12(3):373-383.

¹⁹Jezewski MA, Brown J, Wu YW, et al., Oncology nurses' knowledge, attitudes, and experiences regarding advance directives, *Oncol Nurs Forum*, 2005;32(2):319-327.

²⁰Payne R, Medina E, Hampton JW, Quality of life concerns in patients with breast cancer: evidence for disparity of outcomes and experiences in pain management and palliative care among African American women, *Cancer*, 2003;97(1 Suppl):311-317.

²¹Welch LC, Teno JM, Mor L, End-of-life care in black and white: race matters for medical care of dying patients and their families, *J Am Ger Soc*, 2005;53(7):1145-1153.

²²Earle CC, Neville BA, Landrum MB et al., Trends in aggressiveness of cancer care near the end of life, *J Clin Oncol*, 2004;22(2):315-321.

²³Earle CC, Neville BA, Landrum MB, et al., Evaluating claims-based indicators of the intensity of end-of-life cancer care, *Int J Qual Health Care*, 2005;17(6):505-509.

respected hospitals, marked variation in these parameters remains²⁴—for example, the death rate ranges from 15.9 percent to 55.6 percent in acute care hospitals. Furthermore, families of patients dying in geographic areas that see a high use of ICUs report receiving less emotional support and experiencing less participation in shared decisionmaking compared to families in areas that see a low use of ICUs, which makes it clear that improvement in quality of life is not resulting from more aggressive treatment.²⁵

The NQF-Endorsed National Voluntary Consensus Standards for Symptom Management and End-of-Life Care in Cancer Patients

This chapter presents nine consensus standards for cancer-related symptom management and end-of-life care. One consensus standard is endorsed for accountability, quality improvement, and surveillance (Table 4); one for quality improvement and surveillance (Table 5); and seven for surveillance only (Table 6).

Recommendations for Additional Measure Development

The consensus standard Comfortable Dying, which was recommended for quality improvement and surveillance, should undergo further development as an accountability measure. Additionally, the seven surveillance measures should be further developed as quality improvement measures.

²⁴ Wennberg JE, Fisher ES, Stukel TA, et al., Use of hospitals, physician visits, and hospice care during last six months of life among cohorts loyal to highly respected hospitals in the United States, *BMJ*, 2004;328(7440):607-610.

²⁵ Teno JM, Mor V, Ward N, et al., Bereaved family members perceptions of end-of-life care in U.S. regions with high and low usage of intensive care units, *Am J Geriatr Soc*, 2005;53(11):1905-1911.

Table 4 – National Voluntary Consensus Standard for Symptom Management and End-of-Life Care: Public Accountability, Quality Improvement, and Surveillance

| AREA | CONSENSUS STANDARD |
|---|---|
| Family Evaluation of Hospice Care (FEHC)* | Standardized survey instrument for assessing family perceptions of care rendered to dying hospice patients* |

*The consensus standard is endorsed for accountability in the hospice and for further development for accountability in other healthcare settings, for example, hospital, home health, and nursing home settings.

Table 5 – National Voluntary Consensus Standard for Cancer-Related Symptom Management and End-of-Life Care: Quality Improvement and Surveillance

| AREA | CONSENSUS STANDARD |
|-------------------|---|
| Comfortable dying | Percent of cases with pain on admission to hospice who are made comfortable at 48 hours |

Table 6 – National Voluntary Consensus Standards for Cancer-Related Symptom Management and End-of-Life Care: Surveillance

| AREA | CONSENSUS STANDARD |
|--|--|
| Chemotherapy in the last 14 days of life (overutilization) | Proportion receiving chemotherapy in the last 14 days of life |
| More than one emergency room visit in the last 30 days of life (overutilization) | Proportion with more than one emergency room visit in the last 30 days of life |
| More than one hospitalization in the last 30 days of life (overutilization) | Proportion with more than one hospitalization in the last 30 days of life |
| Intensive care unit admission in the last 30 days of life (overutilization) | Proportion admitted to the ICU in the last 30 days of life |
| Dying in an acute care setting (overutilization) | Proportion dying in an acute care setting |
| Not admitted to hospice (underutilization) | Proportion not admitted to hospice |
| Admitted to hospice for less than three days (underutilization) | Proportion admitted to hospice for less than three days |

NATIONAL QUALITY FORUM

Appendix A

Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (CDP Version 1.7)

The following table presents the detailed specifications for the National Quality Forum (NQF)-endorsed[®] *National Voluntary Consensus Standards for Quality of Cancer Care*. All information presented has been derived directly from measure sources/developers without modification or alteration (except when the measure developer agreed to such modification during the NQF Consensus Development Process). All NQF-endorsed voluntary consensus standards are open source, meaning they are fully accessible and disclosed.

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care

| BREAST CANCER | | | | | |
|---|------------------------------------|--|--|--|---|
| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions/Exclusions/Adjustments | Data Source/Reporting |
| ACCOUNTABILITY, QUALITY IMPROVEMENT, AND/OR SURVEILLANCE | | | | | |
| 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 all 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 ■ Known to be alive within 1 year (365 days) of diagnosis. | Exclude, if any 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 subcutaneous, total, modified radical, or radical mastectomy. ■ 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. |

(more)

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

²Reporting 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.

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

| BREAST CANCER (continued) | | | | | |
|---|-----------------------------|--|--|--|--|
| Measure | IP Owner¹ | Numerator | Denominator | Inclusions/Exclusions/Adjustments | Data Source/Reporting |
| ACCOUNTABILITY, QUALITY IMPROVEMENT, AND/OR SURVEILLANCE | | | | | |
| ADJUVANT CHEMOTHERAPY | ACS | Consideration or administration of multi-agent chemotherapy initiated within 4 months (120 days) of date of diagnosis. | Include, if all 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. ■ AJCC T1c, Stage II or III. ■ Epithelial malignancy only. ■ Primary tumor is estrogen receptor negative and progesterone receptor negative. ■ 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. | Exclude, if any of the following characteristics are identified: <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 tumor. ■ Primary tumor is estrogen receptor positive or progesterone receptor positive. ■ 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. |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

BREAST CANCER (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions/Exclusions/Adjustments | Data Source/Reporting |
|---|--|---|--|--|--|
| ACCOUNTABILITY, QUALITY IMPROVEMENT, AND/OR SURVEILLANCE | | | | | |
| ADJUVANT HORMONAL THERAPY | ACS | Consideration or administration of tamoxifen or third generation aromatase inhibitor initiated within 1 year (365 days) of date of diagnosis. | Include if all 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 or progesterone receptor positive. ■ All or part of 1st course of treatment performed at the reporting facility.² ■ Known to be alive within 1 year (365 days) of date of diagnosis. | Exclude, if any 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 and 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. Reporting: Measure performance rates should be reported as: <ul style="list-style-type: none"> ■ administered therapy. ■ considered therapy. ■ an aggregate rate. |
| COLLEGE OF AMERICAN PATHOLOGISTS BREAST CANCER PROTOCOL | College of American Pathologists (CAP) | Not applicable. | Not applicable. | None. | See www.cap.org/apps/docs/cancer_protocols/2005/breast05_pw.pdf . |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

BREAST CANCER (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions/Exclusions/Adjustments | Data Source/Reporting |
|--|--------------------------|---|---|--|--|
| ACCOUNTABILITY, QUALITY IMPROVEMENT, AND/OR SURVEILLANCE | | | | | |
| 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 of tumor. Data item and code definitions available via Facility Oncology Registry Data Standards (FORDS) Manual. |
| PATIENTS WITH EARLY STAGE BREAST CANCER WHO HAVE EVALUATION OF THE AXILLA | Intermountain Healthcare | 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. | Data item and code definitions available via Facility Oncology Registry Data Standards (FORDS) Manual. |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

| COLORECTAL CANCER | | | | | |
|---|-----------------------------|--|---|---|--|
| Measure | IP Owner¹ | Numerator | Denominator | Inclusions/Exclusions/Adjustments | Data Source/Reporting |
| ACCOUNTABILITY, QUALITY IMPROVEMENT, AND/OR SURVEILLANCE | | | | | |
| ADJUVANT CHEMOTHERAPY | ACS | Consideration or administration of chemotherapy initiated within 4 months (120 days) of date of diagnosis. | Include, if all 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 facility.² ■ Known to be alive within 4 months (120 days) of diagnosis. | Exclude, if any 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. |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

COLORECTAL CANCER (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions/Exclusions/Adjustments | Data Source/Reporting |
|---|-----------------------|--|--|--|---|
| ACCOUNTABILITY, QUALITY IMPROVEMENT, AND/OR SURVEILLANCE | | | | | |
| 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> <ol style="list-style-type: none"> 1. Explicit statement of pN was not required for completeness. 2. Explicit statement of margin involvement for each of the three margins was required for completeness. <p>Exclusions:</p> <ul style="list-style-type: none"> ■ Squamous cell cancer (to exclude anal surgeries). | Pathology reports (for CRC resections). |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

COLORECTAL CANCER (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions/Exclusions/Adjustments | Data Source/Reporting |
|---------|-----------------------|-----------|-------------|-----------------------------------|-----------------------|
|---------|-----------------------|-----------|-------------|-----------------------------------|-----------------------|

ACCOUNTABILITY, QUALITY IMPROVEMENT, AND/OR SURVEILLANCE

| | | | | | |
|--------------------------------------|-----|-----------------|-----------------|-------|--|
| CAP COLON AND RECTUM PROTOCOL | CAP | Not applicable. | Not applicable. | None. | See www.cap.org/apps/docs/cancer_protocols/2005/colonrectum05_pw.pdf . |
|--------------------------------------|-----|-----------------|-----------------|-------|--|

SURVEILLANCE

| | | | | | |
|--|-----|---|---|--|---|
| SURGICAL RESECTION INCLUDES AT LEAST 12 NODES | ACS | ≥12 regional lymph nodes pathologically examined. | <p>Include, if all 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 any 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> |
|--|-----|---|---|--|---|

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

| SYMPTOM MANAGEMENT AND END-OF-LIFE CARE | | | | | |
|---|---|---|---|---|---|
| Measure | IP Owner¹ | Methodology | | Inclusions/Exclusions/Adjustments | Data Source/Reporting |
| ACCOUNTABILITY, QUALITY IMPROVEMENT, AND/OR SURVEILLANCE | | | | | |
| FAMILY EVALUATION OF HOSPICE CARE (FEHC) | NHPCO | Responses to survey instrument. <i>See</i> 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. | Exclusions: 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). |
| QUALITY IMPROVEMENT AND/OR SURVEILLANCE | | | | | |
| COMFORTABLE DYING | National Hospice and Palliative Care Organization | Patients whose 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. |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

SYMPTOM MANAGEMENT AND END-OF-LIFE CARE (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions and/or Exclusions | Data Source |
|---|--|---|--------------------------------|------------------------------|---|
| SURVEILLANCE | | | | | |
| CHEMOTHERAPY IN THE LAST 14 DAYS OF LIFE | Craig Earle, MD, of Dana-Farber Cancer Institute | Patients who died from cancer and received chemotherapy in the last 14 days of life 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: 01D <i>OR</i> NDC Brand descriptions: Alkeran, Cytosan, Methotrexate Sodium, Temodar, VePesid, Xeloda. | Patients who died from cancer. | None. | Administrative data; Medicare-SEER + Death Index. |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

SYMPTOM MANAGEMENT AND END-OF-LIFE CARE (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions and/or Exclusions | Data Source |
|---|--|---|--------------------------------|------------------------------|---|
| SURVEILLANCE | | | | | |
| MORE THAN ONE EMERGENCY ROOM VISIT IN THE LAST 30 DAYS OF LIFE | Craig Earle, MD, of Dana-Farber Cancer Institute | <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</p> <p><i>OR</i></p> <p>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</p> <p><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</p> <p><i>OR</i></p> <p>BETOS codes: M3.</p> | Patients who died from cancer. | None. | Administrative data; Medicare-SEER + Death Index. |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

SYMPTOM MANAGEMENT AND END-OF-LIFE CARE (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions and/or Exclusions | Data Source |
|--|--|---|--------------------------------|------------------------------|---|
| SURVEILLANCE | | | | | |
| MORE THAN ONE HOSPITALIZATION IN THE LAST 30 DAYS OF LIFE | Craig Earle, MD, of Dana-Farber Cancer Institute | Patients who died from cancer and had >1 hospitalization in the last 30 days of life. MEDPAR only: <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. No codes used. | Patients who died from cancer. | None. | Administrative data; Medicare-SEER + Death Index. |
| INTENSIVE CARE UNIT ADMISSION IN THE LAST 30 DAYS OF LIFE | Craig Earle, MD, of Dana-Farber Cancer Institute | Patients who died from cancer and were admitted to the ICU in the last 30 days of life. MEDPAR only: <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 incrdays, which is number of ICU days per visit ■ used hospital admission date variable (admitdate) and then checked if incrdays was >0 for admissions occurring in the last 30 days before death. No codes used. | Patients who died from cancer. | None. | Administrative data; Medicare-SEER + Death Index. |

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

SYMPTOM MANAGEMENT AND END-OF-LIFE CARE (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions and/or Exclusions | Data Source |
|---------|-----------------------|-----------|-------------|------------------------------|-------------|
|---------|-----------------------|-----------|-------------|------------------------------|-------------|

SURVEILLANCE

| | | | | | |
|--|---|--|---------------------------------------|--------------|--|
| <p>DYING IN AN ACUTE CARE SETTING</p> | <p>Craig Earle, MD, of Dana-Farber Cancer Institute</p> | <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 <p><i>OR</i></p> <p>dschgsta = B</p> <p><i>OR</i></p> <p>discddest = 20.</p> <p>The MEDPAR code indicating the status of the beneficiary on the date of discharge from the facility;</p> <p>B = Discharged dead</p> <p>Discddest = The MEDPAR code primarily indicating the destination of the beneficiary upon discharge from a facility; also denotes death or skilled nursing facility/still patient situations</p> <p>20 = died.</p> | <p>Patients who died from cancer.</p> | <p>None.</p> | <p>Administrative data; Medicare-SEER + Death Index.</p> |
|--|---|--|---------------------------------------|--------------|--|

(more)

Appendix A – Specifications of the National Voluntary Consensus Standards for Quality of Cancer Care (continued)

SYMPTOM MANAGEMENT AND END-OF-LIFE CARE (continued)

| Measure | IP Owner ¹ | Numerator | Denominator | Inclusions and/or Exclusions | Data Source |
|---|--|---|--------------------------------|------------------------------|---|
| SURVEILLANCE | | | | | |
| NOT ADMITTED TO HOSPICE | Craig Earle, MD, of Dana-Farber Cancer Institute | Patients who died from cancer without being admitted to hospice. Those without claims in Medicare HOSPICE file. | Patients who died from cancer. | None. | Administrative data; Medicare-SEER + Death Index. |
| ADMITTED TO HOSPICE FOR LESS THAN THREE DAYS | Craig Earle, MD, of Dana-Farber Cancer Institute | Patients who died from cancer and spent fewer than three days in hospice. Medicare HOSPICE file only: ■ Subtracted hospice admission date (admitdate) from death date variable to get hospice length of stay. No codes used. | Patients who died from cancer. | None. | Administrative data; Medicare-SEER + Death Index. |

Figure A-1. Family Evaluation of Hospice and Palliative Care

Please answer these questions based on your experience and the patient's experience while under the care of hospice.

SURVEY INSTRUCTIONS

Please answer each question by choosing the answer that best describes your experience and the patient's experience while under the care of hospice.

- Answer **all** the questions that apply to you by checking the box to the left of your answer or writing in the information in the space provided.
- You are sometimes told to skip over some questions in this survey. When this happens you will see an arrow with a note that tells you what question to answer next, like this:
 - Yes
 - No → **If No, Go to Question A2**

SECTION A

- A1) For about how many days or months did the patient receive hospice services? _____ days _____ months
- A2) As far as you know, did any member of the hospice team speak to the patient or to a family member about the patient's wishes for medical treatment as he/she was dying?
 Yes No
- A3) At any time while the patient was under the care of hospice, did the doctor or another hospice team member do anything with respect to end-of-life care that was inconsistent with the patient's previously stated wishes?
 Yes No

SECTION B

- B1) While under the care of hospice, did the patient have pain or take medicine for pain?
 Yes No → **If No, Go to Question B5**
- B2) How much medicine did the patient receive for his/her pain?
 Less than was wanted Just the right amount More than patient wanted
- B3) Did you or your family receive any information from the hospice team about the medicines that were used to manage the patient's pain?
 Yes No Don't Know
- B4) Did you want more information than you got about the medicines used to manage the patient's pain?
 Yes No
- B5) While under the care of hospice, did the patient have trouble breathing?
 Yes No → **If No, Go to Question B9**
- B6) How much help in dealing with his/her breathing did the patient receive while under the care of hospice?
 Less than was wanted Right amount More than patient wanted
- B7) Did you or your family receive any information from the hospice team about what was being done to manage the patient's trouble with breathing?
 Yes No Don't Know No treatments used for breathing → **If No, Go to Question B9**
- B8) Did you want more information than you got about what was being done for the patient's trouble with breathing?
 Yes No

(continued)

SECTION B (continued)

B9) While the patient was under the care of hospice, did he/she have any feelings of anxiety or sadness?

- Yes No → If No, Go to Question C1

B10) How much help in dealing with these feelings did the patient receive?

- Less than was wanted Right amount More help or attention to these feelings than patient wanted

SECTION C

C1) How often were the patient's personal care needs - such as bathing, dressing, and changing bedding - taken care of as well as they should have been by the hospice team?

- Always Usually Sometimes Never Hospice team was not needed or wanted for personal care

C2) How often did the hospice team treat the patient with respect?

- Always Usually Sometimes Never

SECTION D

D1) While the patient was under the care of hospice, did you participate in taking care of him/her?

- Yes No → If No, Go to Question D5

D2) Did you have enough instruction to do what was needed?

- Yes No

D3) How confident did you feel about doing what you needed to do in taking care of the patient?

- Very confident Fairly confident Not confident

D4) How confident were you that you knew as much as you needed to about the medicines being used to manage the patient's pain, shortness of breath, or other symptoms?

- Very confident Fairly confident Not confident

D5) How often did the hospice team keep you or other family members informed about the patient's condition?

- Always Usually Sometimes Never

D6) Did you or your family receive any information from the hospice team about what to expect while the patient was dying?

- Yes No

D7) Would you have wanted more information about what to expect while the patient was dying?

- Yes No

D8) How confident were you that you knew what to expect while the patient was dying?

- Very confident Fairly confident Not confident

D9) How confident were you that you knew what to do at the time of death?

- Very confident Fairly confident Not confident

(continued)

SECTION E

- E1) Did any member of the hospice team talk with you about **your** religious or spiritual beliefs?
 Yes No
- E2) Did you have as much contact of that kind as you wanted?
 Yes No
- E3) How much emotional support did the hospice team provide to you **prior** to the patient's death?
 Less than was wanted Right amount More attention than was wanted
- E4) How much emotional support did the hospice team provide to you **after** the patient's death?
 Less than was wanted Right amount More attention than was wanted
- E5) While under the care of hospice, did the patient have a need for special medical equipment, such as a hospital bed, a wheel chair, or oxygen?
 Yes No → **If No, Go to Question E8**
- E6) Did the patient receive all equipment needed?
 Yes No → **If No, Go to Question E8**
- E7) How much of a problem, if any, was it to get the needed medical equipment?
 A big problem A small problem No problem
- E8) How often did the patient have to wait too long for the pharmacy to deliver his/her medications?
 Always Usually Sometimes Never Don't Know Pharmacy did not deliver patient's medications

SECTION F

- F1) How often did someone from the hospice team give confusing or contradictory information about the patient's medical treatment?
 Always Usually Sometimes Never
- F2) While under the care of hospice, was there always one nurse who was identified as being in charge of the patient's overall care?
 Yes No
- F3) Was there any problem with hospice doctors or nurses not knowing enough about the patient's medical history to provide the best possible care?
 Yes No

Now, we would like you to *rate* some aspects of the care that the patient received while under the care of hospice.

For questions F4 through F8, please use a scale from 0 to 10, where 0 means the worst care possible and 10 means the best care possible. Circle the number below each question that matches your response.

- F4) How well did the hospice team do at providing end-of-life medical care that *respected the patient's wishes*?
 0 1 2 3 4 5 6 7 8 9 10
 Worst care Best care
- F5) How well did the hospice team *communicate* with the patient and his/her family about the illness and the likely outcomes of care?
 0 1 2 3 4 5 6 7 8 9 10
 Worst care Best care
- F6) How well did the hospice team make sure that the patient's *symptoms were controlled* to a degree that was acceptable to him/her?
 0 1 2 3 4 5 6 7 8 9 10
 Worst care Best care

(continued)

SECTION F (continued)

F7) How well did the hospice team make sure that the patient *died on his/her own terms*?

0 1 2 3 4 5 6 7 8 9 10
Worst care Best care

F8) How well did the hospice team do at *providing emotional support* for you and the patient's family and friends?

0 1 2 3 4 5 6 7 8 9 10
Worst care Best care

SECTION G

G1) Overall, how would you rate the care the patient received while under the care of hospice?

Excellent Very good Good Fair Poor

G2) How would you rate the way the hospice team responded to your needs in the evenings and weekends?

Excellent Very good Good Fair Poor Never contacted evening or weekend services

G2a) Overall, how would you rate the *hospice team members* who provided care?

Excellent Very good Good Fair Poor

G2b) Did the hospice team explain the plan of care to you in a way that you could understand?

Yes No Hospice team did not explain plan of care to me

G2c) How often did you agree with changes in the plan of care?

Always Usually Sometimes Never No changes were made to plan of care

G2d) Did the hospice team's explanation of the Patient's Bill of Rights help you to understand your loved one's rights?

Yes No Hospice team did not explain Patient's Bill of Rights to me

G3) Based on the care the patient received, would you recommend hospice services to others?

Yes No

G3a) In your opinion, was the patient referred to hospice too early, at the right time, or too late during the course of his/her final illness?

Too early → **Go to Question H1** At the right time → **Go to Question H1** Too late → *Please explain*

SECTION H

Please give us the following information about your loved one:

H1) How old was the patient when he/she died? _____ years old

H2) Was the patient male or female?

Male Female

H3) Please choose the one disease group that best describes the **primary illness** that caused the patient to be referred to hospice.
Please choose only one.

Cancers - all types Heart & circulatory diseases Lung & breathing diseases Kidney diseases Strokes

Dementia & Alzheimer's disease AIDS & other infectious diseases Frailty and decline due to old age

Another disease (*Please write in*) _____

(continued)

SECTION H (continued)

- H4) What is the highest grade or level of school that the patient completed?
 8th grade or less Some high school but did not graduate High school graduate or GED 1-3 years of college
 4-year college graduate More than a 4-year college degree
- H5) Was the patient of Hispanic or Spanish family background?
 Yes No
- H6) Which of the following best describes the patient's race?
 American Indian or Alaskan Native Asian or Pacific Islander Black or African-American
 White Another race or multiracial (*Please write in*) _____

SECTION I

Please give us the following information about yourself:

- I1) What is your relationship to the patient?
 Spouse Partner Child Parent Sibling Other Relative Friend
 Other (*Please write in*) _____
- I2) How old were you on your last birthday? (*Please write in*) _____
- I3) Are you male or female?
 Male Female
- I4) What is the highest grade or level of school that you have completed?
 8th grade or less Some high school but did not graduate High school graduate or GED 1-3 years of college
 4-year college graduate More than a 4-year college degree
- I5) Are you of Hispanic or Spanish family background?
 Yes No
- I6) Which of the following best describes your race?
 American Indian or Alaskan Native Asian or Pacific Islander Black or African-American
 White Another race or multiracial (*Please write in*) _____

SECTION J

- J1) Is there anything else that you would like to tell us about the care provided by the hospice team?
 Yes *Please explain.* _____

 No

THANK YOU VERY MUCH FOR YOUR TIME!

PLEASE PUT THIS SURVEY IN THE ENCLOSED ENVELOPE & MAIL IT BACK TO US TODAY.

Table A-1. Family Evaluation of Hospice Care Specifications for Data Collection**1. SURVEY INSTRUMENT** (see Figure A-1)**2. SAMPLING****2.1 Population**

- Bereaved family members of deceased hospice patients. Family is defined broadly to include anyone who is significant to the patient and involved to some extent in his or her care.

2.2 Proxies

- No proxies are permitted to respond instead of a family member.

2.3 Excluded populations

- Respondents are assumed to be adults (18 years of age or older).

2.4 Sampling frame

- One bereaved family member per patient.

2.5 Type of sampling

- Full population of deceased patients for whom a person is identified as a primary caregiver.
- One time basis one to three months after the death of the patient.
- Data are accumulated throughout the year to create a 12-month data file for the hospice.

2.6 Sample size

- Varies according to the number of patients served by the hospice and by the number of deaths in a given month.

3. SURVEY ADMINISTRATION**3.1 Timing**

- Hospices are instructed to contact family members from 1 to 3 months after the death of the patient.

3.2 Mode

- FEHC is usually a mailed paper questionnaire, self-administered survey that the respondent completes and mails back to either the hospice or a third-party vendor. Hospices who wish to administer the survey by telephone may do so. Mode testing has demonstrated equivalent results for mailed and telephone administration of the survey.

3.3 Format

- Survey is administered as a stand-alone survey or combined with hospice specific questions. NHPCO discourages adding questions, but if hospice specific questions are used, the FEHC survey questions must appear first and in the specified order.

4. SCORING AND PATIENT-MIX ADJUSTMENTS**4.1 Data timeframe**

- Data are collected on a monthly schedule and analyzed quarterly.

4.2 Sampling rates

- The full population comprises the sample at all times.

4.3 Domains of care

- Symptom Management (B1, B2, B5, B6, B9, B10)
- Provide Information about Symptoms (B3, B4, B7, B8)
- Inform & Communicate about Patient (D5, D6, D7)
- Attend to Family Needs (E1, E2, E3, E4)
- Provide Coordination of Care (F1, F2, F3)

(more)

Table A-1. Family Evaluation of Hospice Care Specifications for Data Collection (continued)**4. SCORING AND PATIENT-MIX ADJUSTMENTS (continued)****4.4 Scoring**

- Provide Coordination of Care - F1, F2, F3
 - If F1 is answer other than “always” scores 1; else score = 0
 - If F2 is no then score 1; else score = 0
 - If F3 is yes then score 1; else score = 0
 - Numerator is sum of 1 response
Denominator is the number of items = 3
 - At the facility level, avg. the score
 $if n(q14, q15, q16) > 0$
 $then coord = 100 * sum(q14, q15, q16) / 3;$
 $else coord = .;$
label COORD = ‘Coord: Provide Coordination of Care’;
- Attend to Family Needs - E1, E2, E3, E4
 - If E2 = yes then score = 1; else score = 0
 - If E3 = response other than just the right amount score = 1 else score = 0
 - If E4 = response other than just the right amount score = 1 else score = 0
 - Numerator is sum of 1 response
Denominator is the number of items = 3
 - At the facility level, avg. the score
 $if n(q27, q28, q29) > 0$
 $then family = 100 * sum(q27, q28, q29) / 3;$
 $else family = .;$
label FAMILY = ‘Family: Attend to Family Needs’;
- Inform & Communicate about Patient - D5, D6, D7
 - If D5 response other than always than score 1; else score = 0;
 - If D7 = yes then score = 1; else score = 0;
 - Numerator is sum of 1 response
Denominator is the number of items = 2
 - At the facility level, avg. the score
 $if n(q17, q19) > 0$
 $then inform = 100 * sum(q17, q19) / 2;$
 $else inform = .;$
label INFORM = ‘Inform: Inform & Communicate About Patient’;
- Provide Information about Symptoms - B3, B4, B7, B8
 - If B4 = yes then score = 1; else score = 0;
 - If B8 = yes then score = 1; else score = 0;
 - Numerator is sum of 1 response
Denominator is the number of items = 2
 - At the facility level, avg. the score
 $if n(q5, q9) > 0$
 $then infosym = 100 * sum(q5, q9) / 2;$
 $else infosym = .;$
label infosym = ‘Infosym: Provide Information About Symptoms’;

Table A-1. Family Evaluation of Hospice Care Specifications for Data Collection (continued)

4. SCORING AND PATIENT-MIX ADJUSTMENTS (continued)

- Symptom Management
 - Pain - B1, B2
 - Shortness of Breath - B5, B6
 - Anxiety/Sadness - B9, B10
 - Denominator = those who experience the symptom
Numerator = those who received too much or too little help

4.5 Patient-Mix Adjustment

- No patient-mix adjustment is made in scoring the survey
-

5. REPORTING

5.1 Data submission

- Data are submitted to NHPCO by a designated responsible staff member in each participating hospice.*
 - Data are transmitted to NHPCO via an online data submission system housed on the NHPCO Web site.
 - Only survey respondents' data are submitted. No administrative data related to respondents or non-respondents are submitted.
 - Hospice program descriptive data (e.g., type of geographic area served) are entered at the initial data submission and updated as needed.
 - Data submission deadlines occur two weeks after the end of each quarter of the calendar year (i.e., April 15, July 15, October 15, and January 15).
 - Data are analyzed and an individual report is created for each hospice detailing the hospice's results with comparative results for national level and state level data.** An annual summary of national level results is also created and distributed to participating hospices.
-

* Data submission is voluntary at this time. Hospices may use the survey without submitting their data to NHPCO, but those who chose to do so do not receive reports with comparison results.

** A minimum of five hospices must submit data, with no single hospice contributing more than 50% of the data, in order for state level comparisons to be reported for any state.

NATIONAL QUALITY FORUM

Appendix B

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¹During the first phase of this project, Rodger J. Winn, MD, then of the National Comprehensive Cancer Network, and Nancy-Ann Min DeParle, Esq., former administrator of what was then known as the Health Care Financing Administration, served as co-chairs of the Steering Committee. During the second phase, Dr. Winn became project director and Ms. DeParle joined the NQF Board of Directors.

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⁶ Through April 2007

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NATIONAL QUALITY FORUM

Appendix C Commentary

This commentary provides details about issues of significance that were raised, discussed, and resolved in evaluating the performance measures that were submitted and in deriving a research agenda for cancer care in the three priority areas of breast cancer; colorectal cancer; and symptom management and end-of-life care. Additionally, a full discussion of the issues that were raised regarding development of the overarching cancer framework is presented in the body of this report.

Approach to Measure Screening and Evaluation

The Steering Committee followed a six-step process to measure screening and evaluation, establishing specific criteria for screening candidate measures. Because the project focused on three distinct priority areas, three Technical Panels were convened to provide the Steering Committee with technical evaluation of the submitted measures (Appendix B). The Breast Cancer and Colorectal Cancer Technical Panels included experts in breast and colorectal cancer surgery, experts in radiotherapy and chemotherapy, consumers interested in evidence-based medicine, and health services researchers. The Symptom Management/End-of-Life Care Technical Panel included experts in palliative care, hospice care and administration, radiation and medical oncology, nursing oncology, survey methodology, psychosocial support, and health services research. In an attempt to provide consistent guidance across the three panels, a fourth panel, referred to as the Cancer Data and Methods Panel (CDMP; Appendix B), was convened to make recommendations to the Steering Committee on the criteria to be used for assessing candidate consensus standards; it also provided

input on the framework for recommending a set of cancer measures under the National Quality Forum's (NQF's) formal Consensus Development Process (Version 1.7).

Framework

In October 2004, the Steering Committee derived a framework for cancer measurement based on the NQF-endorsed[®] framework for hospital care¹ and the recommendations of the CDMP in October 2004. The cancer framework provided a set of guiding principles for future cancer measurement and reporting activities, guiding the Steering Committee's consideration of candidate consensus standards and its assessment of research gaps.

The Steering Committee noted that because cancer presents as multiple variants of a chronic disease proceeding through major clinical phases, with each phase involving a multiplicity of healthcare providers and treatment in a broad array of care settings, a comprehensive set of consensus standards should cross several dimensions. In order to ensure that eventually a thorough approach to quality assessment eventually would be possible, the Steering Committee included a comprehensive list of specialties and settings that might be included in the measure sets (Appendix D). Additionally, the framework accounts for the many professionals who care for cancer patients as part of their general responsibilities—for example, those who work in the areas of pharmacy, rehabilitation, and case management. The

measure content should specifically relate to cancer care-directed activities.

Three types of measures were to be included in the framework:

- **Outcome.** Priority should be given to outcomes that are considered primary in cancer care: survival, quality of life, patient experience, and cost-effectiveness. If secondary outcomes were to be used, there should be evidence of linkage to primary outcomes, wherever possible. The selection of a specific outcome may be based on its intended use—for example, five-year survival as a national/regional surveillance measure—even though it may not be as useful for public reporting. Of note, the Steering Committee determined that the Agency for Healthcare Research and Quality (AHRQ) patient experience of care measures—that is, the Consumer Assessment of Healthcare Providers and Systems (CAHPS[®]) surveys—could be included and did not need to be addressed separately for cancer care.
- **Process.** Process measures should have a demonstrated link to outcomes, and priority was to be given to processes such as randomized clinical trials that are supported by high-level evidence. In using a process measure based on clinical trial evidence, generalization of the data to the entire cancer population was to be assessed.
- **Structure.** There should be evidence that links structure to outcomes, although the data are unlikely to be generated through randomized control trials. In some instances, the evidence will link structure to a process, which in turn links to an outcome. The Committee

¹National Quality Forum (NQF), *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*, Washington, DC: NQF; 2003.

noted that structural measures may be difficult to interpret, because they may not define the intervening processes. For example, the presence of a discharge planner dedicated to oncology patients may promote adherence to chemotherapy, but data that substantiate this are difficult to gather.

This framework was reviewed and approved by NQF Members as part of their review of the NQF “National Voluntary Standards for Quality Cancer Care: Symptom Management and End-of-Life Care” project in September 2006 and endorsed by the NQF Board of Directors in October 2006.

Scope

The delineation of scope provided the guidelines to determine whether a particular measure would fall within the intended boundaries of a quality measure set. The Steering Committee’s discussion addressed issues that pertained to NQF standardized elements, such as whether a measure is open source or public domain, and also specifically to issues that were related to a cancer-related measure set, although some topics (e.g., degree of control) applied generically.

Clinical Conditions to Be Considered

Including quality measures related to the diagnosis and treatment of an established cancer and screening for cancer was a straightforward matter. However, the issue of whether the management of nonmalignant tumors and precancerous lesions should be included was a subject of discussion. The Steering Committee decided that

because the overarching aim was to lessen morbidity and mortality from neoplastic disease processes, both of these clinical conditions should be included in the scope of the cancer care framework.

Extent of Measure Development

The recommendation that measures should be developed as fully as possible to the extent required for appropriate use was based on the recognition that perfectly developed measures rarely exist and that for cancer care they are particularly sparse. The Steering Committee therefore determined that the amount of development required depends on the proposed use of the measure—for example, for accountability versus internal quality improvement, for intra- versus inter-hospital comparisons, or for pay for performance.

Degree of Control by the Healthcare System

Measures must be under a reasonable degree of control by the healthcare system and must be in the area of the system to which they refer. The Steering Committee believed that no absolute percentage of control could be determined and that the degree of control required for responsibility would vary from measure to measure. For example, the Steering Committee recommended that hospitals be accountable for the delivery of adjuvant chemotherapy for Stage III colorectal patients, even though the delivery of the drug occurs in an outpatient setting post surgery.

Types of Measures to Be Included

The Steering Committee considered measures for accountability, quality

improvement, and surveillance. It decided to recommend measures that would be designated for use as accountability *and* quality improvement measures or for use only as quality improvement measures. In addition, measures would be recommended as surveillance measures that also could be used for purposes of recommending healthcare policy and/or allocating resources. The decision to recommend measures for quality improvement reflected the Steering Committee's view that measure development in cancer care is still in its early phases and that therefore the availability of accountability measures would be limited. The Committee noted the following benefits of recommending quality improvement measures for cancer care:

- NQF endorsement of a quality-of-cancer care measure for quality improvement could speed its evolution to becoming an accountability measure;
- NQF endorsement of quality improvement measures for cancer care could ensure that hospitals and medical groups address quality issues of proven importance and also could prevent "gaming" through the self-selection of quality improvement measures in areas in which the performance level is known to be high;
- the implementation of standardized quality improvement cancer care measures could increase the acceptability of and readiness for future standardized cancer care accountability measures;
- by standardizing quality improvement cancer care measures, different hospital settings, such as urban and rural, could be held to the same standard; and
- quality improvement cancer care measures can be especially useful in identifying institutions within a larger system that are at the lower end of the performance scale, which should lead to raising the thresholds throughout the system.

Selection of Breast and Colorectal Cancer Measures

Because cancer presents as multiple variants of a chronic disease that proceeds through major clinical phases, with each phase involving a multiplicity of healthcare providers and occurring in a broad array of care settings, the Steering Committee noted that the consensus standards would span several dimensions (Appendix D).

The Steering Committee accepted the NQF report *A Comprehensive Framework for Hospital Care Performance Evaluation*² as the basic framework for evaluating specific measures and adopted the recommendations of the CDMP report (Appendix E) in applying this framework to the evaluation of cancer-related measures.

Data Source and Collection Issues

Because the majority of submitted measures were derived using tumor registry data, the Steering Committee discussed the validity of these data as a data source and also examined the impact of the burden of data collection.

²NQF, *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*, Washington, DC: NQF; 2003.

Tumor Registry Data as the Data Source for Breast Cancer Measures

The Steering Committee agreed that measures derived from tumor registry data have distinct advantages. First, the elements represent data that are routinely collected from the medical record for the majority of the nation's cancer patients. This is proof of concept that the data are available, and therefore, hospitals that do not have tumor registries can still be expected to have access to them. Second, the use of tumor registry data definitions ensures that the dataset will be standardized and extensively tested and validated.

Although tumor registry data are considered a reasonable source of data for measures, it must be recognized that the following shortcomings may exist:

- Unless data collection and reporting times are significantly shortened, measures from tumor registries may not be available for another two to three years, which may have substantial impact on the ability to track measures in a timely manner.
- Because only 75 percent of cancer cases are managed in hospitals with Commission on Cancer approval, the availability of data from tumor registries for the remaining 25 percent may be problematic.
- The ability to collect data regarding outpatient therapy, for example, adjuvant hormonal or cytotoxic therapy, may be variable across registries. Estimates of 8 to 18 percent differences between registry and medical chart data have been reported. The Commission on Cancer has an audit process in place, and the accuracy of registry data are further

evaluated by an onsite examiner at the time of program approval.

- Incomplete data may be a problem in selected registries. It is expected that the implementation of accountability measures would encourage better data collection.

Burden of Data Collection

Collecting data to assess measure performance entails a substantial outlay of personnel and financial resources. The cost of data collection will pose a significant burden especially for cancer measures that require medical record review to capture information not available in registries or administrative databases. An important segment of quality of care related to patient-centered issues such as shared decisionmaking may be available only through record review or patient surveys. Submitters should be asked to provide the cost of data collection, which can then be balanced against the costs saved through having high quality.

Breast Cancer Consensus Standards Recommended for Inclusion in the Set

The Breast Cancer Technical Panel reviewed the submitted breast cancer care measures on April 7 and 8, 2005, and the Steering Committee reviewed them on June 6, 2005. The Colorectal Cancer Technical Panel reviewed the submitted colorectal cancer care measures on September 14, 2005, and the Steering Committee reviewed them on December 7, 2005. These deliberations resulted in fewer accountability measure recommendations

than expected (two for breast cancer and two for colorectal cancer), however the deliberations also resulted in recommendations for modifications to quality improvement measures that would result in their potential acceptability as accountability measures. After discussion with the American College of Surgeons (ACS) regarding the Adjuvant Hormonal Therapy and Adjuvant Chemotherapy measures for breast cancer, and Cancer Care Ontario (CCO) regarding the Completeness of Pathology reporting measure for colorectal cancer, both groups indicated their willingness to examine additional data and to revise their measures to address Steering Committee concerns, as noted below.

The Breast Cancer and Colorectal Cancer Technical Panels evaluated the revised measures from these organizations in September 2006, and the Steering Committee reviewed them in October 2006, resulting in an increase in the number of recommended accountability measures to four for breast cancer and three for colorectal cancer. In addition the Steering Committee recommended two breast cancer measures for quality improvement and surveillance and one colorectal cancer measure for surveillance. The Steering Committee also performed an assessment of gaps in the breast and colorectal cancer care measure sets that would benefit from future research.

Measures Recommended for Accountability, Quality Improvement, and Surveillance

Post breast conserving surgery irradiation (ACS)

(Radiation therapy is administered within 1 year [365 days] of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer)

The evidence for the benefit of postoperative radiation in lowering local recurrence rates is well established, with some evidence that survival may be improved. Initially, the Steering Committee had concerns with this measure due to the lack of an age restriction. Following revisions from ACS, age 70 was selected as a cut-off for the measure in order to eliminate variations in performance resulting from large differences in comorbidity based on a hospital's case mix. ACS data from the National Cancer Data Base (NCDB) showed that above age 70 a significant drop-off in radiation rates occurs. Another reason for choosing age 70 was that the data from a major study that indicated that good-risk patients (estrogen receptor [ER] positive, Stage I) older than 70 years old might not require radiation. The under-70 age group was believed to be adequately homogeneous for rare factors such as prior radiation therapy or collagen disease, which might preclude radiation therapy. One suggestion was that the measure should be stratified for reporting by age—that is, age groups 41 to 50, 51 to 60, and 61 to 70, to account for any differences in comorbidity based on age distribution in a hospital's case mix.

Discussion centered on whether the measure should count as compliant those to whom radiation was offered but refused. The Steering Committee decided that these women should not be offered breast conserving surgery if they would refuse irradiation or if they had a contraindication to its use. Although some of the radiation

therapy (RT) rates are lower because of factors such as distance from an RT center, the standard should still be to receive RT. It was hoped that the implementation of the measure would lead to remedial quality improvement or policy initiatives.

Because this is a hospital-level measure, the Steering Committee believed that a hospital should be responsible for whether or not the RT is delivered, even if the patient was to receive follow-up care after surgery at another institution. Similarly it was believed that the hospital should hold its own physicians responsible for follow-up care through its credentialing process.

Adjuvant chemotherapy (ACS)

(Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 years old with AJCC IC, Stage II or III hormone receptor negative breast cancer)

The evidence for the administration of adjuvant chemotherapy to this group is well substantiated. The measure includes “considered” as well as “administered.” The elements subsumed under considered are tumor registry elements routinely collected and consist of patients who are offered chemotherapy and refuse, patients who have contraindications, and patients who die before chemotherapy can be administered. The Steering Committee recognized that variability might exist in how these considered elements are collected, but believed that their inclusion removed biases in the measure that result from different rates of refusal or contraindications in the population. The Committee recommended that the measure be reported as the total percent compliant, the percent administered, and the percent considered, allowing quality improvement programs to assess whether the considered category was being overused.

Initially, the Steering Committee had concerns with this measure due to the lack of an age restriction. It was noted that absence of age restrictions might lead to inappropriate use among older adults. Following revisions from ACS, age 70 was elected as a cut-off to try to minimize the effects of comorbidity or patient preference, because NCDB shows a drop-off above this age. In addition, there was concern that if women older than 70 are included in the measure, inappropriate pressure may be placed on them to receive the therapy. The Steering Committee also was concerned that this measure might be interpreted to mean that adjuvant chemotherapy is not indicated in women older than 70 and recommended further work on a measure for this group to address the problem of ageism.

Upon its initial review, the Steering Committee expressed concern that the measure restricted receipt of chemotherapy received within 60 days of surgery and that neoadjuvant therapy not be included. Only 49 percent of patients received chemotherapy within 60 days of surgery. Subsequent data from ACS showed that the 120-day interval included most of the patients who would eventually receive adjuvant chemotherapy. There was concern that the clinical trials on which the recommendation is based used six to seven weeks as the cut-off, but NCDB data show that fewer than half of patients received therapy in this timeframe. Additionally, by including all chemotherapy within 120 days of the date of diagnosis, neoadjuvant therapy is included. Therefore, the Committee accepted the 120-day period.

Adjuvant hormonal therapy (ACS)

(Tamoxifen *or* third generation aromatase inhibitor is considered *or* administered within 1 year [365 days] of diagnosis for women with AJCC 1C, Stage II or III hormone receptor positive breast cancer)

Solid evidence substantiates the beneficial use of adjuvant hormone therapy in hormone receptor positive patients. This measure initially divided women into pre- and postmenopausal groups and specified the type of hormone therapy to be administered to each. Because it was believed that accurate data about menopausal status could not be abstracted from the medical record, the measure was recommended only for further development. The Steering Committee further noted that a time limit of initiation of hormone therapy should be established. Subsequently, ACS revised the measure and removed the menopausal groupings from the specifications in order to accommodate women who had postoperative complications and to ensure that a more rigid timeframe did not discourage seeking second opinions. The Steering Committee believed that the risk of patients getting the inappropriate agent—that is, aromatase inhibitors for premenopausal women, was probably small and therefore acceptable. The Steering Committee believed that as part of the implementation process, the level of inappropriate use could be monitored.

The inclusion of considered as well as administered therapy was believed to be warranted in order to allow refusal for fear of secondary malignancies or for contraindications such as previous thromboembolism. The one-year timeframe was thought to be adequate to allow for chemotherapy and radiation therapy to be completed before hormone therapy was initiated. Following these changes, the Committee recommended the measure for accountability.

College of American Pathologists Breast Cancer Protocol (CAP)

The Steering Committee initially deferred its decision pending input from representative pathologists regarding the acceptability of the protocol as a voluntary consensus standard. A query to pathology departments of NQF Members on the Provider Research and Quality Improvement Councils yielded only positive responses, and the standard was therefore recommended for accountability. The consensus standard consists of the required data elements of the protocol (see Appendix A).

Measures Recommended for Quality Improvement and Surveillance

Needle biopsy diagnosis (ACS)

(Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection)

Using a preoperative needle biopsy in arriving at a diagnosis allows for preoperative planning and obviates the need for two surgical procedures. Some tumors are not amenable to needle biopsy because of factors such as tumor location. Therefore, further measure development is needed to define these lesions so that they can be consistently excluded from the denominator. If these tumors are removed from the denominator, the numerator target should approach 100 percent, making this measure acceptable as an accountability measure.

Another issue that was considered was that facilities without stereotactic equipment would not be able to comply in all cases. Although theoretically patients in these facilities could be referred to another center, some patients such as those in rural areas might prefer not to travel to unfamiliar facilities and opt for a surgical approach instead. Thus the measure could be biased against smaller, more isolated facilities.

Patients with early stage breast cancer who have evaluation of the axilla (Intermountain Healthcare)

(Percentage of women with Stage I-IIb breast cancer that received either axillary node dissection [ALND] or sentinel lymph node biopsy [SLNB] at the time of surgery—lumpectomy or mastectomy)

The rate of axillary sampling either by ALND or SLNB approaches 100 percent. Although most authorities consider SLNB with its attendant decrease in morbidity—lymphedema and arm-shoulder problems—to be the preferred approach, there is a small possibility that the procedure may decrease survival because of false negative findings. Large randomized trials are ongoing to definitively answer this question. Until these trials are completed, SLNB cannot be accepted as the single standard of care; hence, measurement should not drive its use. The Steering Committee believed strongly that the measure should be stratified in reporting by type of procedure, that is, ALND or SLNB, to allow tracking of SLNB use.

Measures Recommended for Further Development

In addition to the proposed measures for endorsement, two measures were identified that address major breast cancer quality issues and were recommended for further development so that they can be endorsed as soon as the requisite modifications and testing have taken place.

80 percent or more women with breast cancer diagnosed through the program should have initiated treatment within 60 days (National Breast and Cervical Cancer Early Detection Program)

The development of a timeliness measure to address issues of coordination and efficiency of care at all levels of the health-care system was believed to be desirable.

However, the Steering Committee believed that, as developed, this measure addressed only a small percentage of women (6 percent in the National Breast and Cervical Cancer Early Detection Program) and that further research is needed to document the extent of the problem. The Committee also recommended that the use of median time rather than average time, because this threshold might lead to the inclusion of some outliers who were treated appropriately, for example, patients with postoperative complications.

Percent of invasive breast cancer patients with estrogen receptor/progesterone receptor (ER/PR) status documented (ProHealth Care)

The Steering Committee asked the developers to further develop the measure because documentation of “not done” is coded as satisfying the measure. Thus, a hospital could routinely not perform the test, indicate this as “not done,” and be 100 percent compliant. The Steering Committee also felt that the specifications regarding whether estrogen and progesterone receptors were to be considered jointly or separately needed to be clarified. In addition, consideration should be given to including HER2-neu status documentation in the measure.

Measures Not Recommended for Further Consideration

The Steering Committee did not recommend the following submitted measures:

Bilateral breast MRI study of breast cancer patients who are candidates for surgery (Vanderbilt)

The science supporting the routine use of MRI for patients with breast cancer is still in an early investigative stage.

Percentage of women with Stage I-IIb breast cancer who received a lumpectomy (Intermountain Healthcare)

The Steering Committee did not recommend this measure, although the Technical Panel recommended it for quality improvement and surveillance. The Steering Committee questioned whether the measure assesses quality, since there is no difference in outcomes based on the choice of lumpectomy. Because the decision of whether to undergo a lumpectomy is a matter of patient choice, there can be no appropriate benchmark. The Steering Committee encouraged further research on the impact of shared decisionmaking on this process of care, because it is presumed that a low rate of breast conserving surgery may represent deficiencies in shared decisionmaking. In addition, methods to standardize data collection about shared decisionmaking should be developed.

The Committee asserted that consideration also should be given to further development for quality improvement because, in addition to shared decisionmaking, underperformance might reflect a lack of resources, for example, availability of RT facilities. Although the measure might reveal regional differences if used as a surveillance measure, the Steering Committee was hesitant about recommending a measure for surveillance for which there is no benchmark, because there would be questions about how to interpret the results.

Percentage of women with Stage I-II breast cancer treated with lumpectomy that received adjuvant radiation therapy within nine months of definitive surgery (Intermountain Healthcare)

The ACS measure that was proposed for endorsement as an accountability measure excluded women over 70 years of age, and that measure was considered to be more valid.

Percent of women with ductal carcinoma in situ (DCIS) breast cancer that received full axillary node dissection at the time of surgery (either lumpectomy or mastectomy) (Intermountain Healthcare)

This is a negative measure, because a lower rate is better. Although most experts do not recommend axillary dissection for DCIS, several major centers have presented data about the incidence of positive nodes following sentinel node biopsy. Therefore, a definitive standard cannot be said to exist pending the results of ongoing investigations.

(1) Percentage of cases diagnosed early—Stage 0 and 1, and (2) rate of patients diagnosed at facility with Stage 0-1 disease (ProHealth Care)

The percentage of early-stage disease is more a function of screening than of diagnostic and treatment interventions and therefore does not fit into the scope of the breast cancer diagnosis and treatment measure set. In addition, the significance of the increasing incidence of DCIS (Stage 0 disease) following screening mammography is not clear.

90 percent or more women with breast cancer diagnosed through the program should have initiated treatment (National Breast and Cervical Cancer Early Detection Program)

Although appropriate as an outcome for the National Breast and Cervical Cancer Early Detection Program, the submitted measure aiming for 80 percent treatment within 60 days of diagnosis appeared more feasible and was therefore recommended for further development.

Rate of patients diagnosed at facility by a minimally invasive biopsy as the first procedure to attempt diagnosis (ProHealth Care)

The methodology of data collection in the ACS measure selected for further development appeared to be more feasible.

Average number of days elapsed from date of diagnosis to date of first definitive treatment (ProHealth Care)

The benchmark for the measure was not clear. The developer's data showed timeliness to be well under 30 days. There was concern that making the target too short might lead to forced decisionmaking and discourage second opinions.

Percent of prospective case presentation in newly diagnosed breast cancer patients (ProHealth Care)

Although coordination of care is a major issue in breast cancer care, the benefits of prospective case presentation have not been demonstrated.

Percent of breast cancer patients enrolled in treatment or symptom management clinical trials (ProHealth Care)

Although the recruitment of patients to clinical trials is undoubtedly a benefit to science and society, there are no clear-cut data to support the conclusion that patients in clinical trials receive higher-quality care. The Steering Committee recognized that many studies have shown the disparity involved in recruiting minority groups and the elderly into clinical trials, but believed that if quality issues related to disparity were to be addressed, it would best be to do so through measures that assess areas of direct care.

An additional problem with the measure was that, as it is constructed, the patients in the numerator were not necessarily those in the denominator – that is, a patient diagnosed in a prior year may be placed in a trial and be considered to be in the numerator, while the denominator consists of all new patients in a particular year.

Percent of patients who underwent mastectomy at the facility with immediate or delayed reconstruction (ProHealth Care)

There is no benchmark, or acceptable rate, for this measure, because patient preference, in addition to the availability of reconstruction surgeons, affects the rate. The Steering Committee believed that reconstruction is an important patient-centered issue and that methods for assessing whether the choice is offered should be researched.

Percent of breast conservation patients who underwent additional excision(s) subsequent to the initial attempt at definitive tumor resection, for either positive or close margin (ProHealth Care)

It is not clear if a high or low re-resection rate represents high quality: Surgeons with very low rates may be performing unnecessarily extensive resections, while those with high rates may be too conservative. Also, if the acceptable re-resection rate is set too low, it may inhibit surgeons from performing necessary re-resections.

Average number of surgeries experienced per cancer stratified by the highest level of diagnostic biopsy (ProHealth Care)

The ACS measure of whether a needle biopsy was performed prior to surgery was considered to be more straightforward.

Percent of patients who underwent a sentinel lymph node biopsy (SLNB) and then experienced a subsequent axillary recurrence (ProHealth Care)

The incidence of axillary recurrence following SLNB is exceedingly low, making comparisons or trending difficult.

Percent of eligible invasive breast cancer patients who underwent an attempt at sentinel lymph node biopsy (SLNB) (ProHealth Care)

SLNB is widely used in U.S. hospitals, and studies have demonstrated a decrease in postsurgical morbidity (arm edema and arm-shoulder problems). False negative rates have been reported, and the impact of this finding on survival is being investigated in two large randomized trials. The Steering Committee believed it was premature to endorse this measure (and thereby drive the use of SLNBs) before these trial results are known. This was consistent with the National Comprehensive Cancer Network (NCCN) guideline that designates the sentinel node procedure and ALND as alternative management approaches. It was also asked whether the measure might promote the performance of the procedure by untrained personnel, although some members of the Steering Committee thought that this risk was small.

Percent of eligible breast cancer patients who were recommended to receive hormone therapy (ProHealth Care)

Percent of eligible breast cancer patients who received hormone therapy (ProHealth Care)

These two measures are combined into a single measure in the ACS adjuvant hormone measure recommended for accountability. The ACS measure has specific categories for the consideration of hormone use, including patient preference and contraindications.

Colorectal Cancer Consensus Standards Recommended for Inclusion in the Set

Measures Recommended for Endorsement for Accountability, Quality Improvement, and Surveillance

Adjuvant chemotherapy (ACS)

(Adjuvant chemotherapy is considered or administered within 4 months [120 days] of surgery to patients under age 80 with AJCC III [lymph node positive] colon cancer)

The Technical Panel and Steering Committee believed that the evidence for receiving chemotherapy in this group was very good. Initially the measure was recommended for quality improvement because the measure included only those patients who received chemotherapy and did not account for those who refused the recommended treatment and those for whom it was contraindicated. The measure as originally presented also did not have an age cut-off.

ACS re-evaluated the measure and modified it so that it accounted for patient refusal and contraindications and selected age 80 as a cut-off, because data from NCDB showed a significant drop in the rate after this age. The period for receiving chemotherapy was specified as being 120 days from diagnosis, although some Steering Committee members questioned whether the period should be in the six- to seven-week range, which matches clinical trials. Following these revisions, the Technical Panel and Steering Committee voted to recommend the measure for accountability, quality improvement, and surveillance.

The Committee reaffirmed its position that although adjuvant therapy occurs outside the hospital, the hospital program should be held accountable.

Completeness of pathology reporting (CCO)

The required elements are drawn from the CAP Colon and Rectum Protocol and have an evidence-based relationship to making a prognosis and determining treatment management. All elements must be reported to be compliant. The current ACS Commission on Cancer standard is that 90 percent of reports should have all elements. Significant variation in compliance has been demonstrated.

The measure initially was approved for recommendation as an accountability measure, with the contingency that depth of invasion be added to the list of required elements and that CCO reanalyze compliance data with inclusion of this element. A requirement that staging information (pT) be included on the form was accepted by the Steering Committee and re-analysis of compliance data still demonstrated an overall 69 percent compliance rate, with a range of 25 percent to 100 percent. The measure was recommended for accountability.

CAP Colon and Rectum Protocol (CAP)

The Steering Committee believed that the CAP Colon and Rectum Protocol should be the standard for pathology reporting for cancer of the colorectal area. The Steering Committee agreed with the Technical Panel recommendation to endorse only the required elements for accountability. The Committee felt that adopting the protocol would especially encourage the reporting of the radial margin status in rectal cancer, an area of deficient performance across the nation.

Measure Recommended for Endorsement for Surveillance**Surgical resection includes at least 12 nodes (ACS)**

(At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer)

Initially, the Technical Panel recommended this measure for quality improvement and for further development as an accountability measure. The recommendation was based on the assessment that 12 nodes had not been firmly established as a cut-off for improved survival. The Technical Panel thought it was appropriate to exclude rectal cancers, because the data supporting the impact of 12 nodes on survival was not as clear, and neoadjuvant therapy might downstage the disease so that more than 12 nodes would not be retrievable.

The initial Steering Committee assessment was to recommend the measure for accountability, while noting that although the exact number of nodes for a cut-off had been set at different levels in different studies, 12 nodes was consistent with the recommendations of CAP and the NCCN colon guidelines. This was believed to be an excellent measure of the overall quality of surgical oncologic care, because it addresses the adequacy of the surgical procedure and the adequacy of the pathologist's examination of the specimen. Significant variation in the retrieval of 12 nodes has been demonstrated.

Subsequent to this decision, the Steering Committee received data from a major study undergoing review that did not demonstrate a relationship between survival and the retrieval of 12 nodes. The Steering Committee therefore decided to withhold recommendation of the measure for accountability and quality improvement at this time, pending further analyses and studies. The measure was approved for surveillance to encourage the ongoing

monitoring of trends in lymph node retrieval.

In March 2007, NQF endorsed 10 national voluntary consensus standards and 8 recommendations for breast and colorectal cancer. Subsequently, NQF received from the American Society of Colon and Rectal Surgeons (ASCRS) an appeal of the endorsement of this consensus standard. NQF also received two letters in support of the endorsement.

In May 2007, the NQF Board of Directors denied the appeal for the following reasons. ASCRS' appeal asserted that the measure is not supported by sufficient evidence and is not risk adjusted for patient, tumor, and treatment factors. The organization noted that while there is substantial evidence supporting an association between number of lymph nodes retrieved and survival for patients with Stage II colon cancer and possibly Stage I and Stage III colon cancer and rectal cancer, the mechanism underlying this association is unknown and unlikely to be causative. ASCRS also suggested that the number of lymph nodes that can be evaluated in an individual is influenced by patient factors, tumor factors, and treatment factors. The Board acknowledged ASCRS' concern; however, consensus recommendations and nationally accepted, evidence-based guidelines support the use of this measure in delivering quality colon cancer care. The Board accepted the Steering Committee's recommendation and Member approval that endorsement for purposes of surveillance was appropriate and would provide important information regarding whether the measure should be used for accountability in the future. Additionally, the Board noted that the Committee believed that given the possible relationships between lymph node retrieval and quality of care on a combined surgical-pathological level, surveillance of national and regional trends would be useful.

Colorectal Cancer Candidate Consensus Standards Recommended for Further Development

Colonoscopy to the ileocecal valve is performed prior to colon surgery (ACS)

The measure was believed to be important and was recommended for further development. But as constructed, the measure was not acceptable because some patients with obstructing or perforated tumors do not undergo preoperative colonoscopy. The Technical Panel recommended that the denominator be restricted to Stage I, II, and III tumors and that colonoscopies be performed either preoperatively or up to one year postoperatively. A major feasibility issue in the redrafting of the measure will be determining whether the data can be collected. The inclusion of the postoperative colonoscopy would require contacting private offices or patients to determine if the examination had been performed. The Steering Committee also noted the difficulties in determining from the medical record whether the examination reached the ileocecal valve.

Postoperative radial margin status (CCO)

Status of the radial margin has been found to correlate with survival in rectal cancer, and therefore the measure was considered important. Technical difficulties with the measure were defining positivity, for example, 0 to 1 mm versus 3 mm, and the impact of neoadjuvant chemoradiotherapy, which might lead to lower rates in hospitals that employ this approach. In addition, the measure did not include patients whose pathology report did not mention the radial margin.

Adjuvant radiotherapy administered or considered for patients receiving surgical resection of Stage II or III rectal cancer (ACS)

Following initial Technical Panel and Steering Committee recommendations, ACS developed a measure to address administration of adjuvant radiotherapy for patients receiving surgical resection of Stage II or II rectal cancer. Although several Technical Panel members brought up instances in which some investigators questioned the use of radiotherapy, such as for high rectal lesions with minimal invasion, there was general agreement that radiotherapy is the standard approach to Stage II and III rectal cancer. Similarly, the impact of total mesorectal excision on the need for radiotherapy has not been defined; therefore, radiotherapy remains the standard. One Technical Panel member raised the possibility that the definition of rectum be precisely specified – that is, centimeters from the anal verge. The Technical Panel noted that the age 80 cut-off was appropriate. Some members still preferred four months rather than six months as the period for radiation.

The Steering Committee believed that that all Stage III rectal cancer patients under age 80 should be receiving neoadjuvant radiation therapy after surgical resection. It was decided, as specified, that the procedure noted in the measure was out of date. Accordingly, the Steering Committee recommended the measure for further development and suggested that the measure be sent back to ACS for an update to address patients who receive neoadjuvant radiotherapy.

Measures Not Recommended for Further Consideration

Lymph node retrieval and reporting in colon and rectal cancer (CCO)

The measure includes both colon and rectal carcinoma. The Steering Committee agreed with the Technical Panel that rectal carcinoma should not be included, because the impact of retrieving 12 nodes on rectal cancer survival is less clear and the administration of neoadjuvant therapy in rectal cancer can downstage the disease. For this reason, the ACS node retrieval measure was preferred.

Postoperative surveillance colonoscopy after colon resection surgery (Resolution Health)

The measure specifies surveillance colonoscopy within one year of surgery, which is inconsistent with NCCN and American Gastroenterological Association guidelines. A strength of the measure is the use of administrative data, although problems such as lack of clinical information – or staging – need to be addressed. As a result, palliative resections were not excluded and colonoscopy is not usually indicated in these patients. One objection to the one-year colonoscopy is that it might encourage annual colonoscopies – that is, the measure might encourage overutilization of services.

Preoperative liver imaging before colon resection surgery (Resolution Health)

While preoperative liver imaging may theoretically save patients an operation if bilobar liver disease is discovered and the patient's tumor does not require palliative resection, there is no evidence of improved outcome, or survival, if the test is performed. The Committee believed that measures of diagnostic studies would be

acceptable if there was evidence that they provided missing information that was critically important for patient management, but in this instance the relationship was not clearly established. In addition, no data were presented for the prevalence of preoperative liver imaging. If the usage was, in fact, high, or more than 95 percent, there would be no need for a performance measure.

General Research Agenda

Overall, the Steering Committee determined that there is a dearth of valid quality-of-care measures related to breast and colorectal cancer. A coordinated and well-funded research program is needed as a national priority. Major aspects of such a program must first deal with basic conceptual and infrastructure issues in order to produce a standardized set of quality standards.

Database Research

There is currently no standardized database for collecting information. The Steering Committee noted that the emergence of multiple datasets, each with its own definition, could subvert any efforts to collect data across multiple healthcare settings and generate valid accountability measures. The Committee recommended that a mechanism for standardizing data elements or deriving interoperability be sought through public-private initiatives. It noted that the evolution of an electronic medical record that integrates with these databases would be a key element in allowing quality data to be collected at a reasonable cost. The Committee also believed that another avenue for deriving a standardized database would be to expand

the data elements collected in tumor registries that have a solid base of standardized cancer-related data; similarly expanded use of the National Cancer Data Base and Surveillance Epidemiology and End Results (SEER) database should be explored.

The Committee also recognized that data related to patient and family experiences and preferences are not retrievable from most administrative databases and will require survey instruments. It recommended standardization of survey instruments to avoid amassing conflicting and/or non-comparable data from disparate survey tools.

Types of Measures

The Committee noted that the various stakeholders in quality healthcare – providers, consumers, payers, purchasers, and researchers – may have different ideas about what type of measures are most needed to improve quality of care. Some stakeholders may require surveillance measures, while others find that accountability measures meet others' needs. However, the Steering Committee recommended that within these types of measures there should be a prioritization process to ascertain what types of measures best meet everyone's needs. Additionally, the Steering Committee recommended that studies be performed with user groups to determine what measures they consider to be appropriate and to meet their quality assessment needs. The Steering Committee recognized that there is a major need for valid, risk-adjusted outcome measures that would be of significant use to consumers, purchasers, and payers.

Modes of Presentation

For each measure developed, the Steering Committee recommended research to determine how the information could best be relayed to each stakeholder group, so that the data optimally fulfill the usability criteria.

Stability of Cancer-Related Measures

Given the rapidly changing technology of cancer management, the Steering Committee recommended that processes be put in place to assess endorsed consensus standards regularly to assure they are not based on outdated methods and procedures.

Efficiency Measures

The overuse or misuse of services has become increasingly important, given the economic climate of healthcare. A major issue in misuse is inappropriate testing during work-up for new or recurrent disease. The Committee also noted that overuse of aggressive therapy in the terminal phases of illness is a major source of inefficient care and that measures should be devised to provide reasonable thresholds.

Risk-Adjustment Models

In order to develop and implement valid outcome measures, risk-adjustment models will have to be derived to avoid the biases introduced by clinical, demographic, or social confounding factors. These models may have to be specific not only to the particular tumor, but also to the stage or presentation of the disease.

Specific Research Agenda

Because the set of candidate consensus standards for breast and colorectal cancer consisted of relatively few measures, the two Technical Panels and the Steering Committee used the Institute of Medicine quality aims to provide the framework for identifying areas that need further research in order to develop a comprehensive measure set. In many of these areas, no measures exist. The Steering Committee did not attempt to prioritize the list, because that would have involved initiating a full-scale project to establish burden, variation in care, and improvability for each area.

The proposed research agenda included both tumor-specific – that is, breast cancer or colorectal cancer – and cross-cutting potential measures. The cross-cutting measures are to serve as a template for future measure development in other tumor sites as a comprehensive cancer measure set evolves. Selection was based on Technical Panel and Steering Committee expert assessment, using both peer-reviewed studies and each member's individual experience and knowledge that significant variations in care exist and that the issues raised by these deficiencies have a significant impact on patient outcomes.

Selection of Symptom Management and End-of-Life Care Measures

Eleven measures were submitted for consideration. One developer was contacted regarding a measure described in the Southern California EPC report, but ultimately this measure was not considered any further because of a lack of continued maintenance. The Steering Committee changed only one of the Technical Panel recommendations by recommending the Family Evaluation of Hospice Care survey as an accountability measure, rather than for quality improvement and surveillance.³

Symptom Management and End-of-Life Care Consensus Standards Recommended for Inclusion in the Set

The recommendations from the Technical Panel formed the basis of the Steering Committee's initial deliberations, which were based on three categories:

- the measures that should be considered as accountability and quality improvement, quality improvement, and/or surveillance;
- the measures that should undergo further development as accountability, quality improvement, or surveillance; and
- the measures that should not move forward for further consideration.

Recommended for Accountability, Quality Improvement, and Surveillance

The Steering Committee recommended one measure for accountability, which also should be used for quality improvement and surveillance:

Family Evaluation of Hospice Care (FEHC)—National Hospice and Palliative Care Organization (NHPCO)

The Technical Panel recommended this survey measure for quality improvement and surveillance only; as an accountability measure, the Technical Panel recommended further development, indicating that it had not been demonstrated that improvement occurred after implementation of the measure. The Steering Committee, however, disagreed and recommended this measure for accountability as well as quality improvement and surveillance for hospice care settings, and for further development in all three areas for other healthcare settings. The Committee believed that sufficient evidence exists to make the measure appropriate for accountability: 1) the domains have been developed by experts in the field and carry impressive face validity; 2) variation in performance has been demonstrated with a two-fold difference in score between the 25th and 75th percentile for emotional support; and the instrument has been extensively tested in a large number of hospices and is currently being reported to an NHPCO website, although it is not publicly accessible.

The Steering Committee concurred with the Technical Panel's view that no formal studies show that poor scores can be improved based on using the survey, but it noted that this criterion has not been

³One commenter noted that the submitted measures were directed to an adult population, pointing to the need for further work geared toward a pediatric population.

applied to other measures. Given this, the Committee believed that because the scale relates directly to hospice services, it is reasonable to assume that hospices can introduce interventions to improve if deficiencies are found. Committee members noted that this extrapolation might not be true at other levels of healthcare, such as the health plan level, which might not be able to mandate the appropriate changes. Thus, while the measure has been tested in a research context for the hospital, home health, and nursing home settings, testing has not been adequate to recommend the measure for accountability; further testing is needed because the survey includes elements that might be difficult to obtain. For example, it is not clear how readily hospitals can identify date of death and/or contact families for this information on a routine basis.

Other commenters noted the following:

- the length of the survey and its impact on compliance: the measure developer and NHPCO reconfirmed that the length has not been a barrier to high compliance rates;
- narrowing the response period;
- whether characterization of the responder is necessary – for example, blood relationship, time spent with patient, etc.;
- initiating research on the applicability of the survey while the patient is alive – that is, within two weeks of a patient's admission to hospice; and
- developing versions of the survey in languages other than English.

Additionally, another commenter pointed out that the survey addresses the use of opiates and care for dyspnea, although this is not a Food and Drug Administration-approved indication.

The commenter questioned whether NQF standards should endorse “off-label” use.

Concern was raised about the appropriateness of the survey as an accountability measure. The issues raised were as follows: the lack of factor analysis to support the validity of the domains; the low Cronbach alpha scores of two domains; and the use of yes/no questions. In response, the survey developer noted that factor analysis had been performed and reconfirmed by an analysis of the database in 2005. The developer also stated that the low Cronbach alpha scores were found in domains with a low number of items and, in consultation with outside experts, it was decided to include them. The developer asserted that the use of yes/no responses is appropriate for quality assessment, because it relates to satisfaction and is meaningful to providers. Yes/no responses also get around the problem of responders voting high scores on a Likert scale, even if they identify problems.

The comments were sent to the Steering Committee, and several members of the Committee referred them to survey experts in their organizations. The Steering Committee then voted unanimously to uphold its previous action of recommending the survey for accountability.

One commenter who approved the context of the survey said that several formatting issues needed to be addressed to reduce surveyor confusion; these changes also would bring the survey into closer conformity with the CAHPS family of survey instruments. This recommendation was referred to the developer/intellectual property owner for consideration.

Recommended for Quality Improvement and Surveillance

The Steering Committee recommended one measure for quality improvement and surveillance.

Comfortable dying (NHPCO)

Following the Technical Panel's recommendation, the Committee recommended this measure for quality improvement and surveillance in the hospice setting and for further development for accountability in hospice and other settings. The measure was considered to be a good assessment of pain control for quality improvement purposes, because it is based on patients' perceptions. The Committee believed that the measure requires further development for quality improvement and surveillance in settings other than hospice; however, it is not clear whether other settings of care are capable of routinely interviewing patients on admission or of performing 48-hour follow-up. The Steering Committee recommended that if the measure is to be used for accountability, the following issues should be addressed through further development:

- Given patient population differences and hospice patient selection, can it be assumed that all hospices are the same or must adjustments be made to account for these differences?
- Regarding validation that the "yes" and "no" responses of the measure correlate with consistent changes in objective pain measurement scales. Some members of the Steering Committee said that the developers should assess whether the standard 33 percent reduction in pain used in clinical trials could serve as the endpoint.

- Regarding validation that the 48-hour time period is appropriate and should not be shorter, some Steering Committee members felt that patients admitted with severe pain should be assessed for pain control in a shorter period of time – 24 hours.
- Is risk adjustment for severity of pain on admission required – that is, should hospices whose patient populations on average have high levels of pain perform the same on this measure as those who have low levels of pain?
- The measure should be modified to account for patients who cannot report their level of pain.
- Further developers should be directed toward including this assessment in hospitals and nursing homes.
- The scope of the measure should be expanded to include dyspnea, anxiety, and depression.

Recommended for Surveillance

Seven of the eight measures relating to the overuse of services at the end of life were advanced by the Steering Committee for the purpose of surveillance. The Steering Committee agreed that these were critically important, especially given the current concern with financing healthcare. That is, the Committee believed that recommending that the measures be used for surveillance could eliminate aggressive therapeutic interventions with no demonstrable benefit, which in turn could permit the diversion of funds from these activities to more effective modalities of care. Of equal importance, the Steering Committee believed that because these measures often assessed care

that was not patient centered, the elimination of the unnecessary use of these intensive treatments would preserve patient autonomy and focus patients and their families on realistic outcomes.

The Committee discussed several overarching issues relevant to the surveillance measures it recommended:

- **Data source.** The eight candidate consensus standards were derived from the SEER Medicare database. This database allows measures to be evaluated for large numbers of patients, but it does not allow analysis at the hospital or physician levels. Thus the Steering Committee believed that, as presented, the data would support surveillance measurement and that further research, development, and/or testing should be performed before the measures could be recommended for hospital- or physician-level performance measurement.
- **Designation of measures as surveillance measures.** The Committee recommended the measures for surveillance because data from the SEER-Medicare database do not allow hospital or physician comparisons. The Steering Committee believed that all of these measures could be potentially useful as quality improvement measures if supporting data about variations among hospitals and physicians could be obtained. Similarly, health plan data from various plans also would be useful in determining if these measures could be used at the health plan level. Because the utilization of services is at least partially driven by available healthcare resources such as hospices and home care agencies that are not under the direct control of hospitals or physicians, the Steering Committee did not believe that these measures would be appropriate for accountability.
- **Data issues.** The measures use date of death, which is available in Medicare files, as their anchor. The Committee noted that date of death may be a difficult data element to collect: Hospitals and physicians may not even be aware a patient has died, let alone know the exact date, and many health plan administrative databases also do not routinely collect this element. For this reason, the Steering Committee recommended additional testing and development before assessing whether these measures could be used for quality improvement at levels below the population level.

The denominator for many measures will consist of “patients who died from cancer.” Many hospitals may not list cancer as the primary cause of death, making identification of patients difficult.
- **Patient preferences.** Because the decision to pursue aggressive end-of-life treatment may derive from patient preference, the Steering Committee believed it would be important to include methods of accounting for patient preferences as the measures are developed for quality improvement.
- **Aspects to be evaluated for further development as quality improvement measures.** The Steering Committee recommended that each surveillance measure be assessed regarding whether it needs to be risk adjusted for other variables such as comorbidity, age, care setting, and demographic variables (e.g., indigency).
- **Methodology.** The eight utilization measures are based on care rendered to patients prior to their death. The population is identified by their death and their care is then retrospectively evaluated. The validity in determining the quality of care by assessing decedents has been

questioned because biases may be introduced into the samples.⁴ The study of patients prospectively carries with it substantial data burden problems, and for this reason the retrospective technique has been deemed of value,⁵ especially with new refinements to lessen bias.⁶

The measures recommended by the Steering Committee for surveillance were as follows:

Chemotherapy in the last 14 days of life (Craig Earle, MD/Dana Farber Cancer Institute [DFCI])

(Proportion receiving chemotherapy in the last 14 days of life)

The Steering Committee concurred with the Technical Panel's recommendation that a high proportion of chemotherapy in the last 14 days of life reflects poor quality and therefore would be a valuable metric to track. Further research should be performed to validate "14 days" as a threshold. The Steering Committee recognized that all patients receiving chemotherapy in the last 14 days may not reflect overuse, since the measure does not account for patients dying from chemotherapy toxicity, patient preference, early death (e.g., acute leukemia), death from noncancer-related causes, or appropriate use of chemotherapy for palliation. The Steering Committee recommended that, as part of further development as quality improvement measures, these possible confounders be analyzed to determine how they impact the results.

More than one emergency room (ER) visit in the last 30 days of life (DFCI) (Proportion with more than one emergency room (ER) visit in the last 30 days of life)

The Technical Panel recommended this measure for further development for surveillance, believing that patient preference and availability of resources need to be investigated further to determine to what degree the healthcare system has control over performance for this measure. The Steering Committee did not concur, however, and recommended this measure for surveillance, because it covers several dimensions of quality care. It noted that at one level the measure is an index of the adequacy of optimal symptom management, because many emergency department visits are secondary to uncontrolled pain or dyspnea. The measure also reflects coordination of care and the establishment of systems to manage patients at home and thus is valuable as a driver to encourage the establishment of these systems.

The Steering Committee decided that the measure was not yet ready for purposes other than surveillance. For example, because patient decisionmaking often drives an emergency department visit, the responsibility for such a visit may have nothing to do with the hospital or physician. In addition, emergency department visits may be a function of other healthcare resources, such as home health services or case management. Emergency department visits also may reflect whether the patient is under the care of a physician or has no physician directing care. The Committee noted that the healthcare setting may be an important variable and that significant

⁴Bach PB, Schrag D, Begg C, Resurrecting treatment histories of dead patients. A study design that should be laid to rest, *JAMA*, 2004;292:2765-2770.

⁵Earle CC, Ayanian JZ, Looking back from death: the value of retrospective studies of end-of-life care, *J Clin Oncol*, 2006;24:838-840.

⁶Gagnon B, Mayo NE, Laurin C, et al., Identification in administrative databases of women dying of breast cancer, *J Clin Oncol*, 2006;24:856-862.

differences in emergency department usage in urban and rural settings may exist. Additionally, the developer reported that because the measure might need to be risk adjusted for comorbidity, further analysis is necessary to provide a risk-adjustment algorithm if the measure was to be recommended for a purpose other than surveillance. A potential unintended consequence of the measure may be the prolongation of hospital stays to lower the rate of emergency department visits postdischarge.

The Technical Panel recommended further development of the measure as a quality improvement measure, and the Committee concurred, noting that emergency department use may indicate the aggressiveness of cancer care—that is, the reason for the emergency department visit should be categorized because the cause of some visits could be a result of chemotherapy toxicity in the last 30 days of life, which may point to potential quality issues. Also, patients may seek emergency department care for noncancer-related conditions. In other words, linking emergency department visits to diagnostic codes could reveal whether an emergency department visit is appropriate or not and make this of utility as a quality improvement measure.

More than one hospitalization in the last 30 days of life (DFCI)

(Proportion with more than one hospitalization in the last 30 days of life)

Following the Technical Panel's recommendation, the Steering Committee recommended this measure for surveillance because it may reflect an overall assessment of the aggressiveness of treatment and the availability of an integrated healthcare delivery system. The Steering Committee noted that the measure addresses an important patient-centered issue, because the majority of patients prefer to spend their last days at home.

In recommending further development of this measure for quality improvement, the Steering Committee believed that the following issues should be addressed:

1) the admitting diagnosis should be built into the measure to allow adjustment for appropriate, versus avoidable, admissions, and 2) the locus of attribution is not defined and needs to be determined—for example, if one hospital's patient is hospitalized at another hospital, it needs to be determined which facility is responsible.

Intensive care unit (ICU) admission in the last 30 days of life (DFCI)

(Proportion admitted to the intensive care unit [ICU] in the last 30 days of life)

The Steering Committee concurred with the Technical Panel's recommendation of this measure for surveillance, because ample data confirm that intensive care unit (ICU) usage for terminal cancer patients does not lead to beneficial outcomes. The Committee noted that this measure is under the control of hospital policy, in contrast to emergency room visits or hospital admissions. The Steering Committee believed that although this is an excellent measure for quality insurance, the current database used to calculate the measure's source does not include hospital-level data.

The Committee recommended examining refinements to the specifications that address appropriate and inappropriate intensive care unit admissions; the consideration of intensive care unit outcomes; possible adjustments to account for different intensive care unit usage based on hospital characteristics (e.g., small hospitals use the intensive care unit for telemetry; bone marrow transplant centers will have large intensive care unit populations); and whether the specifications should exclude appropriate admissions (e.g., following definitive surgery or the toxicity of adjuvant

therapy). The use of a 30-day threshold given physician inability to predict death should also be validated. It also was recognized that patient/family preference may drive intensive care unit admission and that this should be accounted for in the measure.

Dying in an acute care setting (DFCI)

(Proportion dying in an acute care setting)

Following the Technical Panel's recommendation, the Steering Committee recommended this measure for surveillance, because it measures the overall resources of the community to manage home deaths. The Committee noted that the measure addresses issues of patient preference, because although the majority of cancer patients prefer to die at home, up to 40 percent of cancer patients die in an acute care hospital setting. The Committee acknowledged that in some cases the physician and hospital may not control the decision to hospitalize the dying patient because a strong patient or family preference can override a home-based death, but it noted that in less than 50 percent of cases, a patient will die in the hospital rather than at home because of patient or family preference.

In its recommendations related to developing this measure for quality improvement, the Steering Committee believed that the following issues should be addressed:

- The measure as currently specified is affected by the degree of ancillary health system resources; thus, adjustments should be made to account for such parameters, which include the availability of home care and hospice, as well as nonclinical support, such as the ability to have a caregiver stay with the patient.
- If patient preference is accounted for in the measure, pure administrative data may not be adequate unless collection of preference information is mandated. Otherwise, survey data also will be required.
- An ideal measure may take into account the concordance between patient preference and the site of death.
- Tertiary care facilities may be disadvantaged because they treat sicker, more complex patients.

Not admitted to hospice (DFCI)

(Proportion not admitted to hospice)

The Technical Panel and the Steering Committee recommended this measure for surveillance. The Committee determined that the measure is suitable for surveillance because hospice services are available to more than 95 percent of the U.S. population. It is not clear whether 100 percent performance is achievable nationwide, because sufficient hospice capacity may not exist, especially in rural areas. The Committee noted that one problem is that the specifications do not account for the quality of the available hospice — that is, if the quality is poor, low referral rates may be justified.

In assessing the measure's appropriateness to be used for accountability, the Committee noted that existing data indicate that educational programs and programs promoting referrals increase the number of patients who receive hospice services; clearly, improvement on this measure is possible. Nonetheless, the Committee believed that recommending the measure for accountability might lead to physicians pushing hospice too aggressively, counter to the notion of patient-centered care.

Another issue involved in making hospice use an accountability measure is the designation of the accountable agent – is it the responsibility of the hospice, primary care physician, or oncologist?

With respect to additional development as a quality improvement measure, the Steering Committee recommended factoring patient preference into the specifications – for example, a more appropriate measure might be recommendations for referral to hospice, rather than admissions to hospice. The Committee also recommended additional development to account for physician preference based on perception of the quality of hospice care or the suitability of that care vis-à-vis other home services in the community. Additionally, the Steering Committee noted that because the measure was evaluated for use at the hospital and physician levels, acquiring data on hospice admission might be problematic, because it often was not routinely noted in the medical record.

The Steering Committee pointed out that optimal usage may not be possible because of reimbursement policies – that is, because hospice benefits often preclude therapy such as transfusion, high-priced anti-nausea drugs, and bisphosphonates, patients and families may opt not to receive hospice care. The Steering Committee also noted that while not under control of the health-care system, policymakers should be made aware that current reimbursement policies and the amount of reimbursement provided are inadequate for the provision of uniformly high-quality hospice care.

Admitted to hospice for less than three days (DFCI)
(Proportion admitted to hospice for less than three days)

Consistent with the Technical Panel's recommendation, this measure was recommended by the Steering Committee for surveillance, because many localities

are performing below the threshold. Data show a 2.4-fold difference between the 95 percent and 5 percent levels. The Committee noted that the use of short hospice stays works financially against hospices because per diem payments do not allow adequate reimbursement to cover the cost of admitting a patient to hospice. Some commenters believed strongly that the 3-day threshold was too low and the measure should look at a 7- to 14-day threshold, which would allow for more appropriate hospice services.

One concern raised by the Committee is that measuring performance for this measure may stop physicians who use short admissions from referring at all, rather than providing the opportunity to educate them about current referral patterns. Similarly, the Committee noted that hospices are reluctant to identify physicians with very short referrals for fear of cutting off referrals – that is, if physicians are penalized for short referrals, this may stop referrals to hospice.

The Committee noted that physicians could influence performance on this measure. It also noted that the role of hospitals seems to be less clear, although if publicly reported, hospitals might pay more attention to case management and discharge planning. It is also recognized that nurses, as a vital part of the interdisciplinary team, have considerable influence over whether patients utilize hospice. Therefore, education programs directly related to the entire team should be developed.

Regarding further development, the Steering Committee recommended that the developer account for the issue that patient length of stay is partially a function of patient preference for being referred to hospice. Additionally, the Committee noted that, from a data collection perspective, if the dates of admission to hospice and the

date of death are not ascertainable from an administrative database, it would be difficult to get length of stay from hospice or physician records.

Measures Not Recommended for Further Consideration

The Steering Committee did not recommend 2 of the 11 proposed consensus standards it reviewed.

Proportion starting a new chemotherapy regimen in the last 30 days of life (DFCI)

The Steering Committee concurred with the Technical Panel's recommendation that this measure should not advance. The Committee decided that the measure was problematic because of imprecision in predicting when patients have 30 days to live. The Committee noted that, overall, physicians tend to overestimate the time to death—that is, because it is difficult for physicians to accurately assess this time period with precision, holding them accountable for starting chemotherapy within this period might deny some patients warranted therapy. The Committee also noted that from a data perspective, the computer algorithms for ascertaining whether a regimen is new may be complicated and difficult to implement; the measure calls for previous chemotherapy information that may not be readily available; and ascertaining data of death is difficult to extract from some administrative databases. Overall, the Steering Committee believed that the measure related to the use of chemotherapy in the last 14 days of life is a more accurate assessment of overutilization of chemotherapy.

Self-determined life closure (NHPCO)

Although the Technical Panel recommended this measure for further development and the Steering Committee emphasized that this was an important area for evaluation, the Steering Committee ultimately determined that considerable work needs to be done 1) to account for change of preference—that is, those patients who initially said they did not want to re-enter the hospital, but changed their minds upon change in their clinical condition; 2) to determine how the question of preference should be framed; and 3) to ensure that the measure is not coercive. Since the Steering Committee was not sure how the measure could be modified to account for these issues, the measure was not recommended, although the area of patient preference was considered to be important.

Research Recommendations

Because there is a dearth of sound measures related to symptom management and end-of-life care, the Committee recommended that a coordinated and well-funded program become a national priority. Major aspects of this program must deal with basic conceptual and infrastructure issues in order to produce a comprehensive, standardized set of consensus standards for quality of symptom management and end-of-life care for patients with cancer.

Database Research

Currently, there is no standardized database for collecting information about symptom management or end-of-life care. A mechanism for standardizing data elements or deriving interoperability must be sought through public-private initiatives.

The Steering Committee believed that the potential danger of the emergence of multiple datasets, each with its own variable definitions, could subvert efforts to collect data across multiple healthcare settings and generate valid accountability measures.

The evolution of an electronic medical record that integrates with these databases will be key to allowing quality data to be collected at a reasonable cost. Another avenue for deriving standardized database development would be the expansion of data elements collected in tumor registries that have a solid base of standardized cancer-related data. Similarly, expanded use of the SEER database should be explored.

The Steering Committee recognized that data related to patient and family experiences may not be collectible in typical administrative databases and will require survey instruments. In this instance, standardization to avoid the amassing of conflicting, or at least noncomparable, data from disparate instruments also will be critical.

Types of Measures

Research is needed to determine which type of measures meets the needs of the various healthcare stakeholders. Studies must be performed with user groups to ensure that these groups consider the measures appropriate and that the measures meet the quality assessment needs of the group.

The Steering Committee noted that various stakeholders may have very different ideas about the type of measures that are most needed to improve the quality of care. Stakeholder groups requiring similar types of measures, such as surveillance measures, can then be assessed and a prioritization process can be initiated to ascertain what types of measures best meet the overall needs of the group.

A critical element in establishing that a particular measure meets the needs of a stakeholder group is the soundness of the evidence underlying the measure. For providers, this means that the evidence base must be rooted in the medical literature and be generally accepted as definitive. For other stakeholders, it means that the measure must address an element of care that the group equates with quality care. For purchasers, this may focus on overuse or misuse of services.

Modes of Presentation

For each measure developed, research must ascertain how the information can best be relayed to each stakeholder group, so that the data fulfill the usability criteria.

The Steering Committee noted that there is a lack of data about whether the measures

are considered to be comprehensible or of use to all stakeholders, especially consumers. Before endorsement as accountability measures, research should demonstrate that the measures are in fact useable.

Measurement of Symptoms in Cancer Populations Versus General Patient Group Versus Generic Symptom Categories

Because the management of symptoms such as dyspnea, pain, and depression may be generalizable across many patient populations, cancer patients could be included in general surveys. Research is needed to demonstrate that the results of measuring symptom control in general populations are valid as a measurement of cancer-related symptoms.

Although there is the impression that in many instances generic symptom instruments can be used to assess cancer-related symptoms, the Steering Committee believed that empiric research is needed to demonstrate whether this is in fact valid. Measures using generic instruments must be tested in cancer and noncancer patients to validate that they can be used in diverse populations. Similarly, thresholds will have to be compared between cancer and noncancer populations to determine if a measure would elicit the same results in all populations.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Research is needed to determine how patient-specific data can be collected and still conform to all HIPAA requirements. Research into the development of a confidential unique identifier for patients should be pursued.

Hospital and physician concerns about releasing patient-specific information present a major barrier to collecting and reporting such data. Research is necessary to ensure that HIPAA requirements are followed and that this message is successfully conveyed to healthcare providers. Some members of the Steering Committee believed that ultimately research is needed on deriving a method for assigning a unique identifier to all patients that satisfies confidentiality concerns and that could be used across all domains of information gathering.

Stability of Cancer-Related Measures

Given the rapidly changing technology used in cancer management, measures will need to be continuously assessed to assure that they are not based on outdated methods and/or procedures.

The Steering Committee believed that the persistent use of measures that are rendered obsolescent by scientific advances is a serious threat to the credibility of a quality measuring and reporting system. The Committee believed strongly that a method for performing ongoing review is essential in order to ensure long-term system viability.

Outcomes of Symptom Management

Adequate management of pain and dyspnea is a priority area for physical care management. In the area of managing psychosocial symptoms, the management of depression and anxiety were considered to be of major importance.

The Steering Committee believed that there are specific symptom constellations for which there are scientifically validated assessment instruments and documented interventions that could be employed for amelioration. This was documented in the Southern California EPC report. These areas – pain, dyspnea, depression, and anxiety – should therefore be the initial targets for measurement development. As research leads to adequate measurement tools and appropriate interventions for other symptoms, they should be added to the list.

Intermediate Outcomes of Processes

In selecting process measures, developers also should focus on the intermediate outcomes of those processes, or their direct results. This will help address the dimension of quality regarding how well the processes were carried out.

The Steering Committee believed that in the area of radiation therapy, correct dosing and tumor localization remain critical issues. In surgery, the assessment of the pathology specimen can yield valuable quality information about the adequacy of the surgery. Parameters, such as relative dose intensity for chemotherapy, are not as clear, and further studies will be necessary to delineate that they are the appropriate intermediate outcome measures.

Complication rates, including short-term, mortality rates can also be used to assess intermediate outcomes. Because this has been studied primarily in surgery, basic studies in radiation therapy and chemotherapy would need to be performed. Sophisticated risk-adjustment processes will be needed to ensure that complications are measured in comparable populations.

Patient-Centered Decisionmaking

In the area of palliation, the development of patient-centered measures is critically important, especially in assessing the quality of end-of-life care. Research is needed to develop measures that assess the congruence between the care that is delivered and patient preferences.

The Steering Committee believed that the entire spectrum of patient-centered issues, including the provision of support and information and shared decisionmaking, should be assessed. An area of prime focus should be whether patient and family preferences for aggressive therapy and site of dying were followed. In addition, the Steering Committee believed that measures should be developed to assess the offering and completion of advance directives.

Efficiency Measures

Significant research resources should be directed toward assessing the overuse or misuse of services. This issue will become increasingly important given the economic climate of healthcare. A major issue in misuse is inappropriate testing during work-up for new or recurrent

disease. Overuse of aggressive therapy in terminal phases of illness is a major source of inefficient care, and measures should be devised to provide reasonable thresholds.

The Steering Committee believed strongly that the overuse or misuse of services will become increasingly important. While ultimately these measures should balance costs against quality care, the Steering Committee felt that utilization measures are an important first step in evaluating efficiency that eventually will result in less waste. To be effective in changing behavior, these measures require commitment at all levels of the healthcare system.

In deriving utilization measures, the issues of patient preference and the availability of local resources would need to be considered, and the ability to capture vital information such as dates of services would be required. In addition, the issue of unintended consequences must be addressed. Specifically, regarding the research recommendation calling for the possible development of a radiotherapy measure in the last 14 days of life, it was noted that radiotherapy may be palliative at the end of life and a 14-day window may be difficult to predict.

Pediatric Measures

One commenter noted that the management of pediatric cancer patients may entail factors that may lead to differences in resource utilization when compared to the management of adult patients. NQF staff agreed with this view and recommended ongoing research to identify these factors. In addition, it was recommended that pediatric-oriented measures encompassing patient-centered and family-centered attributes and needs for information also be developed.

NATIONAL QUALITY FORUM

Appendix D

Cancer Care Measure Framework Domains and the IOM Aims

A comprehensive set of consensus standards for quality of cancer care must encompass measures that address the multiplicity of clinical presentations, the array of appropriate healthcare professionals required to manage the cancer patient, the varied settings in which care is delivered, and the vulnerable population with demonstrated lower quality of care. This appendix presents the specific cancer care measure framework domains and domain content areas in matrices with the Institute of Medicine's six aims of healthcare quality. These matrices should facilitate the identification of areas for which measures are needed and should be used to direct research and development initiatives that lead to a comprehensive measure set.

Cancer Care Measure Framework Domains and Aims

| DOMAIN AND DOMAIN CONTENT | IOM QUALITY AIMS* | | | | |
|--|-------------------|------------|--------|---------------------|-----------|
| | SAFE | BENEFICIAL | TIMELY | PATIENT CENTERED | EFFICIENT |
| ONCOLOGY SERVICES | | | | | |
| Pathology | | | | | |
| Radiology | | | | | |
| Surgical oncology | | | | | |
| Radiation oncology | | | | | |
| Medical oncology | | | | | |
| Reconstructive surgery | | | | | |
| Palliative medicine | | | | | |
| Nursing oncology | | | | | |
| Rehabilitation | | | | | |
| Psychosocial | | | | | |
| Case management | | | | | |
| Pharmacy | | | | | |
| Other specialties | | | | | |
| DEMOGRAPHIC POPULATIONS | | | | | |
| Race and ethnicity | | | | | |
| Age | | | | | |
| Socioeconomic status | | | | | |
| Genetically vulnerable | | | | | |
| Family history | | | | | |
| Geographic location | | | | | |
| Environmental | | | | | |
| DISEASE TRAJECTORY AND SYMPTOM CONTROL | | | | | |
| Prevention and early detection | | | | | |
| Diagnosis/staging | | | | | |
| Primary treatment (including treatment on clinical trials) | | | | | |
| Adjuvant therapy | | | | | |
| Monitoring for recurrent disease and second primary tumors and follow-up | | | | | |
| Survivorship | | | | | |
| Recurrent disease | | | | | |
| End-of-life care | | | | | |
| ONCOLOGY CARE SETTINGS | | | | | |
| Office/clinic | | | | | |
| Inpatient hospital | | | | | |
| Nursing home | | | | | |
| Home | | | | | |
| Hospice | | | | | |
| Radiation center | | | | | |
| Surgery center | | | | | |

* The aim of equitable care is a cross-cutting aim that applies across domains.

NATIONAL QUALITY FORUM

Appendix E

Cancer Data and Methods Panel Report

In May 2004, the National Quality Forum (NQF) initiated Phase 2 of a project to endorse national voluntary consensus standards for public accountability, quality improvement, and surveillance in three cancer areas: breast cancer treatment and diagnosis, colorectal cancer treatment and diagnosis, and symptom management/end-of-life care. Additionally, the project was to identify gaps in the set for which research funding for development and/or testing would enhance the set of consensus standards for quality of cancer care in these areas and establish a framework for reporting on and updating the set of consensus standards.

The three Technical Panels conducted the initial reviews of the candidate consensus standards—one for each area. To ensure consistency in the reviews across these three bodies, the Cancer Data and Methods Panel (CDMP) was convened on August 17-18, 2004, to make recommendations to the project's Steering Committee on the criteria for assessing candidate quality measures and to provide input to the Steering Committee on the framework for recommending a set of cancer measures for consideration under the NQF's formal Consensus Development Process (CDP). The CDMP's recommendations were reviewed by the Steering Committee on October 19, 2004. This report reflects the CDMP's recommendations, as modified and approved by the Steering Committee, and served as guidance to the Technical Panels for measure evaluation.

Meeting Aims

The NQF report, *A Comprehensive Framework for Hospital Care Performance Evaluation* (“hospital framework”), identifies six areas to be addressed in the development, evaluation, and implementation of a set of consensus standards.¹ The CDMP deliberations encompassed the first three of these areas:

- establishing the content of the performance measure set;
- evaluating candidate consensus standards; and
- improving and updating the performance measure set.

In order to address these areas, the CDMP focused on the following aspects of the CDP:

- reviewed a framework for assessing the comprehensiveness of the content of a cancer-related quality measure set;
- discussed the evidence requirements for the quality indicators underlying the measures;
- evaluated the criteria in the four domains of measure assessment (importance, scientific acceptability, usability, and feasibility) from a cancer-related perspective;
- discussed the differences and value of accountability versus quality improvement measures in cancer; and
- discussed the role of clinical maps as an adjunct to the development of a set of cancer measures.

This report details the major recommendations made for each of these areas.

CDMP Recommendations Related to Criteria for Assessing Specific Quality Measures

The CDMP approved using the four domains endorsed by NQF in *A Comprehensive Framework for Hospital Care Performance Evaluation*: importance, scientific acceptability, usability, and feasibility.¹ A major theme running through all the domains is an assessment of the measure applicability at several levels.

Comprehensiveness of the Content of the Measure Set

In order to ensure that a set of quality of cancer care measures meets the needs of the complex system of oncology care, a framework is needed that defines the aspects of care and dimensions of the disease that must be addressed by the measure set. The goal is to construct a comprehensive model that encompasses all elements and levels of care. The NQF approach to accomplishing this critical task is to construct a set of matrices that define the content areas to be included in a comprehensive quality appraisal. The columns of these matrices are five NQF-endorsed aims for healthcare (safe, beneficial, patient centered, timely, and efficient). The rows consist of the specific content areas. The prototype for these matrices was derived from the NQF-endorsed[®] hospital framework.²

Each matrix addresses a domain of care that can serve as a theme for the identification of specific measure set content areas.

The CDMP discussed tumor-specific and cross-cutting priorities; demographic populations of particular interest; needs across the trajectory of cancer; and major oncologic services.

Steering Committee Action:

The Steering Committee modified the domains to include Cancer Care Settings in addition to the four other domains. A sixth matrix reflecting the management of symptoms was rejected by the Committee, because it was believed that this domain could be incorporated into the disease trajectory matrix.

The Steering Committee added criteria to each content area, as summarized in Table 1, below. For each content area, the Steering Committee decided the following:

- i. *Tumor-specific and cross-cutting priorities:*
 - (a) *Added symptom management as a cross-cutting area.*
 - (b) *The Steering Committee believed strongly that the area of coordination of care was very important, because cancer care involves multiple hand-offs to ensure optimal work-up and treatment. It was recognized that specific measures might be hard to identify.*
 - (c) *Decisionmaking was added as a separate content area, because there are factors in the healthcare system that promote or inhibit high-quality decisionmaking.*
- ii. *Cancer care services:*
 - (a) *Added oncology-related rehabilitation, case management, and psychosocial services.*
 - (b) *Pharmacy was deemed important especially in the area of safety measures.*
 - (c) *Recognized that role of primary care physicians would have to be included, especially with regard to screening and communication/coordination.*
- iii. *Demographic populations*
 - (a) *Expanded populations to include other vulnerable populations (such as patients and families with genetic or familial cancer and environmentally vulnerable populations).*
 - (b) *Added geographic populations to be able to assess factors such as urban and rural environments and area variations.*
- iv. *Disease trajectory and symptom control:*
 - (a) *The domain of symptom control was added as an overarching dimension, because it cuts across all stages of the cancer trajectory. The Committee wanted to emphasize that management of symptoms was a quality issue at every phase of cancer care.*
 - (b) *Prevention and early detection were added, because these activities led to a decrease in the morbidity of cancer.*
 - (c) *The Committee discussed whether participation in clinical trials should be included and decided that because there were no unequivocal data that participation in a clinical trial leads to improved outcomes, it should be included under primary treatment. The issue of the soundness of a measure related to clinical trials would have to be addressed by the Committee in the context of the submitted measure.*
- v. *Cancer care settings:*
 - (a) *The Committee designated the major care settings for the delivery of cancer care.*
 - (b) *It was recognized that some quality issues might be more problematic in certain settings, e.g., communication in hospitals.*

Table 1 – Domains of Care and Content Areas

1. Tumor-Specific and Cross-Cutting Priorities**■ Domain Content**

- Reflect national goals
 - Applicable across disease stages and patients and include symptoms occurring in all patients and stages
 - Examine potentially curable diseases
 - Include situations where quality of life is paramount
 - Include symptoms occurring in all patients
 - Include symptoms occurring at specific stages
 - Examine provider to provider coordination
 - Examine cancer-specific communication
 - Include the quality of decisionmaking
-

2. Cancer Care Services**■ Domain Content**

- Pathology
 - Radiology
 - Surgical oncology
 - Radiation oncology
 - Medical oncology
 - Reconstructive surgery
 - Palliative medicine
 - Nursing oncology
 - Rehabilitation
 - Psychosocial
 - Case management
 - Pharmacy
 - Other specialties
-

3. Demographic Populations**■ Domain Content**

- Race and ethnicity
 - Gender
 - Age
 - Socioeconomic status
 - Genetically vulnerable
 - Family history
 - Geographic location
 - Environmental
-

Table 1 – Domains of Care and Content Areas (continued)

4. Disease Trajectory and Symptom Control

■ **Domain Content**

- Prevention and early detection*
- Diagnosis/staging
- Primary treatment (including treatment on clinical trials)
- Adjuvant therapy
- Monitoring for recurrent disease and second primary tumors and follow-up
- Survivorship
- Recurrent disease
- End-of-life care

5. Cancer Care Settings

■ **Domain Content**

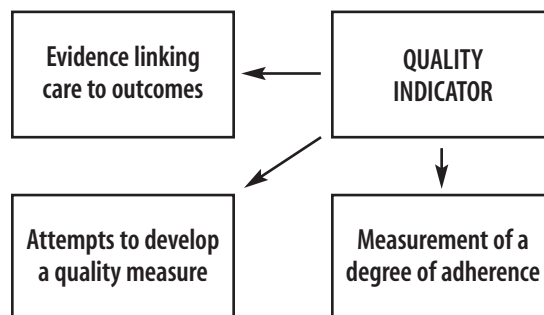
- Office/clinic
- Inpatient hospital
- Nursing home
- Home
- Hospice
- Radiation center
- Surgery center

*Prevention and early detection were included in the framework by the Steering Committee. However, because current funding is limited to diagnosis and treatment, prevention and early detection were not addressed by the CDMP.

Figure 1. Indicators, Measurement, and Measures

Evidence Base for Indicators

As a starting point, the CDMP used the following model depicting the relationship of indicators to measures.³



Quality indicators define a criterion against which performance can be assessed. Measures are the quantification of that assessment. The CDMP evaluated the level and type of evidence that was appropriate for each of five possible types of quality indicators – outcomes, process, structure, patient experience, and access. The quality of this evidence would be used to assess the validity of the indicator. In the case of outcome indicators, there should be evidence that the outcome has been documented as a measure of clinical intervention, while for the other four, the evidence should demonstrate a linkage between the type of indicator and an improvement in outcomes.

The CDMP's recommendations regarding each of the five types of indicators (outcomes, process, structure, patient experience, and access) are summarized in Table 2.

Steering Committee Action:

The Steering Committee approved the following changes to the CDMP's guidance:

- i. The Steering Committee decided that patient experience and access should not be considered separate categories, but rather should be considered with outcome, process, and structure measures. The Steering Committee was mindful that the linkages between structure, process, and outcomes or between primary and secondary outcomes would be established by varying levels of evidence, including "robust" consensus. Because the number of measures in the measure set is likely to be limited, whenever possible the highest level of evidence should be sought. The CDMP recognized that many of the measures in*
- cancer might be process measures, but believed that measures of all types were appropriate and desirable for a comprehensive measure set.*
- ii. Although the Steering Committee elected not to designate patient experience and access as separate measure types, it recommended that a set of principles regarding these areas be transmitted to the Technical Panels. It was emphasized that subsuming patient experience under the other measure types did not lessen its importance as an area to be addressed in a measure set.*
- iii. The Committee removed the stipulation that a measure of patient experience had to be linked to a societal or cultural value, because it believed this might violate cultural competency.*

Criteria for Measure Evaluation

The criteria for assessing candidate performance measures through NQF's CDP is set forth in *A Comprehensive Framework for Hospital Care Performance Evaluation*.¹ This framework is derived from the conceptual underpinning of the NQF's Strategic Framework Board.³

The structure of this assessment is divided into four domains: importance, scientific acceptability, usability, and feasibility. Each domain in turn encompasses several criteria that should be applied in evaluating a measure. The CDMP utilized this framework in the context of applying it to candidate cancer measures in order to provide practical guidance to the Technical Panels. The CDMP's recommendations are outlined in Table 3.

**Table 2 – CDMP Recommendations for Five Types of Indicators
(Outcomes, Process, Structure, Patient Experience, and Access)**

Outcomes

1. Primary outcomes in oncology (survival, quality-of-life/functional status, patient experience, cost-effectiveness) should be used if possible.
 2. If secondary measures are used, there should be evidence of linkage to primary outcomes, *wherever possible*.
 3. The portfolio should be balanced between all types of outcomes.
 4. The selection of a specific outcome may be based on its intended use, e.g., five-year survival for national/regional surveillance, even though it may not be as useful in other settings.
 5. Risk-adjustment strategies should be specified, including reasons for not including them.
-

Process

1. It must have a demonstrated linkage to outcomes.
 2. Evidence should be high level (randomized clinical trials or meta-analysis), if possible. If the evidence for the linkage is based on expert judgment, ample documentation of the rationale should be provided.
 3. The generalizability of clinical trial data to the entire cancer population should be assessed.
 4. Patient preference must be accounted for, even if the linkage between process and outcomes is strong.
-

Structure

1. There should be evidence linking structure to outcomes, although the data may not be high level. In some instances the evidence will link structure to a process, which in turn links to an outcome. In some cases the relationship of structure to outcomes may not define the intervening processes, e.g., volume relationships.
 2. The characteristics of the structural element must be precisely defined.
 3. The setting of the healthcare system to which a structural measure is to be applied must be specified.
 4. The differences in outcomes based on structural elements should be robust.
-

Patient Experience

1. Patients' experiences should be specific to diagnosis and management of their cancer rather than generic experience issues.
 2. The assessment of patient experience may be used for two purposes: a) to assess whether a specific intervention was performed, e.g., flu vaccine and b) to evaluate a patient-centered experience.
 3. There should be evidence that there is a linkage to improved outcomes, e.g., seeing a medical social worker should lead to an improved outcome.
 4. Generalizability should be assessed.
-

Access

1. Access should include availability, timeliness, and coordination of care.
 2. Differences in outcomes as a result of access should be robust.
 3. Access issues should relate specifically to cancer.
 4. The measure of access should be applied at a level of the healthcare system that has control of the aspect of access being measured.
-

Table 3 – CDMP Recommendations for Measure Evaluation Criteria

Importance should be based on the burden of disease as demonstrated by incidence, mortality, and morbidity data, by known variability in care, and the opportunity to improve quality. Clinical or contextual maps may be a method for systematically developing this data.

1. Focus should be on aspects of care affecting large numbers of patients.
 2. Context of the level of care at which care is provided and the ability to affect change at that level is important.
-

Steering Committee Action:

- i. The Steering Committee agreed that cost was an aspect of care that contributed to importance, because NQF was to use a societal perspective.
- ii. It was anticipated that the importance criterion could drive new approaches to data collection and therefore enhance feasibility.

Table 3 – CDMP Recommendations for Measure Evaluation Criteria (continued)

Scientific Acceptability must be carefully evaluated in all its dimensions. Realizing that not all criteria will be met, certain aspects such as validity and reliability are probably necessary for measure acceptance.

| | |
|-----------------------------------|---|
| <i>Preciseness of Definition:</i> | Should be comprehensive and specific, including data elements, data sources, timing of data collection, cohort definitions, exclusions, and risk-adjustment strategies, if present. |
| <i>Reliability:</i> | <ol style="list-style-type: none"> a) A measure should have evidence of inter-rater reliability and reliability over time and location. b) The statistical level to determine reliability may vary according to type of data collected. |
| <i>Validity:</i> | <ol style="list-style-type: none"> a) Face validity should be documented and the rationale provided, especially if based on expert opinion. b) Face validity may vary according to the context, e.g., consumer versus health plan. c) Because quality depends on provider buy-in, there should be face validity for providers. d) Other forms of validity such as criterion validity should be sought. |
| <i>Discriminating:</i> | <ol style="list-style-type: none"> a) In order to make measures as discriminating as possible, the element to be measured should be as precisely defined as possible, e.g., “can climb three stairs unaided” versus “is mobile.” b) Sample size is important in determining whether good discrimination is possible, especially when the measure is intended for accountability. |
| <i>Risk Adjustment:</i> | <ol style="list-style-type: none"> a) If risk adjustment is included in a measure submission, the reason for risk adjusting the measure or the measurement rate must be clearly stated. b) Stratification and exclusions may be used to make measures more meaningful, especially for measures of surveillance and process. c) If risk adjustment is used for process measures, care must be taken that meaningful quality factors are not removed, e.g., socioeconomic status. d) All of the variables used to risk adjust should be described and their precise definitions given. e) The full methodology of the risk-adjustment strategy that is used should be described. |
| <i>Adaptable:</i> | <ol style="list-style-type: none"> a) Because oncology practices occur across many settings, the more settings for which a measure can be applied, the more useful the measure. b) If a measure has not been tested in multiple settings, the Technical Panel will have to make a judgment about whether it can be generalized to nontested settings. |

Steering Committee Action: *The Steering Committee strongly recommended that the NQF Board develop standard definitions and requirements for measure assessment criteria such as reliability and validity, so that each committee and panel would not have to develop its own criteria.*

Table 3 – CDMP Recommendations for Measure Evaluation Criteria (continued)

Usability requires the documentation that a measure is understandable and useful to its target audience and yields meaningful information, but, unfortunately, often this facet of measure soundness has not been scientifically tested. Special attention must be paid to ascertaining whether a measure is generalizable to important subgroups and vulnerable user groups.

1. The degree to which the measure is understood and considered useful by the audience for which it is intended.
 2. If possible there should be documentation of the usability of the measure, although this may not be available.
 3. Consultation with advocacy/patient groups may help determine usability.
 4. Actionability—the potential for a measure to lead to change—is an important aspect of usability.
 5. Consultation with advocacy/patient groups may help determine usability.
-

Steering Committee Action: *One aspect of actionability is whether measures can be used for driving payment, i.e., used as criteria for pay for performance. Examples of inactionable measures would be those entailing changes to structural elements that can not be brought about in a reasonable timeframe – e.g., limited capabilities of rural hospitals, universal access to care.*

Table 3 – CDMP Recommendations for Measure Evaluation Criteria (continued)

Feasibility requires careful assessment of data sources across multiple care settings to ascertain if the measure could be implemented.

1. Burden of data collection in terms of labor and financial should be assessed for every measure.
 2. Data required for measurement should be up to date and accessible.
 3. Extensive use of the measure may point to its usability.
 4. Care must be taken to be sure that if an entity is to be judged by a measure, the entity should have access to the data on which they are being judged.
-

Steering Committee Action:

- i. *The goal is a balance that allows the recommendation of measures that are believed to be strategically important, even if they require expansion of data collecting capacity. In this sense, the goal is to get the most “bang for the buck.”*
- ii. *Another aspect of feasibility is hospital or physician willingness to provide the data. Adequacy of risk adjustment is an important factor in determining this.*
- iii. *The issue of whether a hospital can be held responsible for the care practices of its private physicians is complex. Although this may be a reasonable aim, at this time the mechanisms do not always exist for its accomplishment. Therefore, the Committee accepted the general principle that an entity must have access to data in order to be assessed according to that data.*
- iv. *A possible exception to having access to data in order to be assessed may exist in the instance of satisfaction measures that use patient survey data captured by third-party organizations. In this instance, the hospital has no direct access to the data, but can still be evaluated by them.*

In evaluating these criteria, the CDMP recognized that it was unlikely that a single cancer measure would meet all or even a majority of these measures; the Technical Panels must therefore weigh the strengths and weaknesses of each measure to determine if it should be recommended as a national voluntary consensus standard.

Measures for Accountability and Quality Improvement

A major issue to be addressed in identifying the measure set is whether, in evaluating candidate measures, a distinction should be made between those that are

suitable for accountability versus those appropriate only for quality improvement. Accountability measures are used for public reporting, in pay-for-performance programs, or for the selection of health plans, facilities, or providers by consumers and purchasers. Quality improvement measures may have different evidence, data sources, specificity, etc., because they are only for internal quality improvement initiatives in a local setting. The CDMP discussed whether the same scientific rigor should be applied to both accountability and quality improvement measures, and its recommendations in this regard are summarized in Table 4.

Table 4 – CDMP Recommendations Regarding Accountability Versus Quality Improvement

1. Accountability measures require a high level of scientific validity and reliability to ensure that differences are accurately reported.
 2. The cancer project should evaluate measures that should be designated for public reporting and accountability and measures that should be recommended only for quality improvement uses. The quality improvement measures are not applicable for broad application but are applicable at a local “internal” level. All accountability measures can also be used for quality improvement.
 3. In differentiating the two types of measures, the following principles would apply:
 - a) There should be no difference between accountability and quality improvement measures in the level and soundness of the scientific evidence of the indicator being evaluated. For both types of measures the underlying scientific basis should be sound.
 - b) Sample sizes may differ, with accountability measures requiring large sample sizes to make comparisons that are statistically significant. Different statistical methodology may be used in assessing the two types of measures, e.g., statistical process control for quality improvement measures.*
 - c) A major difference between the two measures may be the feasibility of collecting data. If data cannot be collected in a consistent manner across institutions, they will not be acceptable as an accountability measure. On the other hand, a quality improvement measure only requires that the data be collected consistently within the institution. Similarly, coding may be inconsistent across a broad range of providers, so that the measurements will not refer to the same populations or entities. For quality improvement purposes within a single institution or network, this may be acceptable.
 - d) Measures used for accountability (public reporting) must be transparent and understandable to all segments of the healthcare system, especially consumers.
-

*The Federal Partners provided the following additional comments for the Technical Panels to consider: “Care should be taken to balance statistical stability of large sample sizes with the concerns of small providers who wish to present their performance of process measures of care in public forums on an equal footing with larger providers. Responsible public reporting should include information on confidence intervals, data limitations, and should consider options, such as aggregating across time to increase sample sizes where possible.”

Steering Committee Action:

- i. *The Steering Committee agreed that for the cancer project there should be measures that are recommended for quality improvement only and those that should be recommended for accountability and quality improvement. The uses should be specifically recommended by the Technical Panels.*
- ii. *If possible, Technical Panels should address the issue of the type of accountability that might be addressed by the accountability measures, e.g., public reporting, reimbursement.*
- iii. *Given the small numbers of cases available for measures that are disease specific, once factors such as stage are taken into consideration, cross-cutting measures may be more important for accountability. Additionally, these measures may include roll-up measures such as surgical margins. One issue will be how the Steering Committee will handle measures submitted separately from different Technical Panels addressing similar quality aspects, i.e., surgical margins. Is there a mechanism for melding them?*
- iv. *The difficulties of obtaining adequate sample size may mean that cancer measures may be applied only at the level of the hospital and above. It might not be possible to scale down to the physician office level.*
- v. *Another mechanism to increase sample size for meaningful comparisons is to extend the period of observation, e.g., from one to two or three years.*

Clinical Logic Maps

Clinical and contextual logic maps are schematic representations of the entire clinical spectrum of outcomes for a specific disease or the sequential provision of care (providers and facilities) an individual with a disease experiences, including environmental factors. The nodes on these maps can be coupled with values for prevalence or costs to highlight the key leverage points in the delivery of health-care. The CDMP's recommendations regarding using clinical logic maps are summarized in Table 5.

References

- 1 National Quality Forum (NQF), *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*, Washington, DC: NQF; 2003.
- 2 NQF, *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*, Washington, DC: NQF; 2003.
- 3 McGlynn E, Selecting common measures of quality and system performance, *Med Care*, 2003; 41(1 Suppl):39-47.

Table 5 – CDMP Recommendations Regarding Clinical Logic Maps

1. If available, clinical and contextual maps would be useful as a framework for identifying where measures are available and where gaps exist.
2. The assignment of incidence, economic, and outcome data to the nodes of a map would facilitate an analysis of the importance of specific interventions and point to areas that should be excluded from the purview of the measure set.
3. There are no readily available clinical or contextual maps for oncology; thus, NQF staff should explore the feasibility of creating them.

NATIONAL QUALITY FORUM

Appendix F

Consensus Development Process: Summary

The National Quality Forum (NQF), a voluntary consensus standards-setting organization, brings together diverse healthcare stakeholders to endorse performance measures and other standards to improve healthcare quality. Because of its broad stakeholder representation and formal Consensus Development Process (CDP), NQF-endorsed™ products have special legal standing as voluntary consensus standards. The primary participants in the NQF CDP are NQF member organizations, which include:

- consumer and patient groups;
- healthcare purchasers;
- healthcare providers, professionals, and health plans; and
- research and quality improvement organizations.

Any organization interested in healthcare quality measurement and improvement may apply to be a member of NQF. Membership information is available on the NQF website, www.qualityforum.org.

Members of the public with particular expertise in a given topic also may be invited to participate in the early identification of draft consensus standards, either as technical advisors or as Steering Committee members. In addition, the NQF process explicitly recognizes a role for the general public to comment on proposed consensus standards and to appeal healthcare quality consensus standards endorsed by NQF. Information on NQF projects, including information on NQF meetings open to the public, is posted at www.qualityforum.org.

Each project NQF undertakes is guided by a Steering Committee (or Review Committee) composed of individuals from each of the four critical stakeholder perspectives. With the assistance of NQF staff and

technical advisory panels and with the ongoing input of NQF Members, a Steering Committee conducts an overall assessment of the state of the field in the particular topic area and recommends a set of draft measures, indicators, or practices for review, along with the rationale for proposing them. The proposed consensus standards are distributed for review and comment by NQF Members and non-members.

Following the comment period, a revised product is distributed to NQF Members for voting. The vote need not be unanimous, either within or across all Member Councils, for consensus to be achieved. If a majority of Members within each Council do not vote approval, staff attempts to reconcile differences among Members to maximize agreement, and a second round of voting is conducted. Proposed consensus standards that have undergone this process and that have been

approved by all four Member Councils on the first ballot or by at least two Member Councils after the second round of voting are forwarded to the Board of Directors for consideration. All products must be endorsed by a vote of the NQF Board of Directors.

Affected parties may appeal voluntary consensus standards endorsed by the NQF Board of Directors. Once a set of voluntary consensus standards has been approved, the federal government may utilize it for standardization purposes in accordance with the provisions of the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) and the Office of Management and Budget Circular A-119. Consensus standards are updated as warranted.

For this report, the NQF CDP, version 1.7, was in effect. The complete process can be found at www.qualityforum.org.

THE NATIONAL QUALITY FORUM (NQF) is a private, nonprofit, open membership, public benefit corporation whose mission is to improve the American healthcare system so that it can be counted on to provide safe, timely, compassionate, and accountable care using the best current knowledge. Established in 1999, NQF is a unique public-private partnership having broad participation from all parts of the healthcare industry. As a voluntary consensus standard-setting organization, NQF seeks to develop a common vision for healthcare quality improvement, create a foundation for standardized healthcare performance data collection and reporting, and identify a national strategy for healthcare quality improvement. NQF provides an equitable mechanism for addressing the disparate priorities of healthcare's many stakeholders.

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