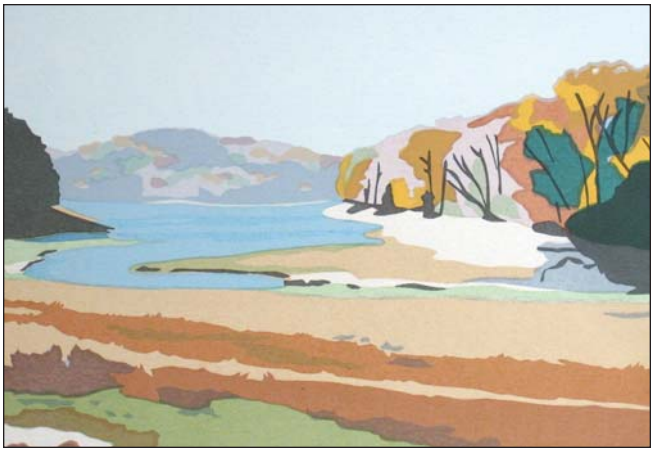

Anne Silber. *In Westchester County*. Serigraph, © 1997.
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A Web-based tool can provide timely quality-of-care practice self-evaluation.

Evolution and Elements of the Quality Oncology Practice Initiative Measure Set

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Background: *Over the past 5 years, the American Society of Clinical Oncology (ASCO) has supported the development of a Web-based quality-reporting tool in response to a recognized need to provide medical oncologists the opportunity to demonstrate the quality of care that they are providing to patients.*
Methods: *The development of quality measures, their basis in the literature, and the descriptions and organizational structure of the measures are discussed.*
Results: *Specific results are the property of practices and are not shared outside of the practices except in aggregate. The system allows collection of information concerning a wide range of quality measures in a short period of time. In the last data collection period in the fall of 2008, information was submitted concerning 81 measures of quality divided into one required and six optional modules from over 250 practices concerning 15,000 patients.*
Conclusions: *The timely collection of information on a wide range of quality measures regarding cancer patients can be efficiently collected using a Web-based data collection tool allowing for practice self-examination and comparison with other practices.*

Background

The American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative (QOPI) is a practice-based quality assessment program that allows medical oncology practices to systematically collect performance data using a set of periodically updated measures, to trend their data over time, and to compare their performance to that of other practices. Supported by ASCO and the participating practices, QOPI has grown over the past 6 years from a simple proposal by Joseph V. Simone, MD, to a program involving over 400 practices in 48 states, two US territories, and eight foreign countries. In this paper, we describe the development of the current measure set.

Early in 2003, Simone invited seven physicians to serve as practice contacts for an initial pilot group, termed "the alpha practices." (The initial seven practices were represented by Christopher E. Desch [Virginia], Peter D. Eisenberg [California], Dean Gesme [Iowa], Joseph O. Jacobson [Massachusetts], Mohammad Jahanzeb [Tennessee], Michael N. Neuss [Ohio], and John Rainey [Louisiana].) In communications describing his vision, Simone laid out his expectations for practice mea-

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sures (Table 1). Importantly, he established several key concepts. First, the measurements would be based on the patient record that was controlled by the medical oncology practice as opposed to combining records across sources such as hospitals, practices, and patient interviews as had been done with considerably greater complexity by the National Initiative for Cancer Care Quality.[1] Second, several features of good care were drawn from the Institute of Medicine's landmark report, *Ensuring Quality Cancer Care*,[2] such as having an accurate picture of the patient's circumstances at the onset of cancer treatment by including an adequate pathologic report and documentation of the patient's cancer stage in the chart. Third, key features of a chemotherapy treatment plan, such as explicit documentation of the treatment regimen and the intent of treatment, were listed. These were later independently included in the definition of an adequate treatment plan.[3] Fourth, and perhaps most important, the recognition that good patient care is patient-centered care was reflected in statements regarding the importance of timely treatment, attention to the presence or absence of pain at any patient encounter, explicit documentation of both inclusion of the patient and her or his family in treatment planning, and recording and explaining to the patient any deviation from initial treatment plans. Finally, systems issues relating to the promotion of clinical research and participation in tumor registries were recognized.

Table 1. — Definition of "Best Practices in Cancer Care"*

All of the following actions must be documented in the patient's record so as to be easily retrieved:

1. All new patients are reported to the cancer registry within 10 days of the cancer diagnosis.
2. Recommendations about initial cancer management are made by experienced professionals.
3. The cancer stage is established and recorded on every patient before definitive treatment is started.
4. For solid tumor patients, the pathology report describes in detail the margin of normal tissue in the tumor specimen, and for leukemia and lymphoma patients, the molecular pathology of the tissue.
5. Before therapy begins, the specific regimen and its goal are described in the chart and to the patient, with a written copy given to the patient and/or family.
6. The patient is offered participation in a therapeutic clinical trial for primary treatment.
7. The diagnostic workup is expeditious so that therapy is started within 30 days of the initial suspicion of cancer.
8. The surgical and diagnostic procedures and the doses and dates of radiation and chemotherapy are documented in detail; deviations from the initial plan are explained to the patient and documented in the record.
9. The patient is asked about the presence and severity of pain at every visit and medicated when needed.
10. The date and nature of tumor recurrence or progression is specifically documented.

* Expectations for practice measures as developed by Joseph V. Simone, MD (personal communication, January 2, 2003).

In the 6 years following Simone's initial observations, the leaders of QOPI have considered the numerous challenges inherent in the emerging field of quality assessment in the practice setting. First and foremost, the events recorded in a patient's chart have surprisingly poor accuracy when compared to what actually occurred. This was noted first by Donabedian[4] and recently emphasized by a study that compared records documentation to reports by standardized patients, which confirmed the poor sensitivity and specificity of the written (electronic or paper) medical chart.[5] Second, all quality measures do not carry equal weight. As also identified by Donabedian,[4] outcome measures trump process measures. Meaningful outcome measures, however, are also subject to a hierarchy. Death is more important than a day off from work or loss of a bodily function. Even death rate without the timing of death may be misleading as immediate death is not the same as death after several years.[6] In oncology, as in many areas of medicine, the interval from treatment to a measurable outcome may be lengthy, the numbers of adverse outcomes small, and statistically valid deviations from average performance difficult to demonstrate for individual practices.[7] However, when the primary intended use of performance data is for practice improvement, process measures can provide clear targets for process improvement.

Current QOPI Process

Over time, QOPI measures have evolved in complexity and scope and have been increasingly used by practitioners. The QOPI process is relatively straightforward. After registration and declaration of a HIPAA-compliant subcontractor relationship through execution of a business associate contract, practice representatives are given access to the QOPI Internet data collection Web site and full chart abstraction instructions and definitions of all data elements. They are then asked to perform chart abstractions twice annually and to submit data that have been stripped of all patient identification to the QOPI observation database. The number of charts averages just under 100 per practice, with that number determined by statistical considerations resulting from the number of practitioners in a particular practice. Practices choose at least two data modules that are based on patient diagnoses or some other specific aspect of management (for example, symptom control or care at the end of life) in addition to a core set of observations. Simple data integrity testing is enforced during data entry, and centralized analysis is performed. Practices have generally been able to see their results (and the national norms) within 1 month of data submission. Periodic representative audits of data have helped hone questions and demonstrate measure reliability.

In the spring of 2003, the data abstraction paper form was a relatively simple, 4-page, 8-question tool that allowed for analysis of data on 12 measures requiring collection of approximately 30 data elements in addition to five pieces of de-identified patient classification

data. The current QOPI abstraction form includes 150 data elements that, when collected, allow for analysis of performance on 81 measures. The oncology community has supported this expansion with increasing numbers of practices voluntarily submitting data.

The QOPI measure development process has remained fairly consistent, starting with nomination of a guideline or other indicator or concept. This is followed by modification and consensus building by a committee of volunteers with clinical, quality, and measurement expertise using a modified Delphi process.[8] After detailed specification development, voluntary pilot testing is undertaken before the measure is included in the appropriate module. The entire process from suggestion to inclusion takes on average less than 9 months, with timing determined by the necessity of spanning two data collection periods that are approximately 6 months apart to allow pilot testing. The measures serve as a metric of practice quality and, in cases when measure concordance is low across practices, may identify as suboptimal a particular practice guideline used to construct the measure or the way in which the measure itself was constructed.

Modules

Current questions are grouped into required core elements and optional modules that are organized around either specific diseases (eg, breast or lung cancer) or another common characteristic, including care at the end of life, symptom management, and clinical trial assessment. Each participating practice must complete, at a minimum, the core questions and two additional modules. Table 2 presents the growth in participation of practices and data collection over the past 3 years. Table 3 lists the module areas and a sampling of measures from the core, symptom management, and end-of-life modules. Table 4 displays the frequency of module choices by practices over the past 3 years. Most practices complete more than required; in the fall 2008 data collection period, the 193 participating US-based practices reported information on more than 18,000 patients, with representation in all of the seven available modules.

Core elements are applicable to nearly all patients included in the QOPI sample, and initial measures were designed to be as broad as possible. However, specification of treatment measures requires identifying the appropriate patient denominator. Within the disease-specific modules, treatment-related measures are derived from guideline recommendations, usually from ASCO[9] or the National Comprehensive Cancer Network (NCCN)[10] practice guidelines. The requirement for exact specification of measure denominator often results in a measure being relevant to only a small number of patients. The QOPI modules are described below.

Comparison of the core module measures to Simone's initial "Best Practices" definition shows remarkable agreement, including requirements for the pathology report to be available, the cancer stage recorded, pain evaluated at every visit, flow sheets in use, and treatment recommendations made with explicit patient discussion (through the process of informed consent). However, with the exception of those related to attention to the presence or absence of pain at every visit, there is the least amount of evidence-based support for these core measures.[11] While it is unlikely

Table 2. — Growth of QOPI Practice Participation, Charts Abstracted, and Measures Over Time

Data Collection Round		Participants (Practices)*	Charts Abstracted	Measures Offered
2002–2005 (Pilot phase)		23	6,000	37
2006	Spring	87	9,357	57
	Fall	113	14,292	52
2007	Spring	142	13,450	53
	Fall	150	13,387	57
2008	Spring	188	17,364	75
	Fall	193	18,384	81

* Submitted at least one chart and excludes international participants.

Table 3. — QOPI Measure Module Groupings and Sample Measures

Module	No. of Measures Included	Sample Measures
Core	16	Pathology report available Staging completed Consent for chemotherapy documented Pain recognized and addressed Treatment plans and summaries available Emotional well-being assessed and addressed
Symptom and Toxicity Management	8	Use of antiemetics by guideline Use of hematopoietic growth factors by guideline Fertility preservation evaluation and counseling
Care at the End of Life	13	Pain recognized and addressed Dyspnea recognized and addressed Hospice enrollment and timing Chemotherapy administration near death
Breast Cancer	13	Family history Adjuvant chemotherapy by guideline Adjuvant hormonal therapy by guideline
Colorectal Cancer	12	Adjuvant chemotherapy by guideline Node examination by guideline Carcinoembryonic antigen monitoring for recurrence Colonoscopy by guideline
Non-Hodgkin Lymphoma	2	Use of granulocytic growth factor by guideline Use of rituximab with CD20 evaluation
Non–Small Cell Lung Cancer	6	Adjuvant chemotherapy by guideline Adjuvant radiation therapy by guideline

that clinical trials relevant to many of these measures (eg, use of flow sheets or pathology reports) will ever be done to demonstrate differences in patient outcomes, these measures are considered important and clinically relevant. QOPI has remained committed to the use of consensus measures when appropriate.

Two newer areas added to the core include those addressing smoking cessation and psychosocial support. The development of the smoking cessation measure generated spirited discussion, with some strongly advocating that physicians are justifiably reluctant to insist or even suggest that patients with terminal disease give up smoking. However, the US Public Health Service has clear recommendations that are endorsed or supported by other organizations, including the American Academy of Family Practice and the American Medical Association Physician Consortium for Performance Improvement, stating that all patients should be offered and encouraged to participate in smoking cessation activities.[12-14] The importance of attention to the whole patient and his or her psychosocial needs was highlighted by the Institute of Medicine (IOM) Report, *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*,[15] released in October 2007. It is illustrative of the rapidity of the QOPI measure development process that the relevant measures were pilot-tested in the spring of 2008 and incorporated as core measures later that year.

The symptom/toxicity management module is based almost entirely on evidence-based ASCO practice guidelines.[16-18] Demonstrating an advantage of ASCO's organizational leadership, the authors of ASCO practice guidelines are asked to suggest indicator statements for relevant guideline derived measures, allowing for a rapid and valid guideline-to-measure development cycle. Measures focused on antiemetic management relative to chemotherapy agents are included in the symptom/toxicity module. Surprisingly, though concordance with ASCO's guideline has always been high for serotonin antagonists and corticosteroids, concordance remains low for use of aprepitant (Emend). It will be interesting to see whether these data change with the availability of an intravenous preparation of aprepitant, which may be equally effective to three oral doses.[19] The final element in the symptom management module addresses the issue of documentation of discussions concerning fertility preservation in patients prior to their receipt of chemotherapy. Though overall concordance with this measure has also been low for all practices, it is anticipated that increased awareness of this guideline will increase concordance on this measure as has been seen previously even without formal practice improvement intervention.[20] This educational function may be seen as another benefit of QOPI participation.

Other supportive care measures are incorporated in QOPI and are discussed more fully elsewhere.[21]

Current diagnosis-related modules represent common cancers for which specialty clinics are often created, including lung, breast, colorectal, and lymphomatous malignancy. Of necessity, the disease-specific measures examine care for carefully selected subsets of patients within each diagnostic category. Stage assignment is critical but difficult, and though the joint ASCO/NCCN breast cancer treatment measures[22] seem straightforward, the stage information can be difficult for chart abstractors to ascertain with certainty. If a practitioner incorrectly assigns a patient to a particular stage grouping that calls for a treatment that is different from the patient's actual stage but records this erroneous stage, QOPI analysis may conclude incorrectly that appropriate treatment was given. Verification of all the information that goes into staging requires significant clinical training and is not considered feasible for QOPI abstraction; thus, the practitioner's staging as reflected in the chart is used to identify measure denominators. As QOPI and electronic data transfer evolve, the feasibility of collecting the granular elements that account for stage will be reassessed as this may provide a better approximation of disease stage. Nonetheless, these measures (and similar colon and rectal cancer measures) have generally high levels of concordance.

Table 4. — QOPI Module Selections Choices by Practices Over Time

Data Collection Round		Practices With Core Measures (%)	Practices With Symptom/Toxicity Management Measures (%)	Modules Assessed by Practices
2006	Spring	N/A	N/A	N/A
	Fall	N/A	N/A	N/A
2007	Spring	100	59.9	Clinical Trial Assessment Breast Cancer Colon/Rectal Cancer
	Fall	100	48.0	Breast Cancer Colon/Rectal Cancer Non–Small Cell Lung Cancer
2008	Spring	100	55.3	Breast Cancer Colon/Rectal Cancer Care at End of Life
	Fall	98.4	53.9	Breast Cancer Care at End of Life Colon/Rectal Cancer

Process-based measures document underuse more easily than overuse of procedures or treatments. For example, in a recent process-based evaluation of outpatient care,[23] only 75.7% of recommended care was performed for the nine breast cancer measures that were included. The rate of appropriate treatment was slightly higher: approximately 80%. However, this analysis included no measure of care overuse or misuse.[24] It is this type of measure that garners great attention in an era of fiscal awareness and cost containment focus. For example, the finding that "at least 12% and probably 20%" of patients receiving trastuzumab (Herceptin) either showed gene underexpression or were not tested" for the target HER-2/neu gene based on a small payer generated study[25] has been widely quoted and identifies an important area of quality concern. QOPI has included measures of overuse for several years, including one specifically addressing the use of trastuzumab in breast cancer patients (with an average practice rate of under 2% administration of adjuvant trastuzumab therapy to patients who were either not tested or treated when testing showed no evidence of gene overexpression). A measure of documentation of the presence of the CD20 antigen in patients receiving rituximab (Rituxan) has been available for several rounds of data collection, and one for the presence or absence of epidermal growth factor receptor (EGFR) and the wild-type KRAS protein will be piloted for patients receiving cetuximab (Erbitux) and panitumumab (Vectibix).

Individual treatment decisions are obviously based on patients' wishes and their informed consent for treatment or, in instances when treatment is stopped, the patient's acknowledgment that the potential benefits of treatment are insufficient to justify further antineoplastic chemotherapy.

We include a measure of potential overuse of chemotherapy as patients near death in the Care at the End of Life Module. Though the issue of prospective vs retrospective analysis of these data has been the subject of controversy,[26] recent information demonstrates that retrospective analysis provides similar information to that obtained prospectively.[27] Measures in this area are based not on a concept of what is right or wrong, but on the observation of variation from the norm and the hope that providing information to a practice about their performance relative to norms will help the physicians in those practices evaluate their performance. Currently, practices receive information on their rates of patient hospice enrollment at specified intervals before death and the rate of chemotherapy administration near the end of life.

Future Steps and Electronic Records

The electronic health record (EHR) has the potential to improve the process of quality measurement. This will have implications for QOPI's current rapid development cycle as EHR release cycles may delay incorporation of these measures, which, by the nature of EHRs, will need to be collected prospectively over a period of time as opposed to harvested retrospectively as is now done. Nonetheless, universal data entry and analysis as opposed to sampling will improve the reliability of data, and there is great hope that this will also improve the process of care directly. The feasibility of using QOPI data elements to generate prospective data collection templates that in turn can help to prompt, at a minimum, improved documentation of appropriate care has been recently demonstrated. In a comparison of documentation of pain assessment with unstructured medical records vs that accomplished with a form that specifically required caregivers to document pain assessment with a template form which prompted the collection of these data elements, the documentation of pain assessment increased from 78% to 87%, the documentation of discussion of intent of chemotherapy increased from 72% to 86.5%, and declaration of the number of chemotherapy cycles planned increased from 54% to 90%.[28]

The QOPI measure set includes a broad collection of process measures regarding care for adult patients with cancer, reflecting inclusion of measures from a variety of sources including evidence-based practice guidelines. Through integration with ASCO's Health Services Committee and its members who develop the ASCO practice guidelines, the time from development of a practice guideline to piloting of a related QOPI measure is often 3 months or less, and fully developed measures can be developed in less than 1 year. The QOPI measures continue to evolve and will serve as the basis for prospective data collection and transmission from electronic records.

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