These 25 practices composing the three pilot groups, along with Kristen McNiff, MPH, at ASCO, did all the spade work in preparing QOPI to be opened to any ASCO member in 2006. QOPI now has 500 participating practices that report data on approximately 35,000 medical records annually. Kudos to all participants for making QOPI a force in promoting quality cancer care.

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Quality Oncology Practice Initiative Certification Program: Overview, Measure Scoring Methodology, and Site Assessment Standards

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The concepts of quality assessment, monitoring, improvement, and accountability are becoming mainstream in US medicine. Pressure to demonstrate high-quality care and a commitment to continuous quality improvement are mounting for health care providers. For a time, quality efforts focused on areas outside of cancer care, most notably on primary care, cardiology, and diabetes care. This is likely a reflection of the complexity of cancer care, the limitations of claims data in providing meaningful quality analyses, and the emotional context of cancer rather than of the confidence that all cancer care is appropriate and safe.

Background

More than a decade ago, the Institute of Medicine increased the focus on oncology with the creation of the National Cancer Policy Board. Its final report, *Ensuring Quality Cancer Care*, identified a need to create systems to assess the quality of cancer care nationally.¹ This seminal publication generated a cascade of quality reports, initiatives, and projects in the years afterward, including the ASCO Quality Oncology Practice Initiative (QOPI).

Joseph Simone, MD, chair of the National Cancer Policy Board, put forth the initial concept for QOPI. In 2002, he recruited a small group of medical oncologists to develop and pilot a voluntary program to assess and improve processes of

care in oncology practices.² QOPI was made available to all ASCO-member medical oncologists and their practices in 2006.

QOPI provides a system for practices to measure processes of care semiannually, using retrospective medical record abstraction methodology. Practice personnel select patients who meet QOPI sampling requirements, starting with the most recent patients seen in practice and proceeding backward in time for up to 6 months to meet the sample size. The number of full-time equivalent medical oncologists or hematologist-oncologists at a practice site determines the QOPI abstraction sample size. The QOPI patient selection methodology and sample size have been previously described.³ A practice submits a limited data set to the QOPI database using a structured, secure online patient report form, and results are analyzed and reported back to the practice.

The analyzed QOPI quality reports are the primary benefit of QOPI participation. Reports are available within 4 weeks of the close of data collection, so practices can use data received for targeted improvement. For each quality measure, reports detail practice-specific data (and office-specific data, if collected at multiple sites) and comparative aggregate data.

The QOPI measures are organized into a required core set and disease- and domain-specific modules. The core measures are

applicable across the majority of medical records abstracted and are required. Disease-specific sets include breast cancer, colorectal cancer, non–small-cell lung cancer, and non-Hodgkin's lymphoma. The domain-specific sets include end-of-life care and symptom/toxicity management. A minimum requirement for practices participating in QOPI is to select and submit data for two modules.

By design, practices participating in QOPI are a self-selected group. Registration for the program remains open year round, resulting in new and returning practices participating in each data submission round. At the time of this writing, more than 640 individual reporting sites in almost 500 practices were registered for the QOPI program.

Volunteer leaders have been encouraged by the ongoing QOPI registration and participation. Voluntary use of practice staff time to participate is considered a testament to oncologists' eagerness to ensure oncologist leadership in defining and measuring quality and embrace improvement in their own practices. Recognizing the commitment on the part of practices involved in QOPI, ASCO has attempted to ensure that QOPI participation and data provide as many benefits as possible (eg, QOPI can be applied to American Board of Internal Medicine Maintenance of Certification and to Continuing Medical Education credits).

As the QOPI program has evolved, participants and ASCO members have asked for enhancements in two major areas:

- Provide additional quality improvement opportunities for those who have participated for several years and/or have more sophisticated improvement processes/goals.
- Position QOPI, a trusted and oncologist-led program, as a solution for payers seeking to implement quality programs in oncology.

To begin to address the second point, ASCO initiated the QOPI Health Plan Program, whereby ASCO notifies health plans selected by participating practices of the successful participation of those practices in a QOPI round. The QOPI Health Plan Program is not performance based; rather, it confirms successful participation in completing medical record abstraction, in a format that is useful for health plans. Plans have recognized QOPI participation in a variety of ways, ranging from practice payment to recognition in provider directories.

Although the QOPI Health Plan Program was a successful first step, it neither fully met existing member needs nor prepared for near-future needs. Participants asked to share performance details from QOPI reports with health plans. Oncologists and their practice staff asked for meaningful ways to include details of their QOPI participation in practice marketing materials.

These member requests led to a detailed review of QOPI, needs assessment, and business plan development. The concept of a certification for outpatient hematology-oncology practices—a

Figure 1. Process to initiate Quality Oncology Practice Initiative (QOPI) Certification.

unique concept to date—was developed. The ASCO Board of Directors approved the development of the QOPI Certification Program in 2008. Beginning with the fall 2009 QOPI abstraction round, all QOPI data reports will include information regarding the QOPI Certification measure scoring requirements. Application for the program will open in January 2010. This article describes the methodology, measures, scoring, and site assessment standards of the QOPI Certification Program. All components of the program were developed by the QOPI Steering Group using a consensus-based process.

QOPI Certification Program Methodology

The QOPI Certification Program provides 3-year certification for outpatient hematology-oncology practices. Certification is accomplished on the basis of practice achievement in two areas:

1. QOPI medical record abstraction measures selected for certification
2. QOPI Certification Site Assessment, conducted on the basis of structural standards

To enter the QOPI Certification Program, a practice must first complete a round of QOPI data abstraction, using the QOPI modules, sampling strategy, and sample size appropriate for certification. The QOPI report provided at the close of data abstraction indicates whether the overall scoring requirements for QOPI Certification were met. If so, the practice may apply for the QOPI Certification Program. The processes to initiate and achieve QOPI Certification are depicted in Figures 1 and 2. A detailed QOPI Certification Program Participation Manual is available to help practices fully understand the certification program expectations, processes, and timeline.

Measure Selection, Sampling, and Sample Size for QOPI Certification

Practices seeking QOPI Certification must complete the core measures and each QOPI module that includes a certification measure applicable to the patient population of the practice

Figure 2. Process of Quality Oncology Practice Initiative (QOPI) Certification. Steps in circles indicate practice actions; steps in squares, QOPI actions or decisions. Orange represents pre-application status; blue, QOPI Certification—pending status; green, QOPI Certification status.

(Table 1). The standard QOPI sampling methodology and sample size requirements^{2,3} apply to QOPI Certification and are documented in detail in the QOPI Users Manual. Sample size requirements per module vary from 24 to 40 medical records, depending on full-time equivalent oncologists in the practice/site.

A new sampling option has been added for multisite practices for 2009, involving the collection of one sample across the multiple office sites in the practice. To use this method, the practice generates or compiles a list of patient visits at all applicable office sites. To ensure that all practice sites and oncologists have a chance of being represented in the sample abstracted, practice personnel must comply with QOPI methodology to select patients, using that list. The new sampling option addresses the fact that multisite practices will likely seek QOPI Certification for the entire practice (rather than for an individual office site). Full participation in as many as five QOPI modules at every office site may not be feasible for large practices. The second option for multisite practices is the standard QOPI model, which involves a distinct medical record pull at each office site. Practices can select the methodology most feasible and appropriate for their quality improvement goals.

QOPI Site Assessment

The QOPI Certification Program includes a newly developed component: an assessment of the concordance of practices with structural quality standards. Using a structured online questionnaire, practices indicate their degree of compliance with the structural standards and provide requested supportive documentation. The QOPI Site Assessment is conducted on the basis of responses and documentation submitted by the practice, supported by audits. A practice must pass the QOPI Site Assessment to achieve QOPI Certification.

QOPI Certification Audit Activities

All sites applying for QOPI Certification undergo audit reviews. Audits occur as part of the QOPI Certification review process before full QOPI Certification is awarded. To verify medical record abstraction data, all certification applicants are instructed to send de-identified medical record documentation for five records selected by ASCO staff. To verify site assessment data, all certification applicants are instructed to send supportive practice documentation. Finally, all practices that apply for QOPI Certification are at risk for an onsite audit. The on-site audit may include a review of medical record sampling, medical record data submitted, and site assessment data submitted. Audits are intended to confirm results, help ensure the integrity of the program, and add to the improvement and learning opportunity of the QOPI Certification Program process. Practices receive notification of audit findings and, if necessary, are given the opportunity to address shortcomings.

Achieving and Maintaining QOPI Certification

As shown in Figure 2, an interim designation of QOPI Certification pending is awarded to practices that meet QOPI Certification measures scoring requirements, submit a complete certification application, submit a complete site assessment questionnaire and supportive documentation, and submit de-identified medical record documentation requested for audit. A practice can maintain QOPI Certification—pending status for 1 year. During that year, the practice must implement any improvements necessary to achieve QOPI Certification and resubmit information as directed, or certification-pending status is lost.

The complete certification term is 3 years from designation of QOPI Certification—pending status. Practices must participate in at least one round of QOPI medical record abstraction annually and meet certification scoring requirements to maintain QOPI Certification—pending or QOPI Certification status. Details of the QOPI Certification Program designations are outlined in Table 2.

QOPI Certification Measures Selection

Since the inception of QOPI, quality measures have been adopted, developed, and maintained under the leadership of volunteer oncologist committees. The processes used to develop and refine QOPI measures have been described elsewhere.²⁻⁵ At the time of certification program development, the QOPI Steering Group benefited from a library of more than 80 tested QOPI measures and several years of historical data. A full listing of QOPI measures can be found at <http://qopi.asco.org>.

The QOPI Steering Group implemented an iterative, consensus-building process to identify the measures appropriate for

Table 1. QOPI Certification Measures: Fall 2009

Module	Measure
Core	1. Pathology report confirming malignancy 2. Staging documented within 1 month of first office visit 3. Pain addressed appropriately (defect-free measure) 4. Documented plan for chemotherapy, including doses, route, and time intervals 5. Chemotherapy intent (curative versus palliative) documented 6. Cigarette-smoking status documented by second office visit 7. Patient emotional well-being assessed within 1 month of first office visit
Symptom/toxicity management	8. Corticosteroids and serotonin antagonist prescribed with moderate or high emetic-risk chemotherapy 9. Infertility risks discussed before chemotherapy with patients of reproductive age
End of life care	10. Pain assessed appropriately (defect-free measure) 11. Hospice enrollment > 7 days before death (defect-free measure)
Breast cancer	12. Combination chemotherapy received within 4 months of diagnosis by women < age 70 years with AJCC stage I (T1c) to III ER/PR-negative breast cancer* 13. Test for HER2/<i>neu</i> gene overexpression 14. Trastuzumab received when HER2/<i>neu</i> is negative or undocumented† 15. Trastuzumab received by patients with AJCC stage I (T1c) to III HER2/<i>neu</i>-positive breast cancer* 16. Tamoxifen or AI received within 1 year of diagnosis by patients with AJCC stage I (T1c) to III ER- or PR-positive breast cancer*
Colorectal cancer	17. CEA within 4 months of curative resection for colorectal cancer 18. Adjuvant chemotherapy received within 4 months of diagnosis by patients with AJCC stage III colon cancer* 19. Adjuvant chemotherapy received within 9 months of diagnosis by patients with AJCC stage II or III rectal cancer* 20. Colonoscopy before or within 6 months of curative colorectal resection 21. KRAS testing for patients with metastatic colorectal cancer who received anti-EGFR MoAb therapy 22. Anti-EGFR MoAb therapy received by patients with KRAS mutation†
NHL	23. Granulocytic growth factor administered with CHOP to patients > age 65 years with NHL 24. Rituximab administered when CD-20 antigen expression is negative or undocumented†

Abbreviations: QOPI, Quality Oncology Practice Initiative; AJCC, American Joint Committee on Cancer; ER, estrogen receptor; PR, progesterone receptor; HER2, human epidermal growth factor receptor 2; AI, aromatase inhibitor; CEA, carcinoembryonic antigen; EGFR, epidermal growth factor receptor; MoAb, monoclonal antibody; NHL, non-Hodgkin's lymphoma; CHOP, cyclophosphamide, doxorubicin, vincristine, prednisone.

* Adjuvant treatment measures.

† For these measures, lower score is better. The inverse of these measures is used to determine certification scoring.

use in the QOPI Certification Program. The major criteria for review included: measures that are evidence based or for which there is strong professional consensus; feasibility demonstrated through QOPI use; an adequate sample size demonstrated through QOPI use; and measure validity/reliability supported by QOPI use, QOPI audits, and/or testing in other settings.

In addition, the QOPI Steering Group sought to develop a diverse measure set. Many of the QOPI measures are reported in a series, with each measure reporting meaningful differences but assessing the same construct. Some QOPI measures are incorporated into combined measures or defect-free measures in analysis. For purposes of selecting measures for the certification program, QOPI Steering Group members chose measures that do not overlap analytically.

Of the 81 reviewed QOPI measures, 24 were ultimately selected for QOPI Certification. Table 1 lists the QOPI Certification Program measures, organized by QOPI module. The specifications for the certification measures were reviewed in light of the use of the measures in the certification setting to ensure that all valid exclusions were captured. The measures selected for the QOPI Certification Program are reviewed and reassessed after each QOPI data collection/reporting round.

QOPI Certification Program Measures Scoring

In developing the scoring requirements for the QOPI Certification Program, QOPI Steering Group members sought an approach that is transparent, fair, rigorous, understandable, and

Table 2. QOPI Certification Program: Levels of Certification and Terms

Status	Definition	Term
QOPI Certification pending	Met or exceeded QOPI Certification measure scoring requirements in one or more QOPI rounds —In reporting certification-pending status, ASCO includes modules completed by the recognized practice —Designation applies to practice that has not yet completed QOPI Site Assessment review/audit process and not yet achieved certification	Until QOPI Certification is awarded; status expires in 12 months if certification is not achieved
QOPI Certification	Met or exceeded QOPI Certification measure scoring requirements in one or more QOPI rounds Met QOPI Site Assessment structural standards Participated in QOPI abstraction at least once per year during 3-year certification term; met scoring requirements —In reporting certification status, ASCO includes modules completed by the certified practice	Until renewal, as long as certification maintenance requirements are met

Abbreviation: QOPI, Quality Oncology Practice Initiative.

flexible enough to allow diverse medical oncology and hematology-oncology practices to be eligible. The QOPI Steering Group determined that scoring requirements for future QOPI rounds should be determined on the basis of analyses of existing QOPI data. Use of a predetermined performance score provides transparency for participating practices and discourages the perception that practices are competing against one another for certification.

The QOPI Steering Group considered but rejected the notion of setting specific performance goals for each certification measure. In any given QOPI round, the number of medical records abstracted by a practice contributing to a specific measure varies, and on occasions, the number can be low. Individual performance thresholds also increase complexity. Instead, a decision was made to develop a model to combine performance across measures in the practice into an overall practice quality score, similar to test scoring for board certification.

An overall practice quality score approach requires adjustment to increase the contribution of specific measures, especially when those measures do not apply to the majority of medical records abstracted. The QOPI Steering Group modeled several scenarios to increase the contribution of QOPI measures related to adjuvant therapy. Weighting was tested but not implemented because of the relatively arbitrary decisions required to assign weights and the complication of the approach. Ultimately, the steering group chose to set a minimum performance requirement for the adjuvant treatment measures. The adjuvant measures appear with an asterisk in Table 1. Thus, the two components of the QOPI Certification Program Scoring Methodology are:

1. Overall quality score: An overall quality score for each practice calculated by aggregating the practice data for each of the 24 quality measures. If a practice does not have any

eligible patients for a specific measure, that measure does not count toward or against the overall quality score of the practice.

Numerator = number of patients in the practice who pass each indicator, contingent on being eligible for the indicator:

$$P_{\text{overall}} = p_{\text{measure 1}} + p_{\text{measure 2}} + \dots + p_{\text{measure 24}}$$

Denominator = number of patients in the practice eligible for each indicator: $N_{\text{overall}} = n_{\text{measure 1}} + n_{\text{measure 2}} + \dots + n_{\text{measure 24}}$

$$\text{Overall quality score} = P_{\text{overall}} / N_{\text{overall}}$$

2. Adjuvant treatment quality score: A minimum performance of 80% is required on the adjuvant treatment certification measures. All adjuvant treatment measures submitted by the practice are analyzed as an overall adjuvant score, using the same equation described for the overall quality score. Practices that have eligible patients for adjuvant measures are required to submit data for those measures. If a practice does not have any eligible patients for any adjuvant measure, this component of scoring is not implemented.

Overall Quality Score Performance Requirement

When determining the scoring threshold for the overall quality score, the QOPI Steering Group members considered that current QOPI participants are a self-selected group of practices committed to quality improvement. Many have participated in QOPI for several years. The performance of these practices on the QOPI Certification measures is likely higher than that of their peers nationally.

Several rounds of QOPI data were analyzed using the overall quality score to determine the scoring cutoff that would identify the top 85th percentile performers on the certification measures. For the fall 2009 QOPI round, the overall quality score performance requirement is 72.62%.

QOPI Certification Site Assessment

The QOPI Certification Site Assessment is the second component of the QOPI Certification Program, intended to review the concordance of a practice with structural quality standards.

In 2008, ASCO and the Oncology Nursing Society (ONS) partnered to develop the standards for safe chemotherapy administration.⁶ The development of these standards has been described in detail in *Journal of Clinical Oncology*. Briefly, a workshop of multiple stakeholders was convened to draft initial standards appropriate for all adult outpatient cancer chemotherapy. A consensus-building process followed, including public comment. The result was the development of 31 standards.

ASCO leaders envisioned that the ASCO/ONS safety standards would be appropriate to become the majority of the QOPI Certification site standards. When reviewing the full set of standards, those that met the following criteria were prioritized for inclusion in the QOPI Certification Program at launch: standards appropriate to implement in oncology practice with short turnaround time (because of the limited time between publication of the ASCO/ONS safety standards and assessment through the QOPI Certification Program); standards that apply broadly to practices that would seek QOPI Certification; standards most crucial for patient safety; and standards that do not duplicate QOPI medical record measures.

The 17 standards selected for QOPI Certification include standards related to staff training, chemotherapy planning documentation, patient education and consent, chemotherapy orders, drug preparation, chemotherapy administration, and monitoring and assessment. A complete list of the standards can be found at www.jop.ascopubs.org and <http://qopi.asco.org/certification>. The remainder of the ASCO/ONS standards will be reevaluated for inclusion at later dates, as will other structural measures. Practices are required to comply with all of the QOPI Site Assessment structural standards to achieve QOPI Certification.

Discussion

The QOPI Certification Program has the potential to engage oncology practices in enhanced performance assessment and improvement. Participation should stimulate practice discussion and encourage review of practice processes, systems, and documentation. Importantly, the QOPI Certification Program will provide demonstrable evidence of high-quality practice performance in a way not supported by QOPI to date. Certification is not mandatory, and the QOPI program will continue as a free member benefit. Oncologists and their practices can choose the approach that best meets their quality improvement needs, marketing goals, and environment.

Like any highly visible new program, it is likely that the QOPI Certification Program will have supporters and detractors among the ASCO membership and broader cancer community. Some may be opposed to the notion of external judgment

of practice quality or disagree with the measures, standards, or scoring. Those who feel that the train has left the station on external assessment might see the QOPI Certification Program as service for ASCO members. There may be disagreement regarding who should define quality in cancer care and determine oncology standards. Finally, some may object to the charge associated with the QOPI Certification Program, intended to help cover some program costs.

Health plans engaged in the QOPI Health Plan Program have provided commentary and feedback on the QOPI Certification Program. Many have noted that performance-based programs will be developed by health plans or others outside the profession, if the profession does not do so. For the QOPI Certification Program to gain traction with health plans, it is crucial that the program include rigorous and transparent standards. Certainly, the existence of the QOPI Certification Program will allow ASCO to advocate for members in a concrete way, discouraging development and implementation of other quality programs, which may require significant practice staff time to generate results that are not considered trustworthy or meaningful for quality. The QOPI Steering Group and ASCO leadership are committed to an ongoing evolution of the QOPI Certification Program and will invite member feedback. An important goal of the program is to help all practices improve cancer care quality and safety. Thus, performance targets are expected to change over time.

The overall quality score calculation and scoring requirement will be revisited after each round of data collection and adjusted as needed on the basis of results. The modeling of historical data used to generate the QOPI Certification scoring requirements has many benefits, but it also has limitations. It is known that practices will select modules and sample differently if they are seeking to apply for the certification program. Some of the variation in measure-level numerators and denominators may decrease. It is possible that concordance will increase as oncologists and abstractors hone in on the importance of these measures and are especially careful about locating relevant data in medical records. On the other hand, changes to specifications for some of the certification measures to be implemented in the fall 2009 QOPI round may push concordance down slightly. Careful review and additional analysis after the fall 2009 round will be important and may determine changes to be implemented in 2010 rounds.

QOPI has evolved rapidly over its 7-year history. It was initially conceived as a tool to allow practices to assess the quality of care provided to their patients by measuring concordance with a limited set of process measures. As the number of participating practices has increased, and experience with measures has grown, QOPI has become a useful benchmark for practices, allowing comparisons with peers and possibly improving performance.⁴ More recently, collaborative networks have been created to enable sharing of best practices, using QOPI to track performance.⁷ The QOPI Certification Program is the next step in a continuum of changes to QOPI that is intended to

additionally improve patient care and respond to a rapidly changing workplace.

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National Collaborative to Improve Oncology Practice: The National Cancer Institute Community Cancer Centers Program Quality Oncology Practice Initiative Experience

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Introduction

The science of cancer care has fundamentally been a data-driven process. Although the clinical significance of research findings and the applicability of results can be debated, there has historically been a system developed for measuring and reporting these types of outcomes to standardize the discourse. There are mutually acknowledged requirements that need to be exceeded to allow for acceptance of a given hypothesis, and a common language has evolved that allows for collaboration between researchers, clinicians, institutions, and policymakers.

Despite this well-respected and carefully crafted tradition in cancer research, the science of measuring the quality of cancer care practice has developed only recently. In response to what was perceived to be a deficiency in the monitoring and reporting of quality measures, the Institute of Medicine released a report in 1999 entitled *Ensuring Quality Cancer Care*.¹ What preceded and shortly followed this report was the development of a series of clinical practice guidelines from multiple organizations both nationally and internationally.²⁻⁵ However, these

guidelines were voluntary, and there was no effective way of tracking compliance in physician offices, where the majority of cancer care was provided. Data from disciplines other than oncology suggested that adherence to guidelines improved quality of care in other clinical areas. These studies were associated with some methodologic challenges,^{6,7} not the least of which were:

- The shifting nature of standards of care
- The validity of the guidelines themselves
- The adequacy of the dissemination of guidelines to providers of care
- The ability to have measurements systems reflect these guidelines
- The acceptance by practitioners of both the guidelines and monitoring process

The efforts to enhance quality cancer care that followed have largely been elaborated by others in this issue of *Journal of Oncology Practice*. ASCO created the National Initiative on Cancer Care Quality in 2000, with the goal of developing mea-