Quality Oncology Practice Initiative Certification Program: Measuring Implementation of Chemotherapy Administration Safety Standards in the Outpatient Oncology Setting

By Terry R. Gilmore, RN, Lisa Schulmeister, MN, APRN-BC, OCN, FAAN, and Joseph O. Jacobson, MD, MSc

American Society of Clinical Oncology, Alexandria, VA; Oncology Nursing Consultant, New Orleans, LA; and Dana-Farber Cancer Institute, Boston, MA

Abstract

The Quality Oncology Practice Initiative (QOPI) Certification Program (QCP) evaluates individual outpatient oncology practice performance in areas that affect patient care and safety and builds on the American Society of Clinical Oncology (ASCO) QOPI by assessing the compliance of a practice with certification standards based on the ASCO/Oncology Nursing Society standards for safe chemotherapy administration. To become certified, a practice must attain a benchmark quality score on certification measures in QOPI and attest that it complies with 17 QCP standards. Structured on-site reviews, initially performed in randomly selected prac-

tices, became mandatory beginning in September 2011. Of 111 practices that have undergone on-site review, only two were fully concordant with all of the standards (median, 11; range, seven to 17). Most practices were subsequently able to modify practice to become QOPI certified. The QCP addresses the call from the Institute of Medicine to close the quality gap by aligning evidence-based guidelines and consensus-driven standards with requirements for oncology practices to develop and maintain structural safety components, such as policies and procedures that ensure practice performance. On-site practice evaluation is a high-impact component of the program.

Introduction

The Quality Oncology Practice Initiative (QOPI) Certification Program (QCP), an affiliate of the American Society of Clinical Oncology (ASCO), was launched in 2010 to recognize medical oncology and hematology/oncology practices that are committed to delivering quality cancer care. The QCP evaluates the performance of an individual practice in areas that affect patient care and safety and builds on the ASCO QOPI. The QCP is a voluntary program that enables medical oncology and hematology/oncology practices to evaluate and improve the quality of the care they provide to their patients.

To achieve QOPI certification, a practice must participate in QOPI and meet or exceed a benchmark score from a library of more than 150 measures that represent a cross-section of QOPI measures, including core and disease- and domain-specific modules. QOPI uses evidence-based quality measures from clinical guidelines, adapted published measures, or measures based on expert consensus. After achieving a passing score on certification measures, a practice submits an application. A practice then undergoes an on-site peer review by a select team of oncology professionals that assesses practice compliance with certification standards based on the ASCO/Oncology Nursing Society standards for safe chemotherapy administration.^{1,2} The certification term lasts 3 years, and the process is repeated for recertification. QCP standards are posted at <http://qopi.asco.org/programdetails>. The 17 standards selected for QOPI certification include those related to staff training, chemotherapy-planning documentation, patient education and consent, chemotherapy orders, drug preparation, chemotherapy administration, and monitoring and assessment. On the basis of the

assessment, QOPI certification is awarded when a practice meets QCP standards.

QOPI Certification Eligibility

Practices were eligible to apply for QOPI certification after the fall 2009 QOPI collection (round one) and have two opportunities each year in which to apply (fall or spring). To date (November 15, 2012), there have been six semiannual certification application rounds, with a total of 206 applicants: 29 applicants in round one, 40 in round two (spring 2010), 40 in round three (fall 2010), 32 in round four (spring 2011), 40 in round five (fall 2011), and 25 in round six (spring 2012).

When a practice applies for certification, practice staff are first asked to attest to compliance with all of the 17 certification standards (Table 1 lists QCP certification site assessment standards). If a practice indicates that it does not currently comply with one or more of the 17 standards, the practice must be able to state that it will be in compliance by the end of certification pending status and submit evidence that the practice is in compliance before certification is awarded.

QOPI Medical Record Abstraction Verification

Practices that wish to apply for certification are required to participate in QOPI data abstraction for five predetermined modules, which include measures designated for QCP, and follow a specified medical record selection strategy. An overall quality score for each practice is calculated by aggregating practice data for the certification designated quality measures and an adjuvant treatment score, based on a subset of treatment mea-

Table 1. QCP Certification Site Assessment Standards*

Standard	Description
1	Qualifications
2	Medical record documentation
3	Consent policy
4	Chemotherapy order standards
5	Double checking of order
6	Drug labeling
7	Intrathecal chemotherapy policy
8	Time-of-administration double check (five Rs†)
9	Extravasation
10	Emergency procedures
11	Medical record documentation at each clinical visit
12	Day-of-treatment assessment
13	Ancillary services—referrals
14	Missed office visit follow-up
15	24/7 triage and toxicity communication
16	Toxicity assessment available before writing chemotherapy orders
17	Cumulative dosing

NOTE. Five Rs are as follows: 1. right patient, 2. right drug, 3. right dose, 4. right time, 5. right route.

Abbreviations: QCP, Quality Oncology Practice Initiative Certification Program.

* Abbreviated.

tures. The 24 QOPI quality measures that were selected for QCP are posted at <http://qopi.asco.org/programdetails>. QCP requires practices to meet scoring thresholds on the overall quality and adjuvant treatment measure scores. QCP staff request deidentified excerpts from medical records for three randomly selected patients from each practice applying for certification. QCP verifies that medical records selected for abstraction meet the selection criteria and confirms that information was abstracted according to specifications. QCP staff reviewers compare the information in the patient records to what the abstractor in the practice recorded and determine if there is concordance (eg, confirm that date of diagnosis was recorded accurately, confirm that there is informed consent documentation). Concordance is reported to the practice as a percentage, with 100% concordance representing correct and accurate data abstraction of the medical records reviewed. A minimum concordance rate of 75% must be met.

ASCO contracted the services of Databank in 2010 to provide secure Health Insurance Portability and Accountability Act–compliant document storage and retrieval options for the records submitted from the practices. Databank receives all medical records and standards documentation directly from the practice and scans all materials into its online system.

QCP Standards Compliance Review

The QOPI certification standards were adapted from the ASCO/Oncology Nursing Society standards for safe chemotherapy administration using a consensus process.³ Selected standards are thought to apply broadly to practices that would seek QOPI certification, are standards that do not

duplicate QOPI medical record measures, and are most crucial for patient safety.

At the inception of QCP, practices were required during the application to submit evidence for meeting five of the 17 QCP standards and to submit relevant policies, procedures, and supporting documentation (eg, staff qualifications, competency checklists, and so on). QCP staff and QCP committee reviewers perform a remote paper review of the materials submitted to determine whether the selected standards have been met. Beginning with round four, this requirement was expanded, and practices were required to submit paper evidence of having met 10 of the 17 standards.

Initially, practices were randomly selected to receive an on-site review, with a goal of performing a 10% audit. In round one, five (17%) of 29 practices and, in round two, 17 (47%) of 40 practices received an on-site review. Reviews are conducted by experienced oncology nurses with advanced degrees who are independent contractors and have received in-depth training in conducting these reviews. Observations from rounds one and two on-site reviews revealed that most of the practices that met the requested standards on paper did not meet them when actual practice was observed. Consequently, the percentage of practices receiving on-site reviews was increased to 47% (round three), 87% (round four), and finally 100% (rounds five and six).

After a practice submits its medical records and standards for a paper audit, it becomes a certification-pending practice, and a structured on-site review is scheduled. On-site review includes reviews of staff roles and qualifications, medical record documentation, and practice policies and procedures, as they relate to the 17 QCP standards. Processes of care, such as chemotherapy-order checking and labeling, are observed. Nurses in the practice are randomly selected for a brief interview to validate staff qualifications and evaluate their knowledge of procedures that are typically not observed during an on-site review (eg, medical emergency management). A structured on-site review report is prepared by the on-site reviewer and appraised by QCP staff. The report, which lists notable positive observations, requirements (actions that must be taken for certification to be awarded), recommendations (optional actions suggested to strengthen practice), and a summary of QOPI medical record abstraction verification findings, is then approved by a volunteer member of the QCP steering committee before being sent to the practice. Practices are given 10 business days to respond to identified requirements and are asked to include a plan for meeting requirements and timeframe within which the requirements will be addressed. Practices then submit evidence of meeting the identified requirements, and the submitted documentation is reviewed by QCP staff and a steering group member. Practices have until 1 year from their application date to fulfill requirements, during which they remain in certification-pending status.

Results From On-Site Reviews

The 206 applicant practices represent 1,585 full-time equivalent (FTE) medical oncologists or oncologist/hematologists.

Practice size ranged from one to 83 FTE medical oncologists or oncologist/hematologists, with 69% of the practices having one to seven FTEs. Half (50%) of the 206 practices described themselves as private independent practices, 14% self-identified as employee practices (ie, hospital contracted or corporation owned), 13% were hospital outpatient departments, 11% were academic practices, 7% were private practices with an academic affiliation, and 5% represented practices that identified themselves as other, such as nonprofit community clinics or National Cancer Institute–designated comprehensive cancer centers.

In six rounds of QCP participation to date (November 15, 2012), 206 practices have applied for certification; 156 have been awarded certification, 44 are in the process of seeking certification, and six have withdrawn from the certification process. The 156 certified practices are located in 40 states (Appendix Fig A1, online only, shows geographic distribution of 153 QOPI-certified practices) and Puerto Rico. A list of certified practices is updated weekly and maintained on the QCP Web site at <http://qopi.asco.org/certifiedpractices>.

Of the 206 applicants considered for certification, 111 had received an on-site review as of November 15, 2012, including 100% of practices beginning with QCP round five. The decision to move to 100% on-site review was made after identifying the differences in practice performance reviewed on paper versus performance reviewed by on-site reviewers. During the first two rounds, 17 (77%) of 22 practices audited met a greater number of standards when a paper review was performed versus when an on-site review was conducted.

Among the 111 practices that have completed an on-site review—and attested to meeting the requirements for all 17 standards—only two (1.8%) were found to be fully concordant during the on-site review, meeting a median of 13 standards, with a range of seven to 17 standards (Fig 1 shows number of standards met by individual practices during on-site review by QCP auditor; each practice had attested to meeting all 17 standards before on-site review). Individual standard performance varied between 40.4% (qualifications, extravasation management) and 100% (toxicity assessment documentation), with a median of 75.3% (Figs 2A and 2B show percentages of practices meeting QCP standards on initial on-site review).

Analysis of QOPI-Certified Practices

QCP was designed to assess the quality and safety of outpatient care, where the majority of cancer care is delivered. That is, according to the Association of Community Cancer Centers, 85% of all adult patients with cancer are treated by community oncology practitioners, and 70% of QOPI-certified practices are community based, with one to seven physicians. QCP is overseen by a steering committee composed of practicing medical oncologists; measures, scoring requirements, and structural standards are continually reassessed to maintain certification rigor.

Most striking in the analysis of the first 3 years of QCP is that although all practices must attest that they comply with the 17 QCP chemotherapy administration safety standards to begin the certification application process, on-site review identi-

Figure 1. Number of standards met by individual practices during on-site review by Quality Oncology Practice Initiative Certification Program auditor ($n = 111$). Each practice had attested to meeting all 17 standards before the on-site review. No practice met fewer than seven standards.

Figure 2. Percentages of practices meeting Quality Oncology Practice Initiative Certification Program standards (A) one to nine and (B) 10 to 17 on initial on-site review ($n = 111$) from January 2010 to November 2012.

fied some level of nonconcordance in 98.2% of practices. Many practices do not have written policies to reflect their actions or do not document their actions in medical records. Discrepancies between what practices stated they were doing on paper and what was observed during the early on-site reviews (rounds one

and two) demonstrated the value and benefit of the on-site review process. As a result, the QCP steering committee set a goal to perform an on-site review of all practices—a goal that was achieved by round five (fall 2011).

Standards that were challenging for practices to meet include standard one (qualifications of staff who prescribe, prepare, and administer chemotherapy), which was met by only 40.4% of the practices during on-site review. Often, practices had policies in place that either did not state which types of practitioners were allowed to prescribe, prepare, or administer chemotherapy or had policies that did not describe staff qualifications or conditions for prescribing chemotherapy (eg, nurse practitioners may amend but not initiate chemotherapy orders; licensed physicians, such as rheumatologists, may prescribe chemotherapy within the scope of their specialty; and so on).

Medical record documentation (standard two, met by 52.8% of practices, and standard 11, met by 53.9% of practices) was another area of deficiency, usually because of an inability to locate medical record documentation of patient psychosocial concerns and need for support (standards two and 11); treatment intent/goals (standard two); treatment plan with doses, schedule, and so on stated (standard two); and performance status and/or clinical status (standard 11).

Standard eight (at least two individuals, in presence of patient, must verify patient identification using at least two identifiers) was met by only 62% of practices, most often because only one nurse verified the chemotherapy dose and went to the chairside to check patient identification. For many practices, the two-person verification of chemotherapy dose and two-person chairside patient identification required a major practice change, but one that was readily implemented by the practices.

Standard nine (extravasation management procedures are defined and align with current literature and guidelines; antidote order sets and antidotes are accessible) was met by just 40.47% of practices on initial on-site review, primarily because of outdated extravasation management procedures and/or lack of antidote order sets and a plan for acquiring extravasation antidotes or plan for sending a patient elsewhere for extravasation treatment if the antidote is not stocked on site. Often staff knew what to do in the event of an emergency or extravasation, but an up-to-date written policy was not available.

At the opposite end of the spectrum, standard 13 (practice/institution maintains referral resources for psychosocial and other supportive care services) was met by 97.3% of practices. Standard 16 (toxicity assessment documentation is available for planning subsequent treatment cycles) was met by all of the practices (100%).

QCP staff observed improvement in submitted documentation after the creation of detailed submission guidelines in September 2010 after round two. These guidelines provided clarification about the information being requested, provided instruction on how documents needed to be deidentified and labeled, and included proven examples of how a standard could be met.

Practices are allowed up to 1 year from the certification-pending date to achieve certification. The shortest individual

time to certification—43 days—was recorded in round three, and the longest amount of time for an individual practice to achieve certification was 13.2 months in round four. The average time to achieve certification ranged from 4.4 months in round one to 6.9 months in round four; the lengthening of time to be certified coincided with the transition to 100% on-site reviews. Of the 206 applicants, 44 are still working toward achieving certification. The length of time to achieve certification is indicative of the rigor of the standards and reflects the intensity of the effort required to reach the quality and safety bar set for these practices.

Although two of the 156 certified practices had no requirements to meet and were awarded certification after their on-site reviews, the vast majority of practices had requirements that needed to be met for certification to be awarded. Nearly all of these practices were eventually able to achieve QOPI certification. Anecdotal reports of the benefits of QOPI certification include increased or maintained reimbursement for oncology care, decreased malpractice liability premiums, recognition as a preferred provider by some health insurance companies, increased patient self-referrals and physician referrals, increased pride in practice and patient satisfaction, decreased staff turnover, and increased visibility.

QCP recognizes the quality improvement efforts of practices that deliver care in the community adult oncology outpatient arena. QCP answers the call from the Institute of Medicine⁴ to close the quality gap by aligning evidence-based guidelines and consensus-driven standards with requirements for oncology practices to have structural components, such as policies and procedures that ensure practice performance.

Participation in the QOPI certification process provides practices with a systematic way to examine and improve practice procedures and identify areas to enhance the quality of cancer care and safe administration of chemotherapy. Such initiatives may lead to greater uniformity of care, which in turn may improve outcomes for patients receiving chemotherapy.

Authors' Disclosures of Potential Conflicts of Interest

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: Terry R. Gilmore, American Society of Clinical Oncology (C); Lisa Schulmeister, American Society of Clinical Oncology (C); Joseph O. Jacobson, American Society of Clinical Oncology (U) **Consultant or Advisory Role:** None **Stock Ownership:** None **Honoraria:** None **Research Funding:** None **Expert Testimony:** None **Other Remuneration:** None

Author Contributions

Conception and design: All authors

Administrative support: Terry R. Gilmore

Provision of study materials or patients: Terry R. Gilmore

Collection and assembly of data: Terry R. Gilmore

Data analysis and interpretation: All authors

Manuscript writing: All authors

Final approval of manuscript: All authors

Corresponding author: Terry R. Gilmore, RN, American Society of Clinical Oncology, 2318 Mill Rd, Ste 800, Alexandria, VA 22314; e-mail: terry.gilmore@asco.org.

DOI: 10.1200/JOP.2013.000886

References

1. Jacobson JO, Wolff AC: Evidence-based medicine: Do clinical practice guidelines contribute to better patient care?—An expert interview with Drs Joseph O. Jacobson and Antonio C. Wolff. <http://www.medscape.org/viewarticle/589088>

2. Jacobson JO, Polovich M, Gilmore TR, et al: Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards: Expanding the scope to include inpatient settings. *J Oncol Pract* 8:2-6, 2012

3. McNiff KK, Bonelli KR, Jacobson JO: Quality Oncology Practice Initiative certification program: Overview, measure scoring methodology, and site assessment standards. *J Oncol Pract* 5:270-276, 2009

4. Institute of Medicine Committee on Quality Health Care in America: Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC, National Academies Press, 2001

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Appendix

Figure A1. Geographic distribution of the 153 Quality Oncology Practice Initiative–certified practices.