Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards: Expanding the Scope to Include Inpatient Settings

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Abstract

In November 2009, ASCO and the Oncology Nursing Society (ONS) jointly published a set of 31 voluntary chemotherapy safety standards for adult patients with cancer, as the end result of a highly structured, multistakeholder process. The standards were explicitly created to address patient safety in the administration of parenteral and oral chemotherapeutic agents in outpatient oncology settings. In January 2011, a workgroup consisting of ASCO and ONS members was convened to review feedback received since publication of the standards, to address interim changes in practice, and to modify the standards as needed. The most significant change to the standards is to extend their scope to the inpatient setting. This change reflects the conviction that the same standards for chemotherapy administration safety should apply in all settings. The proposed set of standards has been approved by the Board of Directors for both ASCO and ONS and has been posted for public comment. Comments were used as the basis for final editing of the revised standards. The workgroup recognizes that the safety of oral chemotherapy usage, nononcology medication reconciliation, and home chemotherapy administration are not adequately addressed in the original or revised standards. A separate process, cosponsored by ASCO and ONS, will address the development of safety standards for these areas.

Introduction

In 2008, ASCO and the Oncology Nursing Society (ONS) initiated a collaborative project to develop standards for safe chemotherapy administration. The project targeted adult patients receiving parenteral and oral chemotherapy in outpatient settings, with a principal focus on patient safety. The end result was the publication of the ASCO/ONS Chemotherapy Administration Safety Standards in 2009.[1,2] Subsequently, both organizations received feedback from their membership and other stakeholders asking for clarification of several standards. In addition, the ASCO-based Quality Oncology Practice Initiative (QOPI) Certification Program, which, as part of its assessment, evaluates outpatient oncology practices regarding their ability to meet 17 safety standards derived from the ASCO/ONS standards, received similar queries.

In January 2011, ASCO and ONS convened a workgroup to review the ASCO/ONS Chemotherapy Safety Standards and the feedback that both organizations had received since publication. Questions had been raised about the interpretation of several standards and the exclusion of the inpatient setting in the initial standards. This article reviews the process that led to the development of the initial chemotherapy safety standards, the process undertaken to review and revise them (Appendix Table A1, online only), and the rationale for the changes that were made.

Standards Development Process

In 2008, volunteer leaders and staff from ASCO and ONS formed a steering group (SG) to develop safety standards for outpatient chemotherapy administration. The SG identified experts from a diverse, multidisciplinary group of stakeholders and invited them to attend a workshop to draft the standards. SG members compiled a synopsis of relevant literature and guidelines, a reference list, and full-text key articles, which were sent to workshop participants in advance of the December 2008 workshop.

Forty stakeholders, including medical oncologists, oncology nurses, oncology pharmacists, social workers, practice administrators, and patient advocates, as well as representatives from American Cancer Society, Association of Community Cancer Centers, National Quality Forum, National Coalition for Cancer Survivorship, The Joint Commission, and Institute for Safe Medication Practices met for a single day and, using a structured process, drafted 64 chemotherapy administration safety standards. The draft standards were subsequently presented to the full group of participants for comment and discussion, and assessed for redundancy and gaps. Participants voted on the draft standards within 1 week of the workshop, and the SG used the voting results to clarify and edit the standards, reducing their number to 35. The draft standards were then disseminated to all ASCO and ONS members and electronically posted for public comment as a Web-based survey. Three hundred twelve respondents provided comments and voted (yes/no) to include each standard. Ten additional responses were made directly to ASCO or ONS. Most standards received "yes" votes from the majority of respondents (range, 82% to 96%). The number of narrative comments on indi-

vidual standards ranged from eight to 76. Many of the comments were simple requests for clarification or rewording suggestions. After the close of the 6-week public comment period (January 29 to March 13, 2009), the SG reviewed the comments and voting results, evaluated all of the standards with less than 90% "yes" votes, and modified language as needed to adequately address issues raised in the open comments. This process resulted in four of the standards being eliminated. The final 31 standards were approved by the SG in April 2009, approved by ASCO and ONS, published online ahead of print in ASCO's *Journal of Clinical Oncology*[1] on September 28, 2009, and reprinted with permission in the November 2009 ONS publication *Oncology Nursing Forum*.[2]

Standards Review Process

In January 2011, a workgroup was assembled by ASCO and ONS to review and, when indicated, revise the ASCO/ONS Chemotherapy Administration Safety Standards. The eight-member workgroup consisted of the original project chairs from ASCO and ONS (Joseph O. Jacobson MD, and Martha Polovich, PhD, RN, AOCN), and representatives from ASCO, ONS, and the QOPI Certification Program. In advance of the meeting, the workgroup received a summary list of questions and comments about the standards that had been received by ONS, ASCO, and the QOPI Certification Program, along with reference articles and other supporting documentation.

The workgroup reviewed the criteria that were used when the standards were initially developed, concurred that the criteria remained current and applicable, and agreed to use them to guide the standards revision discussion (Table 1). All 31 standards were reviewed. Each standard, along with associated questions and comments, was reviewed, and changes or clarifications were made by majority vote. Only standard 16 required substantive change (see below). After a final review, the workgroup unanimously approved the modifications to the standards. In addition, the workgroup recommended that the ASCO/ONS Chemotherapy Administration Safety Standards apply across all treatment settings. The revised standards were then reviewed and approved by the ASCO Executive Committee and the ONS Board of Directors.

Public comment was solicited during a 4-week period from July 12, 2011 to August 11, 2011 by using a Web-based survey (Zarca Interactive, Herndon, VA). After introductory text that explained that public comment was sought on the revised standards as applicable to the extension of their scope to the inpatient setting, each standard was listed separately for voting. The survey tool collected two demographic characteristics of the respondents, primary profession and primary practice setting. For each of the draft standards, respondents voted (yes/no) for applicability to the inpatient setting and provided relevant comments. ASCO and ONS members were notified of the opportunity for public comment via existing member communications, and targeted e-mails were sent to relevant groups and committees including National Cancer Institute, National Comprehensive Cancer Network, Commission on Cancer, Institute for Safe Medication Practices, and The Joint Commission. After close of the public comment period, the workgroup reviewed voting results and all open text comments.

Table 1. Criteria for Developing Final Standards

Final standards should comply with the following criteria
Applicable to diverse organizations providing outpatient chemotherapy to adult cancer patients
Focused on patient safety
Focused on site policies and procedures, and the process of planning for and administering chemotherapy, rather than facility/physical plant characteristics
Apply to each outpatient site administering chemotherapy, unless otherwise specified
Address parenteral and oral chemotherapy regimens
Appropriate for use for internal and external safety monitoring
Compliance with standards, as written, should be measurable
Standard language should be clear enough to ensure reliable, consistent interpretation among users and sites
Final standards in each component should include at least one focused on patient/caregiver teaching

NOTE. This set of criteria should be used in group deliberation to guide and focus discussion concerning the statements in each component of the standards.

Revisions and Clarifications

The most significant change to the ASCO/ONS Chemotherapy Administration Safety Standards was in response to clinicians who questioned why the initial standards were designated for the outpatient setting only. In 2008, to limit scope, the Chemotherapy Administration Safety Standards were explicitly designed to apply only to the outpatient setting, where the majority of patients receive chemotherapy. To determine the feasibility of expanding the standards to the inpatient setting, the workgroup reviewed each of the 31 standards to determine its applicability and appropriateness to the inpatient setting. All were deemed to apply, and the workgroup unanimously approved the proposal to make the standards applicable to the inpatient setting by means of the following change: the scope of the standards was changed from "outpatient" (defined as any non-inpatient treatment setting, with the exclusion of home infusion services) to "all chemotherapy treatment settings."

During the public comment period, 87 individuals responded to the request to vote on whether or not each of the 31 chemotherapy administration safety standards was applicable to the inpatient setting. Agreement for individual standards ranged from 79% to 100%, with only two standards deemed applicable to the inpatient setting by less than 90% of the respondents. Eighty two percent of respondents agreed that standard 20, "a licensed independent practitioner is on site and immediately available during all chemotherapy administration," was applicable to the inpatient setting. Concern focused on the availability of a licensed independent practitioner on site and immediately available, especially during nights, holidays, and weekends. The work-

group reviewed the definition of "licensed independent practitioner," which is defined as "physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law."[1] Given the broad definition, the workgroup concluded that meeting standard 20 in inpatient settings is feasible.

Standard 25, "the practice/institution establishes a procedure for documentation and follow-up for patients who miss office visits and/or treatments" was deemed applicable to the inpatient setting by 79% of respondents. Respondents who did not support this standard for use in the inpatient setting viewed this as an outpatient oncology responsibility. To enhance clarity, the workgroup revised the wording of standard 25 to, "the practice/institution establishes a procedure for documentation and follow-up for patients who miss office visits and/or scheduled treatments." The language changes are intended to more clearly identify responsibility for inpatient providers.

Several respondents inquired why safe handling of chemotherapy was not addressed in the ASCO/ONS Chemotherapy Administration Safety Standards or their revision. Although none of the standards specifically address this issue, ASCO and ONS endorse the safe handling of chemotherapy agents. Published guidelines define the expectations for organizations related to the use of safe handling precautions.[3-7] Education, training, and competency validation for chemotherapy administration must necessarily include this aspect of practice. Organizations must focus on a "culture of safety," because of the relationship between patient and health care workers' safety.[3,4]

The majority of changes to the chemotherapy administration standards required minor wording changes to enable a standard to pertain to the inpatient setting. An example is the requirement to sign a printed version of a verbal chemotherapy "stop" or "hold" order within a designated time frame in accordance with organizational policy.

In keeping with the expanded setting focus, the language of some of the standards required modification. For instance, standard 1 was previously worded as, "The practice has policies, procedures, and/or guidelines for verification of training and continuing education for clinical staff," and is now worded, "The practice/institution has policies, procedures, and/or guidelines for verification of training and continuing education for clinical staff." Revisions involved changing the term "clinic visit" to "treatment day" so that the revised standards apply to any treatment setting where chemotherapy is administered. Similarly, any mention of "practice staff" was changed to "staff."

Standard 2 addresses the requirement for documentation of key patient, disease, and chemotherapy details. The current wording, "Before prescribing a new chemotherapy regimen, chart documentation available to the prescriber includes . . ." was amended to, "Before the first administration of a new chemotherapy regimen, chart documentation available to the practice/institution includes . . ." The rationale for the change is that safe chemotherapy administration requires a team of professionals (physicians, nurses, pharmacists, others) and, therefore, chart documentation should be available not only to the prescriber but to all members of the treatment team (eg, pharmacists, nurses, etc).

Previously, standard 2F (initial psychosocial assessment) and standard 22 (ongoing psychosocial assessment) required "assessment regarding psychosocial concerns and need for support." Wording for these two standards was amended to add "with action taken when indicated," because acting on psychosocial assessment findings, when warranted, promotes patient safety, coping, and comfort.[5,6]

Drug preparation standard 12 previously stated that "A second person independently verifies each order for chemotherapy before preparation, including confirming: two patient identifiers, drug names, drug dose, drug volume, rate of administration, route of administration, and the calculation for dosing, including the variables used in this calculation." An additional item, "cycle and day of cycle," was added to this list of requirements as a safety measure to reduce the risk of timing errors that could potentially result in the patient receiving less than, or more than, the intended amount of chemotherapy.

Standard 13 states that chemotherapy drugs are labeled immediately on preparation and lists the information that must appear on the label. Previously, the standard required that the date and time of preparation and expiration appear on the label. This standard was revised to require that the date and time of preparation must appear on the label; date and time of expiration are required only when chemotherapy is not planned for immediate use (defined as per practice policy and state regulations). This change was made to reduce the risk of an error resulting from two sets of dates and times on chemotherapy labels.

The original language of standard 16 stated, "Informed consent for chemotherapy must be documented by a physician in the practice before chemotherapy administration." Subsequent to the publication of the standards, the workgroup learned that practice patterns vary from state to state and that chemotherapy consent is frequently obtained by advanced practice nurses or other clinical staff. For the revised standards, the workgroup removed the word "physician" from the requirement. This retains the essential intent of the standard—that informed consent for chemotherapy is necessary—without stipulating how consent is documented.

Standard 31 previously stated, "The practice has a process for risk-free reporting of errors or near misses. Error and near miss reports are reviewed and evaluated at least semiannually." The standard was revised to, "The practice/institution encourages the reporting of errors and near misses and has a formal process in place for evaluating the data. Error and near-miss reports are reviewed and evaluated at least semiannually." The words "risk-free" were deleted in recognition that although most events are due to systems failures, some are due to individual decisions or actions for which there must be personal accountability. Clinicians who disregard policies and procedures, for instance, are accountable for their actions when errors occur.[7-9]

Observed variations in interpretation and clinical implementation of several standards prompted the need for further

clarification. For example, standard 1F states that "all clinical staff maintains current certification in basic life support." Some practices inquired whether this standard applies to physicians, especially in states where cardiopulmonary resuscitation (CPR) certification is optional for physicians under state law. The workgroup affirmed that "all clinical staff" includes physicians and that CPR certification enhances safety in settings where chemotherapy is administered.

For some standards, minor wording changes clarify their intent. Standard 22 was originally worded, "At each clinical visit during chemotherapy administration, practice staff assess and document in the medical record . . .." This was amended to, "At each clinical visit or day of treatment during chemotherapy administration . . .." This change more precisely describes the frequency of patient assessment in any setting, such as inpatient or home care. Standard 24 was previously phrased as, "The practice maintains a referral list for psychosocial and other supportive care services." The workgroup agreed that "maintaining a list" limited the intent and amended the wording to, "The practice/institution maintains referral resources for psychosocial and other supportive care services." The revised language encourages organizations to meet this standard in a variety of ways, such as having support personnel (eg, social workers) available to patients, offering support groups and counseling or providing information about these services, referring patients to online or community programs and resources, and so on.

The workgroup recognized that some of the standards are more challenging to implement for oral chemotherapy. Given the increasing use of oral chemotherapeutic agents and the expected FDA approval of multiple new oral agents, the workgroup concluded that oral chemotherapy safety must be addressed, and that the task was beyond the scope of the current project. In addition, the workgroup recognized that the current standards do not adequately address medication reconciliation for nononcologic agents. Chemotherapeutic agents and other medications prescribed by oncologists frequently interact with non–cancer-related medications. Because cancer is primarily a disease of aging adults who often have multiple comorbidities and are taking multiple medications; patients receiving chemotherapy are at particular risk of drug-drug interactions that could result in drug toxicity. Finally, the workgroup acknowledged that chemotherapy delivered by infusion services in the home setting presents unique safety issues not fully addressed by the current standards. These topics were deemed beyond the scope of the current workgroup.

Discussion

When they were developed in 2008, the ASCO/ONS Chemotherapy Safety Standards reflected the consensus of a broad group of stakeholders. The standards were intended to assist oncology practices in creating the safest possible processes for chemotherapy administration. It was understood at the time of their publication that they would require periodic revision. The closing sentence of the Standards publication reminded us that "regular review of these standards will be needed as the practice of medical oncology continues to evolve rapidly."[1]

Although the inpatient setting was not explicitly addressed by the original standards, there is now strong consensus among the members of the workgroup that this is an area of potential vulnerability for our patients. Advances in the delivery of chemotherapy coupled with the ability to better manage toxicities have resulted in a shift of oncology care from the inpatient to the outpatient setting over the last decade. The result for many hospitals has been a reduction in the number of oncology inpatients and a concomitant reduction in the number of experienced chemotherapy staff available to reliably administer chemotherapy.[10] The implications for patient safety are significant. The authors recognize that implementation of the standards in the inpatient setting will be challenging, requiring collaboration between medical oncologists and hospital administration.

The unique risks inherent in the prescription and administration of oral chemotherapy have become clearer since publication of the standards.[11,12] Practices and practitioners have far less ability to directly manage the care of patients who receive oral chemotherapy. This awareness, in conjunction with the rapid increase in the availability of novel oral agents, led to the recommendation to undertake an independent process to create oral chemotherapy safety standards. ASCO and ONS have convened a separate oral chemotherapy safety workgroup that is charged with the responsibility of creating usage guidelines; identifying potential performance measures; and providing final recommendations to modify the existing ASCO/ONS standards, if warranted. In addition, ASCO and ONS recognize the need for defined processes for medication reconciliation and home chemotherapy administration.

As we did previously, we encourage clinicians in all practice settings to assess their compliance with the revised standards. Accomplishing this goal will require close collaboration between medical oncologists, oncology nurses, oncology pharmacists, and cancer program and hospital administrators. Given the many regulatory and economic pressures on organizations, oncology healthcare providers must make a compelling case for the implementation of the standards. Ensuring that these standards are implemented in all settings will promote safe chemotherapy administration for patients with cancer.

The revised ASCO/ONS Chemotherapy Safety Standards can be found at www.asco.org/chemostandards.

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