

American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards

Joseph O. Jacobson, Martha Polovich, Kristen K. McNiff, Kristine B. LeFebvre, Charmaine Cummings, Michele Galoto, Katherine R. Bonelli, and Michele R. McCorkle

From the North Shore Cancer Center, Salem, MA; Duke Oncology Network, Durham, NC; American Society of Clinical Oncology, Alexandria, VA; and Oncology Nursing Society, Pittsburgh, PA.

Submitted July 17, 2009; accepted August 26, 2009; published online ahead of print at www.jco.org on September 28, 2009.

Supported by the American Society of Clinical Oncology and the Oncology Nursing Society.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

Corresponding author: Kristen K. McNiff, MPH, American Society of Clinical Oncology, 2318 Mill Rd, Ste 800, Alexandria, VA 22314; e-mail: kristen.mcniff@asco.org.

The Acknowledgment is included in the full-text version of this article, available online at www.jco.org. It is not included in the PDF version (via Adobe® Reader®).

© 2009 by American Society of Clinical Oncology

0732-183X/09/2732-5469/\$20.00

DOI: 10.1200/JCO.2009.25.1264

ABSTRACT

Standardization of care can reduce the risk of errors, increase efficiency, and provide a framework for best practice. In 2008, the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) invited a broad range of stakeholders to create a set of standards for the administration of chemotherapy to adult patients in the outpatient setting. At the close of a full-day structured workshop, 64 draft standards were proposed. After a formal process of electronic voting and conference calls, 29 draft standards were eliminated, resulting in a final list of 35 draft measures. The proposed set of standards was posted for 6 weeks of open public comment. Three hundred twenty-two comments were reviewed by the Steering Group and used as the basis for final editing to a final set of standards. The final list includes 31 standards encompassing seven domains, which include the following: review of clinical information and selection of a treatment regimen; treatment planning and informed consent; ordering of treatment; drug preparation; assessment of treatment compliance; administration and monitoring; and assessment of response and toxicity monitoring. Adherence to ASCO and ONS standards for safe chemotherapy administration should be a goal of all providers of adult cancer care.

J Clin Oncol 27:5469-5475. © 2009 by American Society of Clinical Oncology

INTRODUCTION

Administration of antineoplastic agents is a complex process fraught with the potential for patient harm. Challenges to patient safety grow as the number of chemotherapeutic regimens expands and oral chemotherapy drugs become commonplace. Despite safety risks, there are few national standards for safe administration, especially in the outpatient adult oncology setting. Providers of outpatient cancer care services are among the stakeholders seeking guidance to achieve the best, safest outcomes of therapy. To meet this need, the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) initiated a collaborative project in 2008 to develop standards for safe chemotherapy administration to adult cancer patients in the outpatient setting. The scope of the project was limited to patient safety and included both parenteral and oral chemotherapy regimens.

Although few true standards exist, a body of literature published over the past decade informed the ASCO/ONS effort. The two organizations, as well as other professional associations, developed guidelines or recommendations to improve the quality and safety of chemotherapy administration in a variety of settings.¹⁻³ The ASCO position state-

ment, published in 2004, outlines minimum-level criteria for safe practice and recognized that most chemotherapy is administered in outpatient settings. Guidelines developed by the ONS and the American Society of Health-System Pharmacists offered comprehensive recommendations, such as safe handling of chemotherapy agents. Late in the development process of the ASCO/ONS standards, the Clinical Oncological Society of Australia published recommendations for safe prescribing, supply, and administration of chemotherapy that address the roles of various practitioners.⁴

Recommendations to improve safety and increase the quality of chemotherapy administration also have been developed in response to reports of chemotherapy administration errors.⁵⁻⁹ Recent studies have specifically addressed medication errors in outpatient chemotherapy administration settings.^{10,11} Recommendations for avoiding chemotherapy administration errors call for standardized approaches, development of policies and procedures for system improvement, and review of errors by interdisciplinary professional staff.^{7-9,12,13}

In addition, increased use of electronic medical record systems may lead to improvement in the safety and quality of outpatient chemotherapy administration. E-prescribing, for example, may prove

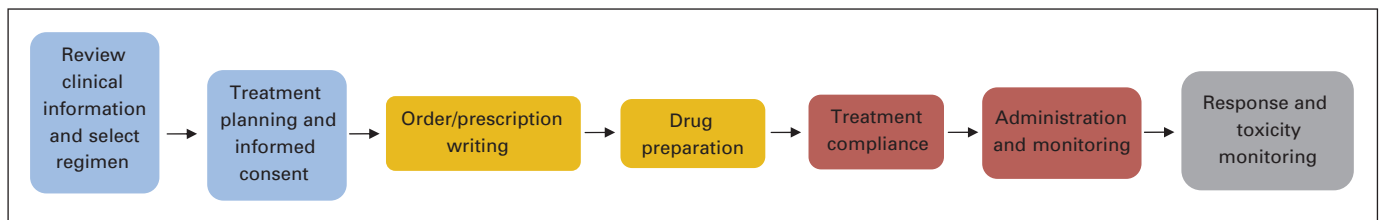


Fig 1. Chemotherapy administration flow.

to be a tool for reducing errors in chemotherapy ordering. Some electronic systems prompt clinicians in a practice to specify standard, evidence-based regimens to be used for specific diagnoses. Automated systems can reduce errors in regimen selection in a busy clinical setting.^{14,15}

Oral chemotherapy agents pose new safety challenges. Adherence is a formidable issue in oral chemotherapy administration; poor adherence has been reported to have a substantial impact on the success of chemotherapy and patient safety.¹⁶⁻¹⁸ The National Comprehensive Cancer Network established a task force to explore the impact of increasing use of oral chemotherapy. They concluded that safety issues stem from a lack of checks and balances in administration, risk of patient noncompliance, lack of monitoring techniques, and a shift to patient management of oral chemotherapy.¹⁶ Despite the need for increased patient education regarding oral chemotherapy and processes to monitor adherence and adverse events, few standards regarding education or monitoring have been developed.^{17,19-21}

This article reports on the ASCO/ONS development and consensus process and the resulting standards for safe chemotherapy administration in hematology/oncology ambulatory care settings.

METHODS

With the goal of developing chemotherapy administration safety standards using a multidisciplinary, consensus-building process, an ASCO/ONS Steering Group of volunteer leaders and staff was assembled in the summer of 2008. The Steering Group chose to reach consensus of final standards by use of a structured workshop, open public comment period, and systematic review of collated data. Steering Group members further defined the scope of the project as pertains to the components of chemotherapy administration illustrated in Figure 1.

The Steering Group selected experts among diverse stakeholders for representation at the workshop, where standards were to be drafted. Appropriate experts were identified by Steering Group members, publications, and recommendations from professional societies. Before the workshop, Steering Group members conducted a literature review and prepared a synopsis of relevant published guidelines and recommendations, a reference list, and full text of key articles. These documents were distributed to workshop participants in advance of the meeting, along with introductory materials regarding the goals, scope, and common definitions. Workshop participants were informed that drafted standards should comply with the stated scope and meet specified criteria (Table 1).

The workshop was convened in December 2008, with 40 participants including medical oncologists, nurses, pharmacists, social workers, practice administrators, and patient advocates. A complete list of workshop participants is posted at <http://www.asco.org/safety> and <http://www.ons.org/clinical/>. Standards were discussed, reviewed, and revised by the workshop participants in small breakout sessions. Scribes recorded the standards, which then were presented to the full group of participants for further comment and discussion. The standards were assessed for redundancy and gaps. Finally, workshop participants were asked to vote on the draft standards within 1 week of the

meeting. Voting results and subsequent review and editing by the Steering Group for redundancy resulted in the public comment standards draft.

Public comment was accomplished using a Web-based survey, Zarca (Zarca Interactive, Herndon, VA). After introductory text that provided common definitions for all standards, 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 inclusion in the final set and provided relevant comments.

The public comment period was 6 weeks (January 29 to March 13, 2009). ASCO and ONS members were notified of the opportunity for public comment via existing member communications and targeted e-mails to relevant groups and committees. Workshop participants were asked to advertise the public comment using their own Web sites and/or communication tools.

After close of the public comment, the Steering Group reviewed voting results and all open text comments. Steering Group members especially evaluated all standards with less than 90% yes votes and assessed whether edits could adequately address issues raised in the open comments. Some draft standards were considered to be goals and were removed from the final standards list.

RESULTS

Workshop participants defined 64 draft standards during the 1-day meeting. On the basis of results of workshop participants' voting and comments, Steering Group members developed a public comment document comprising 35 public comment draft standards. The common definitions developed to apply to all standards are listed in Table 2.

Three hundred twenty-two responses were received after the request for public comment over the 6-week period. The online survey netted 312 responses, and 10 additional responses were made directly to ASCO or ONS. Table 3 lists the primary profession and practice setting of the survey respondents.

Table 1. Requirements for ASCO/ONS Chemotherapy Administration Standards

Criteria
1) Applicable to diverse outpatient hematology/oncology practice settings
2) Understandable and clinically intuitive
3) Realistic to achieve with existing or reasonable resources expectations
4) Valid, based on scientific evidence or strong expert consensus
5) Reliable, allowing consistent implementation and assessment over time and across sites
6) Measurable, allowing performance according to the standard to be assessed for both internal quality assessment and external quality monitoring
7) Actionable, informing practice processes, policies, or procedures

Abbreviations: ASCO, American Society of Clinical Oncology; ONS, Oncology Nursing Society.

DISCUSSION

Moving medicine from a craft-based era to a profession-based field depends on the willingness to adopt principles that transformed industry in the 20th century.³⁷ In addition to the need for enhanced teamwork, decision support tools, and performance measurement, common practices and procedures must be standardized if care is to be as safe and efficient as possible. Uniform approaches to diagnosis and treatment have become commonplace in many medical specialties. For example, adherence to the use of a simple checklist before the placement of a central catheter in the critical care setting results in improved outcomes.³⁸ Because of the complexity of chemotherapy administration and the risk of severe adverse effects, standardizing care in settings where chemotherapy is delivered is essential.

The current article represents a successful collaboration between ASCO and ONS and provides a series of consensus-derived safety standards that are intended to provide a basis for the safe administration of outpatient chemotherapy to adult cancer patients. Standards were defined based on a structured and iterative process that included an open public comment period. We defined a standard as an expectation of care based on well-defined criteria (Table 1). Nearly half of the draft standards were eliminated during the review process either because they were duplicative or did not meet all of the required criteria. The final set of standards is applicable to all outpatient oncology settings; however, it is known that not all practices will be able to achieve all standards immediately on publication.

Development by consensus with public comment was a new process for ASCO and ONS. Both organizations used existing member and public communication mechanisms to publicize the call for public comments, as well as targeted outreach. Additionally, development workshop participants were asked to advertise the public comment using their Web sites/communication tools. There are limitations to the public comment approach. It is unknown how representative the survey respondents are of the membership of ASCO or ONS or of the population of medical oncologists and oncology nurses in the United States in general. In addition, the number of respondents was small compared with the entire membership of either organization. ONS has approximately 37,000 members, and ASCO has more than 27,000. Physicians were under-represented in public comment; however, ASCO/ONS Steering Group members learned that physicians often delegated response to the survey to nurses or others on staff. Ultimately, the comments received reflected many of the diverse professionals involved in chemotherapy administration, as well as patient advocacy groups.

During the public comment period, the ASCO/ONS Steering Group learned of the newly published *Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy* from the Clinical Oncological Society of Australia.⁴ Although the two efforts had different goals and reflect different systems of care, there is significant overlap, and each validates the other.

How should the ASCO/ONS chemotherapy administration safety standards be used? Of importance, the standards are voluntary but represent consensus across a broad range of stakeholders.

Table 2. Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards

Term	Definition
Chemotherapy	All antineoplastic agents used to treat cancer, given through oral and parenteral routes or other routes as specified in the standard. Types include targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumor antibiotics, monoclonal antibodies, and biologics and related agents. Hormonal therapies are not included in the definition of chemotherapy for the standards.
Chemotherapy regimen	One or more chemotherapeutic agents used alone or in combination in a well-defined protocol, generally administered cyclically
Practitioner	Licensed independent practitioner, including physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law
Outpatient chemotherapy setting (site)	Any non-inpatient treatment setting, with the exclusion of home infusion services

Abbreviations: ASCO, American Society of Clinical Oncology; ONS, Oncology Nursing Society.

The online survey presented each proposed standard with the question, “Should this standard be included in the final set?” Response options were “Yes” or “No.” The results were recorded as frequencies and percentages of yes and no votes. Most standards received yes votes from the majority of respondents, with a range of 82% to 96%. Comments about each standard were also recorded. The number of comments varied from eight to 76 comments on individual standards. Many comments were requests for clarification or suggestions for rewording, whereas others were statements for or against individual proposed standards.

The Steering Group reviewed all of the survey data, including the comments, both individually and collectively. The final standards were evaluated for redundancy, revised, and agreed on by the Steering Group in April 2009. Table 4 lists the final 31 standards.

Table 3. Public Comment Respondents' Characteristics

Characteristic	No. of Respondents (N = 312)	%
Primary profession		
Physician	35	11
Registered nurse	173	56
Nurse practitioner	17	6
Clinical nurse specialist	46	15
Pharmacist	20	6
Social worker	10	3
Patient advocate	2	1
Other	7	2
No answer	2	1
Primary practice setting		
Academic medical center	56	18
Community practice	63	20
Hospital	84	27
Ambulatory clinic	82	27
Other	23	7
No answer	4	1

Table 4. ASCO/ONS Chemotherapy Administration Safety Standards

Standards

Staffing-Related Standards

1. The practice has policies, procedures, and/or guidelines for verification of training and continuing education for clinical staff.
 - A. Orders for parenteral and oral chemotherapy are written and signed by licensed independent practitioners who are determined to be qualified by the practice according to the practice's policies, procedures, and/or guidelines.
 - B. Chemotherapy drugs (oral or parenteral) are prepared by a pharmacist, pharmacy technician, or nurse determined to be qualified according to the practice's policies, procedures, and/or guidelines.
 - C. Only qualified physicians, physician assistants, advanced practice nurses, or registered nurses administer chemotherapy.
 - D. The practice has a comprehensive educational program for new staff administering chemotherapy, including a competency assessment, or the practice uses an off-site educational program regarding chemotherapy administration that ends in competency assessment.
Chemotherapy administration education must include all routes of administration used in the practice site (eg, parenteral, oral, intrathecal, intraperitoneal, intravesicular).
An example of an off-site educational program is the ONS Chemotherapy and Biotherapy Course.
 - E. The practice has a standard mechanism for monitoring chemotherapy administration competency at specified intervals.
Annual competency reassessment is recommended.
 - F. All clinical staff maintains current certification in basic life support.^{1,2,4,22-27}

Chemotherapy Planning: Chart Documentation Standards

2. Prior to prescribing a new chemotherapy regimen, chart documentation available to the prescriber includes:
 - A. Pathologic confirmation or verification of initial diagnosis
If original pathology report is unobtainable, note of explanation is in chart.
This standard does not imply the need to rebiopsy if not clinically necessary.
 - B. Initial cancer stage or current cancer status
Cancer stage is defined at diagnosis. Cancer status includes a current description of the patient's disease since diagnosis/staging, if relevant (eg, recurrence, metastases).
 - C. Complete medical history and physical examination that includes, at minimum, height, weight, and assessment of organ-specific function as appropriate for the planned regimen
Example of assessment of organ-specific function as appropriate for the planned regimen: patient plan for cisplatin requires pretreatment assessment of kidney function
 - D. Presence or absence of allergies and history of other hypersensitivity reactions
 - E. Documentation of patient's comprehension regarding medication regimens, including information regarding disease and self-care
 - F. Assessment regarding psychosocial concerns and need for support
Documentation of psychosocial concerns may include: copy of distress, depression, or anxiety screening form in the chart; patient self-report of distress, depression, or anxiety; or chart documentation regarding patient coping, adjustment, depression, distress, anxiety, emotional status, family support and care giving, coping style, cultural background, and socioeconomic status.
 - G. The chemotherapy treatment plan, including, at minimum, chemotherapy drugs, doses, duration, and goals of therapy
 - H. For oral chemotherapy, the frequency of office visits and monitoring that is appropriate to the agent and is defined in the treatment plan^{1-3,5,6,8,22-24,27-30}

General Chemotherapy Practice Standards

3. The practice:
 - A. Defines standard chemotherapy regimens by diagnosis with references readily available, and/or
 - B. Identifies source(s) for chemotherapy regimens, including local or centralized IRB-approved clinical research protocols or guidelines.^{2,29,31,32}
4. For orders that vary from standard regimens, practitioners provide a supporting reference. Reasons for dose modification or exception orders are documented.²⁹
Exception orders may include notation that standard treatment is contraindicated as a result of pre-existing comorbidity, organ dysfunction, or prior therapy.
5. The practice maintains written statements that determine the appropriate time interval for regimen-specific laboratory tests that are:
 - A. Evidence-based when national guidelines exist (eg, ASCO or NCCN guidelines), or
 - B. Determined by practitioners at the site³¹
Documentation of regimen-specific laboratory tests may be part of standardized regimen orders.
6. The practice maintains a policy for how informed consent is obtained and documented for chemotherapy.³³
The practice may provide options for consent (eg, use of chart documentation of patient consent or a signed patient consent form) that allow for variation among practitioners in the practice.
7. If the practice site administers chemotherapy that is prepared (mixed) off-site, the practice site maintains a policy for quality control of that chemotherapy.^{1,34}

Chemotherapy Order Standards

8. The practice does not allow verbal orders except to hold or stop chemotherapy administration. New orders or changes to orders must be made in writing.^{3,27}
Fax and e-mail orders are considered written orders.
9. The practice maintains and uses standardized, regimen-level, preprinted or electronic forms for chemotherapy prescription writing (oral and parenteral).^{14,15}
Standardized forms may be incorporated into e-prescribing software or electronic health records.
10. Order forms inclusively list all chemotherapy agents in the regimen and their individual dosing parameters. All medications within the order set are listed using full generic names and follow Joint Commission standards regarding abbreviations.
Brand names should be included in orders only where there are multiple products or when including the brand name otherwise assists in identifying a unique drug formulation.*

(continued on following page)

Table 4. ASCO/ONS Chemotherapy Administration Safety Standards (continued)

Standards

Complete orders must include:

- A. Patient's full name and a second patient identifier (eg, medical record number, DOB)
- B. Date
- C. Diagnosis
- D. Regimen name and cycle number
- E. Protocol name and number (if applicable)
- F. Appropriate criteria to treat (eg, based on relevant laboratory results and toxicities)
- G. Allergies
- H. Reference to the methodology of the dose calculation or standard practice equations (eg, calculation of creatinine clearance)
- I. Height, weight, and any other variables used to calculate the dose
- J. Dosage
Doses do not include trailing zeros; use a leading zero for doses < 1 mg.
- K. Route and rate (if applicable) of administration
- L. Schedule
- M. Duration
- N. Cumulative lifetime dose (if applicable)
- O. Supportive care treatments appropriate for the regimen (including premedications, hydration, growth factors, and hypersensitivity medications)
- P. Sequence of drug administration (if applicable)^{2,3,14,15,27,29}

Practices are not expected to be in full compliance with this standard if they currently have electronic ordering systems that prevent compliance. Appropriate changes should be implemented as soon as possible to ensure that electronic ordering systems integrate all of these elements. If the information cannot be captured in the electronic system, it should be documented within the patient record.*

- 11. Orders for parenteral/oral chemotherapy should be written with a time limitation to ensure appropriate evaluation at predetermined intervals.^{8,13}

Drug Preparation

- 12. A second person (a practitioner or other personnel approved by the practice to prepare or administer chemotherapy) independently verifies each order for chemotherapy before preparation, including confirming:
 - A. Two patient identifiers
 - B. Drug names
 - C. Drug dose
 - D. Drug volume
 - E. Rate of administration
 - F. Route of administration
 - G. The calculation for dosing (including the variables used in this calculation)^{2,3,10,28,29}
- 13. Chemotherapy drugs are labeled immediately upon preparation, including, at minimum:
 - A. Patient's full name and a second patient identifier (eg, medical record number, DOB)
 - B. Full generic drug name
 - C. Drug administration route
 - D. Total dose to be given
 - E. Total volume required to administer this dosage
 - F. Date of administration
 - G. Date and time of preparation and expiration^{3,35}

Practices are not expected to be in full compliance with this standard if they currently have electronic systems that are unable to meet these labeling requirements. Appropriate changes should be implemented as soon as possible to ensure that electronic labels integrate all of these elements.*

- 14. Practices that administer intrathecal medication maintain policies specifying that intrathecal medication will:
 - A. Not be prepared during preparation of any other agents
 - B. Be stored, once prepared, in an isolated container or location with a uniquely identifiable intrathecal medication label
 - C. Be delivered to the patient only with other medication intended for administration into the CNS³

Patient Consent and Education

- 15. Before initiation of chemotherapy, each patient is given written documentation, including, at minimum:
 - A. Information regarding his/her diagnosis
 - B. Goals of therapy
 - C. Planned duration of chemotherapy, drugs, and schedule
 - D. Information on possible short- and long-term adverse effects
 - E. Regimen- or drug-specific risks or symptoms that require notification and emergency contact information, including:
 - How to use practice call system
 - Symptoms that should trigger a call
 - Who should be called in specific circumstances (oncologist or other provider)
 - F. Plan for monitoring and follow-up^{1,3,18,19,28}

Patient education materials should be appropriate for the patient's reading level/literacy and patient/caregiver understanding.
- 16. Informed consent for chemotherapy must be documented by a physician in the practice prior to chemotherapy administration.^{2,3}
The consent process should follow appropriate professional and legal guidelines. (For more information and sample forms, see <http://www.asco.org/consent>.)
- 17. All patients who are prescribed oral chemotherapy are provided written or electronic patient education materials about the oral chemotherapy before or at the time of prescription.
 - A. Patient education includes the preparation, administration, and disposal of oral chemotherapy.
 - B. The education plan includes family, caregivers, or others based on the patient's ability to assume responsibility for managing therapy.^{1-3,18,23,24,28}

Patient education materials should be appropriate for the patient's reading level/literacy and patient/caregiver understanding.

(continued on following page)

Table 4. ASCO/ONS Chemotherapy Administration Safety Standards (continued)

Standards
Chemotherapy Administration 18. Before administration, at least two practitioners or personnel approved by the practice to prepare or administer chemotherapy: A. Verify patient identification using at least two identifiers (eg, medical record number, DOB) B. Confirm with the patient his/her planned treatment, drug route, and symptom management C. Verify the accuracy of: Drug name Drug dose Drug volume Rate of administration Route of administration Expiration dates/times Appearance and physical integrity of the drugs D. Sign (in record or electronically) to indicate verification was done^{2,8,27} 19. Extravasation management procedures are defined; antidote order sets and antidotes are accessible.^{2,28} 20. A licensed independent practitioner is on site and immediately available during all chemotherapy administration.¹⁻³ Monitoring and Assessment 21. Practice maintains protocols for response to life-threatening emergencies, including escalation of patient support beyond basic life support.^{1,29} <i>It is recommended that emergency protocols are reviewed annually.</i> 22. On each clinical visit during chemotherapy administration, practice staff assess and document in the medical record: A. Changes in clinical status, weight B. Changes in performance status C. Allergies, previous reactions, and treatment-related toxicities D. Patient psychosocial concerns and need for support²⁹ <i>This standard applies to all clinical encounters (practitioner visits and chemotherapy administration visits, but not laboratory or administrative visits).</i> 23. At each clinical visit during chemotherapy administration, practice staff assess and document the patient's current medications, including over-the-counter medications and complementary and alternative therapies. Any changes in the patient's medications are reviewed by a practitioner during the same visit.²⁹ <i>This standard applies to all clinical encounters (practitioner visits and chemotherapy administration visits, but not laboratory or administrative visits).</i> 24. The practice maintains a referral list for psychosocial and other supportive care services.^{2,30} 25. The practice establishes a procedure for documentation and follow-up for patients who miss office visits and treatments.^{17,36} 26. The practice evaluates and documents treatment-related toxicities using standard definitions or criteria selected by that practice.^{28,31} <i>Examples include NCI Common Toxicity Criteria and WHO Toxicity Criteria.</i> 27. The practice has policies and procedures that identify: A. A process to provide 24/7 triage to a practitioner (eg, on-call practitioner, emergency department) for care of toxicities B. Consistent documentation and communication of toxicity across sites of care within the practice (if applicable)^{16,27} 28. Toxicity assessment documentation is available for planning subsequent treatment cycles.¹⁰ 29. The practice has a process to track cumulative doses of chemotherapy agents associated with a risk of cumulative toxicity.¹³ 30. The practice uses standard, disease-specific processes to monitor treatment response (eg, use of evaluations, laboratory results, or scans/imaging) that are based on published literature/guidelines or are determined by the practice.^{1,16} 31. 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.^{27,29} NOTE. Explanatory notes or examples are provided in italics, when applicable. Disclaimer: these standards related to patient safety for chemotherapy administration in the ambulatory/outpatient setting were developed jointly by ONS and ASCO using a consensus process. The standards are intended to reflect current thinking on best practices but are not comprehensive and do not account for individual patient variation. It is the responsibility of each administering agent to determine the best methods for chemotherapy administration for each patient. The standards are not medical advice or legal advice. To the extent that the standards conflict with applicable federal, state, or local legal requirements, practitioners should comply with those requirements. The administering agent is solely responsible for, and assumes all risks of, administering chemotherapy drugs notwithstanding any adherence to the standards herein. ASCO and ONS disclaim any and all liability with respect to the standards and the execution of the standards by any party. Abbreviations: ASCO, American Society of Clinical Oncology; ONS, Oncology Nursing Society; IRB, institutional review board; NCCN, National Comprehensive Cancer Network; DOB, date of birth; NCI, National Cancer Institute. *Implementation exception.

We suggest that medical oncology practice staff assess their own compliance with each of the standards. For areas requiring improvement, practice members should prioritize time and resources and set achievable goals. To help practices rapidly comply with the standards, ASCO and ONS will provide tools and resources to assist in practice implementation (<http://www.asco.org/safety> and <http://www.ons.org/clinical/>). Once compliance has been maximized, practices should create a mechanism for periodic surveillance.

Regulators, payers, and patient advocacy groups have growing influence on the provision of cancer care. Oncology specialty societies are well positioned to respond to these groups by defining and disseminating best practices and standards of care, helping to create an environment of transparency, and creating tools for measuring the components of care. The ASCO/ONS chemotherapy administration safety standards are the result of a successful collaboration led by oncology providers, with broad input from diverse stakeholders. Regular review of these standards will be needed as the practice of medical oncology continues to evolve rapidly.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

Conception and design: Joseph O. Jacobson, Martha Polovich, Kristen K. McNiff, Kristine B. LeFebvre, Charmaine Cummings, Michele Galioto, Katherine R. Bonelli, Michele R. McCorkle

Administrative support: Kristen K. McNiff, Charmaine Cummings, Katherine R. Bonelli

Collection and assembly of data: Kristen K. McNiff, Kristine B.

LeFebvre, Charmaine Cummings, Michele Galioto, Katherine R. Bonelli

Data analysis and interpretation: Martha Polovich, Kristen K. McNiff, Kristine B. LeFebvre, Charmaine Cummings, Michele Galioto, Katherine R. Bonelli

Manuscript writing: Joseph O. Jacobson, Martha Polovich, Kristen K. McNiff, Kristine B. LeFebvre, Charmaine Cummings, Michele Galioto

Final approval of manuscript: Joseph O. Jacobson, Martha Polovich, Kristen K. McNiff, Kristine B. LeFebvre, Charmaine Cummings, Michele Galioto, Michele R. McCorkle

REFERENCES

1. American Society of Clinical Oncology: Criteria for facilities and personnel for the administration of parenteral systemic antineoplastic therapy. *J Clin Oncol* 22:4613-4615, 2004
2. Polovich M, White JM, Olsen M (eds): *Chemotherapy and Biotherapy Guidelines and Recommendations for Practice* (ed 3). Pittsburgh, PA, Oncology Nursing Society, 2009
3. American Society of Health-System Pharmacists: ASHP guidelines on preventing medication errors with antineoplastic agents. *Am J Health Syst Pharm* 59:1648-1668, 2002
4. Clinical Oncological Society of Australia: Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy. <http://www.cosa.org.au/File/Members%20Area/Projects/Reports/Guidelines%20for%20Chemo%20book.pdf>
5. Bonnabry P, Cingria L, Ackermann M, et al: Use of a prospective risk analysis method to improve the safety of the cancer chemotherapy process. *Int J Qual Health Care* 18:9-16, 2006
6. Ford CD, Killebrew J, Fugitt P, et al: Study of medication errors on a community hospital oncology ward. *J Oncol Pract* 2:149-154, 2006
7. Womer RW, Tracy E, Soo-Hoo W, et al: Multidisciplinary systems approach to chemotherapy safety: Rebuilding processes and holding the gains. *J Clin Oncol* 20:4705-4712, 2002
8. Schulmeister L: Preventing chemotherapy errors. *Oncologist* 11:463-468, 2006
9. Schulmeister L: Ten simple strategies to prevent chemotherapy errors. *Clin J Oncol Nurs* 9:201-205, 2005
10. Walsh KE, Dodd KS, Seetharaman K, et al: Medication errors among young adults and children with cancer in the outpatient setting. *J Clin Oncol* 27:891-896, 2009
11. Gandhi TK, Bartel SB, Shulman LN, et al: Medication safety in the ambulatory chemotherapy setting. *Cancer* 104:2477-2483, 2005
12. Goldspiel BR, DeChristoforo R, Daniels CE: A continuous-improvement approach for reducing the number of chemotherapy-related medication errors. *Am J Health Syst Pharm* 57:S4-S9, 2000 (suppl 4)

13. Fischer DS, Alfano S, Knobf MT, et al: Improving the cancer chemotherapy use process. *J Clin Oncol* 14:3148-3155, 1996
14. Shulman LN, Miller RS, Ambinder EP, et al: Principles of safe practice using an oncology EHR system for chemotherapy ordering, preparation, and administration, part 1 of 2. *J Oncol Pract* 4:203-206, 2008
15. Shulman LN, Miller RS, Ambinder EP, et al: Principles of safe practice using an oncology EHR system for chemotherapy ordering, preparation, and administration, part 2 of 2. *J Oncol Pract* 4:254-257, 2008
16. Weingart SN, Brown E, Bach PB, et al: NCCN Task Force Report: Oral chemotherapy. *J Natl Compr Canc Netw* 6:S1-S14, 2008 (suppl 3)
17. Patton J: Increased use of oral chemotherapy drugs spurs increased attention to patient compliance. *J Oncol Pract* 4:175-177, 2008
18. Hartigan K: Patient education: The cornerstone of successful oral chemotherapy treatment. *Clin J Oncol Nurs* 7:21-24, 2003
19. Moore S: Facilitating oral chemotherapy treatment and compliance through patient/family-focused education. *Cancer Nurs* 30:112-122, 2007
20. Hollywood E, Semple D: Nursing strategies for patients on oral chemotherapy. *Oncology* 15:37-40, 2001
21. Lee CR, Nicholson PW, Souhami RL, et al: Patient compliance with oral chemotherapy as assessed by a novel electronic technique. *J Clin Oncol* 10:1007-1013, 1992
22. American Society of Health-System Pharmacists: ASHP guidelines on handling hazardous drugs. *Am J Health Syst Pharm* 63:1172-1193, 2006
23. Birner AM, Bedell MK, Avery JT, et al: Program to support safe administration of oral chemotherapy. *J Oncol Pract* 2:5-6, 2006
24. Birner AM: Safe administration of oral chemotherapy. *Clin J Oncol Nurs* 7:158-162, 2003
25. Oncology Nursing Society: ONS Position Statement: Education of the RN Who Administers and Cares for the Individual Receiving Chemotherapy and Biotherapy, 2007. <http://www.ons.org/publications/positions/EducationOfProfessionalRN.shtml>
26. US Department of Labor Occupational Safety & Health Administration: OSHA Technical Manual:

Controlling Occupational Exposure to Hazardous Drugs. Section VI: Chapter 2. http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html

27. The Joint Commission: National Patient Safety Goals: Disease Specific Care, 2009. http://www.jointcommission.org/NR/rdonlyres/74937937-7B39-447A-AA6F-AFD8BAEE1410/0/DSC_NPSG.pdf

28. Langhorne M, Fulton J, Otto S: *Oncology Nursing* (ed 4). St Louis, MO, Mosby Elsevier, 2007

29. National Quality Forum: Safe practices for better healthcare 2006 update. <http://psnet.ahrq.gov/resource.aspx?resourceID=1588>

30. Institute of Medicine, National Research Council: *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*. Washington, DC, National Academies Press, 2007

31. Perry M: *The Chemotherapy Source Book* (ed 4). Philadelphia, PA, Lippincott Williams & Wilkins, 2008

32. Weingart SN, Brown E, Bach PB, et al: NCCN Task Force Report: Oral chemotherapy. *J Natl Compr Canc Netw* 6:S1-S14, 2008 (suppl 3)

33. Storm C, Casillas J, Grunwald H, et al: Informed consent for chemotherapy: ASCO member resources. *J Oncol Pract* 4:289-295, 2008

34. American Society of Clinical Oncology: Statement regarding the use of outside services to prepare or administer chemotherapy drugs, 2004. <http://www.asco.org/ASCO/Downloads/OutsourcingChemotherapyDrugs.pdf>

35. The Institute for Safe Medication Practices: Principals of designing a medication label for community and mail order pharmacy prescription packages draft document, 2009. <http://www.ismp.org/Tools/guidelines/labelFormats/comments/default.asp>

36. Partridge AH, Avorn J, Wang PS, et al: Adherence to therapy with oral antineoplastic agents. *J Natl Cancer Inst* 94:652-661, 2002

37. James BC: Intermountain Advanced Training Program in Healthcare Delivery Improvement. Salt Lake City, UT, 2008. <http://intermountainhealthcare.org/about/quality/institute/trainingprograms/Pages/home.aspx>

38. Pronovost P, Needham D, Berenholtz S, et al: An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 355:2725-2732, 2006