

2016 Updated American Society of Clinical Oncology/ Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology

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Purpose: To update the American Society of Clinical Oncology (ASCO)/Oncology Nursing Society (ONS) Chemotherapy Administration Safety Standards and to highlight standards for pediatric oncology.

Methods: The ASCO/ONS Chemotherapy Administration Safety Standards were first published in 2009 and updated in 2011 to include inpatient settings. A subsequent 2013 revision expanded the standards to include the safe administration and management of oral chemotherapy. A joint ASCO/ONS workshop with stakeholder participation, including that of the Association of Pediatric Hematology Oncology Nurses and American Society of Pediatric Hematology/Oncology, was held on May 12, 2015, to review the 2013 standards. An extensive literature search was subsequently conducted, and public comments on the revised draft standards were solicited.

Results: The updated 2016 standards presented here include clarification and expansion of existing standards to include pediatric oncology and to introduce new standards: most notably, two-person verification of chemotherapy preparation processes, administration of vinca alkaloids via minibags in facilities in which intrathecal medications are administered, and labeling of medications dispensed from the health care setting to be taken by the patient at home. The standards were reordered and renumbered to align with the sequential processes of chemotherapy prescription, preparation, and administration. Several standards were separated into their respective components for clarity and to facilitate measurement of adherence to a standard.

Conclusion: As oncology practice has changed, so have chemotherapy administration safety standards. Advances in technology, cancer treatment, and education and training have prompted the need for periodic review and revision of the standards. Additional information is available at <http://www.asco.org/chemo-standards>.

Introduction

As oncology providers continue to try to improve, the Oncology Nursing Society (ONS) and the American Society of Clinical Oncology (ASCO) have aspired to provide standards to minimize the risk of errors in chemotherapy ordering, preparation, and administration, including both oral¹ and parenteral therapy, in both the outpatient² and inpatient³ settings. This paper updates previous ASCO/ONS Chemotherapy Administration Safety Standards.

Betsy Lehman, an award winning health journalist, died on December 3, 1994, after receiving an inappropriately high dose of cyclophosphamide chemotherapy for breast cancer.⁴ As her mother later said in the foreword to *The Patient Safety Handbook*, “this aggrieved mother sees in the grim national numbers the sweet young face of a beautiful and talented daughter who left behind two children suddenly bereft.”⁵ Medication errors account for half of the preventable

errors that occur in up to one in four patients who are hospitalized.⁶ Prompted by the tragedy of Ms. Lehman's death, oncology health care providers have been systematically working to improve the safety of chemotherapy administration since at least 1995.⁷

In December 2015, a 49-year-old man died as a result of a chemotherapy overdose, two decades after attention was first focused on chemotherapy administration safety initiatives.⁸ Despite significant effort and intention, errors in the course of chemotherapy administration remain problematic. In a survey, 63% of nurses who administer parenteral chemotherapy reported personal knowledge of medication errors. Of 140 total errors described, medication errors fell into such categories as underdosing and overdosing, schedule and timing errors, administration of incorrect drugs, infusion rate errors, omission of drugs or hydration, improper preparation of drugs, and chemotherapy administered to the wrong patients. Stress, understaffing, lack of experience, and unclear orders were cited as factors believed to contribute to the occurrence of errors.⁹

As chemotherapy-related errors are intercepted at rates of approximately 2%–5%,^{10–12} it is important to note that some types of errors are virtually undiscoverable without continuous monitoring of the preparation process. For example, a person who prepares drugs may select from the wrong drug supply and accidentally substitute one drug vial for another. Similarly, during batch preparation, labels can be incorrectly applied to containers of prepared doses.¹³

This update of the ASCO/ONS Chemotherapy Administration Standards began with a formal systematic literature review. For the first time, the standards were expanded to specifically address chemotherapy safety for pediatric patients. In addition, the standards have been modified in two ways for this revision. First, to add clarity, each standard has been written to cover a single principle. In earlier versions, several ideas were grouped into a single standard. Second, the standards now begin with a set of global standards for health care settings and are organized sequentially to align with the chemotherapy planning and delivery process. The current standards are divided into four sections: General principles, such as drug storage, facility personnel training, continuing education, and universal policies; as well as chemotherapy specific sections that discuss planning and choosing the appropriate treatment, medication preparation and administration, and subsequent monitoring. As with previous versions, the authors intend for the standards to be used by oncology providers to conduct self-assessments and to inform improvement efforts. In addition, we have supported the adoption of the standards for third-party safety assessments,

including by the ASCO Quality Oncology Practice Initiative Certification Program.

Methods

The 2016 standards update was led by a working group from ASCO and ONS, and members with expertise in pediatric hematology and oncology were added. Representatives from the American Society of Pediatric Hematology/Oncology and the Association of Pediatric Hematology Oncology Nurses participated in the revision process.

A formal systematic review of the literature was performed by using MEDLINE. More information about the search is given in the Data Supplement. Working group members reviewed the literature and applied the following inclusion and exclusion criteria: Interventional trials of sequential rates of administration error were given first priority—that is, any reports of a series of events, including identification of errors before and after a change in practice, were included; case series that examined errors were included if they originated in settings in developed countries with more than 50 patient treatments per month—U.S., Canadian, European, and Australian trials were given priority; and single case reports were included if a life-threatening event occurred and the authors demonstrated that a clear cause-and-effect relationship existed. Ninety-seven articles informed this standards update.

Information from the literature review was discussed at a stakeholders' meeting in Alexandria, VA, on May 12, 2015. In addition, the group reviewed summary data regarding implementation. A list of workshop participants is listed in Appendix Table A1. At that meeting, the existing standards were reviewed and evaluated for their applicability to chemotherapy safety in pediatric patients. During this process, the standards were reorganized to reduce redundancy, and an effort was made to separate the standards to have one directive per standard. For example, previous standards included psychosocial concerns with clinical visit assessments, such as vital signs and allergies. In the updated standards, we have separated the psychosocial assessment to be independent from these clinical assessment activities.

A public comment period was conducted using the Zarca Web-based survey tool during a six-week period from December 1, 2015, to January 19, 2016. The sponsoring organizations and workshop participants solicited comments from members. A crosswalk between the current standards and the revised standards was provided to facilitate the process. Contributors were asked to respond to the applicability of each standard to all patient ages and care settings as well as the

potential for each standard to improve patient safety. In addition, responders were asked to provide specific comments about the standards. All public comments were reviewed by the working group and were used to edit, revise, and clarify the standards. Final standards were approved by the ASCO and ONS boards of directors in early 2016.

Results

These 2016 updated standards are presented within a new organizational framework. There were 37 responses to the request for public comments, some of which represented groups of individuals. The majority of respondents were nurses, including clinical nurse specialists, a nurse manager, and an administrator; five physicians provided comments.

Section 1 discusses the environment and routine procedures. The standards discuss both the need to have the right individuals present when treatment is administered and stipulate that their training be sufficient and periodically refreshed for the task at hand. This section also discusses elements for evaluation at a patient's presentation for chemotherapy administration as well as communication to others involved in a patient's care.

Section 2 addresses treatment planning and patient education before the start of treatment. A patient and/or his or her family or surrogate decision makers, including guardians, should be fully informed regarding the goals of treatment, likely results, frequent adverse effects, and potential rare, but more significant, toxicities.

Section 3 details specific standards for ordering, preparing (including labeling), and administering chemotherapy. The importance of independent verification of orders both in drug preparation and administration is noted. Special attention is paid to intravenous drugs, which are fatal if administered via the intrathecal route.

Finally, section 4 discusses monitoring adherence to, and toxicity from, chemotherapy to promote safety both while on treatment and subsequent to therapy.

Pertinent references, for example, review articles and significant studies, were cited to support inclusion of the new or significantly revised standards. Terms within the standards that are highlighted in bold have been defined in the accompanying glossary (see Appendix Table A2).

Standards

Domain 1: Creating a Safe Environment—Staffing and General Policy

1.1 The **health care setting** has **policy** to document the qualifications of **clinical staff** who order, prepare,¹⁴ and administer **chemotherapy**¹⁵⁻²¹ and documents:

- 1.1.1 Description of initial educational requirements and competencies.
- 1.1.2 Description of (at least) annual ongoing continuing education requirements.
- 1.1.3 Description of credentialing processes (licensed independent practitioners) and how credentialing is documented.
- 1.1.4 Description of competency demonstration and how competency is documented.
- 1.2 The health care setting uses a **comprehensive education program** for initial and ongoing educational requirements for all staff who prepare and administer chemotherapy.
- 1.3 At least one clinical staff member who maintains current certification in (age appropriate) **basic life support** is present during chemotherapy administration.
- 1.4 A licensed independent **practitioner** is **on-site and immediately available** to staff who administer chemotherapy in the health care setting.
- 1.5 Before the first administration of a new **chemotherapy regimen**, chart documentation is available that includes at least the following eight elements:
 - 1.5.1 Pathologic confirmation or verification of initial diagnosis.
 - 1.5.2 Initial **cancer stage**, or current **cancer status**.
 - 1.5.3 Complete **medical history and physical** examination, including pregnancy status, as applicable.
 - 1.5.4 Presence or absence of allergies and history of **hypersensitivity reactions**.
 - 1.5.5 Assessment of the **patient's** and/or caregiver's comprehension of information regarding the disease and treatment plan.
 - 1.5.6 Initial **psychosocial assessment**, with action taken when indicated.
 - 1.5.7 The **chemotherapy treatment plan**, including, at a minimum, the patient diagnosis, drugs, **doses**, duration of treatment, and goals of therapy.²²
 - 1.5.8 Planned frequency of office visits and patient monitoring that is appropriate for the individual chemotherapy agent(s).
- 1.6 On each **clinical encounter** or day of treatment, staff performs and documents a patient assessment that includes at least the following eight elements, and takes appropriate action:
 - 1.6.1 Functional status and/or performance status.
 - 1.6.2 Vital signs.
 - 1.6.3 Weight is measured at least weekly when present in the health care setting.
 - 1.6.4 Height is measured at least weekly when present in the health care setting and when appropriate to the treatment population.
 - 1.6.5 Age as appropriate to the treatment population.
 - 1.6.6 Allergies and previous treatment-related reactions.
 - 1.6.7 Treatment toxicities.
 - 1.6.8 Pain assessment.
- 1.7 Staff assesses and documents psychosocial concerns and need for support with each cycle or more frequently, with action taken when indicated.

- 1.8 The health care setting provides information and financial resources and/or refers patients to psychosocial and other **cancer support services**.
- 1.9 The patient's medications are updated at every visit and reviewed by a practitioner when a change occurs.²³
- 1.10 The health care setting has policy for documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments.
- 1.10.1 The health care setting has policy that addresses mandates and processes for pediatric patients that account for legal requirements.
- 1.11 The health care setting has policy that identifies a process to provide 24/7 triage to a practitioner, for example, on-call practitioners or emergency department, to manage treatment-related toxicities and emergencies. If the patient's initial contact is not a practitioner from the treating health care setting, the person having initial patient contact must have continuous access to consultation from an experienced oncology practitioner and the opportunity for transfer of the patient to a facility with dedicated oncology services.
- 1.12 The health care setting has policy for standardized documentation and communication of toxicities, modifications²⁴ in dose or schedule, or discontinuation of treatment.
- 1.13 The health care setting has standardized and clearly defined systems in place to promote a safe **handoff** between all sites of care, including provision of timely, accurate information about a patient's care plan, treatment including schedule for chemotherapy administration, safety concerns including critical laboratory values, current condition, and any recent or anticipated changes.
- 1.14 The health care setting has policy for reporting of adverse events and near misses and has a formal process for collecting and evaluating data at a defined frequency.^{11,13,25,26}

Domain 2: Treatment Planning, Patient Consent, and Education

- 2.1 The health care setting has policy that documents a standardized process for obtaining and documenting chemotherapy **consent** or **assent**.²⁷
- 2.2 Informed consent and assent (optional) for chemotherapy treatment, as appropriate to the treatment population, is documented before initiation of a chemotherapy regimen.
- 2.3 Patients are provided with verbal and written or electronic information as part of an education process before the first administration of treatment of each treatment plan. The content of this educational material will be documented. Educational information includes the following at a minimum:²⁸
 - 2.3.1 Patient's diagnosis.
 - 2.3.2 Goals of treatment, that is, cure disease, prolong life, or reduce symptoms.
 - 2.3.3 Planned duration of treatment, schedule of treatment administration, drug names and supportive medications, drug-drug and drug-food interactions, and plan for missed doses.²⁹

- 2.3.4 Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients.
- 2.3.5 Symptoms or adverse effects that require the patient to contact the health care setting or to seek immediate attention.
- 2.3.6 Symptoms or events that require immediate discontinuation of oral or other self-administered treatments.³⁰
- 2.3.7 Procedures for handling medications in the home, including storage, safe handling, and management of unused medication.
- 2.3.8 Procedures for handling body secretions and waste in the home.
- 2.3.9 Follow-up plans, including laboratory and **provider** visits.
- 2.3.10 Contact information for the health care setting, with availability and instructions on when and who to call.
- 2.3.11 The missed appointment policy of the health care setting and expectations for rescheduling or cancelling.
- 2.4 Education includes family, caregivers, or others on the basis of the patient's ability to assume responsibility for managing therapy. Educational activities will be performed on the basis of the patient's learning needs, abilities, preferences, and readiness to learn.

Domain 3: Ordering, Preparing, Dispensing, and Administering Chemotherapy

- 3.1 The health care setting defines standard chemotherapy regimens by diagnosis with references.^{31,32}
- 3.2 The health care setting verifies institutional review board approval of research regimens.³³
- 3.3 **Orders** for chemotherapy are signed manually or by using electronic approval by licensed independent practitioners who are determined to be qualified by the health care setting.
- 3.4 The health care setting has policy for managing chemotherapy orders that vary from standard regimens. The policy requires a supporting reference and/or authorization by a second licensed independent practitioner.
 - 3.4.1 The rationale for an **exception order** is documented in the medical record.
- 3.5 The health care setting has policy for chemotherapy orders that ensure:
 - 3.5.1 Verbal orders are not allowed except to hold or stop chemotherapy administration.
 - 3.5.2 New orders or changes to orders, including changes to oral chemotherapy regimens, for example, dose adjustments communicated directly to patients, are documented in the medical record.
- 3.6 The health care setting uses standardized, regimen-level, preprinted or electronic forms for parenteral chemotherapy.³⁴⁻³⁷
- 3.7 Chemotherapy orders include at least the following elements:
 - 3.7.1 The patient's name.

| | | | |
|---------|--|----------|---|
| 3.7.2 | A second patient identifier . | | |
| 3.7.3 | The date the order is written. | | |
| 3.7.4 | Regimen or protocol name and number. | | |
| 3.7.5 | Cycle number and day, when applicable. | | |
| 3.7.6 | All medications within the order set are listed by using full generic names. | | |
| 3.7.7 | Drug dose is written following standards for abbreviations, trailing zeros, and leading zeros. | | |
| 3.7.8 | The dose calculation, including: | | |
| 3.7.8.1 | The calculation methodology. | | |
| 3.7.8.2 | The variables used to calculate the dose. | | |
| 3.7.8.3 | The frequency at which the variables are re-evaluated. | | |
| 3.7.8.4 | The changes in the values that prompt confirmation of dosing. | | |
| 3.7.9 | Date of administration. | | |
| 3.7.10 | Route of administration. | | |
| 3.7.11 | Allergies. | | |
| 3.7.12 | Supportive care treatments that are appropriate for the regimen, including premedications, hydration, growth factors, and hypersensitivity medications. | | |
| 3.7.13 | Parameters that would require holding or modifying the dose, for example, laboratory values, diagnostic test results, and patient's clinical status. | | |
| 3.7.14 | Sequencing of drug administration, when applicable. | | |
| 3.7.15 | Rate of drug administration, when applicable. | | |
| 3.7.16 | An explanation of time limitation, such as the number of cycles for which the order is valid. | | |
| 3.8 | Prescriptions for oral chemotherapy, whether to be dispensed by the health care setting or another facility, include the following elements: ³⁸ | | |
| 3.8.1 | The patient's name. | | |
| 3.8.2 | A second patient identifier. | | |
| 3.8.3 | Full generic drug name. | | |
| 3.8.4 | The date of order. | | |
| 3.8.5 | Drug dose, following standards for abbreviations, symbols, and dose designations. | | |
| 3.8.6 | Includes calculation methodology. | | |
| 3.8.7 | Route of administration, special instructions if applicable. | | |
| 3.8.8 | Drug quantity to be dispensed. | | |
| 3.8.9 | Schedule of administration. | | |
| 3.8.10 | Duration of therapy and an explanation of time limitation, such as number of cycles. | | |
| 3.8.11 | Number of refills, with zero being the acceptable default value. | | |
| 3.9 | Chemotherapy is prepared by a licensed pharmacist, pharmacy technician, physician, or registered nurse with documented chemotherapy preparation education, training, and annual competency validation. | | |
| 3.10 | A licensed pharmacist verifies all orders before administration or dispensing of chemotherapy in health care setting that treats pediatric patients under the age of 18 years. | | |
| 3.11 | A second person—a practitioner or other personnel approved by the health care setting to prepare or | | |
| | | | administer chemotherapy—performs three independent verifications : ³⁹ |
| | | 3.11.1 | Before preparation, a second person—a practitioner or other personnel approved by the health care setting to prepare or administer chemotherapy—independently verifies: |
| | | 3.11.1.1 | Two patient identifiers. |
| | | 3.11.1.2 | Drug name. |
| | | 3.11.1.3 | Drug dose. |
| | | 3.11.1.4 | Route of administration. |
| | | 3.11.1.5 | Rate of administration |
| | | 3.11.1.6 | The calculation for dosing, including the variables used in this calculation. |
| | | 3.11.1.7 | Treatment cycle and day of cycle. |
| | | 3.11.2 | Upon preparation, a second person approved by the health care setting to prepare parenteral chemotherapy verifies: |
| | | 3.11.2.1 | The drug vial(s). |
| | | 3.11.2.2 | Concentration. |
| | | 3.11.2.3 | Drug volume or weight. |
| | | 3.11.2.4 | Diluent type and volume, when applicable. |
| | | 3.11.2.5 | Administration fluid type, volume, and tubing. |
| | | 3.11.3 | Before each chemotherapy administration, at least two practitioners approved by the health care setting to administer or prepare chemotherapy verify and document the accuracy of the following elements: |
| | | 3.11.3.1 | Drug name. |
| | | 3.11.3.2 | Drug dose. |
| | | 3.11.3.3 | Infusion volume or drug volume when prepared in a syringe. |
| | | 3.11.3.4 | Rate of administration. |
| | | 3.11.3.5 | Route of administration. |
| | | 3.11.3.6 | Expiration dates and/or times. |
| | | 3.11.3.7 | Appearance and physical integrity of the drugs. |
| | | 3.11.3.8 | Rate set on infusion pump, when used. |
| | | 3.12 | Chemotherapy drugs are labeled immediately upon preparation, and labels include the following 10 elements at a minimum: ⁴⁰ |
| | | 3.12.1 | Patient's name. |
| | | 3.12.2 | A second patient identifier. |
| | | 3.12.3 | Full generic drug name. |
| | | 3.12.4 | Drug dose. |
| | | 3.12.5 | Drug administration route. |
| | | 3.12.6 | Total volume required to administer the drug. |
| | | 3.12.7 | Date the medication is to be administered. |
| | | 3.12.8 | Expiration dates and/or times. |
| | | 3.12.9 | Sequencing of drug administration, when applicable, and total number of products to be given when medication is provided in divided doses—each product should be labeled with the total number of products to be administered and the individual products sequence within that total grouping, for example, one of five, two of two, etc. |
| | | 3.12.10 | A warning or precautionary label or sticker, as applicable, to storage and handling; may be included within the label or on an auxiliary label. |

- 3.13 Labels for medications dispensed from health care setting to be taken at home include:
 - 3.13.1 Patient's name.
 - 3.13.2 A second patient identifier.
 - 3.13.3 Date of preparation and expiration.
 - 3.13.4 Full generic drug name.
 - 3.13.5 **Dosage** form and strength.
 - 3.13.6 Quantity dispensed within each container.
 - 3.13.7 Number of pills per dose when the container holds more than one dose.
 - 3.13.8 Administration schedule, including number of times per day and days on and off treatment, when applicable.
 - 3.13.9 Administration instructions related to food ingestion and other medications.
 - 3.13.10 A warning or precaution statement, as applicable, to storage and handling.
 - 3.13.11 Caution statement label attached to the prepared product, for example, "Caution: chemotherapy" or "HAZARDOUS DRUG."
 - 3.13.12 Storage conditions.
 - 3.13.13 Prescriber name.
- 3.14 The health care setting that administers intrathecal medication maintains policy that specifies that intrathecal medication is:⁴¹
 - 3.14.1 Prepared separately.
 - 3.14.2 Stored in an isolated container or location after preparation.
 - 3.14.3 Labeled with a uniquely identifiable intrathecal medication label.
 - 3.14.4 Delivered to the patient only with other medication intended for administration into the CNS.
 - 3.14.5 Administered immediately after a time-out, double-check procedure that involves two licensed practitioners or other personnel approved by the health care setting to prepare or administer chemotherapy.
- 3.15 The health care setting that administers intrathecal chemotherapy has policy that specifies that intravenous vinca alkaloids are administered only by infusion, for example, mini-bags.
- 3.16 If the health care setting administers chemotherapy that is prepared (mixed) off site, the health care setting maintains policy for quality control of that chemotherapy, including documentation that the offsite pharmacy complies with all applicable regulatory requirements.
- 3.17 If a health care setting maintains its own pharmacy, there is policy regarding the safe storage of chemotherapy, including separation of look-alike products, sound-a-like products, and investigational and agents available in multiple strengths.
- 3.18 Chemotherapy is administered by a qualified physician, physician assistant, registered nurse, or advanced practice nurse as defined in standard 1.1.
- 3.19 Before initiation of each chemotherapy administration cycle, the practitioner who is administering the chemotherapy confirms the treatment with the patient, including, at a minimum, the name of the

drug, infusion time, route of administration, and infusion-related symptoms to report—for example, but not limited to, hypersensitivity symptoms or pain during infusion.

- 3.20 At least two individuals, in the presence of the patient, verify the patient identification by using at least two identifiers.
 - 3.20.1 When chemotherapy is administered in a non-health care setting by a health care provider, a second identifier, such as a driver's license, is used to verify the patient's or parent's identify.
- 3.21 Documentation of chemotherapy administration confirms the verification of the eight elements of standard 3.11.3 and also includes the patient's clinical status during and upon completion of treatment.
- 3.22 Extravasation management procedures are defined and align with current literature and guidelines; antidote order sets and antidotes are accessible within the appropriate timeframe.

Domain 4: Monitoring After Chemotherapy is Administered, Including Adherence, Toxicity and Complications

- 4.1 The health care setting uses standard, disease-specific processes to monitor treatment response and has policy that determines the appropriate time interval for regimen-specific laboratory and organ function tests that are based on evidence and national guidelines when available.
- 4.2 The health care setting has policy for emergent treatment of patients that aligns with current literature and guidelines and addresses:
 - 4.2.1 Availability of appropriate treatment agents.
 - 4.2.2 Procedures to follow and a plan for escalation of care, when required, for life-threatening emergencies.⁴²
- 4.3 The health care setting policy outlines the procedure to monitor an initial assessment of patients' **adherence** to chemotherapy that is administered outside of the health care setting.³⁰
- 4.4 The health care setting has a policy that requires assessment of each patient's ongoing chemotherapy adherence and toxicity at each clinical encounter to address any issues identified.
- 4.5 The health care setting has policy that requires evaluation and documentation of treatment-related toxicities, dose modification related to toxicities, and how these are communicated before subsequent administration.
- 4.6 Cumulative doses of chemotherapy are tracked for agents associated with cumulative toxicity.

Discussion and Conclusion

The need for chemotherapy administration safety standards was first identified in the early- to mid-2000s. At that time, chemotherapy was commonly administered in private practices or community hospital

infusion rooms. Orders for parenteral chemotherapy were usually handwritten or written on preprinted paper order forms. Although chemotherapy dose-checking software was available and used in some facilities, chemotherapy orders were typically checked manually and entered into a generic electronic pharmacy system in facilities in which electronic systems were used. Chemotherapy was frequently prepared by registered nurses; in a 2006 survey, 115 (35%) of 330 registered nurses and 93% of nurses in private practice settings reported preparing chemotherapy.¹⁷ Chemotherapy preparation and administration training was facility specific, and ongoing competency assessments were rarely documented. Vinca alkaloids were usually prepared in syringes and administered by using an intravenous bolus technique, even in facilities in which intrathecal medications were administered. Patient identification procedures also were facility specific and, in many settings, consisted solely of verbal confirmation of the patient's name. Identification bands were infrequently used, especially in private practice settings. Verification of prepared chemotherapy and infusion pump programming was performed by the registered nurse who administered the chemotherapy, and chemotherapy administration was documented on a flowsheet in a paper chart. In most facilities, patients were passively engaged in the chemotherapy administration process and toxicity assessments required in-person clinic or office visits.

Over the past decade, private oncology practices have increasingly merged with, or become acquired by, other entities—for example, practice networks, hospitals, academic centers, etc. Cancer treatment has changed with the introduction of targeted and oral agents. Integrated oncology-focused electronic health record systems have increasingly been used. Whereas chemotherapy is still prepared by registered nurses in some settings, specially trained pharmacy staff prepare the majority of chemotherapy. Technology innovations, including remote camera dose verification and bar coding, have enhanced and streamlined chemotherapy preparation and verification procedures. Online training programs on chemotherapy preparation—for example, ASHP and others—and administration—for example, ONS and/or Association of Pediatric Hematology Oncology Nurses—provide standardized didactic education and are followed by documented competency assessments. Vinca alkaloids are administered in minibags in facilities in which intrathecal medications are administered to avoid inadvertent intrathecal administration. Patient identification procedures include verification of two identifiers and, increasingly, bar-coded armbands and biometric identifiers, for example, fingerprints, facial recognition, etc. Chemotherapy and

infusion pump rate setting verification procedures mandate independent checks by two individuals, and computers-on-wheels provide chair-side access to the patient's electronic health record. Patients are actively engaged in their care and are educated about self-assessment and monitoring. Most patients have access to, and contribute to, their health records via patient portals. Many patients conduct their own toxicity assessments and transmit data to health care providers electronically, for example, e-mail or photographs. Consequently, as chemotherapy ordering, preparation, and administration have changed, so have the standards. The evolution of oncology care has been the driving force behind the periodic updating and revisions to the standards.

The standards represent minimum expectations for ordering, preparing, and administering chemotherapy. They may be implemented in a variety of settings—for example, inpatient or outpatient—and across treatment populations, including pediatric oncology. The standards were created with applicability in mind; in other words, the standards needed to be as applicable to the small practice setting as they are to a comprehensive cancer center.

The standards may be used in a variety of ways. They can guide day-to-day practice, evaluate care delivery, and support the revision of institutional policies and procedures. Some of the standards are used as ASCO Quality Oncology Practice Initiative certification criteria. Because the standards, for the most part, are structure and process standards, they can serve as the springboard for outcomes research. For example, is there a reduction in patient misidentification errors after a new patient identification process is introduced? Do independent double-checks of chemotherapy orders identify potential medication errors? Does comprehensive patient education increase patients' knowledge about oral chemotherapy adherence? These are just a few examples of the many areas of outcomes research that may be conducted.

In addition, the standards can serve as the foundation for best practices, which are evidenced-based processes that help ensure safe chemotherapy administration in a strong culture of safety and quality. For example, to prevent oral chemotherapy prescribing errors, staff at the Dana-Farber Cancer Institute enhanced its electronic ordering system to include weight- and body surface area-based dosing, fields for the patient's cancer diagnosis and intent of therapy (curative vs palliative), and dose-limit warnings.⁴³

The Institute for Safe Medication Practices has identified best practices for medication safety issues and includes several that are applicable to chemotherapy safety, such as methotrexate ordering and dosing.⁴⁴ Examples of best practices abound in the literature

and in practice and, depending on the practice setting, may be achievable or aspirational.

These updated 2016 ASCO/ONS Chemotherapy Administration Safety Standards are presented in the hope that the new organizational schema will make them more intuitive and acceptable. These structural standards provide the underpinning for policies and procedures that are used to support and promote a safe environment for our patients through system improvement. The goal is to aid in implementation by making it easier for practices to adhere to the updated evidence-based standards. These standards are ever-evolving in response to advances in oncology.

The Working Group recognizes Mary Jo Duckwitz and those who attended the ASCO/ONS Chemotherapy Safety Standards Revisions Workshop for their contributions to the development of the manuscript.

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Appendix

Additional Notes

The ASCO/ONS Chemotherapy Administration Safety Standards are intended to reflect current thinking on best practices and, as such, are intended to be a living document; future modifications are expected.

Although the standards were not developed to address this issue, ASCO and ONS endorse the safe handling of chemotherapy agents. Published guidelines define the expectations for organizations and health care workers related to the use of safe handling precautions (American Society of Health-System Pharmacists: *Am J Health Syst Pharm* 63:1172-1193, 2006; National Institute for Occupational Safety and Health: DHHS publication No. 2004-165, 2004; Occupational Safety and Health Administration: OSHA technical manual, 1995; Polovich M: Pittsburgh, PA, Oncology Nursing Society, 2011; US Pharmacopeial Convention, Rockville, MD, 2016). Education, training, and competency validation for chemotherapy administration must necessarily include this aspect

of practice. Organizations should focus on a culture of safety because of the relationship between patient and health care worker safety (Friese CR et al: *BMJ Qual Saf* 21:753-759, 2012; Polovich M, Clark PC: *Oncology Nursing Forum*, 2012).

The standards are not deemed 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.

TABLE A1. ASCO/ONS Chemotherapy Safety Standards Revisions Workshop Participants and Organizations Represented

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|---|--|
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APHON—Association of Pediatric Hematology/Oncology Nurses; ASCO—American Society of Clinical Oncology; ASHP—American Society of Health-System Pharmacists; ASPHO—American Society of Pediatric Hematology/Oncology; HOPA—Hematology/Oncology Pharmacy Association; ONS—Oncology Nursing Society

Note. ASCO staff (additional): Brittany E. Harvey

TABLE A2. Glossary: Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards

| Term | Definition |
|---------------------------------|---|
| Adherence | The degree or extent of conformity to the provider's recommendations about day-to-day treatment with respect to timing, dosing, and frequency. |
| Assent | Assent expresses a willingness to participate in a proposed treatment by persons who, by definition, are too young to give informed consent, but who are old enough to understand the diagnosis and proposed treatment in general, its expected risks, and possible benefits; however, assent, by itself, is not sufficient. If assent is given, informed consent must still be obtained from the patient's parents or guardian, both of which must be done according to all applicable state and federal laws (see Consent). |
| Basic life support | Certification through an accredited class in provisioning resuscitation and management and assessment of life-threatening conditions, including cardiopulmonary resuscitation, controlling bleeding, treating shock and poisoning, stabilizing injuries and/or wounds, and basic first aid. An example would be the American Heart Association's Basic Life Support. Higher medical functions use some or all of the Advanced Cardiac Life Support protocols in addition to basic life support protocols. |
| Cancer stage | A formal, standardized categorization of the extent to which a cancer has spread at diagnosis. Systems vary by tumor type and staging but should be specific to the tissue of tumor origin. Stage should be distinguished from cancer status. Cancer status does change over time. |
| Cancer status | Description of the patient's disease from the time of diagnosis, if relevant (e.g., recurrence, metastases). |
| Cancer support services | A list of informational, psychosocial, and financial resources that are available for cancer support. |
| Chemotherapy | All antineoplastic agents used to treat cancer, administered 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 or course of treatment, generally administered cyclically. |
| Chemotherapy treatment plan | A plan of treatment specific to the patient that is developed before the initiation of chemotherapy. The core elements of a chemotherapy treatment plan are: <ul style="list-style-type: none"> • Diagnosis, including the cancer site, histology, and stage; • goals of therapy—may be specified by the type of template, for example, adjuvant • chemotherapy plan; • patient health status and comorbidities; • surgical history and notable pathology findings; • chemotherapy regimen and starting dosages; • duration of treatment and number of planned cycles; and • major adverse effects of chemotherapy. |
| Clinical encounter | Clinical encounters include each inpatient day, scheduled or unscheduled practitioner visits, home visits, and chemotherapy administration visits, but not laboratory or administrative visits. |
| Clinical staff | Staff involved in patient care—for example, practitioners, registered nurses, etc. |
| Comprehensive education program | A comprehensive educational program is current, evidence-based, and age appropriate. It may be internally developed or an established educational curriculum may be used. Education and competency assessment regarding chemotherapy administration includes all routes of administration used in the practice or institution or home site—for example, parenteral, oral, intrathecal, intraperitoneal, or intravesicular—and safe handling of hazardous chemotherapy agents, and concludes in clinical competency assessment. Examples of education programs for staff administering chemotherapy agents include the ONS/ONCC Chemotherapy Biotherapy Certificate Course and the APHON Pediatric Chemotherapy and Biotherapy Provider Program. |

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TABLE A2. Glossary: Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards (Continued)

| Term | Definition |
|-------------------------------------|--|
| Consent | Consent to treatment is an important part of delivering quality cancer care. Consent is the process by which a patient is provided with sufficient information about the disease diagnosis and treatment options so that the individual can make a reasonable decision about treatment on the basis of an understanding of the potential risks and anticipated benefits of the treatment. Informed consent is not a waiver of rights. |
| Dosage | Includes the amount or quantity of medicine to be taken or administered and implies the duration or the frequency of the dose to be administered—for example, daily, every 21 days, etc. |
| Dose | The amount or quantity of medicine to be taken or administered to the patient each time in a day. |
| Exception order | Notation that the standard treatment is contraindicated as a result of preexisting comorbidity, organ dysfunction, or prior therapy. |
| Functional status | An individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being. |
| Handoff | The transfer of patient information and knowledge, along with authority and responsibility, from one clinician or team of clinicians to another clinician or team of clinicians during transitions of care across the continuum. |
| Health care setting | A medical office or practice, clinic, agency, company, hospital, or institution that provides health care as well as the home environment where health care is provided. |
| Hypersensitivity reaction | A symptomatic interaction between antibodies and allergens that causes an exaggerated and harmful response in the body. Hypersensitivity reactions range from mild to life threatening in severity and symptoms. |
| Identifier (patient identification) | Minimum patient identifiers for positive patient identification are: Last name, first name, date of birth, unique identification number, such as medical record number. Whenever possible, ask patients to state their full name and date of birth. For patients who are unable to identify themselves—pediatric, unconscious, confused, or language barrier—seek verification of identity from a parent or caregiver at the bedside. This must exactly match the information on the identity band, order, or drug label (or equivalent). All paperwork that relates to the patient must include, and be identical in every detail, to the minimum patient identifiers on the identity band. |
| Immediate use | For the purpose of these standards, immediate use is defined as use within 2 hours in accordance with drug stability and state and federal regulations. |
| Independent verification | Independent verification is the act of verifying or checking the status or quality of a component or product independent of the person that established its present state. Independent verification has a higher probability of catching an error than does peer-checking or concurrent verification, as the second person is not influenced by the first person and has freedom of thought. Independent verification catches errors after they have been made. The individual performing the independent verification must physically check the condition without relying on observation or verbal confirmation by the initial performer. True independence requires separation in time and space between the individuals involved to ensure freedom of thought. Independent verification of chemotherapy preparation should include checking the preparation for completeness and accuracy of content, with particular attention given to special preparation instructions. Technology can serve as a surrogate; if practitioners follow procedures in using appropriately developed and applied procedures. Verification may include bar code and/or gravimetric verification and may be performed on site or remotely via digital images or video as allowed by state law or other regulations. |
| Labels | The standards (3.12., 3.13.) require that labels include identified elements at a minimum. Practices or institutions 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. |

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TABLE A2. Glossary: Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards (Continued)

| Term | Definition |
|-----------------------------------|---|
| Medical history and physical | Includes, at minimum, height, weight, pregnancy screening (when applicable), treatment history, 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. |
| On-site and immediately available | Physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure |
| Orders: written and verbal | Orders that are written or sent electronically can be on paper, emailed from a secure encrypted computer system, written, or faxed, and include the prescriber's signature and, in some instances, an identifying number. Verbal orders are those that are spoken aloud in person or by telephone and offer more room for error than do orders that are written or sent electronically. |
| Pain assessment | Assessment of pain in the oncology patient using a multidimensional approach, with determination of the following: chronicity, severity, quality, contributing/associated factors, location/distribution or etiology of pain, if identifiable, and barriers to pain assessment. |
| Parenteral | Introduction of substances by intravenous, intra-arterial, subcutaneous, intramuscular, intrathecal, or intracavitary routes. |
| Patient | The recipient of health care. This includes, when applicable, parents, family members, significant others, lay caregivers, and health care proxies—for example, legal surrogates, guardians/conservators, or health care agents. |
| Performance status | The use of standard criteria for measuring how the disease impacts the patient's daily living abilities. |
| Policy | A written course of action—for example, procedure, guideline, protocol, or algorithm. |
| Practitioner | Licensed independent practitioner, including physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law. |
| Provider | Anyone who administers care to a patient, including, for example, therapists, nurses, and physicians. |
| Psychosocial assessment | An evaluation of a person's mental health, social status, and functional capacity within the community. May include the use of a distress-, depression-, or anxiety-screening form, patient self-report of distress, depression, or anxiety, or medical record documentation regarding patient coping, adjustment, depression, distress, anxiety, emotional status, family support and caregiving, coping style, cultural background, and socioeconomic status. |

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