Antineoplastic Therapy Administration Safety Standards for Adult and Pediatric Oncology: ASCO-ONS Standards

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PURPOSE: To update the American Society of Clinical Oncology (ASCO)-Oncology Nursing Society (ONS) standards for antineoplastic therapy administration safety in adult and pediatric oncology and highlight current standards for antineoplastic therapy for adult and pediatric populations with various routes of administration and location.

METHODS: ASCO and ONS convened a multidisciplinary Expert Panel with representation of multiple organizations to conduct literature reviews and add to the standards as needed. The evidence base was combined with the opinion of the ASCO-ONS Expert Panel to develop antineoplastic safety standards and guidance. Public comments were solicited and considered in preparation of the final manuscript.

RESULTS: The standards presented here include clarification and expansion of existing standards to include home administration and other changes in processes of ordering, preparing, and administering antineoplastic therapy; the advent of immune effector cellular therapy; the importance of social determinants of health; fertility preservation; and pregnancy avoidance. In addition, the standards have added a fourth verification. *(Continued on the next page)*

KEYWORDS antineoplastic therapy administration; guidelines; safety; standards; oncology

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The purpose of these standards is to update the 2016 Updated American Society of Clinical Oncology (ASCO)/Oncology Nursing Society (ONS) Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology.[1-5]

Over the past 15 years, ASCO and ONS have collaborated to create and reassess standards for the administration of antineoplastic therapy to maximize safety for patients with cancer and to minimize inadvertent but preventable harms with this potentially toxic set of compounds.[1,3-6] In 2016, the respective organizations last published updates of these standards; that version explicitly included the pediatric population as does this version.

These standards have been fundamental principles of the two organizations, and a variety of quality programs including ASCO's Quality Oncology Practice Initiative and its certification programs have included selected standards[7] and will be discussed for incorporation in the new ASCO Certified Patient-Centered Cancer Care Standards. These standards focus on the requisite training of individuals involved with the provision of these medications as well as the preparation, labeling, and ultimately the administration of therapy at home[8] or in a health care facility. They are a blueprint for optimizing and standardizing the various steps in the process where medical errors can occur.[9] These standards attempt to inoculate the process against

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STANDARDS: Standards are provided for which health care organizations and those involved in all aspects of patient care can safely deliver antineoplastic therapy, increase the quality of care, and reduce medical errors.

such errors by creating a foundation of consistent interactions and eliminate an environment of operational variability in which medical errors often thrive in the absence of a standardized protocol-driven approach.[10] Despite the focus on eliminating variability, standards that do not change with time or reflect the most current literature and evidence may become obsolete. This is most evident in the change of the fundamental terminology in these standards from chemotherapy to antineoplastic therapy. Since the last major standards update in 2016, there has been a profusion of new drugs and approaches to cancer care including, but not limited to, a variety of genomically determined targeted therapies (largely oral), immunomodulatory agents, bispecific T-cell engagers, and chimeric antigen receptor T-cell antigen therapy, all of which are now mentioned in the standards. Finally, where the administration of antineoplastic therapy had historically been performed either in the hospital setting or in physicians' offices or clinics, it is now not uncommon for treatment to be administered in the home[11] or in a freestanding center to which the ordering physician has no relationship. Conversely, because of a variety of insurance and pharmacy benefit-related requirements, clinics are now occasionally the recipients of pharmaceuticals prepared elsewhere by individuals, not under their employ, for local administration. These standards highlight the relative responsibilities of all parties in these progressively more complicated relationships.

The fundamental reason for publishing these new standards is that despite medical oncology's supporting technology and its evolving sophistication as a science, patient care mistakes and medication errors still happen,[9,12] usually for very simple and very human errors of omission and commission. Attention to the details of operational processes will optimize care and patient safety. The COVID-19 pandemic caused a rather significant disruption in oncology staffing models with resultant high turnover, leaving treatment centers with less experienced and less knowledgeable individuals responsible for the ordering, preparation, and administration of these antineoplastics.[13-17] Updating the standards will provide newer providers with the most up-to-date approaches.

Research Questions

Overarching Research Question

What are standards for ordering, preparing, dispensing, and administering antineoplastic therapy?

These standards address seven overarching research questions across four domains.

Domain 1: Creating a Safe Environment

Research Question 1: Does the care provided by oncology professionals who meet certain qualifications result in fewer medical errors and reduce preventable harm, compared with those who do not?

Research Question 1.1: Does the care provided by health care organization that have specific quality improvement or standardization of care policies in place result in fewer medical errors and reduce preventable harm compared with no or less specific policies?

Research Question 2: Do documentation policies mandated and/or implemented by health care organizations result in fewer medical errors and reduce preventable harm compared with no documentation policies?

Domain 2: Patient Consent and Patient Education

Research Question 3: Do policies on treatment planning, patient consent, and patients' education result in fewer medical errors and reduce preventable harm, compared with those who do not?

Domain 3: Ordering, Preparing, Dispensing, and Administering Oral and Parenteral Antineoplastic Therapies in a Health Care Facility, Organization, or the Home

Research Question 4: Do policies on ordering, preparing, dispensing, and administering antineoplastic therapy result in fewer medical errors and reduce preventable harm, compared with no or less specific policies?

Research Question 5: Do policies on ordering, preparing, dispensing, and administering antineoplastic therapy for patients at home result in fewer medical errors, reduce preventable harm, and increase adherence, compared with no or less specific policies?

Research Question 6: Do policies on ordering, preparing, dispensing, and administering antineoplastic therapy intrathecally or intraventricularly for patients result in fewer medical errors and reduce preventable harm, compared with those who do not?

Domain 4: Monitoring During and After Antineoplastic Therapy Is Administered, Including Adherence, Toxicity, and Complications

Research Question 7: Do policies on post-treatment monitoring of adverse events from antineoplastic therapy result in fewer medical errors and reduce preventable harm, compared with no or less specific policies?

Methods

Standards Development Process

These systematic review-based standards were developed by a multidisciplinary Expert Panel, which included physicians, nurses, pharmacists, experts in treatment of both adult and pediatric patients, a patient representative, and an ASCO staff member with health research methodology expertise (Appendix Table A1).

The standards statements were developed by using a systematic review of evidence identified through online searches of PubMed (January 2015 to January 2023) and CINAHL (January 2015 to April 2023) of systematic reviews, guidelines, best practice statements, interventional trials, observational studies, and clinical experience. Articles were selected for inclusion in the systematic review on the basis of the following criteria:

- Population: Adults, adolescents and young adults, and children with cancer, caregivers of patients with cancer
- Interventions: Antineoplastic protocols or policy and/or documentation policies, education interventions, technological interventions, documentation
- Comparisons: No or less specific policies
- Outcomes: Accidents, medical errors, patient harm, adverse events, adverse drug interventions, adherence, death, hospital admittance.

Articles were excluded from the systematic review if they were (1) meeting abstracts; (2) editorials, commentaries, letters, news articles, and narrative reviews; (3) non-English language; and (4) case series examining errors in low–/ middle–human development index countries with <50 patient treatments per month.

Three full panel meetings were held, and members were asked to provide ongoing input on the standards development protocol, quality and assessment of the evidence, generation of statements, and draft content and review and approve drafts during the entire development of the standards. ASCO and ONS staff met routinely with the Expert Panel co-chairs and corresponded with the panel via e-mail to coordinate the process to completion. All funding for the administration of the project was provided by ASCO.

Standards Review and Approval

The draft statements were released to the public for open comment from September 28, 2023, through October 18, 2023. Response categories of "Agree as written," "Agree with suggested modifications," and "Disagree. See comments" were captured for every proposed statement with 82 written comments received. A total of 71%-100% of the 82 responses either agreed or agreed with slight modifications to the statements, and 14%-29% of the responses disagreed (primarily on the reorganized Domain 3). For 25 of the standards, there was no disagreement. Expert Panel members reviewed comments from all sources and determined whether to maintain original draft statements, revise with minor language changes, or consider major revisions.

All changes were incorporated into the final manuscript before ASCO Evidence-Based Medicine Committee (EBMC) and ONS Board of Directors review and approval. All ASCO-ONS standards are ultimately reviewed and approved by the Expert Panel and the ASCO EBMC and ONS Board of Directors before submission to the *Journal of Clinical Oncology* (*JCO*) *Oncology Practice* for editorial review and consideration for publication.

Standards Updating

The ASCO Expert Panel and staff will work with co-chairs to keep abreast of any substantive updates to the standards. On the basis of formal review of the emerging literature, ASCO will determine the need to update. The ASCO Standards Policies and Procedures Manual (available at http:// www.asco.org/standards) provides additional information about the update process. This is the most recent information as of the publication date.

Target Population and Audience

Target Population

Adult and pediatric patients with cancer receiving antineoplastic therapy and nonprofessional caregivers of patients with cancer.

Target Audience

Oncology clinicians, oncology pharmacists, health care administrators, health care organizations, home health providers, other related health care providers, administrators or organizations, patients, and nonprofessional caregivers.

TABLE 1. Domain 1: Creating a Safe Environment for All Routes of Antineoplastic Therapy

Standards–Domain 1
1.1. The health care organization has a policy to document the qualifications of clinical staff who order, prepare, and administer antineoplastic therapy 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 practitioners) and how credentialing is documented ■ 1.1.4. Description of competency demonstration and how competency is documented and maintained
1.2. The health care organization uses a comprehensive education program for initial and ongoing educational requirements for all staff who prepare and administer antineoplastic therapy
1.3. At least one practitioner who maintains current certification in (age-appropriate) basic life support is present during antineoplastic therapy administration
1.4. A licensed practitioner is on-site and immediately available to staff who administer antineoplastic therapy in the health care organization
Note. Note on terminology changes: 1. Chemotherapy changed to antineoplastic therapy. 2. Health care setting changed to health care organization.

Results

Characteristics of Studies Identified in the Literature Search

A total of 5,248 publications were identified in the primary literature search. After applying the eligibility criteria for fulltext review, 227 publications remained, and the Expert Panel reviewed the results. The identified studies were published between 2015 and 2023. There were 10 RCTs, 17 systematic reviews, and 111 observational studies, and the remainder were organizational policy statements and other noncomparative, nonprospective study types; few were found to be sufficiently relevant. At that point, the Expert Panel decided to use informal consensus, expert opinion, and publications suggested by Expert Panelists to form the basis for the standards. Terms within the standards have been defined in the accompanying Definitions of Terms (Appendix Table A2).

Standards

All standards for documentation and staff education are provided in Tables 1-3, patient consent education is given in Table 4; the ordering, preparing, dispensing, and administering antineoplastic therapy are listed in Tables 5-7, and post-treatment monitoring and adherence are presented in Table 8. Any new or revised standards are identified, and for these standards, the supporting literature review and interpretation are provided. Standards that did not require updating are considered current as of this publication, and the supporting literature review and interpretation are available in detail elsewhere.[1]

Selected Standards—Key Changes and Additions

Domain 1: Safe Environment

Standard 1.2: The health care organization uses a comprehensive education program for initial and ongoing educational requirements for all staff who prepare and administer antineoplastic therapy.

Standard 1.5.3: Complete medical history and physical examination, including fertility status and pregnancy status, as applicable.

Standard 1.5.3.1: The health care organization has a policy for pregnancy testing prior to initiating antineoplastic therapies.

Standard 1.5.3.2: The health care organization has a policy for assessing risk of pregnancy in patients while receiving antineoplastic therapies.

Standard 1.5.3.3: The health care organization has a policy for determining a patient's desire for ongoing or future fertility preservation prior to initiating antineoplastic therapy and making appropriate referrals when feasible.

Standard 1.5.8 (new): Initial and ongoing assessments of social determinants of health and barriers to care including financial and logistical constraints and supports needed to provide access to required medications (if applicable).

Standard 1.7: Weight and height are measured and documented in the medical record in metric

units (eg, kg and cm). Both the measurement and documentation are verified by two individuals, one of whom is a licensed clinician, prior to preparation and administration of a newly prescribed antineoplastic treatment plan. The measurement is repeated when clinically appropriate as determined by the policy of the health care organization.

Standard 1.16 (new): The The health care organization uses an electronic medical record (EMR) ordering format for antineoplastic therapy, when feasible.

Literature review update results and interpretation. For Standard 1.2, no randomized trials were identified by the systematic review. One observational study was identified.[18] The Expert Panel opted to make this minor change to simplify the standard language and define the elements of a comprehensive education program in the glossary.

Regarding pregnancy, a standard for fertility preservation was not specifically mentioned under documentation before the first administration of antineoplastic therapy and therefore was added here. Clinicians should address fertility preservation for appropriate patients prior to first administration and ensure education is provided on potential long-term and short-term infertility risks. Standard 2.3.5 further discusses fertility preservation.[19]

An environmental scan of the literature showed a paucity of literature on pregnancy and cancer treatment[20]; anecdotal information suggests some patients remain at risk of pregnancy or contributing to pregnancy, during antineoplastic treatment. Management options may differ where restriction depends on US state and geography.[21] Despite opportunities to identify pregnancy earlier in the process, if they are missed, the opportunities before administration of antineoplastic therapy are a key point to prevent the potentially negative sequelae of antineoplastic therapy to patients who are pregnant. Pregnancy status is usually discussed in the context of treatment planning and/or ordering. Each health care organization should define the details of its specific policies (see also Standard 2.3.6. on education.) ASCO is currently developing a systematic review-based guideline on pregnancy in patients with cancer. Finally, sexual health is also an important area of discussion.[22,23]

Social determinants of health, defined by the WHO as the conditions in which an individual is born,

TABLE 2. Documentation Before First Administration

Standards–Domain 1 *(continued)*

1.5. Before the first administration of a new antineoplastic therapy regimen, medical record documentation is available that includes at least the following nine 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 fertility status and pregnancy status, as applicable
  - 1.5.3.1. The health care organization has a policy for pregnancy testing prior to initiating antineoplastic therapies
  - 1.5.3.2. The health care organization has a policy for assessing risk of pregnancy in patients while receiving antineoplastic therapies
  - 1.5.3.3. The health care organization has a policy for determining a patient's desire for ongoing or future fertility preservation prior to initiating antineoplastic therapy and making appropriate referrals when feasible
- 1.5.4. Presence of absence of allergies and history of hypersensitivity and anaphylactoid reactions
- 1.5.5. Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and treatment plan including an initial psychosocial assessment, with action taken when indicated and agreeable to the patient
- 1.5.6. The plan for antineoplastic therapy, including, at a minimum, the patient diagnosis, drugs, doses, route of administration, duration of treatment, and goals of therapy (eg, palliative versus curative)
- 1.5.7. Planned frequency of patient assessments and monitoring that is appropriate for the individual antineoplastic agent(s)
- 1.5.8. Initial and ongoing assessments of social determinants of health and barriers to care including financial and logistical constraints and supports needed to provide access to required medications (if applicable)
- 1.5.9. Informed consent and/or assent for the antineoplastic therapy

Note. Note on terminology changes: 1. Chemotherapy changed to antineoplastic therapy. 2. Health care setting changed to health care organization.

grows, lives, works, and ages, can undermine ASCO and ONS expert guidance on best practices for prevention, screening, palliative and supportive care, and disease management for many patients with cancer.[24] One study regarding financial toxicity was found to inform this standard that met the criteria for the

TABLE 3. Documentation: Each Clinical Encounter or Treatment Day

Standards–Domain 1 ***(continued)***
1.6. On each clinical encounter or day of treatment, staff performs and documents a patient assessment that includes at least the following six elements and takes appropriate action: ■ 1.6.1. Functional status and/or performance status ■ 1.6.2. Vital signs ■ 1.6.3. Date of birth ■ 1.6.4. Allergies and previous treatment-related reactions ■ 1.6.5. Treatment toxicities ■ 1.6.6. Pain assessment
1.7. Weight and height are measured and documented in the medical record in metric units (eg, kg and cm). Both the measurement and documentation are verified by two individuals, one of whom is a licensed clinician, prior to preparation and administration of a newly prescribed antineoplastic treatment plan. The measurement is repeated when clinically appropriate as determined by the policy of the health care organization
1.8. Staff screens for and documents the patient's psychosocial concerns and need for support with each cycle or more frequently as indicated, with action taken when indicated and agreeable to the patient
1.9. The patient's medication list inclusive of prescribed and over-the-counter medications, herbal products, and supplements is updated and documented in the medical record at every encounter and reviewed by a licensed practitioner when a change occurs
1.10. The health care organization has a policy for documentation and follow-up for patients who miss or cancel scheduled visits and/or antineoplastic therapy
1.11. The health care organization has a policy that addresses mandates and processes for pediatric patients that account for legal requirements
1.12. The health care organization has a policy that identifies a process to provide 24/7 triage to a licensed 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 organization, the person having initial patient contact must have continuous access to consultation from an experienced licensed oncology practitioner and the opportunity for transfer of the patient to a health care organization with dedicated oncology services
1.13. The health care organization has a policy for standardized documentation in medical record and communication of toxicities, modifications in dose or schedule, or discontinuation of treatment for antineoplastics, regardless of the health care setting
1.14. The health care organization has a policy for hand-off process between all sites of care, which includes patient's care plan, antineoplastic therapy treatment schedule, safety concerns including critical laboratory values, current condition, and any recent or anticipated changes
1.15. The health care organization has a policy for reporting of adverse events (eg, infusion reactions and toxicities), medication errors, and near misses and has a formal process for collecting, evaluating data at a defined frequency, and intervening as appropriate
1.16. The health care organization uses an electronic medical record ordering format for antineoplastic therapy, when feasible
Note. Note on terminology changes: 1. Chemotherapy changed to antineoplastic therapy. 2. Health care setting changed to health care organization.

systematic review, a prospective study of in-office dispensing of oral therapy.[25] Expert Panel members also suggested inclusion of the following studies regarding financial toxicity[26,27] and added this standard to the list of the elements that need to occur before the first administration of a new antineoplastic therapy regimen (starting with Standard 1.5) due to the potential risks of this toxicity to patients and caregivers. ASCO provides further resources on financial toxicity at Cancer.Net[28] (see also Standard 4.6.)

Anecdotal concerns about accuracy of height and weight measurement prompted a supplemental literature search, identifying 12 studies that addressed the topic. In a study of 10,000 randomly selected medical records, authors found errors in 20% of medical records, reflecting clearly mistyped numbers, single-digit errors, decimal misplacement, number transposition, and documentation of pounds rather than kilograms.[29] Errors occurring in measurement, transcription, and documentation were most prevalent.[29-32] To minimize errors in weight and height–based dosing, the Institute of Safe Medical Practices[33] recommends consistent procedures for height and weight measurement, when measured in metric units only. Prior to the start of a new treatment plan, consistent methodology and verification of height and weight by two clinicians, one of which is licensed, have been added to the standards to decrease the risk of documentation error.

The frequency of weight measurement was specifically evaluated in a review of 23 additional studies. Other authors found that a change in body surface area of 10% or greater occurred in 7.6% of patients on active treatment and that weight checks with each visit or cycle were not necessary.[34] However, weight has been studied as an indicator of nutritional status and overall survival in many cancer types.[35-37] The Expert Panel determined that the frequency of measurement of both height and weight after starting a new treatment plan should be based on health care organization policy and reflect the patient population (eg, patient age, diagnosis) and treatment type. Electronic health records, also known as EMRs, have evolved for decades. Although initially configured largely for billing and administrative pursuits, their advances are central to patient care in many institutions. A variety of factors including technological advances, the internet, development of multi-institutional and geographically separated health care facilities, health care reform, and efforts to reduce medical errors and enhance medical research have driven this evolution. With the profusion of genomically driven data now available to many oncologists, the Expert Panel felt it appropriate to add a standard for EMR adoption when feasible.[38-41] ASCO-ONS recognizes the global readership of these standards. Some practices in various settings experience resource constraints and may have to implement this standard with written order entry.

Domain 2: Patient Consent and Patient Education

Standard 1.9: The patient's medication list inclusive of prescribed and over-the-counter medications, herbal products, and supplements is updated and documented in the medical record at every encounter and reviewed by a licensed practitioner when a change occurs.

Standard 2.3.4 (new): *Under Patient's Diagnosis.* Documentation of current medications to include herbal products and complementary medications.

Literature review update results and interpretation. Five observational studies were found by the systematic review relevant to this standard.[42-46] One study identified medication discrepancies in 83% of patients in a student pharmacist-driven service, with 21% of those discrepancies involving a high-risk medication.[42] Authors reported potential herbal-product and drug interactions observed in one of five patients receiving oral anticancer agents.[43] Other authors evaluated over 200 interventions conducted by pharmacists during counseling sessions, and half of these interventions involved herbal-product and drug interactions.[44] In another study, on interactions with oral antineoplastics and other medications, including herbs, there were 51% potential drug interactions in 881 patients; the authors observed some risk factors, for example, polymedication, and specific cancer types.[46] In another descriptive study of drug-drug and drug-food interactions with oral antineoplastics, in 291 patients, there were 736 concomitant medications with only 55% detected.[47]

Patients diagnosed with cancer often have other comorbidities and require multiple medications, which may suffer from unwanted polypharmacy. Furthermore, they may take herbal products and/or complementary medications including vitamins and supplements, which is why it is critical to ensure that patients' medication lists are kept up to date for every visit. Pharmacists and providers should be aware of potential interactions between antineoplastics agents and herbal products and/or complementary medications. Some patients, at times, may not disclose their use of herbal product, supplements, and vitamins during interviews because they may not regard these

as medications. Pharmacists and providers must proactively inquire and document herbal product and complementary medications use within the medication list.

Standard 2.3.5: [*Education on*] Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients.

Literature review update results and interpretation. No randomized trials or new observational studies regarding education on fertility preservation were identified by the systematic review which would change this prior standard. The Expert Panel refers readers to the ASCO Guideline on Fertility Preservation, which ASCO is currently updating,[19] as well as an ONS, APHON, and CANO/ACIO position statement (in press, 2024).[48]

The Expert Panel highlights the importance of policies educating patients regarding fertility issues especially in treatment of the pediatric population. Clinicians should discuss fertility issues in the context of informed consent (see Standard 1.5.3.3), through an interdisciplinary approach incorporating risk assessment, patient education, and potential referral to reproductive specialists for fertility preservation (in press, 2024).[48] Each health care organization should follow evidence-based guidance to define the details of its specific policies.

Standard 2.3.6: [*Education on*] Pregnancy prevention including contraception.[49]

Literature review update results and interpretation. Since teratogenicity is a known complication

TABLE 4. Domain 2: Patient Consent and Patient Education

Standards–Domain 2
2.1. The health care organization has a policy that documents a standardized process for obtaining and documenting informed consent and assent (if applicable) for antineoplastic therapy regardless of route of administration
2.2. Informed consent and assent (if applicable) for antineoplastic therapy, as appropriate to the treatment population, is documented before initiation of the regimen
2.3. Patients are provided with verbal and written or electronic information as part of an education process before the first administration of antineoplastic agents in each treatment plan. The content of this educational material will be documented and should be administered in the patient's preferred language. Educational information includes the following at a minimum: ■ 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, plan for missed doses, drug names and supportive medications, and drug interactions with prescribed drugs, integrative therapies, over the counter drugs, and foods ■ 2.3.4. Documentation of current medications to include herbal products and complementary medications ■ 2.3.5. Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients ■ 2.3.6. Pregnancy prevention including contraception ■ 2.3.7. Symptoms or adverse effects that require the patient to contact the health care organization or to seek immediate attention ■ 2.3.8. Symptoms or events that require immediate discontinuation of oral or other self-administered treatments ■ 2.3.9. Procedures for safe handling medications in the home, including disposal of waste, handling body secretions, storage, safe handling, and management of unused medication, and clean-up of drug spills ■ 2.3.10. Follow-up plans, including laboratory and/or provider visits, and approximate timeline for follow-up radiographic tests ■ 2.3.11. Contact information for the health care organization, with availability and instructions on when and whom to call ■ 2.3.12. The missed appointment policy of the health care organization and expectations for rescheduling or canceling
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 based on the patient's learning needs, abilities, preferences, and readiness to learn
Note. Note on terminology changes: 1. Chemotherapy changed to antineoplastic therapy. 2. Health care setting changed to health care organization.

of antineoplastic therapy,[50] advice on pregnancy prevention logically follows. The literature on intervention, however, is understandably limited. Authors conducted a systematic review and meta-analysis on contraceptive use and counseling. The results included 21 articles showing that contraceptive use and the prevalence of counseling varied widely. The authors found the results of counseling equivocal, with low uptake of contraceptives. The authors state this is an unmet need and that "Although fertility preservation is important for young women with cancer, it should not be the focus to the exclusion of contraceptive counseling."[49] (p. 13) Although the field may still be struggling to find the best intervention, because pregnancy avoidance during therapy is the optimal approach, it is included in the standards.

Domain 3: Ordering, Preparing, Dispensing, and Administering

Note: The standards in Domain 3 have been reorganized to reflect the changes in the location of antineoplastic therapy to include patients' homes and oral antineoplastic therapy facilities.

This includes adding an additional verification. (The 2016 standards referred to three independent verifications. [2016 Standard 3.11])

Note: Standards 3.11.2, 3.12, and 4.2 also include both home and health care facility settings.

Standard 3.12.2. (under 3.12—dispensing and administering, whether in a health care organization or at home): Personnel approved by the health care organization to prepare or administer antineoplastic therapy perform four separate verifications in person or by institutionally approved video-enabled technology.

The elements of each occasion of verification are listed separately (Table 6).

Standard 3.12.2.4. (new): Fourth Verification. In the presence of the patient: at least two licensed clinicians approved by the health care organization to administer or prepare antineoplastic therapy in person or through appropriate institutionally approved video-enabled technology, with at least one person on site, verify the patient's identification using at least two identifiers and document accuracy in the patient's medical record. Document the accuracy of the following elements in the patient's medical record: (see the elements in Standards 3.12.2.4.1—3.12.2.4.6, Table 6).

Standard 3.12.2.2.5 (under second verification [3.12.2.2]): Administration route, filters, and tubing if applicable.

(see also Standard 3.12.2.4.5., under Fourth Verification) Standard 3.12.2.4.5.: Administration set (as applicable), for example, filters, specialized tubing.

Literature review update results and interpretation. As the administration of antineoplastic therapies in the home setting has become more common and preferable for patients with cancer, health care organizations should ensure that the same safety mechanisms are in place, regardless of where a patient receives treatment. This section is primarily based on expert experience and literature suggested by the Expert Panel. Advances in technology (such as video-enabled verification programs) have allowed health care providers to complete virtual safety checks in the drug preparation and administration processes, creating more flexibility for patients to receive care where they prefer.[8] By expanding the standards to include use of institutionally approved video-enabled technology for the required two-person verifications, the Expert Panel acknowledges that technology has become an integral part of increasing access to care, but cautions that reliance on technology can still lead to medication errors or other serious safety events.[9]

Authors of a review of literature and synthesis of practice interviews regarding remote verification of high-risk medications report remote verification at the point of administration is feasible and may be alike live two-person checks; however, no well-designed research has evaluated the impact on safety as of this writing.[51] Acknowledging this research gap, health care organizations that integrate technology for independent verification at the point of administration should ensure that the verification process, including independent inspection portions, is not compromised.

Previous versions of the ASCO-ONS standards required three independent verifications during the order verification, drug preparation, and drug administration processes. The standards reorganized Domain 3 because many antineoplastic drugs are prepared separately from where the patient is receiving treatment (eg, in the home setting or at a stand-alone ambulatory facility) and an additional verification is required to ensure that the drug and its components are accurate and complete immediately prior to drug administration. An additional element was added to the final verification to ensure that the administering health care provider visually inspects the administration set to ensure that it is appropriate for the drug, connected correctly to the patient, and infusing at the prescribed rate. "Tracing the lines" immediately prior to administration reduces errors related to unclamped

TABLE 5. Ordering

Standards–Domain 3: Ordering, preparing, dispensing, and administering oral and parenteral antineoplastic therapies in a health care facility/organization or in the home
3.1. The health care organization defines standard antineoplastic therapy regimens by diagnosis with references
3.2. The health care organization verifies institutional review board approval of research regimens
3.3. Orders for antineoplastic therapy, regardless of route, are signed manually or by using the electronic health record by licensed practitioners who are determined to be qualified by the health care organization
3.4. The health care organization has a policy for managing antineoplastic therapy orders that vary from standard regimens (exception orders) such as using an order set for a disease not assigned, adding a medication not included in the standard regimen, escalation of dose or schedule beyond that defined in the standard regimen ■ 3.4.1. The policy requires a supporting reference and/or authorization by a second licensed practitioner prior to ordering, signing, or administration of an exception order ■ 3.4.2. The rationale for an exception order is documented in the health record
3.5. The health care organization has a policy for antineoplastic therapy orders that ensure: ■ 3.5.1. Verbal orders are not allowed except to hold or stop antineoplastic therapy administration ■ 3.5.2. New orders or changes to orders for antineoplastics, regardless of route, including dose and schedule changes communicated directly to patients, are documented in the medical record
3.6. The health care organization uses standardized, regimen-level, preprinted or electronic orders for parenteral and oral antineoplastic therapies
3.7. If the health care organization administers parenteral antineoplastic therapies that are prepared or compounded offsite, the health care organization maintains a policy for quality control of that product including documentation of the offsite or third party's pharmacy or manufacturing facility that complies with all applicable regulatory requirements
3.8. If the health care organization maintains its own pharmacy, there is a policy regarding safe storage of the antineoplastic agents including separation of look-a-like products, sound-a-like products, and investigational agents available in multiple strengths
3.9. Ordering antineoplastics (both oral and parenteral): Antineoplastic orders must include the patient's name and date of birth. In addition, the following elements must be included in the patient's medical record: ■ 3.9.1. A second patient identifier ■ 3.9.2. The date the order was signed ■ 3.9.3. Prescriber name ■ 3.9.4. Regimen name or protocol name and/or number ■ 3.9.5. Cycle number and day number, when applicable ■ 3.9.6. All medications within the order set are listed by using full generic names ■ 3.9.7. Doses are written following health care organization policy for preventing the use of unapproved abbreviations, omitting trailing zeros, and including leading zeros ■ 3.9.8. The dose calculation, including: □ 3.9.8.1. The calculation methodology □ 3.9.8.2. The variables used to calculate the dose □ 3.9.8.3. The frequency at which variables are re-evaluated, such as weight or laboratory data □ 3.9.8.4. The changes in the values that prompt confirmation or recalculation of doses ■ 3.9.9. The date of administration ■ 3.9.10. The route of administration ■ 3.9.11. Allergies, confirmed prior to administration of antineoplastics ■ 3.9.12. Supportive care medications appropriate for the regimen including premedication, hydration, growth factors, and hypersensitivity and anaphylactoid medications are included in the preprinted or electronic order forms ■ 3.9.13. Parameters that would require holding or modifying a dose, for example, laboratory values, diagnostic test results, or change in patient's clinical status

Continued on the next page

TABLE 5. Ordering *(Continued)*

Standards–Domain 3: Ordering, preparing, dispensing, and administering oral and parenteral antineoplastic therapies in a health care facility/organization or in the home *(continued)*

- 3.9.14. Sequencing of oral and/or parenteral drug administration, when applicable
- 3.9.15. Rate of drug administration for parenteral medications, when applicable
- 3.9.16. Explanation of time limitation, such as number of cycles for which an order is valid

3.10. Ordering Oral antineoplastics: All oral antineoplastics must be ordered in the electronic medical record or on preprinted forms and documented in the patient's medical record whether dispensed by the ordering health care facility, an alternative facility, or a specialty pharmacy. Elements unique to oral antineoplastics should be included in addition to the patient's name and date of birth:

- 3.10.1. Drug quantity or volume to be dispensed
- 3.10.2. Number of refills, with zero being the preferred default value for oral antineoplastics
- 3.10.3. Schedule of administration

3.11. Preparation of antineoplastics (both oral and parenteral)

- 3.11.1. Oral or parenteral antineoplastics are prepared by a licensed pharmacist, pharmacy technician, or registered nurse with documented antineoplastic preparation education, training, and annual competency evaluation
- 3.11.2. Labels for oral or parenteral antineoplastics and supportive care medications are placed immediately upon preparation or compounding whether dispensed from the ordering health care organization, an alternative facility, or a specialty pharmacy, to be administered in the health care facility or in the home:
  - 3.11.2.1. Patient's name
  - 3.11.2.2. Patient's date of birth
  - 3.11.2.3. Prescriber's name
  - 3.11.2.4. Date of preparation and expiration, day and/or time
  - 3.11.2.5. Full generic name of the antineoplastic and supportive care medications
  - 3.11.2.6. Drug dose
  - 3.11.2.7. Route of administration
  - 3.11.2.8. A label denoting HAZARDOUS DRUG, if applicable
- 3.11.3. Labels specific for parenteral medications:
  - 3.11.3.1. Total volume required to administer the drug
  - 3.11.3.2. Total number of products to be administered when the medication is dispensed in divided doses-each product should be labeled with the total number of products to be administered and the individual product sequence within the total grouping, for example: one of five, two of two, etc
  - 3.11.3.3. Date the medication is to be administered
  - 3.11.3.4. A warning or precautionary label or sticker, as applicable, for storage and handling
- 3.11.4. Labels specific for oral medications:
  - 3.11.4.1. Dosage form of the medication
  - 3.11.4.2. Quantity to be dispensed within each container
  - 3.11.4.3. Number of pills per dose when the container holds more than one dose
  - 3.11.4.4. Administration schedule, including number of times per day to take medication and days on or off medication (cycle length) when applicable, and when follow-up is scheduled
  - 3.11.4.5. Administration instructions related to food ingestion and other non-antineoplastic medications taken at home
  - 3.11.4.6. A warning or precaution label, as applicable, for specific storage and handling instructions

Note. Note on terminology changes: 1. Chemotherapy changed to antineoplastic therapy. 2. Health care setting changed to health care organization.

tubing, loose or disconnected lines, ensures multiple lines are infusing at the prescribed rate, the right drug is connected to the right pump, and the proper tubing or filters are used.

Standard 3.12.8 (new): Cytokine release syndrome (CRS) management policy is present and aligns with current literature and guidelines when administering antineoplastics with this potential adverse

TABLE 6. Dispensing and Administration

Standards–Domain 3 *(continued)*

3.12. Dispensing and administering parenteral antineoplastics whether administered in a health care organization or at home

- 3.12.1. A licensed pharmacist verifies all orders before dispensing parenteral antineoplastics in the health care organization that treats pediatric patients under age 18 years
- 3.12.2. Personnel approved by the health care organization to prepare or administer antineoplastic therapy perform four separate verifications in person or by institutionally approved video-enabled technology:
  - 3.12.2.1. First verification. Before preparation of the antineoplastic therapy personnel approved by the health care organization to prepare or administer antineoplastic therapy verifies and documents in the patient's medical record:
    - 3.12.2.1.1. Two patient identifiers
    - 3.12.2.1.2. Drug name
    - 3.12.2.1.3. Drug dose
    - 3.12.2.1.4. Route of administration
    - 3.12.2.1.5. Rate of administration
    - 3.12.2.1.6. The calculations for dosing, including the variables used in the calculation
    - 3.12.2.1.7. Treatment day and cycle
  - 3.12.2.2. Second verification. Upon preparation of the antineoplastic medication, a second licensed clinician approved by the health care organization to prepare antineoplastic therapy verifies:
    - 3.12.2.2.1. The drug vial(s)
    - 3.12.2.2.2. Concentration
    - 3.12.2.2.3. Drug volume or weight
    - 3.12.2.2.4. Diluent type and volume when applicable
    - 3.12.2.2.5. Administration route, filters, and tubing if applicable
  - 3.12.2.3. Third Verification. After preparation and before each antineoplastic therapy administration, at least two licensed clinicians approved by the health care organization to administer or prepare antineoplastic therapy independently verify and document the accuracy of the following elements in the patient's medical record:
    - 3.12.2.3.1. Drug name
    - 3.12.2.3.2. Drug dose
    - 3.12.2.3.3. Infusion volume or drug volume when prepared in a syringe
    - 3.12.2.3.4. Rate of administration
    - 3.12.2.3.5. Route of administration
    - 3.12.2.3.6. Expiration date/times
    - 3.12.2.3.7. Appearance and integrity of the drugs
  - 3.12.2.4. Fourth verification. In the presence of the patient: At least two licensed clinicians approved by the health care organization to administer or prepare antineoplastic therapy in person or through appropriate institutionally approved video-enabled technology, with at least one person on site, verify the patient's identification using at least two identifiers and document accuracy in the patient's medical record. Document the accuracy of the following elements in the patient's medical record:
    - 3.12.2.4.1. Drug name
    - 3.12.2.4.2. Drug dose
    - 3.12.2.4.3. Rate and duration of infusion
    - 3.12.2.4.4. Route of administration
    - 3.12.2.4.5. Administration set (as applicable) eg, filters, specialized tubing
    - 3.12.2.4.6. Infusion pump (if applicable) settings, including rate
- 3.12.3. Before initiation of antineoplastic therapy, personnel approved by the health care organization who is administering the antineoplastic(s) confirms the therapy with the patient, including, at a minimum, the name of the drug, the infusion time, route of infusion, symptoms to report, for example: hypersensitivity symptoms or pain at infusion site
- 3.12.4. Parenteral antineoplastic therapy is administered by a licensed clinician approved by the health care organization as defined in Standard 1.1
- 3.12.5. Documentation in the patient's medical record confirms the four verifications prior to parenteral antineoplastic administration and the patient's clinical status during and upon completion of antineoplastic therapy

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TABLE 6. Dispensing and Administration *(Continued)*

Standards–Domain 3 *(continued)*

- 3.12.6. Infiltration and extravasation management policy is present and aligns with current literature and guidelines. Antidote order sets and the antidotes are accessible within the appropriate time frame for treatment
- 3.12.7. Hypersensitivity and anaphylactoid management policy is present and aligns with current literature and guidelines. Hypersensitivity order sets and medications are accessible within the appropriate timeframe for optimal treatment
- 3.12.8. Cytokine release syndrome management policy is present and aligns with current literature and guidelines when administering antineoplastics with this potential adverse effect. Antidote and cytokine release syndrome–directed therapy order sets and medications are accessible within the appropriate timeframe for optimal treatment

Note. Note on terminology changes: 1. Chemotherapy changed to antineoplastic therapy. 2. Health care setting changed to health care organization.

effect. Antidote and CRS-directed therapy order sets and medications are accessible within the appropriate timeframe for optimal treatment.

Literature review update results and interpretation. New immune effector cell therapies, such as bispecific antibodies that may cause CRS, have been used since the 2016 standards. The Expert Panel expects significant uptake in general oncology clinics and according to ASCO guidance, "The incidence of CRS has been reported to range from 57% to 93%, on the basis of the agent used,"[52] and thus, patients will need anticytokine therapywith reasonable frequency. Data fromclinical trials suggest that while late CRS can occur, the risk of CRS decreases substantially after step-up dosing is complete[53-56] and that anticytokine therapy may decrease the likelihood of subsequent CRS events while maintaining treatment response.[57] Currently, the prescribing information for most bispecific antibody therapies states that patients should receive step-up dosing in the inpatient setting although outpatient step-up dosing protocols exist in the literature.[58-60] The ASCO Guidelines state "Strongly consider evaluation and/ or transfer to a specialty center that has experience with CAR-T toxicity management. If treated in an outpatient setting, it is advisable that patients remain within 2 hours of the treating center for 4-8 weeks post-therapy and should return to their treating center upon experiencing any toxicities."[52]

Domain 4: Monitoring During and After Antineoplastic Therapy Is Administered, including Adherence, Toxicity, and Complications

Standard 4.2: The health care organization has a policy for emergent treatment of patients that aligns with current literature and guidelines and addresses:

4.2.1. Availability of appropriate emergency equipment and rescue agents and antidotes in the health care organization, whether in a health care facility or the patient's home

4.2.2. Procedures to follow and a plan for escalation of care, when required, for life-threatening emergencies. (no change)

Literature review update results and interpretation. The updated standards add that preparation for emergencies must be ensured in the home whether provided by personnel from the health care organization, third party, and/or patients and caregivers. Otherwise, there were no major changes.

Standard 4.6: The health care organization has a policy that requires ongoing assessment of barriers to adherence, including social determinants of health and financial constraints (see also Standard 1.5.8).

Literature review update results and interpretation. Although the data regarding the impact of social determinants of health on adherence to oncologic therapeutics are relatively scarce, studies of medication adherence in general internal medicine populations are more robust, and the Expert Panel extrapolated from that experience and included these standards specific to antineoplastic therapy.[61,62] The oncology literature, like the general medicine literature, however, is notable for suboptimally constructed studies and multiple confounding variables, hence making definitive statements about interventions unreliable. Authors of one oncology systematic review which included studies addressing screening and education, including education of the health care provider, cognitive behavioral therapy, and more, found that no single optimal intervention was "best."[63] An ONS oral adherence guideline makes conditional recommendations for education, screening, coaching, motivational interviewing, and, most importantly for Standard 4.6, ongoing assessment.

The recommendations are mostly based on very low quality of evidence determinations.[64] The absence of high-level data to prove the benefits of intervention did not preclude including this standard. A better understanding of the social context of the patient's cancer journey was sufficient to warrant its documentation.

Discussion

To optimize the safety of cancer care, ONS and ASCO have collaborated to refresh the antineoplastic administration standards. This document provides a blueprint for more than the administration of these potentially toxic medications only. It not only directs the specific act of delivering antineoplastic therapy but also addresses the steps before and after administration. The standards provide a guide for health care organizations to create processes to ensure quality and optimal patient outcomes and safety. The standards begin with the training of staff and patient education and progress through the ordering and preparation of the drugs and the delivery and administration to the patient at the bedside or chairside.

These standards present a minimum for health care organizations providing antineoplastic therapy. ASCO-ONS provides these standards as a foundation for institutions to create their own approaches consistent with their unique staffing characteristics, state laws, and institutional preferences, without intent to establish individual institutional workflow or policies. The standards offer a basis for institutional quality improvement and are consistent with ASCO-COA Oncology Medical Home Standards.[7] Practices aspiring to the new ASCO Certified Patient-Centered Cancer Care Standards to qualify as an oncology medical home will need to adhere to these updated measures.[65]

Ultimately, regardless of the quality of care provided by a health care organization, its success depends on the patient's capacity to receive treatment as planned. The standards continue to stress the importance of assessing social determinants of health, which can significantly affect incidence, adherence, and compliance.[66-68] The providers' role in assessment and management of financial toxicity is more formally highlighted. Although the importance of discussing fertility preservation before the initiation of anticancer therapy has been highlighted in both ONS and ASCO guidance, data from the adolescent and young adult population suggest insufficient implementation.[19,69,70] As a result, the Expert Panel has not only again highlighted the importance of fertility preservation but also added language stressing the need for pregnancy avoidance during treatment because of the risk of teratogenicity.

The refreshed standards also recognize the increasing complexity of antineoplastic therapy with specific mention of therapies and toxicities that were not part of the previous standards. For example, interventions that can induce CRS are mentioned as is maintaining appropriate therapies available to manage these more prevalent toxicities. In addition, the current standards attempt to level the significance of all antineoplastics—whether oral or parenteral, administered in a health care facility or in the home. When possible, the Expert Panel has merged standards when appropriate, regardless of the route of medication administration or setting.

To reduce human error, the ASCO-ONS standards have consistently relied on a double check or

TABLE 7. Intrathecal Administration of Antineoplastic Therapy

Standards–Domain 3 *(continued)*
3.13 Administering antineoplastics directly into the cerebrospinal fluid: The health care organization that administers intrathecally or intraventricularly maintains policy that specifies that these agents are: ■ 3.13.1. Prepared separately from other antineoplastic therapies ■ 3.13.2. Labeled immediately after preparation with a uniquely identifiable label for intrathecal or intraventricular medication ■ 3.13.3. Stored in an isolated container or location after preparation from any other antineoplastic medications ■ 3.13.4. Delivered to the patient only with other medications intended for administration into the central nervous system ■ 3.13.5. Administered immediately after a time out, double check procedure that involves two licensed practitioners or other licensed clinicians approved by the health care organization to prepare or administer antineoplastic therapy ■ 3.13.6. The health care organization that administers antineoplastic therapy directly into the cerebral spinal fluid has policy that specifies that intravenous vinca alkaloids are administered only by infusion, for example, mini bags
Note. Note on terminology changes: 1. Chemotherapy changed to antineoplastic therapy. 2. Health care setting changed to health care organization.

TABLE 8. Domain 4: Monitoring During and After Antineoplastic Therapy Is Administered, Including Adherence, Toxicity, and Complications

Standards–Domain 4
4.1. The health care organization uses standard, disease-specific processes to monitor treatment response based on evidence and national guidelines when available
4.2. The health care organization has a policy for emergent treatment of patients that aligns with current literature and guidelines and addresses: ■ 4.2.1. Availability of appropriate emergency equipment and rescue agents and antidotes in the health care organization, whether in a health care facility or the patient's home ■ 4.2.2. Procedures to follow and a plan for escalation of care, when required, for life-threatening emergencies
4.3. The health care organization has a 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
4.4. The health care organization policy outlines the procedure to monitor initial and subsequent assessment and documentation of patients' adherence to antineoplastic therapy
4.5. The health care organization has a policy that strives to minimize treatment toxicity: ■ 4.5.1. The health care organization has a policy that requires assessment and documentation of toxicity at each clinical encounter to address any issue ■ 4.5.2. The health care organization has a policy that requires documentation of treatment-related toxicities, dose modification related to toxicities, and how these are communicated before subsequent administration ■ 4.5.3. Cumulative doses of antineoplastic therapy are tracked for agents associated with cumulative toxicity
4.6. The health care organization has a policy that requires ongoing assessment of barriers to adherence, including social determinants of health and financial constraints
Note. Note on terminology changes: 1. Chemotherapy changed to antineoplastic therapy. 2. Health care setting changed to health care organization.

verification at various steps of the process of preparing and delivering antineoplastic therapy. Previous standards contained three steps. The refreshed standards now include a fourth verification at the patient's location before administration.

The first verification occurs before the preparation of the drug(s), the second on preparation, and the third before administration. The new fourth verification includes verification of patient identification, drug, dose, and route and ensures that rate settings on any drug delivery device are accurately set and the patient and caregiver or family member know the plan.[8,9,71-74] The fourth verification anticipates that patients might receive the drug at a remote setting for which the health care organization has responsibility. The evolving complexity of oncologic care is not only its enlarging pharmacopeia. Insurers and pharmacy benefit plans have created a variety of novel relationships. Hence, physicians may prescribe drugs that are not administered in settings over which they have direct oversight or through white bagging or brown bagging may be required to administer drugs that have been prepared elsewhere.[75,76] These new standards attempt to clarify the relative responsibilities within these relationships to ensure these antineoplastics' quality, provenance, and administration.

The development of these administration standards results from a careful review of data that define a problem or series of problems,[9] with a paucity of randomized trials to provide solutions. The standards also account for evolving technologies meant to assist in the provision of safe care. Publications highlight the promise of such technology with limited controlled data. As a result, many of these standards are a common sense response to minimize identifiable sources of medical error in the administration of antineoplastics.

Additional information is available at www.asco.org/standards.

Health Equity Considerations

Social determinants of health, defined by the WHO as the conditions in which an individual is born, grows,

Related ASCO and ONS Standards

Oncology Medical Home: ASCO and COA Standards[7]
https://doi.org/10.1200/OP.21.00167

Safe Handling of Hazardous Drugs[82]
https://doi.org/10.1200/JCO.18.01616

Medically Integrated Dispensing[83]
https://bit.ly/4bjRxAn

Fertility Preservation[19]
https://doi.org/10.1200/JCO.2018.78.1914

Geriatric Assessment[84]
https://doi.org/10.1200/JCO.23.00933

ONS Guidelines™ to Support Patient Adherence to Oral Anticancer Medications[64]
https://bit.ly/3X4qxAD

ASCO—American Society of Clinical Oncology; ONS—Oncology Nursing Society

lives, works, and ages, can undermine ASCO-ONS's expert guidance on best practices for prevention, screening, palliative and supportive care, and disease management for many patients with cancer.[24] It is important to acknowledge that many people in the United States and elsewhere do not receive the highest level of cancer care because of the long-term impact of structural racism and the consequential unequal distribution of wealth among racial groups.[77]

In the United States, many patients remain unable to reap the benefits of innovative prevention and early detection programs, biomarker testing, and new cancer therapies because of structural barriers including lack of transportation, stable housing, and adequate insurance coverage as well as food insecurity, health literacy, proximity to a dedicated cancer center, and cost of treatment and other services.[78] In addition, sexual and gender minority people experience stigma along with barriers to cancer screening, prevention, and treatment that contribute to these cancer disparities.[79] Disparities widen in those who are also from a racial or ethnic minority, underscoring the influence of intersectionality in cancer health disparities.[80]

Furthermore, geographic disparities can also affect the quality of care patients receive. Rural patients are more likely to have worse survivorship outcomes and experience higher mortality rates compared with nonrural patients. This can be attributed, in part, to a lower density of specialist providers and dedicated cancer centers as only 21% of nonmetropolitan counties in the United States have one or more practicing oncologists.[81]

Additional Resources

For current information, including selected updates, supplements, slide sets, and clinical tools and resources, visit www.asco.org/standards. The Supplement for the standards includes search terms. Listen to key insights from panel members on the ASCO Guidelines podcast. The ASCO Standards Policies and Procedures Manual (available at www.asco.org/standards) provides additional information about the methods used to develop these standards. Patient information is available at www.cancer.net.

ASCO welcomes your comments on these standards, including implementation challenges, new evidence, and how these standards impact you. To provide feedback, contact us at guidelines@asco.org. Comments may be incorporated into a future refresh. To submit new evidence or suggest a topic for development, complete the online form.

Gender-Inclusive Language

ASCO is committed to promoting the health and well-being of individuals regardless of sexual orientation or gender identity.[85] Transgender and nonbinary people, in particular, may face multiple barriers to oncology care including stigmatization, invisibility, and exclusiveness. One way exclusiveness or lack of accessibility may be communicated is through gendered language that makes presumptive links between sex and anatomy.[86-89] With the acknowledgment that ASCO guidance may impact the language used in clinical and research settings, ASCO is committed to creating gender-inclusive guidance. For this reason, authors use gender-inclusive language whenever possible throughout the standards. In instances in which the standards draw upon data on the basis of gendered research (eg, studies regarding women with ovarian cancer), the authors describe the characteristics and results of the research as reported.

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Appendix 1. Standards Disclaimer

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Appendix 2. Conflicts of Interest

The Expert Panel was assembled in accordance with ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines ("Policy," found at http://www.asco.org/guideline-methodology). All members of the Expert Panel completed ASCO's disclosure form, which requires disclosure of financial and other interests, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the standards. Categories for disclosure include employment; leadership; stock or other ownership; honoraria, consulting or advisory role; speaker's bureau; research funding; patents, royalties, other intellectual property; expert testimony; travel, accommodations, expenses; and other relationships. In accordance with the Policy, the majority of the members of the Expert Panel did not disclose any relationships constituting a conflict under the Policy.

TABLE A1. ASCO-ONS Standards Expert Panel Membership

Name	Affiliation	Role or Area of Expertise
Robert Siegel, MD, FACP, FASCO (Co-Chair, ASCO)	Bon Secours St Francis Cancer Center, Greenville, SC	Hematology/Oncology
MiKaela M. Olsen, DNP, APRN-CNS, AOCNS®, FAAN (Co-Chair, ONS)	Johns Hopkins Hospital and Health System, Baltimore, MD	Oncology Nursing
Lisa Barbarotta, MSN, APRN-BC, AOCNS®	Smilow Cancer Hospital and Yale Cancer Center, New Haven, CT	Oncology Nursing
Alexandre Chan, PharmD, MPH, FCCP, FISOPP, BCPS, BCOP, APh[a]	University of California, Irvine, Chao Family Comprehensive Cancer Center, National Cancer Centre Singapore, Irvine, CA	Oncology Pharmacy
David W. Dougherty, MD, MBA	University of Pennsylvania, Philadelphia, PA	Medical Oncology
Amy Evers, MBA, RN, OCN®, CPHQ	University of Pennsylvania Health System, Philadelphia, PA	Oncology Nursing, Oncology Quality and Safety
Michael Ganio, PharmD, MS, BcPs, FASHP[b]	American Society of Health-System Pharmacists, Bethesda, MD	Pharmacy Practice and Quality
Brad Hunter, MD, MPH	Intermountain Health, Salt Lake City, UT	Cellular Therapy
Kristine B. LeFebvre, DNP, RN, NPD-BC, AOCN®	ONS, Pittsburgh, PA	Oncology Nursing, Oncology Clinical Specialist
Tamara P. Miller, MD, MSCE[c]	Emory University/Children's Healthcare of Atlanta, Atlanta, GA	Medical Oncology—Pediatrics
Therese M. Mulvey, MD, FASCO	Massachusetts General Cancer Center, Boston, MA	Medical Oncology
Amanda Ouzts, PharmD, BCOP, BcPS[d]	Huntsville Hospital, Huntsville, AL	Oncology Pharmacy
Martha Polovich, PhD, RN, AOCN®-Emeritus	University of Maryland School of Medicine, Baltimore, MD	Oncology Nursing
Maritza Salazar-Abshire, MSN, MEd, RN, CPON[e]	Department of Nursing Education, The University of Texas MD Anderson Cancer Center, Houston, TX	Oncology Nursing–Pediatrics, Nursing Education
Elaine Z. Stenstrup, MSN, RN, ACNS-BC, AOCNS®, BMTCN®	City of Hope National Medical Center, Duarte, CA	Oncology Nursing
Christine Sydenstricker, RN, BSN, MBA, CPHQ	Hondros College of Nursing, Akron, OH	Oncology Nursing
Susan Tsai, MD, MHS	Ohio State University Comprehensive Cancer Center, Columbus, OH	Surgical Oncology, ASCO Volunteer Corps
Sarah Temin, MSPH	ASCO, Alexandria, VA	ASCO Practice Guideline Staff (Health Research Methods)

ASCO—American Society of Clinical Oncology; ONS—Oncology Nursing Society
Note. Official Representatives: (a) International Society of Oncology Pharmacy Practitioners (ISOPP), (b) American Society of Health-System Pharmacists (ASHP), (c) American Society of Pediatric Hematology/Oncology (ASPHO), (d) Hem/Onc Pharm Association (HOPA), (e) Association of Pediatric Hematology/Oncology Nurses (APHON).

TABLE A2. Definition of Terms

Term	Definition
Adherence	The degree or extent of conformity to the provider's recommendations about day-to-day treatment regarding timing, dosing, and frequency
Antineoplastic therapy/antineoplastic regimen	All antineoplastic agents used to treat cancer, regardless of the route. Types include targeted agents (eg, small-molecule inhibitors), chemotherapy, and immunotherapy (eg, monoclonal antibodies, checkpoint inhibitors, biologics, cellular therapies). Hormonal therapies are not included in the definition of antineoplastic agents for these standards
Antineoplastic treatment plan	A treatment plan specific to the patient developed before the initiation of antineoplastic therapy
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 definition)
Basic life support	Certification can be obtained and is time limited. (eg, American Heart Association). Basic life support is a term used to describe maintenance of a clear airway and support of breathing and the circulation in cases of cardiac arrest[90]
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 (eg, recurrence, metastases)
Cancer support services	A list of informational, psychosocial, and financial resources available for cancer support
Combination of antineoplastic therapy/regimen	One or more antineoplastic agents used alone or in combination in a well-defined protocol or course of treatment, generally administered cyclically
Clinical encounter	Clinical encounters include each inpatient day, scheduled or unscheduled practitioner visits, home visits, and antineoplastic therapy administration or supportive care visits, but not laboratory or administrative visits
Clinician	Staff involved in patient care—may be licensed (eg, registered nurse or pharmacist) or unlicensed (eg, patient care assistant)
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 antineoplastic therapy administration includes all routes of administration used in the practice or institution or home site and safe handling of hazardous antineoplastic therapy agents and concludes in clinical competency assessment. Examples of education programs for staff administering antineoplastic therapy agents include the ONS/ONCC Chemotherapy Immunotherapy Certificate™ Course and the APHON Pediatric Chemotherapy and Biotherapy Provider Program
Consent	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 based on 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 indicates the duration or the frequency of the dose to be administered—e.g., once daily, once 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	A request for antineoplastics or doses of antineoplastics that differs from the standardly available institutional treatments for a given condition. Examples include using an order set for a disease not assigned, adding a medication not included in the standard regimen, and escalation of dose or schedule beyond that defined in a standard regimen

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TABLE A2. Definition of Terms *(Continued)*

Term	Definition
Functional status	A narrative description of 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 organization	Entity responsible for antineoplastic therapy ordering, preparation, and administration regardless of the setting including but not limited to a medical office or practice, clinic, agency, company, hospital, or the patient or caregiver's home
Health care facility	A location that devotes some or all of its resources (people, places, things) to the delivery of medical services (including the financial and administrative management of those resources), a distinction from the home as a place for the provision of care
Hypersensitivity/anaphylactoid 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. Anaphylaxis reactions range from severe to life-threatening immune reactions
Identifier (patient identification)	A set of parameters which, when taken, are unique to the individual. These can include but are not limited to: 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 and/or from interpreter services (if language barrier) 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 who 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 antineoplastic therapy 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 during the preparation (ie, mixing, compounding) process based on ample evidence showing equivalent safety outcomes and 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	A descriptor which is tightly affixed to an antineoplastic agent which identifies its contents, dose, and parameters of administration. The required components of the label and their verification are detailed in the standards
Licensed practitioner	Any individual permitted by law and by the medical staff and board to provide care and services without direction or supervision within the scope of the individual's license and consistent with individually granted clinical privileges, eg, MD, NP, PA, CNS, etc
Medical record	Document containing specifics of patient care in either electronic or written form
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

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TABLE A2. Definition of Terms *(Continued)*

Term	Definition
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	Patient care communications that are written or sent electronically must be transmitted in a HIPAA-compliant manner. They can be on paper (written or faxed) or e-mailed from a secure encrypted computer system and include the licensed independent practitioner'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
Parenteral	Introduction of substances by intravenous, intra-arterial, subcutaneous, intramuscular, intrathecal, intraventricular, or intracavitary routes
Performance status	The use of standard criteria for measuring how the disease impacts the patient's daily living abilities, usually represented numerically
Policy	A written course of action—for example, procedure, guideline, protocol, or algorithm
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

CNS—certified nursing specialist; HIPAA—Health Insurance Portability and Accountability Act; NP—nurse practitioner; PA—physician assistant