

Professional Practice Considerations

A. Scope and standards

1. Administration of chemotherapy, targeted therapy, and immunotherapy in a variety of settings is within the oncology nurse's scope of practice (Brant & Wickham, 2013).
2. Professional nursing practice is defined and regulated at four levels (American Nurses Association, 2015).
 - a) Practice is defined nationally through the scopes and standards of practice, codes of ethics, and specialty certifications.
 - b) States regulate practice through boards of nursing and nurse practice acts.
 - c) Institutions outline policies and procedures.
 - d) Nurses are individually licensed and consequently are responsible for their individual decisions and actions.
3. In 2008, the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) began an ongoing collaboration to define and later revise safety standards for chemotherapy and other antineoplastic agents. The ASCO/ONS Chemotherapy Administration Safety Standards (Neuss et al., 2016) address staffing-related issues, antineoplastic therapy planning, documentation, orders, preparation, patient education, administration, and monitoring, with application to all settings and patient populations.

B. Professional education

1. To promote a safe level of care for individuals receiving chemotherapy, targeted therapy, and immunotherapy, each institution or supporting agency should provide specialized education and preparation consisting of didactic learning followed by successful completion of a clinical practicum (ONS, 2017).
2. Didactic content is comprehensive, current, and evidence based. At the conclusion of the didactic course, the nurse demonstrates an under-

standing of the following, as identified in the ONS (2017) position statement on the education of the nurse who administers chemotherapy, targeted therapy, and immunotherapy:

- a) Types, classifications, and routes of administration
 - b) Pharmacology of agents, regardless of indications for use
 - c) Pertinent molecular biomarkers
 - d) Chemotherapy and radiation therapy protectants
 - e) Principles of safe preparation, storage, labeling, transportation, and disposal of agents
 - f) Administration procedures
 - g) Appropriate use and disposal of personal protective equipment (PPE)
 - h) Assessment, monitoring, and management of patients receiving therapy in the care setting
 - i) Patient and family education for these agents, specific to side effects and related symptom management, and process for urgent and ongoing follow-up
 - j) Assessment of, education on, and management of post-treatment care, including follow-up care procedures, late or long-term side effects, and physical and psychosocial aspects of survivorship
3. The clinical practicum allows the nurse to apply the knowledge gained in the didactic component to direct patient care situations. Emphasis is placed on the clinical skills that a nurse must demonstrate prior to being deemed competent to administer chemotherapy, targeted therapy, and immunotherapy (see Appendices A and B). At the completion of the clinical practicum, the nurse will be able to perform the following:
 - a) Demonstrate proficiency regarding the safe preparation (when applicable), storage, transport, handling, spill management, adminis-

- tration, and disposal of antineoplastic drugs and equipment.
- b) Identify appropriate physical and laboratory assessments for specific agents.
 - c) Demonstrate skill in venipuncture, including vein selection and maintenance of the site during and after drug administration.
 - d) Demonstrate skill in the care and use of various vascular access devices.
 - e) Identify patient and family education needs in relation to agents.
 - f) Identify acute local or systemic reactions (including extravasation and anaphylaxis) in association with antineoplastic drugs, and identify appropriate interventions.
 - g) Demonstrate proficiency in the safe administration of hazardous drugs (HDs) and disposal of contaminated waste and equipment.
 - h) Demonstrate knowledge of institutional policies and procedures regarding antineoplastic administration.
 - i) Document pertinent information in the medical record.
4. Clinical activities
- a) Pair nurses who are new to antineoplastic drug administration with an experienced nurse who can serve as preceptor, providing clinical supervision and instruction (Lockhart, 2016).
 - b) The preceptor and the nurse establish specific objectives at the beginning of the clinical practicum. Ideally, the nurse and preceptor select an assignment of patients, and the nurse assumes responsibility for planning and providing care for these patients under the guidance and supervision of the preceptor.
 - c) The length of time spent in the clinical practicum should be individualized depending on the nurse's ability and skill in meeting the specific objectives and institutional requirements.
 - d) The nurse should become proficient and independent in administering nonvesicants before progressing to vesicant administration.
 - e) Various clinical settings can be used for the nurse to demonstrate competence in antineoplastic drug administration. It may not be realistic for all settings or agencies to provide on-site education and training. Alternative methods can be used, such as the following:
 - (1) Contracting with larger institutions for didactic education or clinical experience, including experience for specific needs (e.g., vesicant, nonvesicant, IV push, short infusion, continuous infusion)
 - (2) Creating or using a simulated laboratory to substitute for the clinical component
5. Evaluation: An evaluation tool based on the desired outcomes should be used to document the nurse's knowledge of and competency in the following:
- a) Agents and the associated nursing implications
 - b) Technical skills required for the administration of agents (e.g., dose calculation, venipuncture, access device management)
 - c) Patient and family education about the treatment regimen
 - d) Steps to take in the event of an untoward response following drug administration (e.g., anaphylaxis, hypersensitivity reaction, extravasation)
6. Competency may be verified in a simulated setting (e.g., skills laboratory) or as a precepted experience in the clinical setting. Individualize the evaluation/documentation tool to meet the needs of the new nurse and the practice setting, including a minimum number of observed and documented antineoplastic drug administrations. Observed administration of at least three different agents, types, and routes (i.e., nonvesicant and vesicant; IV push and short-term infusion) is recommended.
7. Annual continuing education and ongoing competency assessment are required of staff who order, prepare, and administer antineoplastic agents (Neuss et al., 2016).
- a) Educational content should be designed to meet the needs of staff in the healthcare setting and emphasize new information available.
 - (1) Methods that may be used to identify needs include but are not limited to clinical observation, literature review, staff or patient survey, chart audits, and quality improvement studies.
 - (2) Potential topics include new drugs or drug delivery, reinforcement or training on policies and procedures, and prevention and management of treatment toxicities.
 - b) Competency assessment is ongoing, may be done by peers or supervisory staff, and is measured in several ways (Lockhart, 2016). Examples include the following:
 - (1) Testing: Provide a packet of articles for the staff to read or a live educational program followed by an open-book

- test to measure knowledge. Consider a pre- and post-test to measure individual knowledge gains.
- (2) Return demonstration: Competency checklists can be used to document performance of a technical skill, such as the donning and doffing of PPE used during drug administration. Staff can also be observed and evaluated using a scoring rubric with a checklist of criteria detailing the steps to take in practice. Examples include monitoring a nurse administering a vesicant or completing dose verification. Actions can be observed in practice or a simulated environment and later debriefed.
 - (3) Simulation: Simulation provides a safe environment for staff to practice clinical and critical-thinking skills. Staff can face a clinical challenge and problem-solve the steps to be followed, such as a patient experiencing an infusion reaction or extravasation. Asking nurses, “What would you do if . . .” challenges them to consider the implications of their actions. When a simulation lab is not available, it can be done through role-playing and mock scenarios in nearly any location.
8. Antineoplastic medications administered outside designated oncology areas: The ONS (2017) position statement on the education of the nurse administering and providing care to patients receiving chemotherapy, targeted therapy, and immunotherapy applies to antineoplastic drugs regardless of route, indication, patient population, or setting.
 - a) All nurses should be knowledgeable about the drugs they administer: the mode of action, side effects, and toxicity; dosage range, rate of administration, and route of excretion; potential responses; and interactions with other medications and foods.
 - b) The format, length, and specific focus of educational initiatives, both didactic education and the clinical experience, may vary according to the needs of the staff and setting. Select staff may require drug- or disease-specific education, whereas others will require comprehensive education for all antineoplastic medications.
 - c) Address the educational plan for all individuals working with chemotherapy, targeted therapy, and immunotherapy within institutional policy.
- C. Policies and procedures
 1. Policies should be developed using a systematic, evidence-based approach to promote standardization of practice within an institution. They identify and communicate expectations of practice (Dols et al., 2017).
 2. Once a policy has been implemented, it is imperative that it be enforced and followed by staff. Individuals can be held liable if patient harm results from failure to follow a policy. Institutions can have liability if a policy is not clear, contrasts with another policy, or could be interpreted in different ways.
 3. Collaboration between departments and professionals is recommended when creating antineoplastic policies and procedures. Input from pharmacy, medicine, nursing, environmental services, occupational health, and other departments will result in a more comprehensive policy.
 4. Policies related to antineoplastic drug therapy address processes designed to promote the safe and efficient care of patients receiving these medications, regardless of setting or department. Topics include the following (Neuss et al., 2016):
 - a) Qualifications, including initial educational and ongoing competency requirements, credentialing process, and documentation of staff who order, prepare, and administer chemotherapy, targeted therapy, and immunotherapy
 - b) HD management, including safe drug receipt, storage, compounding, transport, PPE, equipment used to administer HDs, administration, post-treatment care, spill management, disposal of HDs, alternative duty, and medical surveillance (U.S. Pharmacopeial Convention, 2016)
 - c) Order writing and dose verification, including process, standard regimens, rounding, cumulative dose, order format, and communication of modifications
 - d) Informed consent process
 - e) Toxicity monitoring, including standardized documentation and communication of toxicities
 - f) Procedures for care in medical emergencies
 - g) Communication of status during transitions of care
 - h) Reporting of adverse events and near misses
 - D. Antineoplastic medication safety
 1. Prevalence of medication errors: Medication errors cause nearly one death daily and 1.3 million injuries annually (U.S. Food and Drug Administration [FDA], 2017b).

2. Chemotherapy and other antineoplastic drugs are classified as high-alert medications by the Institute for Safe Medication Practices (ISMP, 2014). These medications have narrow therapeutic indices and multiple potential toxicities and often are administered in complex regimens, protocols, and schedules (Griffin, Gilbert, Broadfield, Easty, & Trbovich, 2016; Kullberg, Larsen, & Sharp, 2013).
3. Errors may occur at any point during the drug delivery process (Kullberg et al., 2013; Schwappach & Wernli, 2010; White, Cassano-Piché, Fields, Cheng, & Easty, 2014).
 - a) Ordering/prescribing: unclear or erroneous orders, drug calculation errors, omission of antineoplastic or supportive drugs or hydration, input and transcription errors, errors in cycle or day, cumulative dose documentation or tracking
 - b) Drug preparation: staging/loading the biosafety cabinet with incorrect equipment and supplies, rounding doses, reconstitution, compounding, label application, dispensing
 - c) Drug administration: incorrect drug or dose, schedule or timing errors, patient identification errors, infusion rate errors, route errors
4. Contributing factors to medication errors (Fyhr, Ternov, & Ek, 2017; Keers, Williams, Cooke, & Ashcroft, 2013; Shulman, Miller, Ambinder, Yu, & Cox, 2008; World Health Organization, n.d.)
 - a) Poor communication among healthcare professionals or with patients
 - b) Look-alike, sound-alike medications
 - c) "Batching" or preparing more than one agent at a time
 - d) Distractions/interruptions
 - e) Heavy workload, fatigue, stress
 - f) Lack of systematic processes
 - g) Medication supply and storage issues (e.g., drugs of similar names or dosage strengths stored in close proximity)
 - h) Equipment failures
 - i) Inadequate knowledge or experience of those ordering, preparing, or administering agents
 - j) Patient factors: literacy, language barriers, complexity of care
5. System safeguards: The following strategies have been used to reduce the risk of medication errors in antineoplastic administration (Goldspiel et al., 2015; ISMP, 2014; Neuss et al., 2016; ONS, 2017).
 - a) Develop policies and procedures using interprofessional collaboration, and include strategies to promote adherence.
 - b) Establish a process of educational preparation and competency of those administering, preparing, or ordering chemotherapy, targeted therapy, or immunotherapy. Nurses administering antineoplastic agents are RNs qualified by education and training.
 - c) Ensure current drug information and resources for drug dosing, administration, and side effects are readily available.
 - d) Follow standards regarding chemotherapy, targeted therapy, and immunotherapy orders.
 - (1) Orders are signed manually or by electronic approval by credentialed prescribers (ISMP, 2017; Neuss et al., 2016).
 - (2) Verbal orders for chemotherapy, targeted therapy, and immunotherapy medications are not permitted, except to hold or stop drugs (ISMP, 2017; Neuss et al., 2016).
 - (3) Text messaging of patient care orders is not permitted (Joint Commission, 2016).
 - (4) Standardized electronic or preprinted orders should be used for chemotherapy, targeted therapy, and immunotherapy (ISMP, 2010; Neuss et al., 2016).
 - (a) Orders should be regimen based and include the elements outlined by current safety standards.
 - (b) Use of standardized, regimen-based preprinted or electronic orders has been shown to increase evidence-based oncology care and decrease errors (Meisenberg, Wright, & Brady-Copertino, 2014). The National Comprehensive Cancer Network[®] (www.nccn.org) has disease-specific guidelines and chemotherapy order templates that include suggested patient monitoring for cancer type and stage (e.g., type and timing of imaging) and treatment regimen (e.g., toxicity monitoring). See Appendix C for an example of a chemotherapy order template.
 - (c) Avoid the use of abbreviations, acronyms, and other ambiguous methods of communicating drug information.
 - (5) Safety advantages reported with the use of electronic prescribing over preprinted orders include the removal of interpretation or transcription errors, availability of information about drug doses and schedules, automatic calcu-

lation of medication doses, and alert and error-checking functions (Aita et al., 2013). However, some errors specific for oncology include “cut and paste” errors—propagation of errors from cutting and pasting, and errors resulting from dose reduction or medication changes not being propagated into future cycles.

- (6) A policy should be in place for prescribing chemotherapy, targeted therapy, and immunotherapy regimens that vary from standard regimens. For example, the prescriber may be required to document supporting references for the variance.
- e) Use safety measures provided in electronic health record systems, such as drug interaction alerts, cumulative dose calculation (when applicable), and override restrictions (Weingart, Zhu, Young-Hong, Vermilya, & Hassett, 2014).
- f) Require at least two practitioners approved by the healthcare setting to administer or prepare antineoplastic agents to perform dose and drug verification for all routes of delivery before preparation, upon preparation, and prior to the administration of chemotherapy, targeted therapy, and immunotherapy (Neuss et al., 2016).
 - (1) Independent dual verification (i.e., independent double checks): A process in which a second person conducts a verification of the accuracy of the prescribed therapy, without revealing findings to the other verifier until both have completed the process (ISMP Canada, 2005).
 - (2) Numerous studies have demonstrated the ability of independent double checks to detect up to 95% of errors (Grasha, Reilley, Schell, Trantum, & Filburn, 2001; White et al., 2010).
 - (3) Checklists may help promote a consistent process (White et al., 2010; see Appendix D).
 - (4) Prior to administering antineoplastic agents, review the treatment plan and verify orders, the medication, the patient, and the pump programming (Neuss et al., 2016). See Chapter 11 for greater detail on dose verification.
 - (5) Conducting a comprehensive review of the medication orders rather than simply comparing the product to the order is invaluable in catching prescribing errors (ISMP, 2013).
- (6) Perform drug and dose verification in a distraction-free setting.
- g) Establish procedures for emergency preparedness.
 - (1) Provide 24/7 triage to a provider—for example, on-call practitioners or emergency departments (Neuss et al., 2016).
 - (2) At least one clinical staff member certified in basic life support must be present during chemotherapy administration. Staff certified in advanced cardiac life support or pediatric advanced life support may be indicated depending on the setting and types of treatments delivered (Neuss et al., 2016).
 - (3) Policies, procedures, and standardized orders should be in place for the management of medical emergencies (Schivavone, 2009). Procedures include the process for monitoring/tracking the availability and readiness of emergency equipment and expiration date on medications, including antidotes and rescue agents.
 - (4) Educate staff regarding who to call and the process for contacting the provider/team (e.g., outpatient nurses need to be clear as to whether they should contact 911 or the institution’s code team).
 - (5) Orders for the treatment of infusion emergencies should be available to enable immediate intervention without waiting for the provider’s order. Indications for each medication should be clearly defined (e.g., indications for epinephrine, diphenhydramine, steroids).
 - (6) All team members should understand their role and responsibilities in an emergency situation.
 - (7) Verify that emergency equipment and supplies, including oxygen, are available and working and that staff are aware of their location. Infusion chairs should be functional to change position if needed.
 - (8) Extravasation: Establish policies, procedures, and standardized orders and have antidotes in place for the management of vesicant extravasation (ISMP, 2016; Neuss et al., 2016; see Chapter 13).

- (a) Staff must be knowledgeable regarding the management of extravasation, the location of orders, and the process for obtaining antidotes.
 - (b) Coupled order sets (e.g., inclusion of an order on the antineoplastic therapy order set, such as “Initiate extravasation orders for suspected extravasation”) permit the prompt and evidence-based management of emergencies such as extravasation (ISMP, 2016).
- (9) Ensure that antidotes or rescue agents (where applicable) and directions for use are readily available (ISMP, 2016; Nelson, Moore, Grasso, Barbarotta, & Fischer, 2014).
- (10) Conduct process improvement projects and educational programs designed to provide patients with prompt, evidence-based interventions.
- (a) Evaluate previous emergent situations to determine what worked and areas for improvement.
 - (b) Consider running mock codes and mock infusion reactions. Numerous studies have shown that these drills increase practitioner proficiency and confidence and decrease anxiety (Dorney, 2011; Ruesseler et al., 2012; Scaramuzzo, Wong, Voitle, & Gordils-Perez, 2014).
- h*) Communication and handoffs: Implement a standardized process to promote effective handoffs between nurses and between care sites (as applicable to role) for patients receiving antineoplastic therapy (Neuss et al., 2016).
- (1) Nursing bedside rounds and interprofessional rounds have been found to increase communication and decrease errors (Garcia-Alonso, 2011; Taylor, 2015).
 - (2) Document any missed patient appointments or treatments, and follow up with the patient and other members of the healthcare team (Neuss et al., 2016).
 - (3) Document an accurate treatment summary, including history, previous cancer treatments, and current treatment when a patient is transferred to a different healthcare setting. The ASCO Institute for Quality has example templates on its website (www.instituteforquality.org/cancer-treatment-plan-and-summary-templates).
- i*) Provide ongoing patient education, including information, motivation, and encouragement to patients to become “vigilant partners” in safety measures (Bruce, 2013; Schwappach & Wernli, 2010).
6. Drug shortages
- a*) Drug shortages can have significant clinical effects (Becker et al., 2013; Fox, Sweet, & Jensen, 2014; McBride et al., 2013).
 - (1) Treatment outcomes can be affected by omitted or reduced doses from delays or changes in treatment regimens.
 - (2) Medication errors
 - (a) Healthcare providers are not knowledgeable about substitute medications when the preferred drug is unavailable, potentially resulting in errors in dosing, adverse effects, and drug interactions.
 - (b) A different concentration or brand is purchased, potentially affecting how the dose is prepared, dispensed, and administered.
 - (c) Look-alike/sound-alike medications are purchased from a different manufacturer.
 - (3) Increased costs
 - (a) Cost of replacement medications may be significant. Becker et al. (2013) noted a 1,704% cost increase when paclitaxel was replaced by docetaxel for a single treatment.
 - (b) Labor costs are associated with seeking sources for replacement supplies, managing inventory, updating computer systems for replacement medications, and educating staff.
 - b*) The Food and Drug Administration Safety and Innovation Act, which became law in 2012, requires pharmaceutical companies to notify FDA when a product may be affected by production changes or manufacturing interruptions (U.S. FDA, 2014).
 - c*) FDA (2017a) works with manufacturers to minimize the impact of drug shortages. A list of drugs in short supply is maintained on the FDA website (www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm).

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