CHAPTER 1 Professional Practice Considerations

A. Scope and standards

- 1. The safe administration of antineoplastic treatments in various settings is within the oncology nurse's scope of practice (Lubejko & Wilson, 2019).
- 2. Professional nursing practice is defined and overseen through regulatory influencers and five integral components (American Nurses Association, 2021).
 - *a) Evidence* incorporates scientific and research findings, the expertise of the nurse, and the preferences of the individual.
 - *b) Nursing practice* is the autonomous actions of the professional nurse in any role.
 - *c) Influencers* include state nurse practice acts, the scope and standards that guide practice and specialty practice, and institutional policies and procedures.
 - *d) Safety measures* protect the patient from harm or undesirable outcomes.
 - *e) Quality* strives to obtain desirable outcomes of nursing practice for patients, families, the organization, and the profession.
- 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 addressed staffing-related issues, antineoplastic therapy planning, documentation, orders, preparation, patient education, administration, and monitoring for all settings and patient populations (Neuss et al., 2016).

B. Professional education

- 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, 2020).
- 2. Didactic content is comprehensive, current, and evidence based. After the didactic course, a nurse

must demonstrate an understanding of the following (ONS, 2020):

- *a*) Types of antineoplastic medications, classifications, and routes of administration
- *b*) Pharmacology of agents regardless of indications for use
- *c*) Pertinent molecular biomarkers, including genomic assays
- d) Chemotherapy and radiation therapy protectants
- *e)* Principles of safe preparation, storage, labeling, transportation, and disposal of agents
- *f*) Safe administration procedures
- *g*) Procedures for safe handling of hazardous drugs, including spill management
- *h*) Appropriate use and disposal of personal protective equipment
- *i*) Use of engineering controls, if applicable to the practice setting, including the use of closed-system drug-transfer devices
- *j*) Assessment, monitoring, and management of patients receiving therapy
- *k*) Medication safety and system safeguards, such as infusion pump safety features
- *l*) Appropriate procedures for emergency preparedness, including infusion reactions and extravasation
- *m*) Appropriate documentation of treatment administration, patient education, and planned follow-up care and testing
- n) Patient, family, and caregiver education for these agents, specific to side effects and related symptom management, and the process for urgent and ongoing follow-up
- e) Education and coordination of post-treatment care and testing, adverse events, and long-term side effects; physical and psychosocial impacts of a cancer diagnosis and treatment; and follow-up care during survivorship
- 3. Clinical practicum
 - *a*) The clinical practicum allows the nurse to apply the knowledge gained in the didactic component to direct patient care situations.

- b) Emphasis is placed on the clinical skills that the nurse must demonstrate prior to being deemed competent to administer antineoplastic therapy (see Appendices A and B). The nurse must also display knowledge of organizational policies and procedures related to antineoplastic administration.
- *c)* After the clinical practicum, the nurse will be able to perform the following:
 - Demonstrate proficiency regarding safe preparation (when applicable), storage, transport, handling, spill management, administration, and disposal of antineoplastic drugs and equipment.
 - (2) Identify appropriate physical and laboratory assessments for specific agents.
 - (3) Demonstrate skill in venipuncture, including vein selection and maintenance of the site during and after drug administration.
 - (4) Demonstrate skill in the care and use of various vascular access devices.
 - (5) Identify patient and family educational needs related to agents.
 - (6) Identify acute local or systemic reactions, including extravasation and anaphylaxis, associated with antineoplastic drugs and identify appropriate interventions.
 - (7) Demonstrate proficiency in the safe administration of hazardous drugs and disposal of contaminated waste and equipment.
 - (8) Document pertinent information in the medical record.
- 4. Clinical activities
 - *a)* Pair a nurse new to antineoplastic drug administration with an experienced nurse who can serve as a preceptor and provide 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 a patient assignment. The nurse assumes the responsibility for planning and providing care for this patient under the guidance and supervision of the preceptor.
 - c) The time spent in the clinical practicum is dependent on the nurse's ability to meet 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 competency in antineoplastic drug administration. It may not be realistic for all settings or agencies to provide on-site edu-

cation and training. Alternative methods can be used, including the following:

- Contracting with larger institutions for didactic education or clinical experience for specific learning needs (e.g., vesicant, nonvesicant, IV push, short infusion, continuous infusion)
- (2) Creating or using a simulated laboratory to substitute for the clinical component
- (3) Providing virtual simulation designed to meet specific learning objectives (Konrad et al., 2021)
- Use an evaluation tool based on the desired outcomes to document the nurse's knowledge of and competency in the following:
 - a) Agents and 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.
 - a) The evaluation or documentation tool should meet the needs of the new nurse and the practice setting, including a minimum number of observed and documented antineoplastic drug administrations.
 - *b)* Observed administration of at least three different agents, types, and routes (i.e., nonvesicant and vesicant; IV push and short-term infusion) is recommended.
 - *c)* Competency for nontechnical skills, such as patient education, may be verified by role-playing, case scenarios, and observation (Wahl, 2017).
- 7. Annual continuing education and ongoing competency assessment are required for 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 (e.g., identified practice problems; high-risk, low volume procedures), and new information should be emphasized (Wahl, 2017).
 - Methods that may be used to identify needs include but are not limited to staff or patient surveys, chart audits, quality improvement studies, clinical observation, and literature review.

- (2) Potential topics include new drugs or drug deliveries, 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; Wahl, 2017).
 - (1) Testing
 - (a) Provide a packet of articles for the staff to read or a live educational program followed by an open-book test to measure knowledge.
 - (b) Consider a pretest and post-test to measure individual knowledge gains.
 - (2) Return demonstration
 - (a) Competency checklists can be used to document the performance of technical skills, such as the donning and doffing of personal protective equipment used during drug administration.
 - (b) Staff can also be observed and evaluated using a scoring rubric with a checklist of criteria detailing the steps to take in practice.
 - (c) Examples include monitoring a nurse administering a vesicant or completing dose verification.
 - (*d*) Actions can be observed in a practice or simulated environment and later debriefed.
 - (3) Simulation
 - (a) Simulation provides a safe environment for staff to practice clinical and critical-thinking skills.
 - (b) Staff can face a clinical challenge and problem-solve the steps to be followed, such as a patient experiencing an infusion reaction or extravasation.
 - (c) Asking nurses, "What would you do if . . ." challenges them to consider the implications of their actions.
 - (d) When a simulation lab is unavailable, it can be performed using role-play and mock scenarios in nearly any location.
- 8. Antineoplastic medications administered outside designated oncology areas
 - a) The ONS (2020) position statement on the education of the nurse administering and providing care to patients receiving antineoplastic therapy applies to antineoplastic drugs regardless of indication, route, patient population, or setting.
 - *b*) All nurses should be knowledgeable about the drugs they administer, including mode of action,

side effects, toxicity, dosage range, rate of administration, route of excretion, potential responses, and interactions with other medications and foods.

- c) The format, length, and specific focus of educational initiatives, both didactic education and clinical experience, may vary according to the needs of the staff and setting. Select staff may require drug- or disease-specific education, whereas others require comprehensive education for all antineoplastic medications.
- *d*) The educational plan should be addressed for all individuals working with antineoplastic therapy 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.
 - *a*) Policies identify and communicate practice expectations (Dols et al., 2017).
 - *b)* Procedures are a step-by-step guide to performing a specific task or operation (Esparza, 2019).
 - 2. Once a policy has been implemented, it must be enforced and followed by staff.
 - *a*) Individuals can be held liable if patient harm results from failure to follow a policy.
 - *b)* Institutions can have liability if a policy is unclear, contrasts with another policy, or could be interpreted incorrectly.
 - 3. Review policies and procedures at least every two years to ensure the practice is current with changing technology and evidence (Esparza, 2019).
 - 4. Collaboration between departments and professionals is recommended when creating antineoplastic policies and procedures. Input from the pharmacy, medicine, nursing, environmental services, occupational health, and other departments will result in a more comprehensive policy.
 - 5. 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 (Institute for Safe Medication Practices [ISMP], 2022; Neuss et al., 2016):
 - *a)* Qualifications, including initial educational and ongoing competency requirements, credentialing process, and documentation of staff who order, prepare, and administer antineoplastic therapies
 - b) Hazardous drug management, including safe drug receipt, storage, compounding, transport, use of personal protective equipment, administration, post-treatment care, spill management, disposal, alternative duty, and medical surveil-

lance (Coyne et al., 2019; Polovich & Olsen, 2018; U.S. Pharmacopeial Convention, 2019)

- c) Order writing and dose verification, including process, standard regimens, rounding, cumulative dose, order format, and communication of modifications
- d) Informed consent process
- *e*) Standardized documentation tools for assessment and care
- *f*) Toxicity monitoring, including standardized documentation and communication of toxicities
- g) Procedures for care in medical emergencies
- *h*) Communication of status during transitions of care
- i) Reporting of adverse events and near misses
- D. Antineoplastic medication safety
 - 1. Published research has found that chemotherapy errors occur in at least 1%–3% of adult and pediatric patients (Reinhardt et al., 2019; Weingart et al., 2018).
 - *a*) Reinhardt et al. (2019) found a higher incidence of chemotherapy errors (3.6%) for modified or nonstandard orders.
 - *b)* Other situations identified as a higher risk for error include carboplatin, regimens with three or more agents, and oral chemotherapy (Reinhardt et al., 2019; Weingart et al., 2018).
 - 2. Chemotherapy and other antineoplastic drugs are classified as high-alert medications, regardless of setting, by ISMP (2021). These medications have narrow therapeutic indices (i.e., benefit versus toxicity), multiple potential toxicities, and often are administered in complex regimens, protocols, and schedules (Griffin et al., 2016; Reinhardt et al., 2019; Weingart et al., 2018).
 - 3. Errors may occur at any point during the drug delivery process (Ashokkumar et al., 2018; Reinhardt et al., 2019; Tariq et al., 2021; Weingart et al., 2018).
 - *a)* Ordering or prescribing errors, including unclear, incomplete, or erroneous orders; drug calculation; dose modification; omission of antineoplastic or supportive drugs or hydration; input and transcription; errors in cycle or day; and cumulative dose documentation or tracking
 - b) Drug preparation errors, including staging or loading a biosafety cabinet with incorrect equipment and supplies, rounding doses, reconstitution, compounding, label application, and dispensing (Gilbert et al., 2018)
 - *c)* Drug administration errors, including incorrect drug or dose, schedule or timing, patient identification, infusion rate, and route
 - *d*) Drug monitoring errors, including serum methotrexate level and failure to detect declining left

ventricular function in patients receiving trastuzumab

- 4. Medication errors can occur after patient discharge from hospital settings.
 - a) Nearly 50% of adult and older adult patients had medication errors or unintentional medication discrepancies after hospital discharge, and 20% reported adverse drug events (Alqenae et al., 2020).
 - b) Supportive medications for chemotherapy and immunotherapy (e.g., leucovorin rescue, antidiarrheal agents, steroids, antiviral agents) taken incorrectly in the home setting can lead to serious consequences.
 - c) Patient education, clear instructions, and calendars can help prevent errors (Reinhardt et al., 2019).
- 5. Contributing factors to medication errors (Fyhr et al., 2015; ISMP, 2020; Prakash et al., 2014; Sessions et
 - al., 2019; World Health Organization, 2016)
 - *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 and interruptions
 - e) Heavy workload, fatigue, or stress
 - *f*) Lack of systematic processes or failure to follow safety processes
 - *g*) Medication supply and storage issues (e.g., drugs of similar names or dosage strengths stored in close proximity)
 - *h*) Equipment failure
 - *i*) Inadequate knowledge or experience of those ordering, preparing, or administering agents
 - *j*) Patient factors, including literacy, language barriers, and complexity of care
 - *k*) Ordering errors when using the computer order entry system (e.g., errors due to cut and paste)
- 6. The following strategies have been used to reduce the risk of medication errors in antineoplastic administration (Billstein-Leber et al., 2018; Coyne et al., 2019; Goldspiel et al., 2015; ISMP, 2022; Kuitunen et al., 2020; Neuss et al., 2016; ONS, 2020).
 - *a)* Develop policies and procedures using interprofessional collaboration. Include a risk assessment policy and strategies to promote adherence.
 - b) Establish a process of educational preparation and competency of those administering, preparing, or ordering antineoplastic medications. Nurses administering antineoplastic agents are qualified by education and training.
 - *c)* Ensure current drug information and resources for drug dosing, administration, and side effects are readily available.

- *d*) Measure and document weight in kilograms and height in centimeters.
- e) Use smart infusion pumps and barcode technology when available.
- *f*) Follow standards regarding antineoplastic medication orders.
 - Orders are signed manually or by electronic approval by credentialed prescribers (ISMP, 2017a; Neuss et al., 2016).
 - (2) Advanced practice providers (e.g., clinical nurse specialists, nurse practitioners, physician assistants) identify prescribing as one of the most significant parts of their role (Bruinooge et al., 2018). The ability to prescribe antineoplastic medications is determined by the practice location (state and institution) and patient status.
 - (3) Verbal orders for chemotherapy, targeted therapy, and immunotherapy medications are not permitted, except to hold or stop drugs (ISMP, 2017a; Neuss et al., 2016).
 - (4) Text messaging of patient care orders is not permitted (ISMP, 2017b; Joint Commission, 2021).
 - (5) Standardized electronic or preprinted orders should be used for antineoplastic therapies (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 shown to increase evidence-based oncology care and decrease errors (Coyne et al., 2019; Srinivasamurthy et al., 2021). The National Comprehensive Cancer Network (www.nccn .org) provides 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) Abbreviations, acronyms, and other ambiguous methods of communicating drug information should be avoided.
 - (6) Safety advantages reported with the use of computerized prescriber order entry systems, along with clinical decision support systems, include the removal of interpretation or transcription errors, availabil-

ity of information about drug doses and schedules, automatic calculation of medication doses, and alert and error-checking functions (Knols et al., 2020; Rahimi et al., 2018; Weingart et al., 2018).

- (a) Errors in prescribing continue to occur with computerized prescriber order entry, including dose errors, medication choice, incomplete prescriptions, failure to acknowledge electronic alerts, and failure to validate orders.
- (b) These errors are amplified with new or occasional prescribers and as the complexity of a treatment regimens increases (Weingart et al., 2018).
- (7) A policy should be in place for prescribing antineoplastic regimens that vary from standard regimens. For example, the prescriber may be required to document supporting references for the variance.
- g) Use safety measures provided in electronic health record systems, such as drug interaction alerts, cumulative dose calculation (when applicable), and override restrictions (Rahimi et al., 2018; Reinhardt et al., 2019). In a study examining chemotherapy errors and electronic prescribing, Reinhardt et al. (2019) found that 61% could be avoided through further software development.
- *h*) Require at least two approved practitioners to perform dose and drug verification for all routes of delivery before preparation, upon preparation, and prior to administering antineoplastic medications (Neuss et al., 2016).
 - Independent dual verification (i.e., independent double checks) is a process in which a second person verifies the accuracy of a prescribed therapy without revealing their findings to the other verifier until both have completed the process (ISMP, 2019).
 - (2) Numerous studies have demonstrated the ability of independent double checks to detect up to 95% of errors (Alsulami et al., 2012; ISMP, 2019).
 - (3) Identifying areas of vulnerability, training staff, and using checklists promotes an effective and consistent process (ISMP, 2019; Macias et al., 2018; Schwappach et al., 2018; see Appendix D).
 - (4) Prior to administering antineoplastic agents, the treatment plan should be reviewed. Orders, medication, patient identification, and pump programming must also be verified (Neuss et al., 2016).

See Chapter 11 for more information on dose verification.

- (5) Conducting a comprehensive review of the medication orders, including comparing the previous cycle rather than comparing the product to the order, is invaluable in catching prescribing errors (ISMP, 2019; Reinhardt et al., 2019).
- (6) Drug and dose verification must be performed in a distraction-free setting. Using timeout and speaking-out-loud checks at drug administration has increased safety (Coyne et al., 2019; Kalo et al., 2019; Prakash et al., 2014).
- (7) Creative staffing models can minimize interruptions with dose verification (Baldwin & Rodriguez, 2016).
- (8) Practitioner dose verification combined with automated double checks (e.g., barcode scanning) may improve safety (ISMP, 2019; Macias et al., 2018).
- *i*) Procedures for emergency preparedness should be established.
 - 24-7 triage should be provided (e.g., on-call practitioners, 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 treatment delivered (Neuss et al., 2016).
 - (3) When antineoplastics are administered in the healthcare setting, a licensed independent practitioner must be on site and immediately available to staff (Centers for Medicare and Medicaid Services, 2020; Neuss et al., 2016).
 - (4) Policies, procedures, and standardized orders should be in place to manage medical emergencies (ISMP, 2022; Neuss et al., 2016; Shaker et al., 2020). Procedures include the process for monitoring and tracking the availability and readiness of emergency equipment and the expiration date on medications, including antidotes and rescue agents.
 - (5) Staff should be educated regarding who to call and the process for contacting the provider or healthcare team (e.g., outpatient nurses need to be clear as to whether to contact 911 or the institution's code team).
 - (6) Orders for the treatment of infusion emergencies should be available to enable

immediate intervention without waiting for the provider's order, with indications for each medication clearly defined (e.g., epinephrine, diphenhydramine, steroids) (Shaker et al., 2020).

- (7) All team members should understand their role and responsibilities in an emergency.
- (8) Verify that emergency equipment and supplies, including oxygen, are available and working and that staff are aware of their location. Infusion chairs functional to change position are recommended if needed.
- (9) Policies, procedures, and standardized orders should be established, with antidotes in place to manage vesicant extravasation (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, such as the inclusion of an order on the antineoplastic therapy order set (e.g., initiate extravasation orders for suspected extravasation), permit the prompt and evidence-based management of emergencies such as extravasation (ISMP, 2010).
- (10) Antidotes or rescue agents (where applicable) with directions for use should be readily available.
- (11) Process improvement projects and educational programs should be 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 infusion reaction drills. Numerous studies have shown that these drills increase practitioner proficiency and confidence and decrease anxiety (Josey et al., 2018; LeBoeuf & Pritchett, 2020; Sharour, 2019).
- j) Standardized processes should be designed to promote effective communication and handoffs between care providers and care sites for patients receiving antineoplastic therapy (Coyne et al., 2019; Neuss et al., 2016).
 - The highest safety risk times during drug administration should be identified to allow for clear communication.

- (2) Safety is improved with open interprofessional communication and a clear understanding of roles, responsibilities, accountability, and a process to de-escalate problems.
- (3) Nursing bedside rounds and interprofessional rounds have been found to increase communication and decrease errors (Daniels, 2016).
- (4) Any missed patient appointments or treatments should be documented, and follow-up should occur with the patient and other healthcare team members.
- (5) An accurate treatment summary must be documented, including history, previous cancer treatments, and current treatment when a patient is transferred to a different healthcare setting. The ASCO Institute for Quality provides example templates on its website (www.inst ituteforquality.org/cancer-treatment -plan-and-summary-templates).
- k) Ongoing patient education should be provided, including information, motivation, and encouragement to patients to become vigilant partners in safety measures (Coyne et al., 2019; Weingart et al., 2018).
- Drug shortages in oncology care are multifactorial. Driving forces include low profitability for manufacturers of generic drugs, decreased drug quality in production, mergers of manufacturers, complex supply chains, natural disasters, and regulatory challenges (Jacob, 2020).
 - a) Drug shortages can have significant clinical effects (Alpert & Jacobson, 2019; ISMP, 2018b; Unguru, 2020; U.S. Food and Drug Administration [FDA], n.d.).
 - Treatment outcomes can be affected by omitted or reduced doses from delays or changes in treatment regimens.
 - (2) Medication errors
 - (a) Healthcare providers may not know 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 or sound-alike medications are purchased from a different manufacturer.
 - (3) Increased costs
 - (*a*) Cost of replacement medications may be significant.

- (b) Labor costs are associated with seeking replacement supplies, managing inventory, updating computer systems for replacement medications, and educating staff. These costs are estimated at \$359 million per year (Kacik, 2019).
- (c) Financial and emotional burdens placed on patients can negatively affect patient satisfaction.
- b) The Food and Drug Administration Safety and Innovation Act of 2012 requires pharmaceutical companies to notify FDA when a product may be affected by production changes or manufacturing interruptions (U.S. FDA, 2018).
- c) FDA (n.d.) works with manufacturers to minimize the impact of drug shortages. A list of drugs in short supply is maintained on the FDA website (www.accessdata.fda.gov/scripts/drugshort ages/default.cfm).
- E. Quality and safety monitoring and improvement programs are encouraged in each practice setting (Neuss et al., 2016).
 - Third-party assessments in oncology related to the delivery of antineoplastic medications include the following organizations:
 - *a*) American College of Surgeons Commission on Cancer (ACoS CoC)
 - ASCO Quality Oncology Practice Initiative Certification Program (QOPI)
 - *c)* Foundation for the Accreditation of Cellular Therapy (FACT)
 - 2. Quality monitoring is encouraged in each setting, using internal and external data to establish benchmarks (ISMP, 2022). Topics for monitoring should meet the needs of the practice setting. Examples include the following:
 - *a*) Oral oncolytic management, including adherence, education, and prescribing processes
 - *b)* Care coordination, including communication at the transition of care
 - *c*) Access device management, including with infections and occlusions
 - *d*) Drug administration, including medication errors, safe handling of hazardous drugs, extravasation, and infusion reactions

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