Prepare Pharmacy and Nursing for USP <800>

Each year, approximately 8 million health care professionals throughout the United States are exposed to hazardous drugs (HDs) in the workplace. Depending on the type, quantity, and duration of exposure, consequences can range from transient skin rashes to lifelong complications, including the development of reproductive issues and malignancies. These risks can be minimized through the implementation of safety processes, including engineering controls and closed system drug-transfer devices (CSTDs), policies and procedures defining safe work practices, and the use of proper personal protective equipment (PPE).

Several organizations have established guidelines pertaining to antineoplastic and other HD handling (see use of proper personal protective equipment (PPE)). Several organizations have established guidelines pertaining to antineoplastic and other HD handling (see

Cone Health is a not-for-profit network of health care providers serving patients in multiple counties in North Carolina. The institution’s tag line—The Network for Exceptional Care—highlights its commitment to excellence. Cone Health has more than 100 locations, including six hospitals, three ambulatory care centers, three outpatient surgery centers, four urgent care centers, a retirement community, more than 75 physician practice sites, and multiple centers of excellence.

Recognizing the critical importance of ensuring the safety of those staff handling HDs throughout the medication-use process, Cone Health has made education on HD handling a priority. With the advent of proposed USP Chapter <800>, health systems throughout the US must establish programs, or strengthen existing ones, to address appropriate HD handling policies and procedures (P&Ps) and staff education, including training for pharmacy and nursing that focuses on supplemental engineering control education and the use of CSTDs.

NIOSH and ONS Recommendations

Understanding the NIOSH and ONS recommendations for HD handling, and putting these recommendations into practice, are central to ensuring a safe work environment for staff. NIOSH’s 2004 alert, Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, provides strategies for safe HD use by health care workers, which include:

Assess the Hazards in the Workplace

■ Evaluate the workplace to identify and assess hazards before staff begins working with HDs. As part of this evaluation, guidelines recommend a review of:
  ■ Total work environment
  ■ Physical layout of work areas
  ■ Equipment
  ■ Equipment maintenance
  ■ Types of drugs handled
  ■ Volume, frequency, and form of drugs handled
  ■ Waste segregation, containment, and disposal
  ■ Waste handling
  ■ Spill response
  ■ Decontamination and cleaning procedures
  ■ All potential exposure risks, including HDs, blood-borne pathogens, and chemicals used to deactivate HDs or clean drug-contaminated surfaces

■ Regularly review the inventory of HDs and the corresponding protective equipment and practices, seeking input from affected workers

■ Conduct regular training reviews with all workers in areas where HDs are used

Safe Handling

■ Implement a safe handling program that is reviewed annually based on workplace evaluation

■ Develop procedures and provide training that encompasses safe handling, spill management, proper equipment use, and PPE requirements

■ Incorporate specific drug manipulation techniques into P&Ps

■ Establish general hygiene practices, such as not permitting eating or drinking in all areas where drugs are handled

Use and Maintain Equipment Properly

■ Develop workplace procedures for using and maintaining all equipment designed to reduce exposure, such as ventilated cabinets, CSTDs, needleless systems, and PPE

Last updated in 2014, NIOSH maintains a list of antineoplastics and HDs found in the health care setting. The list is separated into three categories: antineoplastic drugs, non-antineoplastic drugs that meet one or more of the NIOSH criteria for an HD, and non-antineoplastic drugs that primarily have adverse reproductive effects.
ONS also has guidelines for the safe handling of hazardous waste. The second edition of Safe Handling of Hazardous Drugs was published in 2011 and includes information on drug administration, management of spills, safety measures, and details on the adverse effects of HDs.4

**Introduction of USP <800>**

Proposed USP <800> builds upon Chapters <795> and <797>, with a strong focus on the requirements for receiving, storing, compounding, dispensing, administering, and disposing of HDs.2 Its purpose is to describe standards to promote patient safety, worker safety, and environmental protection.3 The development of proposed USP Chapter <800> has been ongoing for several years. Last year, the original draft of USP <800> was revised and reposted in Pharmacopeial Forum for public review, comments, and suggestions prior to final publication.

The Chapter emphasizes education and training for all staff members who may have involvement with HDs, with a strong focus on nursing and pharmacy personnel. For example, to protect against HD exposure, proposed USP <800> frequently notes the importance of CSTDs. First introduced in 1999, CSTDs are designed to contain HD drips, sprays, and vapors.9 Given their ability to protect both the health care worker and the environment, proposed USP <800> recommends the adoption of CSTDs during HD compounding and requires their use during HD administration for protection of the health care worker, patient, and environment.3 A few of the most important recommendations from proposed USP <800> that impact both nursing and pharmacy personnel include3:

1. Each entity must designate a qualified and trained individual to be responsible for developing and implementing HD procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas.
2. All personnel who handle HDs are charged with understanding the fundamental practices and related precautions and also are responsible for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and care environment.
3. CSTDs should be used when administering HDs when the dosage form allows.
4. Personnel who may be exposed to hazardous chemicals must be provided information and training before the initial assignment to handle a hazardous chemical, and also whenever the hazard changes.
5. All personnel who handle HDs must be fully trained based on their job functions (eg, in the receipt, storage, handling, compounding, dispensing, and disposal of HDs). Training must occur before the employee independently handles HDs.
6. Personnel who transport, compound, or administer HDs must document their training according to OSHA standards and other applicable laws and regulations.

Keep in mind that while HD training often focuses on IV medications, proposed USP <800> applies to oral preparations as well. Precautions are necessary with any HD manipulation, including crushing tablets or opening capsules; these activities...
must be performed within a containment primary engineering control (C-PEC), using appropriate PPE. The PPE requirements in proposed USP <800> include two pairs of ASTM-tested chemotherapy gloves, which should be changed every 30 minutes or when the integrity of the gloves has been compromised; disposable gowns and head/hair/shoe covers; and eye and face protection. Additionally, compounding equipment, including mortars, pestles, spatulas, etc., must be designated for use only with hazardous materials.3

Developing a USP <800>
Management Team
Meeting the requirements of proposed USP <800> requires the development of a collaborative, cross-functional health-system team comprising representatives from both pharmacy and nursing, as well as any other departments that will be impacted, such as risk management and custodial care. This team should meet monthly until a USP <800> management plan is established, and quarterly thereafter.

CSTD Training
Among the team’s tasks is determining which elements of CSTD use to include in the training programs for pharmacy and nursing. It is key that training for both professions focuses on pharmacy-nursing collaboration, the value of CSTDs, and how and when to use these devices properly. Emphasize each department’s responsibility to ensure safe HD compounding, handling, and administration.

Education and training also must address the limitations within current CSTD use. Gaps in containment currently exist given issues such as the presence of contamination on drug vials received from the manufacturer; ampule-based drugs that require an open system for filtering; the lack of secured bag spikes, which carry the risk of the IV bag becoming unspiked from the closed system; and routes of administration, such as intraocular, intrathecal, intravesical, or topical, that may require open systems for administration.9

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Five CSTDs have received FDA clearance, including PhaSeal, OntGuard, Spiros with ChemoClave/ChemoLock, Texium with SmartSite ViaShield, and Equashield (see Table 1). Choosing the right CSTD for your organization requires collaboration between pharmacists and nurses. The decision should be evidence-based and should consider available literature demonstrating performance (ie, containment), ease of use, and cost effectiveness.

Institutions that are new adopters of CSTDs may pursue training programs available from each CSTD’s manufacturer. Several manufacturers have training modules or educational videos available on their Web sites, in addition to offering hands-on, onsite training. At institutions where CSTDs are already in use, pharmacy and nursing should develop training programs for new employees. Such programs should incorporate both written and hands-on components to ensure new employee competency. Pharmacists or lead pharmacy technicians with experience in compounding with CSTDs and nurses with experience administering medications using CSTDs should handle the hands-on training of new employees.

Outside Educational Opportunities
Because familiarity with proposed USP <800> and data on CSTD use remain limited, exploring education opportunities that exist outside the institution can help address this deficit. Consider investigating:

1. Local presentations for nurses, pharmacists, and boards of pharmacy
2. Universal and broad health-system education for other personnel
3. Continuing education presentations or other programs available through local area health education centers
4. Case-based learning modules for ongoing education
5. Auditing measures to ensure ongoing safety and compliance

Investing in CSTD Training
Two of the central investments required to develop CSTD training are the costs to implement a program and the time requirements of training. However, the costs and time associated with such an endeavor are insignificant when compared with the potential risks of HD exposure and when viewed in terms of the overall reduction that can be achieved in long-term health-care personnel morbidity and mortality. To ensure the overall success of an HD program, be certain to procure the appropriate resources and allot sufficient time for employee training; in addition, assign experienced individuals to lead training activities.

Continual Quality Improvement
After initiating a training program, continual quality improvement should become the focus. Proposed USP <800> recommends that a qualified and trained individual be designated to create and implement procedures, oversee policy compliance, and develop competency reassessments, which should be performed at least annually, when new equipment is introduced, or when significant procedural changes occur. Additionally, NIOSH and OSHA suggest instituting a medical surveillance program for at-risk employees. Similarly, the proposed USP <800> regulation mandates that hospitals have P&S for medical surveillance and recommends testing and monitoring of staff for HD exposure through medical history, physical examination, laboratory studies, and biological monitoring. One example of a surveillance program is outlined by Massoomi and colleagues as a four-tier program:

- Tier 1: self-surveillance (education efforts, notification of health changes)
- Tier 2: employer/supervisor surveillance (tier one activities plus trending sick call types for high-risk employees, etc.)
- Tier 3: comprehensive medical surveillance (tier one and two activities plus medical and laboratory tests)
- Tier 4: post-exposure surveillance (medical tests, documentation of known exposure, continual monitoring)

All quality improvement and training efforts should be institution-specific, with consideration given to the type and volume of hazardous material used.

Conclusion
The public comment period for proposed USP <800> ended on May 31, 2015. Release of the finalized regulation is anticipated for 2016, although the official date has not been set. The development and evolution of USP <800> reflects a strong focus on safety. Ultimately, the safe handling of HDs will rely on the pairing of proper equipment, such as CSTDs, with the proper training for all personnel involved with HDs. Although the changes that are likely to be required under this new regulation may appear daunting initially, planning and training can ease the transition and help ensure safety for all.

References