Hazardous Drugs and USP<800>

Implications for nurses

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BACKGROUND: Although guidelines for the safe handling of hazardous drugs (HDs) have existed for several decades, they have not been enforceable by state or federal agencies. USP<800>, the latest chapter issued by the U.S. Pharmacopeial Convention, expands on existing guidelines and provides detailed information on compounding and administration. Unlike current guidelines, USP<800> will be enforced by each state’s board of pharmacy or their delegated agency.

OBJECTIVES: This article provides a brief overview of the dangers associated with HDs and the implications of USP<800> for nurses.

METHODS: An overview of nursing-specific requirements from USP<800> are presented, as well as information about closed-system transfer devices, which are required under USP<800> guidelines.

FINDINGS: Although some organizations may already be fully compliant with USP<800>, others will need to make significant changes.

THE DANGERS ASSOCIATED WITH UNINTENTIONAL EXPOSURE to chemotherapy date back more than three decades, when it was discovered that urine from nurses administering these drugs tested positive for mutagenicity (Falck et al., 1979). Subsequent studies have shown widespread environmental contamination during compounding and administration (Connor, 1999, 2006; Connor et al., 2010; Hon, Teschke, Chu, Demers, & Venners, 2013; Hon, Teschke, Demers, & Venners, 2014; Hon, Teschke, Shen, Demers, & Venners, 2015), which contributes to human uptake and subsequent chromosomal damage and reproductive disorders (Hon et al., 2014, 2015; Labuhn, Valanis, Schoenly, Loveday, & Vollmer, 1998; McDaid, Oliver, Roth, Rogers, & Escalante, 2010; Shortridge, Lemasters, Valanis, & Hertzberg, 1995; Valanis, Vollmer, Labuhn, & Glass, 1993a, 1993b, 1997; Valanis, Vollmer, & Steele, 1999). Reproductive effects include infertility, miscarriages, stillbirths, menstrual cycle changes, ectopic pregnancies, spontaneous abortions, low birthweight infants, congenital anomalies, learning disabilities in children of exposed mothers, and pre-term birth (Fransman, Huizer, Tuerk, & Kromhout, 2007; Hemminki, Kyyronen, & Lindbohm, 1985; Lawson et al., 2012; Lorente et al., 2000; Saurel-Cubizolles, Job-Spira, & Estryn-Behar, 1993; Shortridge et al., 1995; Valanis et al., 1997, 1999).

The term hazardous drug (HD) is commonly used to include antineoplastic chemotherapy and other nononcologic agents (e.g., antivirals) that pose similar risks to healthcare workers (Power, 1990). HDs are defined as having any of the following properties: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, and genotoxicity. Structure and toxicity profiles of new drugs that mimic existing drugs are determined to be hazardous by this criteria (Connor, MacKenzie, DeBord, Trout, & O’Callaghan, 2016).

Guidelines

Guidelines for handling HDs were first published by the American Society of Hospital Pharmacists (ASHP) in 1981. ASHP (subsequently renamed the American Society of Health-Care Pharmacists) has issued several updates, most recently in 2006. The Occupational Safety and Health Administration (OSHA) and the Oncology Nursing Society (ONS) also published guidelines in the mid-1980s. ONS has updated its publication several times (Polovich,
HAZARDOUS DRUGS AND USP<800>

“USP<800> is a major step forward for the safety of nurses, pharmacists, and technicians.”

U.S. Pharmacopeial Convention
As a nonprofit organization, the U.S. Pharmacopeial Convention (USP) sets standards for quality and purity of medications. Although implementation varies, most state pharmacy boards use USP sterile compounding guidelines as the benchmark for best practice. Each state pharmacy board or designated agency is charged with inspecting pharmacies to ensure that they are practicing to these standards. Like the JC, USP has historically been concerned with patient safety. Chapter 797 (referred to as USP<797>) was published in 2004 and dealt exclusively with sterile compounding. A revision in 2008 included information on HDs, but did not address the multitude of complex safe-handling issues.

USP<800>
Filling the need for a comprehensive document, the initial draft of USP<800> was published in the spring of 2014 and immediately drew intense criticism from multiple organizations, including the Association of Community Cancer Centers, American Society of Hematologists, ASHP, and 20 individual pharmacy associations. Many of the concerns surrounded proposed procedures and engineering designs that were deemed too costly and or difficult to implement. In retrospect, these objections were not surprising; had the proposed safety measures been quick, simple, and inexpensive, they likely would have already been implemented.

The negative responses mimicked what was experienced in Washington State when the 2011 HD safety law was initially passed. Many state organizations and hospital representatives argued that implementing the 2004 NIOSH Alert guidelines would be cost prohibitive and overly restrictive. These objections resulted in a delay of implementation to allow for engineering controls. The law finally took effect January 1, 2016.

USP responded to the feedback in 2015 by issuing a revision that was finalized in November 2015. Many of the original concerns were addressed, although the majority of the key elements were retained. USP<800> was officially released in February 2016 (USP, 2016). Facilities will have until July 1, 2018 to be fully compliant. Although this may appear to be an unusually long implementation period, organizations need to plan and budget for improved engineering controls in the pharmacy as well as for numerous other requirements. Revisions to USP<800> are already being worked on, although a release date has not been announced.

One very unique aspect to USP<800> is that it includes several areas related specifically to the administration of HDs. This is the first time that a pharmacy-centric organization is directing nursing practice and will be monitored and enforced. Indeed, this is a groundbreaking distinction; prior guidelines, such as those issued by ASHP, NIOSH, or ONS, have not been enforceable. USP<800> will be enforced by each state’s Board of Pharmacy, their delegated agency, and/or the U.S. Food and Drug Administration.

Implications for Nursing
In general, the practice changes required by USP<800> are less dramatic for nursing than for pharmacy, and some organizations may already be fully compliant. However, based on survey results from Boiano, Steege, and Sweeney (2014), most nursing practices will require changes.

Elements of USP<800>
The various aspects of USP<800> are discussed in this article. Table 1 provides a comparison of the 2004 NIOSH Alert guidelines and the USP<800> requirements. The following sections list the major nursing-specific elements of USP<800>, including personal protective equipment (PPE), respiratory protection, personnel training, HD transportation procedures, closed-system transfer devices (CSTDs), spill kits, and documentation of spills.

Personal Protective Equipment
Long recommended by NIOSH, double-gloving is required for HD administration. Gloves must be designated for chemotherapy, conforming to the American Society for Testing and Materials D6978-05 standard. USP worded this section to include any future updates because none of the drugs approved after 2005 have been tested (Connor, Power, Massoomi, & Polovich, 2015).

USP<800> specifies the use of disposable gowns that are able to resist HD exposure. This is a crucial distinction because not all gowns have been tested to withstand HDs (Connor et al., 2015). Unfortunately, no ASTM standard exists for the testing of gowns...
against HDs; organizations should ask the manufacturer to provide written documentation proving the product has been tested. An example of such evidence is found in Table 2.

USP<800> clarifies much of the ongoing confusion surrounding respiratory protection by discussing the appropriate use of respirators. Respiratory protection is not being recommended for administration. However, in dealing with spills, the document becomes quite specific: a full-face chemical cartridge respirator or powered air-purifying respirator (PAPR) for HD is required for larger spills that cannot be contained in a spill kit, or for drugs that can produce vapors.

Limited research has been conducted on HD vaporization (Connor, Shults, & Fraser, 2000; Kiffmeyer et al., 2002). These studies do not include any of the drugs approved in the past 15 years. Vaporization studies are difficult to conduct, and the dissipation of vapors in real-world settings can vary depending on air exchanges in the facility and whether the spill is in a confined space (e.g., patient bathroom) or an area with frequent air exchanges (e.g., a hospital corridor.) A list of identified agents (Connor et al., 2000; Kiffmeyer et al., 2002) includes:

- Carmustine (BiCNU®)
- Cyclophosphamide (Cytoxan®)
- Ifosfamide (Ifev®)
- Thiotepa (Thioplex®)
- Nitrogen mustard (Mustargen®)
- Cisplatin (Platinol®)
- Etoposide (Toposar®)
- Fluorouracil (Adrucil®).

Closed-System Transfer Devices

A CSTD can be defined as a device that prohibits the escape of a HD into the environment (Nygren, Olofsson, & Johannson, 2009), or more specifically, “prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or

### COMPARISON OF NIOSH HD ADMINISTRATION RECOMMENDATIONS AND USP<800> REQUIREMENTS

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>NIOSH 2004 ALERT</th>
<th>USP&lt;800&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves</td>
<td>Double chemotherapy gloves (ASTM rated) for chemotherapy; consider for nonantineoplastic HDs</td>
<td>Double chemotherapy gloves (ASTM D6978-05) for all HDs including reproductive-only HDs</td>
</tr>
<tr>
<td>Gowns</td>
<td>Disposable, with long sleeves, elastic or knit cuffs, and closed fronts</td>
<td>Disposable, with ability to resist chemotherapy; long sleeves, elastic or knit cuffs, closed front, and without seams or closures that could allow HD exposure. Cloth laboratory coats, scrubs, and isolation gowns are specifically prohibited. Must not be worn outside of HD handling areas</td>
</tr>
<tr>
<td>Respiratory protection</td>
<td>Refers to general OSHA recommendations [29 CFR 1910.134] and CDC [42 CFR 84]. Does not specify type or use</td>
<td>Full-face chemical cartridge respirator or PAPR if risk of respiratory exposure when cleaning spills is “larger than what can be contained with a spill kit,” and if “a known or suspected airborne exposure to powders or vapors” occurs</td>
</tr>
<tr>
<td>Face protection</td>
<td>Goggles for all aspects of administration, including disposal</td>
<td>Face shields and goggles for risk of spills (e.g., working above eye level, cleaning spills, surgery)</td>
</tr>
<tr>
<td>PPE</td>
<td>Double-bag HD waste and place in yellow HD container.</td>
<td>Place in special container designated for HDs.</td>
</tr>
<tr>
<td>CSTD</td>
<td>Suggested</td>
<td>Required for HD administration when route allows (suggested for compounding)</td>
</tr>
<tr>
<td>Education</td>
<td>Regular training for all personnel handling HDs</td>
<td>Training required prior to handling HDs, and annually thereafter</td>
</tr>
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</table>
| Medical surveillance | General recommendations referring to ASHP (1990) and OSHA (1999). Suggestions include:  
  • Obtain a medical and exposure history, physical examination, and nonspecific laboratory tests.  
  • Perform wipe testing and biologic monitoring when exposure is suspected or symptoms are observed. | Specific recommendations:  
  • Obtain baseline assessment, including medical and reproductive history and prior exposure to HDs; history should include estimated quantity of HDs handled per week and number of hours spent handling HDs.  
  • Conduct physical examination and perform laboratory tests, such as a CBC.  
  • Develop a follow-up plan for workers who have shown health changes suggesting toxicity or who have been involved in a spill.  
  • Assess medical, reproductive, and exposure histories for employees who leave the facility.  
  • Biological monitoring (i.e., urine and blood testing for specific HDs) is not recommended but may be appropriate after spill exposure. |

*Based on information from NIOSH, 2004

ASTM—American Society for Testing and Materials; CBC—complete blood count; CDC—Centers for Disease Control and Prevention; CSTD—closed-system transfer device; HD—hazardous drug; NIOSH—National Institute of Occupational Safety and Health; OSHA—Occupational Safety and Health Administration; PAPR—powered air-purifying respirator; PPE—personal protective equipment.
vapor concentrations outside the system” (Connor, McLauchlan, & Vandenbroucke, 2007, p. 28).

CSTDs have been recommended in guidelines published by NIOSH and ONS (NIOSH, 2004; Polovich, 2011). However, USP<800> requires their use for antineoplastic administration, which may represent the single most significant change in practice for many nurses, particularly for those outside of oncology settings.

The number of nurses currently using CSTD for HD administration is unknown, and surveys vary considerably. In 2015, Boiano, Steege, and Sweeny reported that 25% of 241 nurses indicated they used a CSTD. However, in another survey, the same authors reported 45% of 1,954 nurses always used them (Boiano et al., 2014). Sixty-two percent of the nurses in this study worked in facilities with 250 employees or more. Data describing CSTD usage in smaller facilities, private practice, rural hospitals, or specifically on nononcology units regardless of facility size, are sparse.

Two major CSTD components exist. The first is designed to prevent the release of aerosols, vapors, and droplets during compounding. In addition to protecting the pharmacist or technician, this also ensures that the exterior of the HD IV bag or syringe is not contaminated, preventing subsequent exposure in patient care areas. A second component is used to transfer the HD from the vial to the IV bag. This component also protects nurses during and after administration by preventing leaks that occur when connecting and disconnecting IV bags, tubing, and syringes. In theory, CSTDs should provide completely dry connections, from compounding through disconnection and disposal.

### Closed-System Transfer Device Design Considerations

Several different CSTD designs are used to prevent exposure. CSTDs can fundamentally be classified as either a membrane-to-membrane device, or a luer to luer device (see Figure

| TABLE 2. CHEMOTHERAPY GOWN PERMEATION TESTING CHEMOPLUS POLY-COATED IMPERVIOUS GOWNS |
|------------------------------------------|------------------------------------------|------------------------------------------|
| TEST CHEMOTHERAPY DRUG AND CONCENTRATION | MINIMUM BREAKTHROUGH DETECTION TIME (MINUTES) | OTHER OBSERVATIONS |
| Carmustine (BiCNU<sup>®</sup>) 3.3 mg/ml (3,300 ppm) | 31 (31, 46, 45.7) | Moderate swelling and no degradation |
| Cisplatin (Platinol<sup>®</sup>) 1 mg/ml (1,000 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |
| Cyclophosphamide (Cytoxan<sup>®</sup>) 20 mg/ml (20,000 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |
| Dacarbazine (DTIC-Dome<sup>®</sup>) 10 mg/ml (10,000 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |
| Doxorubicin hydrochloride (Adriamycin<sup>®</sup>) 2 mg/ml (2,000 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |
| Etoposide (Toposar<sup>®</sup>) 20 mg/ml (20,000 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |
| Fluorouracil (Adrucil<sup>®</sup>) 50 mg/ml (50,000 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |
| Methotrexate (Trexall<sup>®</sup>) 25 mg/ml (25,000 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |
| Mitomycin C (Mutamycin<sup>®</sup>) 0.5 mg/ml (500 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |
| Paclitaxel (Taxol<sup>®</sup>) 6 mg/ml (6,000 ppm) | No breakthrough up to 240 minutes | Moderate swelling and no degradation |
| Thiotepa (Tepadina<sup>®</sup>) 10 mg/ml (10,000 ppm) | 226.1 (226.1, greater than 240, greater than 240) | Slight swelling and no degradation |
| Vincristine sulfate (Marqibo<sup>®</sup>) 1 mg/ml (1,000 ppm) | No breakthrough up to 240 minutes | Slight swelling and no degradation |

Note. Full back gown (Item codes #CT5502, CT5503, CT5504, CT5505); open back gown (Items codes #DP5001G, DP5002G, DP5003G, DP5004G)

Note. Independently tested by Akron Rubber Development Laboratory, Akron, OH. Permeation testing per American Society for Testing and Materials D6978-05 standard test method.

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Membrane devices require the use of a luer adapter to connect with IV tubing and/or a vascular access device (VAD). Presented here is a brief description of each of the available CSTDs. Figure 2 shows each device attached to a syringe, along with their luer adapters, if required.

PHASEAL
Approved for use in 1998, and now owned by Becton Dickinson (BD), Phaseal™ was the first commercially available CSTD. The Phaseal protector is a vial adapter which uses an external expansion chamber to trap vapors during compounding. The membrane-based injector interfaces with the protector for drug transfer and operates with a “push-turn-push” action. It houses a concealed needle and, once engaged, the needle passes through both compressed membranes to allow transfer of the HD from vial to syringe during compounding, and between IV tubing and the adapter on the VAD. Because the needle is withdrawn through the membranes prior to decompression of the membranes, the connections remain dry and the needle remains shrouded.

ON GUARD
Manufactured since 2006 by Teva Medical, the vial adapter for this membrane-based CSTD uses a hydrophobic 0.2μ membrane and an activated charcoal drug-binding matrix to neutralize vapors during compounding. The syringe adapter for On Guard™ functions to transfer HDs from vial to syringe and from IV tubing to a luer adapter on the patient’s VAD. As with Phaseal, a needle passes through the two compressed membrane sections when the device is engaged.

TEXIUM AND SMARTSITE VIALSHIELD
Developed by CareFusion and now owned by BD, Texium® is a closed male adapter similar in general design to the Spiros. It should be used with SmartSite® needle-free devices. In 2013, CareFusion added an external balloon-based vial adapter called Vialshield.

EQUASHIELD II
A unique dual-chambered syringe, Equashield® II is a second-generation membrane-based device that traps vapors in the rear of

FIGURE 1.
MEMBRANE-TO-MEMBRANE AND LUER-TO-LUER CLOSED-SYSTEM TRANSFER DEVICE DESIGNS

Membrane-to-membrane design

Luer-to-luer design

Note. In the membrane to membrane design, the drug passes from A to B via needle after both membranes have been compressed. The needle can be withdrawn only after both membranes have separated. In the luer to luer design, the syringe or tubing attaches to the closed-system transfer device, which screws directly onto the tubing and/or patient vascular access device.

SPIROS AND GENIE
Developed in 2007, Spiros® is a closed male luer device designed to open after being connected to another needleless luer device. The Genie®, a small balloon that becomes inserted into the vial after being spiked, was designed to equalize pressure within the vial. Marketed together as the ChemoClave system, no luer adapters are required. ICU has developed a new external polyethylene lined/metallized nylon balloon vial access device that will replace the Genie and is available for use with either the Spiros luer system or the ChemoLock™ system.

CHEMOLOCK
Developed to compete with other membrane devices, ChemoLock is similar in design but is needle-free, using a thin plastic spike to transfer HD between the two compressed membranes. As with other membrane devices, a luer adapter is required.
the syringe after mating with the membrane in the vial access component. Two concealed needles reside in the end of the syringe assembly; one is used to transfer drug to an IV bag or tubing, and the other to transfer vapors. For IV push administration, an adapter is required to connect the special syringe to IV tubing, and a similar adapter can be placed at the distal end of the IV tubing connected to the patient’s VAD.

Although USP<800> does not require CSTDs for compounding, the adoption of these devices typically involves both pharmacy and nursing. Assembling a multidisciplinary HD team to explore CSTD options and design device trials is recommended (Eisenberg, 2012).

HALO

The newest CSTD is the Corvidia Halo®. This unique membrane-based device incorporates a circumferential balloon to trap vapors during compounding, and uses a needle to allow HDs to pass from the vial to the syringe.

Closed-System Transfer Device Studies

Evaluating the effectiveness of CSTD has been an extremely difficult task, in part related to the lack of a standardized test. Most manufacturers have issued white papers demonstrating the purpose and effectiveness of their product, but these do not represent independent studies published in peer-reviewed journals.

Studies can be performed using the actual drug with wipe testing to determine droplet contamination, or with surrogates used in place of HDs. Drug surrogates, such as fluorescein, which glows under a blacklight; titanium tetrachloride, which releases visible smoke when it comes in contact with atmospheric moisture; and acidic/basic solutions, which are tested with common pH paper, have been used. To date, Phaseal has the greatest number of published studies, followed by Equashield and ChemoClave. The remaining CSTDs have surprisingly little or no supporting evidence. Table 3 provides a reference list of published CSTD studies.

Despite their obvious applicability, clinical studies carry a number of limitations, including preexisting HD contamination at the test site and on the exterior of vials (Connor et al., 2005), cleaning practices, and spills that may or may not be related to the study (Power, 2013). Independent laboratory testing can eliminate most of those variables but may be subject to potential bias. Design components can also change over time. Readers must, therefore, use caution when attempting to interpret a device’s performance if that performance has not been recently validated.

In the fall of 2015, NIOSH developed a draft protocol for testing CSTD vapor containment using 70% alcohol as an HD vapor surrogate. A number of serious weaknesses in the testing protocol were discovered during the required public comment period, and NIOSH has revamped the protocol. Although not finalized, propylene glycol is being suggested as the surrogate instead of alcohol, and other changes to the protocol itself have been recommended.

Although some products will perform better than others, all of them reduce potential exposure when compared to traditional compounding and administration methods. A precedent for differing levels of safety between similar products can be seen in the automotive industry. The National Highway Traffic Safety Administration’s five-star crash test protocol is familiar to most consumers and demonstrates that some vehicles perform better than others. Similarly, vehicle quality and reliability are rated across a relative range by a number of different organizations.
such as J.D. Power and Consumer Reports. Regrettably, no federal agency analogous to these automotive groups that could perform standardized testing of CSTDs exists; even when the NIOSH test protocol is finalized, they will not be performing tests themselves.

Hazardous Drug Communication Program and Education

In addition to CSTDs, organizations will be required to have an HD program in place that includes policies and procedures delineating how drugs are handled, from entry into the facility (e.g., receipt at the pharmacy) through disposal after administration. NIOSH publishes a list of drugs considered to be hazardous (Connor et al., 2016), which is updated every two years. The list is based on whether the drug meets the definition of an HD. However, organizations should create and maintain their own HD list based on drugs that are administered in the facility. This list can be based on dosage form and risk of exposure (Connor, Mackenzie, & DeBord, 2012). Accordingly, USP<800> acknowledges that although some HD dosage forms (e.g., oral) may meet the HD definition, they do not require the same handling procedures necessary for other routes. Each facility must clearly document handling precautions for oral agents (e.g., prohibiting the crushing of pills) in addition to other dosage forms.

Education on safe HD practices must be provided before an RN can independently administer these drugs. Assessment and documentation of competency must be performed annually. Training is also required for any nurse administering nononcologic HDs, potentially creating a significant impact on an institution’s nursing education department. Figure 3 provides a summary of important components of the HD plan described in USP<800> and educational areas to be covered.

Of these items, spill management deserves special attention. Depending on the organization, HD spills may be handled by nurses, housekeepers, or a “code orange staff.” Regardless of personnel, education must be provided and competency assessed annually. One study reported that 9% of the nursing respondents had experienced a spill in the week prior to the survey (Boiano et al., 2014), and it is likely that many spills go unreported. Friese, McArindle, et al. (2015) described spills in an outpatient facility and found that lack of education regarding the use of PPE may have resulted in staff contamination and positive HD urine tests. The need for education as part of a comprehensive HD program has been well documented in the literature (Friese, McCullagh, & Sutcliffe, 2015; Friese, McArindle, et al., 2015; Polovich, 2011; Polovich & Martin, 2011).

Surveillance

NIOSH defines the basic components to HD surveillance: obtaining both a work and a reproductive history, physical examination, laboratory testing such as CBC, and biologic monitoring such as urine testing (McDiarmid, Polovich, Power, Connor, & Weissman, 2013). Medical surveillance is recommended in the NIOSH (2004) guidelines. USP<800> states that personnel who handle HDs should be part of a medical surveillance program. So, although not required, USP<800> does reinforce the prior recommendations. Important elements of a medical surveillance program described in USP<800> can be found in Figure 4.

Conclusion

USP<800> is a major step forward in ensuring the safety of nurses, pharmacists, and technicians who handle HDs. This in-depth, enforceable guideline will have a significant impact on all areas of practice where HDs are compounded and administered. Healthcare facilities will need to perform a gap analysis to determine the depth of practice changes required by USP<800> and then plan and budget accordingly. These changes will require a collaborative effort between pharmacy and nursing departments to make the healthcare environment safer.

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REFERENCES


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