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.

KEYWORDS
hazardous drugs; USP <800>; closed-system transfer device; guidelines

DIGITAL OBJECT IDENTIFIER
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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, Schoeny, Loveday, & Vollmer, 1998; McDiarmid, 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; Hemminski, 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, 2011). After more than 15 years of conspicuous silence, OSHA updated their