USP <800>

Gaining compliance through implementation of a hazardous drug control program

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Hazardous drug (HD) safety has been in the forefront of health care since the announcement in 2016 of U.S. Pharmacopeial Convention General Chapter <800> (USP <800>) Hazardous Drugs—Handling in Healthcare Settings (USP, 2016). Originally planned to be in effect by July 2018, the date was extended to December 2019 (Pirschel, 2017). All healthcare organizations in the United States will be required to have an HD program in place that delineates how drugs are handled, from entry to disposal (Eisenberg, 2017). In addition, the program must provide appropriate personal protective equipment (PPE) and engineering controls, as well as education for staff who handle HDs (Eisenberg, 2017).

To prepare for USP <800>, nursing and pharmacy staff should collaborate with administrators to determine gaps in the organization and develop and implement a plan to address those gaps (Eisenberg, 2017; Polovich, 2017). The first step is to develop an HD list specific to the organization for oncology and non-oncology settings (Polovich, 2017) because not all HDs come with a hazard label (Morgan, Becker, & Jinga, 2017).

Conducting a Gap Analysis

At the University of Washington Medicine/Valley Medical Center, a 300-bed hospital in Renton, a process improvement (PI) group was formed to ask what was needed to meet USP <800> requirements. The group first met in July 2017 and was comprised of staff from the pharmacy, environmental services, regulatory and accreditation, and safety offices, as well as inpatient and outpatient leadership and an oncology clinical nurse specialist (CNS). The CNS facilitated the project, pharmacy staff provided a summary of USP <800>, and the regulatory and accreditation office provided a hazardous drug risk assessment tool to conduct tracers (see Figure 1). Times were established when all group members could participate in data gathering. Tracers were conducted on various nursing units and specialty areas to identify gaps.

Data were compiled and analyzed by the PI group. Gap analysis determined that nurses outside of the oncology departments were unaware of which drugs were hazardous, where to obtain appropriate PPE, how to transport HDs, and where spill kits were and how to use them. The PI group met monthly to discuss these gaps and how to improve on the existing HD program to comply with USP <800>.

Developing a Hazardous Drug Program

Pharmacy and nursing staff members reached out to other hospitals in western Washington for comparison. Current literature on HDs, USP <800>, and Washington state law were reviewed. The current program consisted of a hazardous/non-hazardous approach to safe handling. Only nurses trained in administration of chemotherapy could give HDs, with oral medications being the only exception. After gathering data, the organization determined that a four-tier HD list would improve on current practice and close the identified gaps.