

The Hazardous Drug Handling Policy Landscape

Key Points

- HD policies are developed, implemented, and evaluated at federal, state, professional, and institutional levels.
- Nurses can make meaningful practice improvements by developing and evaluating policies in their workplace.

A complex and fragmented political landscape threatens evidence-based HD policy implementation. Despite these challenges, HCWs have advocated successfully for reforms across states, and professional organizations have heightened awareness. The Conceptual Model for Nursing and Health Policy posits that nurses can support policy efforts across governmental, institutional, and organizational settings (Russell & Fawcett, 2005). This section will review the current landscape and future opportunities across these settings. The section concludes with advocacy opportunities to reform HD handling policies.

Federal Efforts: Occupational Safety and Health Administration and National Institute for Occupational Safety and Health

A review of studies that link HD exposure and health (see Evidence for Occupational Hazardous Drug Exposure section) and the documented health risks to exposed workers (see Adverse Effects of Hazardous Drug Exposure section) shows that while exposures and health risks are implicated in HDs, two key scientific gaps pose noteworthy challenges to federal intervention. First, few longitudinal studies show that HD exposures cause health events, and second, few studies establish dose–response relationships between HD exposures and health events.

The Occupational Safety and Health Act of 1970 established OSHA as part of the U.S. Department of Labor (OSHA, n.d.), with a charge to protect the health and safety of the American workforce. As a regulatory agency, OSHA establishes and enforces safety standards for U.S. workers. The act requires each state to establish specific standards and enforcement plans,

which enables flexibility but also potential confusion. OSHA inspects facilities (either announced or unannounced) for adherence to standards and fines facilities that deviate from standards. However, OSHA cannot enforce advisories, such as guidelines and recommendations.

Two enforceable OSHA standards exist that pertain directly to HDs. Section 1910.1020 requires employers to report incidents, including HD exposures, and permits employees to view their incident records (Access to Employee Exposure and Medical Records, 2014). OSHA also can view these records for reporting purposes. Section 1910.1200, titled Hazard Communication (2014), requires manufacturers and users of hazardous substances to inventory and label them properly, maintain SDSs, and ensure that workers who handle hazardous substances receive training. Our analysis of 2013–2014 data suggests that OSHA fined 29 physician offices a total of \$10,360 for violations of the Hazard Communication Standard. For violations of the same rule, 11 outpatient care centers cumulatively received fines of \$1,440, and 17 hospitals received fines of \$11,842. The available data do not specify clinical specialty nor provide details of the infractions. Although under the “General Duty” clause (Section 5) OSHA also can cite employers for failing to provide a safe and healthy work environment, this is rarely done.

On June 25, 2015, OSHA published a memorandum that announced increased oversight of HCWs’ injuries (OSHA, 2015). Primarily motivated by a National Public Radio report on nurses’ back injuries, the directive stated that new inspections of inpatient facilities and nursing homes will focus on musculoskeletal disorders, workplace violence, bloodborne pathogens, tuberculosis, and slips, trips, and falls (Zwerdling, 2015). In addition, inspections may include reviews of exposure to drug-resistant organisms and hazardous chemicals, including drugs. The directive excludes ambulatory settings, where the majority of antineoplastic drugs in the United States are administered.

A more effective method of controlling workers’ exposure to HDs would be establishment of occupational exposure limits (OELs). However, as outlined previously in these guidelines, the causal relationship between HD exposure and worker health changes has not been clearly established. OELs also are based on airborne exposures, and HCWs are exposed through multiple routes. Consequently, OSHA cannot establish OELs for these substances. In contrast to other work settings, the absence of HDs OELs precludes meaningful enforcement of drug handling guidelines.

Also established in 1970 as an education and research (rather than regulatory) agency, NIOSH, currently part of CDC, investigates the causes, conse-

quences, and interventions for workers' injuries. Primarily, NIOSH conducts its own research but has a relatively small extramural research program. In partnership with external stakeholders, NIOSH issues guidelines for injury prevention across many occupational sectors. However, these guidelines are advisory and not enforceable.

Upon request of employers or employees, NIOSH scientists conduct health hazard evaluations to identify potential workplace hazards and propose solutions. NIOSH has published four evaluations that investigated HD exposures in healthcare settings (Couch & de Perio, 2011; Couch & West, 2012; Page & Couch, 2011; West & Beaucham, 2014). While NIOSH scientists have established recommended exposure limits (RELs) for certain chemicals, such as formaldehyde, no RELs currently exist for HDs (NIOSH, 2007).

The 2004 NIOSH alert on HDs represents the institute's landmark document on research and recommendations to reduce worker exposure. Despite research reports and safe handling guidelines published since the 1980s, NIOSH scientists concluded that workplace contamination and subsequent worker exposure persisted and an alert was necessary (Connor & McDermid, 2006). This alert summarized the extant literature on exposure routes, drugs that NIOSH identified as potentially hazardous, and recommendations for workplaces and individual workers to reduce contamination and exposure. Outside experts from occupational health, industrial hygiene, nursing, and pharmacy contributed to the report. Periodically, NIOSH updates research findings, its latest recommendations, and proposed list of HDs (NIOSH, 2017). Before NIOSH officials issue the final report, the public may comment on draft versions.

In 2011, OSHA and NIOSH partnered with the Joint Commission to recommend that facilities seeking accreditation monitor worker health and establish policies, procedures, and training to mitigate HD exposures. With technical assistance from OSHA and NIOSH, Joint Commission surveyors routinely tour infusion clinics attached to hospitals seeking accreditation and observe HD handling procedures. In 2013, this partnership was renewed for five years (OSHA, 2013). However, the majority of infusion clinics in the United States operate outside of hospitals and do not seek Joint Commission accreditation. Consequently, the majority of settings where HD handling occurs are not monitored by the Joint Commission.

Recent State Initiatives

Federal rules set by OSHA are considered the minimum occupational safety standards. In addition to

federal OSHA inspections, state authorities may conduct their own inspections and fine offending employers. Selected states have enacted legislation or regulatory reforms that are more stringent than federal standards. Since 2010, increased public attention to the plight of HCWs taken ill after HD exposures has catalyzed state-based efforts to require employers to adhere to NIOSH recommendations. However, a 2014 review of federal and state inspections characterized occupational health oversight as "murky" (Jung & Makowsky, 2014, p. 1).

In July 2010, reporter Carol Smith chronicled pharmacist Sue Crump's diagnosis of metastatic pancreatic cancer; she had compounded HDs with little protection since 1980 (Smith, 2010). Crump's story garnered national attention and support from organized labor leaders and the state nurses' association. In April 2011—less than one year later—Washington State passed two key bills. The first would require all facilities in which HDs are administered to follow the 2004 NIOSH alert recommendations (and subsequent updates). The second bill required employers to track potentially exposed employees through a database (Washington State Department of Labor and Industries, n.d.). Bill requirements are being phased in. The rules to establish databases for exposed workers were not yet finalized at the time of this publication.

With the support of the California Nurses Association, the California Healthcare Institute, and several labor groups, California enacted similar legislation in 2013 and the rulemaking process is underway. At the time of this writing, North Carolina is also in the rulemaking phase after a bill passed in July 2014. In January 2015, bills were filed in the New Jersey General Assembly and the Massachusetts House of Representatives. The legislation in New Jersey passed both chambers in May 2017 and was signed into law by Governor Christie on May 11, 2017. In Massachusetts, the legislation was reintroduced in 2017. In March 2015, Michigan Senate Bill 237 was introduced and referred to the health policy committee. During the 2014 session, Maine's legislature did not pass legislation out of its Joint Standing Committee on Health and Human Services. In contrast to bills introduced into state legislatures, the state of Maryland has discussed changes to their existing regulations. An advisory committee of stakeholders has convened to revise regulations that would undergo public comment before they are finalized.

Professional Organizations

USP is a private, nonprofit organization that establishes standards for drug manufacturing, storage, prep-

aration, and administration, among other activities (USP, n.d.). Organized by chapters, select USP standards are enforced by FDA and similar agencies in 120 countries. USP General Chapter 800 aligns with extant recommendations from NIOSH and others (USP, 2016c). Importantly, chapter 800 is enforceable by state boards of pharmacy and other regulators; previous safe handling sections were considered advisory. The chapter addresses all phases of HD handling, including drug administration and disposal. After collating public comments, the expert panel on compounding HDs finalized the chapter on February 1, 2016. The implementation date is December 1, 2019 (USP, 2017a). Readers are encouraged to review this chapter thoroughly to understand the detailed standards, including requirements for external ventilation of preparation areas and employer-provided PPE and training.

After a 2015 stakeholders meeting in Washington, DC, representatives from ONS, ASCO, and the Hematology/Oncology Pharmacy Association issued a joint position statement to summarize their position on HD handling (Tomkins, 2015). The statement recommends that facilities (a) adopt evidence-based strategies to reduce HD exposure to HCWs, (b) provide engineering controls and tested PPE, (c) educate staff and patients on exposure risks and preventive strategies, (d) provide alternate duty to workers attempting to conceive, and (e) establish sound drug disposal policies. The three organizations also pledged to generate and disseminate evidence-based preventive interventions.

Institutional Policy

The term *policy* often connotes unpleasant images of speaking with legislators, slow progress, and long, unreadable documents. Yet nurses can make meaningful practice improvements by developing and evaluating policies in their workplace. Such policies form the backbone of high-quality, reliable nursing practice. Facilities in which HDs are administered often establish institutional policies that govern the ordering, storage, preparation, administration, disposal, and documentation surrounding HDs. Nursing participation in these efforts can ensure that policies reflect the latest evidence base, are congruent with NIOSH recommendations, and are feasible to implement in practice.

Institutions rarely make HD policies publicly available. Thus, it is challenging to assess their quality and comprehensiveness. As part of the NIOSH-funded Drug Exposure Feedback and Education for Nurses' Safety study, the research team identified substantial variation in the content of institutions' HD handling policies (Friese, Mendelsohn-Victor, et al., 2015).

A Canadian team proposed essential elements of a robust institutional policy for HD exposure management, with healthcare executives as the intended audience (Easty et al., 2015). These recommendations may help nurses as they participate in policy development and evaluation. Policies should undergo periodic expert review to incorporate the latest research evidence (Graham, Mancher, Wolman, Greenfield, & Steinberg, 2011).

Conclusions and Implications for Nursing

HD policies are developed, implemented, and evaluated at federal, state, professional, and institutional levels. Nurses have the opportunity to participate across these levels to ensure policies can be implemented effectively (Russell & Fawcett, 2005). Given the limited data available on exposed workers' long-term health, nurses should report HD exposures to their employers and ensure that permanent records are kept. Locally, nurses can develop and revise HD administration policies.

Nursing policy efforts at the state or federal level need not be onerous. Often overlooked, nurses should review both state and federal opportunities to comment publicly on bills or rules that address HD handling. At the federal level, draft regulations for public comment can be viewed at www.regulations.gov. States vary in their public commenting procedures. Policy makers and the public respond positively to personal narrative, and the public views nurses as highly trustworthy professionals (Riffkin, 2014). Through letters to the editor or commentaries, nurses can use poignant personal experiences to raise concerns and propose solutions (Friese, 2015a, 2015b). Nurses can testify before state or federal authorities as they consider legislative or regulatory reforms.

While the impetus for HD handling policy is diffuse, this fragmentation may be viewed as an opportunity for nurses to participate at levels most comfortable to them. Through sustained interest in emerging research findings, evidence-based advocacy efforts, and effective messages to key stakeholders, nurses can play an important role in developing sound HD handling policy that protects workers' safety and health.

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