

Safe Handling of Hazardous Drugs in Healthcare



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What are Hazardous Drugs?



Hazardous drugs (HDs) are drugs known or suspected to cause adverse health effects from exposures in the workplace. Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs and other miscellaneous drugs. The majority of HDs belong to the category of antineoplastic drugs.

Antineoplastic drugs are chemotherapy agents used to control or kill cancer cells.

Cytotoxic drugs inhibit or prevent the function of cells within the body. The most common forms of cytotoxic drugs are known as antineoplastic, and sometimes these terms are used interchangeably. Some of these drugs may be used to treat non-cancerous conditions such as rheumatoid arthritis and psoriasis. Antineoplastic drugs tend to be more damaging to cancer and other fast dividing cells [8].

These drugs can disrupt the growth and function of both healthy and diseased cells, resulting in toxic side effects for treated patients. *These actions can also cause adverse effects in health care workers who are inadvertently exposed [8].*

The National Institute for Occupational Safety and Health (NIOSH) in the United States is taking the lead in classifying hazardous drugs. They indicate that drugs that exhibit one or more of the following *six characteristics* in humans or animals should be handled as hazardous, and as such standard precautions around hazardous drugs should be taken [2, 8, 9, 10]. A list of hazardous drugs has been prepared by NIOSH and they have committed to updating it regularly [9].

Six Characteristics of Hazardous Drugs

Characteristic	Description
Carcinogenic	A substance or agent that can cause cancer.
Teratogenic or Other Developmental Toxicity	A substance or agent capable of producing fetal malformation
Reproductive Toxicity	Adverse effects on the male and/or female reproductive systems caused by exposure to a toxic substance or agent. The adverse effect may be expressed as alterations in sexual behavior, decreases in fertility, or fetal loss during pregnancy.
Genotoxic	A substance or agent causing deleterious action on a cell's genetic material affecting its integrity; the degree to which something causes damage to or mutation of DNA.
Organ toxicity at low doses	Toxicity of an organ or on health produced by a pharmaceutical when it is administered in low doses (e.g., liver damage, local necrosis of exposed tissue, etc.).
Similar Drugs	Substances whose structure and toxicity are similar to those based on one of the above criteria.

What are the Risk of Exposure?

Both clinical and non clinical workers who are involved in handling, preparing, administering hazardous drugs or working with patients/clients receiving a hazardous drug may be at risk. Workers may be exposed during transportation, distribution, preparation and disposal of hazardous drugs or waste containing hazardous drugs in either the healthcare or home setting [8]. In some cases, precautions for handling waste may need to remain in place for 48 hours and up to 7 days depending on the drug used. It is important to check with the manufacturer's instruction to ensure the efficacy of the cleaning agent.

Individuals at risk of exposure may include: [8]:

- Pharmacists and pharmacy technicians
- Shipping and receiving personnel
- Nurses and physicians
- Operating room, laboratory, and other allied health professionals
- Environmental services personnel (e.g., housekeeping, laundry, and waste management)
- Nursing services, personal support workers, paramedics and other community workers.

Potential route of exposure:

- Absorption through the skin (e.g., contact with contaminated surfaces, objects or body fluids)
- Inhalation of dusts or aerosols (e.g. over pressurizing vials)
- Accidental injection (e.g., injuries involving needle sticks and other contaminated medical sharps); and
- Unintentionally ingestion (e.g., contaminated food or objects, such as finger and pencils, placed in the mouth)

High risk tasks that may expose workers to hazardous drugs may include, but are not limited to [8]:

- Counting, crushing or breaking powdered tablets
- Preparing, handling, administering, and disposing of solutions
- Handling and disposing of drug administration equipment, contaminated waste, and patient body fluids, feces and urine; and
- Cleaning up spills and/or contaminated excreted bodily fluids.

Action Item - Recognize

Healthcare organization should create and keep current a list of drugs considered to be hazardous in their workplace. Use the criteria and sources of information provided by NIOSH, as well as specific information found in each manufacturer's Material Safety Data Sheet (MSDS) [8, 10] to create a list of Hazardous Drugs used in their specific department. This should be done by qualified individuals (usually trained in toxicology /pharmacology/ occupational hygiene).

What are the Effects of Exposure?

Although the potential benefits of hazardous drugs outweigh the risks of side effects for ill patients, there are no benefits of exposure for health care workers. Even exposures at very low doses to certain drugs may be hazardous for workers who handle them or work near them.

Following are the **acute** health effects that have been reported in hospital workers exposed to hazardous drugs [9]:

Abdominal pain	Headaches and dizziness
Coughing and facial flushing	Hair thinning/loss
Dermatitis, irritation of skin, eyes, and mucous membranes	Menstrual cycle disruption and fetal loss
Nausea, vomiting and diarrhea	

Health effects of *chronic* occupational exposures are not completely understood at this point. Information mainly comes from data in animals and patients where the drug was administered as a treatment for illness. Occupational exposures usually occur at much lower doses than in patients; however healthcare workers may be exposed over a longer period [12].

Based on the findings of studies, the International Agency for Research on Cancer (IARC) has judged a number of hazardous drugs as being possibly or probably carcinogenic to humans. Some specific drugs have been classified as carcinogenic to humans when studies have demonstrated the development of secondary tumours in patients undergoing chemotherapy [12].

The IARC evaluations have also determined that a number of hazardous drugs produce developmental or teratogenic effects (e.g., congenital malformations) in laboratory animals. Conflicting findings were reported when studies were conducted that examined the relationship between occupational exposures and reproductive outcomes, such as miscarriages, birth defects, low birth weight, and infertility [12]. In the absence of scientific evidence showing that these agents are safe, the precautionary principle requires that exposures to HDs be minimized to as low as possible.

What are the Elements of a Hazardous Drug Exposure Control Program?

Employers are responsible for developing and implementing an effective hazardous drug exposure control program. In healthcare facilities covered under the Health Care and Residential Facilities Regulation, this must be done in consultation with the Joint Health and Safety Committee. Research has indicated that healthcare workers are being exposed to a greater extent when adequate controls are not implemented. As a risk reduction strategy, the hierarchy of controls (engineering controls, administrative controls, safe work practice and personal protective equipment (PPE)) should be utilized to prevent occupational exposures in workers. Training and education for workers at risk of exposure to HD's or contaminated waste is a critical component of an effective control program.

Action Item - Assess

Read your drug manufacturer's drug product safety sheets to understand the specific risks of the hazardous drugs you are working with.

The elimination of a drug or the substitution of less hazardous products is often not an option for clinical reasons. The following exposure control program elements should be in place at all times, where hazardous drugs are used, transported, stored, handled, or disposed:

The following controls should be selected and implemented based on a risk assessment.

Engineering Control includes:

- General and local ventilation systems (e.g., class II type B2 or III biological safety cabinets (BSC))
- Compounding aseptic containment isolators
- Facility design and layout (e.g., airlocks, negative pressure rooms)
- Safety engineered needles (SENs) and needleless systems
- CSA puncture and fluid resistant containers (for needles, syringes, and vials)
- Closed-system drug transfer devices (CSDTD)

Action Item - Control

A combination of engineering controls, administrative controls, safe work practices and personal protective equipment (PPE) should be utilized to prevent occupational exposures to workers from hazardous drugs.

Administrative / Safe Work Practice Controls include:

- Hazardous drug inventory, product safety sheets, and labeling system
- Management policies (e.g., purchasing controls, restricted areas, PPE and techniques for safely removing PPE, respiratory protection program, good hygiene practices including hand hygiene, isolation and securing of medications)
- Scheduling and job rotation (e.g., limiting frequency and duration, protection for pregnant workers)
- Information, instruction and training programs (e.g., health risk information and safe handling precautions that may include: the risks and hazards of exposure; appropriate

equipment and engineering controls; hand hygiene; use of PPE; environmental cleaning; what to do in case of exposure)

- Safe work practices (e.g., drug preparation, handling and administering techniques, cleaning and decontamination surfaces and equipment, use of plastic backed absorbent material to reduce dispersion and facilitate the clean-up of any spilled medication).
- Spill control protocols (e.g. spills kits and use of emergency eyewash stations and showers)

Spill Kit should be available and should include:

<input type="checkbox"/>	Protective disposable gowns (preferably lint free, low permeability fabric), hair and shoe covers
<input type="checkbox"/>	Goggles/face shield
<input type="checkbox"/>	2 pairs of chemotherapy gloves or thick quality disposable gloves such as nitrile or neoprene.
<input type="checkbox"/>	NIOSH approved respirator when there is a risk of inhaling drug aerosols
<input type="checkbox"/>	Absorbent plastic backed sheets or spill pads
<input type="checkbox"/>	Decontaminating agent (e.g. detergent and water, or commercial equivalent)
<input type="checkbox"/>	Puncture resistant container
<input type="checkbox"/>	Procedures for spill clean-up
<input type="checkbox"/>	Incident report forms

- Procedures for safe handling and disposal of cytotoxic waste
- Medical surveillance program
- Accident/incident reporting and investigation
- Post accidental exposure and follow up protocol
- Workplace inspections and compliance observations (e.g., assessment of techniques)
- Occupational hygiene / environmental monitoring,
- Regular maintenance of equipment and certification if applicable (e.g. Class II BSC requires certification annually).

Personal Protective Equipment includes:

- Disposable gowns made of a lint-free, low-permeability fabric
- Face and eye protection (e.g., when splash, spray or aerosols are possible)
- NIOSH approved respirator when there is a risk of inhaling drug aerosols (e.g., spill cleanup, and other emergency situations).
- ASTM (American Society for Testing and Materials) approved chemotherapy gloves, thicker gloves (.18 to .23 mm), or the use of two pairs of good quality, powder-free disposable nitrile or neoprene gloves (as specified by a risk assessment and review of the manufacture's recommendations)

Action Item - Evaluate

Evaluate the effectiveness of the program by verifying that the controls are working as expected and the hazard has been eliminated or adequately controlled. The controls should be communicated to affected employees. Supervisors should ensure the controls are being used properly.

Applicable Ontario Occupational Health & Safety Legislation & Guidelines

Health care workplaces are required to comply with applicable provisions of the Occupational Health and Safety Act (OHSA), R.S.O. 1990, c.0.1 and its Regulations. Employers, supervisors and workers have rights, duties and obligations under the OHSA.

Ontario Regulation 67 / 93. Health Care and Residential Facilities Regulation. Sections 8, 9, 10 and 97.

Ontario Regulation 833, Control of Exposure to Biological or Chemical Agents. Sections 3, 7.2 and 8

Additional Guidelines

CSA Standard Z316.6-07- Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste

CSA Standard Z317.10-09 “Handling of Waste Materials in Health Care facilities and Veterinary Health Facilities”

CSA Standard Z317.2-01- Special Requirements for Heating, Ventilation, and Air Conditioning (HVAC) Systems in Health Care Facilities

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CSA Standard Z8000-11 Canadian health care facilities

CSA Standard Z94.3-07 - Eye and Face Protectors

CSA Standard Z94.4-11 -Selection, use and care of respirators

Note: The Ministry of Labour (MoL) has not established Occupational Exposure Limits (OELs) for hazardous drugs. Likewise, currently no NIOSH recommended exposure limits (RELs), OSHA permissible exposure limits (PELs), or American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) exist [8].

Some pharmaceutical manufacturers, however, have developed risk-based occupational exposure limits (OELs) to be used in their own manufacturing settings, and this information may be available on material safety data sheets (MSDSs) or from the manufacturer [8]. For questions about specific antineoplastic drugs, organizations can contact their Regional Cancer Program for advice on safe handling.

Action Item

Adherence to the principles of *prudent avoidance* and keeping exposures *as low as reasonably achievable* (ALARA), should be abided by given the known and potential health hazards associated with hazardous drugs and recent evidence indicating that surface contamination is more widespread than previously believed [5, 6].

References

1. American Society Health System Pharmacists (ASHP). (2006). ASHP Guidelines on Handling Hazardous Drug. Retrieved from <http://www.ashp.org/doclibrary/bestpractices/prepgdlhazdrugs.aspx>
2. Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales (ASSTAS); *Prevention Guide Safe Handling of Hazardous Drugs*, (2007). Retrieved from <http://www.irsst.qc.ca/media/documents/pubirsst/cg-002.pdf>
3. Cancer Care Ontario. (2007). *Program in Evidence Based Care: Safe Handling of Parenteral Cytotoxics*.
4. Cancer Care Ontario – A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO): *Safe Handling of Cytotoxics*, (2013). Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2790670/>
5. Hon C-Y, Teschke K, Chua P, Venners S, & Nakashima L. (2011). Occupational exposure to antineoplastic drugs: Identification of job categories potentially exposed throughout the hospital medication system. *Safety and Health at Work* 30(2), 273–81.
6. Hon C-Y, Teschke K, Chu W, Demers P, Venners S. (2013). Antineoplastic drug contamination of surfaces throughout the hospital medication system in Canadian hospitals. *Journal of Occupational and Environmental Hygiene* 10(7), 374–83.
7. International Society of Oncology Pharmacy Practice (ISOPP); *ISOPP Standards of Practice*, (2007). Retrieved from http://www.oncosystems.com.tr/dosyalar/_ISOPP_Standards_of_Practice_-_Safe_Handling_of_Cytotoxics.pdf
8. NIOSH. (2004). *Preventing Occupational Exposures to Antineoplastics and Other Hazardous Drugs in Health Care Settings*. Retrieved from <http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf>
9. NIOSH. (2012). *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*. Retrieved from <http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf>
10. NIOSH. (2009). *Personal Protective Equipment for Health care Workers Who Work with Hazardous Drugs*. Retrieved from <http://www.cdc.gov/niosh/docs/wp-solutions/2009-106/pdfs/2009-106.pdf>
11. The Ottawa Hospital. (2011). *Pharmacy Standards of Practice. For the Preparation of Cytotoxic Drugs. Policies and Procedures*.
12. HSE Information Sheet. MISC615 Safe Handling of Cytotoxic Drugs. (2003). Retrieved from <http://www.hse.gov.uk/pubns/misc615.pdf>
13. CSA. 2002. *Handling of waste materials in health care facilities and veterinary health care facilities*. CAN/CSA/Z31.10-01. Canadian Standards Association.
14. Government of South Australia. (2012). *Guideline for South Australian Health Services - Safe Handling Cytotoxic Drugs and Related Wastes*. Retrieved from <http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/medicines+and+drugs/hazardous+drugs/guidance+documents+for+the+safe+handling+of+hazardous+drugs>