

Title: Hazardous Drugs - Safe Handling	<input checked="" type="checkbox"/> Policy	<input checked="" type="checkbox"/> Procedure	<input type="checkbox"/> SOP
Category: Patient Care Services Sub-category: Patient Related – Medication, Safety: Environment	Distribution: Pharmacy, All Patient Care Areas, Regional Cancer Program		
Endorsed: VP, Patient Experience and Chief Nursing Executive, RVP, Regional Cancer Care Signature:	Approval Date:	Jun. 10, 1999	
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CROSS REFERENCES: (OHS-OS-213) Personal Protective Equipment, (OHS-oh-120) Hazardous Drugs - Acute Exposure, (PAT-5-74) Chemotherapy for Malignancy

1. PURPOSE

To provide guidelines for the safe administration of hazardous drugs, the prevention of exposure and appropriate disposal of hazardous drug waste.

2. POLICY STATEMENT

Hazardous drugs are divided into different categories of risk. Depending on the level of risk, the parameters for how they are prepared/handled and the level of Personal Protective Equipment (PPE) required may differ. Hazardous Drugs are categorized as follows: “Level 1 – Cytotoxic Hazardous Drugs”, “Level 2/3 - Hazardous Drugs”, and “Biohazard” (see definitions below). The PPE and safety precaution requirements recommended in this policy are for hazard protection and to reduce potential risk. Staff are to wear the highest level of PPE required. For example sterile compounding or Infection, Prevention & Control (IPAC) guidelines may require more PPE than outlined in this policy depending on the task or patient’s infectious status.

3. SCOPE

This policy applies to all staff, professional staff and learners that may be exposed to hazardous drugs or byproducts.

- Only Chemotherapy trained Registered Nurse (RN) may administer Level 1 parenteral drugs for the treatment of cancer, including all medications ordered in the chemotherapy regimen.
- Level 1 – Cytotoxic Hazardous Drugs may be administered by all Registered Nurses (RN) for other medical diagnoses.
- Level 2/3 – Hazardous Drugs may be administered by RNs and Registered Practical Nurses (RPN) and according the Parental Drug Therapy Manual.

4. DEFINITIONS

Biohazard Drugs– *A drug that contains living organisms with potential to cause infection in humans. Refers to medications that are listed on https://informed.tbrhsc.net/main-page/home/resources/hazardous-drug-list-pharmacy_final.pdf*

Hazardous Drugs – *Medications classified as hazardous level 1, 2, 3 and biohazard that require specific precautions as per the Safe Pharmaceutical Handling Evaluation collaborative classification.*

Impervious Gown – *Coated gown specifically marketed for handling chemotherapy and has been tested by a manufacturer for resistance to permeability by hazardous drugs.*

Level 1 – Cytotoxic Hazardous Drugs – *Likely carcinogenic to humans. Refers to medications that are listed https://informed.tbrhsc.net/main-page/home/resources/hazardous-drug-list-pharmacy_final.pdf*

Level 2/3 – Hazardous Drugs – *Possibly carcinogenic or have a reproductive risk. Refers to medications that are listed on https://informed.tbrhsc.net/main-page/home/resources/hazardous-drug-list-pharmacy_final.pdf*

Nitrile Gloves – A glove that meets the American Society for Testing and Materials (ASTM) standards and has been tested for the permeation of various chemotherapy drugs. Comprised of Nitrile Butadiene Rubber, and not latex.

5. PROCEDURE

5.1. Drug Categories of Risk and Labelling

- To ensure safety, staff must first check label on the drug to determine safe handling requirement
- Labelling will include printing on the package or an auxiliary label (if appropriate and space permitting). The drugs in each category are labelled with:
 - Level 1 – Cytotoxic Hazardous Drugs will be labelled as one of “Cytotoxic” or “Chemotherapy”
 - Level 2/3 – Hazardous Drugs will say “Hazardous”
 - Biohazard drugs will be labeled as “Biohazard”

5.2. Safe Handling of Drugs

5.2.1 General Guidelines

- Read the label of the medication and determine if it falls under one of the hazard categories.
- Minimize contact with products. Do not crush or manipulate the product, please contact pharmacy if manipulation or crushing is required.
- Visually inspect any liquid medication supplied by pharmacy for droplets. If any medication has leaked out of the syringe /IV bag and into the outer sealed transport bag, contact pharmacy to discuss disposal of the unopened bag and request a replacement dose from pharmacy (if applicable).
- Wash hands with soap and water after handling hazardous drugs (hand-hygiene with alcohol-based sanitizer is not adequate to remove chemical contaminants).
- Any PPE that is contaminated must be changed immediately.

5.2.2 Drug Preparation

- Level 1 – Cytotoxic Hazardous Drugs will be prepared by pharmacy.
- Level 2/3 - Hazardous Drugs can be prepared in the patient care area with required PPE and if containment measures are available. Pharmacy will provide the medication in a ready to use format when possible or provide direction for preparation.
- Before preparing the drug:
 - 5.2.2.1** Gather drug, all necessary supplies, and PPE required as per Table 1.
 - 5.2.2.2** Select an area free from clutter and interruptions (e.g. medication room). Minimize contact with other equipment and surfaces.
 - 5.2.2.3** Work on a plastic-backed pad when preparing hazardous drugs to absorb any potential spills.
 - 5.2.2.4** Use a hospital approved disinfectant wipe for cleanup of working area.

Table 1 – PPE for Hazardous Drug Preparation in Patient Care Areas

Activity	Category	PPE Required
Injections, irrigations inhalation, oral dissolved (on direction of the pharmacist)	Level 1 - Cytotoxic Hazardous Drugs	Prepared in pharmacy only
	Level 2/3 - Hazardous Drugs	Nitrile gloves, regular gown, N95 mask, eye protection
	Biohazard	Prepared in pharmacy only
Oral Tablet	All Levels	Nitrile gloves
Oral suspension/liquid, Topical, Intravaginal, Rectal, Patches, Drops	Level 1 - Cytotoxic Hazardous Drugs	Nitrile gloves, impervious gown
	Level 2/3 - Hazardous Drugs	Nitrile gloves, regular gown

5.3 Drug Administration in the Patient Care Area

5.3.1 Gather appropriate PPE as per Table 2 and required administration supplies.

Table 2 – PPE for Hazardous Drug Administration

Route of Administration	Category	PPE Required
Parenteral, Intraocular, intrapleural, intrathecal, intraperitoneal	Level 1 - Cytotoxic Hazardous Drugs	Nitrile gloves, impervious gown. If risk of aerosolization (IV push): N95 mask If risk of splashing: eye protection
	Level 2/3 - Hazardous Drugs & Biohazard	Nitrile gloves, regular gown. If risk of splashing: N95 mask and eye protection
Intravesical	Level 1 - Cytotoxic Hazardous Drugs	Nitrile gloves, impervious gown, N95 mask and eye protection.
	Level 2/3 - Hazardous Drugs & Biohazard	Nitrile gloves, regular gown, N95 mask and eye protection.
Inhalation	Level 1 - Cytotoxic Hazardous Drugs	Nitrile gloves, impervious gown and N95 mask. If risk of splashing: eye protection
	Level 2/3 - Hazardous Drugs	Nitrile gloves, regular gown and N95 mask. If risk of splashing: eye protection
Oral tablet	Level 1 - Cytotoxic Hazardous Drugs	Nitrile gloves
	Level 2/3 - Hazardous Drugs	Nitrile gloves
Oral suspension/liquid, Topical, Intravaginal, Rectal, Patches, Drops	Level 1 - Cytotoxic Hazardous Drugs	Nitrile gloves and impervious gown
	Level 2/3 - Hazardous Drugs	Nitrile gloves, and regular gown

5.3.2 Wash hands and don PPE.

5.3.3 Place a blue pad under the work area at the patient’s bedside if risk of spill (e.g. parental, suspension). When administering hazardous drugs through a Y-site tubing, place a gauze pad around the Y-site to reduce the possibility of releasing the drug into the environment.

5.3.4 Parenteral bags of admixed solution (diluent solution with drug added) will be attached as secondary lines to a main or primary IV line of compatible solution.

5.3.5 For Level 1 – Cytotoxic Hazardous Drugs;

5.3.5.1 Flush the tubing with 25mL of primary compatible fluid using the back fill technique and continue to infuse the flush post infusion of the hazardous drug as per the Parental Drug Therapy Manual.

5.3.5.2 Place cytotoxic precautions sign outside of the patient’s room. Patients do not require any isolation or private rooms. Add the “Cytotoxic Medication” sticker to the front of the patients chart with the date that the cytotoxic precautions will start and end and document on the patient Kardex.

5.3.5.3 If a medication is obtained from pharmacy and not administered, please contact the pharmacy.

5.4 Disposal of Hazardous Drug Waste





5.4.1 Staff must wear the same level PPE as per Table 2 when disposing of hazardous drug waste.

5.4.2 Discard gloves or gowns immediately if contaminated.

5.4.3 Bags and solution administration sets should be discarded in an appropriate Hazardous Waste Container as per Table 3 below.

- 5.4.4 Remove PPE before leaving patient care area, disposing in an appropriate waste container as per Table 3.
- 5.4.5 Wash hands with soap and water immediately after gloves are removed.
- 5.4.6 Waste must be stored in a designated area.

Table 3 – Disposal of Medication Waste

Medication Waste	Level 1 – Cytotoxic Hazardous Drugs & Biohazard Drugs	Level 2/3 - Hazardous Drugs
The medication container (e.g. syringe, IV bag, needles, bottle etc.) IV tubing Anything sharp that has come into contact with a Hazardous Drug	Biohazard or Cytotoxic Waste Container 	Pharmaceutical Waste Container 
Soft Waste that has come into contact with the medication (e.g. gown, gloves, plastic-backed absorbent pad)	Red plastic bag in a garbage can 	Regular black plastic garbage bag in a garbage can 

5.5 Disposal of Bodily Fluids

- 5.5.1 When handling bodily fluids post hazardous drug administration, the following precautions must be followed and appropriate PPE must be worn as per Table 4.
 - For Level 1 – Cytotoxic Hazardous Drugs:
 - 5.5.1.1 Wear the PPE as per Table 4 for seven days post administration. PPE for bodily fluids precautions should be followed throughout the course of therapy (e.g. daily or weekly dosing).
 - 5.5.1.2 Incontinence in children or adults may cause direct irritation of the skin. Cleanse skin and apply a protective cream.
 - 5.5.1.3 Flush the toilet with the lid down after disposing of excreta. When no lid exists, cover the open toilet with a blue pad to prevent splashing.
 - 5.5.1.4 Disposable items must be used when the possibility of contamination of urine, stool, or other excreta. Discard disposable items (e.g. disposable urinals, bedpan liners, incontinent products) in a red garbage bag.
 - 5.5.1.5 Foley catheters, colostomy bags, ileal conduit bags, and other soiled disposable appliances are to be discarded in red garbage bag.
 - 5.5.1.6 Place all linens and laundry into a clear plastic bag and label “Cytotoxic” using cytotoxic chart sticker.
 - 5.5.1.7 Infants born to the parent receiving Level 1 – Cytotoxic Hazardous Drugs will follow the same precautions.
 - 5.5.1.8 Rinse bedpans/urinals/emesis basins/examination trays and place with other equipment for cleaning. No special labeling required.
 - For Level 2/3 – Hazardous & Biohazard Drugs:
 - 5.1.1.1 Follow routine PPE precautions for exposure to blood or bodily fluids as per Table 4.
 - 5.1.1.2 Follow routine practices for soiled linens and garbage.

- 5.1.1.3 Foley catheters, colostomy bags, ileal conduit bags, and other soiled disposable appliances are to be discarded as per routine practices in the yellow biohazard bag.
- 5.1.1.4 Rinse bedpans/urinals/emesis basins/examination trays and place with other equipment for cleaning. No special labeling required.

Table 4 – PPE for Handling Bodily Fluids

Activity	Category	PPE Required
Patient care where there is potential for contact with excreta	Level 1 - Cytotoxic Hazardous Drugs	Nitrile gloves and impervious gown. If risk of splashing: face shield
E.g. hygiene, collecting samples (blood, urine), emesis, mother's milk, emptying body fluids from containers (e.g. bedpans, urinals, catheter/drainage/colostomy bags), soiled equipment, changing /cleaning incontinent patient	Level 2/3 - Hazardous Drugs & Biohazard	Routine precautions: Nitrile gloves If risk of exposure: regular gown If risk of splashing: face shield
Indirect care (health professional talking with the patient) and light contact with the patient (auscultation, walking assistance)	Level 1 - Cytotoxic Hazardous Drugs, Level 2/3 - Hazardous Drugs & Biohazard	Routine precautions.
Handling bedding (including clothing) NOT soiled with excreta or drug	Level 1 - Cytotoxic Hazardous Drugs, Level 2/3 - Hazardous Drugs & Biohazard	Routine precautions: Nitrile gloves.
Handling bedding (including clothing) <u>visibly soiled with excreta</u>	Level 1 - Cytotoxic Hazardous Drugs	Nitrile gloves and impervious gown. If risk of splashing: face shield
	Level 2/3 - Hazardous Drugs & Biohazard	Routine precautions: Nitrile gloves If risk of exposure: regular gown If risk of splashing: face shield

6. Emergencies

- In all areas where hazardous drugs are administered the following must be available:
 - Hazardous Spill Kit available in the immediate care area.
 - An eye wash station.
- Refer to OHS-oh-120b Hazardous Drugs - Acute Exposure.

6.1 If a Hazardous Drug (All Levels) Spill Occurs:

6.1.1 Assess the spill and quarantine the area:

- Identify a person to isolate the area and divert traffic from the spill of all people not directly involved in managing the spill.
- Ideally, an individual other than the one involved in the spill should manage the cleanup.
- **For Level 1 – Cytotoxic Hazardous Drug Spills – Call housekeeping and pharmacy to advise and assist in the spill management.**

6.1.2 Obtain spill kit and PPE as per Table 5. Double glove when cleaning up a spill.

6.1.3 Clean up the spill using supplies in the spill kit:

- 6.1.3.1 If the hazardous drug is a solid or powder, an absorbent pad moistened with water must be used to cover and wipe the spill.

- 6.1.3.2 If the hazardous drug is a liquid, absorb the liquid with spill pads. Cleanup should begin from the area of least to most contamination.
- 6.1.3.3 Ensure all fluid from the spill is contained and absorbed.
- 6.1.3.4 Carefully remove any glass fragments using disposable brush and dustpan. Place fragments into an appropriate medication sharps container.
- 6.1.3.5 Wash the spill area using a cloth wetted with detergent and water starting from area of least to most contamination. Repeat this process 3 consecutive times.
- 6.1.3.6 Rinse the area with water.
- 6.1.3.7 Area should be wiped several times with bleach-based wipes.
- 6.1.4 Disposal:
 - 6.1.4.1 Discard all contaminated material in disposable red hazardous garbage bag.
 - 6.1.4.2 Remove PPE leaving inner gloves on and discard outer PPE in red hazardous garbage bag
 - 6.1.4.3 Seal the bag using inner gloves.
 - 6.1.4.4 Place bag into second red hazardous waste bag.
 - 6.1.4.5 Remove inner gloves and place in second red hazardous bag and seal.
- 6.1.5 Wash hands thoroughly with soap and water.
- 6.1.6 Submit an online Safety Report. **Contact/leave voice mail for the areas manager/supervisor** with details of spill incident and to replace spill kit.

Table 5 – PPE for Spill Management

Activity	Category	PPE
Spill Management	Level 1 - Cytotoxic Hazardous Drugs	Double nitrile gloves, impervious gown, cartridge respirator if fit tested (if none available – N95 mask) and eye protection.
	Level 2/3 - Hazardous Drugs & Biohazard	Double nitrile gloves, regular gown, N95 mask, eye protection

7. RELATED PRACTICES AND/OR LEGISLATIONS

Safe Pharmaceutical Handling Evaluation (SaPHE) collaborative classification (draft). (2024).

8. REFERENCES

Cancer Care Ontario (2022). Safe Handling Cytotoxics. Retrieved Feb 7, 2024.

<https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2161>

Safe Pharmaceutical Handling Evaluation (SaPHE) collaborative classification (draft). (2024).