Safe Work Procedure for Preparation of Parenteral Hazardous Drugs

Site Applicability

All Providence Health Care sites, including acute, long term care, and ambulatory care areas, where hazardous drugs are prepared outside of pharmacy.

Practice Level

Basic:

- All clinicians with medication preparation and administration within their scope.

Requirements

A risk assessment (Appendix A) must be in place for this Safe Work Procedure to be followed.

Need to Know

- The final dosage form of a drug is a unit-dose packaged drug, ready to be administered to the patient without any preparation by the clinician.
- Preparation is any action taken to alter a drug product by means other than compounding or repackaging.
- When a hazardous drug is provided in the final dosage form the clinician is to follow the precautions outlined in the Control Matrix of the Exposure Control Program (Appendix B) for administration.
- This document outlines the steps to follow when preparation of the hazardous drug is required outside of pharmacy.
- Based upon a point of care risk assessment, conduct preparation in a low traffic area such as a medication room, alcove, or the patient's room as appropriate.
- All areas where hazardous drugs are stored, prepared or administered must have a Cytotoxic Spill Kit available

Equipment and Supplies

- Accelerated hydrogen peroxide wipes (i.e. Accel Intervention)
- Syringe
- Needle with filter (for ampoule)
- Needle (for vials)
- Plastic backed pad
- PPE:

- Two pairs of chemo-approved gloves
- Chemo-approved gown
- Eye and face protection (i.e. medical mask, and full face shield, or goggles)

Procedure

Work Surface Preparation:

1. For all procedures below, place plastic backed pad on surface on which the hazardous drug will be prepared.

Withdrawing from a vial (no dilution or reconstitution required):

1. Remove cap from the drug vial(s).
2. Scrub/clean septum (silicone/rubber seal) with alcohol swab, allow to dry.
3. Insert needle and inject air (same volume to be removed) into medication vial.
4. Withdraw correct medication dose into syringe.

Withdrawing from an ampoule:

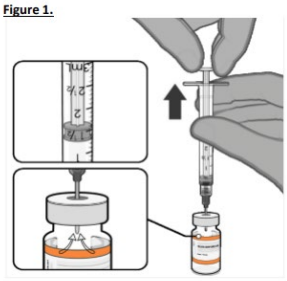
1. Ensure that all medication is collected in the bottom of the ampoule (i.e. no liquid remaining in ampoule tip and neck).
2. Follow local procedures if using an ampoule breaking device.
3. If not using an ampoule breaking device, open and place a sterile alcohol swab package over ampoule tip and neck to minimize risk of splatter on opening.
4. If a scored point is on the ampoule, take care to turn scored point away from you and break ampoule on scored line by pulling tip towards you to snap off.
5. Use a filtered needle to withdraw medication from ampoule.
6. Change needle and discard filtered needle and ampoule body and tip in hazardous waste sharps (Group 1) or regular sharps container (Group 2).

Reconstituting medication in a vial:

1. Attach an unfiltered blunt fill needle to the syringe.
2. Remove cap from both the drug vial, and diluent vials if using.
3. Scrub/clean vial septum/s (silicone/rubber seal) with alcohol swab, allow to dry.
4. Inject air into the diluent vial equal to the volume to be withdrawn (not required if using a polyampule).
5. Withdraw the required volume of diluent.
6. Inject the diluent into the medication vial.

7. Equalize vial pressure before removing the needle from the vial by withdrawing an equal amount of air to the diluent added from the 'air portion of the vial' into the empty diluent syringe (See Figure 1 below).

Figure 1.



8. Mix the medication and diluent per drug specific instructions (i.e. PDTM, manufacturer's instructions).
9. Insert needle and inject air (same volume to be removed) into medication vial, withdraw correct dose into syringe.
10. Refer to Diluting section below if dilution in an IV bag is required.

Diluting:

1. In an IV bag (e.g. minibag):
    a. Wipe minibag port with an alcohol swab.
    b. Slowly inject hazardous drug into the minibag.
    c. Remove the needle from the minibag port.
    d. Dispose of needle and syringe as one unit.
    e. Wipe the minibag port again with an alcohol swab to physically remove residual contamination.
    f. Apply a hazardous drug auxiliary label in addition to the regular medication label.
    g. Ensure that IV lines are primed with a compatible IV solution prior to attaching minibag.
        - **WARNING**: Do NOT prime lines with hazardous drugs.

Labelling:

1. In addition to standard labelling requirements, apply a Hazardous Drugs Group 1 or Hazardous Drugs Group 2 label to prepared syringes and IV bags.

Work Surface Cleaning

1. After each procedure above the work surface must be cleaned and decontaminated using a two-step process using accelerated hydrogen peroxide wipes (i.e. Accel Intervention).

Related Documents

- Diluting Medications for Parenteral Administration
- Low Level Cleaning and Disinfection (Infection Control)

References

Adapted from provincial Safe Work Procedure *Hazardous Drugs Safe Work Procedure: IV IM IP and SC Parenteral Administration in Care Settings*

Appendices

- Appendix A: Risk Assessment
- Appendix B: Providence Health Care Hazardous Drug Control Matrix

Appendix A: Risk Assessment

A. Detailed Risk Assessment

Site:	All PHC acute, long term, and ambulatory sites	**Unit:**	Generic template
Date of assessment:	02-FEB-2022	**Next review date** **(1 year)**	02-FEB-2022
Name of Drug:		**Drug Group (1 or 2)**	Group 1 or 2
Route of Administration:	IM, IV, SC	**Formulation:**	Parenteral

1. Reason pharmacy unable to provide final dosage form. Check all that apply:
   - ☒ Biological safety cabinet (BSC)/ Containment – Primary Engineering Control (C-PEC) not available
   - ☒ Pharmacy staff are not available (e.g. qualifications, outside of operational hours)
   - ☒ Transportation limitations/restrictions
   - ☒ Stability of drug
   - ☒ Anticipated urgency (i.e. urgent need for drug administration)

2. Proposed deviation from standard practice (e.g. drug will be crushed, mixed, combined etc.):
   a) Reconstituted
   b) Withdrawal (partial or full)
   c) Dilute (e.g. mini-bag or syringe)

3. Based on the required type of preparation, what are the potential exposure routes (i.e. without control measures in place, how could staff be exposed?). Check all that apply:
   - ☒ Absorption (skin and eye contact)
   - ☐ Inhalation
   - ☒ Ingestion (eating/drinking)
   - ☒ Puncture (needle stick)
   - ☐ Other (describe):

4. Based on the type of preparation and/or formulation, is there a risk of environmental contamination?
   - ☒ Yes
   - ☐ No

B. Alternate Control Measures for Development of Safe Work Procedures

Use the list below to identify control measures for the development of Safe Work Procedures (SWP) or reviewing an existing Safe Work Procedure for applicability. Note that when identifying control measures, **the hierarchy of controls must be considered**. In this process, engineering controls must be considered prior to or, in addition to, personal protective equipment (PPE).

The following lists can help to identify control options. Check all that applies and provide details in the SWP on how the control measures are utilized to prevent exposure. Refer to the Exposure Control Plan: Managing the Risks.

1. Proposed Engineering Control(s):
   - ☐ Closed System Transfer Device
   - ☐ Filtered Venting Device
   - ☐ Pill crusher (enclosed system)
   - ☐ Pill dissolver (enclosed system)
   - ☐ Pill cutter (enclosed system)
   - ☐ Other (describe):
   - ☒ None. No engineering controls are appropriate for alternate practice.

2. Proposed Administrative Control(s):
   - ☒ Education on the safe preparation technique and equipment (e.g. filtered venting device)
   - ☒ Identification of a location(s) for preparation which minimizes the number of individuals (staff, patients etc.) potentially exposed to hazardous drugs.
   - ☒ Methods used for minimizing surface contamination identified (e.g. using dedicated equipment, put an absorbent pad down)
   - ☒ Products and processes are in place for cleaning space post-preparation
   - ☒ Drug transportation and storage practices identified
   - ☒ Hazardous Drugs Spill kit is available and staff are trained on how to use it.

3. Required PPE (refer to ECP Control Matrix, Decision Support Tools, and consider all potential routes of exposure):
   - ☒ Chemo-approved gloves (two pairs)
   - ☒ Chemo-approved gown
   - ☒ Eye/face protection
   - ☐ Respiratory protection
   - ☐ Other (describe):

C. Safe Work Procedure

A Safe Work Procedure must be written considering all of the factors identified in both the **A. Detailed Risk Assessment** and **B. Alternative Control Measures** sections above. The SWP must be approved as per this risk assessment process prior to the administration of the drug.

Recommendation for SWP:

- ☒ Utilize a standardized Safe Work Procedure, all components are achievable.
- ☐ Modify an existing standardized Safe Work Procedure.
- ☐ Develop a unit or area based Safe Work Procedure.
- ☐ No appropriate alternate practices or SWP can be identified, consult with your Health Authority Hazardous Drugs Working Group.

Risk Assessment and Safe Work Procedure Developed By:	
Occupational Health and Safety	Hygienist, Occupational Health and Safety
Pharmacy	Pharmacy Coordinator
Professional Practice and Nursing	Practice Consultant
Risk Assessment and Safe Work Procedure Endorsed By:	
Clinical Operations	Executive Director Acute Care Program Director Seniors Care
Occupational Health and Safety	Director, Occupational Health and Safety
Professional Practice and Nursing	Director, Professional Practice and Nursing
Pharmacy	Director, Pharmacy (Acute Care) Director, Pharmacy (Long Term Care)

Appendix B: Providence Health Care Hazardous Drug Control Matrix

PROVIDENCE HEALTH CARE – HAZARDOUS DRUGS CONTROL MATRIX

BC Hazardous Drug Control Matrix Nursing Section			Group 1					
			Parenteral (IV, IVe, IM, SUBCUT, IT, IP)	Oral Solid (Tablet, Capsule)	Oral Liquid	Topical, Rectal & Vaginal	Implants and Ophthalmic	Inhalation Therapy
LABELLING MEDICATION								
TRANSPORT IN FACILITY			Do not use tube system		Do not use tube system	Do not use tube system if liquid		
			• If transporting drugs in a reusable outer container - two pairs of chemo-approved gloves are required • If transporting drugs in a disposable outer container (e.g. plastic bag), PPE is not required • Ensure a Hazardous Drugs spill kit accompanies drug transport or is readily available					
PREPARATION OF DRUGS BY NURSING	PERSONAL PROTECTIVE EQUIPMENT (PPE)		**See Safe Work Procedures**					
PRIMING IV LINES			• Do not prime IV lines with hazardous drugs					
MEDICATION ADMINISTRATION Drugs in final dosage form (including when using CSTDs)	PPE	Gloves	two pairs of chemo-approved gloves	one pair of chemo-approved gloves	two pairs of chemo-approved gloves			
		Gown	chemo-approved gown	None	chemo-approved gown if risk of splash			chemo-approved gown
		Eye/Face	eye/face protection	None	eye/face protection if risk of splash			eye protection
		N95	None					N95 Required
WORK SURFACE CLEANING			• Wear two pairs of chemo-approved gloves, chemo-gown, eye/face protection if risk of splash • Use Accelerated Hydrogen Peroxide 0.5% (e.g. Accel Intervention wipes™)					
PRECAUTIONARY PERIOD Place precautionary signage at the bedside or entrance to client room			The precautionary period is 48 hours following each administration of a Group 1 HD • **During** precautionary period o Required PPE: two pairs of chemo-approved gloves, chemo-approved gown, eye/face protection if risk of splash for any activities for which there is a risk of contact with BBF • **Outside** precautionary period o Follow routine precautions when handling blood and body fluids					
LABORATORY			• During an individual's precautionary period all blood, urine and stool samples; other body fluids visibly contaminated with blood (except swabs and sputum) and tissues or organs not in fixatives must be labelled with a **laboratory HD1 label** • All laboratory specimens from a patient in the precautionary period are to be placed in an outer sealed plastic bag. Blood specimens may be tubed, and must be labelled and placed in two sealed bags, with the outer bag labelled					
LAUNDRY			• **During** precautionary period: All linen to be placed **in Group 1 HD labelled laundry bag** o Required PPE: two pairs of chemo-approved gloves, chemo-approved gown, eye/face protection if risk of splash • **Outside** precautionary period: All linen to be placed in **regular laundry bag** o Required PPE: Follow routine practices					
			Drug Waste		**Sharps**	**BBF Waste**		**Other Waste (e.g. PPE and packaging)**
SPILL MANAGEMENT Hazardous drug spill kits in all areas where hazardous drugs are handled			**Intact solid dosage form** Required PPE: one pair of chemo-approved gloves **All other dosage forms:** Manage spills according to Hazardous Drug Spill Procedures for size of spill. See Appendix L in ECP		• Manage spills according to Hazardous Drug Spill Cleanup Procedures for size of spill. See Appendix L in ECP			
WASTE MANAGEMENT Acute/Long Term Care (i.e., in facility)			**Controlled Substances:** Pharmaceutical Waste Bin **Non-Controlled Substances:** Cytotoxic Waste Bin		Cytotoxic Sharps Container	Where possible, disposed of through the sewer. Where not disposed of through sewer, use a leak-proof cytotoxic container.		Cytotoxic container
			Required PPE: • two pairs of chemo-approved gloves • chemo-approved gown if risk of splash • eye/face protection if risk of splash					

Acronyms: CSTD = Closed System Transfer Device IV = Intravenous IVe = Intravesicular IM = Intramuscular SUBCUT = Subcutaneous IT = Intrathecal IP = Intraperitoneal BBF = Blood and Body Fluid HD = Hazardous Drug

PROVIDENCE HEALTH CARE – HAZARDOUS DRUGS CONTROL MATRIX

BC Hazardous Drug Control Matrix Nursing Section			Group 2 HD2				
			Parenteral (IV, IVe, IM, SUBCUT, IT, IP)	Oral Solid (Tablet, Capsule)	Oral Liquid	Topical, Rectal & Vaginal	Implants and Ophthalmic	Inhalation Therapy
LABELLING MEDICATION			Precautions Required | Hazardous Drug GROUP 2  					
TRANSPORT IN FACILITY			Do not use tube system		Do not use tube system	Do not use tube system if liquid		
			• If transporting drugs in a reusable outer container - two pairs of chemo-approved gloves are required • If transporting drugs in a disposable outer container (e.g. plastic bag), PPE is not required • Ensure a Hazardous Drugs spill kit accompanies drug transport or is readily available					
PREPARATION OF DRUGS BY NURSING	PERSONAL PROTECTIVE EQUIPMENT (PPE)		**See Safe Work Procedures**					
PRIMING IV LINES			• Do not prime IV lines with hazardous drugs					
MEDICATION ADMINISTRATION Drugs in final dosage form (including when using CSTDs)	PPE	Gloves	two pairs of chemo-approved gloves	one pair of chemo-approved gloves	two pairs of chemo-approved gloves			
		Gown	chemo-approved gown	None	chemo-approved gown if risk of splash	None		Chemo approved gown
		Eye/Face	eye/face protection if risk of splash	None	eye protection if risk of splash	None		eye protection
		N95	None					N95 required
WORK SURFACE CLEANING			• Wear two pairs of chemo-approved gloves, chemo-gown, eye/face protection if risk of splash • Use Accelerated Hydrogen Peroxide 0.5% (e.g. Accel Intervention wipes™)					
PRECAUTIONARY PERIOD			• Not applicable to Group 2 HD					
LABORATORY			• Use routine practices for collection, labelling and transport					
LAUNDRY			• All linen to be placed in regular laundry bags					
			Drug Waste		**Sharps**	**BBF Waste**	**Other Waste (e.g. PPE and packaging)**	
SPILL MANAGEMENT Hazardous drug spill kits in all areas where hazardous drugs are handled			**Intact solid dosage form** Required PPE: one pair of chemo-approved gloves **All other dosage forms**: Manage spills according to Hazardous Drug Spill Procedures for size of spill. See Appendix L in ECP		• Follow routine precautions			
WASTE MANAGEMENT Acute/Long Term Care (i.e., in facility)			**Controlled Substances**: Pharmaceutical Waste Bin **Non-Controlled Substances**: Cytotoxic Waste Bin		Regular Sharps Container	Where possible, disposed of through the sewer. Where not disposed of through sewer use regular garbage or anatomical or biohazardous waste per usual practices.	Regular garbage	
			Required PPE: • one pair of chemo-approved gloves • chemo-approved gown • eye/face protection if risk of splash		• Follow routine practices and standard procedures			

Acronyms: **CSTD** = Closed System Transfer Device **IV** = Intravenous **IVe** = Intravesicular **IM** = Intramuscular **SUBCUT** = Subcutaneous **IT** = Intrathecal **IP** = Intraperitoneal **BBF** = Blood and Body Fluid **HD** = Hazardous Drug

First Released Date:	02-FEB-2022
Posted Date:	29-MAR-2023
Last Revised:	29-MAR-2023
Last Reviewed:	29-MAR-2023
Approved By:	PHC
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