Site Applicability

This procedure is applicable to all areas at BC Children's and BC Women's Hospital that administer Hazardous Drugs.

Practice Level/Competencies

Required Education:

- Online learning curriculum titled Hazardous Drugs: Safety for Staff who Administer Hazardous Drugs is required for all clinicians who administer hazardous drugs (nurses, NPs, and physicians).
- The below listed competencies are required for registered nurses.

To administer Group 1 Hazardous drugs, including chemotherapy and biotherapy agents, to non-oncology patients, the nurse must:

- Possess knowledge of safe handling guidelines for hazardous drugs and safe disposing of hazardous drugs and waste products
- Familiarize self with mechanism of action, administration guidelines, and side effects of chemotherapy and biotherapy agents as outlined in the parenteral drug manual and other resources
- Be able to provide patient/family teaching in relation to side effects and management of side effects

To administer chemotherapy and biotherapy agents to oncology/BMT patients, the nurse must:

- Ensure that a chemotherapy checklist has been completed by **two chemotherapy certified RNs** (see Completing the Chemotherapy Checklist Procedure).
- Be knowledgeable about pediatric cancer diagnosis and treatment, hematopoeisis and immune response, treatment modalities, and psychosocial issues in pediatric oncology as attained through education and experience.
- List and describe chemotherapy and biotherapy agents and classifications and their mode of action, administration considerations, toxicity and symptom management, and late effects
- Demonstrate understanding of treatment roadmaps, protocols, and clinical trials.
- Be able to teach patients/families about their diagnosis, treatment, including side effects of chemotherapy/biotherapy being provided and the overall cancer experience.

These competences to be achieved through:

- Completion of the APHON (Association Pediatric Hematology/Oncology Nurses) Chemotherapy and Biotherapy Provider course
- Completion and sign off on the Chemotherapy Validation Tool with the Oncology CRN or CNE

NOTE: Oral chemotherapy may be administered by a Registered Nurse to an oncology patient if the nurse has attained the competencies as outlined above for administration of Group 1 Hazardous drugs to non-oncology patients, provided a chemotherapy checklist has been completed and verified by 2 chemotherapy competent nurses. Oral chemotherapy must be double checked by 2 RNs prior to administration.

Peripheral Chemotherapy Competencies:

- Non-vesicant: same as above
- Vesicant:
  - Able to identify vesicant agents and describe action for prevention and management of extravasation

Ordering of Chemotherapy/Biotherapy Agents

Chemotherapy/biotherapy orders are to be written by:

a. a physician and countersigned by a pharmacist, **OR**
b. a pharmacist and countersigned by a physician, **OR**
c. 2 physicians

At least 1 of the physicians writing or co-signing the order will be an attending oncologist, oncology fellow or oncology clinical associate who has received additional education and training in ordering and administration of (Hazardous Drug Group 1) chemotherapy/biotherapy.

The pharmacist writing or co-signing the order must have received additional education and training in ordering and preparation of chemotherapy/biotherapy.

Verbal or telephone orders are **NOT** acceptable for antineoplastic therapy.

Preparation of Group 1 Hazardous Drugs

Oral, intravenous, intramuscular, subcutaneous, and intrathecal Group 1 Hazardous Drugs will be prepared and dispensed by the pharmacy in final dosage form. When an exception occurs, nurses must follow risk assessment recommendations and the safe work procedure. The safe work procedure will identify protective equipment required.

Closed System Transfer Device (CSTD)

Whenever possible, a closed system transfer device (e.g. ChemoLock™) should be used when administering antineoplastics and all other agents that are classified as hazardous drugs. See Hazardous Drug Handling Policy.

Policy Statement(s)

- HCPs handling hazardous drugs will receive appropriate training, including spill management procedures.
  HCPs will adhere to safe handling precautions, when handling hazardous drugs and when handling body waste contaminated with hazardous drugs (within the 48 hour precautionary period), as outlined in Hazardous Drug Handling Policy. Vascular access patency must be determined prior to administration of intravenous chemotherapy/biotherapy

Equipment & Supplies

- Personal protective equipment descriptions:

PPE	ICON	Description
Gloves		**Chemo-approved gloves** are essential when handling hazardous drugs, cleaning up hazardous drug spills, and while caring for patients during the precautionary period. **Chemo-approved gloves must be:** • Tested for chemotherapy drug permeability following latest version of ASTM D6978 *"Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs"* and approved for use within the health authorities. See ECP for more details. • Changed out according to the manufacturer's limit for permeation or every 30 minutes • Powder-free • Sufficient length to cover the cuff of the user's gown (if worn). Depending on the fit of the PPE, this may be achieved with regular cuff length gloves. Extended cuff gloves may be required for individuals who have potential wrist skin exposure when wearing a gown.
Chemo-approved gowns		**Chemo-approved gowns** worn for protection from hazardous drug exposure must be: • Low-linting, non-shedding • Full back coverage • Closed front and secured in the back (by fasteners/ties) • Long sleeved with elasticized cuffs • Fluid resistant material (preferably disposable) • Made of materials that have been tested and shown resistance to permeability by hazardous drugs (e.g., polyethylene-coated polypropylene, other laminate materials): • The gown must be tested to a panel of chemotherapy drugs (the same as used in glove testing) as per the latest version of American Society for Testing and Materials (ASTM) F739 (*Chemical permeability test*) or similar testing protocol. A gown worn while providing care must not be worn outside of the care area. It must be removed prior to leaving the care area to prevent potential spread of contamination. The same gown can be worn again when providing care to the same patient or cohort of patients if this does not contravene any site-specific infection control practices.
N95 Respirator		**N95 Respirator:** A respirator that filters particles from the air. They must be fit tested and worn properly to ensure that contaminated particles within the air are not inhaled.
Eye and Face Protection= Goggles + medical mask or face Shield	  	**Eye and Face Protection:** Requires use of both Goggles and a Medical Mask, or a Face Shield. Protective eyewear must be worn where there is a risk of splash to the eyes. It must be able to prevent exposure to hazardous drugs and may be disposable or reusable. Eye protection can be achieved by wearing: • Properly fitted safety goggles with medical mask (i.e., surgical or procedure) • Transparent full-face splash shield with medical mask • Full-face piece elastomeric respirator or powered-air purifying respirator NOTE: Prescription glasses, safety glasses, and medical mask (with an attached visor only) are **NOT** acceptable for splash protection. Medical masks with attached visors are intended for droplet precautions, they do not prevent splashes from coming overtop of the shield or prevent liquid running down the face into the eyes. **Goggles:** Must be face sealing with or without side vents. If used with N95 respirators, goggles must also be worn with N95 Respirators. **Medical mask:** A loose-fitting single-use filtration device worn over the nose and mouth of staff to prevent contaminants being released into the immediate environment and to protect the wearer from spray or splash. **Face Shield:** Must be long enough to cover the nose and mouth. A face shield can be used in place of goggles and medical mask when these are indicated in the tables on required PPE below. A face shield can also be worn with an N95 Respirator instead of goggles.
Head Cover and Facial Hair Cover		**Hair Covers / Bouffant / Hijab Cover:** Must cover all exposed hair and / or hijab completely.
Shoe Covers		**Shoe Cover:** Disposable, single use.

- Personal protective equipment required for administration of **Group 1 Hazardous Drugs**:

Drug Formulation	Administration of Group 1 Hazardous Drugs Personal Protective Equipment Required						
							
Oral tablets, capsules	✓ 1 Pair & touchless technique						
Oral liquids, topical, non-liquid PV & PR, implants, topical ophthalmic	✓ 2 Pairs	Don Chemo-approved gown if risk of splash		Don Eye/Face Protection if risk of splash			
Parenteral: IV, Subcut, IM, IT, IP	✓ 2 Pairs	✓ Chemo-approved gown		✓ Eye/Face Protection			
	Engineering Control: when available use CSTD						
Inhalation Therapy *Risk assessment and SWP including drug-specific information & drug administration environment is required to determine respiratory protection details.	✓ 2 pairs	✓ Chemo-approved gown	✓ N95*		✓ Eye/Face protection		

- Personal protective equipment required for administration of **Group 2 Hazardous Drugs**:

Drug Formulation	Administration of Group 2 Hazardous Drugs Personal Protective Equipment Required						
							
Oral tablets, capsules	✓ 1 Pair & Touchless Technique						
Oral liquids, topical, non-liquid PV & PR	✓ 2 Pairs	Don Chemo-approved gown if risk of splash		Don Eye/ Face Protection if risk of splash			
implants, topical ophthalmic	✓ 2 Pairs						
Parenteral: IV, Subcut, IM, IT, IP	✓ 2 Pairs	Don Chemo-approved gown if risk of splash		Don Eye/ Face Protection if risk of splash			
	Engineering Control: when available use CSTD`						

- Disposable plastic backed absorbent pad
- Access to Hazardous Drug Spill Kit
- Complete and double signed chemotherapy checklist
- Hazardous Drug label to attach to infusion tubing as needed
- Hazardous drug in sealed plastic bag
- Physician's order for chemotherapy
- Hazardous Drug Handling Record
- Pre-filled normal saline flush syringes as needed (for IV Bolus administration)
- Chlorhexidine/alcohol swabs (for IV bolus, IM, and SQ administration)

Hazardous Drug Administration Procedure

STEPS	RATIONALE
1. **CONFIRM** that you meet the competencies to administer Group 1 hazardous drug (including chemotherapy and biotherapies)**.**	*Only RNs who have received the APHON chemotherapy/biotherapy provider certification and who have been validated at BCCH may administer IV, IM, and SQ chemotherapy/biotherapy to oncology patients.*
2. **ENSURE** a chemotherapy checklist has been completed, verified, and documented in Powerchart. **NOTE:** For Oncology/BMT patients, checklist must be completed by two chemotherapy competent RNs	*A completed chemotherapy checklist confirms that 2 RNs have completed the validation of patient BSA/weight, lab values, diagnostic test results, medication, route and calculation of dosing based on patient's treatment protocol.*
3. **REVIEW** chemotherapy checklist and parenteral drug monograph for any special instructions for patient care needs and monitoring requirements	
4. **ENSURE** emergency equipment is functioning and emergency drugs, if required, are readily available.	*To manage potential immediate drug reactions/adverse effects.*
5. **CHECK** hazardous drug dispensed with prescriber order and VERIFY with a second RN: a. Patient Name b. Patient MRN c. Medication Name d. Dose e. Route f. Timing g. Rate and method of administration h. Volume of medication i. Diluent fluid	*IV group 1 hazardous drugs must be verified by at least one chemotherapy certified RN. This confirms correct drug dispensed as per prescriber order.*
6. EXPLAIN procedure and PROVIDE education to patient and their family/caregivers. REVIEW side effects and management strategies as required.	*Evaluates and reinforces understanding of previously taught information and confirms consent of procedure.*
7. IDENTIFY patient and VERIFY hazardous drug with a second RN against patient name band or valid hospital photo ID a. Patient name b. Patient MRN	*Failure to correctly identify patients prior to procedures may result in errors.*
8. PERFORM hand hygiene	*Routine infection control practices; reduces transmission of microorganisms.*
9. DON personal protective equipment (PPE)	*Minimizes exposure risk.*

Intermittent and Continuous Intravenous (IV) Administration	
10. Follow steps 1-9.	
11. PREPARE equipment using aseptic technique. Where available, a closed luer-lock system (i.e. Texium caps) should be used on all secondary line hazardous drug infusions.	
12. Prime lines as appropriate a. If you are not using a CSTD, all chemotherapy administered via primary/secondary line, with the exception of Vincristine, should be fast primed first. All non-reactive chemotherapies are primed by running 15ml's of IVF as a "basic secondary" through the pump into the patient at a fast rate. All reactive chemotherapies are primed with 12mls. Do not disconnect the tubing from the patient during priming.	*Prior to programming the rate for the hazardous medication, the line must be safely primed with the medication to ensure accurate rate and time of administration.*
13. If administering a vesicant, check blood return from patient's central line. **NOTE:** A central venous catheter access is not available, and a vesicant must be given via peripheral intravenous catheter, the PIV must be less the 24 hours old. **NEVER** administer a vesicant without a brisk blood return (if using a PIV this is to be assessed before, during, and after administration). Limit peripheral vesicant infusion to IV push or infusions less than 60 minutes in duration. **DO NOT** use an infusion pump for peripheral vesicant administration. RN must remain with the patient during the entire infusion.	*It is necessary to ensure adequate blood return prior to administering a vesicant drug to ensure that the central line is in the appropriate place and to minimize the risk of severe tissue damage.* *If using a PIV to administer, the PIV must be new and have brisk blood return to minimize the risk of severe tissue damage.*
14. Program pump to **ADMINSTER** hazardous drug as ordered. A second RN is required to do an independent double check of pump programming when administering chemotherapy via infusion pump.	
15. DOFF PPE and dispose appropriately in the hazardous drug waste container	*PPE worn to administer hazardous drugs should be considered contaminated and disposed of appropriately*
16. If hazardous drug is a vesicant and is infusing over longer than 4 hours, DON PPE and confirm placement of central line by checking blood return Q4H until completion of infusion	*To minimize risk of tissue damage.* *When the hazardous drug is still infusing, it is appropriate to use the closest port to the patient to check blood return without having to disconnect the line.*
17. Once the infusion is complete DON PPE and FLUSH the hazardous drug with a compatible IV solution. Flush volume is 25 ml for primary/secondary infusions or until line is visibly cleared of medication.	*Flushing the line ensures all of the medication is infused.*
18. Once IV lines are no longer needed for hazardous medication administration, don PPE and REMOVE equipment keeping tubing and infusion bag/syringe connected. DISPOSE entire system as one in a hazardous drug waste container. PERFORM hand hygiene using soap and water.	*Safe handling guidelines to protect health care providers, patients, visitors, and environment from contamination by hazardous/cytotoxic agents.* *Alcohol-based hand rub does not remove drug residue.*

Intravenous (IV) Direct Bolus Administration	
19. Follow Steps 1-9.	
20. **PLACE** disposable plastic backed absorbent pad under vascular access connection site.	*Minimizes exposure of skin and surrounding areas to potential droplets of chemotherapy.*
21. PREPARE equipment using aseptic technique.	
22. CONFIRM patency of vascular access site. **ASSESS** for easy aspiration of blood, easy flushing of saline, and for any adverse patient response (pain, swelling, redness). Remove dressing as necessary to ensure site clearly visible. **IF PATENCY CANNOT BE CONFIRMED, DO NOT ADMINISTER CHEMOTHERAPY.** **NOTE:** A central venous catheter access is not available, and a vesicant must be given via peripheral intravenous catheter, the PIV must be less the 24 hours old. **NEVER** administer a vesicant without a brisk blood return (if using a PIV this is to be assessed before, during, and after administration). Limit peripheral vesicant infusion to IV push or infusions less than 60 minutes in duration. **DO NOT** use an infusion pump for peripheral vesicant administration. RN must remain with the patient during the entire infusion.	*To avoid possible infiltration/extravasation.*
23. ADMINSTER chemotherapy as per prescriber order. **ASSESS** for blood return every 2 ml and **OBSERVE** site for signs of infiltration. **If administering more than one chemotherapy agent, flush with 5-10 ml normal saline between drugs.** **NOTE:** If any pain, swelling, redness, or resistance occurs during drug administration, stop administration and assess patency.	*Confirms ongoing patency.*
24. FLUSH catheter with appropriate volume and heparin lock/saline lock or recommence infusion as ordered.	*Completes drug administration.*
25. Once administration complete dispose of used supplies as described in waste disposal section below.	*Supplies used to administer hazardous drugs should be considered contaminated and disposed of appropriately.*
26. Doff PPE and place in a hazardous drug (cytotoxic) waste container as described in waste disposal section below.	*PPE worn to administer hazardous drugs should be considered contaminated and disposed of appropriately*
Intramuscular (IM) Administration	
27. Follow steps 1-9.	
28. Landmarking, the rotation of sites, maximum administration volume guidelines, and the mechanics of administering hazardous drugs via IM are the same for administering other medications via this route. Please see Intramuscular Medication Administration Procedure and Hazardous Drug Handling Policy	*Consideration: If two injections are needed, administer the injections with a second RN simultaneously to decrease pain and anxiety related to injection* *Vesicants and irritant chemotherapeutic agents are never administered via this route.*
29. Follow steps 25-26.	

Subcutaneous (SC) Administration	
30. Follow steps 1-9.	
31. Landmarking, the rotation of sites, maximum administration volume guidelines, and the mechanics of administering hazardous drugs via SC are the same as for administering other medications via this route. Please see Subcutaneous Medication Administration Procedure and Indwelling Subcutaneous Catheter (Insuflon): Insertion, Medication Administration and Removal and Hazardous Drug Handling Policy	*Vesicants and irritant chemotherapeutic agents are never administered via this route.*
32. Follow steps 25-26.	
Oral Administration	
33. Follow steps 1-9.	
34. Steps for administration of oral group one hazardous drugs are the same as for administering other medications via this route. Please see Oral Medication Administration Procedure and Hazardous Drug Handling Policy. Prior to administration the two RNs must confirm that a checklist has been completed appropriately, and co-sign the medication.	***Note:*** *For more information about manipulating tablets and capsule on nursing units, refer to Appendix A of the Hazardous Drugs: Handling Precautions Procedure*
35. Follow steps 25-26.	

Waste Disposal

1. Dispose of used supplies and absorbent pad in cytotoxic waste container (HD Group 1) or in regular garbage (HD Group 2).
2. Dispose of used sharps in the cytotoxic sharps container (HD Group 1) or in a regular sharps container (HD Group 2).
3. Dispose of any partial or wasted dose in a cytotoxic waste container (HD Group 1 or 2) or pharmaceutical waste container (HD Group 2).

Post Administration Precautionary Period for Group 1 Hazardous Drugs (all routes of administration)

Additional precautions must be observed when handling patient blood and body fluids for 48 hours following the administration of a Group1 hazardous drug. See Hazardous Drug Handling Procedure for further details.

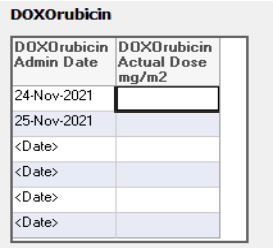
Documentation

DOCUMENT on MAR and appropriate records:

- Date, time
- Drug, dose, route, method of administration
- Pre-, concurrent, and/or post-hydration intravenous fluids
- Pre-medications
- Patient's tolerance to treatment (side effects, interventions to minimize or alleviate side effects)
- Patient/family education

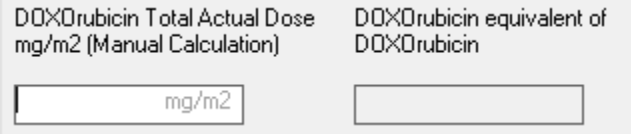
DOCUMENT current and cumulative anthracycline and bleomycin drug administration on the Lifetime Cumulative Dosing (LCD) PowerForm when applicable. Do this by following these steps:

1. Once the **LCD** form is open, enter the protocol dose (mg/m2) of the anthracycline that the patient received today in the correct table (Screen shot is not the full form)



Fill in today's date and the dose given in mg/m2.

2. **Manually add** today's dose in mg/m2 along with any previous documented doses and the calculated value into the **Total Actual Dose** box.



The system will then use the conversation factor to calculate the anthracycline equivalent for that medication.

NOTE: *For some medications, the conversion is different for adult patients and pediatric patients, in which case you will see two Total Actual Dose Boxes. Cerner PowerChart will not allow you to document in the adult box on a pediatric patient.*

COMPLETE Hazardous Drug Handling Record:

- Record the number of hazardous drug doses prepared or administered under the appropriate date; add drug name(s) in space provided at the bottom of the table if not already listed
- Maintain a monthly Handling Record and submit with annual performance review to your unit leader

Patient & Family Engagement/Education

- All patients and families who are receiving Hazardous Drugs as a part of treatment for an oncologic diagnosis or for a hematopoietic stem cell transplantation should receive New Diagnosis Teaching. This must be documented on the Oncology New Diagnosis: Teaching Flowsheet.
- Patients and families must receive education on the additional precautions that are to be observed when handling client blood and body fluids for 48 hours following the administration of a Group 1 Hazardous Drug. If a patient will be discharged during the precautionary period, education around chemotherapy and safety at home should be provided (See Precautions During Treatment Section of the Children's Oncology Group Teaching Powerpoint).

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Definitions

Hazardous Drug: A drug that: **(a)** is accompanied by prescribing information in the "package insert" that specifies special handling information (Manufacturer Special Handling Information-MSHI) to protect workers handling the drug; or (b) is identified as a carcinogenic hazard, developmental hazard, reproductive hazard, genotoxic hazard, or other hazard by exhibiting one or more of the following toxicity criteria in humans, animal models, or in vitro systems:

- carcinogenicity
- developmental toxicity (including teratogenicity)
- reproductive toxicity
- genotoxicity
- organ toxicity at low doses, or
- structure and toxicity profile that mimics existing drugs determined hazardous by exhibiting any one of the previous five toxicity types unless the drug also exhibits a molecular property that may limit the potential for adverse effects in healthcare workers from exposure to the drug.

Group 1 Hazardous Drug: Drugs that contain MSHI in the package insert and/or meet the NIOSH definition of a hazardous drug and are classified by the NTP (National Toxicology Program) as "known to be a human carcinogen" and/or classified by the IARC (International Agency for Research on Cancer) as "carcinogenic" or probably carcinogenic"

Group 2 Hazardous Drug: Drugs that meet the NIOSH definition of a hazardous drug but are not drugs that have MSHI or are classified by the NTP as "known to be a human carcinogen" or classified by IARC as "carcinogenic" or "probably carcinogenic" (some also may have adverse development and/or reproductive effects)

Chemotherapy Competent RN: an RN who has completed the APHON chemotherapy/biotherapy provider course and successfully completed the exam and has completed the validation process with the Hem/Onc/BMT CRN or CNE

Extravasation: inadvertent leakage of a vesicant drug or solution into the tissues surrounding an intravenous (IV) site

Treatment Protocol: documented treatment plan, including research protocols, standards of care, or individual treatment plans.

Vesicant: An agent that can cause redness, pain, blistering and serious progressive tissue damage if it leaks into tissue outside the vein (extravasates). Can cause blistering and local or extensive tissue necrosis with or without ulceration and may become evident only days or weeks after exposure.

Developed By

BCCH Oncology, Hematology, BMT Program – Quality & Safety Leader

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08-FEB-2022	C-0506-12-61183 Medication Administration: Hazardous Drugs Including Chemotherapy And Biotherapy	Approved at: Pharmacy, Therapeutics & Nutrition Committee

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