HAZARDOUS AND CYTOTOXIC DRUGS: ADMINISTRATION AND HANDLING - CHW

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- Hazardous drugs include cytotoxic, immunosuppressant, immunomodulating and antiviral drugs.
- Cytotoxic and hazardous drug solutions are to be prepared, administered and disposed of in accordance with NSW WorkCover guide, "Cytotoxic Drugs and Related Waste Risk Management Guide 2008" (1), the minimum standard for clinical practice and a legislative occupational health and safety requirement.
- All cytotoxic and hazardous drugs whether administered by the oral (PO), intramuscular (IMI), subcutaneous (SCI), intrathecal (IT) or intravenous (IV) route, should be:
  - handled with extreme care,
  - administered by an **accredited RN** or medical officer,
  - managed using appropriate Personal Protective Equipment (PPE) (Appendix 2)
- **Checking Cytotoxic and hazardous drugs**:
  - Cytotoxic drugs must be checked by two persons, one accredited RN, the second checker must be a Registered Nurse (Year 2 – 8th year thereafter) or medical officer. The drug must be administered by the accredited RN or medical officer.
  - For **BMT patients**, all cytotoxic drugs must be checked by **two accredited RNs** or one accredited RN and one medical officer.
  - Intrathecal medications must be checked by an accredited Oncology RN and the accredited medical officer administering the medication. The accredited RN checking the medication must remain present for the administration of the medication.
- **Staff Training and Accreditation**: There are two levels of training (level 1 & level 2) available at CHW for staff that handle and administer cytotoxic drugs and related waste:
  - **Level 1 training is provided to**: Nursing staff, Medical staff, Pharmacy staff and Laboratory staff.

- **Level 2 training is provided to**: Supervisors and managers, Maintenance and stores personnel, Cleaners and waste handlers, Couriers and porters, Patients/Carers and family members.

- Nursing staff are required to complete an initial **Accreditation Program** and a biennial reaccreditation program to be deemed competent to administer cytotoxic drugs. There are two levels of accreditation available:
  1. Cytotoxic Administration Accreditation-Full
  2. Administration of Hazardous Drugs
- Staff must adhere to waste management and spill management processes according to NSW Health Policy Directives
- Staff Exposure: Cytotoxic Exposure Sheet records (Appendix 1)
- Strict guidelines apply for PPE which must be worn when preparing or administering cytotoxic or hazardous drugs or managing cytotoxic waste or patient waste.
- Urgent management of extravasation is essential. Refer to IV Extravasation Management – CHW Practice Guideline.
- **Vincristine should always be administered via a minibag, not via a syringe**. Refer to High Risk Medications – CHW Policy - Vincristine for further information.

CHANGE SUMMARY

- Updated terminology to include reference to Hazardous drug administration and management
- Update cytotoxic extravasation
- Update medical staff training
- Update nursing accreditation criteria for assessors and addition of Administration of cytotoxic immunosuppressant, antiviral and immunomodulator accreditation
- Subcutaneous / Intramuscular injections section
- Inclusion of inhaled hazardous drug section and link to new policy pending
- Inclusion of Eye Drop - Cytotoxic section
- Personal Protective Equipment requirements table
- Surveillance

READ ACKNOWLEDGEMENT

- All staff members who administer and handle cytotoxic drugs and related waste at CHW must read and acknowledge this document.
- All staff members who care for patients receiving cytotoxic drugs must read and acknowledge this document.

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1 Introduction

1.1 Hazardous Drugs

NSW Health defines hazardous drugs as: 'Regulated substances (including solids, liquids and gases) that have been classified by the National Occupational Health and Safety Commission (NOHSC) criteria because they are hazardous to health and require particular care during use.' Cytotoxic agents are one group of agents falling under the classification of hazardous substances.[2,3,4]

Drugs are considered hazardous if they exhibit one or more of the following six characteristics:

1. Carcinogenicity
2. Mutagenicity
3. Teratogenicity
4. Reproductive or fertility impairment
5. Serious organ toxicity or adverse health effects at low doses in experimental animal models; toxic substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve serious, acute or chronic health risks.
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria. [1, 3, 4, 9]

Cytotoxic agents are hazardous substances which are detrimental or destructive to cells used in the treatment of malignant and/or other diseases. They have been shown to be mutagenic, carcinogenic and/or teratogenic, either in treatment doses in animal and bacterial assays.

Cytotoxic and hazardous drug solutions are to be prepared, administered and disposed of in accordance with NSW WorkCover guide [1], "Cytotoxic Drugs and Related Waste Risk Management Guide 2008"

There are certain agents/medications for example immunosuppressant, immunomodulator and anti-viral drugs, currently administered in CHW that are identified as hazardous. These drugs require care in their handling and administration. For further information refer to Appendix 2 for specific information on personal protective equipment requirements.

All cytotoxic and hazardous drugs [including oral suspension and tablets, intramuscular (IMI) and subcutaneous (S/C) injections, intrathecal (IT) and intravenous infusions (IV)] should be handled with extreme care and must be administered by an accredited RN or Medical Officer[1, 5, 9, 11, 12, 13].

Cytotoxic drugs will be labelled "**CYTOTOXIC**".

Other potentially hazardous agents will be labelled with a sticker identifying them as requiring special precautions when handling and administering.

Definitions [1, 2, 3, 4, 17]

- **Carcinogenicity**: the ability to cause cancer.
- **Mutagenicity**: genotoxicity or the ability to cause a change or mutation in genetic material
- **Teratogenicity**: the ability to cause defects in foetal development or foetal malformations; a teratogen and other developmental toxicities that can be manifested at any point in the life span of the fetus.
- **Chemotherapy**: Cytotoxic Agents used in the treatment of neoplastic disease.
- **Immunosuppressants**: an agent that induces immunosuppression. Immunosuppression is defined as: Prevention or interference with the development of immunologic response; may reflect natural immunologic unresponsiveness (tolerance), may be artificially induced by chemical, biologic, or physical agents, or may be caused by disease. Refer to Appendix 2
- **Immunomodulators**: Diminish the immune system. Substances that alters the immune response by augmenting or reducing the ability of the immune system to produce antibodies or sensitised cells. Refer to Appendix 2
- **Monoclonal Antibodies**: Pure type of antibodies which target specific antigens , substances that specifically bind to target cells or proteins and stimulate the patient's immune system and produce an immunological responses with consequential direct or indirect anti-tumour effect.
- **Anti-Virals**: any of several drugs used to treat viral infections. The drugs act by interfering with a virus's ability to enter a host cell and replicate itself with the host's cell's DNA. Refer to Appendix 2

2 Staff Training and Accreditation

2.1 Training Levels

There are two levels of training available at CHW for staff that handle and administer cytotoxic drugs and related waste [1, 5].

Level 1 training is provided to	Level 2 training is provided to
Nursing staff	Supervisors and managers
Medical staff	Maintenance and stores personnel
Pharmacy staff	Cleaners and waste handlers
Laboratory staff	Couriers and porters
	Patients/Carers and family members
Appropriate level 1 and 2 training is provided within the relevant department or clinical area.	

2.2 Medical Staff

All medical staff that routinely managing or administer cytotoxic medication are required to complete an initial Accreditation Program, along with ongoing and a biennial reaccreditation.

The regular and ongoing accreditation is to ensure personal and patient safety with regard to administration and spill management.

The accreditation program will consist of completing the eLearning module 1 from the Cancer Institute NSW titled 'Handling antineoplastic drugs and related waste safely'. This training is recorded as CSK949 in their training transcript within the learning management system for both initial and biennial assessments and forwarded to Staff Services for their employment file. Accreditation will also include reading this document.

To administer intrathecal (IT) medication, all New Fellows, Oncology Treatment Centre (OTC) Career Medical Officers (CMO's) and select senior registrars require accreditation. The accreditation process involves:

1. being familiar with this document;
2. reading and understanding the powerpoint presentation outlining CHW procedure for intrathecal medication and the inherent risks;
3. Watch the WHO video "Learning from Error: Part 1&2" at: http://www.who.int/patientsafety/education/vincristine_download/en/
4. The new staff member will be assessed by a Consultant Oncologist on entry to the position and based on experience it will be prospectively decided how many supervised lumbar punctures will need to be observed. There will need to be between 3 and 6 intrathecal administrations observed, including observation of all aspects from collection of the medication to completion of the procedure; this will need to be no less than 3. Once these procedures have been performed and signed off by an accredited member of staff: either a Consultant Oncologist or OTC Career Medical Officer (CMO) a letter of accreditation is produced which is forwarded to Department Head of Pharmacy, Staff Services and is included in their Departmental Employment File.

NE Oncology Services to be notified of all completed accreditations within CHW.

NE Oncology Services are responsible for documentation only. Medical staff are responsible for accrediting medical staff.

2.3 Registered Nurses

All nursing staff within Oncology Services are required to complete the eLearning module 1 from the Cancer Institute NSW titled 'Handling antineoplastic drugs and related waste safely'. This training is recorded as CSK949 in their training transcript within the learning management system.

For nursing staff to meet the required level 1 training, they must undertake the CHW Cytotoxic Administration Accreditation Program. This program consists of theoretical and practical components and in order to attain accreditation all components must be completed.

There are 2 levels of Cytotoxic Administration Accreditation:

1. **Cytotoxic Administration Accreditation- Full**. Staff members that have completed this accreditation program are accredited to administer any cytotoxic drug within CHW. This training is recorded as CSK 1544 in their training transcript within the learning management system. It is expected that full accreditation will be completed within 2 years of commencing employment within Oncology Services.

i. Administration of Hazardous Drugs

Staff members who have completed Administration of Hazardous Drugs Accreditation are limited to the administration of the drugs outlined in their specific area.

Full Cytotoxic Administration Accreditation process is as follows:

- Registered nurses identify the need for Full Cytotoxic Administration Accreditation in their clinical setting.
- Discuss with NUM, NE or CNE the appropriate timing to undertake the accreditation process and any support which may be required.
- Attend the Cytotoxic Administration Study Day (at any stage, but prior to practical assessment). Following attendance at the study day, each staff member has a 12 month timeframe in which to complete all components of their accreditation.
- Successfully complete the eLearning module (Cancer Institute NSW) "Handling anti-neoplastic drugs and related waste" (available through learning.kids).
- Successfully complete the **CHW Cytotoxic Administration Learning Package.** (Must be completed before practical assessment competencies are commenced**).**
- Successfully complete the Clinical Competencies for Administration of Cytotoxic Medications as outlined in the cytotoxic agents training and assessment matrix. Assessments must be conducted by the NE Oncology Services, CNE or an endorsed accredited assessor.
- NE, CNE or endorsed accredited assessor to complete the Cytotoxic Administration Accreditation paperwork and file a hard copy of the accreditation within a designated area in the clinical unit.
- Completed assessment documents are to be sent to the NE Oncology Services for final sign off, certificate and entering into HETI.
- Completed accreditation, including the assessor's details, is to be recorded in the learning management system.

NE Oncology Services to be notified of all completed accreditations within CHW

Administration of Hazardous Drugs accreditation process is as follows:

- Registered nurses identify the need for administration of Hazardous Drugs accreditation in their clinical setting.

Discuss with NUM, NE or CNE the appropriate timing to undertake the accreditation process and any support which may be required.Staff are to complete:

- Spill management DVD and Quiz
- ADAC Handling antineoplastic drugs and related waste safely - eLearning guide
- Attend the following Inservices:

  - Hazardous Drug Legislation and Policy
  - Cell biology
- Attend the demonstration session of routes required for area
- Complete learning package
  - Administration of Hazardous Drugs Learning Package
  - Area specific Learning Package
- Successful complete clinical competency assessments as per specific area
- NE, CNE or endorsed accredited assessor to complete the ***Administration of Hazardous Drugs*** paperwork and file a hard copy of accreditation within a designated area in the clinical unit.
- Completed accreditation, including assessor's details, is to be recorded in the learning management system.

Recognition of prior learning gained at a post graduate level is to be negotiated by the candidate with their Nursing Unit Manager and the Nurse Educator Oncology Services.

Accredited Assessors for full accreditation

Cytotoxic accreditation assessment must be performed by the Nurse Educator Oncology Services or an accredited and endorsed Oncology Services Clinical Nurse Educator.

Fully accredited Oncology Services nursing staff, with greater than 5 years paediatric oncology experience may, in consultation with the Nurse Educator Oncology Services, be endorsed to perform up to two practical assessments per accreditation program.

All accredited assessors (other than the NE Oncology Services) must maintain full Cytotoxic Accreditation.

Accredited Assessors for Hazardous Drug accreditation

The following designated positions are able to assess clinical competence in the administration of hazardous drugs :

1. NE Oncology Services, CNE and endorsed staff as outlined for full accreditation.
2. Clinical Nurse Educators (endorsed by the NE Oncology Services) with approved accreditation who work in clinical areas other than Oncology Services where hazardous drugs are administered.

Maintenance of Accreditation

All staff members with Cytotoxic Accreditation are required to regularly update their knowledge of new procedures, treatments and protocols by attending relevant professional development and education sessions. [1, 5, 10]

Staff members with either level of Cytotoxic Administration Accreditation are required to undergo a biennial assessment and successfully complete the e-learning module (Cancer Institute NSW) "Handling anti-neoplastic drugs and related waste" to maintain their

accreditation. [3, 8, 17] In addition, staff with full accreditation will be required to complete Level A or Level B cytotoxic education within the 2 year period as deemed appropriate by the NE Oncology Services and their ward CNE.

For staff who are fully cytotoxic accredited, the biennial assessment is to be undertaken in consultation with the NE Oncology Services or Oncology CNE.

The biennial assessment is recorded as CSK1567 and the e-learning module is recorded as CSK949 in their training transcript within the learning management system.

Staff members who do not undertake the biennial assessment and complete the e-learning module will have their cytotoxic accreditation status reviewed by the NE Oncology Services in consultation with the employee's manager.

Staff members who take a leave of absence from CHW for greater than two years will have their accreditation status reviewed. For staff members absent for less than 2 years, upon their return to work, a biennial assessment will be undertaken to assess their knowledge and skill in the administration of cytotoxic drugs. If not deemed competent by virtue of this process, staff will be required to complete the full cytotoxic accreditation process again.

Staff members who have achieved either level of accreditation are required to maintain a record of their cytotoxic drug administration in order to retain their accreditation. Staff members are required to administer no less than 20 agents (oral, SC, IV) within the 2 year period prior to undertaking the biennial assessment and provide supporting documentation (exposure record chart). (Note: Staff completing full accreditation must ensure that no less than 15 agents are IV administered.)

If this quota is not met, staff will have an additional 2 months in which to complete the required 20 cytotoxic drug administration quota. Staff who remain unable to complete the requirement will be referred to management.

Cytotoxic Administration Accreditation Program

The Cytotoxic Administration Accreditation Program is co-ordinated by the Nurse Educator Oncology Services at CHW and the CNE KCC at SCH. The program is a SCHN accreditation program.

The following information is collected and maintained by CHW: [1, 2, 3, 4]

- A list of personnel approved to administer cytotoxic drugs.
- Training records which identifies date, topics and presenters, attendees, evaluations and assessed competencies. These records are kept for a minimum of five (5) years.
- Individual employee records and health monitoring records. These records are kept for a minimum of thirty (30) years. Refer to Section 16 Spill Management and Section 17.2 Reporting and recording staff exposure.
- The responsibility for keeping and maintaining these records remains with the relevant Department Heads, Nurse Managers and Nursing Unit Managers, Clinical Nurse Educators and the Nurse Educator Oncology Services.

3 Checking Cytotoxic Drugs

The general principles of drug administration apply as per CHW Policy: Medication and Handling, however cytotoxic medications are ordered on the Cytotoxic Drug Administration Sheet (CDAS-OP2). **Any errors or omission of required information in the Cytotoxic Drug prescription will prohibit the medication from being administered**. Cytotoxic drug prescription errors must be entered into the incident management reporting system (IIMS) for monitoring and prevention purposes.

- Cytotoxic medications must be checked by two persons, one accredited RN; the second checker must be a Registered Nurse (Year 2 – 8th year thereafter) or medical officer. The drug must be administered by the accredited RN or medical officer. (1, 5, 18)
- Cytotoxic medications for BMT patients must be checked by two accredited RNs or one accredited RN and one medical officer.(19)
- Cytotoxic medications are to be checked 'out loud' with both checkers present beside the patient
- There should be a verbal 'time out' immediately prior to the administration of the cytotoxic medication where the medication is again checked 'out loud' against the medication order to verify: (4, 10)
  - Patient details
  - Drug for administration
  - Drug calculation and dose of drug
  - Volume and rate of administration
  - Expiry date of drug
- Intrathecal medications must be checked by an accredited oncology RN and the medical officer administering the drug. Refer to section 10 Intrathecal Medications for further information. (6, 5, 12)
- A copy of the patient's treatment protocol should be provided with the medication order to ensure the drug dose, order of administration and infusion time can be checked against the protocol.(5, 18)
- All sections of the CDAS-OP2 must be completed, legible and legal before a drug is administered.
- Prior to commencing Cytotoxic Therapy for the first time and prior to any subsequent course, it must be clearly documented by the medical staff in the patient's clinical record what drugs are planned to be administered as charted on CDAS-OP2. (1, 9, 18)
- Prior to each cycle of treatment the patient must have a weight and height measured and recorded in Powerchart for a BSA to be calculated and the drug dosage adjusted if necessary(1,5, 9, 18)
- If the prescribed dosage of cytotoxic drug differs by >10%, consulting medical officers should be contacted regarding changes to dosage.

4 Personal Protective Equipment (PPE)

One of the greatest risks of occupational exposure to hazardous or cytotoxic drugs is during administration of the drugs and handling of patient or related waste. Exposure may occur due to direct exposure with unchanged drug or active metabolites. Exposure may occur from solid or liquid aerosols, liquid spills or splashes and needle stick injuries. (18)

PPE to be worn for all cytotoxic drugs and cytotoxic waste or patient waste

The following PPE must be worn for the preparation and administration of all Cytotoxic drugs and when managing cytotoxic waste or cytotoxic patient waste.)

- A particulate respirator mask (P2/N95) ***not surgical mask***.

- A long sleeved gown of impermeable material with elasticised cuffs (e.g. Tyvek). Gowns should be used for a maximum of 1 shift.

  Note: If caring for infectious patients, infection control policy must be observed.

- Protective eyewear- can be goggles or protective eyewear with side shields.
- Cytotoxic safe gloves (Chemo-protectant gloves).

Refer to Appendix 2 for further details on PPE requirements when handling cytotoxic drugs and related waste.

Note: In addition to the above PPE, standard precautions also apply.

Additional equipment that should be utilised in the administration of intramuscular and subcutaneous cytotoxic drugs (in order to mitigate exposure risk in the event of a spill) includes:

- Disposable injection trays.
- Plastic backed absorbent sheets are to be placed under any injection or administration site.

5 Oral Cytotoxic Drugs

All cytotoxic drugs pose an exposure risk and it is recommended that staff utilise PPE when handling them.

When administering oral cytotoxic drugs, the drugs must be assessed as coated or uncoated to determine the level of PPE required. Refer to Appendix 6.

Cytotoxic gloves should be worn and 'non-touch technique' utilised for coated cytotoxic medications. However, full PPE should be worn and a 'non-touch' technique utilised for the administration of uncoated tablets. Examples of uncoated tablets which are administered at CHW include 6-mecaptopurine, methotrexate and thioguanine. (1, 4, 5, 10, 11, 13, 14, 18)

When handling and/or administering uncoated oral tablets, syrup or suspension cytotoxic medications **Full PPE MUST be worn**.

Where possible, oral cytotoxic tablets and capsules should be given whole:

Oral cytotoxic drugs MUST NEVER BE CRUSHED

The practice of **breaking or cutting oral cytotoxic drugs MUST BE AVOIDED**

Disperse tablets if an oral liquid is not available; this should be undertaken in the CYTOTOXIC DRUG SAFETY CABINET (CDSC).

If the cabinet is unavailable request dispersion by pharmacy

Calculated doses should be rounded to the nearest tablet strength where possible (whole or half). Half tablets must be prepared in Pharmacy.

The following guidelines are specific to the administration of oral cytotoxic drugs:[1,10, 11, 12, 13, 14]

- Never crush cytotoxic tablets.
- Do not split or dissolve cytotoxic tablets in clinical areas – this must always be done in the Pharmacy Department or in a Cytotoxic Drug Safety Cabinet (CDSC).
- Where doses are less than a whole tablet, the oncology pharmacist is to be contacted to organise an alternative dosage form e.g. liquid or half tablet.
- If a child vomits within 30 minutes following the administration of the oral cytotoxic drug, contact the medical officer to determine if another dose should be administered.
- Prior to preparing or administering of oral cytotoxic drugs, it should be determined whether it is coated or uncoated to determine the level of PPE required.
- Confirm if there are any food interactions that can occur with oral cytotoxic drugs. See: Appendix 3.
- Confirm that the cytotoxic drug is compatible with the nasogastric or gastrostomy tube and that the drug does not adhere to the internal surface of the tube resulting in suboptimal dosing. Refer to MIMS on line or ward pharmacist. https://www.mimsonline.com.au.acs.hcn.com.au/Search/DNC.aspx?ModuleName=Product

6 Subcutaneous / Intramuscular Injection

Cytotoxic drugs are not to be administered via an implanted subcutaneous injection device (e.g. Insuflon).

The injection administration site for both subcutaneous and intramuscular injections must be rotated for each dose.

Full PPE is required

7 Intravenous Infusions

At CHW, Closed System devices are used for the administration of cytotoxic drugs.

The following guidelines should be followed [18],

- Central venous access devices must be checked for patency and blood return to confirm placement prior to the administration of any cytotoxic medication.
- Only needles, syringes and other equipment with luer-lock fittings are to be used in the administration of cytotoxic drugs.
- A plastic backed absorbent pad is placed under the administration work area.
- A closed system administration set is to be utilised.
- Ensure the closed system administration set has a minimum of three purple CYTOTOXIC labels.
- All cytotoxic drugs that are administered via an IV infusion set are to be connected using an extension set with a T-Connector valve and male luer lock.

- Compatibility of medications must be checked prior to using the extension set with a T-Connector valve and male luer lock. Where medications are incompatible, separate infusion lines are to be used. IV tubing is primed with a compatible non-cytotoxic fluid (0.9% normal saline or 5% glucose) before attaching to the IV mini bag loaded with the cytotoxic drug. An aseptic technique is to be used when attaching the IV mini bag containing the cytotoxic drug.
- A piece of sterile gauze is wrapped around the entry port of the IV mini bagflask containing the cytotoxic drug to minimise exposure from droplet or spill.
- Do not attach the bag whilst hanging. Attach the bag only when it is flat on the preparation area.
- At CHW, a Cytotoxic Drug Safety Cabinet (CDSC) is available in Camperdown Ward if additional exposure mitigation is indicated.
- The IV line is flushed following completion of the infusion with 20mL of non-cytotoxic compatible fluid
- The empty IV mini bag remains connected with the administration set and is disposed of intact into the cytotoxic waste container.
- The administration of vesicants via peripheral, midline or long lines must be performed by an accredited medical officer. Prior to administering a vesicant the patency of the line is to be checked by observing for backflow. Vesicants are never to be given via an antecubital fossa line and the cannula must not be more than 24 hours old.

The cytotoxic drug Vincristine is always administered in a minibag, not via a syringe (1).

8 Inhaled or Nebulized Hazardous Drugs

Policy under development – link to be advised

9 Eye Drops Hazardous Drugs

- Wear Full PPE
- Hold a small tissue or gauze under the eye, just below the lower eyelashes, to protect the skin and absorb any excess solution
- Pull the lower eyelid down to form a 'pouch', instil drop into 'pouch'
- Release the eyelid gently and try to have patient close eye for 30 seconds
- Gently wipe the eye with moist clean tissue or gauze
- Dispose of tissues or gauze into a cytotoxic waste container.

10 Syringe Pump Infusions

Principles for administration via a syringe pump are as Section 7 above plus:

- There are additional components to add to the closed system administration sets for syringe pumps only:
  - A bifuse closed male luer connector attached to a blood taking port and spike for administration of a single medication.
- Place a non-return valve on the end of the IV line extension tubing and prime with a compatible non-toxic fluid.
- Using an aseptic technique attach the loaded syringe ensuring the closed male luer connector is firmly connected. On completion of the infusion, the syringe is removed at the non-return valve and discarded into the cytotoxic waste container. The residual cytotoxic drug is manually flushed through the non-return valve with 2-5mL of compatible non-cytotoxic fluid.

- Disconnect the tubing safely and discard the entire infusion line intact into the cytotoxic waste container.

11 Intrathecal Medications [1, 5, 6, 7, 8, 9, 12, 18]

11.1 Prescription of Intrathecal Medications

- Oncology Consultants, Oncology Fellows and Oncology Treatment Centre (OTC) Career Medical Officers (CMO's) are the only members of the medical staff authorised to prescribe intrathecal (IT) medications.
- Methotrexate, Cytarabine and Hydrocortisone are the only drugs prescribed for intrathecal administration. Carboxypeptidase–G2 can be given intrathecally in rare cases of intrathecal methotrexate overdose.
- **Folinic acid (Leucovorin) can be fatal if administered intrathecally.**
- Intrathecal medications and intravenous Vinca Alkaloids (Vincristine or Vinblastine) are NEVER to be prescribed for administration on the same day.
- All prescriptions for IT cytotoxic are written on cytotoxic administration charts (CDAS-OP2) and checked by the Oncology Pharmacist prior to dispensing.

11.2 Labelling and Packaging

- All intrathecal medications are clearly labelled with patient and drug details.
- All medications for intrathecal administration are drawn up in luer slip syringes.
- All intrathecal medications are clearly labelled with a prominent warning label on the syringe and outer bag to identify '**FOR INTRATHECAL USE ONLY'**.
- All intrathecal medications are packaged and dispensed separately from other cytotoxic medications.

11.3 Transport and Storage

- All intrathecal medications are stored in the Pharmacy Department in designated areas for intrathecal drugs only
- Intrathecal medications are only to be delivered by the Oncology Pharmacist to the designated clinical area or designated clinician who is performing the lumbar puncture.
- Outside of the pharmacy department, intrathecal medications are stored in the designated intrathecal medication fridge in OTC. This medication fridge is in a separate room in OTC thus separating intrathecal medications from other medications.
- Syringes of standard doses of intrathecal methotrexate and cytarabine are available in the dedicated medication fridge for use in emergency situations. The Oncology pharmacist should be notified each time this stock is accessed.
- Intrathecal medications are ONLY to be removed from intrathecal medication fridge by the clinician undertaking the procedure.
- There is no storage of intrathecal medications in any ward area.

11.4 Checking and Administration

- Intrathecal medications should only be administered within 'normal working hours' when a full range of specialist expertise, knowledge and support is readily accessible.
- Intrathecal medications may ONLY be administered by Oncology Consultants, Oncology Fellows and OTC CMO's. In some circumstances senior registrars will be trained and accredited to administer intrathecal medications but they will only be accredited to administer methotrexate.
- Intrathecal medications should be checked 'out loud' with a fully accredited Oncology Registered Nurse and the accredited Oncology medical officer beside the patient.
- There should be a verbal 'time out' immediately prior to the injection of the intrathecal medication where the medication is again checked 'out loud'.
- No other cytotoxic medications should be available in the treatment area during lumbar punctures and the administration of intrathecal therapy.
- The fully accredited Oncology RN (second checker) for intrathecal medication is to remain present until the intrathecal medication administration is complete.

INTRAVENOUS VINCA ALKALOIDS (vincristine or vinblastine) are **never** prescribed **on the same day** as the **administration of INTRATHECAL medications**.

Vinca alkaloids (vincristine or vinblastine) are clearly labelled with a prominent sticker which states '

FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES'

12 Patient and Family Education

Patient and family education must be completed prior to administration of cytotoxic or hazardous medications. [3, 7, 8, 15, 24] Appropriate verbal and written educational resources are provided to the patient and family and include:

- Cytotoxic or hazardous drug
- Concomitant medications and fluids
- Treatment protocol and cycle of treatment
- Potential side effects and symptom management
- Waste Management
- Adverse and long terms side effects

There are printed resources and information sheets available in Oncology Services.

On discharge, patients, parents and/or family members are provided with the Homecare Guidelines "Safe handling of Cytotoxic Drugs and Related Waste in the Home - CHW"

Pregnant or breastfeeding mothers or parents trying to conceive are to be educated on cytotoxic or hazardous patient waste and cytotoxic or hazardous drug waste management as per the Homecare policy.

13 Transporting Patients

Patients receiving cytotoxic medication should remain on the ward and where possible transportation of patients should be avoided while intravenous cytotoxic drug infusions are in progress. If a patient is transported whilst a cytotoxic drug infusion is in progress, a staff member trained in spill management and a spill kit must accompany the patient. [1, 9, 18]

14 Drug Labelling, Packaging, Transporting and Storage

Prepared cytotoxic drugs should be packaged and transported in leak-proof bags/containers and labelled appropriately with a cytotoxic warning label. Quantities of cytotoxic drugs stored in the wards should be restricted to those required for short term use and be stored in a designated area to facilitate quick and efficient containment of any spill. [3, 24]

In accordance with NSW WorkCover guide [1], "Cytotoxic Drugs and Related Waste Risk Management Guide 2008, suppliers and employers have specific responsibilities for labelling cytotoxic drugs that are hazardous substances. In NSW, the supplier must ensure hazardous substances are appropriately labelled.

An employer must ensure that a container that holds a hazardous substance used at work, including one supplied to or produced within the employer's place of work, is appropriately labelled and that the label is not removed, defaced or altered.

The label must*:

- clearly identify the hazardous substance
- provide basic health and safety information about the substance, including any relevant risk phrases and safety phrases.

15 Extravasation

Extravasation is defined as the inadvertent administration or leakage of a vesicant medication or solution into the surrounding tissue instead of into the intended vascular pathway (NSW Cancer Institute). If extravasated or infiltrated, some cytotoxic drugs cause irritation, ulceration and potential burns. Extravasation can occur peripherally (through an IVC) or centrally (through a CVAD).

A cytotoxic extravasation is best avoided; therefore the following should be implemented:

- Do not attempt to give an intravenous drug unless you are confident of accessing the vein.
- Never use the antecubital veins as extravasation in this area can be catastrophic.
- The administration of a vesicant via a peripheral or long line must be undertaken by a Medical Officer.
- Cannulae should not be >24 hours old.

Blood backflow must be confirmed for all CVADs prior to the administration of cytotoxic drugs. If blood flow is difficult or does not flow smoothly consult Medical Officer for treatment of potential blockage prior to administering cytotoxic drugs.

15.1 Immediate Management of a Cytotoxic Extravasation

In the event of a cytotoxic extravasation injury the initial management should occur as SLAP.

STOP the injection or intravenous infusion immediately.

LEAVE the central venous access device (CVAD) in place.

ASPIRATE any residual drug from the CVAD using a sterile syringe.

PLAN

- **CALL** **for assistance** - notify medical officer, pharmacist and or a senior nurse
- **COLLECT** the extravasation kit
- **ASSESS** the affected area for the presence of symptoms e.g. erythema, swelling, burning, pain and **TRACE** the affected area with a marker pen
- **PHOTOGRAPH** the area
- **REMOVE** the IV device or port needle. Do not apply pressure. If a central venous catheter is in situ this should remain in position - refer to a medical officer for further instructions
- **INITIATE** appropriate drug specific management measures as per protocol
- **ADMINISTER** pain relief if indicated
- **REFER** to a plastic surgeon if indicated

In the event of a mixed drug extravasation it is recommended to act in accordance with the drug that has the most harmful properties. Refer to Appendix 5

15.2 Cold/Warm Compresses

For some cytotoxic drugs a warm or cold compress is required for the treatment of the extravasation injury.

Cold Compresses

The topical application of cold compresses is recommended for the management of extravasations with some drugs classed as vesicants and irritants with vesicant properties with the exception of the vinca alkaloids (vincristine, vinblastine, vinorelbine) and oxaliplatin.

Intermittent cooling is thought to:

- causes vasoconstriction, localising the extravasation
- reduce local inflammation and pain
- may decrease cellular uptake of drug

Drug name	Class/clinical procedure	Warm or Cold compress	Antidote
Bortezomib	Irritant	**Cold** compress (initial for comfort measures)	Not indicated

Busulfan	Irritant	**Cold** compress (initial for comfort measures)	Not indicated
Carboplatin	Irritant	**Cold** compress (initial for comfort measures)	Not indicated
Cidofovir	Non- Irritant	**Cold** compress (initial for comfort measures)	Not indicated
Cisplatin <0.5mg/ml	Irritant	**Cold** compress (initial for comfort measures)	Not indicated
Cisplatin >0.5mg/ml	Vesicant (treated as an **Irritant with Vesicant properties**)	**Cold** compress apply 15 to 20 minutes FOUR times daily for 48 hours	No recommended antidote
Dactinomycin	**Vesicant**	**Cold** compress apply 15 to 20 minutes FOUR times daily for 48 hours	Dimethyl sulfoxide (DMSO) 99% solution
Daunorubicin	**Vesicant**	**Cold** compress apply 15 to 20 minutes FOUR times daily for 48 hours	Dimethyl sulfoxide (DMSO) 99% solution
Doxorubicin	**Vesicant**	**Cold** compress apply 15 to 20 minutes FOUR times daily for 48 hours	Dimethyl sulfoxide (DMSO) 99% solution
Doxorubicin Liposomal	**Irritant with Vesicant properties**	**Cold** compress apply 15 to 20 minutes FOUR times daily for 48 hours	No recommended antidote **DO NOT** use DMSO 99% solution
Etoposide	Irritant	**Cold** compress (initial for comfort measures)	Not indicated
Etoposide Phosphate	Irritant	**Cold** compress (initial for comfort measures)	Not indicated
Idarubicin	**Vesicant**	**Cold** compress apply 15 to 20 minutes FOUR times daily for 48 hours	Dimethyl sulfoxide (DMSO) 99% solution
Irinotecan	Irritant	**Cold** compress (initial for comfort measures)	Not indicated
Melphalan	**Irritant with Vesicant Properties**	**Cold** compress apply 15 to 20 minutes FOUR times daily for 48 hours	No recommended antidote
Mitozantrone	**Irritant with Vesicant Properties**	**Cold** compress apply 15 to 20 minutes FOUR times daily for 48 hours	No recommended antidote

Warm compresses

Topical application of warm compresses is recommended for use in vinca alkaloid (vinblastine, vincristine) extravasations because:

- the application of warmth may decrease local drug concentration, increasing the blood flow which results in enhanced resolution of pain and reabsorption of local swelling
- the application of cold has been shown in animal models to increase the risk of tissue damage

- the application of warmth has been reported to be synergistic with hyaluronidase

16 Waste Management

16.1 Cytotoxic Waste

Cytotoxic waste includes any residual cytotoxic drug following a patient's treatment, and the materials or equipment associated with the preparation, transport or administration of the drug therapy.

It includes:

- drugs in all forms, contaminated stock, and cytotoxic drugs returned from a patient
- contaminated waste from preparation processes
- sharps and syringes, ampoules and vials
- intravenous infusion sets and containers
- empty cytotoxic drug bottles
- cotton wool from bottles containing cytotoxic drugs
- used (old) HEPA or chemical filters and other disposable contaminated equipment
- contaminated personal protective equipment – e.g. gloves, disposable gowns, shoe covers, respirators
- swabs, cloths, mats and other materials used to clean cytotoxic contaminated equipment, or to contain spills
- contaminated body substance receptacles – e.g. disposable vomit bags
- dressings, bandages, nappies, incontinence aids and ostomy bags
- heavily soiled and contaminated bedding that is unable to be cleaned
- contaminated specimens from the laboratory
- cytotoxic pharmaceuticals past their recommended shelf life, unused or remaining

16.2 Cytotoxic Patient Waste

Most cytotoxic drugs are primarily eliminated from the patient by renal or faecal excretion however they may also be eliminated in a patient's blood and sweat. All body substances may be contaminated with the unchanged drug or with active drug metabolites.

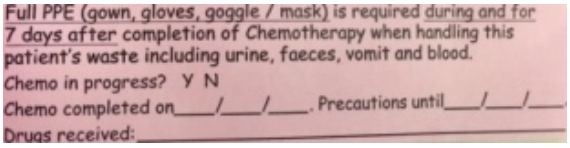
Exposure to cytotoxic waste may occur through:

- removing or inserting catheters
- handling vomitus, blood, excreta, or fluid drained from body cavities
- handling bedpans, urinals, emptying urinary catheter bags, colostomy or urostomy
- vomit bags, wet nappies and incontinence pads, and wet dressing materials

- handling bed linen or clothing soiled with a patient's waste, or potentially contaminated with the drug or active drug metabolites
- cleaning spills
- tracheal suctioning.

Because excretion routes and times vary, CHW observes a **7-day excretion protection period** or staff should refer to their local area's policy. **Full PPE is worn for a seven day period from the completion of cytotoxic treatment when handling patient bodily fluids**.

A **purple Excretion Alert Sticker** is available that can be placed at the front of the medical record to assist in identifying patients who are excreting cytotoxic waste.


Full PPE (gown, gloves, goggle / mask) is required during and for 7 days after completion of Chemotherapy when handling this patient's waste including urine, faeces, vomit and blood.
Chemo in progress? Y N
Chemo completed on___/___/___. Precautions until___/___/___
Drugs received:

On discharge, patients, parents and/or family members are provided with the Homecare Guideline. "Safe handling of Hazardous or Cytotoxic Drugs and Related Waste in the Home - CHW"

16.3 Safe work procedures

Safe work procedures should be adopted and emphasise the need to:

- avoid skin contact with a patient's bodily substances
- use closed systems where possible, to prevent generating aerosols
- Label all specimens sent to the laboratory as contaminated with cytotoxic, using a purple 'cytotoxic' sticker and placed in a cytotoxic specimen bag.

Full PPE is required to be worn when:

- Containing and cleaning-up spills using appropriate spill kit
- Disposing of waste, such as urine or faeces into a pan steriliser
- Disposing of contents of colostomy or urostomy
- Disposing of cytotoxic bags, incontinence aids, disposable nappies and heavily exuding dressing materials into bags and in a cytotoxic waste bin
- When managing cytotoxic contaminated equipment or body waste during drug excretion period wear personal protective equipment
- Attending to urinalysis or stool collection
- Collecting blood samples from patients regardless of peripheral or from central venous access device.
- Appliances such as colostomy, ileostomy or urostomy bags, urinary catheters or incontinence aids, disposable nappies and heavily exuding dressing materials are double bagged prior to weighing and placed into the appropriate cytotoxic/hazardous

waste bin. Nappies should be placed in a cytotoxic zip locked waste bag and transferred to the dirty utility for disposal into the cytotoxic waste bin.

Testing urine from a bottle:

NOTE: Urine is NOT decanted into a jug for measurement due to the risk of aerosol contamination.

Staff are required to wear full Cytotoxic PPE. The urine is to be collected in a clear urine bottle so staff can both measure and visualise urine during procedure. . If the testing by urinalysis, open the sluice machine, using the sluice machine for barrier protection throughout the procedure. Staff are to hold the urine bottle inside the sluice machine and slightly tip the bottle so a minimal amount of urine is poured on the dipstick. Staff are to place the cytotoxic dipstick onto a plastic absorbent sheet placed on the dedicated bench. Once urinalysis is obtained the cytotoxic dipstick and plastic absorbent sheet are to be disposed of in the designated cytotoxic waste bin. The bench is to be then wiped down with 70% alcohol wipes. If there is any spill of urine onto the bench or surrounding area, staff are to use the Cytotoxic spill kits as per manufacturer instructions. Following completion of the following steps staff are to remove Cytotoxic PPE and dispose of in Cytotoxic waste bin.

Urine required to be measured should be:

- weighed
- measured using a "witches hat" (disposable toilet and pan liners)

16.4 Toilets

Patients using the toilets should be instructed to be seated when urinating to reduce the risk of splashes and aerosol contamination. Patients should be instructed to close the toilet lid and to use a full flush. When a lid is not present, consider covering the open toilet with a plastic-backed liner prior to flushing to prevent splashing

All equipment should be sterilised (using minimum of "disinfectant and detergent" setting on the sluice steriliser) and any protective equipment discarded.

16.5 Contaminated Linen

Refer to the policy: Linen Management – CHW for details.

Bed mattresses contaminated with patient excreta should be cleaned with Sodium Hypochlorite (bleach) such as Domestos.

17 Spill Management

A cytotoxic spill requires immediate management and must be effectively controlled so as to avoid unnecessary contamination of the environment. Cytotoxic spills include any spill of drug whether it is powder or liquid and spills of patient waste such as urine/vomit, blood and faeces.

The following applies:

- All areas where cytotoxic drugs are prepared, stored or administered must have a Cytotoxic Drug Spill Kit and Sodium Hypochlorite available.

- All staff working in these areas should be trained in spill management.
- Cytotoxic Spill kits are available from stores – order number 503189
- A Spill kit will effectively contain a spill up to 1,000mL.
- **In the event of a spill**, priority should be given to removing all patients and non-essential staff from the area to minimise exposure risk. When managing any drug which has been spilt on personnel, the first priority is the removal of the drug from the person. This may include contaminated clothing. Flushing the contaminated areas with copious amounts of water for 15-20 minutes is first line management. In these instances someone other than the affected operator should clean up the spill.

1. Notify the Pharmacy Department of the incident, naming the cytotoxic agents involved and the extent of the spill, they may be required to supply an additional dose.
2. Notify the Consultant/Fellow of the spill; for assessment of the child's medication dose requirements.
3. Complete an IIMS notification.
4. The NM/NUM is responsible for keeping a record of spills (from IIMS) for each exposed staff member. Upon cessation of employment, record/s are forwarded to WHS & IM Department for storage in Staff Health Personnel file for 30 years.
5. It is a legal requirement that all spills involving Cyclophosphamide must be reported to WorkCover NSW. WHS & IM Department are responsible for the provision of reports to WorkCover.

Equipment

- Cytotoxic Spill Kit
- Sodium Hypochlorite (Domestos brand)

For more information refer to NSW WorkCover guide, "Cytotoxic Drugs and Related Waste Risk Management Guide 2008":

Cyclophosphamide exposure [1, 2, 17, 9]

- Refer to section17.3.

18 Personnel Management [1, 2]

Little is known about the long term effects of occupational exposure to low level doses of cytotoxic or hazardous drugs. Currently, there is no process of biological monitoring or health assessment which is sufficiently specific to adequately predict the effects of exposure to cytotoxic or hazardous drugs.

Therefore the primary focus of safety during the preparation and handling of cytotoxic or hazardous drugs must be on the control of the working environment and safe working practices. Current literature suggests that staff involved in the handling and administration of cytotoxic or hazardous drugs should have medical assessments performed for epidemiological studies.

18.1 Health Surveillance

Medical assessments are performed at the commencement of employment (baseline assessment) for all staff involved in the preparation and administration of cytotoxic drugs. Refer to the Cytotoxic Drug: Health Surveillance Program (Appendix 4) or contact the WHS & IM Department for further information.

Staff who may have been **exposed to cyclophosphamide** during the course of their employment will, on termination, receive the following cyclophosphamide exit statement: http://chw.schn.health.nsw.gov.au/o/forms/ohs/staff_health/letter_to_staff_-_cyclophosphamide.pdf

Pregnant staff, or those anticipating pregnancy or those breastfeeding, that are involved in the preparation or administration of cytotoxic drugs and handling of related waste are to be informed of the occupational hazards associated with exposure during cytotoxic drug preparation and administration and handling of related waste. Pregnant staff, or those anticipating pregnancy or those breastfeeding may **elect not to administer chemotherapy** and alternative duties may be offered.

- Staff should discuss the options with the NM/NUM and complete the following form: http://chw.schn.health.nsw.gov.au/o/forms/ohs/staff_health/family_planning_document.pdf

18.2 Reporting and Recording Staff Exposure

Daily exposure records "Cytotoxic Exposure Sheets" (see Appendix 1) are to be completed by all employees involved in the preparation and administration of cytotoxic drugs [3] and are stored in the NM/NUM office until the staff member's employment ceases. The exposure records will be stored electronically for long term confidential storage (30 years). Contact the WHS & IM Department for further information.

Employees should **report any side effects or exposure** related to the handling of cytotoxic or hazardous drugs or contaminated waste to the NUM and WHS & IM Department.

18.3 Cyclophosphamide Exposure

- In the event of cyclophosphamide exposure (which could be in the form of a spill or needlestick) the staff member must arrange to have blood and urine screening tests conducted by Admitting Officer in Emergency Department: contact extension 52448, 52450 or 52454.
- Samples must be collected between 3-12 hours following exposure. The following form is to be used: http://chw.schn.health.nsw.gov.au/o/forms/ohs/staff_health/cyclophosphamide_exposure_screening.pdf
- The exposure incident must be documented in IIMS.
- All cyclophosphamide exposure incidents must be notified to the WHS&IM Department.
    - The WHS&IM Department will report these exposure incidents to WorkCover NSW

19 Related Documents

- CHW Safe Handling of Cytotoxic Drugs & Related Waste in the Home – CHW Homecare guidelines guideline number O/C/06:8130-01:01:

http://chw.schn.health.nsw.gov.au/o/documents/policies/homecare/2006-8130.pdf (accessed 5/11/2014)

- CHW Safe handling of Immunosuppressive and Cytotoxic Drugs for Children who have undergone Renal or Liver Transplantation Homecare guideline number O/C/06:8122-01:01 http://chw.schn.health.nsw.gov.au/o/documents/policies/homecare/2006-8122.pdf (accessed 5/11/2014)
- CHW Policy "High Risk Medications at CHW" (policy number 1/C/10:8020): http://chw.schn.health.nsw.gov.au/o/documents/policies/policies/2010-8020.pdf (accessed 5/11/2014)

20 References

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11. Cancer Institute NSW: Resource Document- Safe Handling and Waste Management of Hazardous Drugs https://www.eviq.org.au/Home.aspx (accessed June 2012)
12. Cancer Institute NSW: Resource Document- Safe Administration of Antineoplastic drugs https://www.eviq.org.au/Home.aspx (accessed June 2012)
13. Cancer Institute NSW: Table of Uncoated and Coated Oral Cytotoxic Tablets https://www.eviq.org.au/Home.aspx (accessed June 2012)
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Appendix 1: CYTOTOXIC Exposure Sheet

Name: _____ Employee No.: _____ Department: _____

Date	Name of Drug	Dosage	Time in contact	Route of admin.	Activity	PPE used	Sign.
	Checked By NUM CNE (circle)			**Signature**			

Legend:
F-PPE = Full Personal Protective Equipment (Gown, Gloves, Goggles and Mask)
P-PPE = Anything less than full PPE. If less than full PPE is worn, staff members are required to specify which items of PPE were worn.

This form is to be reviewed and filed annually by the Manager. Completed forms are to be scanned and filed and stored electronically by WHS.

Appendix 2: Personal Protective Equipment Requirements

DRUG NAME & CLASSIFICATION	HAZARD RISK	PPE REQUIREMENTS
CHEMOTHERAPY		
Amasacrine	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Asparaginase Erwinia	Teratogenic	Gloves, gown, mask, goggles
Asparaginase Leunase	Teratogenic	Gloves, gown, mask, goggles
Belomycin	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Busulphan IV	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Carboplatin	Mutagenic, teratogenic	Gloves, gown, mask, goggles
Carmustine (film coated capsules)	Mutagenic, carcinogenic, teratogenic	Gloves only
Cisplatin	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Cladribine	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Cyclophosphamide	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Cytarabine	Mutagenic, teratogenic	Gloves, gown, mask, goggles
Cytarabine IT	Mutagenic, teratogenic	Gloves, gown, mask, goggles
Dacarbazine	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Dactinomycin	Carcinogenic, mutagenic	Gloves, gown, mask, goggles
Daunorubicin	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Daunorubicin liposomal	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Doxorubicin	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Epirubicin	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Etoposide Phosphate	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Etoposide	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Fludarabine	Carcinogenic, teratogenic	Gloves, gown, mask, goggles
Hydroxyurea	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Idarubicin	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Ifosfamide	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Irinotecan	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Lomustine oral (coated tablet)	Mutagenic, carcinogenic, teratogenic	Gloves only

DRUG NAME & CLASSIFICATION	HAZARD RISK	PPE REQUIREMENTS
Melphalan IV	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Mecaptopurine oral (uncoated tablet)	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Methotrexate IV	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Methotrexate IT	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Methotrexate oral (uncoated tablet)	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Mitotane oral	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Mitozantrone	Mutagenic, carcinogenic	Gloves, gown, mask, goggles
Procarbazine (film coated capsules)	Carcinogenic	Gloves only
Temozolamide oral (coated tablet)	Teratogenic	Gloves only
Tenioposide	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Thioguanine oral (uncoated tablet)	Mutagenic, carcinogenic, teratogenic	Gloves, gowns, mask goggles
Thiotepa	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Topetecan	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Vinblastine	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Vincristine	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Vindesine	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Vinorelabine	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
IMMUNOSUPPRESSANT		
Azathioprine IV	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Azathioprine oral tablets (coated tablet)	Mutagenic, carcinogenic, teratogenic	Gloves only
Azathioprine oral suspension	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Cyclosporin IV	Carcinogenic	Gloves, gown, mask, goggles
Cyclosporin oral (film coated capsule)	Carcinogenic	Gloves only
Cyclosporin oral liquid	Carcinogenic	Gloves, gown, mask, goggles
Mycophenolate mofetil IV	Teratogenic	Gloves, gown, mask, goggles
Mycophenolate mofetil (coated oral tablet/capsule)	Teratogenic	Gloves only
Mycophenolate mofetil oral suspension	Teratogenic	Gloves, gown, mask, goggles
Tacrolimus IV	Carcinogenic, teratogenic	Gloves, gown, mask, goggles
Tacrolimus oral (film coated capsules)	Carcinogenic, teratogenic	Gloves only

DRUG NAME & CLASSIFICATION	HAZARD RISK	PPE REQUIREMENTS
Tacrolimus oral suspension	Carcinogenic, teratogenic	Gloves, gown, mask, goggles
ANTI VIRALS		
Cidofovir	Carcinogenic, teratogenic	Gloves, gown, mask, goggles
Ganciclovir IV	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Valganciclovir oral (film coated tablets)	Mutagenic, carcinogenic, teratogenic	Gloves only
Ganciclovir oral suspension (valganciclovir)	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
Ribavirin	Teratogenic	Gloves, overalls, CDSC
MISCELLANEOUS		
All-trans retinoic acid oral (tretinoin)	Carcinogenic, teratogenic	Gloves, gown, mask, goggles
Cis-trans retinoic acid oral (isotretinoin)	Mutagenic, carcinogenic, teratogenic	Gloves, gown, mask, goggles
MONOCLONAL ANTIBODIES/IMMUNOMODULATORS		
Basiliximab	*No studies have been conducted	Gloves, gown, mask, goggles
Daclizumab	Teratogenic	Gloves, gown, mask, goggles
Bevacizumab	Teratogenic	Gloves, gown, mask, goggles
Infliximab	Carcinogenic	Gloves, gown, mask, goggles
Rituximab	Carcinogenic	Gloves, gown, mask, goggles
Gemtuzumab (Myelotarg)	Teratogenic	Gloves, gown, mask, goggles
Ch 14:18	*Trial drug- no studies have been conducted	Gloves, gown, mask, goggles

***NB** As no studies have been conducted, to ensure the long term safety of staff, CHW recommends that full PPE be worn when administering these drugs.

Appendix 3: Food Interactions

Medication	With or Without Food	Other
Azathioprine	With or immediately after food	
Capecitabine	With food or within 30 minutes after the end of a meal.	
Cyclosporin	With or without food	**No grapefruit juice.** Apple or Orange juice satisfactory for dilution
Dabrafenib	On an empty stomach	At least 1 hour before food **OR** 2 hours after food
Dasatinib	With or without food	**DO NOT** take antacids within 2 hours of this medication as they interfere with absorption (absorption is pH dependent)
Imatinib	With food	**No grapefruit juice**
Isotretinoin	With food or soon after food	Avoid excessive skin exposure to sunlight. Limit intake of vitamin A. Concomitant treatment with vitamin A must be avoided
Lomustine	On an empty stomach – at least one hour before food or two hours after food.	Swallow whole
6-Mecaptopurine	On an empty stomach – 30mins before food/milk **OR** 2 hours after food. Note: If on Study 9 - On an empty stomach – 30mins before food/milk **OR** 1 hour after food	Do not take milk or dairy products within 2 hours of taking this medication
Methotrexate	With or without food	Avoid excessive skin exposure to sunlight.
Mycophenolate mofetil	With or without food	**DO NOT** take antacids within 2 hours of this medication as they interfere with absorption
Procarbazine	With or without food	Avoid excessive skin exposure to sunlight Important: Specific Food restriction before?, during and for **2 weeks** after finishing course including aged cheeses, vegemite, overripe fruits, bananas, large amounts of chocolate, tea and cola
Sorafenib	On an empty stomach	without food or with low or moderately fat meal Avoid high fat meal
Sunitinib	With or without food	**No grapefruit juice**
Tacrolimus	On an empty stomach -1hour before food/milk **OR** 2-3 hours after food/milk.	**No grapefruit juice** Avoid excessive skin exposure to sunlight
Temozolomide	On an empty stomach- 1 hour before food/milk	

Medication	With or Without Food	Other
6-Thioguanine	On an empty stomach – 30mins before food/milk **OR** 1-2 hours after food	Do not take milk or dairy products within 2 hours of taking this medication
Trametinib	On an empty stomach	At least 1 hour before food **OR** 2 hours after food
Valganciclovir	With food	
Vorinostat	With food or immediately after food	

Appendix 4: Health Surveillance

Introduction

This program has been developed in accordance with the Cytotoxic Drugs and Related Waste Risk Management Guide – WorkCover NSW 2008 (www.workcover.nsw.gov.au) and the Work Health Safety Legislation (www.workcover.nsw.gov.au) and Associated Codes of Practice 2011 (www.legislation.act.gov.au).

Health Surveillance

Workplace

Health Surveillance will be voluntarily offered to staff directly handling or administering cytotoxic drugs within SCHN in the following areas:

- Camperdown
- Variety
- Oncology CNC
- OTC
- RTC
- Pharmacy
- Pathology
- Animal Laboratory

The procedure for voluntary health surveillance will include:

- Work history to be undertaken using a questionnaire.
- Record of use of personal protective equipment
- Full blood count
- Biochemical analysis
- Follow up with Occupational Physician or doctor of choice as required.

Additional tests may also be undertaken as deemed necessary by the Occupational/treating physician.

Reporting and Recording Staff Exposure

This procedure acknowledges the daily exposure records 'Chemotherapy Exposure Sheets' that are to be completed by all employees involved in the preparation and administration of cytotoxic drugs.

These exposure records will be stored for long-term confidential storage (30 years).

Employees should report any side-effects or contamination related to the handling of cytotoxic drugs or contaminated waste to the NUM and the WHS & IM Department.

1. **Baseline Health Surveillance**:

   i. Periodic Health Surveillance will form part of the Cytotoxic Drug administration and handling procedures.

   ii. The minimisation of potential exposures to Cytotoxic drugs requires that all staff ensure that they adhere to the safe systems of work set out in the Cytotoxic Drug Administration and Handling Procedures.

   iii. All staff will be given the opportunity to participate in baseline health surveillance.

   iv. This screening will not be mandatory and staff will have the opportunity to elect not to participate in the health surveillance program.

   v. Information fact sheets will be provided by each department for all staff who prepare or administer cytotoxic drugs to advise them of the potential health risks associated with cytotoxic exposure and the tests to be undertaken.

   vi. Participating staff will be offered an occupational exposure questionnaire blood samples for assessment.

   vii. The blood screening tests undertaken as a part of this periodic surveillance will include;

   - FBC
   - Electrolytes
   - Liver Function
   - B12
   - Folate
   - Feratin
   - Thyroid Function

   viii. All screening will be undertaken internally via the WHS & IM Department with all screening undertaken by the Pathology Unit within the hospital for testing. All samples will be de-identified to ensure staff confidentiality.

   ix. Test results will be forwarded to the occupational physicians overseeing the program for evaluation and follow-up.

   x. Any Staff counselling associated with any periodic health surveillance or test results will be provided by Quality Occupational Health at Merrylands, or staff may seek counselling and follow-up from a doctor of their choice.

   xi. Any follow up for non-work related conditions as determined by Quality Occupational Health will be directed to the staff member for follow up with a doctor of their choice. The cost of all treatment referrals or follow up for all non-work related conditions will be the staff member's responsibility.

   xii. Staff will be regularly provided with updates and in-service training to reinforce the use of safe work practices.

   xiii. Accurate records of staff exposures and all test results will be maintained by the hospital for a period of up to 30 years.

2. Baseline Data

A questionnaire will be provided for new employees to ascertain their occupational history and past exposure with administration of cytotoxic drugs before commencement of work with Cytotoxic / hazardous Drugs. This questionnaire will include a thorough medical history.

New employees will be requested to provide specific baseline data at the time of their job application.

Baseline blood tests are to be provided by the new employee prior to the staff commencing administration of cytotoxic drugs. This cost will be incurred by the employee upon commencement.

The Baseline data required will be;

- FBC
- Electrolytes
- Liver Function
- B12
- Folate
- Thyroid Function
- Feratin

1. Termination

Baseline blood tests and a letter detailing the direct involvement in the administration and use of Cytotoxic drugs will be offered to staff at the time of termination where they have been directly administering or handling cytotoxic / hazardous drugs. Baseline blood results to be made available will include;

- FBC
- Electrolytes
- Liver Function
- B12
- Folate
- Thyroid Function
- Feratin

Biological Monitoring

Biological monitoring is not a requirement under the legislation.

SCHN will not undertake biological monitoring of exposed staff. Should annual surface test results reveal potential exposures despite the safe systems of administration in place then consideration may be given to implementing this type of screening in the future.

NB: Should there be a spill or known exposure to cytotoxic drugs then biological screening will be provided for any staff affected as per the above procedure See Section 17.3.

Planning Parenthood, Pregnancy and Lactation

Employees who are pregnant, breastfeeding or planning parenthood and are involved in the preparation or administration of cytotoxic drugs and the handling of cytotoxic contaminated waste will be informed of the reproductive risks and possible effects on foetal development.

This information is available in the above procedure and on 'Chemalert' on the Intranet.

Personnel required to perform these duties may elect not to do so. In such cases appropriate and suitable alternative duties must be provided."

Summary

The Health Surveillance Program – Sydney Children's Hospitals Network (SCHN)

Key Guidelines	Implementation at SCHN
An occupational physician has been appointed to oversee the program.	• Quality Occupational Health Services
Perspective employees will be provided with information about the risks of working with cytotoxic drugs prior to their use of the drugs.	• Fact Sheets • Training and In-service Training on safe work practices • Quality Occupational Health Services if required.
Baseline health monitoring is conducted by the encumbent's appointed medical practitioner before an employee commences work with cytotoxic drugs.	• Baseline blood screening at the cost of new staff member is required prior to commencement • Fact Sheets regarding potential exposure is to be provided by SCHN NUM's.
Health Surveillance will be conducted during the period that the employee works with any cytotoxic drugs.	• Conduct health screening as soon as possible in the following situations: a. After a reportable spill or sharps injury occurs. b. If an employee advises she is pregnant, considering pregnancy or is breastfeeding. • The review should take account of the previous medical examination and include: a. Health advice and counselling. b. Report. Follow up the review on one month by Quality Occupational Health Services as required.
Health monitoring is offered on termination of employment where cytotoxic drugs are used.	• Health Surveillance, blood tests and counselling as required.
Consultation	• Cytotoxic Handling Committee meetings quarterly. • Fact Sheets • Regular In-service Training on safe work practices • Quality Occupational Health Services as required.
System Auditing	• Regular in-house auditing of the cytotoxic administration handling and safe systems of work will be undertaken. • Regular surface testing will be conducted in areas where the drugs are prepared or administered.

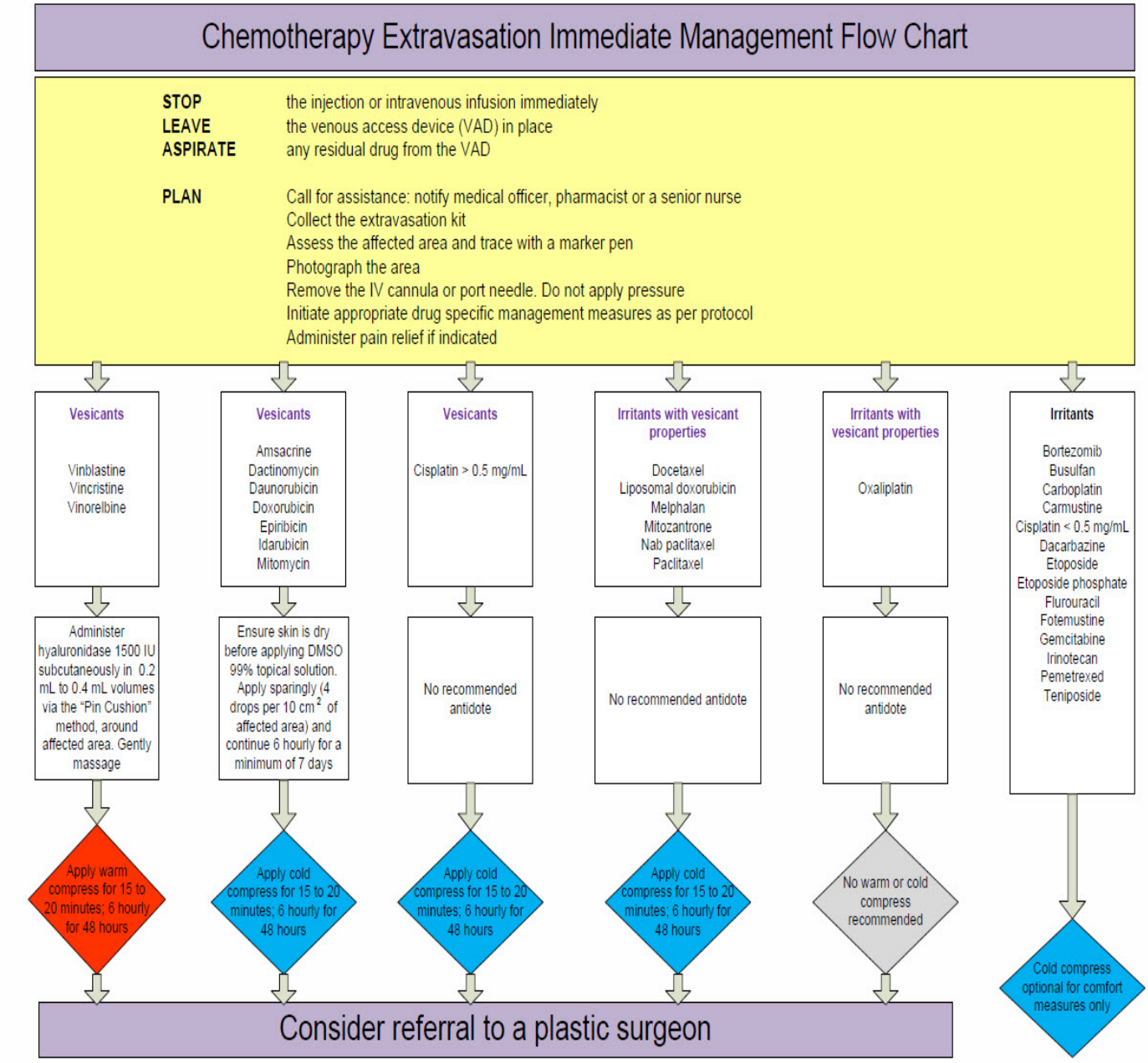
The Service Provider

Quality Occupational Health at Merrylands are authorised WorkCover Occupational Physicians and Registrars who have been selected to oversee the program.

The management of cytotoxic drug health surveillance will be overseen by QOH's Workcover approved doctors.

- Liaison with QOH regarding the drugs handled and the potential exposures based on our current practices has been undertaken as a part of this program development.

Appendix 5: Chemotherapy Extravasation



Appendix 6: Cytotoxic Administration of a Cytotoxic Tablet

***NOTE: Ensure drug/food interactions prior to preparation**

Refer to Australian Drug information found at https://www.mimsonline.com.au.acs.hcn.com.au/Search/Search.aspx

Or speak with your local pharmacists or drug interaction information

Uncoated tablets

Procedure

1. Identify an appropriate designated safe area to prepare cytotoxic drug.
2. Clean all work surfaces with a large 2 % chlorhexidine gluconate in 70% alcohol swab.
3. Prepare equipment.
4. Place a plastic backed absorbent pad/sheet under the work administration area in appropriate designated work area utilising a laminar flow if available
5. Perform hand hygiene.
6. Don full PPE
7. Transfer tablets/capsules from their original container, into the designated medication cup or syringe and place a red cap to seal the syringe
8. At the bedside perform the “time out” checking of the patient details with second RN (see section 4)
9. Instruct the patient to take the tablet/capsule directly from the medication cup, without handling. If tablet requires dilution parents are given the required fluid to dissolve. Ensuring they are wearing appropriate PPE and an appropriate cap is placed at the end of the syringe. Pharmacy can be contacted for alternate form. Before deciding on route for administration please refer to the Australian Drug Information (MIMS) via the intranet or speak to your local pharmacist or administration interactions, i.e. Not to be administered via nasogastric tube
10. If the patient has had any handling of the drug make sure they wash their hands
11. Place contaminated medication cup or syringe into a cytotoxic zip lock bag and dispose of as cytotoxic waste
12. Remove PPE dispose of as cytotoxic waste.
13. Perform hand hygiene.
14. If a child vomits within 30 minutes of administration of the oral cytotoxic the medical officer should be notified to determine if another dose should be administered. If dose is to be repeated pharmacy will need to be notified to ensure patient receives entire course of the drug.

Coated tablets

Procedure

1. Identify an appropriate designated safe area to prepare cytotoxic drug.
2. Clean all work surfaces with a large 2 % chlorhexidine gluconate in 70% alcohol swab.
3. Prepare equipment.
4. Place a plastic backed absorbent pad/sheet under the work administration area in appropriate designated work area utilising a laminar flow if available
5. Perform hand hygiene.
6. Don Cytotoxic safe gloves
7. Transfer tablets/capsules from their original container, into the designated medication cup or syringe and place a red cap to seal the syringe
8. At the bedside check the patient details with second RN against the medication order.
9. Instruct the patient to take the tablet/capsule directly from the medication cup, without handling. If tablet requires dilution parents are given the required fluid to dissolve. Ensuring they are wearing appropriate PPE and an appropriate cap is placed at the end of the syringe. Pharmacy can be contacted for alternate form. Before deciding on route for administration please refer to the Australian Drug Information (MIMS) via the intranet or speak to your local pharmacist or administration interactions, i.e Not to be administered via nasogastric tube
10. If the patient has had any handling of the drug make sure they wash their hands
11. Place contaminated medication cup or syringe into a cytotoxic zip lock bag and dispose of as cytotoxic waste
12. Remove PPE dispose of as cytotoxic waste.
13. Perform hand hygiene.
14. If a child vomits within 30 minutes of administration of the oral cytotoxic the medical officer should be notified to determine if another dose should be administered. If dose is to be repeated pharmacy will need to be notified to ensure patient receives entire course of the drug.

Liquid suspension

Procedure

1. Identify an appropriate designated safe area to prepare cytotoxic drug.
2. Clean all work surfaces with a large 2 % chlorhexidine gluconate in 70% alcohol swab.
3. Prepare equipment.
4. Place a plastic backed absorbent pad/sheet under the work administration area in appropriate designated work area utilising a laminar flow if available
5. Perform hand hygiene.
6. Don full PPE
7. Transfer liquid suspension from their original container, into the designated medication cup and or syringe, and draw up prescribed amount and place a red cap to seal the syringe
8. At the bedside check the patient details with second RN against medication order
9. Instruct the patient to take the liquid suspension directly from the medication cup, without handling. Before deciding on route for administration please read the medication administration leaflet to ensure there are no specific requirements for administration. i.e. Not to be administered via nasogastric tube
10. If the patient has had any handling of the drug make sure they wash their hands
11. Place contaminated medication cup or syringe into a cytotoxic zip lock bag and dispose of as cytotoxic waste
12. Remove PPE dispose of as cytotoxic waste.
13. Perform hand hygiene.
14. If a child vomits within 30 minutes of administration of the oral cytotoxic the medical officer should be notified to determine if another dose should be administered. If dose is to be repeated pharmacy will need to be notified to ensure patient receives entire course of the drug.