Cambridgeshire and Peterborough NHS Foundation Trust

CYTOTOXIC DRUG GUIDELINES

Version 1.1

Document control sheet - Cytotoxic Drug Guidelines

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Version	Date	Author	Comments
1.0	March 2022	Sarah Woodley	Converted to a guideline. Removed information on risks management, including pregnancy, training, exposure, COSHH and RIDDOR which is available on the HSE website, and provided a link to this site. Policy statements added to the Medicines Policy. Removed the requirement to obtain a written copy of the treatment plan before prescribing in inpatient settings
1.1	June 2023	Sarah Woodley	Removed adults from title and extended scope to include children. Updated throughout to include Children's Community Specialist Nursing Service and administration of intravenous cytarabine in accordance with approved SOP.

Policy Circulation Information

Notification of policy release:	All staff who handle cytotoxic medicines. To be placed on the Trust internet documents that guide practice website.

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1. Introduction

Cytotoxic drugs are used widely in healthcare settings as well as in the community in the treatment of cancers as well as other diseases.

The *Health and Safety Executive Safe handling of cytotoxic drugs in the workplace* (https://www.hse.gov.uk/healthservices/safe-use-cytotoxic-drugs.htm) provides information to employers and employees on the occupational hazards associated with cytotoxic drugs and the precautions to take when handling them.

This guideline should be read in conjunction with the following:

- Medicines Policy
- MMSOP052 Oral Methotrexate in Inpatient Settings
- Infection Prevention and Control Policy
- Incident Reporting and Management Policy
- Waste Management Guidelines
- Control of Substances Hazardous to Health (COSHH) Policy
- The Royal Marsden Hospital Manual of Clinical Nursing Procedures, current edition
- Great Ormond Street Manual of Children's Nursing Practices.

2. Purpose

- Provide a safe and consistent approach to prescribing, administration, storage and disposal of cytotoxic drugs and contaminated patient waste.
- To minimise potential risks to both patients and healthcare staff.

3. Scope and Target Group

- In accordance with the Medicines Policy, Trust staff must **not** prescribe or administer intrathecal, intravesical, intrapleural, intraperitoneal, intra-arterial and intravenous cytotoxic drugs,

  The only exception is for intravenous cytarabine which may be administered within the Childrens Community Specialist Nursing Service by specialist RNs who have the appropriate up to date IV cytotoxic training and competencies. The administration is strictly in accordance with the approved standard operating procedure and the prescription and supply are issued by the acute hospital specialist team.
- Staff must not prepare or reconstitute parenteral cytotoxic drugs; only pre-filled syringes may be administered.
- Intravenous infusions commenced elsewhere may be taken down by Trust staff in accordance with the directions of the service responsible for the treatment (see 5.7).
- This guideline applies to healthcare staff in all Trust settings who are involved in prescribing, administering, transporting, storing and disposing of cytotoxic drugs, including patient's homes, inpatient settings and other clinical areas. However, it does **not** apply to hormonal or anti-hormonal therapies used to treat cancer.
- It also applies to staff who may be exposed to excreted cytotoxic products from patients who have received cytotoxic drugs within the last seven days. (Excreta from treated patients may contain unchanged cytotoxic drugs or active metabolites)

4. Duties and Responsibilities

The following specific duties and responsibilities apply:

4.1. Service / Clinical Managers

- Service / clinical managers must ensure that:
    - Local arrangements are in place to comply with medicines management requirements and Health and Safety legislation such as the Control of Substances Hazardous to Health (COSHH) Regulations 2002.
    - Local risk management arrangements are in place that comply with risk management policies.
    - They are aware of the guidance on pregnancy and breast feeding and that risk assessments are carried out as appropriate.
    - The appropriate equipment and personal protective equipment is readily accessible to their staff (e.g. cytotoxic spillage kit, protective glasses, purple lidded bins etc), see 5.1.1

4.2. Registered Nurse, Nursing Associate, other Health Care Staff

- It is the responsibility of each staff member to establish whether the medicine they are being asked to administer is cytotoxic.
- Ensure that:
    - They are aware of the guidance on pregnancy and breast feeding see New and expectant mothers at work: Your health and safety - HSE
    - They have received the necessary training in relation to the medicines used.
    - They follow the safety requirements for each cytotoxic medicine in accordance with the COSHH safety guidance and manufacturer's information.
    - The appropriate equipment and personal protective equipment is available and used appropriately (e.g. cytotoxic spillage kit, protective glasses, purple lidded bins etc.) see 5.1.1
    - Medication is administered in accordance with an appropriately written prescription.
    - The patient is monitored appropriately during treatment and appropriate action is taken if a problem arises.
    - They are aware of the risks and precautions to take when handling cytotoxic drugs and dealing with a spillage.
    - Other healthcare staff caring for patients who are receiving or have recently received cytotoxics (within 7 days) are aware of the precautions to take for handling and disposal of waste and bodily fluids which may be contaminated with cytotoxic drugs.
    - Any issues, problems or concerns are escalated to the line manager.

4.3. Prescriber

- Prescribers are not permitted to prescribe intrathecal, intravesical, intrapleural, intra-arterial and intravenous cytotoxics within the Trust.
- Cytotoxic drugs for cancer chemotherapy and non-malignant conditions must only be initiated by trained and competent specialists.
- Prescribers within the Trust must only prescribe cytotoxic drugs in accordance with the guidance in this policy, see 5.5.

4.4. All Healthcare staff

- All healthcare staff caring for patients who are receiving or have recently received cytotoxics (within 7 days) must be aware of the precautions to take for handling and disposal of waste and bodily fluids which may be contaminated with cytotoxic drugs.

5. Guidance

5.1. Risk Management and Safety

- A risk assessment should be undertaken to identify the risks to patients and staff (including pregnant workers) see the Health and Safety Executive Safe handling of cytotoxic drugs in the workplace (https://www.hse.gov.uk/healthservices/safe-use-cytotoxic-drugs.htm).
  This includes what you need to do regarding COSHH and Control of exposure, and reporting incidents under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR).
- All cytotoxic drugs are classified under the Control of Substances Hazardous to Health (CoSHH) Regulations 2002. This places specific duties on employers and employees with regards to information, training, safe handling and disposal of substances hazardous to health. Anyone handling cytotoxic drugs or involved in their disposal must adopt safe handling techniques and wear appropriate protective clothing to prevent unnecessary exposure. A CoSHH risk assessment should be undertaken. Further guidance and help with CoSHH Assessments is available from the H&S Team by emailing :- healthandsafety@cpft.nhs.uk
- Staff must always wash hands with soap and water using the right techniques after handling or cleaning up spillages of cytotoxic drugs.

5.1.1. Personal Protective equipment (PPE)

- Cover cuts and scratches with a waterproof plaster or dressing, and when removed the hands wash hands with soap and water.
- Personal protective equipment should be worn by staff handling and administering cytotoxic drugs and dealing with any cytotoxic waste. When administering cytotoxic medicines wear gloves and a plastic apron, and where appropriate masks and protective eye wear if there is a risk of splashes or sprays.
- The following PPE and general equipment should be available for staff to use when necessary:
  - Gloves (latex or nitrile – according to Trust Policy.)
  - Disposable plastic apron or gown
  - Protective glasses or visor
  - Face mask
  - Cytotoxic spillage kit available from NHS supplies (Item MJZ015) – see 5.10
  - Eye wash kit
  - Purple lidded sharps bin

5.1.2. Accidental exposure

- Deal with accidental exposure to cytotoxic drugs promptly and complete an incident report. Further information is available from Infection Control or Occupational Health.
  - **Skin** – Immediately remove contaminated clothing flush the affected area with large volumes of cold running water for at least 10 minutes. After

copious flushing, wash the skin with liquid soap and water. Rinse and repeat. Seek medical attention from Accident and Emergency. Report to Occupational Health and the clinical lead / manager. Monitor the area and avoid the use of creams and lotions for 24 hours.

- **Eye** - Immediately irrigate the eyes and surrounding area with copious amounts of cold water for approximately 10 minutes. Seek urgent medical advice or attend Accident and Emergency immediately for a medical review. Inform Occupational Health and the clinical lead / manager.
- **Needle stick Injury** - Treat as for any other needle stick injury. Allow the wound to bleed freely. Wash with soap and cold water for at least 10 minutes. Seek medical advice immediately and report to Occupational Health and the clinical lead / manager.

- For contaminated clothing see 5.10 Spillages.
- Make a record of any accidental exposure to cytotoxic drugs in the individual's personal file.

5.2. Supplies of cytotoxic drugs

- Cytotoxic drugs should **not** be stocked by clinics, departments or wards.
- Individual patient supplies of cytotoxic drugs for cancer chemotherapy are obtained by the patient via the centre providing the specialist oncology or haematology service.
- Cytotoxic drugs for non-malignant conditions (e.g. Methotrexate for rheumatoid arthritis) may be obtained from Trust pharmacy departments for the individual patient on a prescription written by an appropriate medical practitioner in accordance with the appropriate shared care guidance or MMSOP.
- Supplies of cytotoxic drugs should be supplied in a form that is ready to use (e.g. tablet, prefilled syringe). It is not permitted for Trust staff to prepare or reconstitute parenteral cytotoxic drugs.

5.3. Transportation of cytotoxic drugs

- Cytotoxics should only be transported by healthcare staff in exceptional circumstances. Staff transporting cytotoxics should know what to do in the event of a spillage and have access to a cytotoxic spillage kit.

5.4. Storage of cytotoxic drugs

- Clearly label containers of cytotoxic drugs (e.g. CYTOTOXIC).
- Store cytotoxic drugs in accordance with the manufacturer's instructions, separated from other medicines if possible.
- Keep cytotoxics be stored in their original packaging until immediately prior to administration.
- Within the patient's own home, responsibility for safe storage lies with the patient or carer. Healthcare staff should advise on the safe and appropriate environment for storing cytotoxic drugs and disposing of waste or unwanted medicines.
- In inpatient settings, oral cytotoxic drugs can be stored in the locked trolley or bedside locker if they are clearly labelled as cytotoxic.

5.5. Prescribing (Inpatient Settings)

- Cytotoxic drugs for cancer chemotherapy and non-malignant conditions must only be initiated by appropriately qualified and competent specialists. Initiation should not take place within the Trust.
- For non-malignant conditions (e.g. methotrexate in rheumatoid arthritis), prescribing must be in accordance with the appropriate shared care guidance or other local procedure (e.g. *MMSOP052 Oral Methotrexate in Inpatient Settings*).
- In inpatient settings anyone who prescribes on-going oral anticancer medicines should seek assurance that a written treatment plan is in place and should be aware of the ongoing guidance on monitoring and treatment of toxicity.
- Before prescribing the cytotoxic drug, the prescriber must consider whether the patient is fit to continue with the treatment and consider whether the patient's clinical status has changed significantly (e.g. performance status, ability to swallow, disease progression, blood counts, deterioration of renal / liver function, toxicity etc.)
- If the treatment plan is not known, or the patient is not fit for treatment, seek specialist advice before continuing.
- The prescriber must ensure that the patient's condition and clinical response to medication is monitored and reviewed by appropriate healthcare staff as dictated by the patient's condition and ensure that the outcome of monitoring and blood results are acted upon.

5.6. Administration (all Settings)

- Before accepting the patient, carry out a risk assessment to ensure the medicine can be administered safely in the setting, the patient's safety can be maintained during administration and staff have the competence and skill required to administer the medicine.
- Ensure there are clear arrangements for prescribing, monitoring and reviewing treatment and ensure that the clinician who holds responsibility for the medical management of the patient is clearly identified and that all the necessary checks and monitoring have taken place.
- Ensure the patient is fully informed prior to administering the cytotoxic drug and has received written information about their chemotherapy.
- Check that the patient's general health and performance status is acceptable and that any critical test results have been checked to ensure the patient is fit and it is safe to continue treatment.
- Administration should be undertaken in a quiet area, away from passing "traffic" and interruptions, and where possible without carpets. Avoid areas where food or drink may be consumed.
- Administer medicines in accordance with the Medicines Policy and *MMSOP010 Administration of Medicines by Registered Healthcare Professionals.*
- Staff must always wash hands with soap and water using the right techniques after handling or cleaning up spillages of cytotoxic drugs.

5.6.1. Oral Formulations

- Do not handle cytotoxic drugs. When administering cytotoxic drugs use a "no touch" technique and wear gloves to minimise the risk of exposure when handling

containers, as well as a plastic apron and protective glasses if there is a chance of splashing (e.g. with liquid formulations).

- Wherever possible use tablets or capsules in preference to solutions.
- Do not break, crush or split cytotoxic tablets or open capsules. Do not use tablets / capsules if loose powder or liquid is present in the medicine container.
- The patient should swallow tablets and capsules whole with plenty of water and should not bite or chew them. Follow the manufacturer's instructions on whether the medicine is given with or before food.
- It is preferable for the patient to unwrap / pop out the tablet / capsule from the blister strip and self-administer the cytotoxic drug if possible, with supervision from the nurse responsible for administration.
- Patients, carers and staff should wash their hands thoroughly after administration.
- If the patient is unable to take tablets or capsules, contact the prescriber or pharmacist about the possibility of an alternative liquid preparation.
- If liquid preparations are prescribed, seek advice on safe handling from pharmacy.
- If oral tablets, capsules or liquids are dropped or spilt the dose must not be used and should be cleared up and disposed of in accordance with the instructions in 5.10.
- Dispose of empty containers, blister strips, spoons, pots and other waste in accordance with 5.11.

5.6.2. Parenteral Formulations

- Intrathecal, intravesical, intrapleural, intra-arterial and intravenous cytotoxic drugs must not be administered by Trust staff except in the Children's Community Specialist Nursing Service where trained and competent specialist RNs may administer intravenous cytarabine in accordance with the approved SOP (see 3).
- In healthcare settings, two healthcare professionals must be involved in administration of parenteral cytotoxic drugs, but the Trust recognises that this is not always possible in patient's own homes.

5.6.3. Subcutaneous (SC) and Intramuscular (IM) Injections

- Wear gloves and a plastic disposable apron when administering subcutaneous / intramuscular cytotoxics.
- Use a luer lock syringe and make sure the needle is securely connected. Do not aspirate prior to injection.
- Adopt standard administration technique for SC / IM injections when administering cytotoxic medicine, unless specific recommendations on the method are made by the manufacturer.
    - Administer subcutaneous injections using a pinch technique and a 90^{o} angle.
    - Administer intramuscular injections using the Z track technique. This involves displacing the skin and the subcutaneous layer in relation to the underlying muscle so that the needle track is sealed off before the needle is withdrawn minimising reflux.
- Take special care to ensure that the injected solution does not leak onto surrounding tissue, which could result in contamination of skin, clothes or bedding.
- Cover injection site with a plaster / non-allergic dressing.
- Dispose of cytotoxic contaminated waste and equipment as described in 5.11.

5.6.4. Topical Preparations (e.g. cream, ointment, gel)

- Some cytotoxic drugs are administered topically to the skin (e.g. fluorouracil cream).
- Wear gloves and a plastic disposable apron when applying topical cytotoxics. Other PP equipment may be needed depending on the exact method of administration.
- Unless directed otherwise, apply the cytotoxic preparation to the affected area only using a gloved figure or cotton wool / applicator. If the preparation comes into contact with unaffected skin, wipe the area with gauze and warm soapy water.
- Avoid contact with the eyes, nose, mouth or areas close to mucous membranes.
- Do not cover the skin with a dressing, unless specifically advised to do so.
- If necessary, after the required contact time, rinse the preparation off the area carefully. If the preparation has been applied to a large area, the patient should shower rather than bathe, to ensure that they do not sit in bath water that contains drug residue. Clean the bath or shower thoroughly after use. Staff bathing or showering the patient or cleaning should wear full PPE due to the risk of splash contamination.
- Observe the patient for acute skin reactions (i.e. severe burning or rashes) that may indicate a hypersensitivity reaction. If this occurs, discuss with the prescriber.
- Some cytotoxic drugs (e.g. fluorouracil) may cause redness, soreness, scaling and peeling of the affected skin after one or two weeks of use. This may last for several weeks after the treatment is stopped.
- Dispose of cytotoxic contaminated waste and equipment as described in 5.11.

5.7. Ambulatory cytotoxic drug administration

- Patients may be discharged from hospital on infusion chemotherapy to be continued at home.
- It is essential that patients, their carers and community nurses receive training in how to react in cases of equipment failure or problems with long term central venous access devices (CVADs).
- The community nurse must ensure that adequate advice and information has been provided in writing from the specialist service including:
  - The name of the drug(s) and duration of infusion
  - Care of the central venous access device (CVAD), the frequency of dressing changes and how to care for the site.
  - How to inspect for signs of infection or other complications
  - Potential problems and management and 24 hour on-call telephone numbers
  - Procedure for disconnection of ambulatory chemotherapy if applicable
  - Information on safe disposal and how to deal with a chemotherapy spillage in the home
  - Ongoing care of the line including flushes.
  - Additional support and training for the nurses involved must be provided by the discharging team, before the patient can be accepted (e.g. training in pump and line management).

5.8. Patient Information

- Patients and their relatives must be given relevant information including written leaflets relating to their treatment, safe storage and handling of cytotoxic medicines, patient waste and safe disposal, and contact details should any adverse effect be experienced. Information on risks of handling patient waste (e.g. urine, faeces and

vomit should also be provided, see 5.12). These should be provided by the specialist initiating therapy.

- Patients, relatives and carers should be warned to keep the handling of cytotoxic drugs to a minimum and that as far as possible the cytotoxic drugs should only be handled by the patient for whom they are prescribed.

5.9. Complications

- Complications associated with specific cytotoxic drug regimes for individual patients are highlighted in the patient's individual treatment plan or outlined in the local shared care guidance.
- The patient should be referred urgently to secondary care, if they have any of the following symptoms:
    - Temperature of 37.5°C or above
    - Shivering episodes, sweating or flu-like symptoms
    - Chest pain
    - Uncontrolled gum or nose bleeds or unusual bruising
    - Mouth ulcers that prevent eating or drinking
    - Severe diarrhoea and / or uncontrolled vomiting
    - Cough or shortness of breath
    - Rash
    - Neurosensory / motor loss
    - Symptoms of sepsis or shock
- Extravasation (i.e. inadvertent leakage of a cytotoxic drug solution into the surrounding tissues, rather than into the vascular pathway) can occur with any intravenous cytotoxic drug, however it is only considered to be problematic with those compounds that are known to be vesicant or irritant. Staff involved in caring for patients who have recently received vesicant drugs must be made aware, by the specialist service responsible for administration, of the risks involved, and be advised on how to recognise signs and symptoms of extravasation, and the appropriate urgent action to take. Extravasation with a vesicant drug should be treated as a medical emergency (999).

5.10. Spillages

- Cytotoxic spillage kits should be available to staff handling, administering or disconnecting cytotoxic drugs. Kits are available from NHS supplies (Item MJZ015). A CoSHH Assessment and SOP for this spill kit and its contents is available on Teams at https://cpft.sharepoint.com/:f:/r/sites/HealthandSafetyResources/Shared%20Documents/General/COSHH/Spill%20Kits?csf=1&web=1&e=JLOWnX
- Spillages of cytotoxic drugs must be dealt with immediately by the member of staff who is trained and competent in handling cytotoxic drugs as follows, and in accordance with the procedures outlined in the kit. (Cleaning up must not be delegated to domestic staff).
- Staff must always wash hands with soap and water using the right techniques after handling or cleaning up spillages of cytotoxic drugs.

Contaminated clothing:

- Wearing appropriate PPE (apron, splash face mask and gloves), rinse the clothing under running water in the sluice.

- Squeeze dry and place in a red plastic bag for laundering as contaminated waste, or purple striped bag for disposal.
- If laundering at home, wash twice at high temperature separately from other washing.

5.11. Disposal of Cytotoxic Waste

- In patient's homes and non-healthcare settings the patient, their relatives or carer should be advised to return oral cytotoxic drugs to a community pharmacy if they are no longer required or have expired.
- In healthcare settings dispose of unwanted oral and parenteral cytotoxic drugs into a purple lidded sharps bin in the original packaging (e.g. blister pack, bottle etc.) Waste cytotoxics must **not** be transported.
- Dispose of prepared unused doses into a purple lidded sharps bin. If possible, put in a sealable plastic bag or lidded pot before placing in the purple lidded bin.
- In all settings dispose of empty containers, including empty strips and blister packs, and any equipment used to administer cytotoxics (e.g. spoons, pots etc.) in accordance with current waste guidance into a purple-lidded sharps bin for incineration (as pharmaceutical hazardous waste). Sharps bins used for cytotoxic waste should be fitted with an absorbent pad to ensure any residual liquid will not spill or leak.
- Do not discharge the contents of syringes, but cap lines and tips to prevent leakage.
- Wear disposable gloves and a plastic apron throughout the disposal process.
- Put soft cytotoxic waste (e.g. aprons, gloves, paper towels etc) in a thick heavy duty, yellow and purple plastic clinical waste bag, which should then be sealed and labelled "cytotoxic waste".
- Clean non-disposable items (e.g. commodes and equipment) in accordance with the waste / infection prevention and control guidance.
- If bedding or linen is contaminated, risk assessment the level of soiling. If there is only a small amount of soiling treat the bedding/ linen as infected linen and place in a red bag for laundry. If there is heavy soiling of the bedding/linen handle as contaminated waste, double bag in a purple striped bag and send for incineration at very high temperatures.
  Dispose of Patient's own bedding / linen if heavily contaminated, or if appropriate wash twice on a very high temperature separately from other washing.
- Clearly label all cytotoxic waste containers (bins and sacks) in accordance with the waste guidance to provide a clear audit trail through the disposal chain. The Trust must ensure that cytotoxic waste is appropriately transported and safely disposed of by an authorised agent in accordance with waste regulations.

5.12. Patient waste and bodily fluids

- Patient waste (e.g. urine, faeces or vomit), may contain high concentrations of cytotoxic agents or active metabolites both during administration and up to seven days after treatment has ceased. Staff handling excreted waste and bodily fluids should take universal precautions and ensure waste is clearly marked as "cytotoxic" and take steps to establish whether any additional precautions are needed.
- In inpatient settings, patients should have separate toilet facilities to staff and visitors. Men should sit on the toilet rather than stand when passing urine to minimise the risk of splashing / contamination from cytotoxic containing urine. Flush toilets twice with the lid down.

- If bedpans are used, dispose of the contents in a sluice; double flush the sluice and the put the bedpan through the washer twice at high temperature.
- Dispose of other receptacles (e.g. catheter bags and soiled pads etc), as cytotoxic waste (e.g. double wrapped in a purple striped bag and labelled ‘cytotoxic waste’).
- Any spilt patient waste should be treated as a cytotoxic spillage.

6. References

- London Integrated Care Systems Guidelines for the Safe Prescribing, Handling and Administration of Systemic Anti Cancer Therapy July 2015, London Cancer Alliance.
- The Royal Marsden Hospital Manual of Clinical Nursing Procedures
- Health and Safety Executive, Safe handling of cytotoxic drugs in the workplace http://www.hse.gov.uk/healthservices/safe-use-cytotoxic-drugs.htm
- UKONS UK Oncology Nursing Society 24 Hour Triage Rapid Assessment and Access Tool Kit for Primary Care Health Care Professionals