London Integrated Care Systems (ICSs)
Guidelines for Safe Prescribing, Handling and Administration of Systemic Anti-Cancer Therapy

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**Relevant external law, regulation, standards**
- Manual for Cancer Services 2011
- Department of Health Guidance
- National Confidential Enquiry into Patient Outcome and Death (NCEPOD) 2008
- National Chemotherapy Advisory Group (NCAG)
- Cancer Reform Strategy
- Medicines and Healthcare products Regulatory Authority (MHRA)
- National Patient Safety Agency (NPSA)
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Introduction

This document has been reviewed by the Chemotherapy Nursing and Pharmacy Groups of the London Integrated Cancer Systems (ICS), London Cancer (LC) and London Cancer Alliance (LCA). It is intended for use across each of the London ICS sites providing systemic anti-cancer chemotherapy treatment (SACT).

With the kind permission of the authors, this document has been based around existing Guidelines and Policies across each of the London ICSs.

This policy is intended to safeguard patients and staff by defining best practice for all disciplines involved in systemic anti-cancer chemotherapy treatment (SACT).

Throughout this policy the term chemotherapy is used to refer to all SACT the majority of which are cytotoxic.

The term "cytotoxic" is generally used to refer to any agent that may be genotoxic, oncogenic, mutagenic or teratogenic. The health risk of any procedure involving cytotoxic drugs stems from the inherent toxicity of the drug and the extent to which workers and patients are exposed. Although in therapeutic doses some of these drugs are known to produce neoplastic changes in the long term, there is conflicting evidence on the effect of the much lower level of occupational exposure.

Cytotoxic administration throughout London should be provided by a multidisciplinary team in which doctors, specialist nurses and pharmacists work to approved written protocols, to provide integrated care both within the hospital and the community.

The handling and administration of cytotoxic drugs are potentially hazardous to the healthcare professionals involved in their preparation and administration, and to the patients receiving them. While the risks to patients are, in the main, well documented and can be balanced against the clinical benefits, the risks to health care staff are largely theoretical. It is therefore prudent, with the present state of knowledge, to take every reasonable precaution to protect staff from unnecessary exposure.

These guidelines aim to minimise these risks by promoting the safe handling and administration of cytotoxic drugs nationally and throughout London. It should be read in conjunction with other national policies and relevant policies available in each individual Trust. The policy has been written using best available evidence and practice, and will be reviewed as other guidance and evidence becomes available.

We are grateful to all the pharmacists, clinicians, nurses and healthcare professionals across the London ICSs who have contributed to the production of this document.
Associated documents
These guidelines support:

- Operational policies for the safe prescribing, handling and administration of cytotoxic drugs produced by each of the Trusts in London

Scope
This document is aimed primarily at staff delivering chemotherapy for patients, both adult and paediatric, with malignant disease within the Integrated Cancer Systems in London, i.e. London Cancer and London Cancer Alliance. It does not deal with cytotoxic chemotherapy specifically for any other indication including that for immunosuppression purposes or for the treatment of non-malignant disease, e.g. methotrexate for rheumatoid arthritis. Individual Trusts should, where necessary develop supplementary policies and guidelines to cover these circumstances and it is recommended that the principles outlined in this document should be used to inform those policies.

For the purposes of this document, the term cytotoxic drug is used to refer to all drugs with direct anti-tumour activity including conventional anticancer drugs, monoclonal antibodies and targeted treatments (for example imatinib, sunitinib) and drugs such as thalidomide. Relevant drugs are listed in the most recent version of the British National Formulary (BNF) Pharmaceutical Press, Section 8.1. Drugs affecting the immune response, including antiproliferative immunosuppressants, are listed in section 8.2. of the British National Formulary (BNF). If in doubt, refer to the Summary of Medical Product Characteristics available at www.medicines.org.uk for the individual drug concerned.

Some elements of this document will not apply to cytotoxic chemotherapy used within the context of a clinical trial, for example provision of Out of Hours services. For specific clinical trial recommendations always refer to local Standard Operating Procedures and specific clinical trial documentation.

Review
These guidelines will be routinely reviewed at least every three years. The committee/group responsible for chemotherapy in each of the ICSs will also review whether changes are needed whenever there is a change is policy.
1 HEALTH AND SAFETY including exposure, handling and Personal Protective Equipment (PPE)

Cytotoxic drugs interfere with cell division, but as this action is not specific to tumour cells, normal cells may also be damaged. As a result, they can produce significant side effects in treated patients, but the level of damage to those exposed due to occupational exposure is difficult to quantify. This, together with the increasing complexity of chemotherapy, has raised concerns about the risks to health care workers involved in the preparation and administration of chemotherapy and/or the caring of patients undergoing treatment.

For healthcare personnel the potential for exposure exists during tasks such as drug reconstitution and preparation, administration and disposal of waste equipment or patient waste. Hence, all staff involved in the delivery of services to cancer patients must be aware of all health and safety procedures. This applies to clinicians, nursing staff, pharmacy staff, domestic staff in the relevant pharmacy and clinical areas, and portering staff carrying cytotoxic drugs or cytotoxic waste.

The more common routes of exposure are; contact with skin or mucous membranes (e.g. spillage and splashing), inhalation (over-pressurising vials), and ingestion (e.g. through eating, drinking or smoking in contaminated areas or from poor hygiene). Less likely routes of exposure include needle-stick injuries, which can occur during the preparation or administration of these drugs.

Some cytotoxic drugs can cause acute or short term health effects including irritation to the skin, eyes and mucous membranes.

Information on chronic or long-term health effects of cytotoxic drugs mainly comes from data in animals and from patients given therapeutic doses. It is not certain how relevant this is to workers since any occupational exposures are likely to be at much lower levels.

Health workers preparing cytotoxic doses without adequate precautions have been shown to contaminate themselves and their work environment. Reports of increased foetal loss and birth abnormalities as well as anecdotal reports of toxicity unrelated to genetic damage have been published. The full implications of this in relation to healthcare workers remains unclear. It must be emphasised that these reports relate to exposure occurring prior to the introduction of cytotoxic drug handling precautions and guidelines. The adoption of improved handling techniques and the use of isolators has reduced the potential for exposure to cytotoxic drugs significantly.

1.1 Staff Monitoring.

All relevant new employees, as outlined above, should receive an orientation to the current ‘Guidelines related to the Safe Prescribing, Handling and Administration of Systemic Anti Cancer Treatment Drugs’ as soon as possible after commencement of employment. [http://www.hse.gov.uk/healthservices/safe-use-cytotoxic-drugs.htm](http://www.hse.gov.uk/healthservices/safe-use-cytotoxic-drugs.htm) ‘Safe Handling of Cytotoxic Drugs in the Workplace, 2013’ states that if a risk cannot be eliminated, a staff surveillance programme must be implemented. There is currently no form of biological monitoring or health assessment technique that is sensitive or specific enough to adequately predict the effect of chronic long-term exposure. It is therefore recommended that staff monitoring (e.g. blood or urine testing) is not routinely undertaken until improved methodology and means to interpret the data are available. Hence, the primary focus of safety during the preparation and administration of cytotoxic drugs must be on control of the working environment, minimising exposure and safe practice.
1.2 Personnel Records.

Managers responsible for staff likely to be exposed to cytotoxic drugs should keep a record of drug exposure for each member of staff in accordance with the Health and Safety Executive (HSE) guidance. In the absence of any specific guidance, it would be good practice to include Monoclonal antibodies (MAb’s) (c),(d),(e) and Gene therapy products.

In the absence of defined limit of cytotoxics detected by staff or environmental monitoring, staff records should also be kept detailing all deviation from working standards e.g. accidental exposure due to spillage.

1.3 Pregnancy and Breastfeeding.

There should be no significant exposure to cytotoxic drugs if good handling practices are strictly adhered to. As some pregnancies are unplanned, or staff unwilling to discuss plans for conception, the emphasis must be on the reduction of exposure for all staff at all times. There have been some studies suggesting adverse effects on the foetus as a result of the mother working with cytotoxic drugs. Many of these studies, however, were carried out, or based on exposure during the 1980’s at a time when the use of personal protective equipment and safety isolators was not well established. Some later studies have failed to find a significant association with foetal adverse effects.

As the pre-conception period is not included in any health and safety advice, managers must ensure that a COSHH (Control of Substances Hazardous to Health) (a) risk assessment is carried out in all areas where cytotoxic drugs are handled in order to assess the level of risk and the adequacy of control measures in place. Directions on how risk assessments can be completed can be found at http://www.hse.gov.uk/risk/index.htm. The risk assessment should assume that there may be a new or expectant mother working in the environment in the following twelve months. Precautions must be in place at all times to minimise exposure by using protective garments, appropriate equipment, as well as safe and validated work practices. This applies to both male and female staff exposed to both investigational agents and licensed drugs.

This policy, along with local Trust policies and procedures aim to reduce the risk of exposure to these drugs as far as possible. However, as there is no known limit where exposure is thought to be safe, employees must be fully informed of the potential reproductive risks.

Employees should notify their managers as soon as possible if they are pregnant, trying to conceive or are breastfeeding. This is particularly important as the greatest risk is during the first three months of pregnancy, when rapid cell division and differentiation occurs. This will ensure compliance with HSE guidance which states that all pregnant staff, or those trying to conceive, should be removed from duties involving the preparation of cytotoxic drugs.

When an employee discloses pregnancy, a risk assessment specific to the individual must be carried out and any appropriate action taken.

All staff should be fully informed of the reproductive risks by:
- Receiving verbal and written information on induction in the area handling these drugs
- Signing to say they have read and understood the relevant risk assessments
- Providing opportunity for discussion of any concerns
- Any risk assessment carried out should follow local policy and be signed and dated by all relevant parties

Pregnant or breastfeeding staff will be expected to make an informed choice about working with cytotoxic drugs. Staff who choose not to work with cytotoxic drugs will not be expected to be involved in directly preparing or administering chemotherapeutic agents or handling waste from patients treated
with chemotherapy. If appropriate, the line manager and Human Resources Department, will agree any new temporary arrangements together with the member of staff and ensure that she is adequately supported during her pregnancy. The Human Resources Department will be consulted if no suitable alternative employment is found.

New, expectant and breastfeeding mothers should be specifically advised against any direct involvement in the management of a cytotoxic drug spillage.

Safe handling procedures must be audited and documented on a regular basis to ensure continuing staff compliance and to reduce risks to as low a level as is reasonably practicable.

1.4 Monoclonal Antibody (MAbs)

The preparation of MAbs should be individually risk assessed, taking into account the allergic potential based on the origin of the MAb and toxicities arising from the therapeutic use. Together with the NPSA risk assessment tool for intravenous medicines, an overall risk score should then be used to decide whether manipulation should be within an aseptic unit (high risk) or permitted in a clinical area (low/negligible risk). It is recommended that Trust approval should be obtained for MAbs assessed as high risk being manipulated in clinical areas.

There should be a local guideline and procedure in place on the safe handling of MAbs, if appropriate.

1.5 Gene therapy

Gene therapy or gene transfer therapy are often confused with MAbs and the safe handling of these agents is outside the scope of this document. It generally involves deliberate introduction of genetic material into somatic cells for therapeutic, prophylactic or diagnostic purposes. There are cases of viral vector gene therapy that can be infective and so should never be manipulated in clinical areas.

1.6 Control of Exposure to cytotoxic drugs

The following guidance applies to all staff handling cytotoxic drugs during administration, handling of patient waste and cleaning of spillage. A full COSHH risk assessment must be undertaken in all areas handling cytotoxic drugs. Directions on how risk assessments can be completed can be found at http://www.hse.gov.uk/risk/index.htm. The risk assessment should define the specific Personal Protective Equipment (PPE) to use in each activity where cytotoxic drugs are handled.

Recommended Good Practice

- Work should be organised to minimise quantities of drugs used.
- Keep to a minimum the number of employees potentially exposed and the duration of exposure.
- All staff should ensure the safe handling, storage and transport of cytotoxic drugs and waste material containing or contaminated by them.
- Good hygiene practices and suitable welfare facilities should be provided to ensure that staff eating, drinking and smoking are prohibited in all areas where cytotoxic drugs are handled.
- Staff working with cytotoxic drugs must be trained on the risks and precautions to take when handling cytotoxic chemotherapy and newer agents, for example monoclonal antibodies.
- Local procedures must always be followed in relation to administration of cytotoxic chemotherapy and monoclonal antibodies.
1.6.1 Handling guidelines for Oral Chemotherapy

- Oral anti-cancer medicines can be potentially hazardous if handled carelessly.
- Accidental exposure which may arise from handling uncoated tablets, loose capsules or oral liquids should be minimised.
- Hands should be washed thoroughly after handling any oral anti-cancer medicine.
- In exceptional circumstances, if crushing of tablets or capsule opening is deemed essential disposable gloves, apron, mask and protective eye wear must be worn. Crushing should take place in a controlled area, using commercially available devices that are specifically designed for this purpose. Care must be taken in cleaning or disposing of such devices, which will contain fine powder of the oral anti-cancer medicine.

1.6.2 Personal Protective Equipment (PPE) to be Used When Handling Cytotoxic Drugs.

It is important to ensure PPE offers adequate protection and is designed specifically for handling cytotoxics. PPE with ‘CE’ marking (in accordance with Directive 93/68/EEC) satisfies the essential requirements of the relevant European health, safety and environmental protection legislation.

The correct use of PPE can shield staff from exposure to cytotoxic drugs and minimise the health risks but only if the following criteria are met, the PPE is:

- Suitable for the task
- Suited to the wearer and the environment
- Compatible with other PPE in use
- In good condition
- Worn correctly

Pharmacy staff preparing cytotoxic drugs within pharmacy preparation units will wear personal protective clothing as defined by local standard operating procedures. Employers need to ensure that staff are trained in the use of PPE and that the PPE is adequately maintained and stored.

The following recommendations are considered to be the absolute minimum protective clothing/equipment that should be worn in clinical areas for the defined work tasks. Local policy, or specific and individual staff needs may dictate the use of further supplementary protection.

1.6.3 Hand protection (Gloves):

Cuts and scratches on the skin should be covered with a waterproof dressing to prevent infiltration of the skin if gloves are damaged. Staff with dermatological conditions (e.g. eczema) should be referred to occupational health for assessment of fitness to operate in their role.

Hands must be washed thoroughly with liquid soap/detergent or alcohol gel before and after the use of gloves.

Gloves must be worn at all times appropriate to the task being undertaken.

Gloves must:

- Always be disposable and preferably powder free
- Be worn at all times when contact with cytotoxic drugs is possible
- Be changed regularly, always between patients and immediately after they become damaged or contaminated.
If the inner surface of a glove becomes contaminated, exposure will occur. Therefore once disposable gloves are removed, they should not be re-applied, but disposed of as detailed in section relating to disposal.

The need for sterile or non-sterile protective gloves will depend on the procedure they will be used for. They should fit appropriately and be close fitting to ensure dexterity. Individual practitioner’s preferences should be considered with regard to sensitivity and dexterity. Only gloves designed for handling cytotoxic chemotherapy should be used and it should not be assumed that all gloves are impermeable. Nitrile and latex gloves both offer good protection from cytotoxic contamination. The specific gloves to be used will be defined in Trust standard operating procedures (SOPs).

For spillages, industrial thickness gloves (> 0.45mm) made of latex or neoprene, nitrile or synthetic rubber are recommended. Alternatively double latex or nitrile gloves can be used.

1.6.4 Eye protection:

The use of eye protection should be considered whenever splashes or sprays of cytotoxic drugs might be generated, for example during intracavitary administration and when clearing up cytotoxic spillages. Eyewash kits and spillage kits must be readily at hand for use in all areas where handling of cytotoxic drugs occurs.

Eye protection:
- Should fully enclose the eyes and comply with BS EN166.
- Be disposable where possible or capable of undergoing decontamination cleaning.

1.6.5 Torso protection (Plastic aprons):

Disposable plastic aprons will provide limited protection and prevent absorption into clothing when used where splashing or spraying is possible.

1.6.6 Gowns:

Laboratory coats must not be used. Disposable gowns are preferable for preparation and spillage. They should:
- Have a closed front, long sleeves and elastic or knitted cuffs.
- Be made of low permeability fabric for example saranex/tyvek laminated material or spun bonded polypropylene laminated with polyethylene.

1.6.7 Respiratory protection:

Surgical masks do not offer protection against inhalation of fine dust or aerosols. When inhalation of solid or liquid particles are a risk, an FFP2 or FFP3 filtered face piece respirator should be used.

Inhalation is not a significant risk for staff administering prepared cytotoxic drug doses. Therefore, staff are not required to wear masks during administration.

Respiratory protection should also be used when dealing with a cytotoxic spillage.
### 1.6.8 Summary Table of recommended PPE for each handling activity:

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<td>✓</td>
<td>✓ *</td>
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</tr>
<tr>
<td>Waste Disposal</td>
<td>✓</td>
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<td>✓ *</td>
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<tr>
<td>Spillage</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

*recommended when there is a risk of spraying, splashing or aerosols
** recommended if preparation is not taking place in closed containment technology

### 1.7 Facilities required for administration of Chemotherapy

Cytotoxic drugs should be administered in a dedicated therapeutic environment with appropriate facilities for safe administration and within safe working staffing levels. The area should also have an annual risk assessment undertaken to ensure fitness for purpose, in line with the recommendations of NPSA alert Promoting Safer Use of Injectable Medicines, 2007/20\(^{(h)}\). This assessment should encompass ‘Equality Impact Assessments’. Checks of medical equipment used within the area must also be undertaken on an annual basis.

Areas designated for the administration of cytotoxic drugs should have all relevant policy and protocol documents available.

Facilities should include easy access to expert help and all the equipment necessary for the management of emergencies.

Storage of cytotoxic drugs within clinical areas must comply with Manual for Cancer Standards specifications \(^{(m)}\). See section 3.5 of this document for specific storage requirements.
1.7.1  Equipment needed in chemotherapy administration areas

All areas in which cytotoxic drugs are administered within an Acute Trust must have the following equipment and staff trained to use them:

- Emergency bell.
- Resuscitation equipment (or access to it as defined by local practice).
- Drugs for the management of emergencies – cardiac arrest and anaphylaxis.
- Extravasation kit.
- Cytotoxic spillage kit.
- Eye wash / access to running water.

Electronic pumps used to assist administration must be appropriately installed, validated, and have a current maintenance certificate. The practitioner should observe the equipment for consistent performance. They should also be appropriate for the prescribed purpose and used by a competent practitioner only (as defined by local written policy) at all times.

Staff should use the Trust governance process and the MHRA for reporting adverse incidents, as well as acting upon any MHRA hazard and safety notices and any NPSA alerts or rapid response reports.

1.8  DISPOSAL OF CYTOTOXIC WASTE

Biological agents (including monoclonal antibodies) used in cancer treatment should be treated in the same way as cytotoxic drugs for the purposes of waste disposal since it is not yet clear how hazardous it is if there is inadvertent exposure to these agents.

The recommendations in this section act as a guide, and are supplementary to those detailed in Individual Trust Waste Disposal policies.

Information aimed at patients and carers regarding disposal of cytotoxic waste in the home or community environment is outlined in Appendix 1.

1.8.1  Used Disposable Equipment

While wearing gloves and plastic apron place any needles, syringes, giving sets, empty ampoules/ vials or infusion bags into a rigid sharps disposal box with a purple lid to denote cytotoxic waste. Giving sets should not be removed from infusion bags prior to disposal.

Used oral administration spoons, medicine pots or oral syringes should be double bagged in clinical waste disposal bags with a purple stripe or placed in a sharps box with a purple lid.

The sharps disposal box must have purple colour coding to denote cytotoxic waste as well as a purple lid so it will be incinerated at 1000ºC to ensure degradation of the cytotoxic agent.

Sharps disposal boxes containing cytotoxic waste must be regularly collected.
1.8.2 Contaminated Non-Disposable Equipment/Items

Re-usable plastic or metal trays should be rinsed with cold water into a sluice (to remove traces of cytotoxic agents) and then washed with detergent and hot water (to prevent cross-infection). Wear gloves and apron.

If non-disposable equipment or items are sent to another department for terminal cleaning, they must be transported in sealed leak-proof bags or containers. These should be clearly labelled with a purple stripe indicating that they are potentially contaminated by cytotoxic drugs.

1.8.3 Protective Clothing and Wipes

Contaminated protective clothing, wipes, plastic aprons and gloves worn during the administration of chemotherapy should be double bagged in clinical waste disposal bags with a purple stripe or placed in a sharps box with a purple lid to be sent for incineration.

After a cytotoxic spillage (dealt with according to the cytotoxic spillage procedure), arrangements must be made for immediate collection of the rigid cytotoxic sharps bin with purple lid for incineration.

1.8.4 Part Used Doses

Continue wearing protective clothing to dispose of part used doses. Syringes may be capped but needles must not be resheathed. If disposing of an infusion bag leave the giving set in place and clamp it off. Place the syringe/bag in a purple striped yellow bag and place into a rigid sharps box with a purple lid which denotes cytotoxic waste to be sent for incineration.

1.8.5 Unused Oral Doses

Any unused oral doses (e.g. tablets that have been dropped or oral liquids that have been refused etc) should be disposed of in a cytotoxic sharps box with a purple lid. To minimise the risk of damage and potential contamination, they should be discarded as follows:

- Loose tablets/capsules: Put into a sealable plastic bag or a medicine bottle / sample pot securing the lid, before placing in a cytotoxic sharps box with a purple lid.
- Oral liquids: Pour into a medicine bottle / sample pot securing the lid, before placing in a cytotoxic sharps box with a purple lid.
- Other oral SACT still in the original packaging, which has not left the Trust, may be returned to pharmacy for possible reuse. Note on the label that the package has not left the Trust, may be an appropriate way to differentiate.

1.8.6 Patient Waste/Body Fluids

Patient waste e.g. urine, faeces, vomit may contain high concentrations of cytotoxic drugs or active metabolites both during administration and up to seven days after treatment has ceased. Particular care should be taken with patients receiving high dose chemotherapy or intravesical treatment.

It has been shown that these unchanged cytotoxic drugs or active metabolites can be irritant to the skin, eyes and mucous membranes. Although evidence of long-term toxicity is inconclusive and conflicting, all staff handling waste should take reasonable precautions to limit exposure and ensure absorption does not occur.
The use of universal precautions applies here, as with all body fluids.

- Wear gloves and protective aprons
- Double flushing of sluices after emptying potentially cytotoxic contaminated matter from bedpans, catheter bags, dialysis bags etc. is recommended. Bedpans should be put through a bedpan washer twice at high temperature.
- Staff are advised to follow the precautions described in individual Trusts Control of Infection Policies.
- Ideally patients should use separate toilet facilities to staff. Men should be advised to void sitting down to minimise splashing. Following voiding, toilets should be flushed with the lid down (again to minimise splashing).
- For patients who have received intravesical BCG therapy a strong bleach based detergent should be poured into the toilet after voiding.

1.8.7 Soiled Bedding / Linen

A risk assessment should be undertaken of soiled bedding and linen to determine the level of soiling and therefore the appropriate action to be taken.

If there is only a small amount of soiling the bedding/linen should be treated as infected linen and handled as such, placed in a red bag and sent to the hospital laundry according to the procedures described in the individual Trust Control of Infection Policy and Procedures.

If there is heavy soiling of the bedding/linen it should be handled as contaminated waste, double bagged in a yellow bag with purple stripe and sent for incineration.

1.8.8 Nappies

Non-disposable nappies should be treated as infected linen and handled according to the procedures described in the individual Trust Control of Infection Policy and Procedures.

Disposable nappies should be ‘double bagged’. They should be placed in a tied plastic bag and then in a clinical waste disposal bag with a purple stripe to indicate cytotoxic waste and sent for incineration.

1.8.9 Disposal of waste in primary care/ community care

Each CCG must have a policy in place to ensure that cytotoxic waste is appropriately transported and safely disposed of by an authorised agent in accordance with EU waste regulations 1).

1.8.10 Information for patients producing cytotoxic waste at home

Patients producing cytotoxic waste at home must have information and equipment to manage this and be alert to the risk to others in the home. An example of an information leaflet which can be given to patients is shown in Appendix 2

1.9 CYTOTOXIC SPILLAGES

A cytotoxic spillage kit must be available, at all times, in all clinical areas where cytotoxic drugs are administered, and in all pharmacy areas where cytotoxic drugs are handled or stored. All staff must know how to use it and where it is stored. A risk assessment should be undertaken to determine the number of kits that should be available at each site to deal with a large spill. At no time must access to a kit be impeded by blocking the surrounding area. If a kit is used it must be replaced immediately.

Cytotoxic spillage kits are available from pharmacy or Supplies Departments, depending on local practice. The cytotoxic spillage kits may be prepared in-house by pharmacy or commercially available spillage kits may be used, as long as a local risk assessment is carried out to ensure that the contents, and the procedure outlined, are appropriate.
CONTENTS OF IN-HOUSE CYTOTOXIC SPILLAGE KITS FOR HOSPITAL USE

Recommended contents of a cytotoxic spillage kit are:
- Absorbent granules/pads/sheets/paper towels
- 2 pairs of powder free gloves (latex or nitrile)
- Protective gown (e.g. Saranex/Tyvek laminated)
- Disposable shoe coverings
- FFP2 or FFP3 Filtered Face Piece Respirator; NOT surgical mask
- Safety glasses BS EN 166
- Clinical Hazardous waste bag (red)
- Cytotoxic waste bag (purple stripe)
- 1 large sharps bin with purple lid
- 10 self-seal plastic bags
- A “Warning! -Cytotoxic spill” sign
- Forceps

1.9.1 Immediate Action

- Restrict access to the spillage area.
- Alert other members of staff in the vicinity and inform a senior member of staff.
- If you have been injured or contaminated, another member of staff must deal with the spillage while you receive attention for the injury or contamination following the procedure detailed in section 1.10
- New and expectant mothers should not have direct involvement in the management of a cytotoxic spillage.
- Turn off all fans and reduce any draughts.
- Open a Cytotoxic Spillage Kit.
- If protective clothing has been contaminated during the spillage, remove the contaminated items and put on fresh protective clothing from the spillage kit. Place all contaminated items in the 'sharps' bin.
- Before dealing with the spillage ensure you have:
  - Put on a disposable protective gown.
  - Put on a pair of protective plastic armlets, if available.
  - Put on a pair of gloves (Tuck the armlet sleeves inside the glove cuffs).
  - Put on a mask (preferably a respirator).
  - Put on protective eye wear.
  - Put on a pair of plastic overshoes (only if spillage is on the floor).

1.9.2 Subsequent Action

For Trusts using pharmacy prepared Cytotoxic Spillage Kits: The procedure outlined in this section should be followed.

For Trusts using commercially available Cytotoxic Spillage Kits: The procedure as outlined in the pack should be followed. Such procedures should also be accessible in all relevant ward, clinic and pharmacy areas.
1.9.2.1 Liquid spillages

- Put paper towels in a ring around the spill to contain the fluid so that it cannot spread to a larger area.
- Pick up any broken glass using the tweezers and place it in the purple lidded ‘sharps’ bin.
- Cover the liquid with paper towel until all the fluid has been absorbed.
- Keep adding paper towels until the fluid has distributed itself throughout the towel and the towel is just moist i.e. when the towel is picked up the fluid will NOT drip out of the towel.
- Pick up the moist towel and place it into the self-seal plastic bags. Seal the bags and place in the purple lidded sharps bin. Be careful not to contaminate the outside of the sharps bin.

1.9.2.2 Powder spillages

- Use the paper towels to create a ring around the spill. This will contain any fluid added to wet the powder and prevent it spreading to a larger area.
- Pick up any broken glass using the tweezers and place it in the ‘sharps’ bin.
- Carefully cover the spillage with a large layer of paper towel moistened with water for irrigation, this will prevent mobilisation of the powder particles, and so contain the spillage.
- Add a little more water through the towel until all the powder has been wetted.
- Add paper towels until the fluid has distributed itself throughout the towel and the towel is just moist i.e. when the towel is picked up the fluid will NOT drip out of the towel.
- Carefully pick up the wetted powder with the moist towel and place into the self-seal plastic bags. Seal the bags and place in the purple lidded ‘sharps’ bin. Be careful not to contaminate the outside of the Sharps bin.

1.9.2.3 Oral Dosage form spills

- If an oral dose is dropped, wear gloves to pick it up and dispose of it in a cytotoxic waste bin with a purple lid.
- Damp dust the area with a wet paper towel to ensure all the fragments have been collected.
- Dispose of the towel in a cytotoxic waste bin with a purple lid.
- Document lost dose in the patient’s healthcare record and on the prescription, as appropriate.
- Oral liquid spills should be cleaned up as the ‘liquid spills’ section, 1.9.2.1.

1.9.3 Final clean up

- Pick up the paper towel used to create a ring around the spill, seal in self-seal bag and place in the ‘sharps’ bin. Be careful not to contaminate the outside of the cytotoxic purple lidded ‘sharps’ bin.
- Use the water for irrigation and additional paper towels to clean the contaminated area and place used paper towel in a self-seal bag. Repeat this at least five times working from the outside of the contaminated area inwards to prevent spreading the contamination.
- Place all the self-seal bags, tweezers, protective clothing, protective eye wear and respirators in the cytotoxic sharps bin.
- Put the purple lid on the cytotoxic sharps bin and seal.
- Tape up the cytotoxic sharps bin with cytotoxic hazard tape.
- The floor and all other contaminated surfaces should be given a routine clean a minimum of three times using the appropriate locally approved detergent for the surface to be cleaned, as soon as possible.
- A Trust Adverse Incident Form should be completed and the Head of Department and Occupational Health informed.
- Arrange for immediate collection of the purple-lidded cytotoxic sharps bin or return it to pharmacy.
- Ensure a replacement cytotoxic spillage pack is obtained immediately and the pack is stored in its designated storage area.
• Inform the Pharmacy Cytotoxic Preparation Unit of any spillage, as drugs may have to be remade.

1.10 PERSONAL ACCIDENTS

If a patient, member of staff or visitor is involved in a spillage of cytotoxic drugs or potentially contaminated patient waste the following procedures must be followed.

All such events/accidents should be reported to a senior member of staff and fully documented on the local Trust adverse incident forms.

Information aimed at patients and carers regarding personal accidents in the home or community environment should be available locally. See an example outlined in Appendix 1.

• Undertake a suitable and sufficient assessment of the risk in order to inform the implementation of appropriate control measures to ensure safe practice is followed.
• Staff should be familiar with local procedures and regularly trained to deal with cytotoxic spillages.
• There should be specific SOPs to deal with:
  • Spillage within the cytotoxic reconstitution area
  • Spillage within wider areas of the Pharmacy Department
  • Spillage within ward/clinical areas of the hospital
  • Spillage within the home environment

1.10.1 Skin

• Remove any contaminated clothing immediately.
• The contaminant must be removed from the skin as rapidly as possible by flushing the affected area with a large volume of cold water. If running water is not immediately available, bottles or bags of sterile water or normal saline should be kept as an alternative.
• After initial copious flushing with water, the contaminated skin should be thoroughly washed with liquid soap or antiseptic scrub and water. After rinsing, the process should be repeated.
• Shower facilities should be available for use if large areas of skin are contaminated.
• Do not use hand creams and emollients as these may aid absorption of the drug.
• Medical attention must be sought from the nearest Accident & Emergency Department.
• An adverse incident report form must be completed, and the Head of Department & Occupational Health informed.

1.10.2 Eyes

• An eye-wash kit should be available in all areas where chemotherapy is administered.
• The contaminant must be removed as rapidly as possible by flushing the eyes and surrounding areas with a large volume of sterile normal saline using an eye wash station where available. Alternatively cold tap water can be used if necessary.
• Medical attention must be sought immediately from the nearest Eye Clinic or Accident & Emergency Department.
• An adverse incident report form must be completed and the Head of Department & Occupational Health informed.
1.10.3 Needlestick injuries

- Allow the wound to bleed freely.
- Wash the puncture site/wound thoroughly with copious amounts of cold water.
- If the needle contained any cytotoxic drug contaminant, check the vesicant status of the drug by referring to the extravasation policy, or by seeking advice from a senior oncology or haematology pharmacist.
- Report the incident immediately to a senior member of staff.
- Follow the Trust’s Needle stick injury procedure, and consider seeking advice from the Accident & Emergency Department and Occupational Health, especially if the needle had been in contact with a patient.

1.10.4 Clothing

- Any contaminated clothing must be removed immediately. Put on gloves and an apron. Rinse the clothing under running tap water in the sluice. Squeeze dry and place in a red plastic bag if being sent for laundering as contaminated waste, or a purple striped bag if being sent for incineration.
- Uniforms or hospital linen should be double bagged in the appropriate laundry bags and sent to the hospital laundry according to the procedures described in the individual Trust Control of Infection Policy and Procedures.
- Personal clothing should be taken home for laundering. Such items should be laundered twice where possible. The first wash should be separate from other clothing. They may be laundered with other items for the second wash.
- Dispose of gloves and apron into a double yellow clinical waste bag with a purple stripe.
- If there is a likelihood that the drug has soaked through the outer clothing, underwear must be removed and treated as above, and the area of skin treated as in section 1.10.1 above.
1 References


(e) Clinical Oncology Society of Australia; Position Statement: Safe handling of monoclonal antibodies in healthcare settings 2013


(g) http://www.ce-marking.org/what-is-ce-marking.html

(h) Promoting the Safer Use of Injectable Medicines, NPSA 2007/20, http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812


(j) HSE- Personal Protective Equipment at Work, a brief guide , INDG174(rev2), published 06/13

(k) QuapoS 4 ‘Quality Standard for the Oncology Pharmacy Service’ published by the German Society of Oncology Pharmacy (DGOP e.V.) for the European Society of Oncology Pharmacy (ESOP) as the result of the Conference for Standardisation in Oncology Pharmacy, September 2008 in Luxembourg, Section 4.3


(m) Manual for Cancer Standards, Chemotherapy, 11-3S-106, 2011
2.1 London ICS Policy Clinical Governance

The responsibilities of different staff groups in relation to this London ICS Guidance are outlined below with regard to systemic anti-cancer treatments (SACT).

In this section, SACT is referred to as any anti-cancer therapy including chemotherapy, monoclonal antibodies, targeted therapy, immunotherapy and supportive therapies such as bisphosphonates, anti-emetics, hydration and other medication defined on the regimen protocol.

The SACT dataset is a mandated national dataset (b), managed by the chemotherapy intelligence unit (CIU). From a governance perspective, there is a requirement for all providers to enter data into the relevant fields for all anti-cancer therapies. It is advised that this should include bisphosphonate therapy and oral SACT treatments. Currently, there is not a requirement to submit data on other supportive therapies, such as anti-emetics etc. For more information, please refer to the website.

http://www.chemodataset.nhs.uk/home.

2.1.1 Integrated Cancer System responsibility

- Ensure that this policy is reviewed and kept up to date with best practice
- Audit providers within the ICS’s to ensure that providers are complying with the guidance set out within this document.

2.1.2 Senior Management within Individual Trusts

- Designate responsibility for the implementation of this guidance, through the Chemotherapy Leads to the appropriate managers and staff.
- Ensure that all managers and supervisory staff participating in the provision of systemic anti-cancer services are familiar with, and adhere to, this guidance and in accordance with local Trust policies relating to the safe and appropriate administration of SACT.
- Are accountable for clinical and corporate governance.
- Ensure that all relevant staff are fully familiar with this guidance, and that they are properly trained in, and comply with, all policies and procedures
- Ensure that the health and safety of patients, public and staff are given primary consideration when implementing or altering processes, programs, locations, or physical facilities related to systemic anti-cancer therapies. Risk assessments should be carried out as appropriate (see section 1.3).
- Ensure that all requests to change work assignments from staff that are pregnant, breastfeeding or trying to conceive, are accommodated, in working with systemic anti-cancer therapies.
- Ensure that appropriate and properly maintained facilities and equipment are available to all staff handling cytotoxic drugs.
- Ensure training records are maintained for each employee for 3 years from the date training occurred and personnel records are maintained as per local HR policy.
- Ensure that the service is reviewed against current Control of Substances Hazardous to Health Regulations (COSHH) with an authorised Trust COSHH advisor.
• Ensure that any member of staff, dealing with systemic anti-cancer therapy of a cytotoxic nature, including those transporting therapy, has received training in dealing with a spillage (see section 1.9).

2.1.3 All Staff

• Ensure that all safety requirements according to COSHH guidelines and this Guidance are followed.

• Only carry out activities using substances hazardous to health when competent or trained to do so.

• Follow departmental standard operating procedures where available.

• Report all unsafe acts and conditions.

• Actively participate in the training programs provided.

• Staff should use the Trust governance process and the MHRA for reporting adverse incidents, as well as acting upon any MHRA hazard and safety notices and any NPSA alerts or rapid response reports.

2.2 Staff responsibilities and standards

• All staff involved in the prescribing, dispensing and administration of SACT, must be appropriately trained and competent (a).

2.2.1 Prescribers Responsibility (including non-medical prescribers)

Trusts must maintain a register of clinical staff designated to prescribe systemic anti-cancer therapy, the list should be updated at least annually.

Categories of prescribers will be defined locally by individual Trust so not all the points listed below will apply to all prescribers.

Prescribing of oral systemic anti-cancer medicines in primary care should be considered exceptional and must only be undertaken within agreed shared care guidelines. A register of such guidelines must be kept.

• The decision to initiate systemic anti-cancer therapy treatment should be made by a Consultant and the patient’s treatment should be discussed at an appropriate Multidisciplinary team meeting (MDT).

• Only appropriately qualified and competent Consultant Medical Oncologists, Clinical Oncologists, Haematologists, Paediatric Oncologists, Staff Grades, Associate Specialists or Specialist Registrars in training (ST3 or above) may initiate a new course and prescribe the first cycle of systemic anti-cancer therapy for the treatment of cancer patients, as per Trust guidance.

• The prescriber should inform the patient’s general practitioner of the intention to start the course of systemic anti-cancer therapy and provide sufficient information for action to be taken in the event of the patient experiencing side effects.

• Prescribing of second or subsequent cycles may be delegated to Specialist Registrars in training (ST3 or above), non-medical independent or supplementary prescribers who have completed the
necessary training, are registered with their professional body and are authorised by their Trust to prescribe within their competence. Delegation of this responsibility is only permitted if the relevant Consultant has given clear written details of the patients treatment plan, documented in the patient’s healthcare record and that the regimen being prescribed is included in the Network/Trust agreed list of regimens. If modifications of doses are required, the Consultant or the Specialist Registrar in training (ST3 or above) must document this in the healthcare record. For non-medical prescribers if such modifications are outlined in the patient’s protocol, then the same applies. NB individual Trusts may have different guidelines defining the specific role of junior medical staff. All these prescribers should have completed the Trust/Network training programme and be accredited to prescribe systemic anti-cancer therapy (c)(d).

- Medical doctors who are provisionally registered with the GMC (FY1 and FY2) MUST NOT prescribe systemic anti-cancer therapy, for the treatment of malignant disease.
- All prescribers, including non-medical prescribers must comply with the Trust medicines guidance and related codes of practice.

Medical and Non-medical Independent Prescribers are responsible and accountable for:

- The assessment of patients with diagnosed or undiagnosed conditions and for decisions about the clinical management required, including prescribing.
- Carrying out reviews of the patient’s progress at regular intervals, including the recording of performance status, investigation results and serious toxicities following a previous cycle of systemic anti-cancer therapy, depending on the nature and stability of the patient’s condition.
- Identifying possible drug related adverse incidents and reporting them within the Trust risk management scheme and where appropriate the MHRA via the Yellow card scheme.
- Non-medical prescribers authorised to prescribe medicines within the individual Trust will be included on a Trust register of non-medical prescribers.

Non-medical prescribers (NMPs) may only prescribe medicines for NHS patients under the care of the Trust within the speciality in which they have demonstrated competence (g).

NMPs should maintain a defined list/description of drugs within their scope of practice, e.g. in a job plan, job description, which should be periodically reviewed.

NMPs should maintain their own professional development, in the context of their clinical responsibilities and work in accordance with their local Trust NMP guidance.

Non-medical prescribers should have clear referral pathways for situations outside their scope/competence and recognise those situations where it is inappropriate for them to prescribe.

The Non-medical Independent prescriber must obtain the patient’s verbal consent before prescribing any medicine.

Non-medical independent prescribers can prescribe within their competence, any licensed medicine for any medical condition. They can also prescribe medicines for ‘off-label’ use where this is part of accepted clinical practice. The ‘off-label’ uses should be listed either within the BNF or the Trust formularies and not be specifically restricted. Non-medical Independent prescribers can prescribe unlicensed medicines.

Both pharmacists and nurse independent prescribers are able to prescribe controlled drugs schedule 2-5 for any medical condition within their competence.
Supplementary prescribers

- In the case of supplementary prescribing written consent is obtained by the patient signing the Clinical Management Plan (CMP) before any prescribing activity takes place.
- The supplementary prescriber is accountable and responsible for:
  - Prescribing within the limits of the Clinical Management Plan (CMP)
  - The CMP is a legal requirement of supplementary prescribing.
  - Ensuring that patients are aware of the scope and limits of supplementary prescribing and how the patient can obtain other items necessary for their care.
  - Altering the medicines prescribed, within the limits set out in the CMP, if monitoring of the patient’s progress indicates that this is clinically appropriate.
  - Monitoring and assessment of the patient’s progress as appropriate to the patient’s condition and the medicines prescribed.
  - Consulting the independent medical prescriber as necessary.
  - Accepting professional accountability and clinical responsibility for their prescribing practice.
  - Recording prescribing and monitoring activity contemporaneously in the common patient record.

- Supplementary prescribing must be supported by regular clinical review of the patient’s progress by the independent medical prescriber, at pre-determined intervals appropriate to the patient’s condition and the medicines to be prescribed.

- A supplementary prescriber can prescribe within their competence, any medicines stated in the CMP including controlled drugs, and unlicensed (‘off-label’) uses of licensed medicines.

- All the standards above apply to prescriptions for oral systemic anti-cancer therapy to same extent as systemic anti-cancer therapy given by other routes to comply with the NPSA rapid response alert of 2008 ‘Risks of incorrect dosing of oral anti-cancer medicines’.

2.2.2 All prescribers are responsible for:

- Checking the allergy status of the patient and for any potential interaction between patient’s current medicines (including those bought over the counter) and their systemic anti-cancer therapy or supportive care medicines.

- Confirming the appropriate regimen within the national algorithm or from the agreed regional/local list of regimens for the tumour site concerned.

- Ensuring that the body surface area (BSA) calculations are appropriate and have been made using a recent weight. Dosing should be carried out according to local or ICS guidance if the patient is obese or has a high BSA. In Trusts where dose banding is approved the prescriber may amend the dose to the nearest acceptable parameter specified in the approved list of dose banding levels, or indicate on the prescription that ‘dose banding is appropriate for this patient’, in accordance with local Trust policies.

- Ensuring the doses prescribed for children are calculated according to the relevant protocol, i.e. mg/kg or based on BSA using the UKCCLG (previously the UKCCSG) BSA chart.
 Ensuring that in obese children, guidelines in the individual protocols are followed, or the weight for the 97th centile for age should be used.

 Ensuring accurate dosing. A maximum of +/-5% variance (according to protocol dosages) in dosage calculation is permitted, or as defined by local guidance.

 Prescribing and monitoring all cytotoxic drugs and supportive therapies including anti-emetics and hydration. This includes the on-going monitoring of toxicities and amendment of supportive medicines where required.

 Ensuring that maximum cumulative doses of anthracyclines and bleomycin have not been exceeded. If these drugs have been given to the patient at other Trusts e.g. tertiary referral to a Cancer Centre from a District General Hospital, the referring unit should provide information on cumulative doses already received, as appropriate.

 Equally, it would be appropriate for the Trust receiving the referral to ensure a previous treatment history of any relevant therapy that may impact on/influence treatment is obtained.

 Specifying the route of administration and for parenteral doses, the duration of infusion on the prescription (f).

 Ensuring the patient has appropriate venous access prior to prescribing infusions of vesicants.

 Ensuring there is an appropriate interval between each treatment day and cycle, within a course, as defined by the protocol.

 Ensuring the patient is given written information regarding the systemic anti-cancer therapy they will be given.

 Ensuring the patient is fully informed of their treatment and has given informed consent.

 Ensuring that all relevant safety parameters such as complete blood counts, renal and hepatic function have been checked and that the patient is fit to receive treatment. If doses are modified due to variance of these parameters, the reason for dose modification should be recorded on the prescription and in the patient’s healthcare record.

 Ensuring that performance status is recorded prior to each course and cycle of systemic anti-cancer therapy.

 If a patient is to be treated with a chemo-radiation protocol, it is essential that this is clear on the prescription so that the relevant nursing and/or pharmacy staff are aware.

 Wherever possible, systemic anti-cancer therapy should be initiated during normal working hours when access to specialist staff is more likely to be available (c)(d). Only in exceptional circumstances may systemic anti-cancer therapy be initiated outside of normal working hours after discussion with the patient’s consultant and key operational staff. The reasons for initiating systemic anti-cancer therapy out-of-hours must be documented in the patient’s healthcare record. See section 3.6 for details of Out of Hours services.

 Prescriptions for all systemic anti-cancer therapies should be electronic, not verbal, and changes to any of these prescriptions must be documented electronically via the e-prescribing system. If a
prescription is amended local guidance should be followed for the electronic prescription to be amended and a new electronic prescription to be created before the treatment is administered or dispensed (a).

- After the final cycle, within a given course, the prescriber should ensure that there is a treatment record for each patient, stating whether the course was completed or not. If the course was not completed, the reasons for cessation should be documented. For completed courses of non-adjuvant treatment, a reference to the response should be documented.

- An end of treatment summary should be produced according to ICS pathway board guidelines (a). Guidance about these can be found here: [http://www.ncsi.org.uk/what-we-are-doing/treatment-summary/](http://www.ncsi.org.uk/what-we-are-doing/treatment-summary/) A generic template of an end of treatment summary is found here: [http://www.ncsi.org.uk/wp-content/uploads/Treatment-Summary-Template1.doc](http://www.ncsi.org.uk/wp-content/uploads/Treatment-Summary-Template1.doc) This document must be sent to the patient’s GP as hand over of care following discharge from the oncologist and copy should also be given to the patient.

The Academy of Medical Royal Colleges has recently published a report on the safer prescribing of cytotoxic agents, which should be incorporated into local governance policies as appropriate. Further information can be found at the following link: [http://www.aomrc.org.uk/doc_download/9829-safer-prescription-of-cytotoxic-agents-v-2-april-2015.html](http://www.aomrc.org.uk/doc_download/9829-safer-prescription-of-cytotoxic-agents-v-2-april-2015.html)

### 2.2.3 Pharmacists Responsibilities

- An appropriately trained pharmacist, accredited and on the Trust register for this activity, must clinically screen all prescriptions for cytotoxic drugs prescribed for the treatment of malignant disease and document that the prescription has been clinically screened.

- It is inappropriate for Non-Medical Pharmacist Prescribers to prescribe and screen the same prescription.

- Prior to a cytotoxic dose being prepared the pharmacist must verify the prescription according to the protocol or treatment regimen (h), clarify and resolve any discrepancy and check that:

  - The appropriate regimen/protocol has been selected, with correct sequencing.
  - The BSA calculations are appropriate for the patient taking into consideration the patient’s age and other factors. If a patient is 30% over their ideal body weight, or BMI is greater than 30, the pharmacist will contact the prescriber and discuss possible implications and the need for dose reduction or dose capping.
  - For children, the doses should be calculated according to the relevant protocol, i.e. mg/kg or based on BSA using the UKCCLG BSA chart.
  - For obese children, guidelines in the individual protocols should be followed, or the weight for the 97th centile for age should be used.
- An accurate dose has been prescribed. A maximum of +/- 5% variance (according to protocol dosages) in dosage calculation is permitted, or as defined by local guidance.
- Dose modifications to previous treatments are maintained if appropriate.
- All SACT and supportive therapies (including anti-emetics, hydration etc.) have been prescribed as appropriate
- Maximum cumulative doses for anthracyclines and bleomycin have not been exceeded. If these drugs have been given to the patient at other Trusts e.g. tertiary referral to a Cancer Centre from a District General Hospital, the referring unit should provide information on cumulative doses already received, as appropriate.
- The route of administration and the duration of infusion have been specified on the prescription.
- The volume and medium of infusion is appropriate with respect to the patient, protocol and pharmaceutical stability.
- There is an appropriate interval between treatment and cycles.
- All relevant safety parameters such as complete blood counts, renal and hepatic function are reviewed and drug doses modified where necessary.
- The patient is not allergic to any prescribed medicines.
- The dates for administration of systemic anti-cancer therapy are clearly stated.
- The prescription has been signed by an appropriate clinician, either in the electronic or written form.
- In Trusts where dose banding is approved the pharmacist may amend the dose to the nearest acceptable parameter specified in the ICS/Trust approved list of dose banding levels. This endorsement must be made in line with local Trust policies.
- Ensuring that an appropriate funding stream is in place for the SACT drugs in the regimen, e.g. Cancer Drugs Fund
- If the prescription is for a new systemic anti-cancer therapy regimen, not included on the current ICS SACT regimens list, or is prescribed ‘off protocol’ the oncology/haematology pharmacist must discuss the case with the responsible Consultant. For further information see section 2.5. A copy of an original paper from the responsible Consultant, detailing the protocol should be obtained, or the pharmacist should satisfy himself/herself that the prescription is appropriate in the individual patient’s circumstances before the prescription can be dispensed. If there is any doubt, a senior oncology/haematology pharmacist should be consulted. If there are cost implications with the new regimen funding streams will need to be identified e.g. Cancer Drug Fund
- In the absence of a local guidance, discrepancies exceeding plus or minus 5% of the dose, calculated according to the patient’s treatment plan, must be clarified with the Prescriber/Consultant.
- The pharmacist will resolve any discrepancies identified with the prescriber/Consultant prior to dispensing the medication(s). The actual prescription, and electronic prescribing systems, will be amended as per local guidance, and any changes will be communicated to other team members.
The pharmacist will complete documentation of the discrepancy and the resolution.

- The same standards and checks must be carried out for oral systemic anti-cancer therapies prescriptions as for systemic anti-cancer therapy administered by any other route \(^{(e)}\). Processes should be in place to minimise waste of oral SACT.

### 2.2.4 Nurses Responsibilities

- Registered nurses are responsible for safe administration of systemic anti-cancer therapy prescribed to the correct patient as outlined in the individual Trusts guidance for Administration of Medicines by Nurses/Midwives and the Nursing and Midwifery council (NMC) Standards.

- All prescriptions for SACT must be checked by a chemotherapy certified/accredited nurse on the Trust Chemotherapy Administration register.

- It is inappropriate for Non-medical Nurse Prescribers to prescribe and administer the same prescription.

- The chemotherapy nurse is responsible for ensuring that:
  - The correct weight on each cycle and height on cycle 1 have been recorded.
  - The BSA calculations are appropriate.
  - All systemic anti-cancer therapies including supportive treatments have been prescribed.
  - The patient is not allergic to the prescribed medicines.
  - The route of administration and the duration of infusion have been specified on the prescription.
  - Ensuring the patient has appropriate venous access prior to administering cytotoxic drugs.
  - There is an appropriate interval between treatments days and cycles within a course.
  - All relevant safety parameters such as complete blood counts, renal and hepatic function, toxicities and patient evaluation are in line with the patient’s treatment plan and protocol guidelines.
  - Ensuring that the patient is fully informed of their treatment and has given written consent.
  - Ensuring the patient has their next relevant appointment booked, for further systemic anti-cancer therapy or to the outpatient clinic, as appropriate.

- Patients should also be assessed holistically for the need of any additional psychological, social or spiritual support at each cycle \(^{(a)}\).

- The nurse should ensure that monitoring and timely management of patient specific toxicities takes place.

- It is the nurse's responsibility to ensure all side effects including fertility issues have been discussed and documented prior to commencement of treatment.

- A nurse may not accept verbal orders for SACT or for adjustments to doses of SACT.

- Prior to administration of SACT the nurse must check:
2.3 Prescriptions

For the purposes of this document the term prescription will also refer to "Patient Specific Directions" as defined by the Department of Health.

- Prescriptions for SACT must be complete, clear and simple to follow. Each Prescription should contain the following:
  - Date prescribed.
  - Patient name, date of birth, hospital number and/or NHS number as appropriate.
  - Patient’s weight, height (where appropriate) and BSA. NB: Height is not necessary for paediatric prescriptions.
  - Allergy status, always declare if ‘No known allergies’
  - For prescriptions containing carboplatin the uncorrected GFR should be stated for adult patients and Creatinine EDTA half-life or uncorrected GFR should be stated for paediatric patients. N.B.
    - eGFR results are not validated for use in prescribing systemic anti-cancer therapy doses
    - When using EDTA half-life to estimate renal function the result which is ‘uncorrected’ for BSA should be used for dosing Carboplatin
    - When using EDTA half-life to estimate renal function for all other cytotoxic drugs the result which is ‘corrected’ for BSA should be used.
  - Ward / clinic.
  - Consultant name.
  - Protocol code, regimen name or clinical trials name and randomisation arm and randomisation number (where appropriate).
  - Disease site and indication
  - Cycle number and/or course number, as appropriate.
  - Name of drug - use approved generic drug names; no abbreviations.
  - The individual dose must be written in mg or units and target AUC for carboplatin.
  - The frequency per day and the number of days of treatment.
  - Route of administration (the abbreviations IT or IP are not acceptable, intra-thecal intra-peritoneal or intra-pleura must be written in full). The same applies for other routes where potential for miss-administration could occur for example intra-vesical must also be written in full.
For Infusions, details of diluent/solution and volume.

- Duration of infusion and any other administration instructions.

- Starting dates (and times when appropriate) and dates for successive days of treatment within the cycle, particularly when there are gaps within the cycle.

- Supportive therapies, including anti-emetics, hydration and any additional drugs as defined by the protocol.

- Reason for any dose modifications and their current performance status (may only be in the patient’s records).

Prescriptions for oral systemic anti-cancer therapy must contain clear directions, including the dose, frequency and duration, including start and stop dates where applicable. This is to avoid patients being treated for longer than intended. Oncology, haematology and paediatric haematology and oncology staff must prescribe cytotoxic drugs for patients using an electronic prescribing system, and it is an NHS England requirement for all systemic anti-cancer therapy providers to implement an electronic prescribing system.

Printed copies of prescriptions generated via an electronic prescribing system should comply with all the criteria specified above.

Electronic systems used for the prescribing, preparation and administration of cytotoxic drugs should have:

- Secure mechanisms to guarantee the security of access to those healthcare professionals alone who are competent to take part in the prescribing, clinical screening, preparation and administration of SACT.

- Clear audit trails for recording who has taken part in the provision of SACT, from the prescriber, to the pharmacy clinical screening and preparation to the administration by nursing staff.

- Where the whole process of prescribing, clinical screening and administration of systemic anti-cancer therapy is recorded electronically (i.e. there is no paper based recording of any part of the process), the system should provide all the relevant details listed above, in a manner that does not introduce new risks to the process.

- Where electronic prescribing systems are used, the process for adding and deleting regimens onto the system must be clearly set out in Standard Operating Procedures and each element pertaining to prescribing, clinical screening and administration should be validated by the appropriate clinical discipline involved in that element of the pathway.

- Where multiple electronic systems are available in Trusts to record activity related to the patients SACT journey (for example, electronic-noting and electronic patient medication administration systems, in addition to electronic prescribing for SACT), there must be clear operating procedures in place to describe what information is documented where, in order to minimise the risk of duplication or omission of important data.

Prescriptions for intrathecal administration must follow the Trust and National Guidance for the administration of Intrathecal chemotherapy. This may be prescribed using paper proformas as long as there is compliance with trust and National Guidance.
2.4 Consent for treatment and patient counselling

- All patients receiving SACT should be fully informed of their treatment and must have given full written consent for each new course of treatment \(^{(a)}\). Practice may vary throughout London on who actually takes consent and ensures it is documented, but this should be defined by local guidance.

- It is good practice to ensure that consent is taken following initial pre-treatment consultation and secondary consent at the point of administration.

- Consent should be documented on the appropriate form (e.g. the Department of Health form and/or a protocol/trial specific consent form), but this should be defined by local guidance. Patients must receive a copy of the signed consent form.

- If a change in systemic anti-cancer therapy regimen or re-challenge with a previously used systemic anti-cancer therapy regimen is necessary, patients should be re-consented, after having received regimen specific details. This should be documented as above.

- Paediatric patients/carers should be given a copy of the signed consent form to keep in their patient held record, and be advised to take this when receiving treatment at the Principal Treatment centre or their relevant Paediatric Oncology Shared Care unit (designated Level 1, 2 or 3 under the review of paediatric oncology services). A copy of the consent form should also be sent to the child’s POSCU to be retained in the patient’s healthcare record.

The counselling points below are applicable to oral systemic anti-cancer therapy \(^{(e)}\):

- Written information including regimen details, treatment plan and arrangements for monitoring should be given to the patient including 24 hour contact details for specialist advice. The use of oral systemic anti-cancer therapy patient diaries is recommended. (See LCA oral SACT documentation or equivalent for London Cancer).

- Patients must be adequately counselled to ensure their understanding of the regimen details, storage conditions and handling precautions. Handling precautions are particularly important during long maintenance courses such as for childhood leukaemia.

- Medicine spoons, oral syringes and cups used for administration in the home should be reserved for systemic anti-cancer therapy treatment only, washed thoroughly between doses and safely disposed of at the end of treatment.

- The multi-disciplinary team should ensure that the patient is given appropriate information at each stage of their ‘SACT journey’. The use of ‘information prescriptions’ should be encouraged to standardise this process. Ideally, most information should be given at a pre-treatment visit and reinforced at subsequent visits.

- Patients should be asked about any problems or side-effects that have occurred since their previous cycle of treatment.
Designated members of the multi-disciplinary team must ensure that the patient understands the following:

- How and when to take their medicines including ‘gaps’ off treatment
- Any dose modifications and understands why this is necessary
- What to do if a dose is missed
- What to do in the event of vomiting after a dose
- Common side-effects and what action to take if they occur
- How to obtain further supplies - if needed
- To return any unused oral anti-cancer medicines to the hospital pharmacy
- The role their GP is expected to play in treatment

- A contingency plan for the patient should be provided in writing, regarding potential accidents, spillage or improper storage in the home.

- Patients should be told who their ‘key worker’ is and given details of appropriate and readily accessible 24 hour points of contact if further advice is needed. Ideally this information should be contained in a personal chemotherapy handbook given to the patient at the start of their treatment.

- Any written information provided should be added to the ‘Patient Held Record’, where given.

- Effective communication between primary, secondary care and patients is central to safe and effective treatment. Suggested ways of providing communication support to patients and healthcare professionals who come into contact with the patient would be to implement patient held records and patient held SACT diaries.

- All patients must receive appropriate written information in accordance with NPSA guidance. This should be in the form of the manufacturer’s Patient Information Leaflet (PIL) and, where available, a locally approved information leaflet.

- Oral anti-cancer medicines should not be supplied to a patient unless he/she has received education relating specifically to the medicines, the intended treatment plan and likely side-effects. It is important that the patient accepts their roles and responsibilities relating to their treatment.
2.5 SACT 'Off Protocol' Prescribing

- In exceptional circumstances, it may be necessary to treat a patient with a SACT regimen not on the current list of accepted ICS or ultimately identified on the NHS England SACT algorithms \(^{(a)}\). This may arise for instance when:
  - Current available regimens do not meet the clinical need of the patient, e.g. toxicity profiles of existing regimens are incompatible with the patient’s clinical condition.
  - The route of administration of an existing regimen is inappropriate or inaccessible.

- Regimens not on the current list of accepted ICS or NHS England SACT algorithm for the particular tumour site are referred to as ‘Off protocol regimens’.

- If an ‘Off Protocol’ regimen is to be used, the Consultant must document the intended regimen in the patient’s healthcare record this must include the following details:
  - The name of each drug.
  - The intended dose of each drug in milligrams or units per m\(^2\) or per kilogram. For Carboplatin the desired AUC should be quoted.
  - The schedule on which each drug is given and the route of administration.
  - The overall length (in days) of each cycle must be stated as well as the interval between cycles.
  - The total number of cycles to be given.
  - The reason for prescribing a protocol not included on the current ICS/NHS England Chemotherapy regimens list.

- It is recommended that monitoring tests (e.g. full blood counts (FBC), biochemistry and tumour markers) should be specified for the regimen and intervals also stated, dose modifications should also be stated for when results of tests may be outside normal limits.

- An ‘off protocol’ form must be completed and the treatment schedule should be discussed with pharmacy. Where available, any published protocol details should be provided to pharmacy by the prescriber.

- An Off Protocol Form specifies details to enable all healthcare professionals responsible for the patient’s care to have appropriate information in order to deliver safe and effective treatment.

- A Cancer Drug Fund (CDF) or Individual Funding Request (IFR) application process \(^{(b)}\) may need to be followed, before the Off Protocol Regimen form is completed. If not on the CDF approved list, an application for adding the new regimen to the National CDF list should also be considered.

- A minimum of 2 copies of the completed ‘off protocol’ form should be made. A copy should be kept in the patient’s healthcare record, the second copy should be sent to the Head of the Clinical SACT service or the lead oncology pharmacist who should then table this for discussion at a future meeting of the local SACT group and the ICS SACT group or the ICS Drugs and Therapeutics Committee or the NHS England Area Team pharmacist.
• Application for **REGULAR USE** of a new SACT regimen must be made via the pathway board at the ICS of the particular tumour site concerned, by the prescriber. This will lead to the regimen being reviewed and the regimen being added to the list of approved regimens if appropriate. An application for adding the new regimen to the National CDF list should also be considered.

• More information on the CDF can be found on the NHSE website ([http://www.england.nhs.uk/ourwork/pe/cdf/](http://www.england.nhs.uk/ourwork/pe/cdf/)).
2. References


(b) 2013/14 NHS STANDARD CONTRACT FOR CANCER: CHEMOTHERAPY (ADULT), NHS England B15/S/a

(c) Chemotherapy Services in England: Ensuring quality and safety. A report from the National Chemotherapy Advisory Group DH August 2009

(d) National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report 2008


(f) NPSA (2007) Promoting Safer use of Injectable Medicines [http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59812](http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59812)

(g) Joint BOPA & CNPF: Guidance For The Development Of Pharmacist Non Medical Prescribing And Review Of Patients Receiving Anticancer Medicines (July 2009), updated 2011

(h) BOPA Standards for Clinical Pharmacy Verification of SACT (Jan 2010)
3 PURCHASING, PREPARATION, SUPPLY, TRANSPORTATION AND STORAGE OF CHEMOTHERAPY.

3.1 Purchasing, Receipt and Storage in Pharmacy

The purchasing, receipt and storage of cytotoxic drugs in pharmacy are carried out in accordance with agreed procedures by the Pharmacy Department within the London Integrated Cancer Systems. Pharmacy will ensure the effective control of the quality of these products.

- When purchasing cytotoxic drugs, risk assessments should be carried out, as appropriate, to ensure that appropriate products are used. For example, wherever possible blister packed capsules or tablets are preferable to loose preparations, and products in vials would be preferable to ampoule formulations.
- Access to cytotoxic agent storage areas in pharmacy must be limited to authorised staff. All such storage areas will be clearly labelled with cytotoxic warnings.
- Main stocks of cytotoxic drugs will be held in the Pharmacy Department, under appropriate conditions.
- Clinical trial supplies of cytotoxic drugs should be kept separate from main stocks in pharmacy.
- Cytotoxic drugs should not routinely be available as ward stock. They should always be dispensed for individual patients. In exceptional circumstances cytotoxic drugs may be kept as ward stock only if a risk assessment has been carried out.
- In all areas where cytotoxic drugs are stored they must be stored separately from other drugs. The storage areas must be clearly labelled as areas where cytotoxic drugs are stored.
- Intrathecal chemotherapy doses should be stored in a separate designated area (refer to local policy in conjunction with the National Guidance). (c)
- Storage must be designed in a manner that will prevent containers of cytotoxic agents from becoming damaged.
- Cytotoxic spillage kits should be available in all areas where cytotoxic drugs are stored. (b)
  Damaged cartons of cytotoxic agents are to be discarded into a rigid sharps box with a purple lid as stipulated in the ‘Safe Management of Healthcare Waste Memorandum (HTM 07–01)’(a) issued by the Department of Health which provides guidance on the secure and legally compliant management of clinical waste. These should be labelled as cytotoxic waste and dealt with as per the Trust waste disposal policy.

All clinical waste handling and disposal procedures must comply with the following regulations: (a)

- The Environmental Protection Act 1990 (including the Duty of Care Regulations)
- The Controlled Waste Regulations 2012
- The Hazardous Waste Directive 2011
- The Carriage of Dangerous Goods Regulations

3.2 Procedures for handling chemotherapy prescriptions

- All prescriptions should be received in pharmacy in a timely fashion according to local Trust policy.
- Dispensing and preparation of cytotoxic agents must take place in Pharmacy (see section 3.3).
- In emergencies, out of hours chemotherapy preparation may be done by nursing staff who have been trained and assessed as competent to prepare chemotherapy doses safely and who have access to an approved biological safety cabinet.
• Preparation of cytotoxic agents must take place in filtered vertical laminar airflow cabinets or isolators situated in a specifically controlled and monitored environment. The equipment must be certified at least annually.

• All pharmacy or nursing staff preparing cytotoxic agents will follow the individual Trust pharmacy procedures.

• An appropriately trained and accredited pharmacist on the Trust register will check all prescriptions. The pharmacist will resolve any discrepancies identified with the prescribing doctor prior to dispensing the medication(s).

• To facilitate drug preparation, in some Trusts, changes to a previously written prescription may be made by an oncology or haematology pharmacist upon verbal confirmation from a doctor. Any changes on the prescriptions should be appropriately annotated by the pharmacist or prescriber. Individuals should check their local Trust policy relating to this issue.

• The pharmacist performing the clinical screening will document that the prescription is approved for preparation, this may be the original prescription or specific Trust documentation designed for this purpose.

• Appropriately trained and accredited pharmacy staff are responsible for the accurate preparation, documentation, labelling, determining and allocating the correct expiry and storage conditions for a cytotoxic dose. Trusts may keep registers of staff authorised to carry out some of these activities. (b)

• The pharmacist or accredited technician on the appropriate Trust register performing the final product check will ensure correct documentation, computer entry, ensure appropriate order preparation, dispense and release the medication for the patient.

• Oral SACT prescriptions may be dispensed by non-NHS providers, e.g. commercial chemist contractors or homecare companies. It is good practice for the clinical screening of these prescriptions to be completed by appropriately trained specialist pharmacists within the Trust or, if not, by trained and accredited staff in the external company.

3.3 Supply & preparation of Cytotoxic Drugs

Many pharmacy departments in acute Trusts delivering cytotoxic chemotherapy across London operate a centralised cytotoxic preparation service providing parenteral cytotoxics individually dispensed and ready for administration to named patients. Some may also outsource the preparation of these drugs from commercial suppliers. Regardless of the source, the reconstitution is carried out within HEPA filtered vertical laminar flow air cabinets or isolators situated in a specifically controlled and monitored environment. These facilities provide operator protection, as well as ensuring maintenance of the sterility of the products. These units must be subject to regular inspection from local Pharmacy Quality Control Departments and/or the Medicines and Healthcare Regulatory Agency (MHRA). (b)

Trained pharmacists and technicians, whose aseptic techniques are regularly validated, carry out all the preparation operations following standard operating procedures. Accredited pharmacists carry out clinical checks of all chemotherapy prescriptions. Only accredited staff, on the Trust register, can clinically screen, prepare, dispense and check chemotherapy doses. (b)

In most situations during normal working hours, preparation of cytotoxic drugs in a clinical area, outside pharmacy, is unacceptable.

In certain settings however, the preparation/reconstitution of drugs in clinical areas may be carried out if a formal risk assessment has been conducted. A policy and procedure should be written and approved by senior managers. Where possible, such cytotoxic drug preparation should use closed systems. An example of this is the preparation, by trained urology staff, of mitomycin C as a bladder instillation using the commercially available Mito-In device.

For details of pharmacy opening hours and contact numbers see Appendix 2.
All formulations of cytotoxic drugs must be supplied and labelled in accordance with Medicines and Health Regulatory Authority (MHRA) and the National Patient Safety Agency (NPSA) guidance and according to Trust Standard Operating Procedures (SOPs).

Cytotoxic tablets, capsules and oral liquids should be labelled in accordance with local SOPs and in line with national guidance, for example the NPSA RRR2008/001(b).

Topical Preparations containing cytotoxic drugs should be labelled in accordance with local SOPs.

### 3.4 Transportation of cytotoxic drugs

- Prepared cytotoxic agents must be transported in designated transport bags or boxes. These should be sturdy, secure and leak-proof and should be clearly labelled: **CYTOTOXIC DRUGS - HANDLE WITH CARE**. Additional precautionary labels should be added to the containers and the transport bags or boxes as appropriate, for example room temperature or refrigerated storage required.
- All Trust staff involved in the transportation of cytotoxic drugs must be trained to follow the ‘Cytotoxic Spillage’ procedure.
- Intrathecal doses must be transported separately to all other medication. (Refer to local Trust Intrathecal Policy in conjunction with National Guidance).
- Pneumatic tubes may be used for transporting cytotoxic agents in some Trusts, when this is the case a documented risk assessment should be in place (refer to local Trust Guidelines and policy)
- If damaged or leaking cytotoxic products are received on the wards or day units, the receiver should put on gloves and an apron, and place the damaged product into a leak proof container and the Trust Spillage procedure followed as appropriate. The product should be immediately returned to pharmacy, or disposed of according to the Trust Disposal of Waste procedure.
- Any cytotoxic drugs received on the ward or day units, but not administered, must be safely returned to the Pharmacy Department as soon as possible and the pharmacy staff informed of the reason why it was not administered.
- Cytotoxic drugs that are to be transported outside of the hospital should be placed in sturdy, leak-proof transport bags or boxes. They should be clearly labelled as ‘Cytotoxic – Handle With Care’. Details of the recipient and delivery address should be clear. The label should also contain the name and address of the originating hospital and a direct contact in pharmacy in case of an emergency.

### 3.5 Storage in Clinical Areas.

- Chemotherapy drugs must be delivered to a qualified nurse on the ward who takes responsibility for the appropriate storage, as stated on the label attached to the cytotoxic agent.
- Bags/boxes will not be left unattended or with untrained staff on arrival.
- Access to cytotoxic drug storage areas on wards or day units must be limited to authorised staff.
- Storage must be designed in a manner that will prevent containers of cytotoxic drugs from falling. Such storage areas should be clearly labelled with cytotoxic warning labels.
- Pharmacy staff are responsible for correct storage of drugs prior to delivery to wards.
- Nurses are responsible for the correct storage of cytotoxic drugs delivered to wards and clinics prior to use. The storage should be in appropriate and designated areas. (b)
- Cytotoxic agents must be stored separately from other drugs.
  - Parenteral doses of chemotherapy should be stored in a designated locked chemotherapy refrigerator or cupboard.
  - Intrathecal doses must be stored in a designated intrathecal storage area. Refer to Trust Intrathecal policy.
- Oral doses can be stored in a locked drug trolley, cupboard or refrigerator, as long as they are clearly labelled as cytotoxic.

- Any refrigerators used for the storage of chemotherapy doses should be monitored at least daily to ensure that the temperature is maintained between 2 to 8 degrees centigrade. The measured temperature should be recorded and local procedures followed for actions to be taken if the temperature is out of range.

3.6 Out of Hours Initiation and Administration of Chemotherapy

Whenever possible, all cancer chemotherapy should be initiated, and as much as is feasible, administered within normal working hours. The risk of accidents is increased when complex cytotoxic regimens are given outside normal working hours, particularly errors of incorrect drug and patient identification, and using the incorrect route of administration of cytotoxic drugs.

3.6.1 Exceptional Circumstances.

Patients may only be commenced on a new chemotherapy program beyond normal Monday to Friday working hours in the following circumstances:

- Acute Leukaemia - unanticipated admission of a newly diagnosed patient or a newly diagnosed relapsed patient.
- Haematological malignancy patient with CNS involvement.
- Superior vena cava (SVC) obstruction - in a patient with small cell lung cancer, germ cell tumour or a haematological malignancy.
- Spinal cord compression – in a patient with germ cell tumours, Ewing’s sarcoma, neuroblastoma or a haematological malignancy.
- In exceptional circumstances, acute medical crisis brought on by rapidly growing tumour.

As far as possible transplant protocols should be scheduled to avoid chemotherapy being initiated out of hours. A Consultant Oncologist, Haematologist or Paediatric Oncologist must determine that it would be absolutely inappropriate to delay chemotherapy. The decision must be recorded in the medical notes by the responsible Consultant.

If the patient presents at a cancer unit with a medical emergency, as outlined above, it may be appropriate for the patient to be transferred to the associated Cancer Centre where specialised Oncology or Haematology medical and nursing support is more readily available.

Pharmacy and relevant nursing staff should be contacted as soon as possible after the decision to treat a patient with chemotherapy out of hours has been made.

3.6.2 Out Of Hours Preparation of Chemotherapy Doses

Whenever possible, all cancer chemotherapy should be initiated, and as much as is feasible administered, within normal working hours. However, there are some exceptional circumstances as outlined in section 3.6.1 where chemotherapy may need to be initiated and administered out of hours.

Different arrangements currently exist for emergency doses required out of normal pharmacy hours at each site within each Acute Trust in London (see Appendix 2).
In situations such as expired cytotoxic doses or split infusion bags, for patients who are receiving ongoing chemotherapy treatment regimens, contact the on call pharmacist for advice.

For emergency intrathecal chemotherapy out of hours, refer to the local Trust Intrathecal Policy. (c)

3.6.3 Out of Hours Cytotoxic Preparation in Clinical Areas

The pharmacy department will normally prepare all cytotoxic drugs, in line with national guidance. Some Trusts in London also have an out of hours preparation service available (see Appendix 3).

For those Trusts where out of hours pharmacy preparation services are not available, preparation may, in emergencies, be by nursing staff.

The requirement for nursing staff to reconstitute cytotoxic drugs should be negligible, as national guidelines specify that cytotoxic reconstitution should be centralised within a dedicated pharmacy facility.

Only staff trained and assessed as competent can prepare chemotherapy doses safely and will have access to an approved biological safety cabinet or isolator. The isolator used in these circumstances may be in the pharmacy, or in a ward area.

Protective clothing appropriate to the area where the reconstitution is being carried out should be worn. Ward Isolator or biological safety cabinet: An apron and two pairs of gloves are recommended which should ideally be of different materials e.g. vinyl & latex.

Pharmacy: as detailed in pharmacy procedures.

See Appendix 4 for guidelines for nursing staff on the preparation of cytotoxic drugs under these circumstances.

A list of nursing staff assessed as competent to carry out reconstitution of cytotoxic doses must be kept in pharmacy and copies kept by the Lead Chemotherapy Nurse and Lead Clinician for Chemotherapy for the individual Trust.

A record should be kept in the pharmacy department at individual Trusts of all occasions when chemotherapy has had to be prepared out of normal pharmacy hours. Copies of these records should be made available to the Lead Chemotherapy Nurse and the Lead Clinician for Chemotherapy.

3. References

(a) Department of Health, Technical Memorandum 07-01: Safe management of healthcare waste 2013


(c) HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy
4 ADMINISTRATION

A competent practitioner in consultation with the patient should select the most appropriate vascular access device.

The selection of the appropriate route for venous access should be based on the patient’s short – and long-term best interests.

A practitioner skilled in cannulation and/or administration of IV chemotherapy (having been assessed against a venepuncture and cannulation competency programme) is key to preventing infiltration and extravasation (a).

When administering drugs intravenously via a peripheral cannula or Central Venous Access Device (CVAD), the professional must be knowledgeable about:

- Which patients are at risk of infiltration and extravasation
- Sequence of the drugs
- How the rate of administration and route can impact on the risk
- How to prevent extravasation
- How to recognise and manage extravasation should it occur (See section 6).

Cytotoxic drugs should NOT be given if there is any doubt regarding the patency of the venous access device.

4.1 Selection of Device

4.1.1 Peripheral Venous Cannulation (a)

When inserting the cannula, the professional must be knowledgeable about where to site the cannula, which gauge cannula to use (the smallest possible to accommodate the therapy) and general good practice, such as not cannulating directly below a venepuncture site or failed cannulation attempt when administering vesicants (as there can be a leak from the old site) and the purpose of the cannulation. For example:

A large vein is required for high flow rates.

Irritant solutions or drugs require good flow to assist haemodilution.

The most appropriate location for a peripheral cannula is considered to be the forearm, although a large straight vein over the dorsum of the hand is preferable to a small vein in the forearm. The superficial veins of the arm are commonly chosen for the cannulation as they are numerous, easily detectable with wide lumens and thick walls, and the skin is less sensitive. Most common are basilic and cephalic veins.

(a)

Avoid:

- Siting a cannula over a joint, particularly the antecubital fossa, as tissue damage following extravasation in this area has very serious consequences. Therefore the antecubital fossa should never be used for the administration of vesicant or irritant chemotherapy.
- Veins in the lower limbs in adults due to high risk of DVT and increased risk of injury.
- Veins close to arteries or deep lying vessels as accidental puncture can cause painful spasm or prolonged bleeding.
- Areas affected by invading tumour, haematoma, inflamed or sclerosed areas.
• Limbs where there is lymphatic impairment following surgery, chemical occlusion, through drug precipitate, of a vein or radiotherapy even if there is no obvious lymphoedema.
• AV fistulas (Haemodialysis patients) should never be used
• Areas proximal to skin lesions or wounds.
• Use of dominant arm if possible in order to maintain patient mobility and independence.

The following patients are at increased risk of extravasation and extra caution should be taken:
• Elderly patients
• Patients with fragile veins
• Patients with thrombocytopenia
• Paediatric patients

If there are any doubts regarding cannula patency, recannulate the patient.
The use of ported cannulae are not recommended due to their increased infection risk. Site of cannula placement and date should be documented in patient’s records as per local policy. Number and sites of attempted cannulation should also be documented.

4.1.2 Central Venous Access Devices (CVADs)

Where the recipient of therapy has insufficient or unsuitable peripheral veins, infusions are prolonged or venous access becomes difficult, insertion of a central venous catheter may be indicated. Types of CVADs include: peripherally inserted central catheters, skin-tunnelled catheters e.g. Hickman and Groshong and totally implanted vascular access devices (ports)
Central venous access is the route of choice if the drugs or fluids are to be administered over a long duration, if drugs are irritant to the peripheral veins, or have the potential to cause tissue necrosis.
It is often assumed that once a patient has a CVAD in place, extravasation will not be a problem. However, the number of CVAD extravasations is estimated at 3-6% of all extravasations. Although the incidence of extravasation is lower with CVAD’s, detection may be delayed and hence the severity of injury may be greater. (a)
The routine care and maintenance of CVAD should follow local guidelines.

4.2 Sequencing of drugs (a)

Vesicant cytotoxics should always be given before non-vesicant cytotoxic/non cytotoxic drugs. The exception to this is where patients require supportive therapy e.g. pre-hydration and anti-emetics prior to vesicant therapy. If there is any uncertainty around the sequencing of the drugs then advice should be sought from an experienced chemotherapy nurse or pharmacist

4.3 Monitoring (a)

This is the key to early detection of infiltration or extravasation and allergic reaction. The patient and the vascular access device should be monitored frequently before, during and after administration for:
• Leakage at the site.
• Venous irritation.
• Phlebitis.
• Flare reaction.
• Allergic reaction.
• Anaphylaxis.
• Extravasation.
• Known side effects.
The nurse must always confirm patency by ensuring there is blood return and by flushing with at least 5-10 ml of 0.9% sodium chloride before administering any vesicant solution or intravenous medication (b).

Prior to chemotherapy administration it is important to establish that there is a free flowing rapid and consistent drip rate on gravity with a compatible infusion.

Since one of the first symptoms of infiltration or extravasation is discomfort at the site of cannulation or a burning stinging pain, it is important that the nurse explains to the patient, before the first drug is administered, what kind of symptoms to look out for and to report them immediately. Any change in sensation should be verbalised by the patient and checked by the nurse, it may be particularly important to ensure children are able to raise these issues. It may be local irritation and venous spasm, but the early warning provides the opportunity to stop and investigate, and prevent any further leakage of drug into the tissues.

To ensure visibility at all times, an appropriate clear dressing should be fixed over the cannula or CVAD as per local policy. It is important that cannulae and giving sets are secured efficiently to ensure that the cannula does not become dislodged.

Opaque bandages should not routinely be applied to cannula sites when chemotherapy is in progress. With a CVAD it should be possible to obtain blood return. If no blood return is obtained, there must be further verification of the patency of the device, as per local policy.

4.3.1 Stop administration if:

- There is any doubt about the checks that have been carried out. See section 2.2.4 for further information on appropriate checks.
- The patient requests the treatment to stop.
- The patient demonstrates side effects or complications, particularly signs of anaphylaxis or extravasation.
- The equipment fails to function effectively.

4.4 General Principles of Intravenous Administration. (a) (b)

Use of aseptic non-touch technique should be maintained throughout intravenous administration (as per local policy).

Systematic site management (including dressings and cleaning of needle free access devices) should follow local policy.

Ensure appropriate protective clothing is worn as per local policy.

Checking should follow procedure previously described in section 2.2.4. Patient details should be confirmed verbally with the patient/carer, and with their wristband, against the prescription immediately prior to administration by the person giving the treatment.

Maintain a closed system by using luer-lock syringes/connections i.e. needle-free connectors, for the administration of all cytotoxic drugs.

Appropriate needle-less systems must be used, to comply with EU directives.

Check the connections on the giving set for leakage or cracking.

Inspect sealed bags before opening to ensure no spillage has occurred within the bag.

Open the cytotoxic doses directly onto the tray or dressing pack.

Place a sterile gauze swab under the injection port during administration. Administration should be performed over a sterile towel with waterproof backing to protect skin and surfaces from potential cytotoxic leakage.

Do not expel air from syringes. If air is in a syringe, hold it in such a way that the air is up near the plunger when the entire drug is expelled and the air is reached.

Ensure that the giving set is primed with a suitable flushing solution.
Always insert the giving set into the cytotoxic infusion at waist height to minimise the risk of contamination in the event of a spillage. This should be carried out over a clean tray. It is recommended that the bag is in a horizontal position and the port through which the set is placed is not kinked. This reduces the risk of the giving set piercing through the port and causing a leakage.

Ensure correct rate of administration. Refer to the protocol, manufacturers guidelines or seek advice from the Haematology/Oncology Pharmacist.

Flush well between drugs using either sodium chloride 0.9% or 5% glucose, depending on drug compatibility. If in doubt contact pharmacy.

If the drug is prone to photodegradation, ensure that the infusion solution is covered to protect it from light, including the IV line or use an appropriate giving set. See manufacturers’ guidelines and local policy.

Maintain regular observation of IV device sites for signs of swelling or inflammation, the patient for adverse signs and symptoms and the rate of infusion. The frequency of observation will depend on the drug, duration of infusion and clinical condition of patient, and should be agreed locally.

If a special giving set or filter is required, (e.g. paclitaxel), use only those recommended. Failure to use the correct infusion set and/or filter may risk contamination, dose reduction, and adverse clinical event for patient and/or litigation.

It is recommended that units minimise the different types of infusion devices used, to minimise confusion and the potential for error.

Giving sets should be changed every 48 hours, except for patients undergoing high dose chemotherapy, bone marrow or stem cell transplant when giving sets should be changed in compliance with local policy, at least every 96 hours.

On completion of dose administration clear away and dispose of all equipment, waste and sharps as outlined in section 1.8.

Record the administration on the prescription sheet, in the medical, nursing notes, and/ or electronic prescribing system if available.

In the event of an adverse event necessitating an incomplete administration, it should be clearly documented how much of the dose was administered and the reasons for discontinuation of treatment. Medical staff and pharmacy should also be notified. For disposal of part-used doses see section 1.8.4.

4.5 Administration of bolus chemotherapy for adults

Where bolus irritant or vesicant chemotherapy drugs are to be given peripherally to adults – administer the bolus chemotherapy drug via the side arm of a giving set (or equivalent system) via a fast running drip of sodium chloride 0.9% or compatible solution in order to reduce irritation. This is not necessary when being given centrally.

4.6 Administration of bolus chemotherapy for children

Where bolus irritant or vesicant chemotherapy drugs are to be given to children or adolescents - these should be administered as for adults unless it would cause fluid overload. It may then be administered as a bolus directly into the central venous access device or peripheral cannula, followed by a flush of at least 10ml of 0.9% Sodium Chloride or compatible fluid.

Most chemotherapy given to children is administered via a central venous access device. Peripheral cannulae are used very rarely and extreme care must be taken when administering any bolus chemotherapy via this route.
4.7 Administration of Vesicant Drugs

For examples of vesicant drugs see section 6.9.

Ideally vesicants should be given via a newly sited cannula. Ensure that it is patent and bleeds back. Ensure that the drug is reconstituted with the correct solution and dilution. Observe and educate the patient regarding the risks.

Check for blood return every 2-5 ml during administration and before and after each drug during bolus administration.

Doses of vinca alkaloids for all patients treated in dedicated paediatric settings should be administered from syringes as a bolus, regardless of the age of the patient. Giving sets should be flushed with at least 10ml of 0.9% sodium chloride after administration.

Doses of vinca alkaloids for all patients treated in teenage, adolescent or adult settings should be administered from 50ml minibags, over 5-10 minutes, regardless of the age of the patient.

Other vesicants (e.g. paclitaxel, amsacrine, carmustine, dacarbazine and streptozocin) can be administered as an infusion through a peripheral cannula with care and close supervision. These infusions should be given over the shortest duration possible.

Vesicant cytotoxic drugs should be administered before non-vesicants unless the protocol specifies otherwise.

4.8 Administration of Irritant Drugs

For examples of irritant drugs see section 6.9

Use a new cannula if possible. Ensure that it is patent and bleeds back. Ensure that the drug is reconstituted with the correct solution and dilution. Observe and counsel the patient regarding the risks.

4.9 Administration of Non-Vesicant Drugs

For examples of non-vesicant drugs see section 6.9

Use a new cannula if possible. Ensure that it is patent and bleeds back. Ensure the drug is reconstituted with the correct solution and dilution. Observe and counsel the patient regarding the risks.

Non-vesicant infusions should be administered via an infusion pump.
4.10 Subcutaneous / Intramuscular Chemotherapy

A subcutaneous injection is given beneath the epidermis into the fat and connective tissue underlying the dermis.

An intramuscular injection is given into the muscle.

4.10.1 Specific additional equipment

- Personal Protective Equipment
- Sterile dressing pack or sterile field or gauze
- Clean impermeable tray.
- Appropriate size needle for administration (as per local policy).
- Skin cleanser (as per local policy).
- Cytotoxic waste bin.
- Dressing trolley.

4.10.2 Procedure

Ensure consent is obtained prior to procedure
Explain procedure to the patient
Ensure the patient is comfortable and has had specific information regarding their treatment.
Inspect sealed bag before opening to ensure there is no spillage within the bag. Open the bag directly onto the injection tray.
Thoroughly wash hands prior to glove application.
Choose a suitable site for the injection, and prepare the skin as per local policy.
Carefully remove the connector top from the luer-lock syringe and attach appropriate gauge needle.
Ensure needles for administration are secure taking great care to minimise risk of spillage on the skin.
Using a pinch technique for a subcutaneous injection, administer the injection using a 90° angle.
Aspiration is not required prior to the injection.
Administer an intramuscular injection 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.
Remove the syringe and needle, covering the site with low lint gauze and ensuring there is no leakage from the site.
Apply dressing if appropriate.
If further injections are required, rotate the site of administration.
Dispose of all cytotoxic contaminated waste immediately as described in section 1.8.
4.11 Intrapleural Instillation

Following drainage of a pleural effusion, the doctor may wish to instil a cytotoxic drug, into the pleural cavity, via the mechanism used for drainage, i.e. the pleural drain.

4.11.1 Specific additional equipment

- Dressing trolley and dressing pack.
- 10 ml Sodium Chloride 0.9%.
- 10 ml syringe and needles, as required.
- Personal Protective Equipment.
- Chest drain clamp (x2)
- Chemical safety glasses.
- Incontinence sheet (x 2).
- Hypoallergenic tape.
- Cytotoxic waste bin

4.11.2 Procedure

Refer to local policy/guidelines on thoracocentesis (chest drain insertion)
Pre-medication should be administered prior to the pleuradesis procedure, as prescribed.
Explain and discuss the procedure with the patient and ensure that consent has been obtained
Thoroughly wash hands before preparing required equipment.
Ensure patient privacy
Ensure the patient is comfortable.
Advise the patient to report adverse local and systemic symptoms.
Position the patient sitting up, as for drainage of pleural effusion.
Take equipment trolley to the bedside.
Place an incontinence sheet under the patient and another over clothing on the side of the aspiration/instillation.
Thoroughly wash and dry hands prior to glove application. (Refer to local Infection Control Policy).
Ensure protective eyewear is worn.
Open and assemble sterile products and one pair of sterile gloves.
Nursing staff should assist with the administration procedure as required.
The cytotoxic drug should be instilled into the pleural cavity by an appropriately trained and accredited doctor.
The intercostal(s) tube should be clamped for one hour following intrapleural administration of the cytotoxic drug. This prevents the drug from immediately draining back out of the pleural space.
Patient rotation is not necessary after intrapleural administration, except for when talc is used
Following administration by the doctor, ensure the patient has easy access to a call bell and items for the management of potential emesis.
Clamp the drainage tube and wait the prescribed period of time before draining excess fluid.
Record patient’s respiration rate every 15 minutes for 1 hour and then 4 hourly thereafter.
Dispose of all cytotoxic contaminated waste immediately into cytotoxic waste bin.
Wash hands thoroughly after the procedure.
Drain fluid if required and dispose of as “Cytotoxic Waste” (see section 1.8.6).
Intravesical instillation is the administration of cytotoxic drugs directly into the bladder, via a urinary catheter.

4.12.1 Specific additional equipment

- Disposable catheter
- Urinary drainage bag or catheter valve for catheter already in place
- Disposable incontinence pads.
- Cytotoxic waste bin.
- Dressing trolley.
- Personal Protective Equipment
- Catheter packs.
- Clamps

4.12.2 Procedure

This may be done with a disposable catheter or with a catheter already in situ.

Ensure that written consent has been obtained.
Explain the procedure to the patient.
The cytotoxic drug should be instilled by an appropriately trained and accredited doctor or nurse.
Ensure patient privacy.
Ensure the patient is comfortable and has had any specific information regarding their treatment.
Clean dressing trolley with locally approved cleaning solution.
Thoroughly wash hands.
If required, catheter insertion and management of existing catheters should follow local policy and principles of best practice.
Ensure the patient’s bladder is empty prior to the administration of the chemotherapy.
Connect the bladder syringe/urotainer securely to the catheter, release the clamp and instil the drug slowly into the bladder. Rapid instillation can be painful, especially if the bladder wall is scarred from previous surgery.
Carefully check that there are no signs of leakage of drug around the catheter site.
Reclamp the catheter if the catheter is to remain in. Disconnect the syringe / urotainer from the valve using a cotton swab to absorb any drops left on the end of the valve.
Remove temporary catheter with syringe / urotainer attached and dispose of as cytotoxic waste (see section 1.8)
If a drainage bag is being used, connect this to the valve but do not open the valve, to allow retention of the drug within the bladder for at least one hour.
Clear away all contaminated disposables. (see section 1.8)
Ensure the comfort of the patient, assisting him/her to reposition themselves and ensure they have easy access to a call bell. Encourage the patient to walk about if able or to turn from side to side in bed.
Advise the patient of the need to retain the drug for one to two hours if possible. If the patient has an urge to void or if the catheter is bypassing, it will be necessary to open the valve before the allotted time.
If catheter in situ after one to two hours: Wash hands thoroughly before putting on disposable gloves.
Attach a urine drainage bag. Unclamp the catheter and allow drainage of the bladder contents into the drainage bag for 15 minutes.
Remove the drainage bag and connect a new one if the catheter is to remain in situ, as per local policy. The contents of the drainage bag (drug and urine) should be emptied into a sluice followed by two flushes. A strong bleach based detergent should be poured into the sluice after voiding, for patients who have received BCG therapy. The bag should then be disposed of as cytotoxic waste. If a temporary catheter was used the patient should void directly into the toilet. Men should sit down to avoid splashing.

Advise patients to wash genitalia thoroughly to minimise potential skin irritation from contact with cytotoxic drugs.

Dispose of all cytotoxic contaminated waste immediately as described in section 1.8.

4.13 Intraperitoneal Instillation (a)

Following drainage of the peritoneum, the doctor may wish to instil a cytotoxic drug(s) into the peritoneal cavity, via the mechanism used for drainage.

4.13.1 Specific Additional Equipment.

- Dressing trolley and dressing pack.
- 10 ml Sodium Chloride 0.9%.
- 10 ml syringe and needles, as required.
- Personal protective equipment (disposable apron, sterile gloves).
- Chemical safety glasses.
- Incontinence sheet (x 2).
- Clamp for catheter
- Catheter drainage bag (if catheter to remain in situ)
- Syringe or infusion bag containing prescribed chemotherapy agent
- Hypoallergenic tape.

4.13.2 Procedure.

See local policy/guidelines on abdominal paracentesis (drainage of ascites).
Explain and discuss the procedure with the patient and ensure that consent has been obtained
Ensure patient privacy
Position the patient and ensure they are comfortable.
Thoroughly wash hands.
Advise the patient to report any adverse local and systemic symptoms.
Position the patient supine with one or two pillows and with the peritoneal access site exposed.
Check all the details on the cytotoxic drug against the patients prescription.
Take cytotoxic drug, necessary equipment and trolley to the bedside.
Prior to instillation pre-warm infusate to body temperature
Place an incontinence sheet under the patient and another over clothing on the side of the aspiration/instillation.
Thoroughly wash and dry hands prior to glove application. (Refer to local Infection Control Policy).
Ensure personal protective equipment including protective eyewear is worn.
Open and assemble sterile products and one pair of sterile gloves.
The cytotoxic drug should be instilled into the peritoneal cavity by an appropriately trained and accredited doctor. Nursing staff should assist with the administration procedure as required. Following administration by the doctor, ensure patient has easy access to call bell and items for the management of potential emesis. Dispose of all cytotoxic contaminated waste immediately into cytotoxic waste bin. Wash hands thoroughly after the procedure. Clamp the drainage tube and wait the prescribed period of time before draining excess fluid. To ensure the drug comes into contact with the entire peritoneal cavity, turn the patient as follows: Lay on left side. Lay on the back. Lay on the right side. Lay on the front. The duration in each position should be 15 minutes, unless otherwise prescribed. Wash hands thoroughly after the procedure. Observe the patient regularly for comfort. Monitor temperature 4hourly. Drain fluid if required and dispose of as “Cytotoxic Waste” (see section 1.8.6).

4.14 Administration of Chemoembolisation

Chemoembolisation is a combination of local delivery of chemotherapy and a procedure called embolisation to treat cancer, most often of the liver.

4.14.1 Specific additional equipment

- This procedure is undertaken as a sterile procedure and will require the same standard as a theatre. It should be undertaken in a dedicated radiology room with the appropriate scanning equipment.
- All the products used for the procedure will be fit for purpose and ordered appropriately.
- As there is a risk of chemotherapy spray during this procedure, it is important that all staff in the facility protect themselves from chemotherapy spills. Visors and other protective equipment such as a sterile gown that is not made from a semi permeable material should be used.

4.14.2 Procedure

In chemoembolisation, anti-cancer drugs are injected directly into a cancerous tumor. In addition, synthetic material called an embolic agent is placed inside the blood vessels that supply blood to the tumor, in effect trapping the chemotherapy in the tumor. This procedure is undertaken in tertiary referral centres who have dedicated teams and expertise to care for patients requiring this procedure.

Only a designated Consultant or Senior Specialist Registrar experienced in this procedure should prescribe chemoembolisation. Written consent should be sort prior to the procedure. Chemoembolisation can only be carried out by, or under the direct supervision of, a designated trained Consultant Radiologist who has expertise in the technique and understands the safe handling of cytotoxic drugs.
The cytotoxic drugs that are usually used in the procedure are doxorubicin or epirubicin, usually in an emulsion with Lipiodol, and cisplatin (without Lipiodol). As the shelf life of the cytotoxic preparation is relatively short, planning and co-ordination with the pharmacy department is essential.

Loose connections could cause potential chemotherapy spray as the drug is administered at high pressure; therefore all connections must be checked prior to the administration taking place. The procedure should follow locally agreed policies. A risk assessment should also be undertaken on an annual basis as well as retraining of staff to ensure clinical governance is met.

Once the procedure has taken place, the patient is moved to a dedicated ward for careful monitoring for up to five days. Under no circumstances should the patient be nursed on a general ward.

4.15 Administration of Topical Cytotoxic Chemotherapy (a)

Topical application is the administration of creams, or ointments, or gels containing cytotoxic drugs. Cytotoxic drugs for topical administration may come in a number of different formulations, including creams, ointments, gels and solutions. Topical cytotoxic drugs may be applied either directly to the skin or as ear or eye drops.

4.15.1 Specific Additional Equipment.

- A clean tray.
- Sterile dressing pack.
- Clinical waste bag. Cytotoxic sharps bin.
- Gloves.
- Apron.
- Gauze.
- Cotton wool and cotton tipped applicators.
- 10ml water for injection and dropper (for eardrop application)

NB: Other additional equipment may be required depending on the specific method of topical administration.

4.15.2 Procedure for Topical Application of Cytotoxic Creams, Ointments, or Gels

Ensure consent is obtained prior to procedure

Explain procedure to the patient

Ensure the patient is comfortable and has had specific information regarding their treatment.

Wash hands before preparing the required equipment

Wash the affected area on the skin with mild soap and dry thoroughly before the application.

Thoroughly wash and dry hands (Refer to local Infection Control Policy).

Put on gloves and protective apron.

Apply the preparation (cream, ointment or gel) using gloved fingertips, cotton wool or cotton tipped applicators.

Unless directed otherwise, apply the cytotoxic preparation to the affected area only.

Avoid contact with the eyes, nose, mouth or areas close to mucous membranes.

If the preparation comes into contact with unaffected skin, wipe the area with gauze and warm soapy water.

If the preparation is to be applied to the entire body, use gauze. Apply the preparation more lightly to the groin, armpits, inside bends of elbows, and backs of knees because of the increased risk of dermatitis.

Do not cover the skin with a dressing, unless specifically advised to do so.
If necessary, after the required contact time, the preparation should be rinsed off the area carefully. If the preparation has been applied to a large area, the patient should be advised to have a shower, rather than a bath, to ensure that they do not sit in bath water that contains drug residue. Once the drug has been showered off, the patient can have a bath if desired.

Once the application is completed, dispose of all cytotoxic contaminated waste immediately into cytotoxic waste bin as outlined in section 1.8. Wash hands thoroughly after the procedure.

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 as the drug dose, or frequency, may need to be reduced on subsequent applications.

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. There are not usually any systemic side effects of the drug unless the majority of the skin is being treated.

If treatment is to be continued at home, ensure that the patient/carer is provided with appropriate information concerning the application of the preparation, handling and disposal instructions (see Appendix 1) and details of obtaining further medicine supplies if needed.

4.16 Administration of Cytotoxic Solutions as Ear Drops (a)

Very rarely, solutions of cytotoxic drugs may be administered as ear drops. Chlormethine (mustine) has been shown to be effective when applied directly into the ear for involvement of the external auditory canal in Langerhans Cell Histiocytosis.

Only a designated consultant or senior Specialist Registrar who is experienced in administration of chemotherapy via this route should prescribe chemotherapy for treatment. Chemotherapy administered via this route can only be carried out by, or under the direct supervision of a designated trained Consultant or Specialist Registrar who has expertise in the technique and understands the safe handling of cytotoxic drugs.

4.17 Carmustine Implantation (Gliadel Wafers).

Carmustine implant (Gliadel Wafer) is a biodegradable wafer that is implanted into the resection cavity at the time of surgery for malignant glioma or glioblastoma multiforme which have returned, and delivers carmustine chemotherapy directly into the tumour site.

The procedure should only be carried out by experienced neurosurgeons.

All theatre staff must be aware of the relevant health and safety procedures around safe handling and disposal of cytotoxic waste.

4 References


5 SCALP COOLING

Alopecia is a common side effect of many cytotoxic drugs and can be the most distressing side effects for both men and women (a).

Scalp cooling is not appropriate for all patients, regimens or diagnoses (b).

5.1 The use of scalp cooling for the prevention of chemotherapy induced alopecia

The most common method of preventing alopecia is by scalp cooling (c) (g) (j)

This works in 3 ways
- Reduction of perfusion of hair follicles by vasoconstriction decreasing scalp blood flow
- Reduction of temperature dependant cellular uptake of chemotherapy
- Reduction of intra-follicular metabolic rate

5.2 Scalp cooling should not be offered to

- Patients with haematological diseases
- Patients with gestational trophoblastic disease
- Patients with germ cell tumours
- Patients receiving drugs that cause hair loss where there is no evidence for the effectiveness of scalp cooling
- Patients who have already received a first course of chemotherapy and who declined scalp cooling

5.3 Indications for scalp cooling

Scalp cooling may be offered to patients (male and female) who have solid tumours such as breast cancer, who are receiving the following drugs as single agents or in combinations:

a. Doxorubicin (d) (e)
b. Epirubicin (f) (i)
c. Docetaxel (h) (i)
d. Paclitaxel (j)

The drugs listed above are the only drugs where research has been performed and has shown that scalp cooling is effective

5.4 Scalp cooling Procedure

There are a variety of scalp cooling machines available and the procedure should be carried out according to the individual manufacturer’s information. All staff responsible for using the scalp cooling equipment must be trained in the use of the individual equipment.
Following an explanation of the procedure along with the degree of success that the patient may expect, the nurse should obtain a verbal consent from the patient. The patient should understand that s/he could withdraw at any stage. It should be documented in the patient notes or care plan that the patient is undergoing scalp cooling in order to facilitate continuity of care.

Staff should ensure that the patient understands that in order for scalp cooling to continue to work they must undergo the procedure with every course of chemotherapy and that if they choose to discontinue the procedure, then they will lose their hair. The suitability of continuing scalp cooling should be discussed at each visit. This is particularly relevant in patients who in spite of severe patchy hair loss may wish to continue. They should be informed of the risk of ice burns and that the thickness of padding used to protect from ice burns may reduce the effectiveness of cooling.

All caps should be cleaned using soap and water or wiped with a detergent wipe after each use.

5. References


(c) David J, Speechley V. Scalp cooling to prevent alopecia. Nurs. Times 83(32), 36-37 (1987)


(e) Semsek D. Scalp hypothermia for 3 hours reduces alopecia after anthacycline based chemotherapy. Ann. Oncol. 11(Suppl.4), 154 (2000)


(g) Adams L et al. The prevention of hair loss from chemotherapy by the use of cold air scalp cooling. Eur.J.Cancer Care 1(5), 16-18 (1992)


EXTRAVASATION

This section is to provide clear and concise guidelines on how to minimise the risk of an infiltration or extravasation injury when administering cytotoxic drugs, and to provide guidance on the management of these injuries.

6.1 Definitions

Extravasation
This is the inadvertent leakage of a vesicant solution from the vein into surrounding tissue which can lead to tissue necrosis (a).

Infiltration
This is the inadvertent administration of non-vesicant solutions or medications into the surrounding tissues. Although the solutions themselves cannot cause damage to the tissues, if the volume of fluid is large, the swelling can caused nerve or venous compression. The site must therefore be observed, the degree of swelling documented and significant symptoms, such as numbness or loss of sensation or mobility in the affected area or limb, treated accordingly (b).

Chemical Phlebitis/Venous Irritation
Phlebitis is the inflammation of the tunica intima (innermost layer) of the vein, and is recognised as a marked inflammation along the length of the vein. This can be painful for the patient causing a burning sensation or generalised pain in the affected area. There are three types of phlebitis; mechanical, chemical and infective. In terms of chemical the causative factors can be the pH of the drug, or the concentration.

Induration
The hardening of a normally soft tissue or organ, especially the skin, caused by inflammation, infiltration or fluid.

Venous Flare Reaction
This is a localised inflammatory response characterised by a localised erythema (redness), venous streaking and pruritis (itching) along the pathway of the injected vein. Sometimes described as ‘nettle rash’, it is not usually painful; it generally occurs with anthracyclines and will settle spontaneously (b).

Venous Spasm
This refers to the sudden spasm of the vein causing vasoconstriction. It does not usually cause pain or local irritation, but can be recognised by the loss of blood return during the administration procedure. It is usually caused by local irritation of the vein, drug pH or temperature, and will happen immediately after injection of the medication (b).
Neutral agent, Group 1
Inert or neutral compounds that do not cause inflammation or
damage

Inflammatory agent, Group 2
Capable of causing mild to moderate inflammation and flare in local
tissues

Irritant agent, Group 3
Capable of causing inflammation and irritation

Exfoliant agent, Group 4
Capable of causing inflammation and shedding of skin

Vesicant agent, Group 5
Capable of causing pain, blistering, and inflammation of the local skin, underlying flesh and structures, leading to
tissue death and necrosis

6.2 Duties & Responsibilities
Nurse and medical managers of staff working in clinical areas administering the drugs discussed in this guidance must ensure their staff are aware of their responsibilities to the patient in the event of an infiltration or extravasation injury.

All staff trained in managing infiltration and extravasation injury will be expected to follow the guidance set out in this document, supported by local hospital policy. Any incident involving an intravenous drug that is not covered by these guidelines or a local hospital policy should be discussed with a member of the cancer clinical pharmacy team to determine the safest and most appropriate course of action for the patient.

The team involved in managing an extravasation; the chemotherapy nurse, CNS, oncologist/haematologist, Cancer Nurse Specialist includes referral to Plastic surgery but other specialists may be required if the extravasation is severe e.g. Intensive Care, Vascular surgery, Orthopaedics.

All staff involved in administering intravenous and cytotoxic medication must have undertaken appropriate training, and receive annual updates of their skills and competence.

All infiltration and extravasation injuries must be reported via the hospitals incident reporting system.
6.3 Risk assessment and prevention

Each administration of an intravenous solution or drug should be risk assessed by the individual performing the procedure to ensure that all necessary precautions have been taken to ensure the patients safety, reducing the risk of infiltration or extravasation injury.

Patients may hesitate in reporting sudden infusion related symptoms for many reasons including wanting to be seen as a ‘good’ patient, anxiety and fear, cultural reasons, or differences in how they express reports of pain. Assessing the most appropriate way for the patient to communicate with you during the procedure must be considered.

- **Age**: Young children and the older persons may need similar issues considering before administration of their intravenous therapy:
  - Communication: They may not be able to understand the implications of the procedure, so may not be able to communicate the key symptoms of pain or discomfort.
  - Language barriers: if English is not the first language for the patient, ensure they have adequate interpreting services during the procedure.
  - Venous integrity: the very young and elderly have more fragile veins and skin.
  - Compliance: young children may find sitting still difficult, and an elderly patient may be confused or agitated.

- **Medical history**: Cancer patients may have additional risks due to the following:
  - Poor peripheral access; fragile veins, lack of available veins due to previous intensive drug therapy.
  - Multiple venepuncture sites above potential cannulation points.
  - Lymphodema of limbs.
  - Previous lymph node excision, reducing cannulation options.
  - Radiation recall phenomenon, possible in patients recently treated with radiotherapy.
  - Previous sites of infiltration or extravasation injury.
  - Compromised circulation.
  - Altered sensory perception.
  - Unconscious patients.
Intravenous device issues: The method of drug administration is important to consider for each patient as each peripheral or central access device will have associated risk factors. Each patient should have an assessment of their venous access made to ensure the most appropriate device is used.

Peripheral access:

- The importance of skilled cannulation and administration techniques is paramount in preventing extravasation. Only appropriately trained staff should cannulate the patient, and administer systemic cytotoxic drugs.
- Avoid cannula placement over bony prominences, the antecubital fossa, around the wrist or the dorsum of the foot or ankle.
- Avoid small and fragile veins.
- Ideally, vesicants should not be administered into a cannula placed for another purpose in case phlebitis has occurred.
- ‘Butterfly’ devices with metal needles must not be used to administer any intravenous medication. Only plastic cannulas should be used to reduce the risk of extravasation injury.
- All devices placed must be adequately secured with dedicated intravenous dressings.
- Avoid multiple venepunctures to the same vein. If it is necessary to do so, the principle of starting distally and proceeding proximally must be adhered to.
- Consider if a patient has blood sampling or a cannula removed proximal to the chosen cannulation point as cannulation for vesicant administration should be avoided below these points for at least 24 hours.
- It is recommended that, where possible, vesicants are delivered via a new cannula and that consideration is given to changing the cannula after 24 hours, if to continue with vesicants.

Central access devices:

- Ensure good venous return before using the device.
- For implanted ports, ensure the port access needle is the right length and completely advanced into the port. Ensure the needle is adequately secured.
- Do not use less than a 10ml syringe due to the risk of catheter damage caused by increased pressure on the device.
- Vesicants administered centrally can be administered via an infusion pump.
● Agent related: Considering the classification of drug(s) to be administered will influence the method and sequence in which the drugs are given to optimise safety.

  ○ Vesicant potential.

  ○ Volume required to administer cytotoxic drug.

  ○ Drug concentrations; drugs must not be reconstituted to give solutions in higher concentrations than that recommended by the manufacturer. For any advice relating to this issue, contact your area's cancer pharmacist.

  ○ The need to use the same vein for vesicant administration. May need to consider central access alternative.

  ○ Ensure all anti-emetics given before any cytotoxic chemotherapy. Vesicant drugs should then be given before non-vesicants when the veins integrity is at its greatest. The exception to this will be if patients require hydration prior to their other drugs. Ensure increased monitoring if a peripheral access device has been heavily used for pre medication and hydration prior to vesicant administration.

● Clinician related risks: All individuals administering any intravenous medication and/or cytotoxic medication must have appropriate training.

  ○ Ensure adequate knowledge and skills to complete drug administration safely.

  ○ Ensure adequate ability to manage intravenous access device.

● Environment: It is important to ensure the area where the drugs are administered is suitable for such tasks.

  ○ It must have appropriate emergency equipment to manage the potential risks associated with drug administration including extravasation, spillage drug reaction, and cardiac arrest.

  ○ Have suitable treatment areas to allow staff to administer the drugs with minimal interruptions.

  ○ Ability to give vesicant drugs within working hours, 09.00 – 18.00. The exception will be vesicant infusions running via a central venous access device over a 24 hour period, or in an emergency e.g. some haematology patients. Vesicants must never be administered subcutaneously.
6.4 Patient education \(^{(m)}\)

Patients must be informed about the risk of extravasation prior to the procedure, and asked to report any change in sensation at the intravenous site, especially pain or a burning sensation during administration.

See Administration section 4 regarding the administration of cytotoxic drugs.

6.5 Signs and Symptoms \(^{(c)}\) \(^{(g)}\)

Extravasation should be suspected if one or more of the following symptoms occur:

- Burning, stinging, or any discomfort at the injection site.
- Swelling, redness or blistering at the injection site.
- Resistance is felt on the plunger of the syringe of a bolus injection.
- Absence of free flow of an infusion during drug administration.
- No blood return is obtained. If found in isolation this is not necessarily a sign of extravasation. It may be appropriate to consider in this instance whether it is safe to administer a vesicant drug.
6.6 Immediate management

IMMEDIATE ACTION FOR ALL DRUG CATEGORIES
(Peripheral Cannulae)

STOP the infusion / injection, disconnect drip. DO NOT REMOVE THE CANNULA

Inform and reassure the patient

Put on protective clothing required.
Aspirate back as much of the drug as possible from the cannula

Inform a senior member of nursing and/or medical staff

REMOVE THE CANNULA

Mark the extravasation area with a pen, take a digital image if possible, and apply a non-adhesive dressing

The Flush out technique should be considered for all vesicant extravasations, or following discussion with a plastic surgeon for large volumes of irritant extravasations

Timely access to healthcare professionals trained in the flush-out technique e.g. plastic surgeon, chemotherapy nurse

Yes

Plastic surgeon, nurse or other trained healthcare professional performs flush out

Follow up with plastic surgeon

No

Antidotes as per Local policy

Inform the patient’s oncologist / haematologist of the subsequent treatment plan

Complete required documentation
IMMEDIATE ACTION FOR ALL DRUG CATEGORIES
(CENTRAL VENOUS ACCESS DEVICES)

STOP the infusion immediately. Leave the central venous access device in place

- Inform and reassure the patient
- Put on protective clothing required.
- Attempt to aspirate as much drug as possible from the central venous access device
  - For implanted ports, aspirate then remove the needle
  - For PICC or other tunnelled devices monitor for subcutaneous extravasation
- Inform a senior member of nursing and/or medical staff
- Discuss options for device removal

Mark the extravasation area with a pen, take a digital image if possible
Plastic surgeon, nurse or other trained healthcare professional performs flush out

The Flush out technique should be considered for all vesicant extravasations, or following discussion with a plastic surgeon for large volumes of irritant extravasations

Timely access to healthcare professionals trained in the flush-out technique
- e.g. plastic surgeon, chemotherapy nurse

Yes     No

Plastic surgeon, nurse or other trained healthcare professional performs flush out
Antidotes as per Local policy

Follow up with plastic surgeon

Inform the patient’s oncologist / haematologist of the subsequent treatment plan

Complete required documentation
6.7  Plastic Surgery Intervention including the Flush Out Technique (o)

In cancer centres / units where plastic surgery facilities are available on-site it is recommended that the patient is referred for plastic surgery opinion as soon as is practicably possible after the detection of a vesicant extravasation or large volumes of irritant drugs. Intervention by a plastic surgeon at this point, to perform the flush out technique, may enable removal of a significant proportion of the cytotoxic residue from the subcutaneous tissue.

In some Trusts nurses and doctors other than plastic surgeons are trained to carry out this procedure.

Only appropriately trained doctors or nurses may perform the flush-out technique for superficial peripheral extravasations where there is no visible skin damage or extensive swelling.

All patients who have undergone the flush out procedure should be reviewed within 24 hours of the procedure being carried out by a senior member of their team, and regularly thereafter.

6.8  Subsequent Management of Extravasation (b)

Peripheral AND central access devices

- Assess the likelihood of soft tissue injury by referring to the table of vesicant drugs, see section 6.9. If the drug is not listed, confirm its classification with pharmacy.
- If multiple drugs were infusing, treat the extravasation as for the most vesicant agent.
- Encourage gentle movement of affected limb or area.
- Monitor the site daily for pain, erythema, skin changes and necrosis.
- Arrange for a photograph to be taken if necessary, when extravasation is first suspected and at each stage of follow up, in compliance with local governance arrangements. Copies should be filed in the patient’s medical notes.
- Consider the prescription of analgesics on a prn basis if required.
- An information leaflet on extravasation should be given to the patient.
  See examples in Appendix 5

Ensure that the used extravasation kit is immediately replaced.
6.8.1 Vesicant drugs, Group 5

Extravasation of a vesicant drug is very serious as it can result in tissue necrosis and loss of limb function.

Management of the extravasation of vesicant drugs is centred on minimising the damage caused by the drug as well as reducing any inflammation, pain and discomfort.

6.8.2 Neutral, inflammatory, Irritant and exfoliant drugs, Groups 1, 2, 3 & 4

These drugs may cause mild to moderate inflammation, irritation, discomfort and pain but are unlikely to result in tissue breakdown.

If multiple drugs were infusing, treat the extravasation as for the most irritant agent.

Management of the extravasation of irritant and non-vesicant drugs is centred on reducing any inflammation, pain and discomfort. The following treatment plan should be adhered to:

- Encourage movement of the limb.
- Provide the patient with an extravasation patient information leaflet. See example in Appendix D
- Supply a tube of hydrocortisone cream 1% from the extravasation kit and ask the patient to apply it twice daily to affected area to reduce further inflammation.
- Supply or administration of medicines used to treat patients with extravasation must comply with the governance processes within the relevant hospital, i.e. by prescription or by Patient Group Directives (PGD).
- Provide advice regarding pain relief and supply analgesia to the patient if necessary.
- Complete all necessary extravasation documentation as outlined in section 6.10 of this policy.
6.8.3 Use of antidotes and hot or cold packs

The flush-out technique for the removal of extravasation fluid should be considered before the use of antidotes.

The use of antidotes to treat vesicant extravasations should be considered in the following circumstances:

- Following consultation with a plastic surgeon and/or extravasation team or if recommended by local Trust policy.
- Where plastic surgery advice or intervention is not possible, e.g. acutely sick in-patient that cannot be transferred. In this instance seek advice from your specialist cancer pharmacist regarding treatment options.

The extravasation should be managed according to the size and location of the affected area and the classification of cytotoxic agent involved. If a large volume extravasation has occurred as much fluid as possible should be aspirated. Please note; it may not be possible to aspirate any fluid.

Individual hospital guidelines should contain details of the individual management of vesicant extravasations, including details of any recommended antidotes.

Individual hospital guidelines should also indicate whether hot or cold packs should be used with or without the antidotes for specific drugs.

- **Localise using** cold pack to limit the spread of the infiltration/extravasation, as per local policy.
- **Disperse using** warm pack to promote vasodilation and encourage blood flow in the surrounding tissue, therefore dispersing the infiltration/extravasation away from the area affected, and decreasing local effects, as per local policy.

In the event that an antidote is to be used, this must be prescribed by the oncologist or haematologist reviewing the patient or under a PGD on a standard hospital prescription chart, and where applicable on a discharge summary or outpatient prescription.
### 6.9 Classification of cytotoxic drugs

Classification of **cytotoxic** drugs according to their ability to cause tissue damage and/or necrosis if infiltration or extravasation occurs:

- **(d)** infiltration
- **(f)** extravasation

**FOR NEW OR TRIAL DRUG NOT LISTED, PLEASE CONTACT YOUR CANCER PHARMACIST TO DISCUSS A RISK ASSESSMENT AND MANAGEMENT STRATEGY**

<table>
<thead>
<tr>
<th>Neutrals (Group 1)</th>
<th>Inflammatory agents (Group 2)</th>
<th>Irritants (Group 3)</th>
<th>Exfoliants (Group 4)</th>
<th>Vesicants (Group 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asparaginase ☐</td>
<td>Fluorouracil ≠</td>
<td>Carboplatin ≠</td>
<td>Aclarubicin ≠</td>
<td>Amsacrine ≠</td>
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<tr>
<td>Bevacizumab ☐</td>
<td>Methotrexate ≠</td>
<td>Etoposide ≠</td>
<td>Cisplatin ≠</td>
<td>Cabazetaxel ≠</td>
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<tr>
<td>Bleomycin ☐</td>
<td>Raltitrexed ≠</td>
<td>Irinotecan ≠</td>
<td>Bendamustine ≠</td>
<td>Carmustine ≠</td>
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<tr>
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<td></td>
<td>Temsirolimus ≠</td>
<td>Docetaxel ≠</td>
<td>Dacarbazine ≠</td>
</tr>
<tr>
<td>Cetuximab ☐</td>
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<td>Teniposide ≠</td>
<td>Liposomal Daunorubicin ≠</td>
<td>Dactinomycin≠</td>
</tr>
<tr>
<td>Cladribine ☐</td>
<td></td>
<td></td>
<td>Liposomal</td>
<td>Daunorubicin ≠</td>
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<td></td>
<td>Eribulin ≠</td>
<td>Idarubicin ≠</td>
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<td></td>
<td>Gemcitabine ☐</td>
<td>Mitomycin ≠</td>
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<tr>
<td>Eribulin ☐</td>
<td></td>
<td></td>
<td>Ifosfamide ☐</td>
<td>Mitozantrone ≠</td>
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<tr>
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<td></td>
<td>Interleukin 2 ☐</td>
<td>Mustine(Chlormethine) ≠</td>
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<td></td>
<td></td>
<td>Melphalan ☐</td>
<td>Paclitaxel ☐</td>
</tr>
<tr>
<td>Interleukin 2 ☐</td>
<td></td>
<td></td>
<td>Pemetrexed ☐</td>
<td>Streptozocin ≠</td>
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<tr>
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<td></td>
<td></td>
<td>Pentostatin ☐</td>
<td>Trabectedin ≠</td>
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<tr>
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<td></td>
<td>Rituximab ☐</td>
<td>Trastuzumab ≠</td>
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<td>Rituximab ☐</td>
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<td>Thiotepa ☐</td>
<td>Vinblatine ☩</td>
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<tr>
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<td></td>
<td>Trastuzumab ☐</td>
<td>Vincristine ☩</td>
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<tr>
<td>α-interferons ☐</td>
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<td></td>
<td>α-interferons ☐</td>
<td>Vinorelbine ☩</td>
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<tr>
<td>Iodinated Contrast Medium ☒</td>
<td></td>
<td></td>
<td>Iodinated Contrast Medium ☒</td>
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</tbody>
</table>

Ostensibly inert or neutral compounds that do not cause inflammation or damage.

| Capable of causing mild to moderate inflammation and flare in local tissues. | Capable of causing inflammation and irritation. | Capable of causing inflammation and shedding of skin. | Capable of causing pain, inflammation and blistering of the local skin, underlying flesh and structures, leading to tissue death and necrosis. |

**Key:**

- ☒ Cover extravasation site with a heat pad
- ≠ Cover extravasation site with an ice pack
6.10 Documentation

See Appendix 6 for an extravasation patient management flow chart and other examples of documentation.

In the event of an extravasation the following documentation must be completed:

- A local hospital incident form must be completed with all details related to the extravasation, including the number of attempts to aspirate extravasation drug.
- Any documentation used at individual trusts for the follow up and monitoring of extravasation injuries should be completed.
- Patients should be given an information leaflet to explain the management of their extravasation. See example in Appendix 5.
- It is important that the patient’s next review is recorded in their healthcare record. See examples in Appendix 6.
6. References


(d) Electronic Medicines Compendium Link: www.medicines.org.uk/emc

(e) Parsons R. M. Extravasation policy for all drugs, chemotherapy & non-chemotherapy, (2008), NHS Tayside.


(h) Bharkhada, D. Guideline for management of extravasation, (2011), East Midlands Strategic Clinical Networks

(i) Harrold K. Management of Extravasation of Cytotoxic Chemotherapy from a Peripheral or Centrally Inserted Device (CVAD), (2011), Mount Vernon Cancer Network.

(j) Managing an extravasation procedure (2013). Cardiff and Vale University Health Board.


(m) Schulmeister L. Vesicant chemotherapy – the management of extravasation, Cancer Nursing Practice 8(3) (2009).


APPENDIX 1

ADVICE FOR PATIENTS AND CARERS FOR THE DISPOSAL OF CYTOTOXIC WASTE AND MANAGEMENT OF CYTOTOXIC SPILLAGES IN THE HOME.

This leaflet contains the answers to some questions patients and carers may have about the disposal of cytotoxic waste and the management of a cytotoxic spillage in the home.

GENERAL INFORMATION

- Keep all cytotoxic medication in a safe place according to the storage instructions on the product label (refrigerator or at room temperature).
- Ensure that all medicines, administration equipment and sharps bins are out of the reach of children or pets.
- If you are the carer, and are pregnant, think you may be pregnant or are breast feeding, it is preferable that you do not handle cytotoxic drugs, or waste, unless absolutely necessary.
- Always wash your hands thoroughly after handling cytotoxic drugs or waste,

DISPOSAL OF CYTOTOXIC WASTE

How should I dispose of empty medicine containers/bottles?

- Empty chemotherapy medicine bottles, cartons, tubes or ointment jars can be thrown away in household waste. Put lids / caps on the containers before discarding.
- Medicine spoons, syringes and cups used to give oral chemotherapy should be washed and discarded in household waste after the course of treatment has been completed.

How should I dispose of intravenous infusion devices/bags and/or syringes?

- Empty infusion devices, bags or syringes that are used for the administration of cytotoxic drugs should be disposed of in a ‘sharps bins’. These bins are available from the hospital.
- Once the sharps bin is ‘three-quarter’ full, it should be sealed and returned to the hospital ward/clinic on your next visit.

What should I do with unused cytotoxic medicines?

- All unused cytotoxic medication (tablets, capsules, oral liquids, ointments, infusors, and syringes for intravenous administration) should be returned to the hospital pharmacy department, or ward/clinic. They should NOT be flushed down the toilet or thrown away in household waste

How should body fluids be disposed of?

- Urine, stools and vomit can contain cytotoxic drugs, or their breakdown products, for as long as seven days after a patient has received treatment.
- Therefore, it is important that patients/carers wear gloves when handling urine, stools, vomit, contaminated bed linen and nappies for seven days following treatment. You should either use the gloves provided by the hospital, or a pair of rubber household gloves kept especially for this
• Gloves should be changed immediately if torn or contaminated.
• The contents of vomit bowls/bedpan/urinals should be flushed down the toilet. Any disposable containers should then be double bagged and disposed of in the household waste. Non-disposable containers should be washed thoroughly in warm soapy water.
• Nappies and gloves should be double bagged and disposed of in the household waste.
• Contaminated bed linen and clothes should be washed separately to other items (as outlined in the spillage section).

MANAGEMENT OF LIQUID CYTOTOXIC SPILLAGES

General Information
• Any liquid spillages of cytotoxic drugs onto the floor, or on your clothes or skin should be dealt with immediately to minimise potential harm to yourself or other people.
• You must wear gloves when dealing with a chemotherapy spillage. Make sure that they are not damaged, torn or split. Keep a separate pair of gloves for dealing with a spillage and an extra pair in case the other ones get damaged. If you have been provided with a spillage kit, use the contents of the kit for a large spillage.
• Remember to inform a health care professional as soon as possible that you have had a spillage so that replacement medication can be arranged if necessary.

What should I do if there is a cytotoxic spillage on work surfaces, furniture or floors?
• Cover the spillage using absorbent paper towels, and ensure that all the liquid has been mopped up. The work surface, furniture or floor should then be wiped clean using warm soapy water (i.e. washing up detergent) as soon as possible. This should be repeated.
• All used absorbent towels should be double-bagged in plastic bags and then disposed of in household waste.
• If you have been provided with a home spillage kit, follow the instructions in this.

How should I deal with a cytotoxic spillage onto the skin?
• Wash the area with plenty of tap water. This should then be repeated using warm soapy water, and the area gently dried.
• Do not apply any moisturising cream or hand cream on the affected area.
• If redness or irritation lasts for longer than a few hours, contact your GP or ward/clinic.

How should I deal with a cytotoxic spillage in the eyes?
• Immediately flush the eyes and the surrounding areas with large volumes of cool tap water. This should be done for at least ten minutes.
• Go to your nearest Casualty Department as it is important that you seek medical attention for any spillages into the eye.

How should I deal with a cytotoxic spillage onto clothing/bed linen etc?
• Wearing a pair of gloves, blot dry with a paper towel and remove the contaminated clothing immediately.
• The clothes/linen should be washed separately from other clothing as soon as possible. Where possible, repeat the wash cycle to ensure all drugs are completely removed.
• If the drug has soaked through the clothes to the skin, this should be dealt with as outlined above.
If you are in any doubt, please contact your clinical area where you are receiving treatment.

24 hour contact number..................................................................................................

(Individual areas to complete)
## APPENDIX 2
Pharmacy Cytotoxic reconstitution unit opening hours, including Out of Hours arrangements for preparation of chemotherapy

### LONDON CANCER

#### North East

<table>
<thead>
<tr>
<th>TRUST</th>
<th>Opening hours</th>
<th>Comments</th>
<th>Out of hours provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barking, Havering &amp; Redbridge University Hospitals NHS Trust</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not available out of hours. In an emergency the on call pharmacist should be contacted via the hospital switchboard.</td>
</tr>
<tr>
<td>Barts Health NHS Trust, St. Bartholomew &amp; Royal London Hospitals</td>
<td>9.00 hrs. to 17.30 hrs Monday to Friday 9.00 hrs. to 12.30 hrs Saturdays and bank holidays</td>
<td>Chemotherapy doses must be ordered and confirmed by 3.30pm (in order to guarantee a same day pharmacy preparation service)</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>Homerton University Hospital NHS Foundation Trust</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td>All parenteral cytotoxic doses are ordered from Barts Health via the Pharmacy Department at the Homerton. 24 hours notice is necessary.</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>Barts Health NHS Trust, Newham University Hospital</td>
<td>9.15 hrs. to 17.00 hrs Monday to Friday</td>
<td>All parenteral cytotoxic doses are ordered from an external supplier via the Pharmacy Department. 72 hours notice is necessary.</td>
<td>Chemotherapy preparation is not available out of hours. In an emergency bleep 736.</td>
</tr>
<tr>
<td>Barts Health NHS Trust, Whipps Cross University Hospital</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
</tbody>
</table>
# Opening Hours and Comments

<table>
<thead>
<tr>
<th>TRUST</th>
<th>Opening hours</th>
<th>Comments</th>
<th>Out of hours provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royal Free London NHS Foundation Trust, Barnet &amp; Chase Farm</td>
<td>09.00 to 17.00 hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>North Middlesex University Hospital NHS Trust</td>
<td>08.30 to 17.00 hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not available out of hours. In an extreme emergency the on call pharmacist should contact the Production Manager to decide on access to doses that may be required for haematological emergencies.</td>
</tr>
<tr>
<td>Great Ormond Street Hospital NHS Foundation Trust</td>
<td>08.45 to 17.15hrs Monday to Friday</td>
<td>Chemotherapy doses must be ordered and confirmed by 3.30pm in order to guarantee a same day pharmacy preparation service.</td>
<td>Chemotherapy preparation service provided for planned short expiry chemotherapy and emergencies on Saturdays, Sundays and Bank Holidays up to 12noon. No chemotherapy preparation service outside these hours. In an emergency resident pharmacist to be contacted.</td>
</tr>
<tr>
<td>Princess Alexandra Hospital NHS Trust</td>
<td>08.30 to 17.00 hrs Monday to Friday</td>
<td>Chemotherapy doses are prepared in Pharmacy. Only Trastuzumab SC can be prepared outside of pharmacy.</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>Royal Free London NHS Foundation Trust, Royal Free Hospital</td>
<td>09.00 to 17.00hrs Monday to Friday; 09.00 to 12.30 hrs Saturday and Bank Holidays (Closed Christmas day)</td>
<td>Chemotherapy doses must be ordered and confirmed by 3.30pm in order to guarantee a same day pharmacy preparation service.</td>
<td>An out of hours service for emergencies is available. The duty Oncology or Haematology doctor should contact the on-call pharmacist via the hospital switchboard.</td>
</tr>
<tr>
<td>University College London Hospitals NHS Foundation Trust</td>
<td>09.00 to 17.00 hrs Monday to Friday</td>
<td>Chemotherapy doses must be ordered and confirmed by 3.30pm (Monday to Thursday) and by 3pm on Fridays, in order to guarantee a same day pharmacy preparation service.</td>
<td>An out of hours service for emergencies is available. The Oncology, Paediatric or Haematology Registrar should contact the on-call pharmacist via the hospital switchboard. The request will be passed on to the on call cancer services pharmacist who will liaise directly with the medical team. If necessary they will arrange for preparation and supply of the emergency doses. There is an out of hours emergency on call service available on Saturdays, Sundays and bank holidays, 9am to 5pm.</td>
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<tr>
<td>Whittington Hospital NHS Trust</td>
<td>9.00 to 17.00 hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
</tbody>
</table>

**LONDON CANCER ALLIANCE**

**North West**

<table>
<thead>
<tr>
<th>TRUST</th>
<th>Opening hours</th>
<th>Comments</th>
<th>Out of hours provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>London North West Healthcare NHS Trust Northwick Park, Ealing &amp; Central Middlesex Hospitals</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>Hillingdon Hospital NHS Foundation Trust</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td>No parenteral chemotherapy is prepared on site. All doses provided by a commercial supplier. 48 hours notice is required.</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>West Middlesex University Hospital NHS Trust</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td>All parenteral doses of chemotherapy are made in pharmacy</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>Chelsea &amp; Westminster NHS Foundation Trust</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td>Chemotherapy preparation is not available out of hours.</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>----------------------------------------</td>
<td>--------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Imperial College Healthcare NHS Trust Hammersmith &amp; Charing Cross Hospitals</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td>Not available out of hours. We have a number of standard doses available via the on call pharmacist but will not prepare anything else. The doses are: Methotrexate 50mg, 68mg &amp; 85mg syringes Etoposide 200mg in N/Saline 1 litre Cisplatin 40mg in N/Saline 1 litre Cyclophosphamide 250mg &amp; 500mg Mitoxantrone 14mg Intrathecal Methotrexate 12.5mg</td>
<td></td>
</tr>
<tr>
<td>East &amp; North Herts NHS Trust, Mount Vernon Hospital</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td>All parenteral doses of chemotherapy are ordered from a commercial supplier via the Pharmacy Department. 4pm cut off for same day delivery. Trastuzumab SC is prepared by nurses. Chemotherapy preparation is not available out of hours. In exceptional emergency cases, Baxter may be contacted via on call pharmacist.</td>
<td></td>
</tr>
</tbody>
</table>
## LONDON CANCER ALLIANCE

### South West

<table>
<thead>
<tr>
<th>TRUST</th>
<th>Opening hours</th>
<th>Comments</th>
<th>Out of hours provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epsom &amp; St Helier University Hospitals NHS Trust</td>
<td>08.30 to 17.00 hrs</td>
<td></td>
<td>Chemotherapy preparation is not available outside these hours unless in an emergency, following discussion with the on-call pharmacist</td>
</tr>
<tr>
<td>Kingston Hospital NHS Trust</td>
<td>09:00- 17:00 hrs</td>
<td>No chemotherapy is prepared on site. All doses provided by a commercial supplier</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>Croydon Health Services NHS Trust, Croydon University Hospital</td>
<td>08.45 to 17.30 Monday - Friday</td>
<td></td>
<td>Chemotherapy preparation is not available out of hours. No Emergency call out service.</td>
</tr>
<tr>
<td>Royal Marsden NHS Foundation Trust</td>
<td>09.00 to 17.30 Monday, Saturday mornings 09.00 to 12.00</td>
<td>Chemotherapy doses must be ordered and confirmed by 16.00 in order to guarantee a same day pharmacy preparation service.</td>
<td>Routine chemotherapy preparation is not available out of hours. On call pharmacist to be contacted in emergency situations.</td>
</tr>
<tr>
<td>St Georges Hospital NHS Trust</td>
<td>08:30 hrs to 17:30 hrs</td>
<td></td>
<td>Chemotherapy preparation is only available in an emergency following discussion with senior technical services on-call pharmacist</td>
</tr>
</tbody>
</table>
## South East

<table>
<thead>
<tr>
<th>TRUST</th>
<th>Opening hours (Service)</th>
<th>Comments</th>
<th>Out of hours provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guy’s &amp; St Thomas’ NHS Foundation Trust</td>
<td>Guys site 09.00 – 17.30hrs Monday to Friday</td>
<td>There is no chemotherapy preparation service on the St Thomas’ site</td>
<td>For clinical queries there is a pharmacist residency service which is supported by a back-up pharmacy oncology on-call team. Chemotherapy preparation is not formally available outside these hours unless it is an emergency, following discussion with the back up pharmacy oncology on-call team.</td>
</tr>
<tr>
<td>King’s College NHS Foundation Trust, King’s College Hospital</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td>Chemotherapy preparation is not formally available outside these hours unless in an emergency, following discussion with the on-call pharmacist</td>
<td></td>
</tr>
<tr>
<td>King’s College NHS Foundation Trust, Princess Royal Univ. Hospital</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td>Chemotherapy preparation is not formally available outside these hours unless in an emergency, following discussion with the on-call pharmacist</td>
<td></td>
</tr>
<tr>
<td>Lewisham &amp; Greenwich NHS Trust, Queen Elizabeth Hospital</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td>Chemotherapy preparation is not formally available outside these hours.</td>
<td></td>
</tr>
<tr>
<td>Oxleas NHS Foundation Trust, Queen Mary’s Hospital Sidcup</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td>No Chemotherapy is prepared on site. All doses provided by a commercial supplier</td>
<td>Chemotherapy is not available outside these hours.</td>
</tr>
<tr>
<td>Lewisham &amp; Greenwich NHS Trust, Lewisham Hospital</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td>Chemotherapy preparation is not formally available outside these hours.</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 3

EXAMPLE of CHEMOTHERAPY OFF PROTOCOL FORM

This form must be completed by the requesting consultant for all cancer chemotherapy protocols that are not on the Network or Trust approved list. Once completed please contact the oncology pharmacist to verify the protocol and confirm availability. A copy of the completed form should be filed in the patient’s medical notes and a copy sent to the Head of the Clinical Chemotherapy Service.

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Hospital Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth:</td>
<td>Hospital:</td>
</tr>
</tbody>
</table>

**Indication / reason for ‘off protocol’ treatment:**

<table>
<thead>
<tr>
<th>Proposed Protocol:</th>
<th>Drug</th>
<th>Dose</th>
<th>Frequency</th>
<th>Route</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intended dose of each drug in mg or units per sq. metre or per kg. For Carboplatin the desired AUC should be quoted</td>
<td>Days of treatment or number of doses</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please state overall course length and interval between course start dates.*

*How many cycles in total will be given?*

*Is continued treatment conditional upon anything?*

*How often will the patient be reviewed?*

*Has this been discussed at a MDT meeting*  

Y/N  

Date:

**Supportive care information:** (may be completed by pharmacist)

**Critical tests and frequency:**
References:

<table>
<thead>
<tr>
<th>Consultant</th>
<th>Name [print]</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Funding Approval : applied for / agreed / not applicable</th>
<th>Name [print]</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Verified by Senior Oncology Pharmacist</th>
<th>Name [print]</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 4

Guidelines for Nurses or Medical Staff Who May Be Reconstituting Cytotoxic Drugs.

The requirement for medical or nursing staff to reconstitute cytotoxic drugs should be negligible, as national guidelines specify that cytotoxic reconstitution should be centralised within a dedicated pharmacy facility.

This section is for those Trusts where out of hours pharmacy preparation services are not available. In such cases, nursing or medical staff may prepare the cytotoxic doses according to local Trust procedures. These staff must have been trained and assessed as competent to prepare chemotherapy doses safely and must have access to an approved biological safety cabinet or isolator.

These guidelines are supplementary to any local policies and procedures that are available.

Carefully check the drugs required against the patient’s prescription. Following local policy, prepare a worksheet and a label ensuring that the details of the method of reconstitution, appropriate diluents and volume calculations are included.

Wash hands thoroughly before putting on gloves.

Assemble all materials required including drugs, diluents, infusion bags, labels, Luer-lock syringes, 21g needles, swabs, sterile dressing pack, locally approved surface cleaning agent, or alcohol impregnated wipes and instrument trays.

Place all the materials required into a tray. NB: Use a separate tray for each patient and each drug.

Check that the isolator or biological safety cabinet is functioning correctly by following the instructions available in each location. Spray all internal surfaces with the locally approved surface cleaning agent and wipe, while wearing gloves. Do NOT spray or swab the filter at the back of the laminar flow cabinet.

Spray and wipe an instrument tray with the locally approved surface cleaning agent and place it in the centre of the cabinet/isolator base. Place a sterile dressing pack or a ‘spillage mat’ in the tray to cover the surface. This is to contain any spillage and all reconstitution must be carried out over this tray.

Disinfect all materials prior to transferring them to the cabinet/isolator by spraying and wiping with the locally approved surface cleaning agent.

Reconstitute and/or prepare the cytotoxic drugs for each patient individually, observing the following points as a guide to safe technique:

- Only place one drug into the cabinet at a time.
  - Luer-lock syringes must be used and all connections checked for tightness.
  - In order to prevent the formation of an aerosol, the air exchange method must be used.
  - When adding diluent to a powder, it should be allowed to run slowly down the side of the vial, which should be gently rotated to ensure thorough wetting. The solution should not be withdrawn until the powder has completely dissolved.
  - Vials should be punctured as few times as possible and needles inserted vertically.
  - When expelling air from a syringe containing a cytotoxic drug, ensure the tip of the needle is still inside the vial or ampoule.
  - Syringes should not be filled more than three-quarters full.
When more than one addition needs to be made to a bag of infusion fluid, a butterfly should be used to avoid multiple punctures of the bag additive port.

- Syringes should be capped with Luer-lock caps. Infusion bags should have a blue additive cap placed over the addition port.

When making more than one dose, label each cytotoxic syringe or bag before proceeding to the next.

When reconstitution and preparation of the cytotoxic drugs is completed, thoroughly clean the inside of the cabinet/isolator with locally approved surface cleaning agent and wipes.

Dispose of all waste materials into a cytotoxic sharps bin (see section 14.1). Remove all protective clothing and safely dispose of it (see section 14.3). Thoroughly wash hands and dry them.

Wearing PVC gloves, fully label the prepared cytotoxic drugs, once again checking the details against the patient’s prescription chart.

Package the drugs for delivery to the patient.

**Ensure that the worksheet(s) are complete and are sent to Pharmacy for their records.**

**NB:**

- Any drug doses prepared out of hours should where possible be used immediately, or within 12 hours of preparation.

- Before administration, the prepared dose should be checked by a second member of staff, ideally a chemotherapy trained nurse or another oncology/haematology doctor.

- The arrangements for administration of chemotherapy outside of normal working hours should be as per standard procedure.
Sample Patient Information Sheet on Extravasation

What is extravasation?
Extravasation is when a drug has leaked outside of the vein. You may have noticed pain, stinging, swelling or other changes to the skin at the site of the cannula or the nurse may have noticed that the drug wasn’t flowing in easily.

Why did this happen?
We don’t know why the drug has leaked into the tissues although it can happen sometimes even though we take all essential precautions to avoid it. The important thing is that it has been detected and treated.

Why is extravasation a problem?
If extravasation goes untreated it can lead to pain, stiffness and tissue damage.

What treatment have I received to prevent this tissue damage?
The Doctor / Nurse has given you the recommended treatment for the drug that has leaked. This means that you shouldn’t have any problems. You need to keep looking at the area every day to make sure the treatment has worked.

What do I need to do?
1) Gently exercise the affected arm or hand. Take mild pain killers if you need to.
2) Look at the area once a day:
   - Has the area changed colour or increased in redness?
   - Is the area blistering, peeling or flaking?
   - Is the area more uncomfortable?
   - Is the pain making it difficult for you to exercise the arm or hand?

When should I contact you?
If you answered yes to any of the questions in section 2) above or you have any other concerns then you should contact us.
Patient information sheet - Extravasation

Drug name:

You are being given this information sheet because some of the drug you have been given has leaked outside of the vein and into the surrounding tissue. This is called either an infiltration or an extravasation depending on which type of drug was involved.

While the drug was been administered, you may have noticed a sudden onset of pain, swelling, redness or leaking of the drug from administration site, or the drug may have stopped flowing into your vein or central venous access device as easily, which would have been the first signs of a possible extravasation occurring. Although the majority of drugs do not cause any lasting damage, there are some drugs that can cause damage to the surrounding tissues if not treated adequately following this event.

Your chemotherapy nurse will have already treated your initial symptoms following the extravasation to try and prevent any further problems occurring.

Depending on the drug involved, you may be asked to wait and be seen by a plastic surgeon so that they can assess the area and decide if you need a procedure called a ‘flush out’ which involves making small incisions around the affected area and ‘flushing’ out the drug with saline to minimise the damage to the tissues. If this procedure needs to be performed, the plastic surgeon and nurse will explain the process in more detail.

The treatment recommended for you following discharge from hospital is: (Please tick)

<table>
<thead>
<tr>
<th>Cold/ice pack, elevate limb, monitor the area, and report any changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat pack, elevate limb, monitor the area, and report any changes</td>
</tr>
</tbody>
</table>

Gentle exercise of the affected area and pain killers can also help ease symptoms.

Although the initial treatment you received will help to minimise any lasting effects, you need to continue to monitor the area, and report any changes, including redness, blistering, increasing pain, swelling, or signs of skin breakdown to your chemotherapy nurse.

Date: __________________ Time: __________________ Location: __________________

Telephone contact number: __________________

PLEASE BRING THIS FORM WITH YOU WHEN YOU NEXT ATTEND FOR FOLLOW UP
APPENDIX 6

Extravasation management, reporting, and patient follow example documentation

<table>
<thead>
<tr>
<th>Infiltration or extravasation incident occurs</th>
<th>Manage incident as instructed in the guidance</th>
<th>Give the patient a 'Patient information sheet', Appendix 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>complete the 'Follow up form following Infiltration/ extravasation, page 3/3'. Ensure this document is filed in the patients notes.</td>
<td>complete the 'Infiltration/ extravasation immediate actions form, page 2/3'. Ensure this document is filed in the patients notes.</td>
<td>complete the 'Infiltration/ extravasation report form page 1/3'. Ensure this document is filed in the patients notes.</td>
</tr>
</tbody>
</table>

For patients that had an infiltration of any other agent, groups 1, 2 & 3, with a volume large enough to compromise the affected area, ensure either telephone or clinic follow up for the incident has been arranged. Ensure documentation completed.

Complete a hospital Incident Form

For patients that had an extravasation involving exfoliant or vesicant agents, groups 4 & 5, possibly requiring a flush out procedure, ensure either telephone or clinic follow up for the incident has been arranged. Ensure documentation completed.

Any digital images taken should be filed in the patients notes.
Infiltration/Extravasation report form for peripheral cannula incidents (Page 1/3)

Please ensure an incident form is completed

<table>
<thead>
<tr>
<th>Patients name:</th>
<th>Hospital number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of birth:</td>
<td>Sex: Male/Female</td>
</tr>
<tr>
<td>Chemotherapy regimen:</td>
<td>Course no:</td>
</tr>
<tr>
<td>Drug name:</td>
<td>Bolus or infusion?</td>
</tr>
<tr>
<td>Was the drug being administered via a fast running drip?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>If using an infusion pump; type and serial number</td>
<td></td>
</tr>
<tr>
<td>How much of the drug have been administered? (mg of dose)</td>
<td></td>
</tr>
<tr>
<td>Approximately how much of the drug has infiltrated/extravasated?</td>
<td></td>
</tr>
</tbody>
</table>

Signs and symptoms experienced by the patient:

<table>
<thead>
<tr>
<th>Signs &amp; symptoms</th>
<th>Burning Yes/No</th>
<th>Stinging Yes/No</th>
<th>Leaking cannula site Yes/No</th>
<th>Swollen cannula site Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannula site status</td>
<td>Indurated Yes/No</td>
<td>Swollen Yes/No</td>
<td>Red Yes/No</td>
<td>Blistered Yes/No</td>
</tr>
<tr>
<td>Infusion related indicators</td>
<td>Blood return Yes/No</td>
<td>Resistance on syringe plunger Yes/No</td>
<td>Absence of free flow of infusion Yes/No/NA</td>
<td></td>
</tr>
<tr>
<td>Any other comments</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Extravasation site

Please draw on the diagram below indicating the position of the cannula, infiltration/extravasation area, and the length and width of the affected area.

![Diagram of arm showing extravasation]

Staff name and designation: Clinical area:

Signature:
Infiltration/Extravasation immediate actions form for peripheral cannula incidents (Page 2/3)

Patients name:  
Hospital Number:  

Immediate nursing management

<table>
<thead>
<tr>
<th>Nursing actions and management</th>
<th>Action completed</th>
<th>Comments</th>
<th>Time, date and nurses signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop the infusion and disconnect infusion set</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirate drug from cannula</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove the cannula following assessment</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark affected area with a pen</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply topical hydrocortisone 1% to the area</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply warm pack</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply cold pack</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevate the limb</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Photograph taken</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inform appropriate medical staff</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flush out technique required?</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refer patient to plastic surgery team</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implement any further medical treatment prescribed</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Give patient the information sheet</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete incident form</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Replace extravasation kit</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Follow up form following infiltration/extravasation incident via a cannula (page 3/3)

Patients name:___________________________   Hospital number: _________________

Site of extravasation incident:________________________________________________

Follow up performed by: ____________________________________________________

Continuing assessment

<table>
<thead>
<tr>
<th>Day post incident</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin colour</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Skin integrity</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Skin temperature</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Oedema</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Mobility of area</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Grading scale

<table>
<thead>
<tr>
<th>Scale</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin colour</td>
<td>Normal</td>
<td>Pink</td>
<td>Red</td>
<td>Blackened</td>
<td></td>
</tr>
<tr>
<td>Skin integrity</td>
<td>Normal</td>
<td>Blistered</td>
<td>Skin loss</td>
<td>Tissue loss</td>
<td>Necrosis</td>
</tr>
<tr>
<td>Skin temperature</td>
<td>Normal</td>
<td>Warm</td>
<td>Hot</td>
<td></td>
<td>Exposure of underlying structures</td>
</tr>
<tr>
<td>Pain</td>
<td>Normal</td>
<td>Tender</td>
<td>Sore to touch</td>
<td>Pain at rest</td>
<td>Pain requiring analgesia</td>
</tr>
<tr>
<td>Oedema</td>
<td>Normal</td>
<td>Minimal; non-pitting</td>
<td>Swollen; pitting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>Normal</td>
<td>Present</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobility of area</td>
<td>Normal</td>
<td>Slightly limited</td>
<td>Very limited</td>
<td>Immobile</td>
<td></td>
</tr>
</tbody>
</table>

Action taken:

Next review date (if required):____/____/_____
Infiltration/Extravasation report form for CVAD incidents (Page 1/3)

Please ensure an incident form is completed

<table>
<thead>
<tr>
<th>Patients name:</th>
<th>Hospital number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of birth:</td>
<td>Sex: Male/Female</td>
</tr>
<tr>
<td>Date:</td>
<td>Time:</td>
</tr>
<tr>
<td>Chemotherapy regimen:</td>
<td>Course no:</td>
</tr>
<tr>
<td>Cannula type &amp; size:</td>
<td>Clinical area:</td>
</tr>
<tr>
<td>Drug name:</td>
<td>Bolus or infusion?</td>
</tr>
<tr>
<td>Was the drug being administered via a fast running drip?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>If using and infusion pump; type and serial number</td>
<td></td>
</tr>
<tr>
<td>How much of the drug have been administered? (mg of dose)</td>
<td></td>
</tr>
<tr>
<td>Approximately how much of the drug has infiltrated/extravasated?</td>
<td></td>
</tr>
</tbody>
</table>

Signs and symptoms experienced by the patient:

<table>
<thead>
<tr>
<th>Signs &amp; symptoms</th>
<th>Burning</th>
<th>Stinging</th>
<th>Leaking CVAD site</th>
<th>Swelling near CVAD site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cannula site status</th>
<th>Indurated</th>
<th>Swollen</th>
<th>Red</th>
<th>Blistered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infusion related indicators</th>
<th>Blood return</th>
<th>Resistance on syringe plunger</th>
<th>Absence of free flow of infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No/NA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Any other comments</th>
</tr>
</thead>
</table>

Extravasation site

Please draw on the diagram below indicating the position of the CVAD, infiltration/extravasation area, and the length and width of the affected area.
Infiltration/Extravasation immediate actions form for central venous access device incidents

Page 2/3

<table>
<thead>
<tr>
<th>Nursing actions and management</th>
<th>Action completed</th>
<th>Comments</th>
<th>Time, date and nurses signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop the infusion and disconnect infusion set</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirate drug from device</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove the device (if appropriate)</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark affected area with a pen</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply topical hydrocortisone 1% to the area</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply warm pack</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply cold pack</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Photograph taken</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inform appropriate medical staff</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flush out technique required?</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refer patient to plastic surgery team</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implement any further medical treatment prescribed</td>
<td>Yes/No/NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Give patient the information sheet</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed incident form</td>
<td>Yes/No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Follow up form following infiltration/extravasation incident via a CVAD (page 3/3)

<table>
<thead>
<tr>
<th>Patients Name:</th>
<th>Hospital number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of incident:</td>
<td>Follow up performed by:</td>
</tr>
<tr>
<td>Site of incident:</td>
<td></td>
</tr>
</tbody>
</table>

**Continuing assessment**

**Day post incident**

<table>
<thead>
<tr>
<th>Skin colour</th>
<th>Skin integrity</th>
<th>Skin temperature</th>
<th>Pain</th>
<th>Oedema</th>
<th>Pyrexia</th>
<th>Mobility of area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Normal</td>
<td>Normal</td>
<td>Normal</td>
<td>Normal</td>
<td>Normal</td>
<td>Normal</td>
</tr>
<tr>
<td>Pink</td>
<td>Blistered</td>
<td>Warm</td>
<td>Tender</td>
<td>Minimal; non-pitting</td>
<td>Present</td>
<td>Slightly limited</td>
</tr>
<tr>
<td>Red</td>
<td>Skin loss</td>
<td>Hot</td>
<td>Sore to touch</td>
<td>Swollen; pitting</td>
<td></td>
<td>Very limited</td>
</tr>
<tr>
<td></td>
<td>Tissue loss</td>
<td></td>
<td>Pain at rest</td>
<td></td>
<td></td>
<td>Immobile</td>
</tr>
<tr>
<td></td>
<td>Necrosis</td>
<td></td>
<td>Pain requiring analgesia</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Grading scale**

<table>
<thead>
<tr>
<th>Scale</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin colour</td>
<td>Normal</td>
<td>Pink</td>
<td>Red</td>
<td>Blackened</td>
<td></td>
</tr>
<tr>
<td>Skin integrity</td>
<td>Normal</td>
<td>Blistered</td>
<td>Skin loss</td>
<td>Tissue loss</td>
<td>Necrosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Exposure of underlying structures</td>
</tr>
<tr>
<td>Skin temperature</td>
<td>Normal</td>
<td>Warm</td>
<td>Hot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>Normal</td>
<td>Tender</td>
<td>Sore to touch</td>
<td>Pain at rest</td>
<td>Pain requiring analgesia</td>
</tr>
<tr>
<td>Oedema</td>
<td>Normal</td>
<td>Minimal; non-pitting</td>
<td>Swollen; pitting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>Normal</td>
<td>Present</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobility of area</td>
<td>Normal</td>
<td>Slightly limited</td>
<td>Very limited</td>
<td>Immobile</td>
<td></td>
</tr>
</tbody>
</table>

**Action taken:**

Replace extravasation kit [Yes/No]
Next review date (if required): ____/____/_______
# Extravasation Assessment Form

**Patient Name:**

**Date of Birth:**

**Sex:** M / F

**Hospital No.:**

**Date and Time of Extravasation:**

**Name of Drug/s Involved:**

**Dose and Volume:**

<table>
<thead>
<tr>
<th>Extravasation Site:</th>
<th>IV Device involved:</th>
<th>Drug Delivery Method:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day 1</td>
<td>2</td>
</tr>
</tbody>
</table>

### Section 1.01

(a) **Date**

(b) **Time**

1.11 (c) **Skin Colour**

(d) **Skin Temperature**

(e) **Skin Integrity**

(f) **Oedema**

(g) **Mobility**

(f) **Fever**

(g) **Numbness**

Scale 1 – 4

**VAS score**

(see below)

(h) **Pain Scale 1–4**

(see page 3 for details)

* May be omitted if signs and symptoms of extravasation are resolved
Visual Analogue Scale: Please add up the daily total from the grading chart below to obtain the VAS score:

<table>
<thead>
<tr>
<th>Grading Chart</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.12 Skin colour</td>
<td>Normal</td>
<td>Pink</td>
<td>Red</td>
<td>Blanched area surrounded by red area</td>
<td>Blackened</td>
</tr>
<tr>
<td>Skin integrity</td>
<td>Unbroken</td>
<td>Blistered</td>
<td>Superficial skin loss</td>
<td>Tissue loss &amp; exposed subcut tissue</td>
<td>Tissue loss &amp; exposed bone /muscle with necrosis crater</td>
</tr>
<tr>
<td>Skin temperature</td>
<td>Normal</td>
<td>Warm</td>
<td>Hot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oedema</td>
<td>Absent</td>
<td>Non-pitting</td>
<td>Pitting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobility</td>
<td>Full</td>
<td>Slightly limited</td>
<td>Very limited</td>
<td>Immobile</td>
<td></td>
</tr>
<tr>
<td>Numbness</td>
<td>Nil</td>
<td>Slight tingling</td>
<td>Pain and tingling</td>
<td>Absences of any sensory sensation</td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>Normal</td>
<td>Elevated</td>
<td></td>
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</tbody>
</table>
### Progress Graph

<table>
<thead>
<tr>
<th>Score</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 7</th>
<th>Day 14</th>
<th>Day 21*</th>
<th>Day 28*</th>
<th>Day 35*</th>
<th>Day 42*</th>
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<tbody>
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</tbody>
</table>

(a) to (g)

**VISUAL ANALOGUE SCORE:**
Please mark on the graph in **BLUE** • with the total score of the day’s assessment.

(h)

**PAIN:** Please mark with a **RED** • how painful the site is today.
How to use this tool

The idea is to assess and measure the extravasation damage over a set period of time (see dates above). This tool is a scoring system which alerts the nurse/doctor who is assessing the patient’s injury to see if there is an improvement, is remaining the same or is progressively getting worse. If the assessor feels there is no improvement, this tool would be the first indicator to either change the treatment plan and/or refer the patient back to the plastic team.

The days are specific and are used as a guideline to assess the patient’s injury over a period of time. The assessment should be completed by 11am on the days specified. The assessor uses the Grading Chart to describe the injury site. The numbers from the Grading Chart is then totalled up and placed into the Visual Analogue Scale (VAS) box as an overall score of the extravasation injury. The pain assessment is undertaken as a separate score as this is what the patient describes the impact of the pain at the injury site (See above).

The overall idea of this tool is to measure the improvement in the patient’s injury site. Scoring zero in both the injury and pain assessment should indicate that full recovery has taken place.

Pain Assessment and Pain Scale:
The pain assessment is complex as the assessor has to relay on how the patient described the pain on the day of the assessment. To simplify the extravasation pain scale, this tool will only use a scale from 1 – 4 interpreted as:

0 = no pain  
1 = mild discomfort at site  
2 = troublesome pain especially on movement  
3 = excessive pain at site and/or able to fully move limb

IV Device Involved: specify if peripheral venous cannula, PICC, central venous line, hickman line, etc

Drug Delivery Method: specify method of delivery of extravasated drug eg. syringe bolus, alaris syringe driver, baxter volumetric pump, gravity pump, etc

Further guidance
If further guidance on extravasation management is required, please refer to the Extravasation Guideline and refer the patient to the Plastics team or Tissue Viability Team for further assessment and treatment as necessary.
APPENDIX 7

Contributors to the Development of the Pan London Guidelines for the Safe Prescribing, Handling and Administration of Systemic Anti Cancer Treatment Drugs

Working Party of Chemotherapy Nurses and Oncology Pharmacists groups of the London Cancer Alliance and London Cancer Integrated Cancer Systems

Distributed to the following groups for comment:

Medicines and Chemotherapy Steering Group, London Cancer Alliance
Chemotherapy Reference Group, London Cancer