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

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Introduction
This document has been produced by collaborative working between the Network Chemotherapy Boards of North Central London & West Essex Cancer Commissioning Network and North East London Cancer Network, the Drugs and Therapeutics Advisory Committee of South East London Cancer Network, the North West London Cancer Network Drugs, Therapeutics and Chemotherapy Committee, and the South West London Cancer Network Chemotherapy Group. It is intended for use across each of the sites providing systemic anti cancer chemotherapy treatment.

With the kind permission of the authors, this document has been based around the Policy and Guidelines for the Safe Prescribing and Handling and Administration of Cytotoxic Drugs produced by the North and North East London Cancer Network (May 2005), and built upon using existing Guidelines and Policies across each of the London Cancer Networks.

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.

This policy aims to minimise these risks by promoting the safe handling and administration of cytotoxic drugs throughout London. It should be read in conjunction with other 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 five Networks 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 with malignant disease. 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 partially 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 Standard Operating Procedures and specific clinical trial documentation.
1 HEALTH AND SAFETY

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 and 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 data 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. COSHH 2002 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 these posts 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 guidance, it would be good practice to include Monoclonal antibodies (MAb’s) 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 to 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) 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 aims 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 is also to comply with HSE guidance, stating that all pregnant staff, or those trying to conceive, should be removed from duties involving the preparation of cytotoxic drugs.

At the point where an employee discloses pregnancy, a risk assessment specific to the individual should 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
- 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 staff compliance and to reduce risks to as low a level as is reasonably practicable.

1.4 Monoclonal Antibody (MAbs)

Monoclonal antibodies affect a wide range of biological functions and staff handling them should be aware of the nature of each product and specific associated problems. As these agents may contain material of animal origin, they are potentially biohazardous and so direct handling should be minimised, and protective clothing worn to the same level as for traditional cytotoxic medicines. There is also a theoretical risk of operator sensitisation as MAbs are proteinaceous in nature and staff should be made aware of this.

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 could then be used to decide whether manipulation should be within an aseptic unit (high risk) or permitted in a clinical area. It is recommended that Trust approval should be obtained for MAbs, if assessed as high risk, being allowed to be 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 is often confused with MAbs and the safe handling of this agent 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 should not 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.

1.6.1 Recommended Good Practice

• Work should be organised to minimise quantities of drugs used.
• The number of employees potentially exposed and duration of exposure should be kept to a minimum.
• 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.

1.7 Minimising Exposure.

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 Effective Equipment (PPE) to use in each activity where cytotoxic drugs are handled.

1.8 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.

1.8.1 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 glove application.

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.

Consideration needs to be given as to whether the procedure requires sterile or non-sterile protective gloves. They should fit appropriately and be close fitting to ensure dexterity. Individual practitioner’s preferences should be considered with regard to sensation 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. 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.

1.8.2 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.

1.8.3 Torso protection (Plastic aprons):

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

1.8.3.1 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.
1.8.4 Respiratory protection:

Surgical masks do not offer protection against inhalation of fine dust or aerosols. When 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 be used when dealing with a cytotoxic spillage.

For Protective equipment to be used in the event of a cytotoxic spillage:

Refer to section 14 re spillage

1.9 Recommendations for PPE in handling activities:

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<thead>
<tr>
<th>Activity /PPE</th>
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<th>Gown/Apron</th>
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<td>Spillage</td>
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*recommended when there is a risk of spraying, splashing or aerosols

** recommended if preparation is not taking place in closed containment technology

Disposal and Decontamination of Personal Protective Equipment

All aprons, gowns, gloves and disposable personal protective clothing should be disposed of according to the guidelines in section 12 re waste management.

Reusable equipment (eyewear and respirators) may be cleaned thoroughly with mild detergent and water before reuse.
2 CLINICAL GOVERNANCE

The responsibilities of different staff groups in relation to this Pan London Policy are outlined below.

2.1 Senior Management within Cancer Networks and Individual Trusts

- Designate responsibility for the implementation of this Policy.
- Ensure that all managers and supervisory staff participating in the provision of chemotherapy services are familiar with, and adhere to, this Policy.
- Are accountable for clinical and corporate governance.

2.2 Department Managers and Supervisory Staff

- Ensure that all relevant staff are fully familiar with this Policy, 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 cytotoxic agents. Risk assessments should be carried out as appropriate.
- Make every effort to ensure that all requests to change work assignments from staff that are pregnant, breastfeeding or trying to conceive, are accommodated.
- Ensure that appropriate and properly maintained facilities and equipment are available to all staff who are handling cytotoxic drugs.
- Ensure personnel records, are maintained for the duration of employment of each employee plus 13 years, and training records for 3 years from the date training occurred.
- Ensure that the service is reviewed against the current COSHH (Control of Substances Hazardous to Health) regulations with an authorised Trust COSHH advisor.
- Ensure that any member of staff transporting cytotoxic drugs has received training on dealing with a spillage.

2.3 Employees and Medical Staff.

- Ensure that all safety requirements according to COSHH guidelines and this Policy are followed.
- Only carry out hazardous activities when competent or trained to do so.
- Follow departmental standard operating procedures where available.
- Report all unsafe acts and conditions.
- Actively participate in the recommended health surveillance programs.
- Actively participate in the training programs provided.
- Inform managers/supervisors if they are pregnant, breastfeeding or trying to conceive.
3 STAFF RESPONSIBILITIES AND STANDARDS

Trusts must maintain a register of clinical staff who are designated to prescribe cancer chemotherapy, the list should be updated at least annually.

3.1 Prescribers Responsibility (including non-medical prescribers)

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

- The decision to initiate chemotherapy 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 the first course and prescribe the first cycle of chemotherapy for the treatment of cancer patients, as per Trust policy.

- The prescriber should inform the patient’s general practitioner of the intention to start the course of chemotherapy 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 chemotherapy.

- Medical doctors who are provisionally registered with the GMC (FY1) MUST NOT prescribe chemotherapy, for the treatment of malignant disease.

- 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 must comply with the Trust medicines policy and related codes of practice.

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

- Non-medical prescribers will be expected to 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.

- The Non-medical Independent Prescriber is 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 chemotherapy, 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 or via the green card system for the National Extravasation Information Service.

- Accepting professional accountability and clinical responsibility for their prescribing practice.

- 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.

- Nurse independent prescribers can currently prescribe a limited number of controlled drugs for specified indication

- Pharmacist independent prescribers cannot currently prescribe controlled drugs.

- 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.

3.1.1 All prescribers are responsible for:

- Checking the allergy status of the patient and for any potential interaction between patient’s current medicines and their chemotherapy or supportive care medicines.
• Confirming the appropriate regimen from the agreed 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. If a patient is 30% over their ideal body weight, or body mass index (BMI) is greater than 30, the need for dose reduction or dose capping should be considered.
• In Trusts where dose banding is approved the prescriber may amend the dose to the nearest acceptable parameter specified in the Network/Trust 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.
• For children, the doses should be calculated according to the relevant protocol, i.e. mg/kg or based on BSA using the UKCCLG (previously the UKCCSG) 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.
• Ensuring accurate dosing. A maximum of +/-5% variance (according to protocol dosages) in dosage calculation is permitted, or as defined by local policy.
• Prescribing and monitoring all cytotoxic drugs and supportive therapies including antiemetics and hydration. This includes the ongoing 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.
• Specifying the route of administration and for parenteral doses, the duration of infusion on the prescription.
• 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 chemotherapy treatment they will be given.
• Ensuring the patient is fully informed of their treatment and has given 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.

• If a patient is to be treated with a chemo-radiation protocol, it is essential that the prescriber makes this clear on the prescription, and notifies the relevant nursing and/or pharmacy staff.
• If a patient is to be treated off-protocol, refer to section 3.6
• Wherever possible, chemotherapy should be initiated during normal working hours when access to specialist staff is more likely to be available. Only in exceptional circumstances may chemotherapy be initiated outside of normal working hours after discussion with the patient’s consultant and key operational staff (i.e. chemotherapy nurses and oncology
pharmacists). The reasons for initiating chemotherapy out-of-hours must be documented in the patient’s healthcare record. See section 6 for details of Out of Hours services.

- Prescriptions for all cytotoxic drugs should be electronic (or pre-printed proforma, not hand written), not verbal, and changes to any of these prescriptions must be documented electronically or in writing as per local policy. If a prescription is amended, the changes should be signed and dated by the doctor or the pharmacist (as per local policy) before the treatment is administered or dispensed.

- 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.

3.2 Pharmacists Responsibility

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

- Prior to a cytotoxic dose being prepared the pharmacist must verify the prescription according to the protocol or treatment regimen, clarify and resolve any discrepancy and check that:
  - The appropriate regimen/protocol/proforma 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 UKCCCLG 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 policy.
  - Dose modifications to previous treatments are maintained if appropriate.
  - All cytotoxic drugs and supportive therapies including antiemetics and hydration have been prescribed.
  - 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 chemotherapy 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 Network/Trust approved list of dose banding levels. This endorsement must be made in line with local Trust policies.
- If the prescription is for a new chemotherapy regimen, not included on the current Network Chemotherapy regimens list, or is prescribed ‘off protocol’ the oncology/haematology pharmacist must discuss the case with the responsible Consultant. 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. For further information see section 3.6 for Off Protocol prescribing.
- In the absence of a local policy, 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 policy, and any changes will be communicated to other team members as appropriate. The pharmacist will complete documentation of the discrepancy and the resolution.

3.3 Nurses Responsibility

- Registered nurses are responsible for safe administration of chemotherapy prescribed to the correct patient as outlined in the individual Trusts policy for Administration of Medicines by Nurses/Midwives and the Nursing and Midwifery council (NMC) Guidelines. The nurse is also responsible for handing over of this information to other nursing staff as required to ensure continuity of care.
- All prescriptions for cytotoxic agents must be checked by a chemotherapy certified nurse. The chemotherapy nurse is responsible for ensuring that:
  - The correct weight and height have been recorded.
  - The BSA calculations are appropriate.
  - 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 policy. In the absence of a local policy, 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 appropriate dose banded dose has been selected. In Trusts where dose banding is approved the pharmacist may amend the dose to the nearest acceptable parameter specified in the Network/Trust approved list of dose banding levels. This endorsement must be made in line with local Trust policies. The nurse will administer the dose...
banded dose and check that the variance is a maximum of +/- 5% from the calculated dose.

- Dose modifications to previous treatments are maintained if appropriate.
- All cytotoxic drugs and supportive therapies including antiemetics and hydration have been prescribed.
- The patient is not allergic to the prescribed medicines and there are no interactions with any of the patient’s regular 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.

- Patients should also be assessed for the need of any additional psychological, social or spiritual support.
- The nurse should ensure that monitoring and timely management of patient specific toxicities takes place.
- It is the nurse’s responsibility to ensure fertility issues have been discussed and documented prior to commencement of treatment.
- A nurse may not accept verbal orders for cytotoxic drugs or for adjustments to doses of cytotoxic drugs.

3.4 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 cytotoxic drugs 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 chemotherapy 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 or course number.
- 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, intrathecal intraperitoneal or intrapleural must be written in full). The same applies for other routes where potential for miss-administration could occur for example intravesical must also be written in full.
- For Infusions, details of 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.
- Antiemetics, hydration and any additional drugs as defined by the protocol.
- Reason for any dose modifications.

- Prescriptions for oral chemotherapy 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, for further details see section 8 for recommendations for oral chemotherapy.
- Oncology, haematology and paediatric haematology and oncology staff should prescribe cytotoxic drugs for patients using an electronic prescribing system, if available.
- 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 cytotoxic drugs.
  - Clear audit trails for recording who has taken part in the provision of cytotoxic drugs, 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 cytotoxic chemotherapy 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.

- In those Trusts where electronic prescribing system are not available, chemotherapy should be prescribed by using appropriate prescription proformas.
- Prescriptions for intrathecal administration must follow the Trust and National Guidance for the administration of Intrathecal chemotherapy.

### 3.5 Consent for treatment

- All patients receiving chemotherapy should be fully informed of their treatment and must have given full written consent for each new course of chemotherapy. Practice may vary throughout London on who actually ensures the consent is documented, but this should be defined by local policy.
- It is good practice to ensure that consent is taken following initial pre-treatment consultation and 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 policy. Patients must receive a copy of the signed consent form.
- If a change in chemotherapy regimen or re-challenge with a previously used chemotherapy 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.

### 3.6 Chemotherapy 'Off Protocol' Prescribing

- In exceptional circumstances, it may be necessary to treat a patient with a chemotherapy regimen not on the current list of accepted Network Chemotherapy regimens list. 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.
- Chemotherapy regimens not on the current list of accepted Network Chemotherapy regimens 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 m² 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 Network 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.

An example of an Off protocol form is outlined in Appendix G. This form can be adapted for local use, providing these details are provided as a minimum, in line with the recommendations of the Manual for Cancer Services.

If there are funding/formulary implications with the use of the 'Off protocol regimen', the Trust funding/formulary approval processes must be considered and followed, before the Off Protocol Regimen form is completed.

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 Chemotherapy service or the lead oncology pharmacist who should then table this for discussion at a future meeting of the local chemotherapy group and the Network Chemotherapy group or the Network Drugs and Therapeutics Committee.

Application for REGULAR USE of a new chemotherapy regimen must be made via the Network Tumour Site Specific Group (TSSG) / Tumour Working Group of the particular tumour site concerned, to the Network Drugs Group and/or Trust Drugs and Therapeutics Group/ New Drugs Panel as appropriate for each network, by the prescriber.
4 PURCHASING, PREPARATION, SUPPLY, TRANSPORTATION AND STORAGE OF CHEMOTHERAPY.

4.1 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 networks. The 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 only be kept as ward stock 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).
- 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.
- Damaged cartons of cytotoxic agents are to be discarded into a rigid sharps box. These should be labelled as cytotoxic waste and dealt with as in per the Trust waste disposal policy.

4.2 Preparation of cytotoxic drugs

- 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 5).
- In emergencies, out of hours chemotherapy preparation may be done by nursing or medical 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 flow air or isolators situated in a specifically controlled and monitored environment. The equipment must be certified at least annually.
- All pharmacy, medical, 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.
- 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.

4.3 Supply of Cytotoxic Drugs

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.

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

4.4 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.

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.

4.5 Storage in Clinical Areas.

Chemotherapy drugs must be delivered to a qualified nurse on the ward who takes responsibility for the appropriate storage, as defined 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.

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.
5 PREPARATION OF CYTOTOXIC DRUGS

5.1 Pharmacy Cytotoxic Preparation Services

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).

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.

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 A and Appendix B.
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.

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.

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 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 B).

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.
6.3 Out of Hours Cytotoxic Preparation in Clinical Areas

The pharmacy departments 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 B).

For those Trusts where out of hours preparation services are not available, in emergencies preparation may be by nursing or medical staff. These staff will have been trained and assessed as competent to 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. See Appendix C for guidelines for nurses or medical staff who need to reconstitute cytotoxic drugs, under these circumstances.

A list of nursing and medical 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.

6.3.1 Protective Clothing

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.

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. See Appendix C for suggested guidance for preparing cytotoxic drugs in these circumstances.

Pharmacy: as detailed in pharmacy procedures.
7 ADMINISTRATION OF CYTOTOXIC DRUGS

Chemotherapy should only be administered in named designated clinical area/s where it has been agreed as part of the service level agreement. An operational policy should indicate what type of clinical activity takes place within the service.

Administration of cytotoxic drugs via all routes must be carried out by nursing or medical staff who have been trained and assessed as competent according to a Network agreed competency framework. Competency should be assessed annually. A register should be maintained which details the staff that are authorised to administer chemotherapy unsupervised.

Staff administering cytotoxic drugs must have current general knowledge of the drugs being given. They should be aware of the correct administration procedure, following an agreed protocol. They should be aware of possible immediate, short and long term systemic and local side effects and the actions to be taken if these occur. They should also be aware of patients educational, psychological, supportive care needs and overall treatment plan.

Staff who are undergoing their chemotherapy training may only give chemotherapy under the direct supervision of authorised staff.

Double-checking of chemotherapy doses is recommended as best practice. Immediately prior to administration the nurse or doctor who will be administering the chemotherapy should check the chemotherapy with a registered IV competent nurse, doctor or pharmacist familiar with chemotherapy administration. Neither professional should have been involved in the dispensing process. See section 15 for administration in the home/community.

Cannulation of a patient for intravenous chemotherapy should be carried out by a staff member who has been trained and assessed as competent.

7.1 Facilities

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 the use of injectable medicines, 2007/20. This assessment should encompass ‘Equality Impact Assessments’. Checks of medical equipment used within the area must 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.

For storage of cytotoxic drugs within clinical areas see section 4.5.
7.2 Equipment

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.

For the equipment required within a community setting see section 15.

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.
8  PRESCRIBING, DISPENSING AND ADMINISTRATION OF ORAL ANTI-CANCER MEDICINES

The use of oral anti-cancer medicines is increasing in scope and complexity. Benefits to patients include treatment at home and ability to feel empowered to be more in control of their disease. However, oral chemotherapy can be associated with similar toxicity to intravenous (IV) chemotherapy.

In January 2008, the National Patient Safety Agency (NPSA) issued a Rapid Response Report - ‘Risks of incorrect dosing of oral anti-cancer medicines’ which outlines good practice standards relating to the prescribing, dispensing or administration of oral chemotherapy and also standards for counselling and information provision to patients.

In October 2010, the NPSA produced a Quarterly Themed Review of patient safety incidents involving anti-cancer medicines and this makes particular reference to oral chemotherapy http://tinyurl.com/NPSAChemotherapy

The report of the National Chemotherapy Advisory Group (NCAG) also made recommendations to improve the quality and safety of chemotherapy services that are relevant to oral chemotherapy.

The guidance outlined below incorporates key recommendations from the above reports.

8.1 Principles of Safe Practice

- Each Healthcare organisation must ensure that it has in place policies and procedures which define and describe safe use of oral anti-cancer medicines in accordance with the guidance outlined in the National Patient Safety Agency Rapid Response Report 2008/001 issued in January 2008.
- Prescribing, dispensing and administration of oral anti-cancer medicines must be carried out to the same standard as injected therapy
- All staff involved must have ready access to regimen protocols and treatment plans including guidance on monitoring and treatment of toxicity
- Patients must be fully informed and receive verbal and up to date written information about their medicines including 24 hour contact details for specialist advice.
- Written consent to treatment must also be obtained prior to commencement of treatment.
- 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 chemotherapy diaries.

8.2 Prescribing

- Treatment must be initiated by a cancer specialist
- Prescribing must be by authorised prescribers, on the Trust register, and be within the context of a written protocol and treatment plan
- Prescribing of oral anti-cancer medicines for adults and paediatric patients treated at Principal Treatment Centres must always be done via an electronic prescribing system or on pre-printed pro-forma prescriptions, in line with requirements of the Manual of Cancer
Services and the peer review process. Hand written prescriptions are not recommended and all trusts should work towards using electronic prescribing.

- Oral anticancer medicines which are prescribed as a single agent or part of a combined chemotherapy regimen must be included in the Trust’s agreed list of chemotherapy regimens, which in turn should form a part of the Cancer Networks agreed list of chemotherapy regimens.
- All deviations from protocol such as dose modifications must be clearly described on the prescription. Follow the process for prescribing an off-protocol medicine in section 3.6 as appropriate.
- Prescribing of oral 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.

8.3 Prescription verification

- Prior to dispensing, all prescriptions for oral anti-cancer medicines must be verified and signed* by a pharmacist who has undergone specialist training, demonstrated their competence and is locally authorised for this task, i.e. on the local register. Verification includes assessment that the prescription is appropriate for the patient and that all safety checks have been undertaken, as defined in local policy.
  * includes auditable electronic authorisation in e-prescribing systems

8.4 Dispensing and Labelling

- Staff verifying or dispensing prescriptions, and on the appropriate register, must have access to the protocol and treatment plan from the hospital that initiated treatment and to advice of an oncology specialist pharmacist in that hospital – such that they can confirm that the prescribed dose is appropriate for the patient and that the patient is aware of the required monitoring arrangements
- Dispensary staff should work to detailed standard operating procedures
- Label details should comply with NPSA recommendations as defined in local policy
- All dispensed containers should be labelled with a ‘Cytotoxic’ warning label
- Automated dispensing systems should only include oral anti-cancer medicines that are available as unit doses (e.g. Temozolomide and Idarubicin). A local risk assessment should be carried out prior to inclusion.
- Tablets or capsules should not be handled directly. All staff should use a ‘no touch’ technique or wear gloves to minimise risks of exposure
- Counting triangles designated only for use for cytotoxic drugs should be used. These should be cleaned after use with IMS (Industrial Methylated Spirit 70%), or an alternative locally approved agent, and a wipe. Wipes should be disposed of as cytotoxic waste.
- Automated counting machines should NEVER be used for oral anti-cancer medicines.
- During normal working hours, all quantities of oral anti-cancer medicines should have a physical double check (count) prior to release to patient.
- Ideally, tablets should never be crushed or halved and capsules should never be opened. Where a commercial liquid preparation is not available and Pharmacy is able to extemporaneously prepare a formulation this must be done in an appropriate controlled environment.
- Oral anti-cancer medicines should not routinely be dispensed in compliance aids or monitored dose systems, unless a full risk assessment has been carried out.
When dispensing tablets or capsules, sufficient quantity for the complete cycle of treatment should be supplied. It is not appropriate to supply original packs of oral anti-cancer medicines if this means the patient will receive more tablets/capsules than required for their intended course.

When dispensing short courses of oral anti-cancer drugs in liquid formulations, the exact quantity required (plus an overage of approximately 10ml) should be supplied. Work over a leak-proof tray to contain any spillage. For patients on maintenance treatment (for example, mercaptopurine for paediatric leukaemic patients), it is more appropriate to dispense a complete original container.

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.

8.5 General Guidelines for Handling and Administration of Oral Formulations

- 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.
- Patients should be advised to swallow tablets or capsules whole and not to chew them. Patients and carers should wash their hands thoroughly after taking/administering oral anti-cancer medicines.
- Do NOT use any tablets or capsules if it is evident that loose powder or liquid is present in the container, where this would not be expected (e.g. where tablets are damaged or liquid filled capsules have leaked). Request a replacement from the Pharmacy department.
- On wards or in clinics, oral doses should be dispensed into a medicine pot prior to administration to the patient. Blister/foil packed oral medicines should not be removed from their wrapper but dispensed into a medicine pot with the blister intact. Patients with poor manual dexterity or impaired vision can have the dose unwrapped at the bedside by a nurse. This reduces the number of manipulations and prevents exposure from opened blisters within the original container.

8.6 Spillage

- For all spillages assess the need for using a cytotoxic spillage kit together with the personal protective equipment contained within it (see section 14).
- If an oral dose is dropped, wear gloves to pick it up and dispose of it into a cytotoxic waste bin. Damp dust the area with a wet paper towel to ensure all fragments are collected. Dispose of the towel as contaminated waste. Document lost dose in the patient’s healthcare record and on the prescription, as appropriate.
For oral liquid spills, wear gloves and gown, soak up the spill and clean the area immediately using soapy water and wipes or paper towels. Dispose of these in a cytotoxic waste bin. It is recommended that a spillage kit is used for volumes greater than 50ml.

In wards or clinic areas, used administration spoons, medicine pots or oral syringes should be disposed of in cytotoxic waste, see section 12.

8.7 Patient Education and Information

- Written information including regimen details, treatment plan and arrangements for monitoring should be given to the patient. The use of oral chemotherapy patient diaries are recommended.

- Before every treatment cycle, all patients should be seen by an Oncologist, Haematologist, Specialist Nurse or trained Oncology Pharmacist.

- 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 chemotherapy 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 ‘chemotherapy 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.
9 ADMINISTRATION OF INTRAVENOUS CHEMOTHERAPY

- 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 the administration of IV chemotherapy (having been assessed against a venepuncture and cannulation competency programme) is key to preventing infiltration and extravasation.

- 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 11 for further information on extravasation.

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

9.1 Selection of Device

9.1.1 Peripheral Venous Cannulation

- 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: median (not usually used for chemotherapy administration), cubital, basilic and cephalic veins.
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 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 of a vein or radiotherapy even if there is no obvious lymphoedema.
- 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 patients records as per local policy. Number and sites of attempted cannulations should also be documented.

9.1.2 Central Venous Catheters
- 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 CVAD’s include: peripherally inserted central catheters, skin-tunnelled catheters e.g. Hickman and Groshong lines and totally implanted vascular access devices e.g. Bard Port
- Central venous access is the route of choice if the drugs or fluids are to be administered over a long duration, 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.
- The routine care and maintenance of CVAD should follow local guidelines.

9.2 Sequencing of drugs

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, pharmacist or doctor.
9.3 Monitoring

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.
- 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. If it is necessary to bandage the site, then the cannula should be observed frequently.
- 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.

9.3.1 Stop administration if:

- There is any doubt about the checks that have been carried out. See section 3.3 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.

9.4 General Principles of Intravenous Administration.

- 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. See section 1.8.
Checking should follow procedure previously described in section 3.3. Patient details should be confirmed verbally with the patient/carer, or with their wristband, immediately prior to administration by the person giving the treatment.

- Maintain a closed system by using Luer-lock syringes/connections e.g. bionector hubs, for the administration of all cytotoxic drugs, appropriate needle-less systems are recommended.
- 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 or yellow clinical waste bag. 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 catheter 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, adverse clinical event for patient and/or litigation.
- It is recommended that units minimise the different types of 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 every 24 hours.
- On completion of dose administration clear away and dispose of all equipment, waste and sharps as outlined in section 12.
- 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 12.4
9.5 Administration of bolus chemotherapy for adults

- Where bolus chemotherapy drugs are to be given 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.

9.6 Administration of bolus chemotherapy for children

Where bolus chemotherapy drugs are to be given to children or adolescents - these should 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.

9.7 Administration of Vesicant Drugs

For examples of vesicant drugs see section 11.12.

- 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.
- 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.
- 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 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.
- Infusion pumps are not generally recommended for the administration of peripheral vesicant drugs, however new infusion devices are now on the market which are licensed for this indication and are available in some clinical areas. When an electronic infusion device is used to administer a vesicant medication, a low-pressure device should be the instrument of choice.
- Vesicant cytotoxic drugs should be administered before non-vesicants unless the protocol specifies otherwise.
9.8 Administration of Irritant Drugs

For examples of irritant drugs see section 11.12.

- 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.
- Infusions are usually administered under gravity control. When an electronic infusion device is used to administer a vesicant medication, a low-pressure device should be the instrument of choice.

9.9 Administration of Non-Vesicant Drugs

For examples of non-vesicant drugs see section 11.12.

- 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.
10 ADMINISTRATION VIA SPECIFIC ROUTES

10.1 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.

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

10.1.2 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.
- If further injections are required, rotate the site of administration.
- Dispose of all cytotoxic contaminated waste immediately as described in section 12.

10.2 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.
10.2.1 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

10.2.2 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 intercostals (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 patients respiration rate every 15 minutes for 1 hour and then 4 hrly
- 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 12).
10.3 Intravesical Instillation

Intravesical instillation is the administration of cytotoxic drugs directly into the bladder, via a urinary catheter.

10.3.1 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.

10.3.2 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.
- 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 (section 12)
- 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 12).
- 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 (reference 7). 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 problems following contact with cytotoxic drugs.
- Dispose of all cytotoxic contaminated waste immediately as described in section 12.

10.4 Intraperitoneal Instillation.

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.

10.4.1 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.

10.4.2 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 12).

### 10.5 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.

#### 10.5.1 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.
10.5.2 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.

- A designated Consultant or Senior Specialist Registrar experienced in this procedure should only 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.

10.6 Administration of Topical Cytotoxic Chemotherapy.
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.

10.6.1 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.
10.6.2 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 12.
- 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 F) and details of obtaining further medicine supplies if needed.
10.7. Administration of Cytotoxic Solutions as Ear Drops

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.

- A designated consultant or senior Specialist Registrar who is experienced in administration of chemotherapy via this route should only 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.

10.8 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.
11 EXTRAVASATION.

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

11.1 Definition.

Extravasation is defined as the accidental leakage of vesicants from its intended compartment (the vein) into the surrounding tissue. This usually occurs when intravenous medication passes from the blood vessel into the tissues around the blood vessel and beyond. Depending on the substance that extravasates into the tissues the degree of injury can range from a very mild skin reaction to severe necrosis. Infiltration is the inadvertent administration of non-vesicant medication or solution into the surrounding tissue which may result in a very mild skin reaction to deep pitting oedema.

Extravasation of the drug can occur with both peripheral and central venous access devices. The impact and extent of extravasation is dependent on: drug specific factors, the concentration of the infusion solution, the volume extravasated and the location on the patient.

11.2 Prevention of Extravasation.

Extravasation injury is best managed through prevention. The following factors should be taken into account before peripheral venous cannulation since they are associated with increased risk of extravasation:

- If the patient is elderly, confused or agitated
- Patients unable to communicate, e.g. sedated, unconscious, confused, language issues.
- Patients with fragile veins, sclerosed veins or mobile veins,
- Patients with impaired circulation from peripheral vascular disease, Raynaud’s phenomenon or lymphoedematous limbs
- Patients with thrombocytopenia
- Patients with peripheral neuropathy or any neuromuscular degenerative disease
- Obesity
- Previous radiotherapy
- Certain medication e.g. anticoagulants, steroids
- Paediatric patients
11.3 Cannulation

- The importance of skilled cannulation and administration techniques is paramount in preventing extravasation. Only appropriately trained staff should administer systemic cytotoxic drugs.

- A nurse should assess venous access prior to a patient starting chemotherapy to decide on the most appropriate device.

- Only plastic cannulae should be used, to reduce the risk of extravasation.

- Use of appropriate gauge cannula for the required flow rate and size of veins should be considered.

- Secure the cannula, ensuring the cannula entry site is visible.

- 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.

11.4 Education

Patients must be informed about the risk of extravasation and asked to report any change in sensation at the intravenous site, especially pain or a burning sensation before administering any agent.

See Administration section 9 regarding the administration of cytotoxic drugs.

11.5 Training

All staff should be trained and assessed as competent in extravasation recognition and management (see Education and Training section 16).

11.6 Signs and Symptoms

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 of a drug.
- 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.

See below in section 11.12 for the Classification of Cytotoxic Drugs (Vesicant, Irritant or non-irritant)
11.7 Immediate management

It is essential that there is an immediate response to extravasation. In the first instance the extravasation kits should be employed and first aid treatment procedures should be followed (see below).

Extravasation kit contents are listed in the local policy.

**First aid management:**
- Stop infusion
- Aspirate as much of infusate as possible
- Inform others for expert advice/help.
- Mark site
- Remove cannula
- Elevate limb and provide analgesia if required
- Take digital image to establish extent of damage (if possible)
- Respond all the while to the patient
IMMEDIATE ACTION FOR ALL DRUG CATEGORIES

**PERIPHERAL CANNULAE**

STOP the infusion / injection, disconnect drip.

DO NOT REMOVE THE CANNULA

Inform the patient what is happening

ASPIRATE back as much of the extravasated drug as possible

Inform / delegate a colleague to inform a member of nursing and/or medical staff

If not already, put on protective clothing required e.g. gloves, gown, goggles

REMOVE THE CANNULA

Mark the extravasated area with a pen and apply a non-adhesive dressing

Take digital image (if possible)

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 professional trained in flush out technique e.g. plastic surgeon, chemotherapy nurse

Yes

Plastic surgeon or nurse performs flush out

Follow up with plastic surgeon

No

Antidotes as per local policy

Inform the patient’s oncologist / haematologist/ the most senior oncologist/haematologist on duty of the subsequent treatment plan.
IMMEDIATE ACTION FOR ALL DRUG CATEGORIES
(CENTRAL VENOUS ACCESS DEVICES)

STOP the infusion immediately

↓

Leave the central venous catheter in place.

↓

Attempt to aspirate as much drug as possible with a new syringe.

↓

For ports, aspirate then remove needle

↓

Inform a senior member of nursing and/or medical staff

↓

Organise X-ray of line or Lineogram

↓

For Vesicant Extravasations or large volumes of irritant drugs refer to plastic surgeon as soon as possible after detection

11.08 Vesicant drugs

- 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.

- There is a lack of robust clinical evidence for the use of preventative plastic surgery intervention and topical / systemic administration of antidotes in treating extravasation injuries caused by vesicant drugs. The recommended treatment of such injuries as described in this policy is based on small clinical studies and the consensus of professional opinion and practice in this area.
11.09 Plastic Surgery Intervention including the Flush Out Technique

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. See Appendix A for contact details. In some Trusts nurses 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. Those trained must have completed the network role development profile for flush-out technique and follow the agreed procedure.

All patients who have undergone the flush out procedure should be reviewed within 24 hours of the procedure being carried out.

11.10 SUBSEQUENT MANAGEMENT OF EXTRAVASATIONS

11.10.1 Peripheral Cannulae

- Assess the likelihood of soft tissue injury by referring to the table of vesicant drugs, see section 11.12. 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.
- Monitor the site daily for pain, erythema, skin changes and necrosis.
- Arrange for a photograph to be taken if necessary.
- Consider the prescription of analgesics on a prn basis if required.
- An information leaflet on extravasation should be given to the patient, see example in Appendix E.

*Ensure that the used extravasation kit is immediately replaced. New kits are available from pharmacy*

11.10.2 Irritant and non-vesicant drugs

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:

- Elevate the limb and encourage movement.
- 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 Trust, i.e. by prescription or by Patient Group Directions.
- Provide advice regarding pain relief and supply analgesia to the patient if necessary.
- Complete all necessary extravasation documentation as outlined in section 11.11 of this guideline.

11.10.3 Use of antidotes and hot/ cold packs

Flush out technique for the removal of extravasated 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 – i.e. acutely sick in-patients cannot be transferred

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

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

Individual Trust guidelines should also indicate whether hot or cold packs should be used with or without the antidotes for specific drugs. NB: the application of heat, cold packs or DMSO can
lead to further unnecessary burns to the skin. They should only be used on the direct advice of the plastic surgeon/ extravasation team. For example:

- Cold packs may be used where the intention is to localise and neutralise, all cytotoxic drugs.
- Hot packs may be used where the intention is to spread and dilute i.e. with vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine), after cold pack for at least 5 minutes.

In the event that an antidote is to be used, this must be prescribed by the oncologist / haematologist reviewing the patient or under a PGD on a standard trust prescription chart and where applicable on a discharge/ outpatient prescription.

11.11 Documentation.

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

- A local Trust incident form must be completed with all details related to the extravasation, including the number of attempts to aspirate extravasated drug.

- National Extravasation Information Service (NEXIS) ‘Green card’, (available from http://www.extravasation.org.uk/home.html). Once completed, two photocopies should be made with one copy being filed in the patient’s notes and the other being sent to the Chemotherapy lead nurse. The Original form should be posted to NEXIS at the following address: Extravasation Report Co-ordinator, c/o St Chad’s Unit, City Hospital, Dudley Road, Birmingham, B18 7QH.

- A Nexis ‘Green Card’ should be available in the extravasation kit. See Appendix D

- Any documentation used at individual trusts for the follow up and monitoring of extravasation injuries, should be completed in addition to the ‘green card’ documentation.

- It is important that the patient’s next review is recorded in their healthcare record.

Trusts may like to consider developing Patient Group Directives for the treatment of extravasation in order to minimise delays in prescribing of medicines used in its treatment.

Patients should be given an information leaflet to explain the management of their extravasation. See example in Appendix E
11.12 Classification of drugs

(based on treatment required for extravasation)

Cytotoxic drugs are classified as vesicants, irritants or non-vesicants

Please note:

- Any agent extravasated in high enough concentration may be irritant

This table is not an exhaustive list. In the event that an extravasation is suspected for a drug / solution not on the list, the extravasation treatment algorithm above should be followed. An oncology Pharmacist or the Trust’s Pharmacy medicines information department should then be contacted to provide the extravasation classification of the drug / solution involved.

<table>
<thead>
<tr>
<th>Vesicants</th>
<th>Irritants</th>
<th>Non-vesicants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amsacrine</td>
<td>Arsenic trioxide</td>
<td>Asparaginase</td>
</tr>
<tr>
<td>Busulphan</td>
<td>Cisplatin</td>
<td>Alemtuzumab</td>
</tr>
<tr>
<td>Carmustine</td>
<td>Carboplatin</td>
<td>Bleomycin</td>
</tr>
<tr>
<td>Chloromethine (Mustine)</td>
<td>Etoposide</td>
<td>Bortezomib</td>
</tr>
<tr>
<td>Dacarbazine</td>
<td>Fluorouracil</td>
<td>Cetuximab</td>
</tr>
<tr>
<td>Daunorubicin</td>
<td>Irinotecan</td>
<td>Cladribine</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>Liposomal Doxorubicin</td>
<td>Cyclophosphamide</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>(Caelyx)</td>
<td>Cytarabine (Cytosine)</td>
</tr>
<tr>
<td>Epirubicin</td>
<td>Methotrexate</td>
<td>Fludarabine</td>
</tr>
<tr>
<td>Idarubicin</td>
<td>Mitoxantrone</td>
<td>Gemcitabine</td>
</tr>
<tr>
<td>Liposomal Daunorubicin TBC</td>
<td>Oxaliplatin</td>
<td>Gemtuzumab</td>
</tr>
<tr>
<td>Mitomycin C</td>
<td>Topotecan</td>
<td>Ifosfamide</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td></td>
<td>Melphalan</td>
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<tr>
<td>Streptozocin</td>
<td></td>
<td>Pentostatin</td>
</tr>
<tr>
<td>Treosulfan</td>
<td></td>
<td>Raltitrexed</td>
</tr>
<tr>
<td>Vinblastine</td>
<td></td>
<td>Rituximab</td>
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<tr>
<td>Vinorelbine</td>
<td></td>
<td>Thiotepa</td>
</tr>
<tr>
<td>Vindesine</td>
<td></td>
<td>Trastuzumab</td>
</tr>
<tr>
<td>Vincristine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 www.extravasation.org.uk accessed 14th May 2009

2 www.cancercare.on.ca Drug monographs accessed 14th May 2009

3 Communication with Schering-Plough 15th May 2009
4 Communication with Cephalon Ltd 15\textsuperscript{th} May 2009

5 Communication with Janssen-Cilag 15\textsuperscript{th} May 2009

6 Communication with Sanofi-Aventis 27\textsuperscript{th} May 2009
12 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 F.

12.1 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 placed in a double clinical waste disposal bag with a purple stripe or 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 can be incinerated at 1000°C to ensure degradation of the cytotoxic agent.

Sharps disposal boxes containing cytotoxic waste must be regularly collected.

12.2 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.

12.3 Protective Clothing and Wipes

Contaminated protective clothing, wipes, plastic aprons and gloves worn during the administration of chemotherapy should be placed in a double clinical waste disposal bag with a purple stripe or sharps box with a purple lid, marked as cytotoxic waste 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.
12.4 Part Used Doses

While still wearing protective clothing, cap any syringes. 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.

12.5 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.

12.6 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 Policy Manuals.
- 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 twice, 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.

12.7 Soiled Bedding / Linen

A risk assessment should be under taken 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 Trusts 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.
12.8 Nappies
Non-disposable nappies should be treated as infected linen and handled according to the procedures described in the individual Trusts 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.

12.9 Disposal of waste in primary care/ community care
Each Primary Care Trust 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.
13 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 F.

- Undertake a suitable and sufficient assessment of the risk to inform the implementation of appropriate control measures to ensure safe practice is followed.
- Staff should be familiar with local standard operating 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 the wider areas of the Pharmacy Department
  - Spillage within ward/clinical areas of the hospital
  - Spillage within the home environment

13.1 Skin

- Remove any contaminated clothing immediately.
- The contaminant must be removed 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.

13.2 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.
13.3 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 or Occupational Health, especially if the needle had been in contact with a patient.

13.4 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 Trusts 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 13.1 above.
14 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 (referring to the March Guidelines, see Appendix H for minimal contents of an in-house Cytotoxic Spillage Kit). Alternatively 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.

Information aimed at patients and carers regarding cytotoxic spillages in the home or community environment is outlined in Appendix F.

14.1 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 following the procedure detailed in Section 13.
- 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.
  - 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).

14.2 Subsequent Action

For Trusts using pharmacy prepared Cytotoxic Spillage Kits: The procedure as outlined in sections 14.2.1 to 14.2.3 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.
14.2.1 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 '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 ‘sharps’ bin. Be careful not to contaminate the outside of the sharps bin.

14.2.2 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 ‘sharps’ bin. Be careful not to contaminate the outside of the Sharps bin.

14.2.3 Final cleanup

- 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 'sharps' bin.
- Use the water for irrigation and paper towel 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 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.
15 COMMUNITY CHEMOTHERAPY

15.1 Delivering intravenous chemotherapy closer to home

The provision of chemotherapy outside the traditional acute hospital chemotherapy day unit will require careful consideration and be heavily influenced by a variety of local and national considerations. This section is intended as a guide to those considering this as a service development and is not intended to be a totally proscriptive or exhaustive list.

In recent years the number of patients receiving their chemotherapy treatment outside the acute hospital setting has expanded. Whilst this option might not be suitable for all patients, increasingly those with less complex chemotherapy treatments for solid cancers and haematological malignancies are being treated in alternative settings, including community hospital clinics, mobile units or in their own home.

Community chemotherapy services maybe provided by outreach services from the acute hospitals or by independent providers. Independent providers may deliver chemotherapy to patients on behalf of the NHS, medical insurance companies or for patients who are self-funding. All independent providers should be formally assessed as to their suitability to deliver community chemotherapy.

Community chemotherapy refers to the administration of a complete cycle of chemotherapy to a patient in a location other than a designated chemotherapy day unit/clinic. This may be delivered by an NHS chemotherapy nurse as part of a hospital outreach service or by an independent provider working in local partnership with the NHS.

Offering patients who fulfil certain criteria the option of completing their chemotherapy treatment in the community is in line with recent NHS policy initiatives. These aim to provide patients with more choice and convenience over where and when they are treated.

Moving care out of hospital and into the community is more than just a change of location. Transforming patient treatment in this way presents challenges in terms of managing clinical risk, maintaining clinical standards and ensuring adequate communication as patients’ progress along their care pathway. Patients choosing community chemotherapy remain under the control of their hospital consultant. At any point the patient, if they wish to do so, should be able to be repatriated back to the acute setting to continue their treatment.

Community chemotherapy treatment involves the use of a variety of central venous catheters for chemotherapy administration, infusion devices and other equipment such as cannula and extravasation kits. It is essential that the prescribing, dispensing and administration of community chemotherapy should be organised and managed safely and effectively to the same standards as those for hospital based treatment and will need to comply with the National Chemotherapy Peer Review Measures (Manual of Cancer Services 2004). Certain chemotherapy administration procedures are not suitable for home delivery and these include prolonged or complex intravenous infusions, intrathecal, and intraperitoneal administration or drugs associated with an increased risk of serious adverse effects.
15.2 Selecting patient groups for Community Chemotherapy

The provision of chemotherapy administration and care outside the acute hospital setting requires careful planning to ensure continuity of care and mitigate clinical risk. Community chemotherapy services need to be safe, of high quality, equitable and offer the maximum benefit to patients and the NHS.

- The individual chemotherapy regimens which can be given in the community and to which groups of patients should be agreed at Network Level.
- The criteria for selecting patients to be offered chemotherapy in a community setting should be agreed locally.
- The location and nature of community chemotherapy services needs to be agreed locally.

All patients need to be formally assessed before receiving chemotherapy in a community setting. Multidisciplinary assessment tools used in practice may vary and as a minimum requirement the following factors should be assessed to ensure:

- The patient has consented to chemotherapy
- The chemotherapy regimen is appropriate for community administration
- The routes of chemotherapy administration are appropriate
- The patient wants to be treated in the community
  - The patient has a good understanding of their disease and the treatment side effects
- The patient has a permanent address
- There is a clear management plan for the patient, detailing the laboratory tests and assessment that needed to be carried out, when and acceptable clinical parameters
- Readmission pathways are clearly identified at the time of referral
- The patient is aware of the 24hr pathway

15.3 Suitability of the environment for home chemotherapy

If the patient is to be treated in their own home the environment should also be assessed to ensure that:

- The patient has access to a working telephone or a good mobile phone signal is available in the house
- There is hot and cold running water
- There is a safe area clear of obstacles and hazards for the patient and visiting nurse
- There is a place for the patient to be comfortable whilst receiving treatment
- The patient is happy for treatment to be administered in this environment
- The visiting nurse feels happy and safe in the patient’s home environment
15.4 Delivering chemotherapy in a community setting

The minimum requirements are:

- There is a clear statement detailing responsibilities and accountability.
- There is a clear procedure covering the selection and referral of patients to the community chemotherapy service.
- The prescribing, dispensing, handling, managing spillages and waste disposal of chemotherapy should be to the same standards as per acute Hospital, refer to relevant sections in this guidance.
- If reviewing the patient’s laboratory results and patient assessment for the chemotherapy cycle is to be carried out by the community chemotherapy service, the person carrying out this role must be trained and assessed as competent to do so.
- Chemotherapy should only be administered by chemotherapy nurses who have been trained and assessed as competent as per Cancer Network Policy, see section 16.3.
- Each patient should have a management plan, detailing when tests and assessments should be carried out and acceptable clinical parameters.
- There should be clinical treatment policies, procedures and protocols including the management of anaphylaxis, allergic reactions and extravasation. Including access to emergency services.
- A formalised 24hr pathway should be in place.
- Patient clinical data should be recorded and the acute hospital should be able to access this.
- Arrangements should be in place for the manufacture and supply of cytotoxic drugs and supportive care medications
- Policies and procedure should be in place for carrying out laboratory tests.
- Arrangements in place for referring patients back to hospital who feel unwell or wish to be repatriated back to the acute setting for their treatment
- The routine collection of patient feedback
- Audit of the service

15.5 Support for patients

Patients should be presented with the alternatives about the location of care clearly and coherently at the appropriate point in their patient journey. Community chemotherapy should be presented as a choice and patients should be reassured that they will still receive the full range of acute hospital services.

As a minimum requirement all providers should

- Provide written information about their chemotherapy treatment, likely side effects, and who they should contact if they feel unwell.
- Ensure copies of this information are sent to the patient’s GP
- Comply with local policies regarding 24 hour telephone advice service
- Provide patients with written information on the main aspects of home treatment, key information about their treatment and contact details
- Participate in surveys of patients satisfaction with home treatment
15.6 Administering subcutaneous, intramuscular, topical chemotherapy and continuous chemotherapy infusions by community and district nurses

Community nurses and district nurses who have been trained and assessed as competent may administer subcutaneous, intramuscular, topical and continuous chemotherapy infusions in a patient’s home. Policies should be in place for these procedures regarding; prescribing, dispensing, safe handling, administering and waste disposal as detailed in these guidelines for acute Trusts.

15.7 Patients administering oral chemotherapy at home

Refer to guidelines in Section 8 on Oral chemotherapy.

15.8 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 at home. An example of an information leaflet which can be given to patients is shown in Appendix F.
16 EDUCATION AND TRAINING

Mandatory training in chemotherapy is required for all healthcare professionals involved in the prescribing, reconstitution, dispensing and administration of chemotherapy. These staff should have explicit knowledge of cytotoxic therapy, including the potential hazards to personnel, the environment as well as the effects on patients and the care they require. Knowledge of regulatory frameworks to support safety with cytotoxic drugs is essential to the employee’s area of work. Education and training should focus on the “whole patient” experience.

Practical training is essential and should be assessed through a competency based framework as stated in the Manual of Cancer Services (2004) and Chemotherapy Services in England: Ensuring Quality and Safety; a report from the National Chemotherapy Advisory Group (NCAG 2009).

Training and information should also be provided for ancillary staff and the wider allied health professionals who come into contact with cytotoxic chemotherapy or with patients who have received chemotherapy e.g. community staff, health care assistants and porters.

16.1 Training programmes for Nursing and Medical Professionals

An agreed network training programme should be in place. The network training programme should specify the methods and length of training staff receive, and include theory that underpins practice, practical supervision and testing of agreed competencies.

At a minimum the training programme should include the following:

- Knowledge of the principles of chemotherapy
- Safe handling of cytotoxic drugs
- The various routes of chemotherapy with focus on intravenous and oral routes, to include warning of the dangers of incorrect administration of vinca alkaloids
- Knowledge and demonstrated competence in Intrathecal chemotherapy as instructed by Department of Health HSC 2008/001 policy. NPSA and national guidance relating to the safe use of vinca alkaloids and NPSA Rapid Response Alert (NPSA/2008/RRR004) relating to the safe use of oral anti cancer medicines.
- Consent and information giving
- Holistic assessment of patients receiving chemotherapy.
- Supportive care
- Selection and use of equipment:
  - Infusion control devices,
  - Scalp cooling and any other equipment used for chemotherapy service delivery.
  - Peripheral and central venous access devices, including line complications.
- Recognition of complications associated with chemotherapy including myelosuppression and its appropriate management.
- Common chemotherapy side effects including nausea, vomiting, stomatitis, diarrhoea, infertility, phlebitis and alopecia.
- Chemotherapy related oncological emergencies:
  - Management and treatment of anaphylaxis
  - Management and treatment of extravasation
  - Management and treatment of neutropenic sepsis
  - Management and treatment of tumour lysis syndrome
- Containment and exposure, including the procedure for handling cytotoxic spillage.
- Health and safety associated with chemotherapy administration, including protective clothing, safe handling and correct waste disposal.
- Knowledge of the principles of clinical trials and GCP
- Knowledge of local treatment protocols/regimens and information on the specific hazards associated with the drugs used.
- Patient education, information and resources

16.2 Prescribing Chemotherapy

Medical and non medical prescribers who are involved in prescribing chemotherapy should receive training and competency assessments in order to be accredited to prescribe, as detailed in section 16.1. Non medical staff prescribing chemotherapy should be educated on an accredited non medical prescribing course and assessed in that area of practice.

Each Trust should maintain a register of named medical and non medical staff who have been reviewed as competent to prescribe chemotherapy.

16.3 Medical and Nursing Staff Administering Chemotherapy

A named chemotherapy nurse for each clinical chemotherapy service is responsible for training and assessing the competencies of staff on an annual basis. The named chemotherapy nurse must be accredited at level 6 or above in a chemotherapy education module.

Each Trust should maintain a register of named nursing and medical staff who have been reviewed as competent to administer chemotherapy.

Each Trust should maintain a register of medical staff trained to administer Intrathecal chemotherapy unsupervised. A register of checkers for Intrathecal administration should also be available. Please refer to local Trust policy.

Competence to administer chemotherapy should be re-assessed and reconfirmed annually.

16.4 Pharmacy Staff

16.4.1 Handling

Pharmacy staff involved in the handling of cytotoxic drugs e.g. purchasing and receipt of goods, packaging, storage, transportation etc., must adhere to the management of health and safety at work regulations 1999; COSHH ACOP guidance and RIDDOR.

Staff should satisfactorily complete the following initial training programme relating to their role in handling cytotoxic drugs. These training records should be retained by Trust managers.
- Read the sections in the ‘Guidelines for the Safe Prescribing, Handling and Administration of Systemic Anti Cancer Drugs’ that are relevant to their work.
- Have received training and education on the health risks associated with handling cytotoxic drugs.
- Be familiar with the national guidance and local policy on intrathecal chemotherapy.
- Be familiar with information on the specific hazards associated with the drugs used.
16.4.2 Preparation

Professional and technical staff expected to participate in the aseptic preparation of cytotoxic drugs must be trained and assessed as competent with respect to specific Trust SOPs and competency frameworks as designated by the Network Chemotherapy Group. A designated officer may issue a certificate of competence to staff who have achieved a satisfactory level of competence in the relevant activities. An appropriate pharmacy manager will ensure that training is updated and reassessed at appropriate intervals and that training records are maintained. The manager may maintain a register of staff holding a certificate of competence.

Pharmacy staff assessed as competent to aseptically prepare and dispense chemotherapy must have:
- Explicit knowledge of the ‘Guidelines for the Safe Prescribing, Handling & Administration of Systemic Anti Cancer Drugs’.
- Explicit knowledge of the national guidance and local policy on intrathecal chemotherapy.
- Practical training in aseptic technique where applicable, and local procedures on cytotoxic reconstitution from a designated officer or pharmacist acting under his / her authority.

16.4.3 Clinical Screening of Chemotherapy Prescriptions (including oral chemotherapy)

It is recommended that pharmacists who are involved in the clinical screening of chemotherapy prescriptions and/or provide a clinical pharmacy service to wards where Haematology/Oncology patients are cared for should undertake an additional Trust specific training program. Only once assessed as competent can prescriptions for chemotherapy be checked unsupervised. When competencies for screening of chemotherapy prescriptions are defined nationally e.g. BOPA standards for chemotherapy prescription verification, such guidelines should be followed.

Each Trust should maintain a register of named pharmacy staff who have been assessed as competent to clinically screen chemotherapy prescriptions.

16.5 Domestic Staff

All domestic staff (including agency staff) involved in cleaning duties in clinical areas should have received training and education on the health risks associated with cytotoxic drugs and cytotoxic waste, and the consequences of ineffective cleaning.

16.6 Portering Staff

All portering staff involved in transporting cytotoxic drugs should have received training and education on the health risks associated with cytotoxic drugs and cytotoxic waste. They should be familiar with the procedures for handling cytotoxic spillages.

16.7 Other staff in clinical areas
All other staff in clinical areas involved in assisting with the administration or, preparation of cytotoxic drugs, or transporting cytotoxic drugs (including volunteers) should undergo an induction to ensure they are aware of the risks associated with chemotherapy.

16.8 Multidisciplinary education and training

Where possible staff should attend multidisciplinary training and education programmes.
# APPENDIX A

Network and Trust Cancer services contact names and numbers

## North Central London & West Essex Cancer Commissioning Network

<table>
<thead>
<tr>
<th>NCL &amp; WECCN</th>
<th>Phone Numbers</th>
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<tbody>
<tr>
<td>Nurse Director</td>
<td>020 7685 6212</td>
</tr>
<tr>
<td>Network Lead Chemotherapy Nurse</td>
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</tr>
<tr>
<td>Lead Pharmacist</td>
<td>020 7685 6219</td>
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<thead>
<tr>
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<td>020 8216 4641</td>
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<tr>
<td>Senior Production Pharmacist</td>
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<td>020 8216 4000 bleep 2583</td>
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<tr>
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<tr>
<td>Senior Chemotherapy Sister</td>
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<td>Charge Nurse Mulberry Ward</td>
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<td>Senior Pharmacist- Haematology/Oncology</td>
<td>020 7405 9200 ext. 5201 or bleep 0388</td>
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<tr>
<td>Senior Pharmacist - Cytotoxic Office Manager</td>
<td>020 7405 9200 ext. 5140</td>
</tr>
<tr>
<td>Senior Pharmacist - BMT</td>
<td>020 7405 9200 ext. 5201 or bleep 0782</td>
</tr>
<tr>
<td>Senior Technician - Cytotoxic Unit Manager</td>
<td>020 7405 9200 ext. 5140</td>
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<tr>
<td>Inpatient Clinical Nurse Specialist</td>
<td>020 7405 9200 bleep 0488</td>
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<tr>
<td>Senior Sister – Elephant Day Care</td>
<td>020 7405 9200 ext. 0046</td>
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<tr>
<td>Safari Day Care</td>
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<tr>
<td>IV therapy team</td>
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<tr>
<td>Nurse Practice Educator</td>
<td>020 7405 9200 bleep 0905</td>
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<tr>
<td><strong>North Middlesex</strong></td>
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<tr>
<td>Specialist Clinical Haem/Onc Pharmacist</td>
<td>020 8887 2000 ext. 2554 or bleep 657</td>
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<tr>
<td>Lead Nurse Cancer Services</td>
<td>020 8887 2000 ext. 3151, Mobile 07918748580</td>
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<tr>
<td>Pharmacy Production Manager</td>
<td>020 8887 2000 ext. 3069</td>
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<tr>
<td>Chemotherapy Co-ordinator Nurse Specialist &amp; PICC Line inserter</td>
<td>020 8887 2000 ext. 3383 or bleep 105</td>
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<tr>
<td>Day Chemotherapy Ward Nurse Manager</td>
<td>020 8887 4251</td>
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<tr>
<td>Ward Manager Oncology Ward &amp; PICC Line inserter</td>
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<td>Technical Services Pharmacist</td>
<td>01279 444 455 ext. 7348</td>
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<tr>
<td>Head of Cancer Nursing, Galen House Cancer Unit</td>
<td>01279 694 927</td>
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<td>CNS Haematology Unit</td>
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<td>Principal Pharmacist, Technical Services</td>
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<tr>
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<td>Aseptic Manager</td>
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<td>Paediatric Directorate Pharmacist</td>
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<tr>
<td>Lead Cancer Nurse</td>
<td>0845 155 5000 ext. 71414</td>
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<tr>
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<td>Inpatient Chemotherapy Team</td>
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<tr>
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<tr>
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<tr>
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<tr>
<td>Oncology Pharmacist</td>
<td>01708 435042</td>
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<tr>
<td>Chemotherapy Nurse Practitioner</td>
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<tr>
<td>Senior Sister - Chemotherapy Day Unit &amp; Outpatients</td>
<td>01708 435 285</td>
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<tr>
<td>Ward Manager, Mandarin B Ward</td>
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<tr>
<td>Children’s Macmillan Nurse</td>
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### Barts and the London

NB: some telephone numbers are due to change

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<td>Head of Clinical Chemotherapy Service &amp; Lead Pharmacist</td>
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<tr>
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<tr>
<td>Chemotherapy Nurse Consultant</td>
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<td>St Bartholomew’s ext: 55022</td>
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<tr>
<td>Ward Manager : Ward 4A (previously Bodley Scott 2)</td>
<td>020 3465 5500</td>
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<tr>
<td>Ward Manager: Ward 5A (previously GHF)</td>
<td>020 3465 5566</td>
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<tr>
<td>Ward Manager: Ward 5B (previously Rahere Ward)</td>
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<tr>
<td>Ward Manager: Ward 7A (previously Paget Ward)</td>
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<tr>
<td>Ward Manager Bodley Scott Day Unit</td>
<td>020 7601 8590 / 8077 / 8855</td>
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<td>020 7601 8776 / 8853</td>
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<tr>
<td>Macmillan Paediatric Nurse Specialist</td>
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### Homerton

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<tr>
<td>Chief Pharmacist</td>
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### Newham

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<td>020 7363 8232</td>
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<tr>
<td>Haematology CNS</td>
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<tr>
<td>Rainbow Ward (paediatrics) Sister</td>
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### Whipps Cross

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<tr>
<td>Lead Nurse, Chemotherapy and Acute Oncology Service</td>
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<td>Lead Cancer Nurse</td>
<td>020 8535 6980</td>
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<tr>
<td>Sister – Woodlands Day Unit</td>
<td>020 8535 6917</td>
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<tr>
<td>Haematology CNS</td>
<td>020 8539 5522 bleep 343 or ext. 5208</td>
</tr>
<tr>
<td>Head of Nursing for Paediatrics</td>
<td>020 8539 5522 ext. 5778</td>
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South East London Cancer Network

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<tr>
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<td>Network Nurse Director</td>
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<td>Network Medical Director</td>
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Guy's & St Thomas’ NHS Foundation Trust

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<tr>
<td>Lead Aseptic unit (Cancer) Pharmacist (STH &amp; GSTFT)</td>
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<td>Lead Cancer Nurse</td>
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<td>Lead Chemotherapy Nurse</td>
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<tr>
<td>Lead clinician, Systemic therapy</td>
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King's College Hospital

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<tr>
<td>Lead Clinician for chemotherapy services</td>
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<tr>
<td>Head of Nursing for cancer and palliative care</td>
<td>020 3299 4293</td>
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<tr>
<td>Lead Chemotherapy Nurse</td>
<td>020 3299 3335 bleep 07699 115 300 and ask for call sign KH3081</td>
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<tr>
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<tr>
<td>Lead Haematology Pharmacist</td>
<td>020 3299 3972 bleep 07699 115 300 and ask for call sign KH1133</td>
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<tr>
<td>Associate Director of Aspect Services</td>
<td>020 3299 3974</td>
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<tr>
<td><strong>South London Healthcare Trust at Princess Royal University Hospital</strong></td>
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<tr>
<td>Lead cancer Pharmacist</td>
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<tr>
<td>Lead Cancer Nurse</td>
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<tr>
<td>Chartwell Treatment Suite</td>
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<tr>
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<tr>
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<tr>
<td>Lead Chemotherapy nurse</td>
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<tr>
<td>Cancer services pharmacist</td>
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<tr>
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<td>Chemotherapy Day Unit</td>
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<tr>
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South West London Cancer Network

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<tr>
<td>Senior Pharmacist, Haemato-oncology</td>
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<td>Cancer Services Pharmacist</td>
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<td>Cancer Services Pharmacist</td>
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## North West London Cancer Network

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<td>Cancer Services Pharmacist</td>
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<td>Cancer Services Pharmacist</td>
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<tbody>
<tr>
<td>Senior Lead Cancer Pharmacists</td>
<td>020 3311 1645 or 1707</td>
</tr>
<tr>
<td>Senior Haematology Pharmacist</td>
<td>020 8383 2624</td>
</tr>
<tr>
<td>Trust Lead Chemotherapy Nurse</td>
<td>Mobile 07771 371 537</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>North West London Hospitals Trust (Northwick Park &amp; Central Middlesex Hospitals)</th>
<th>Phone Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Services Pharmacist</td>
<td>020 5569 2220</td>
</tr>
<tr>
<td>Lead Chemotherapy Nurse</td>
<td>020 8235 4197</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>West Middlesex Hospital</th>
<th>Phone Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Services Pharmacist</td>
<td>020 8321 6935/5883 or 020 8560 2121 bleep 090 or bleep 499</td>
</tr>
<tr>
<td>Lead Chemotherapy Nurse</td>
<td>020 8321 6264 bleep 528</td>
</tr>
</tbody>
</table>
**APPENDIX B**

**Pharmacy Cytotoxic reconstitution unit opening hours, including Out of Hours arrangements for preparation of chemotherapy**

<table>
<thead>
<tr>
<th>TRUST</th>
<th>Opening hours</th>
<th>Comments</th>
<th>Out of hours provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barnet &amp; Chase Farm</td>
<td>09.00 hrs to 17.00 hrs Monday to Friday</td>
<td>Chemotherapy preparation is not available out of hours.</td>
<td></td>
</tr>
<tr>
<td>North Middlesex</td>
<td>08.30 hrs to 17.00 hrs Monday to Friday</td>
<td>Chemotherapy preparation is not available out of hours.</td>
<td>In an extreme emergency the on call pharmacist should contact the Production Manager at home and it is at his discretion to decide what course of action is necessary.</td>
</tr>
<tr>
<td>Great Ormond Street</td>
<td>08.50 hrs to 17.20 hrs 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>Short expiry drugs and intrathecal doses for Monday morning are made on Sundays by prior arrangement only. No other out of hours chemotherapy preparation service is available. In a medical emergency the duty Oncology or Haematology doctor should contact the on call pharmacist via the hospital switchboard.</td>
</tr>
<tr>
<td>Princess Alexandra</td>
<td>08.30 hrs to 17.00 hrs Monday to Friday</td>
<td>Chemotherapy preparation is not available out of hours.</td>
<td></td>
</tr>
<tr>
<td>Royal Free</td>
<td>09.00 hrs to 17.30hrs Monday to Friday; 09.00 hrs 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>UCLH</td>
<td>09.00 hrs to 17.15 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>There is an out of hours emergency technician on call service available on Saturdays, Sundays and bank holidays, between 9am to 5pm.</td>
</tr>
<tr>
<td>TRUST</td>
<td>Opening hours</td>
<td>Comments</td>
<td>Out of hours provision</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>BHR</td>
<td>9.00 hrs. to 17.00 hrs 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 is not available out of hours. In an emergency the on call pharmacist should be contacted via the hospital switchboard.</td>
</tr>
<tr>
<td>BLT</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>All parenteral cytotoxic doses are ordered from BLT 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>Homerton</td>
<td>9.00 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.</td>
</tr>
<tr>
<td>Newham General</td>
<td>9.15 hrs. to 17.00 hrs Monday to Friday</td>
<td>Chemotherapy preparation is not available out of hours. In an emergency bleep 736.</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>Whipp Cross</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td>Chemotherapy preparation is not available out of hours.</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
</tbody>
</table>
### South East London Cancer Network

<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 at Guy’s</td>
<td>09.00 – 17.30hrs Monday to Friday</td>
<td>There will be no formal chemotherapy preparation services on the St Thomas’ site from February 2011</td>
<td>For clinical queries there is a pharmacist residency service which is supported by a back-up oncology on-call team. Chemotherapy preparation is not formally available outside these hours unless it is an emergency, following discussion with the back up oncology on-call team.</td>
</tr>
<tr>
<td>King’s College Hospital</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not formally available outside these hours unless in an emergency, following discussion with the on-call pharmacist</td>
</tr>
<tr>
<td>South London Healthcare Trust at Princess Royal University Hospital</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not formally available outside these hours unless in an emergency, following discussion with the on-call pharmacist</td>
</tr>
<tr>
<td>South London Healthcare Trust at Queen Elizabeth Hospital, Woolwich</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not formally available outside these hours unless in an emergency, following discussion with the on-call pharmacist</td>
</tr>
<tr>
<td>South London Healthcare Trust at Queen Mary’s Sidcup</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td>No Chemotherapy is aseptically prepared on site, chemotherapy preparation is provided by a commercial supplier.</td>
<td>Chemotherapy preparation is not formally available on site.</td>
</tr>
<tr>
<td>Lewisham Healthcare Trust</td>
<td>09.00 – 17.00hrs Monday to Friday</td>
<td></td>
<td>Chemotherapy preparation is not formally available outside these hours.</td>
</tr>
</tbody>
</table>
### South West London Cancer Network

<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 Hospital</td>
<td>08.30 hrs-17.00 hrs</td>
<td>All parenteral cytotoxic doses are ordered from Baxter healthcare via the Pharmacy Department. 48 hours notice is required.</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</td>
<td>09:00- 17:00</td>
<td>All parenteral cytotoxic doses are ordered from Baxter healthcare via the Pharmacy Department. 48 hours notice is required.</td>
<td>Chemotherapy preparation is not available out of hours</td>
</tr>
<tr>
<td>Mayday Hospital</td>
<td>08.45 to 17.30 Monday - Friday</td>
<td>Chemotherapy preparation is not available out of hours. No Emergency call out service.</td>
<td></td>
</tr>
<tr>
<td>Royal Marsden Hospital</td>
<td>09.00 to 17.30 Monday to Friday, 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. (service under review)</td>
</tr>
<tr>
<td>St Georges Hospital</td>
<td>08:30 hrs to 17:30 hrs</td>
<td>Chemotherapy preparation is only available in an emergency following discussion with senior technical on-call pharmacist</td>
<td></td>
</tr>
<tr>
<td>TRUST</td>
<td>Opening hours</td>
<td>Comments</td>
<td>Out of hours provision</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>----------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>North West London 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</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td>All parenteral cytotoxic doses are ordered from Baxter healthcare via the Pharmacy Department. 48 hours notice is required.</td>
<td>Chemotherapy preparation is not available out of hours.</td>
</tr>
<tr>
<td>Ealing 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>
<tr>
<td>West Middlesex 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>
<tr>
<td>Chelsea &amp; Westminster Hospital</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td></td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
</tr>
<tr>
<td>Imperial College Healthcare NHS Trust</td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
<td></td>
<td>9.00 hrs. to 17.00 hrs Monday to Friday</td>
</tr>
</tbody>
</table>
APPENDIX C

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.
## APPENDIX D

### Sample Extravasation Documentation form

**Green Card Report - please enter all available details**

<table>
<thead>
<tr>
<th>Male ☐</th>
<th>Female ☐</th>
<th>Age ☐</th>
<th>Ethnic Origin</th>
<th>Height(m) ☐</th>
<th>Weight(kg) ☐</th>
<th>Drug causing extravasation</th>
<th>Dose ☐</th>
<th>Infusion fluid and volume</th>
<th>Given as</th>
<th>Yes ☐</th>
<th>No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>White British</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Has the patient received I.V antibiotics in the last 3 months?**

- Yes ☐
- No ☐

**If YES please specify**

- [ ]

**Has the patient had previous :- Drug Hypersensitivity ☐ Phlebitis ☐**

- ☐

**Were the drugs being administered via a pump or syringe driver?**

- Yes ☐
- No ☐

**If YES please indicate model**

- [ ]

**Is the Patient on any of the following Therapies?**

- Anticoagulants ☐ Antiplatelets ☐
- Antihistamines ☐ Diuretics ☐
- Hormone Therapy ☐ Antifibrinolytics ☐
- Vasodilators ☐ Steroids ☐

---

Pan London Guidelines for Safe Prescribing, Handling and Administration of Cytotoxic Drugs
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<table>
<thead>
<tr>
<th>Time of Cannulation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No of attempts at cannulation</td>
<td></td>
</tr>
<tr>
<td>Ease of Cannulation</td>
<td></td>
</tr>
<tr>
<td>Other Method of Administration</td>
<td>Other (please specify)</td>
</tr>
<tr>
<td>Details of Extravasation Treatment (Drug, Dose, Procedure)</td>
<td></td>
</tr>
</tbody>
</table>

Did the Patient experience any of the following prior to or after the suspected extravasation?

<table>
<thead>
<tr>
<th></th>
<th>Prior</th>
<th>Post</th>
<th>Time Post Extravasation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Tingling</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Swelling</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Redness/Flare</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Itching</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Cold</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Extravasation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of Extravasation</td>
<td></td>
</tr>
<tr>
<td>Acute extravasation treatment started at</td>
<td></td>
</tr>
</tbody>
</table>

THIS SECTION IS NOT COMPULSORY

Contact Name for Dr ☐ Nurse ☐ Pharmacist ☐ Tel no  |  |
**Further Details:**

<table>
<thead>
<tr>
<th>Email</th>
</tr>
</thead>
</table>

**Does the patient suffer from any of the following possible contributary factors?**

<table>
<thead>
<tr>
<th>Raynaud's Disease</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>☐</td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td>☐</td>
</tr>
<tr>
<td>Lymphoedema</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Has the patient had either of the following in the last month, to the affected side?**

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiotherapy</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

**Additional Comments:**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
</table>

**Was the patient able to communicate adequately in English?** Yes [☐] No [☐]

**If not, please give reason:**

---
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.
APPENDIX F

ADVICE FOR PATIENTS AND CARERS ON 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 ‘cytotoxic 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 purpose. The waste and gloves (when discarded) should sealed in a plastic bag before disposal. Patients/carers should be advised to minimise splashing, for example male patients may be advised to sit when urinating.
APPENDIX G

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:**

**Proposed Protocol:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Frequency</th>
<th>Route</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<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>Rate of infusion, infusion fluid and volume</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>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name [print]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Funding Approval: applied for / agreed / not applicable

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

Verified by Senior Oncology Pharmacist

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

CONTENTS OF IN-HOUSE CYTOTOXIC SPILLAGE KITS FOR HOSPITAL USE

The MARCH Guidelines recommend the following contents of a cytotoxic spillage kit:

- Absorbent granules/ pads/ sheets/ paper towels
- 2 pairs of powder free gloves (latex or nitrile)
- Protective gown (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
APPENDIX I

Cytotoxic Spillages  Liquid

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. If a kit is used it must be replaced immediately. At no times must access to a kit be impeded by blocking the surrounding area. Cytotoxic spill kits are available from pharmacy.

Immediate action in the event of a spillage

• restrict access to the spillage area
• alert other members of staff in the vicinity and inform the Senior Nurse in charge
• 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
• turn off all fans and reduce any draughts
• open a Cytotoxic Spill 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 any spillage ensure you have put on:
• a 3/4 length gown or white plastic apron
• a pair of protective, plastic armlets
• a pair of gloves (ditch the rubber gloves for the future)
• eye goggles
• a pair of plastic overshoes (if the spillage is on the floor)

1. Use blue paper towels in a ring around the spill to contain the fluid so that it cannot spread to a larger area.

2. Pick up any broken glass using the tweezers and place in the ‘sharps’ bin.

3. Cover the liquid with blue paper towel until all the fluid has been absorbed. Keep adding more blue paper towel 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).

4. Pick up the moist towel and place into the self-seal plastic bag.

5. Seal the bag and place in the ‘sharps’ bin. Take care not to contaminate the outside of the ‘sharps’ bin.

6. Pick up the blue paper towel used to create a ring around the spill, seal in the self-seal bag and place in the ‘sharps’ bin.

7. Use the water for irrigation and blue paper towel to clean the contaminated area and place the used paper towel in a self-seal bag. Repeat this at least 5 times working from the outside of the contaminated area inwards to prevent spreading the contamination.

8. Place all of the self-seal bags, tweezers and protective clothing in the ‘sharps’ bin. Return protective glasses to the pharmacy department.

9. Put the lid on the ‘sharps’ bin and seal.

10. Tape up the ‘sharps’ bin with cytotoxic hazard tape and a location sticker.

Checklist:

• the floor and all other contaminated surfaces should have a routine clean a minimum of 3 times with an appropriate cleaner as soon as possible
• fill in an Accident Report Form
• inform the Head of Department and Occupational Health
• arrange for the immediate collection of the ‘sharps’ bin and obtain a replacement
• inform the pharmacy manufacturing department in case drugs used to be removed

Your nearest spillage kit is located at:

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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. If a kit is used it must be replaced immediately. At no times must access to a kit be impeded by blocking the surrounding area. Cytotoxic spill kits are available from pharmacy.

**Immediate action in the event of a spillage**
- restrict access to the spillage area
- alert other members of staff in the vicinity and inform the Senior Nurse in charge
- 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
- turn off all fans and reduce any draughts
- open a Cytotoxic Spill 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 any spillage ensure you have put on:
- a 3/4 length gown or white plastic apron
- a pair of protective, plastic armlets
- a pair of gloves (look the armpit sleeves inside the glove cuffs)
- mask
- eye goggles
- a pair of plastic overshoes (if the spillage is on the floor)

Use the blue paper towel to create a ring around the spillage. This will contain any fluid added to wet the powder and prevent it from 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 blue paper towel moistened with water for irrigation, this will prevent mobilisation of the powder particles and therefore contain the spillage.

**Powder**

Add a little more water through the towel until all the powder has been wetted. Add more blue paper towel until all 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 wetted powder with moist blue paper towel and place into the self-seal plastic bags. Seal the plastic bags and place into the ‘sharps’ bin. Be careful not to contaminate the ‘sharps’ bin.

Pick up the blue paper towel used to create a ring around the spillage, seal in the self-seal bag and place in the ‘sharps’ bin.

Use the water for irrigation and blue paper towel to clean the contaminated area and place the used towel in a self-seal bag. Repeat this at least 5 times working from the outside of the contaminated area inwards to prevent spreading the contamination.

Place all self-seal bags, tweezers and protective clothing in the ‘sharps’ bin. Return the protective glasses to pharmacy.

Put the lid on the ‘sharps’ bin and seal.

Tape up the ‘sharps’ bin with cytotoxic hazard tape and a location sticker.

**Checklist:**
- the floor and all other contaminated surfaces should be thoroughly cleaned a minimum of 3 times with an appropriate cleanser as soon as possible
- fill in an Accident Report Form
- inform the Head of Department and Occupational Health
- arrange for the immediate collection of the ‘sharps’ bin and obtain a replacement
- inform the pharmacy manufacturing department in case of the drug need to be removed

Your nearest spillage kit is:

Pan London Guidelines for Safe Prescribing, Handling and Administration of Cytotoxic Drugs
Version 1.0
## Glossary of Common Terms, Names, Abbreviations etc

<table>
<thead>
<tr>
<th>Term/name/abbreviation</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC</td>
<td>Area Under the Curve</td>
<td>Cycle 1 FEC - Fluorouracil 600mg/m², Epirubicin 60mg/m² and Cyclophosphamide 600mg/m² are administered on Day 1 and repeated every 21 days.</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
<td>Cycle 1 FEC - Fluorouracil 600mg/m², Epirubicin 60mg/m² and Cyclophosphamide 600mg/m² are administered on Day 1 and repeated every 21 days.</td>
</tr>
<tr>
<td>BSA</td>
<td>Body Surface Area</td>
<td>Cycle 1 FEC - Fluorouracil 600mg/m², Epirubicin 60mg/m² and Cyclophosphamide 600mg/m² are administered on Day 1 and repeated every 21 days.</td>
</tr>
<tr>
<td>Cycle of chemotherapy</td>
<td>A discreet block of treatment where chemotherapy is delivered on specified days within a repeated time frame.</td>
<td>Cycle 1 FEC - Fluorouracil 600mg/m², Epirubicin 60mg/m² and Cyclophosphamide 600mg/m² are administered on Day 1 and repeated every 21 days.</td>
</tr>
<tr>
<td>Course of chemotherapy</td>
<td>A course of chemotherapy consists of a sequence of various cycles of chemotherapy</td>
<td>6 cycles of FEC would constitute a course</td>
</tr>
<tr>
<td>Extravasation</td>
<td>The leakage of intravenous drugs from the vein into the surrounding tissue</td>
<td>Extravasation</td>
</tr>
<tr>
<td>Regimen</td>
<td>The name or acronym assigned to a specific combination of cytotoxic drugs given at specific doses on specific days</td>
<td>FEC - Fluorouracil 600mg/m², Epirubicin 60mg/m² and Cyclophosphamide 600mg/m² are administered on Day 1 and repeated every 21 days.</td>
</tr>
<tr>
<td>Protocol</td>
<td>Description of the treatment plan and dose modifications for a specific chemotherapy regimen, containing sufficient detail for all healthcare professionals involved in the treatment of cancer patients to be aware of the particular clinical parameters and supportive treatment required for that regimen.</td>
<td>Protocol</td>
</tr>
<tr>
<td>SACT</td>
<td>Systemic anti cancer treatment</td>
<td>SACT</td>
</tr>
</tbody>
</table>
APPENDIX K

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Drugs, Therapeutics and Chemotherapy Committee, North West London Cancer Network

UKONS London Group
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