POLICY FOR THE SAFE HANDLING AND ADMINISTRATION OF CYTOTOXIC DRUGS IN ADULTS WITH CANCER

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CONTENTS

1 INTRODUCTION

Cytotoxic drugs are used to treat cancer and a number of other disorders. They act by killing dividing cells by preventing their division, acting on normal as well as malignant cells. Cytotoxic agents may have genotoxic, oncogenic, mutagenic and teratogenic properties. Their use therefore poses certain risks to those handling and receiving them. This policy is designed to ensure the safety of staff and patients who come into contact with these drugs.

This policy is intended to safeguard patients and staff by defining best practice for all disciplines involved in cytotoxic chemotherapy.

The handling and administration of cytotoxic drugs are hazardous potentially to the Health care 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 Thames Valley Cancer Network. 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.

Intrathecal chemotherapy will not be included in this policy (see separate National and Local policies).

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 BNF. If in doubt, refer to the Summary of Medical Product Characteristics available at www.medicines.org.uk for the individual drug concerned.

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 a biohazard and direct handling should be minimal 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 alert 20 http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812 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 assessed as high risk before being allowed to be manipulated in clinical areas.

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

Gene therapy

Gene therapy or gene transfer therapy and the safe handling of this agent is outside the scope of this document. Refer to Health and Safety Executive guidance and European Association of Hospital Pharmacy guidance on pharmacy handling of gene medicines (European Journal of Hospital Pharmacy Practice 13 ((5);29-39, 2007).

2 CLINICAL GOVERNANCE

The responsibilities of different staff groups in relation to this TVCN Policy are outlined below. Education and training of each staff group will be dealt with in a separate Network wide Training and Education policy and local policies.

TVCN Chemotherapy Cross Cutting Group and Individual Trusts

- Designate responsibility for the implementation and regular review 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.

Responsibilities

1. Each Trust will identify the following posts, a designated Head of Chemotherapy Services, Lead Chemotherapy Nurse and Lead Chemotherapy Pharmacist as recommended in the IOG.

2. The Head of Chemotherapy Services for each Trust is responsible for ensuring implementation and adherence to this policy.

3. The Head of Chemotherapy Services for each Trust will ensure that all first cycles of chemotherapy are prescribed by a Solid tumour Oncologist or Haemato-oncologist (Consultant, SpR or specialist staff grade) and that a register of staff competent to administer chemotherapy unsupervised is maintained. The evidence for this will be audited annually using an electronic prescribing system. Decisions to initiate a course of chemotherapy should, unless in exceptional circumstances, be made at Consultant level with the patient and carer fully involved on an informed choice basis. Prescribing decisions should be fully informed by knowledge of the patient's performance status, concurrent co-morbidities and the results of up to date investigations. These patient specific factors will also constitute a baseline so that response to treatment can be evaluated

4. Cytotoxic drugs may only be prescribed by Consultant haemato-oncologist or solid tumour oncologist medical staff. Specialist registrars, Specialist non career grades and non-medical prescribers can prescribe chemotherapy when appropriately trained. All prescriptions should be prescribed using an electronic prescribing system. 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.

5. Careful reassessment is needed before the start of any subsequent cycle of treatment. This should include reassessment of performance status, documentation of any serious toxicity (e.g. grade 3 or 4 toxicities) and appropriate blood tests. Dose modifications should be made where necessary. Response to treatment should be documented at appropriate intervals.

6. The Chief Pharmacist in each Trust is responsible for the education and development of pharmacy staff in the handling, reconstitution, disposal of cytotoxic drugs and clinical screening of chemotherapy prescriptions in conjunction with an electronic prescribing system. They must ensure that only appropriately trained staff may be involved in the screening of chemotherapy prescriptions, reconstitution, labelling, administration and disposal of cytotoxic drugs using an electronic prescribing system.

7. Cytotoxic drugs may only be reconstituted in facilities specifically approved for the purpose.

8. The Lead Chemotherapy Nurse for each Trust is responsible for the education and development of nursing staff in the handling, administration and disposal of cytotoxic drugs. Nurses are only able to administer chemotherapy unsupervised if they have undertaken an accredited Chemotherapy course.

9. Cytotoxic drugs may only be administered in designated areas (See appendix 1).

10. Senior staff in each department may refer to the occupational health department in each Trust to carry out health surveillance as necessary and appropriate assessment of staff exposed to cytotoxic products.

11. The Lead Cancer Pharmacist for each Trust is responsible for ensuring compliance with the Control of Substances Hazardous to Health Regulations and associated legislation within their designated areas.

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.

Prescribers Responsibility (including non-medical prescribers) for injectable and oral anti cancer medicines

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

- 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
- 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 patient's 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 follow the same practice if modifications are in accordance with the protocol or if they have

been discussed and confirmed with the Medical Consultant 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 prescriber must obtain the patient's verbal consent before prescribing any medicine.
- The Prescriber and Non-medical Prescriber is responsible and accountable for:-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.

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.
- Completing a Trust chemotherapy referral form to inform the nurse and pharmacy who will be treating the patient
- Ensuring that the body surface area (BSA) calculations are appropriate and have been made using a recent weight. If a patient is more than 30% over their ideal body weight, or body mass index (BMI) is greater than 30, then at TVCN it has been agreed we use ideal body weight + 30% to calculate BSA.The need for dose reduction or dose capping must be discussed with the treating Consultant.
- Ensuring patient weight is within 10% of weight used for BSA calculations.
- In Trusts where dose banding is approved the presciber 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. Automatic on Aria
- 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 and exfoliants
- 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.
- Ensuring that the patients fertility has been discussed as appropriate
- If a patient is to be treated off-protocol, refer to TVCN policy **Guidelines for the use of non-Network approved chemotherapy regimens in exceptional circumstances**
- Wherever possible, chemotherapy should be initiated during normal working hours defined in each Trusts Operational policy 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 document in the patient's healthcare record.
- Prescriptions for all cytotoxic drugs must be made electronically using the Network E-prescribing system. In exceptional cases, pre-printed proformas can be acceptable provided that they have been through a quality assurance procedure similar to that required for protocols to be accepted onto the E-prescribing system (ie checked by a Lead clinican, Lead pharmacist etc(? local to Trust))[Suggest reference the Aria checking procedure here] Changes to prescriptions must be made either electronically (amending the original e-prescription with the pharmacist's knowledge) recording the reasons in an electronic note attached to the electronic patient record. For hand written proforma prescriptions, 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. The aim will be for all to use the TVCN end of treatment report currently under pilot.

Pharmacists Responsibility

- An appropriately trained pharmacist must clinically screen all prescriptions for cytotoxic drugs prescribed for the treatment of malignant disease in accordance with the TVCN policy for screening chemotherapy prescriptions.
- 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 for diagnosis.
- 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
- 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 appropriate 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 TVCN Guidelines for the use of non-Network approved chemotherapy regimens in exceptional circumstances and ensure that funding has been secured via the Cancer drugs fund/IFR.
- 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.

Nurses Responsibility

- Registered Chemotherapy trained 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 double checked by a chemotherapy competent nurse and IV competent nurse (as a minimum for checking chemotherapy). The chemotherapy nurse is responsible for ensuring that:
- The correct weight and height have been recorded.
- 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. Automatic on Aria
- 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 intravenous 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 according to Local policy
- A nurse may not accept verbal orders for cytotoxic drugs or for adjustments to doses of cytotoxic drugs.

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 glomerular filtration rate (GFR) or EDTA should be stated for adult patients
- Estimated GFR (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 area under curve (AUC) for carboplatin.
- The frequency per day and the number of days of treatment.
- Route of administration (the abbreviations IT or IP is not acceptable, intrathecal intraperitoneal or intrapleura must be written in full). The same applies for other routes where potential for mis-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).
- Ant-iemetics, 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 5.1 for recommendations for oral chemotherapy.
- Oncology and haematology 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.
- 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 (including re-challenge of a chemotherapy regimen following previous treatment). The benefits and risks associated with chemotherapy need to be carefully discussed with the patient who should also be provided with high quality written information to supplement face to face communication.
- It is good practice to ensure that consent is taken by an appropriate Health care professional (according to local policy) 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.

3 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 of 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.

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 Cytotoxic 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.

Personnel Records

Managers responsible for these posts should keep a record of drug exposure for each member of staff in accordance to the Health and Safety Executive (HSE). 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 record should also be kept detailing all deviation from working standards e.g. accidental exposure due to spillage.

Pregnancy

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.

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 an 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. 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 where all pregnant staff 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 the chemotherapy course
- Signing to say they have read and understood the relevant risk assessments in the chemotherapy workbook and when the course is successfully completed this section must be copied and retained by the chemotherapy manager.
- 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 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.

Expectant 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.

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.

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.

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

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 clothes 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.

Protective clothing in Pharmacy appropriate to the area where the reconstitution is being carried out should be worn.

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.

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.

Torso protection (Plastic aprons)

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

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.

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:

Recommendations for PPE in handling activities:

Activity/PPE	**Gloves**	**Gown/apron**	**Eye protection**	**Respiratory problems**
Receipt of Raw Materials	✓	✓		
Receipt of Raw Materials	✓	✓		
Preparation	✓	✓**	✓**	
Administration	✓	✓	✓*	
Waste Disposal	✓	✓	✓	✓*
Spillage	✓	✓	✓	✓

* 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 re waste management.

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

Disposal of Cytotoxic Waste

Biological agents (including monoclonal antibodies) used in cancer treatment should be treated in the same way as cyctotoxic 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.NB Gene therapy is outside the scope of this document which is a biological agent

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 X.

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. Giving sets should not be removed from infusion bags prior to disposal.

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 1000ºC to ensure degradation of the cytotoxic agent.

Sharps disposal boxes containing cytotoxic waste must be regularly collected.

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 indicating that they are potentially contaminated by cytotoxic drugs.

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 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.

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 yellow bag and place into a rigid sharps box with a purple lid which denotes cytotoxic waste to be sent for incineration.

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.

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.

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

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

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.

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. Please refer to the TVCN Home spillage policy

- 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:Please refer to the TVCN spillage guidelines
- 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

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.

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.

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.

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 Manual.
- 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 above.

4 PURCHASING, PREPARATION, SUPPLY, TRANSPORTATION AND STORAGE OF CHEMOTHERAPY

Reconstitution of cytotoxic drugs

The Chief Pharmacist for each trust is responsible for ensuring that cytotoxic reconstitution services are provided in appropriate facilities. This will either be in a Trust pharmacy or contracted licensed cytotoxic facility. Handling procedures for manufacturing staff are documented in the standard operating procedures for the department.

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. 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 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.
- Storage must be designed in a manner that will prevent containers of cytotoxic agents from falling.
- 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.

Preparation of cytotoxic drugs – ask re intravesicle

- 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 9)- cross check
- 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, staff preparing cytotoxic agents will follow the individual Trust pharmacy procedures.
- An appropriately trained and accredited pharmacist 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.
- The pharmacist or accredited technician performing the final product check will ensure correct documentation, computer entry, ensure appropriate order preparation, dispense and release the medication for the patient.

Dispensing and Labelling oral chemotherapy NPSA rapid response report NPSA/2008/RRR001 included

- Staff verifying or dispensing prescriptions 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 TVCN e prescribing label guidelines
- 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 isolator
- Oral anti-cancer medicines should not be dispensed in compliance aids or monitored dose systems.

- When dispensing tablets or capsules, sufficient quantity for the complete cycle of treatment should be supplied.
- 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 alert on oral chemotherapy published in 2008 This should either be in the form of manufacturer's PIL or 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.

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

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.
- 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 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 or disposed of as soon as possible.
- Cytotoxic drugs that are to be transported outside of the hospital should be placed in sturdy, leakproof 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.

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.
- 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.

Preparation of Cytotoxic Drugs

Pharmacy Cytotoxic Preparation Services

Many pharmacy departments in acute Trusts delivering cytotoxic chemotherapy across TVCN 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.

In most situations during normal working hours, preparation of cyotoxic 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.

Chemotherapy should only be prepared as per the TVCN Chemotherapy protocols and the chemotherapy electronic prescribing system to comply with the NPSA alert 20 published in 2007, in conjunction with Trusts own intravenous guidelines

5 OUT OF HOURS INITIATION AND ADMINISTRATION OF CHEMOTHERAPY

Please refer to Each Trusts Local Policy

It is recommended that wherever possible, all cancer chemotherapy should be started in an unhurried environment with minimal distractions within normal working hours Monday – Friday, as this is when access to specialist staff is most likely to be available. The exceptions are:

- Continuous infusions
- Regimens where chemotherapy is administered for more than 5 consecutive days
- Timed chemotherapy
- Chemotherapy given more than once a day
- Emergency chemotherapy

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. This is defined in each local policy

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 or Haematologist must determine that it would be absolutely inappropriate to delay chemotherapy. The decision must be recorded in the medical notes by the responsible Consultant. And discussion with the lead chemotherapy team –lead chemotherapy Clinician ,Pharmacist and nurse should be the next step

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.

Refer to Local Trust Chemotherapy policy for process if an emergency dose of chemotherapy was required out of normal pharmacy hours in exceptional circumstances.

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 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.

Chemotherapy should only be adminstered as per the TVCN Chemotherapy protocols and chemotherapy electronic prescribing system to comply with the NPSA alert 20 published in 2007.

Administration of cytotoxic drugs via all routes must be carried out by nursing staff who have been trained and assessed as competent according to a Network agreed competency framework. Please note this does not include INTRATHECAL CHEMOTHERAPY 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 Immediately prior to administration the nurse who will be administering the chemotherapy should check the chemotherapy with a registered IV competent nurse, familiar with chemotherapy administration. Neither professional should have been involved in the dispensing process.

Facilities. when administering cytotoxic chemotherapy:

Cytotoxic drugs should be administered in a dedicated therapeutic environment with appropriate facilities for safe administration and within safe working staffing levels. The area should also have an annual risk assessment undertaken to ensure fitness for purpose, in line with the recommendations of NPSA alert promoting 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.

In summary

- An area that is not used as a thoroughfare — to limit unnecessary exposure.
- An area with adequate storage, lighting and suitable work surfaces.
- Good hand-washing facilities.
- Access to privacy for patients when required.
- Designated patient toilets.
- Access to emergency call system and/or telephone.

- Facilities for the safe disposal of cytotoxic waste.
- Easy access to relevant drug information, policies, procedures and guidelines.
- An area that is easy to clean.

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.

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.

Patient / carer information

'All patients should be given both verbal and written information about their treatment, likely side effects and whom they should contact if problems arise (either within or outside normal working hours). All patients should have access to 24-hour telephone advice with active management of access to appropriate emergency care.' (refer to NCAG Report 2009 – pg 5)

Patients / carers will be actively involved in decision making about their treatment. In addition to verbal information given during consultations –face to face education, patients will be offered written information specific to the regimen they will be treated with. Information sheets from the Macmillan Cancer Support website will be given to patients and carers which include potential side effects and any necessary precautions. Patients will also be given a chemotherapy alert card with 24 hour contact details for use in emergency. The nurse should rehearse with the patient and carer what to do if complications occur following chemotherapy covering at least the following complications

- Neutropenic sepsis
- Cytotoxic extravasation
- Nausea and vomiting
- Stomatitis,other mucositis and diarrhoea

The NCAG report also recommends that the patients pre chemotherapy assessment/new patient assessment by their chemotherapy nurse should be done on a separate day or time to the

chemotherapy consultation/ treatment wherever possible as patients report they are too anxious to take in advice given.

A GP information sheet will be sent to provide GPs highlighting the treatment regimen being administered, expected toxicities and contact numbers to be used in event of complications (Primary care resource pack – management of chemotherapy side effects).

Patients receiving infusional cytotoxic therapy at home will also be given written information regarding the management of chemotherapy spillage. (Home chemotherapy spillage guidelines) and a spillage kit.

Relevant primary healthcare staff will be informed when a patient is being treated with infusional chemotherapy in the community.

Following a course of chemotherapy consideration should be given to proactive support for patients

6.1 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.Do we need to add here if patient unable to take orally – give IV
- 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 (for example 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.

Patient Education and Information specific to oral chemotherapy

- 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.

6.2 Administration of Intravenous Chemotherapy

- A competent practitioner in consultation with the patient should select the most appropriate vascular access device. Please see TVCN Central venous access policy
- 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 a venepuncture and cannulation competency programme) is key to preventing infiltration and extravasation. Please see extravsation policy.

Checks before administration

The patient's performance status should be recorded prior to each cycle (in line with the NCAG recommendations in response to NCEPOD) of chemotherapy by the healthcare professional undertaking the patient review. Blood tests and relevant results/ investigations and toxicities should

be recorded as identified by the specific regimen which must be reviewed by the doctor/nurse prior to administration. Prior to the first cycle of chemotherapy the blood results should be current and no more than 7 days previously and 48 hours pre subsequent cycles of chemotherapy. Patients should receive pre-chemotherapy counselling ideally on a separate time/day to the actual treatment ensuring that written informed consent is obtained.

Verification of the patient and chemotherapy
This must be undertaken by a registered nurse and checked by another registered nurse, , at least one of whom has been assessed as competent to administer chemotherapy.

To verify a patient's chemotherapy, check the following for each drug:

- Positive identification of patient using triple identity checks.
- Blood parameters as per chemo protocol e.g. the platelet and neutrophil count.
- The name of the drug and dose must match exactly that prescribed on the prescription.
- The patient's name and hospital number must be on the cytotoxic product label.
- The name of the drug must correspond exactly with the prescription
- Cycle of chemotherapy to be administered.
- Check the drug has been appropriately stored.
- Visual check of drug for precipitate and leakage.
- The dose corresponds with the body surface area measurements.
- The drug is to be administered by the route and over the duration intended.
- The drug is to be administered in the correct sequence.
- The drug will not expire before administration is completed.
- Check the patient has received the correct anti-emetic drugs, where appropriate.
- The details on the prescription match the patient's identification (as per local policy).
- Any dose or schedule modification must be documented clearly, with reasons for changes in the patient's notes.
- If there are any discrepancies do not proceed, seek advice

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
- The pump is infusing correctly – using pump checks according to local policy
- 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 or glucose 5% depending on drug administered 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 verbalized 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.

Stop administration if

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

General Principles of Intravenous Chemotherapy 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 – gloves and apron are worn as per local policy and infection control guidelines
- Checking should follow procedure previously described in section 1 Patient details should be confirmed verbally with the patient, 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 (See manufacturers guidelines)
- 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 24 hours.
- On completion of dose administration clear away and dispose of all equipment, waste and sharps as outlined in section 2
- Record the administration on the prescription sheet, in the medical, nursing notes, and electronic prescribing system .
- 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 vials see Section 2

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.

Administration of Vesicant Drugs

- Vesicant cytotoxic drugs should be administered before non-vesicants unless the protocol specifies this.
- Ideally vesicants should be given via a newly sited cannula. Ensure that it is patent and bleeds back.
- Observe and educate the patient regarding the risks.
- Check for blood return every 2-5 ml during administration and before and after each drug during bolus administration.
- Doses of vinca alkaloids for all patients treated in teenage, adolescent or adult settings should be administered in 50ml minibags, over 5-10 minutes, regardless of the age of the patient.
- Other vesicants (e.g. paclitaxel, amsacrine, carmustine, dacarbazine, mannitol and streptozocin) can be administered as an infusion through a peripheral line 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.
- When there are 2 vesicant drugs the vinca alkaloid should be administered second.

Administration of Irritant Drugs.

- Use a new cannula if possible. Ensure that it is patent and bleeds back.
- 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.

Administration of Non-Vesicant Drugs.

- Use a new cannula if possible. Ensure that it is patent and bleeds back.
- Observe and counsel the patient regarding the risks.
- Non-vesicant infusions should be administered via an infusion pump.

6.3 Administration of 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.

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.

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 90o 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 2.

6.4 Administration of Intravesical Instillation

Cytotoxic drugs are given intravesically for the treatment of superficial bladder cancer. They are either given as a single dose to reduce the risk of tumour seeding post-operatively (13), or as a course to treat recurrent or high risk tumours. They may be vesicant drugs.

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
- Spillage kit
- Clamps

Procedure

- European Association of Urology(14) guidelines suggest that administration of intravesical chemotherapy post-operatively should occur within 6 hours of resection of bladder tumour. Ensure that the drug has been prescribed and that authorisation to give the drug has been given by the clinician post-operatively (patients found to have muscle invasive cancer or bladder perforation during surgery may not be given intravesical chemotherapy).

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 2)
- 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 2).
- 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 2.

6.5 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.

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.

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 2.
- 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 and details of obtaining further medicine supplies if needed.

APPENDIX 1

24 hour contact numbers

Trust	Department / Ward	In Hours contact number	Out of Hours contact number
Buckinghamshire Hospitals NHS Trust Mid and South Buckinghamshire	Cancer Care and Haematology Unit, Stoke Mandeville	(01296) 315125	(01865) 235012 (01865) 235014
	Sunrise Cancer Unit, Wycombe	(01494) 426238	(01865) 235012 (01865) 235014
	Ward 5, SMH (open 24 hours)	(01296) 316336 (01296) 316339	(01296) 316336 (01296) 316339
Heatherwood and Wexham Park Hospitals NHS Trust	Eden Ward in-patients (Open 24 hours)	(01753) 633150/1	(01753) 633150/1
	Eden Day Unit (open Mon to Fri 0900-1700)	(01753) 633153	(01753) 633150/1
	Chemotherapy Suite KEVII (Open Tues/Wed 8-5)	(01753) 636479	(01753) 633150/1
Milton Keynes General NHS Trust	Macmillan Day Unit	01908 660033 bleep 1090 Acute Oncology/Haematology ANP	01908 660033 bleep 1090 Acute Oncology/Haematology ANP
	Ward 22		
Northampton General Hospital	Talbot Butler Ward (open 24 hours for oncology patients)	(01604) 545334	(01604) 545334
Oxford Radcliffe Hospitals NHS Trust	Triage Assessment Unit Open Monday to Friday 8am-8pm	01865 572192 (only to be given to Oncology patients at present).	01865 572192
	CRUK Early Phase Chemo Clinical Trials Unit:	01865235017 & 01865 235610.	01865 572192
	Brodey Centre Horton General Hospital	(01295) 229034	Oncology – (01865) 572192 24 hour helpline Haematology – (01865) 235048
	Oncology Ward (General and radiotherapy) (open 24 hours)	(01865) 235012 (01865) 235014	(01865) 235012 (01865) 235014
	Oncology Day Treatment Unit/oral chemotherapy patients. Open Mon to Fri 0900 -1700	(01865) 235128	01865 572192
	Haematology Day Treatment unit Open Mon to Fri 0900 - 1700	(01865) 235554	(01865) 235048
	Haematology ward (Open 24 hours)	(01865) 235048	(01865) 235048
Royal Berkshire NHS Foundation Trust	West/King Edward Ward	(0118) 322 7464	(0118) 322 7470/1
	Berkshire Cancer Centre	(0118) 322 7890	(0118) 322 7470/1
	Adelaide Ward	(0118) 322 7470/1	(0118) 322 7470/1

APPENDIX 2: ADMINISTRATION OF CHEMOTHERAPY VIA SPECIFIC ROUTES

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.This should be done by a Dr trained to undertake this procedure and with a chemotherapy trained nurse from the chemotherapy ward/unit.

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

Procedure

- Refer to local policy/guidelines on thoracocentesis (chest drain insertion)
- Pre-medication should be administered prior to the pleurodesis 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 (reference 14).
- 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 2).

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.This should be done by a Dr trained to undertake this procedure and with a chemotherapy trained nurse from the chemotherapy ward/unit

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

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.
    - ay 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 2).

Administration of Chemoembolisation.

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

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.

Procedure

In chemoembolization, 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.

Procedure for Application 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.

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.

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