



GUI DELINES FOR THE SAFE USE OF CYTOTOXIC CHEMOTHERAPY IN THE CLINICAL ENVIRONMENT

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GUIDELINES FOR THE SAFE USE OF CYTOTOXIC CHEMOTHERAPY IN THE CLINICAL ENVIRONMENT

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INTRODUCTION

This document presents Guidelines for the use of cytotoxic chemotherapy in the clinical environment.

It has been developed in response to NHS MEL(1997)66 which gives guidance on standards of practice for chemotherapy services, pharmaceutical care and nursing services required for cancer patients in Scotland.

It aims to summarise and augment currently available clinical guidelines including:

- Joint Council for Clinical Oncology (JCCO). Quality Control in Cancer Chemotherapy. Managerial and Procedural Aspects. 1994.
- Royal College of Nursing (RCN). The administration of Cytotoxic Chemotherapy Clinical Practice Guidelines. Recommendations. 1998.

This document should be used along with these clinical guidelines when developing local or national policies, procedures and standards. It covers certain high-risk aspects of cancer chemotherapy, for instance extravasation and intrathecal administration, in considerably more detail than is found in either of these references.

The scope of this document encompasses the following patient groups:

- 1. Patients receiving cytotoxic chemotherapy for the treatment of cancer.
- 2. Patients of all age groups.

This document does not include:

The use of cytotoxic drugs for the treatment of non-malignant disease.

The administration of cytotoxic chemotherapy at home, where there is insufficient data available to determine the effect on patient outcomes, or cost to the health service

Sources of Evidence

The information and evidence used to compile this document came from multi-disciplinary and multiprofessional sources including local protocols in use within hospitals treating patients with cancer in Scotland.

The recommendations in this document are referenced in two ways. When references are displayed in the title, a large part of the section will be derived from these references. When references are displayed within the text they relate to that specific point. All the references used within a section are given at the end of that section.

1 PRESCRIBING CYTOTOXIC CHEMOTHERAPY FOR PATIENTS WITH CANCER

1.1 **Prescribing Requirements**¹

- 1.1.1 The initial decision to prescribe cytotoxic chemotherapy must be made by a consultant or a senior specialist with appropriate experience (as defined by local policy). This person should record their decision and the proposed plan of treatment in writing.
- 1.1.2 Before each course of cytotoxic chemotherapy the patient should be reassessed as being fit to receive the prescribed treatment by an appropriately qualified, competent practitioner (as defined by local policy).
- 1.1.3 Cytotoxic chemotherapy should be prescribed by an appropriately qualified, competent practitioner (as defined by local policy). Prescribing should be in accordance with written local treatment protocols that are readily available in the ward, clinic and pharmacy department.
- 1.1.4 Cytotoxic chemotherapy regimens should wherever possible be prescribed on a standardised chemotherapy prescription form that has been designed for this purpose. It is recommended that each time a new protocol is used, a standardised prescription form is devised giving details of the regimen and the drug administration details. This may be designed by the pharmacist or doctor and must be verified by both the initiating consultant or the senior specialist (who will sign and date the prescription) and by the pharmacy department. Computer generated forms may be used.
- 1.1.5 The cytotoxic chemotherapy prescription form must provide sufficient patient and drug details to allow verification of the prescription. The information should include: patient name; date of birth; unit number; height & weight; diagnosis; haematology/biochemistry results (as required by the protocol).
- 1.1.6 For new regimens or ad-hoc cytotoxic chemotherapy, the prescription should be written by the patient's consultant or a senior specialist with appropriate experience.
- 1.1.7 The design of the administration chart (which may also be the prescription form) should be agreed by medical, pharmacy and nursing staff to ensure it includes all necessary information for the prescribing, preparation and administration of the cytotoxic chemotherapy (as defined by local policy).

1.2 **Oral cytotoxic Chemotherapy**¹

- 1.2.1 The first prescription for outpatient oral cytotoxic chemotherapy must contain a clear time limit after which a consultant or senior specialist must review the patient's progress.
- 1.2.2 At each review, a limit to the number of courses must be specified, after which a consultant or senior specialist must review the patient again
- 1.2.3 Labels on oral cytotoxic chemotherapy and high dose steroids should make clear the time limit on treatment e.g. "for 5 days then stop".
- 1.2.4 Protocols giving details of oral cytotoxic chemotherapy treatment regimens should be available in the pharmacy dispensary to allow treatment and dosage verification.

1.3 **Prescription Verification**^{1,2}

- 1.3.1 All prescriptions for cytotoxic chemotherapy should be verified by an appropriately qualified, competent practitioner (as defined by local policy) to ensure calculations, drug dose, route, timing and scheduling are correct.
- 1.3.2 Recommendations on dose reductions and criteria for delay or dose alterations relating to blood chemistry and toxicity must be readily available to both prescriber and verifier.
- 1.3.3 When the drugs are dispensed there will be verification procedures built into the dispensing processes in the pharmacy.
- 1.3.4 Before the drugs are administered there must be verification that the drugs to be administered are as detailed on the prescription forms that the administration, route and schedule is correct and that the correct patient receives the drugs.

- 1. Royal College of Nursing (RCN). The administration of Cytotoxic Chemotherapy Clinical Practice Guidelines. Recommendations. 1998.
- 2. Joint Council for Clinical Oncology (JCCO). Quality Control in Cancer Chemotherapy. Managerial and Procedural Aspects. 1994.

2 PREPARATION AND SUPPLY OF CYTOTOXIC CHEMOTHERAPY

2.1 **Preparation**

- 2.1.1 Cytotoxic chemotherapy should be prepared within the pharmacy department or in a pharmacy-controlled facility within a clinical area¹.
- 2.1.2 Premises in which chemotherapy is prepared must meet the standards for aseptic dispensing as required by the report on Aseptic Dispensing for NHS Patients² and MEL(1996)95³.
- 2.1.3 In every instance, cytotoxic chemotherapy should be prepared to the same standard out of hours as within normal working hours.
- 2.1.4 No cytotoxic chemotherapy should be prepared outwith a pharmacy controlled facility.
- 2.1.5 All cytotoxic chemotherapy should be prepared by appropriately trained staff^{1,4}.
- 2.1.6 All cytotoxic chemotherapy prepared by a pharmacy department will have a shelf-life assigned to it, based on the stability of the product⁵
- 2.1.7 If cytotoxic chemotherapy is prepared in an environment other than the pharmacy department, it should be used immediately after it has been prepared. The administration of infusions produced in this way should be completed within 12 hours of preparation⁶

2.2 Transport

- 2.2.1 The cytotoxic chemotherapy prepared by the pharmacy department must be packaged to ensure no escape, leak or spillage during handling and carriage.
- 2.2.2 Packaging must be suitable for the product and robust enough to withstand normal conditions of transport and handling.
- 2.2.3 Packaging must be:
 - a) robust
 - b) tamper proof
 - c) able to provide protection for the handler
 - d) able to contain any leakage
 - e) labelled to identify of the nature of the contents
 - f) labelled to state the name and address of the sender and recipient

2.2.4 Procedures should be available for dealing with spillage during transport. Any such spillage incident should be recorded in writing by the person or persons involved on either a purpose-designed form or a local incident reporting form.

- 2.2.5 Persons transporting cytotoxic chemotherapy must be trained in the actions to be taken in the event of a spillage and the reporting of such an incident.
- 2.2.6 Cytotoxic chemotherapy is classified as prohibited or restricted material by the Postal Service and should therefore not be sent by routine post. Special arrangements are required with the carrier being made aware of the hazardous contents. Storage handling and packaging requirements need to be agreed. For further information contact the Royal Mail International Headquarters.
- 2.2.7 If products require refrigeration, the cold chain should be monitored and protected.

2.3 Storage

- 2.3.1 The product should be received by a staff member who will be responsible for opening the package and ensuring that it is stored safely and in an appropriate manner until required for use.
- 2.3.2 Storage at the ward/clinic should be according to current recommendations for drug storage in hospitals. There should be an area specifically for hazardous drugs and it should be labelled as such. The physical storage requirements set out on the label should be met e.g. refrigeration between 2-8°C.

2.4 Labelling⁴

- 2.4.1 Labels for cytotoxic chemotherapy must comply with the legislation and include the following information:
 - a) the intended route of administration
 - b) the generic name of the chemotherapy drug
 - c) the quantity of drug
 - d) where appropriate, the vehicle into which the drug has been dissolved or diluted
 - e) the final volume for bolus doses and the approximate final volume for infusions
 - f) information such as a unique identification number and dispensing date that will facilitate the identification of all drugs, solvents, diluents or infusion solutions
 - g) shelf-life
 - h) storage requirements
 - i) patient's name and location
 - j) name and address of the cytotoxic chemotherapy dispensary
 - k) manufacturers recommendations, as set out in the latest Summary of Product Characteristics

- 2.4.2 The person receiving the cytotoxic chemotherapy and storing it prior to administration must be able to identify the intended patient without opening the final protective covering.
- 2.4.3 The labelling and packaging should allow all the label details required for administration to be visible before the final protective covering is opened.

- 1. The Society of Hospital Pharmacists of Australia Committee of Speciality Practice in Oncology SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments. Aust J Hosp Pharm 1999; **29:** 108-116. Sections 6.1 & 6.3.
- 2. Aseptic Dispensing for NHS Patients. London. The Department of Health 1995.
- Aseptic Dispensing for NHS patients. Edinburgh. The Scottish Office Home and Health Department. MEL(1996) 95.
- 4. Allwood M, Stanley A, Wright P. (eds.) The Cytotoxics Handbook. Third Edition. Oxford. Radcliffe Medical Press 1997. p13 & 61.
- 5. Aseptic Dispensing for NHS Patients. London: The Department of Health, 1995.
- 6. British National Formulary 38. Appendix 6, Intravenous Additives. September 1999

3 ADMINISTRATION OF CYTOTOXIC CHEMOTHERAPY

3.1 General Points

- 3.1.1 The aim of this section is to provide guidance that will minimise the risk of exposure of staff and patients to cytotoxic chemotherapy and its unwanted effects, such as extravasation.
- 3.1.2 Cytotoxic chemotherapy must be prescribed by the medical staff as described in section 1.
- 3.1.3 The approved local procedure for the administration of medicines must be adhered to in all situations¹.
- 3.1.4 Whenever practicable, to minimise the risk of adverse incidents, cytotoxic chemotherapy should only be administered during normal working hours, or in specialist units where support services and expert advice are available^{2,3}.
- 3.1.5 Patients should receive cytotoxic chemotherapy in designated wards or outpatient clinics that are equipped to deal with any emergencies that may arise from the treatment^{2,3}.
- 3.1.6 All intravenous cytotoxic chemotherapy should be administered by medical or nursing staff who have received education and training in the administration of cytotoxic chemotherapy^{2,3}.
- 3.1.7 Staff should demonstrate their competency on a regular basis and keep written records of their training and competency reviews.
- 3.1.8 The local procedure for verifying and recording the administration of medicines must be adhered to throughout¹.
- 3.1.9 The Pharmacy should provide access to information on the nature of the cytotoxic chemotherapy being administered. This should include toxicity, treatment of acute exposure and a COSHH (1994) risk assessment in addition to information required to ensure patient safety during therapy⁴. This must be held in the pharmacy and in the clinical area.
- 3.1.10 The final checks before chemotherapy is administered are set out in the UKCC Standards for Administration of Medicines.
- 3.1.11 The person administering the medication must be satisfied that the patient's performance status is similar to that seen by the prescribers when the prescription was written e.g. the patient has not suddenly deteriorated or developed an infection.

3.2 Guidelines for the Intravenous Administration of Cytotoxic Chemotherapy

- 3.2.1 All staff who administer cytotoxic chemotherapy should be formally trained in the administration procedures including the use of infusion control equipment. Detailed guidelines are given in Appendix 1.
- 3.2.2 There should be an extravasation treatment policy in place to allow staff to deal promptly and appropriately with extravasation caused by cytotoxic chemotherapy. Guidelines for the recognition and treatment of extravasation caused by cytotoxic chemotherapy are given in Appendix 2.

3.3 Guidelines for Oral Cytotoxic Chemotherapy

- 3.3.1 Disposable gloves must be used when handling containers and oral cytotoxic chemotherapy².
- 3.3.2 Tablets must not be crushed, nor capsules opened or the medication tampered with in any way.
- 3.3.3 The scheduling of the regimen should be discussed with the prescriber to ensure that whole tablets are prescribed wherever possible.
- 3.3.4 If the patient is unable to take the drug in the form presented, contact the Pharmacy Department. The Pharmacy may be able to supply another form, or dispense a modified form in a safer environment. Information about the hazards of modifying dosage forms should be given to everyone concerned with the patient's care².
- 3.3.5 The medication label should warn users that the drug is cytotoxic and therefore should be handled with care, preferably only by the patient. Direct contact with the dosage form must be kept to a minimum.
- 3.3.6 The availability of liquid formulations from 'specials' manufacturers can be investigated and their use authorised by the Trust Chief Pharmacist.
- 3.3.7 Medicine spoons /cups used for the administration of oral cytotoxic drugs must be disposed of into appropriately marked puncture-proof bins for incineration.

3.4 Guidelines for Intrathecal Cytotoxic Chemotherapy

3.4.1 There have been a number of fatalities where intravenous chemotherapy has been wrongly administered by the intrathecal route. Therefore special precautions must be taken at all stages of the prescribing, preparation and administration of drugs intended for the intrathecal route⁵.

3.4.2 Detailed guidelines are given in Appendix 3.

3.5 Guidelines for Other Routes of Administration

- 3.5.1 These include the intravesical, intrapleural, intraoccular, topical, subcutaneous and inhaled routes.
- 3.5.2 Seek advice from a clinician for full details of administering cytotoxic chemotherapy by these routes².
- 3.5.3 Follow the same principles of safe administration as for the parenteral and oral routes.

3.6 Spillage of Cytotoxic Chemotherapy

3.6.1 Guidance for minimising the risk of spillage of cytotoxic chemotherapy and spillage management measures are given in Appendix 1.

- 1. United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC). Standards for the Administration of Medicines. London, October 1992.
- 2. Royal College of Nursing (RCN). The administration of Cytotoxic Chemotherapy Clinical Practice Guidelines. Recommendations. 1998.
- 3. Joint Council for Clinical Oncology (JCCO). Quality Control in Cancer Chemotherapy. Managerial and Procedural Aspects. 1994.
- 4. American Society of Health System Pharmacists. ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs. 1990, reviewed 1996. In: AHFS Drug Information 1999: 1029-1038.
- 5. Paediatrics Hospital Chief Pharmacists Groups and the Paediatric Oncology Pharmacists Group. Guidance on the Management of Intrathecal Therapy in Paediatric Oncology. March 1998. Letter.

4 DISPOSAL OF CYTOTOXIC CHEMOTHERAPY

4.1 General Points¹

- 4.1.1 A written local protocol for the disposal of all items contaminated with cytotoxic chemotherapy should be available and communicated to all personnel involved in the administration of this therapy.
- 4.1.2 The protocol must clearly identify the person with overall responsibility for the disposal of cytotoxic waste within the hospital/clinic and other legislative requirements.
- 4.1.3 Items which may be considered to be contaminated include: bottles, vials, personal protective equipment and other materials used in the preparation and administration of cytotoxic chemotherapy. Any material or equipment that has been used to collect vomit or excreta from patients who have received cytotoxic chemotherapy must also be disposed of as contaminated waste.
- 4.1.4 All staff who handle cytotoxic chemotherapy or waste, or work in areas where they are used must be trained appropriately in the risks and appropriate practices for handling and disposing of waste. Their understanding of and adherence to local policies and protocols should be monitored.
- 4.1.4 Guidance on the handling of cytotoxic chemotherapy during administration is given in Section 3 and Appendix 1of this document.
- 4.1.5 Handling of contaminated items following spillage of cytotoxic chemotherapy should follow local protocols.
- 4.1.6 A licensed waste disposal company should be employed to remove and dispose of cytotoxic waste.

4.2 Used Administration Devices and Contaminated Clinical Waste

- 4.2.1 Suitable containers, clearly labelled and reserved solely for cytotoxic waste, should be available in all areas where these drugs are handled.
- 4.2.2 These should be brightly coloured and marked with the nature of the contents. They should be made of plastic and conform to Health and Safety legislation, be puncture and leak-proof with tightly fitting lids which can be sealed when the container is full.

- 4.2.3 There should be a layer of absorbent material such as clay pellet cat litter in the bottom of the cytotoxic waste container to avoid accidental splashing from liquid waste².
- 4.2.4 In some circumstances, the licensed waste disposal company will supply appropriate waste containers. Where this is the case, details of the supply procedures should be in the local policy.
- 4.2.5 Contaminated materials such as bottles, infusion bags, personal protective equipment and other materials used for administering cytotoxic chemotherapy should be placed in the cytotoxic waste container after use.
- 4.2.6 Contaminated needles, giving sets and tubing should be disposed of intact and not clipped, to avoid the risk of aerosolisation¹.
- 4.2.7 The cytotoxic waste containers should be segregated from other clinical and non-clinical waste and not allowed to accumulate. Facilities for the storage and transportation of the cytotoxic waste awaiting destruction must not expose personnel to any risk from the waste².
- 4.2.8 On no account is clinical cytotoxic waste (as described above) to be disposed of into the domestic sewerage system. Recommendations for the safe handling of excreta from patients receiving cytotoxic chemotherapy are given in Section 5 of this policy.

4.3 Unused Cytotoxic Chemotherapy

- 4.3.1 Unused doses of cytotoxic chemotherapy must be returned to the pharmacy department for disposal in cytotoxic waste containers as bulk-contaminated waste.
- 4.3.2 If the unused cytotoxic chemotherapy is to be removed from the clinical setting, then the guidance for safe transportation in Section 2 of this policy must be followed.

- 1. Royal College of Nursing (RCN). The administration of Cytotoxic Chemotherapy Clinical Practice Guidelines. Recommendations. 1998.
- 2. Allwood A, Stanley A, Wright P (eds.) The Cytotoxics Handbook. Third Edition. Oxford. Radcliffe Medical Press 1997.
- 3. American Society of Health System Pharmacists. ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs. 1990, reviewed 1996. In: AHFS Drug Information 1999: 1029-1038.

5 MINIMISING EXPOSURE TO CYTOTOXIC CHEMOTHERAPY

5.1 **General Points**^{1,2}

- 5.1.1 Risk to staff who prepare, transport, handle and administer cytotoxic chemotherapy will be minimised by:
 - a) providing an adequate protective environment
 - b) providing an Occupational Health monitoring programme

c) ensuring effective written procedures are available to complement ongoing staff training for all elements of the service including spillage and disposal of contaminated wasted) regularly auditing the elements of the cytotoxic chemotherapy service

- 5.1.2 No definitive guidelines for Occupational Health monitoring for health care staff working with cytotoxic chemotherapy are available nationally. Local policies should be followed.
- 5.1.3 Due to potential exposure to cytotoxic chemotherapy, pregnant staff should not handle or administer cytotoxic chemotherapy. If this is not operationally possible, then all precautions must be in place to minimise exposure.

5.2 General Guidelines for Handling Patients' Waste^{3,4}

- 5.2.1 Depending of the type of cytotoxic chemotherapy, blood, vomit, drain/wound exudates, urine and faeces may contain high levels of cytotoxic agents for up to 7 days after administration.
- 5.2.2 Where no data are available, assume that precautions must be taken for 48 hours after administration.
- 5.2.3 It should be assumed that there will be a high concentration of oral cytotoxic chemotherapy present in patients' vomit for up to 2 hours after administration.

5.3 Guidelines for the Hospital/Clinic⁴

5.3.1 A specially designated toilet should be available for patient use. Male patients should be instructed to sit while urinating and to flush the toilet thoroughly with the lid closed to avoid aerosol release.

- 5.3.2 Disposable absorbent pads should be provided in beds and on chairs. Mattresses and pillows should be protected with plastic covers.
- 5.3.3 Disposable bedpans, urinals and sick-bowls should be used where available.
- 5.3.4 Scales should be used for urine measurement to avoid having to pour the urine into a measuring jug. This avoids aerosol formation.
- 5.3.5 Staff disposing of patients' excreta must wear gloves and a gown.
- 5.3.6 Excreta may be disposed of via the sewer. Used disposable materials must be discarded with the cytotoxic waste if they are visibly contaminated.

5.4 **Guidelines for the Domestic Environment**

- 5.4.1 Patients should be made aware that their excreta will be contaminated with cytotoxic chemotherapy. If possible, they should be given an indication of how long to take precautions for their particular regimen.
- 5.4.2 The risk to other family members is low and it is safe to dispose of excreta into the domestic sewerage system, avoiding aerosol formation as above.
- 5.4.3 Disposable gloves should be used when clearing up vomit or accidental spillage of excreta.

- 1. Occupational exposure to cytotoxic drugs. Seminar. Pharm J 1999;263(7053):65-67
- 2. Allwood A, Stanley A, Wright P (eds.) The Cytotoxics Handbook. Third Edition. Oxford. Radcliffe Medical Press 1997.
- 3. Bos JM, Swart EL. Cytotoxics Preparation and Administration Manual. University Hospital Vrije Universiteit, Amsterdam, January 1998.
- 4. The Scottish Office Department of Health: Scottish Infection Manual. 1998

6 **RECOMMENDATIONS**

In drawing up the guidelines the subgroup identified gaps in the evidence base and a lack of policies and procedures. This section provides recommendations on the work required to address the deficiencies.

6.1 **Prescribing Cytotoxic Chemotherapy for Patients with Cancer**

6.1.1 Systems need to be developed which ensure that prolonged coursed of oral cytotoxic chemotherapy cannot be inadvertently prescribed and dispensed in the community.

6.1.2 Prescribing protocols should be developed from treatment guidelines. These protocols should include detailed explanations of the scheduling of treatments, dosage calculations and the criteria for making dosage adjustments. Full details of the appropriate routes, timing and methods of administration for every cytotoxic drug and supportive treatment in the regimen should be included in the protocol.

6.2 **Preparation and Supply of Cytotoxic Chemotherapy**

6.2.1 A centralised shelf-life stability database is required, which should be updated regularly and provide interpretation of the available data. Ideally this should be a user-friendly resource which defines the shelf-life for specific products made and stored under specified conditions.

6.2.2 A policy and procedures should be in place for competency based training for all personnel involved in the transportation of cytotoxic chemotherapy. The policy and procedures should include action to be taken in the event of an accident or spillage and how to correctly report the incident.

6.3 Administration of Cytotoxic Chemotherapy

6.3.1 National standards, based on best practice, need to be agreed for the administration of cytotoxic chemotherapy by the intrathecal route.

6.3.2 Research is required to determine the requirements for the administration of chemotherapy by routes other than intravenous, oral and intrathecal. (see section 3.5.1)

6.3.3 The information required in best practice guidelines and the contents of spillage kits requires further research.

6.3.4 National guidelines for the management of spillage should be developed.

6.3.5 A policy and procedures should be in place for competency based training relating to the drugs used, their side effects & emergency treatment of adverse effects for personnel involved in the administration of cytotoxic chemotherapy.

6.3.6 A policy and procedures should be in place for competency based training for spillage management for personnel involved in the administration of cytotoxic chemotherapy.

6.4 **Disposal of Cytotoxic Chemotherapy**

6.4.1 At local level there is a need to clarify in the definition of cytotoxic waste.

6.5 Minimising Exposure to Cytotoxic Chemotherapy

6.5.1 National guidelines should be produced for the monitoring of health care staff working with cytotoxic chemotherapy.

6.5.2 Further research into the levels and potential risks when handling patients waste is needed prior to the development of national guidelines.

6.6 Extravasation of Cytotoxic Chemotherapy

6.6.1 An evidence based guideline is required for the management of extravasation. The guideline should include the management of extravasation involving more than a cytotoxic chemotherapeutic drug.

6.6.2 Guidelines on the approach to the treatment of extravasation involving more than one cytotoxic drug are required.

6.6.3 Training standards need to be defined to ensure all staff administering chemotherapy competent in the management of extravasation.

6.6.4 All sites undertaking the administration of cytotoxic chemotherapy should be externally audited against agreed national standards.

6.6.5 Extravasation kits should be standardised to meet the requirements

APPENDIX 1

GUIDELINES FOR THE INTRAVENOUS ADMINISTRATION OF CYTOTOXIC CHEMOTHERAPY

1.1 **Policy Guidelines**

- 1.1.1 All staff working with cytotoxic chemotherapy should receive a copy of the extravasation treatment policy. The policy must also be readily available wherever chemotherapy is administered.
- 1.1.2 There should be a suitably stocked extravasation kit in all areas where cytotoxic chemotherapy is administered. The kit must be regularly checked for completeness and expired stock. Reference should be made to the locations of the kits in the extravasation policy.
- 1.1.3 In the event of an extravasation incident, accident or spillage involving cytotoxic chemotherapy, the procedures for dealing with these events, as set out in Appendix 2 and Section 3 of this document must be followed. The incident must be recorded using local reporting procedures for such events.
- 1.1.4 The person administering the treatment must ensure that adequate protection is provided to the patient and themselves. The area around the injection site should be protected from accidental spills with absorbent pads¹ and the person administering the treatment should wear the following protective clothing²:
 - a) plastic apron
 - b) disposable PVC or surgical latex gloves
 - c) eye protection (to British Standard EN166), face protection and eyewash should be available in any area where a COSHH assessment has determined that there is a risk of generating splashes or sprays of aerosols containing cytotoxic drugs².
- 1.1.5 The choice of vascular access device depends on the patient and the quantity of cytotoxic chemotherapy to be administered^{2,3}. Is recommended that small gauge Teflon[®] or silicon cannulae with Luer-lok[®] attachments should be used wherever possible.
- 1.1.6 For the slow infusion of high-risk drugs, a central line, peripherally inserted central catheter (PICC) or other long line should be used whenever possible.
- 1.1.7 The cannula site should be chosen carefully, the first choice being the forearm. The dorsum of the hand, the anticubital fossa, the feet or other sites in close proximity to joints, tendons, nerves or major arteries are not to be used unless no other access is available. Avoid using limbs with compromised circulation^{3,4}.

- 1.1.8 To ensure patency of a peripheral IV site, cytotoxic chemotherapy should be given through a recently sited cannula. Cannulation should be performed proximal to any recent venepuncture i.e. blood sampling or failed cannulation attempts.
- 1.1.9 The venous access device should be inserted without difficulty using aseptic technique. It should be fastened and secured, using transparent dressings, in a manner that allows the area to be observed during the administration of the cytotoxic chemotherapy.
- 1.1.10 Ideally, all bolus IV cytotoxic chemotherapy should be administered via a fast flowing infusion of a fluid compatible with the drug being administered². Advice on compatibilities is available from the pharmacy. Flush the line with this fluid and verify the patency of the vein immediately prior to the administration of chemotherapy and regularly thereafter. If there are any doubts, stop and investigate. Re-site the cannula if the patency of the venous access is still not entirely satisfactory⁴.
- 1.1.11 The patient must be asked to report any sensation of burning, pain or swelling at, or distal to, the venous access site during the administration of cytotoxic chemotherapy^{2,3}.
- 1.1.12 If more than one cytotoxic drug is to be administered at the same time, the most vesicant should be administered first.
- 1.1.13 All personnel must be aware of the local procedures to be followed in case of exposure to accidental spillage of, or skin/eye contact with hazardous drugs. These procedures are to include immediate treatment, medical follow-up and incident reporting.
- 1.1.14 The administration checks before the administration of chemotherapy should follow the guidelines set out in this document and the UKCC Standards for the Administration of Medicines⁵.
- 1.1.15 The administration of bolus chemotherapy should never be hurried. Bolus doses of vesicant or irritant chemotherapy should be injected into a compatible free-flowing fluid and be allowed to be diluted by the carrier solution. Continuous assessment of the IV site is essential.
- 1.1.16 Line patency may also be checked by stopping the infusion and observing back-flow of blood into the cannula.
- 1.1.17 If mechanical or electronic infusion pumps are being used for infusions of chemotherapy, these should be set at the lowest possible pressure, as the cannula may continue to operate after extravasation has occurred. This may be a particular problem at low run-rates⁴.

- 1.1.18 The use of mechanical or electronic infusion pumps must comply with the guidance set out in the Scottish Office Home and Health Department document on the Management of Infusion Systems⁶.
- 1.1.19 Patients receiving infusions of cytotoxic chemotherapy should have their cannula site checked regularly. Infusion pump alarms should be investigated promptly, as it may indicate extravasation is occurring.
- 1.1.20 After administration, the IV line should be flushed with a sufficient volume of drugcompatible fluid to ensure that all of the drug is cleared from the needle and line².
- 1.1.21 When the cannula is removed, pressure should be applied with sterile gauze for 3-4 minutes and the injection site inspected for adverse reactions or continued bleeding before a dressing is applied.
- 1.1.22 All materials must be disposed of as per local policy. Refer to the guidelines for the disposal of cytotoxic-contaminated waste in section 4.
- 1.1.23 Care is required when administering chemotherapy through central lines to avoid contamination and infection. The safe use of central lines should be set out in local protocols and all staff manipulating these lines should undergo formal training in the aseptic techniques required by local protocols.

1.2 Spillage of Cytotoxic Chemotherapy

- 1.2.1 The risk of spillage should be minimised by having appropriate training for all staff involved in the preparation and administration of cytotoxic chemotherapy.
- 1.2.2 Cytotoxic chemotherapy should be transported in suitable sealed containers.
- 1.2.3 Protocols for dealing with a spillage along with an appropriate spillage kit should be available in all areas involved with the handling of cytotoxic chemotherapy.
- 1.2.4 The location of spillage kits should be prominently displayed in the clinical areas.
- 1.2.5 Persons transporting cytotoxic chemotherapy must be trained in the actions to be taken in the event of a spillage and the reporting of such an incident
- 1.2.6 A detailed protocol is available in the RCN recommendations section 13^2 .

- 1. American Society of Health System Pharmacists. ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs. 1990, reviewed 1996. In: AHFS Drug Information 1999: 1029-1038.
- 2. Royal College of Nursing (RCN). The administration of Cytotoxic Chemotherapy Clinical Practice Guidelines. Recommendations. 1998.
- 3. Allwood A, Stanley A, Wright P (eds.) The Cytotoxics Handbook. Third Edition. Oxford. Radcliffe Medical Press 1997.
- 4. CP Pharmaceuticals. Extravasation how quickly could you act? July 1999
- 5. United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC). Standards for the Administration of Medicines. London, October 1992.
- 6. The Scottish Office Home and Health Department, the management of Infusion Systems, May 1995.

APPENDIX 2

EXTRAVASATION OF CYTOTOXIC CHEMOTHERAPY^{1,2}

2.1 Awareness of Risk Factors

2.1.1 **Patient Risk Factors**

- 2.1.1.1 Extravasation injuries are both more common and more severe in children and neonates compared to adults. Infants may not be able to describe the location or nature of their pain.
- 2.1.1.2 Elderly patients can be more at risk of extravasation injury due to:
 - a) interference with cannula if the patient is confused or agitated
 - b) reduced pain sensation
 - c) fragile skin and veins
- 2.1.1.3 Patients with communication difficulties from whatever cause will be more at risk of extravasation injuries going unnoticed. The patient's carer, parents or partner should have their attention drawn to these risks.

2.1.2 **Risks Related to Medical History**

- 2.1.2.1 Cancer patients have additional risks due to:
 - a) fragile, mobile veins that are difficult to cannulate
 - b) 'recall' phenomenon, in patients previously given radiotherapy
 - c) possible previous extravasation site which would be at risk of further damage when subsequent cytotoxic chemotherapy is given, even if administered at a different site
 - d) limbs with lymphoedema due to poor venous flow (into which chemotherapy must never be administered)
- 2.1.2.2 Repeated venepuncture, whether due to previous treatments or intravenous drug abuse, increases the risk of extravasation injury.
- 2.1.1.3 Other disease states may increase the risk of extravasation injuries or inhibit their detection, such as:
 - a) peripheral vascular disease
 - b) Raynaud's phenomenon
 - c) diabetes
 - d) superior vena cava syndrome

2.1.3 Cannulation Site Risks

- 2.1.3.1 Sites associated with severe extravasation injuries include the dorsum of the hand and foot, the ankle, the antecubical fossa and also near joints or joint spaces where there is little soft tissue for the protection of underlying structures.
- 2.1.3.2 Infusing vesicant cytotoxic chemotherapy via peripheral venous devices increases the risk of extravasation injury.

2.1.4 **Risks Associated with Cannulation Techniques**

- 2.1.4.1 The factors that have the greatest bearing on the likelihood of problems occurring are the position and size of the cannula and the length of time that the cannula remains in-situ.
- 2.1.4.2 The risk of extravasation injury is increased by making multiple attempts at venepuncture before the intravenous device was established.
- 2.1.4.3 The use of steel needles increases the risk of problems occurring.
- 2.1.4.4 Extravasation may not be noticed immediately when running infusions of cytotoxic chemotherapy overnight.
- 2.1.4.5 Administration of cytotoxic chemotherapy by inexperienced staff increases risk.
- 2.1.4.6 Winged infusion devices i.e. butterfly needles, are associated with a greater risk of extravasation. The use of these devices is not recommended.
- 2.1.4.7 When an infusion pump alarm sounds, extravasation may be occurring and this should be investigated immediately.

2.2 **Recognition & Assessment of Extravasation Injuries**

- 2.2.1 Extravasation should be treated as a medical emergency and immediate action must be taken.
- 2.2.2 The members of staff identified as sufficiently experienced in assessing extravasation injuries must be informed immediately.

- 2.2.3 Early detection is important to minimise damage and should be suspected if one or more of the following is observed or experienced by the patient:
 - a) modest or severe pain, burning, stinging or any acute changes at the injection site
 - b) redness, swelling or leakage at the injection site

c) the infusion does not flow freely, or resistance is experienced when attempting to give drugs by bolus into fast flowing drips or infusions

d) no blood return is observed on aspiration – however, the presence of blood does not exclude extravasation

2.2.4 The administration of daunorubicin or doxorubicin (and possibly other anthracyclines) is associated with a "flare" reaction causing raised red streaks following the line of the vein accompanied by pruritis or oedema. Although there is good blood return, the patient may experience pain and stinging. However, these episodes are transient. Extravasation first aid treatment should be given (see 2.3) and hydrocortisone 1% cream applied. If uncertain whether a flare or extravasation has occurred, the area should be reassessed after 1 hour.

2.3 First Aid

- 2.3.1 Explain to the patient that extravasation may have occurred and the procedure for dealing with it. Obtain their co-operation for this treatment.
- 2.3.2 Stop the injection/infusion immediately leaving the cannula in place.
- 2.3.3 Aspirate any residual drug and blood from the cannula. This will allow the direct removal of as much of the drug at the site of the extravasation as possible and thereby minimise progressive local injury and reduce subsequent tissue damage.
- 2.3.4 If the local extravasation policy uses the antidote methodology, leaving the cannula in place will allow the direct application of antidotes to the site of the extravasation.
- 2.3.5 In all other instances, remove the cannula.
- 2.3.6 The site of extravasation should then have either a cold compress or heat pack applied depending on the specific agent that has caused the injury.
- 2.3.7 It is important that the extravasation treatment policy sets out clearly whether heat or cold should be applied for every vesicant cytotoxic drug in use. Getting this wrong could exacerbate the injury.

- 2.3.8 Apply topical steroid to the site of the extravasation injury.
- 2.3.9 Await the arrival of a member of staff identified as experienced in assessing extravasation treatment requirements. Assessment should take place as a matter of urgency.
- 2.3.10 Provide appropriate analgesia.

2.4 Treatment Approaches for Extravasation of Cytotoxic Chemotherapy

Two treatment strategies for the treatment of extravasation injuries are described in the literature. The first approach requires the parenteral and local application of antidotes for all extravasation injuries. The second approach involves a flush out technique carried out by plastic surgeons for more serious extravasation injuries.

The quality of evidence to support the antidote approach to the treatment of extravasation injuries in humans falls into levels III and IV, as defined by the US Agency for Health Care Policy and Research. Some animal studies using antidotes falls into level IIb, but this evidence is often inconclusive, sometimes contradictory and is still controversial. The evidence to support the flush out technique falls into level III. There is no data comparing these two methods of treatment.

The choice as to which method should be used should be taken by a multidisciplinary group after considering the following points:

- 2.4.1 The level of staff experience with the antidote methodology.
- 2.4.2 The availability of antidotes.
- 2.4.3 The familiarity of the plastic surgeon with the flush out technique, or the availability of other staff trained in this technique.
- 2.4.4 The availability of the plastic surgeon or other trained staff to respond to extravasation injuries. This must be within a time limit of one hour.
- 2.4.5 The procedures in place, if any, for the treatment of extravasation injuries caused by noncytotoxic drugs.
- 2.4.6 The cover arrangements for staff with the defined roles within the procedure. Consideration must be given to administration outwith normal working hours and to periods of annual leave for staff with these roles.
- 2.4.7 The role of each member of staff in the referral and treatment pathway. They must be aware of their role and have the training appropriate to it.

2.4.8 The requirements for plastic surgery to ulcerated areas of skin should be anticipated and referral pathways agreed irrespective of which treatment methodology is used for the extravasation injury.

2.5 Policy Requirements for Treating Extravasation of Cytotoxic Chemotherapy using the Antidote Methodology

- 2.5.1 The level to which patients are treated using antidote methodology will depend upon the symptoms, the type of agent and the volume of fluid that has extravasated. The treatment should be balanced against these risk factors.
- 2.5.2 To assist in the assessment of the injury, the extravasation treatment policy must classify the cytotoxic drugs into vesicants, irritants and non-irritants.
- 2.5.3 The extravasation treatment policy should differentiate between drugs that are to be treated by spreading and dilution from those that need to be localised and neutralised. Those requiring spreading and dilution are the drugs that need the application of heat in the initial first aid period. Those drugs that require treatment by localisation and neutralisation are those requiring first aid treatment with cold compresses.
- 2.5.4 All the agents to be used as antidotes should be readily available in suitably stocked and regularly checked extravasation kits. These kits should be placed in all areas where cytotoxic chemotherapy is administered. Storage sites must be listed in the extravasation treatment policy. The location of these kits should be prominently displayed in the clinical areas.
- 2.5.5 Guidelines on the use of antidotes should be drawn from recent review articles and accepted texts such as the latest edition of the Cytotoxics Handbook¹.
- 2.5.6 The follow up and review requirements for the extravasation injuries should be set out clearly for carers and written in the patient's hospital records.
- 2.5.7 Appropriate analgesia should be continued as required.
- 2.5.8 Details of the incident and treatments must be documented in the patient's notes. A 'Green Form'³ for reporting the extravasation incident should be initiated. This form is available from the pharmacy and should be completed after approximately one month to allow for the inclusion of outcome data.
- 2.5.9 Continued monitoring may be necessary for several days. If the skin viability is compromised, treatment by a plastic surgeon is essential.
- 2.5.10 A local record of extravasation injuries should be held for review and audit purposes and for reasons of clinical governance.

2.6 **Policy Requirements For Treating Extravasation of Cytotoxic Chemotherapy Using The Flush Out Technique**

- 2.6.1 The level to which patients are treated using the flush out technique will depend upon the symptoms, the type of agent and the volume of fluid that has extravasated. The treatment should be balanced against these risk factors.
- 2.6.2 To assist in the assessment of the injury, the extravasation treatment policy must classify the cytotoxic chemotherapy drugs into vesicants, irritants and non-irritants.
- 2.6.3 The procedure for contacting the plastic surgeons should be set out clearly, with the agreed response time not exceeding one hour.
- 2.6.4 In situations where the flush out technique is inappropriate, the extravasation treatment policy must define the role of antidotes and other treatment required for these injuries.
- 2.6.5 Guidelines on the use of antidotes should be drawn from recent review articles and accepted texts such as the latest edition of the Cytotoxics Handbook¹.
- 2.6.6 All the agents to be used in the flush out technique (and for those injuries where it would be inappropriate to use this approach) should be readily available in suitably stocked and regularly checked extravasation kits. These kits should be placed in all areas where cytotoxic chemotherapy is administered. Storage sites must be listed in the extravasation treatment policy. The location of these kits should be prominently displayed in the clinical areas.
- 2.6.7 The follow up and review requirements for the extravasation injuries should be set out clearly for carers and written in the patient's hospital records.
- 2.6.8 Appropriate analgesia should be continued as required.
- 2.6.9 Details of the incident and treatments must be documented in the patient's notes. A 'Green Form'³ for reporting the extravasation incident should be initiated. This form is available from the pharmacy and should be completed after approximately one month to allow for the inclusion of outcome data.
- 2.6.10 Continued monitoring may be necessary for several days. If the skin viability is compromised, treatment by a plastic surgeon is essential.
- 2.6.11 A local record of extravasation injuries should be held for review and audit purposes and for reasons of clinical governance.

2.7 Surgical Intervention

- 2.7.1 Independent of which method of extravasation treatment is used, a referral pathway for the treatment of ulcerated areas of skin should be anticipated and agreed as part of the extravasation treatment policy.
- 2.7.2 The early appearance of firm induration on the skin often signifies the eventual development of ulceration. The induration may not necessarily be painful.
- 2.7.3 If the surface of the skin appears white, with no capillary filling, the full thickness of skin is damaged. Again this often signifies the development of skin ulcers over a period of weeks. The time to ulcer development is dependent upon the agent that has caused the extravasation injury.
- 2.7.4 Necrotic areas of tissue require surgical intervention.

- 1. CP Pharmaceuticals. Extravasation how quickly could you act? July 1999
- 2. Allwood A, Stanley A, Wright P (eds.) The Cytotoxics Handbook. Third Edition. Oxford. Radcliffe Medical Press 1997.
- 3. Green Form Extravasation Report Co-ordinator St Chads Unit, Dudley Road Hospital Birmingham. Sponsor CP Pharmaceuticals.

APPENDIX 3

GUIDELINES FOR INTRATHECAL CYTOTOXIC CHEMOTHERAPY¹

3.1 **Policy guidelines**

- 3.1.1 Written policies and guidelines are required for the management of intrathecal therapy.
- 3.1.2 Giving intravenous cytotoxic chemotherapy by the intrathecal route may be fatal. The guidelines must be followed at all times.
- 3.1.3 Patients should only receive intrathecal cytotoxic chemotherapy in designated area where the members of staff are routinely involved in the administration of drugs by the intrathecal route.

3.2 Training

3.2.1 All medical, nursing and pharmacy staff must receive training appropriate to their level of involvement in the prescribing, verification, handling, preparation and administration of intrathecal therapy. They must be made aware of the dangers associated with the inadvertent administration of intravenous cytotoxic chemotherapy by the intrathecal route.

3.3 **Prescribing**

- 3.3.1 Prescriptions for cytotoxic chemotherapy for intrathecal administration should be written on standardised pre-printed prescription verified by the patients consultant or by a doctor of specialist registrar grade or above who has received training according to local policies (see section 1).
- 3.3.2 The prescription should clearly state the drug that is to be administered by the intrathecal route.

3.4 **Preparation**

- 3.4.1 Intrathecal doses must only be prepared in pharmacy aseptic departments (see section 2)
- 3.4.2 Intrathecal cytotoxic chemotherapy must never be kept as ward or theatre stock.

- 3.4.3 If appropriate to local circumstances, intravenous doses of vincristine can be supplied diluted in the syringe to a volume greater than that associated with intrathecal doses. This may not be possible for paediatric practice.
- 3.4.4 Where possible the intrathecal doses should be supplied or made when conformation has been received of the patient receiving the intravenous dose or vice-versa.

3.5 Labelling and Packaging

- 3.5.1 The labelling must comply with the manufacturers recommendations set out in their latest product Data Sheet.
- 3.5.2 The unabbreviated route of administration must be included on labels.
- 3.5.3 Warning labels may be included:
 a) Vincristine WARNING FOR INTRAVENOUS USE ONLY
 b) Methotrexate FOR INTRATHECAL USE
- 3.5.4 Intrathecal doses should be packed in a way as to highlight that the product is different from intravenous drugs. For example, different coloured containers might be used for intrathecal products, or the transport containers may be clearly labelled for intrathecal use. The packaging of cytotoxic chemotherapy must comply with the manufacturers' recommendations.

3.6 **Delivery**

- 3.6.1 Intrathecal injections must be delivered in separate transport containers from cytotoxic chemotherapy being administered by other routes.
- 3.6.2 Intrathecal therapy should be delivered directly to the location for administration.
- 3.6.3 Where possible the supply of intrathecal doses and intravenous doses should be separated by time (see below).

3.7 Administration

3.7.1 Intrathecal doses should be administered by a doctor of specialist registrar grade or above who has received training in the administration of intrathecal cytotoxic chemotherapy. They should have undergone a supervised training period. Intrathecal therapy should not be administered by junior doctors unless under the direct supervision of a senior doctor or unless they have been specifically trained.

- 3.7.2 Prior to intrathecal administration the doctor administering the therapy must verify details with a second, experienced person and the prescription chart must be signed by both.
- 3.7.3 Scheduling of intrathecal therapy must take account of the availability of trained staff.
- 3.7.4 Intrathecal injections and injections for other routes of administration must not take place at the same time.
- 3.7.5 The designated area for administering intrathecal injections should be geographically separate from areas where other cytotoxic chemotherapy is given. e.g. intrathecal doses in an operating theatre and intravenous doses on the ward or outpatient clinic.
- 3.7.6 Intrathecal injections should be supplied directly to the designated area where the dose is to be administered.

Reference:

1. Paediatrics Hospital Chief Pharmacists Groups and the Paediatric Oncology Pharmacists Group. Guidance on the Management of Intrathecal Therapy in Paediatric Oncology. March 1998. Letter.