Protocol for the Safe Administration of Intrathecal and Intraventricular Chemotherapy

Version Number 14

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SAFE ADMINISTRATION OF INTRATHECAL AND INTRAVENTRICULAR CHEMOTHERAPY

CLINICAL PROTOCOL

1 Background

1.1 At least 55 incidents are known to have occurred around the world (a number of these in England) in which the intravenous vinca alkaloid drug vincristine has been injected intrathecally (via spinal injections) during chemotherapy treatment of a cancer patient. Vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are intended for intravenous use only. If injected intrathecally they cause paralysis almost always followed by death. The dilutions and labelling of vinca alkaloids are outlined in the National Patient Safety Agency (NPSA) rapid response report NPSA/2008/RRR004 entitled Using Vinca Alkaloid Minibags (Adult/Adolescent Units). Death from the erroneous intrathecal administration of a vinca alkaloid is likely to be subject to scrutiny under the Corporate Manslaughter & Corporate Homicide Act 2007.

1.2 As a result of these incidents the Government has developed national guidance so that practice will be uniform across the whole country. In this way, staff moving from one Trust to another will not have to adapt to different procedures in different Trusts and patient safety will be enhanced.

1.3 National guidance was originally contained within HSC/2001/022, issued in November 2001. The Government has since issued Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy in August 2008 (HSC/2008/001) and this supersedes previous guidance. This guidance sets out the minimum requirements for NHS Trusts providing an intrathecal chemotherapy service. Whilst the guidance predominantly relates to treatment given by lumbar puncture it is also relevant to intra ventricular chemotherapy (i.e. via injection into the ventricles of the brain).

1.4 This clinical protocol provides details of the local implementation within Salisbury NHS Foundation Trust (SFT) of the updated national guidance for intrathecal and intraventricular chemotherapy. The Chemotherapy Policy Working Group as part of the Central South Coast Cancer Network has also agreed the core contents of the protocol.

2 The protocol

2.1 Overall responsibility

2.1.1 The Chief Executive of SFT has overall responsibility for ensuring compliance with the national guidance.

2.1.2 The Chief Executive (CE) has identified the lead doctor as the “designated intrathecal chemotherapy (ITC) lead” to oversee compliance with the national guidance and to be accountable to the CE on this matter.

2.2 Staff responsibility

2.2.1 Medical, nursing and pharmacy staff are all responsible for ensuring that this protocol is strictly adhered to and for challenging colleagues if the protocol is not being adhered to or if the actions of an individual may cause potential risk to a patient.

2.2.2 The Lead Oncology Pharmacist has delegated responsibility for reviewing this protocol at least annually with relevant colleagues, on behalf of the ITC Lead.

2.3 Register of designated personnel

2.3.1 Only designated personnel who have been trained and assessed as competent by SFT may undertake relevant activities from the following tasks:
- Prescribing intrathecal chemotherapy;
- Clinical Pharmacy verification;
- Dispensing intrathecal chemotherapy (i.e. preparing the dose, filling the syringe, labelling the syringe and placing it in packaging for transport);
- Issuing intrathecal chemotherapy from the pharmacy;
- Transporting intrathecal chemotherapy;
- Checking intrathecal chemotherapy drugs prior to administration; and
- Administering intrathecal chemotherapy.

2.3.2 Staff assessed as competent in one or more of the above tasks will be entered into the register of designated personnel (see Appendix 1).

2.3.3 The ITC Lead has overall responsibility for holding the register and ensuring that it is maintained and kept up to date. However, the day to day responsibility for maintaining individual aspects of the register has been delegated to other senior staff as follows:
- Medical Director for medical staff
- Director of Nursing for nursing staff
- Chief Pharmacist for pharmacy staff.

2.3.4 A copy of the latest edition of the register of designated personnel, a copy of the updated national guidance and a copy of this protocol must be kept in the yellow intrathecal chemotherapy files held in each of the following areas:
- Pharmacy
- Pembroke Unit dealing with chemotherapy - one copy for day case and one copy for inpatients. A file must be located in the designated intrathecal chemotherapy room during an administration.

2.3.5 A system to ensure that only the latest edition of the register is available to staff is operated by the Lead Oncology Pharmacist.

2.3.6 Provisional entry onto the register is not permitted for any member of staff.

2.3.7 Individuals named on the register of designated personnel must demonstrate that they are competent to fulfil their designated role(s) and that they have been assessed as such.

2.3.8 Staff moving from another hospital to SFT may bring with them their certification in their training log book or other training record. However, they will NOT automatically be added to the SFT register, but rather, on arrival, individuals will need to be assessed as competent before being entered on to the SFT register.

2.3.9 All references to the register in the National Guidance and this clinical protocol refer to the Intrathecal Chemotherapy register of Designated Personnel. They do not refer to any other register such as the medical register.

2.4 Induction, training and continuing professional development

2.4.1 The ITC Lead Trainer, the Lead Oncology Pharmacist, has overall responsibility for induction, training and continuing professional development relevant to intrathecal chemotherapy.

2.4.2 Responsibility for induction, training and continuing professional development of medical staff relevant to intrathecal chemotherapy has been delegated within SFT by the ITC Lead Trainer to the ITC Lead. Responsibility for induction of nursing staff has been delegated within SFT by the ITC Lead Trainer to the Lead nurse for ITC. These roles should be reflected in the individual's job description.

2.4.3 The professional leads are responsible for their designated staff groups and for ensuring that:
- All staff (including consultants) who are new to a ward or department involved in intrathecal chemotherapy are provided with a formal induction which complies with
the national guidance for the safe administration of intrathecal and intraventricular chemotherapy;

- This formal induction course, covering all potential clinical hazards associated with intrathecal chemotherapy, the danger posed to patients if intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are accidentally administered intrathecally and new safer practice recommendations for the presentation of intravenous vinca alkaloids exists for all staff (nursing, pharmacy and medical – including new consultants to the hospital), appropriate to their proposed role in the intrathecal chemotherapy service i.e. prescribing, dispensing, issuing, checking, administration;

- As part of the induction/training it is made clear to all staff involved with the care and treatment of patients receiving intrathecal chemotherapy that they should challenge colleagues if, in their judgement, either protocols are not being adhered to or the actions of an individual may cause potential risk to a patient. Challenging of a colleague should not be seen as adversarial, but as an additional check to improve patient safety and reduce risk;

- Staff involved in any aspect of intrathecal chemotherapy must read and understand the updated national guidance and the local protocol as part of their induction and formal assessment as competent to be placed on the register of designated personnel. All staff, including consultants must sign a formal written confirmation that they have received and read both these documents before being allowed to practice their respective roles (record sheet provided - see Appendix 2). This signed confirmation must be updated annually;

- All staff on the register are able to demonstrate they are competent for the roles they will be expected to undertake in providing an intrathecal chemotherapy service and that this competence is reviewed. The annual assessment includes a review of how often staff on the register carry out procedures related to intrathecal chemotherapy

- Assessment of competence is conducted annually and is clearly documented (see certificate of competence Appendix 3).

- The training and assessment of each individual is not undertaken by the same person.

- Assessments must be carried out by the relevant assessor.

- Training must be carried out by either of the two trainers for their professional groups as outlined in Appendix 4. In exceptional circumstances the lead oncology pharmacist can train doctors and the ITC lead can train both pharmacy and nursing staff.

- The trainer and assessor are competent to undertake the duties commensurate with their job.

- Assessed staff are issued with a certificate (see Appendix 3) to demonstrate that they have completed their training (or refresher training) and are competent/remain competent to be included on the appropriate register.

- A copy of the completed competence certificate is retained with the register of designated personnel and a copy placed in the individual’s personal file.

- All designated staff receive regular updates about the practical administration of intrathecal chemotherapy and attend a training programme on an annual basis as part of their continuing professional education, to ensure that their knowledge is up to date. Practical involvement with intrathecal chemotherapy is regarded as continuing education and training of all staff on the register of designated personnel.

- The names and responsibilities of the professional leads are listed in Appendix 4.
- It is the responsibility of those individuals on the register to ensure that any colleagues they involve in the ITC service are on the register for the task in question. Clinical staff that are not involved in providing an intrathecal chemotherapy service (i.e., not on the register for a given task), but are likely to work in areas where different aspects of the ITC service are provided should not take part, or be asked to take part, in any part of this process.

2.5 Prescribing

2.5.1 Only a Consultant Haematologist or Haematology ST3/SpR on the register of designated personnel is allowed to prescribe intrathecal chemotherapy.

2.5.2 FT1, FT2, ST1 and ST2 grades must never prescribe intrathecal chemotherapy.

2.5.3 Non-medical prescribers will not prescribe intrathecal chemotherapy.

2.5.4 No new medical staff, including Consultants, are allowed to prescribe intrathecal chemotherapy until they have: received appropriate induction/training; their competency is agreed and documented; and, their name has been included on the register as a member of staff designated to prescribe intrathecal chemotherapy.

2.5.5 Intrathecal chemotherapy must be prescribed on the dedicated ‘Intrathecal Chemotherapy Prescription Chart’ (Appendix 5).

2.5.6 The drug name and route of administration must be clearly written in full on the Intrathecal Chemotherapy Prescription Chart.

2.5.7 The only cytotoxic chemotherapy drugs that can be prescribed and administered intrathecally are METHOTREXATE and CYTARABINE (cytosine arabinoside—either the liposomal or non-liposomal formulation). Liposomal cytarabine must be prescribed by trade name, Depocyt, and the non-liposomal form as cytarabine.

2.5.8 Although hydrocortisone is not handled as a cytotoxic medication it is considered good practice to prescribe, dispense and administer intrathecal doses of hydrocortisone in the same manner as methotrexate and cytarabine.

2.5.9 Sections 1 through 3 on the prescription must be completed before it is sent to Pharmacy.

2.5.10 Intrathecal and intravenous cytotoxic chemotherapy drugs must only be issued and administered in the order described below:

- For adult patients: the intravenous doses are made and administered first, and only after this are the intrathecal doses dispensed and administered. See 2.9.

NB: Intrathecal administration of cytotoxic agents to paediatric patients MUST NOT be undertaken within SFT: all paediatric patients requiring intrathecal chemotherapy MUST be referred to University Hospital Southampton NHS Foundation Trust for this procedure.

2.6 Preparation and dispensing

2.6.1 Only pharmacy staff whose names appear on the register of designated personnel are allowed to dispense intrathecal chemotherapy drugs.

2.6.2 Individuals named on the register of designated personnel will have demonstrated that they are competent to clinically verify, dispense and/or issue intrathecal chemotherapy and have been assessed as such.

2.6.3 The Lead Oncology Pharmacist on behalf of the Chief Pharmacist will maintain the register of designated pharmacy personnel who can clinically verify, dispense, label and issue drugs for intrathecal chemotherapy. An up to date copy of the register will be held in pharmacy and located with all other relevant SFT protocols relating to chemotherapy.

2.6.4 Only on call pharmacists on the register of designated personnel may issue Intrathecal Chemotherapy Kits for use in emergency situations out of normal working hours.

2.7 Storage in the pharmacy

2.7.1 Intrathecal doses are prepared for IMMEDIATE use and therefore doses do not normally need to be stored prior to use. If however it is not possible to collect the intrathecal doses
immediately from pharmacy they are stored within pharmacy in a designated lockable refrigerator. Storage of any other product in this refrigerator is strictly forbidden.

2.7.2 Doses of intrathecal hydrocortisone or Depocyte should be stored at room temperature in the designated lockable box.

2.7.3 Prepared intravenous doses awaiting collection must be stored totally separately from intrathecal doses, in either the aseptic services ‘collection’ refrigerator, or out tray, as appropriate.

2.7.4 If for some reason it is not possible to administer the intrathecal dose immediately after collection from the pharmacy, the dose MUST be returned to pharmacy for disposal. Storage of intrathecal doses in clinical areas is prohibited.

2.7.5 Unused syringes must be returned to Pharmacy along with the intrathecal chemotherapy prescription. The names of the people transporting the syringe to Pharmacy and the member of Pharmacy who accepts the syringe must be recorded along with a note indicating what happened to the dose, eg disposed of as cytotoxic waste, in the comments section of the prescription.

2.7.6 All staff involved in the return of unused intrathecal chemotherapy syringes should be on the register of designated personnel.

2.8 Issuing of drugs

2.8.1 The doctor giving the injection must be bleeped or telephoned to attend pharmacy and collect the intrathecal dose(s) in person from the pharmacy department and take them directly to the area for administration.

2.8.2 If the doctor is unable to attend the pharmacy, a designated member of pharmacy staff may be asked to deliver the intrathecal dose(s) directly to the administration area. In such circumstances the dose(s) MUST ONLY be given to the administering doctor.

2.8.3 The pharmacist releasing the intrathecal dose(s), the person handing the dose(s) to the doctor (‘handed out by’) and the doctor accepting receipt of the dose(s) must all be on the register of designated personnel and must each sign the prescription chart with their full signature in the boxes provided.

2.8.4 The doctor must only collect intrathecal chemotherapy dose(s) for a single patient at a time.

2.9 Timing/sequencing of issue of drugs

2.9.1 Intravenous chemotherapy drugs MUST be issued at a different time from intrathecal drugs for chemotherapy. Intravenous chemotherapy drugs must be issued first. Only following written confirmation that any intravenous chemotherapy drugs for the named patient for that day have already been administered will the intrathecal chemotherapy drugs be prepared and issued by the pharmacy.

2.9.2 Intrathecal doses are given a maximum expiry of 3 hours. This necessitates preparation on the day of administration and prevents preparation in advance.

2.9.3 Intrathecal doses will not be prepared by pharmacy until the intravenous doses have been given. The prescription must be returned to pharmacy after administration of the intravenous doses with the relevant signatures for administration, to allow the preparation and subsequent release of the intrathecal dose(s).

2.9.4 Where a regimen involves intrathecal chemotherapy combined with continuous intravenous chemotherapy, the intrathecal doses may only be given once the intravenous infusion has started. Written confirmation that the intravenous infusion has begun must be received by pharmacy before the intrathecal doses will be prepared and issued.

2.9.5 The pharmacist checking the prescription prior to release of the intrathecal preparation must:

- Endorse the batch book accordingly, i.e. Intravenous doses given
- Record in the batch book the time that the chart was received in pharmacy.
2.10 Labelling, packaging and transportation
2.10.1 For all intrathecal doses the route of administration (largest font size) and the drug name are highlighted on the syringe label which must also include the patient’s name. All labels include the phrase: For intrathecal use only.
2.10.2 All prepared intrathecal doses are packed in RED plastic wrapping. RED wrapping is used exclusively for intrathecal doses.
2.10.3 All other doses for administration by intravenous or other routes are packed in BLUE or CLEAR or BLACK plastic wrapping.
2.10.4 Intrathecal doses are transported in chemotherapy envopacks, which are clearly labelled regarding their contents, for example, ‘Intrathecal doses for adult patient on Pembroke Unit – For collection from the pharmacy by Doctor ONLY’.
2.10.5 Intrathecal doses awaiting collection are stored within pharmacy in either a designated refrigerator (methotrexate and cytarabine) or in the designated lockable box (hydrocortisone and Depocyte).
2.10.6 Doses wrapped in RED plastic must NEVER be packaged or transported together with doses wrapped in either BLUE or CLEAR or BLACK plastic.
2.10.7 Intrathecal chemotherapy kits for use in emergency situations out side normal working hours are stored in the aseptic unit for collection by the on call pharmacist. There are no specific packaging requirements for these kits.

2.11 Patient consent
2.11.1 Patient information is available on ICID (see Appendix 8). The patient should receive this and have time to read, digest the information and ask any questions prior to consent.
2.11.2 Full patient consent is required for a course of chemotherapy rather than each dose within the course². However, when attending for each dose, patients should be explicitly informed of the nature of the procedure, the route of administration and the drug to be administered.

2.12 Patient reviews
2.12.1 A Consultant Haematologist or Haematology ST3/SpR on the register of designated personnel must review all patients before intrathecal chemotherapy is administered. This review is to ensure that the patient is fit enough to receive treatment, the correct tests have been conducted, the correct chemotherapy has been prescribed and that the Consultant or ST3/SpR administering the intrathecal dose is on the register of designated personnel.

2.13 Location
2.13.1 Intrathecal chemotherapy must be administered in an area where no other chemotherapy drugs are being given or stored. This area should be a separate room ie, with walls and a door. A side room on the day case area of the Pembroke unit dealing with chemotherapy, has been designated for administration of intrathecal chemotherapy. When this area is being used for intrathecal cytotoxic administration any other use of the room is prohibited. If this side room is not available, another side room on the day case area will become the designated room.
2.13.2 All other forms of chemotherapy administration in the designated room are specifically prohibited for the entire session during which an intrathecal dose is being given. The session begins when the intrathecal chemotherapy arrives and ends 1 hour after the administration.
2.13.3 Chemotherapy drugs for intravenous use must NEVER be stored in the designated area, even when the area is not in use.
2.13.4 If the patient is too ill to be moved to the designated side room on the Pembroke Unit day case area (for example, a patient in ITU or if the patient is septic or neutropenic and needs to be nursed in a side room on the Pembroke unit in-patient ward) then it should be documented in the patient’s notes that the patient was too ill to be moved and that treatment was given out side the designated area. It is recognised that using a separate room may not be possible in an operating room or ITU. A yellow ITC folder must be collected and placed in this room during the administration.
2.14 Checks

2.14.1 Only a Consultant Haematologist or Haematology ST3/SpR named on the register of designated personnel is allowed to administer intrathecal chemotherapy. When preparing to treat a patient with intrathecal chemotherapy these staff must use a formal checking procedure to ensure that the right drug and the right dose is given to the right patient - see 2.14.3

2.14.2 It is essential that cytotoxic agents for intrathecal administration are checked by both the DOCTOR administering the drug and a chemotherapy trained NURSE on the register (or a nurse on the intrathecal register who has been trained and deemed competent to carry out this check, if a chemotherapy trained nurse is not available) before the dose is administered. On NO account are two doctors allowed to undertake these checks.

2.14.3 The formal checking procedure will include the route of administration, drug name, dose, volume, expiry, patient name and patient hospital number on the syringe label against both the prescription and patient name band. The checks made must be recorded on the prescription chart by signing (with full signature) the ‘checked by’ box and completing details outlined on the intrathecal prescription chart.

2.14.4 Should they wish, patients should be encouraged to check the name and dose of the drug(s) written up on the prescription with those on the label of the syringe. The intention in such situations is not to remove the responsibility of the clinicians for ensuring that the patient receives the required treatment, or to put responsibility at the patient’s door but rather, through their engagement, add another safety check to the process.

2.14.5 Both the doctor and the nurse involved with the checking procedure must have received appropriate, recorded training as described above and must be named on the register of designated personnel. It is the doctor’s responsibility to check the register of designated personnel to confirm that the checking nurse is on the register of designated personnel.

2.14.6 The checking nurse must witness the administration of the dose of intrathecal chemotherapy.

2.15 Administration

2.15.1 Only doctors named on the Trust’s register of designated personnel may administer intrathecal chemotherapy.

2.15.2 The outer red wrapper of the intrathecal chemotherapy syringe should not be removed until the moment of injection. The volume of the drug contained within the syringe should be checked against the labelled volume. If the volume is more than 5ml the process must be STOPPED, the volume rechecked and Pharmacy contacted. The prescription chart should only be signed (with full signatures) after the administration of the drug is complete.

2.15.3 A technically difficult lumbar puncture may need the assistance of staff not on the register of designated personnel, eg a radiologist to position the needle under imaging control. These staff must NEVER be involved in any other aspect of the process. Intrathecal chemotherapy MUST only be administered by a member of staff on the register of designated personnel as outlined in 2.3 and 2.15.1.

2.16 Out of Hours procedures

2.16.1 Intrathecal doses will usually only be administered within normal working hours, 9am to 5pm Mondays to Fridays. In emergency situations only, the out of hours preparation and administration of intrathecal chemotherapy may exceptionally be needed. The need to use the emergency kit must be authorised by a consultant haematologist on the register of designated personnel.

2.16.2 An ‘intrathecal chemotherapy kit’ containing a vial of methotrexate, equipment needed to prepare a syringe and instructions for use (Appendix 6) are kept in pharmacy.

2.16.3 The syringe may only be prepared by the Haematology Consultant or Haematology ST3/SpR on the register of designated personnel administering the dose.

2.16.4 In the event that an out of hours dose is needed, the on call pharmacist on the register of designated personnel must attend the pharmacy to issue the emergency kit. The on call pharmacist must record the batch numbers of the methotrexate vials plus intrathecal
chemotherapy kit on the intrathecal prescription chart and sign both the ‘pharmacy release by’ and the ‘handed out by’ sections. The administering doctor will sign the ‘accepted by’ section when handed the kit by the pharmacist.

2.16.5 In the formal checking procedure the route of administration, drug name and strength on the vial label must be checked by both the checking nurse and the administering doctor prior to preparation of the syringe. Both the nurse and doctor must independently calculate the volume of injection corresponding to the prescribed dose. The prescribed dose must be 12.5mg; this corresponds to a volume of 0.5ml.

2.16.6 The intrathecal syringe must be prepared by the administering doctor in the presence of the checking nurse. The volume of methotrexate in the syringe should be compared with the calculated volume. The checks described in 2.14 must also be undertaken and recorded accordingly.

2.16.7 Both the ITC Lead and Lead Trainer would need to be notified that this procedure had taken place outside normal working hours. Why the situation had arisen, actions taken and outcome should be clearly documented on the intrathecal chemotherapy prescription.

2.17 Labelling and dilution of vinca alkaloids

2.17.1 For vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine), labels must have the patient name, name of the product, route of administration, dose and a clear warning of the consequences of administration by other routes – i.e. For INTRAVENOUS USE ONLY – FATAL if administered by other routes.

2.17.2 In all situations within the Trust vinca alkaloids must be diluted to a volume of 10ml or greater. See Appendix 7.

2.18 Potential complications

2.18.1 Failure to follow this protocol may potentially result in patient death if a vinca alkaloid is accidentally administered by the Intrathecal route. Should such an incident occur, advice should be sought from the on call neurologist at University Hospital Southampton NHS Foundation Trust.

2.19 After care

2.19.1 Adult patients should remain flat for at least 30 minutes after administration of intrathecal drugs and then sit up for a further 30 minutes.

3 Patient Information

3.1.1 A patient information leaflet covering this topic is available on ICID - see appendix 8. The administering doctor should explain the nature of the procedure, route of administration and drug(s) to be administered to the patient. Where possible, the patient should be involved in the checking procedure, see 2.14.4.

3.1.2 This explanation should be fully documented in the patient’s health care record or on the intrathecal chemotherapy prescription chart, which should be filed in the patient’s health care record, by the doctor. A copy of the prescription should be forwarded to the ITC Lead Trainer for audit purposes.

4 Audit

4.1 Standards

4.1.1 Standard Statement: All doses of intrathecal chemotherapy will be prescribed, dispensed, labelled, packaged, distributed, checked and administered as described in this protocol.

4.1.2 Structure

i. All personnel involved in this practice will receive this protocol.

ii. Each clinical area where the administration of cytotoxic intrathecal chemotherapy takes place will have access to the Protocol for the Safe Administration of Intrathecal and Intraventricular Chemotherapy and the national guidance.
iii. A current copy of the register of designated personnel will be kept in each of the following areas: Pembroke unit and Pharmacy.

4.1.3 Process
i. All staff working in areas involved with cytotoxic intrathecal drugs should have undergone a formal induction programme, appropriate to their proposed role, including the safe administration of intrathecal chemotherapy.

ii. Only designated personnel will be involved with cytotoxic intrathecal drugs.

iii. All designated personnel involved with cytotoxic intrathecal drugs should have received training including the potential clinical hazards associated with cytotoxic chemotherapy and the consequences of accidental administration of vinca alkaloids by the intrathecal route.

iv. All staff on the register of designated personnel working in areas involved with cytotoxic intrathecal drugs should be familiar with and have access to both the protocol for the safe administration of intrathecal chemotherapy and intraventricular chemotherapy, and national guidance.

v. Departmental managers will continually monitor their departments to ensure that staff working in their area are complying with the protocol.

vi. Any breach of protocol should be recorded on a Trust Adverse event report form and the departmental manager immediately informed.

4.1.4 Outcome
i. Cytotoxic intrathecal drugs are only prescribed, dispensed, labelled, packaged, distributed, checked and administered by staff identified on the register.

ii. All cytotoxic intrathecal drugs are prescribed, dispensed, labelled, packaged, distributed, checked and administered according to the protocol.

iii. Cytotoxic intrathecal drugs are only administered in designated areas.

iv. Methotrexate and cytarabine are the only cytotoxic chemotherapy drugs administered by the intrathecal route.

4.2 Audit tool
Audit Reference No.: Cytotoxic intrathecal chemotherapy
Topic: Safe administration of intrathecal and intraventricular chemotherapy.
Sub-topic: Staff and patients involved with cytotoxic intrathecal chemotherapy
Care Group: Staff and patients involved with cytotoxic intrathecal chemotherapy
Standard Statement: All doses of intrathecal chemotherapy will be prescribed, dispensed, labelled, packaged, distributed, checked and administered as described in this protocol.

i. Each member of staff on the register of designated personnel working on the Pembroke unit and in Pharmacy will have received a copy of this standard, the Protocol for the Safe Administration of Intrathecal and Intraventricular Chemotherapy and the National Guidance.

ii. Each doctor on the register of designated personnel will have received a copy of this standard, the Protocol for the Safe Administration of Intrathecal and Intraventricular Chemotherapy and the National Guidance.

iii. Each clinical area involved with the prescription, dispensing, labelling, packaging, distribution, checking and administration of cytotoxic intrathecal chemotherapy should have access to a copy of this standard, the Protocol for the Safe Administration of Intrathecal and Intraventricular Chemotherapy and the National Guidance.

iv. The Departmental/Ward head continually monitors their staff to ensure compliance with the standard and reports breaches via the SFT Adverse Event reporting scheme.

v. The Medical Director maintains the doctors section of the register of designated personnel.
vi. The Director of Nursing maintains the nurses section of the register of designated personnel.

vii. The Chief Pharmacist maintains the pharmacy staff section of the register of designated personnel.

4.3 Patient survey

4.3.1 No patient survey has been undertaken to date. An audit is planned for 2013/2014.

4.4 Risk management

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<th>Factors</th>
<th>Risk Management</th>
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<tr>
<td>Administration factors</td>
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<tr>
<td>Incorrect prescription of chemotherapy.</td>
<td>Pharmacy, Nurses and Doctors to check the prescription against chemotherapy treatment protocol.</td>
</tr>
<tr>
<td>Inexperienced staff involved with intrathecal chemotherapy.</td>
<td>Staff to have appropriate training in the safe administration of intrathecal chemotherapy. Only staff on the register involved.</td>
</tr>
<tr>
<td>Intravenous drugs administered by intrathecal route.</td>
<td>“High risk” intravenous drugs (vinca alkaloids) diluted to volume of 10ml or more and given BEFORE intrathecal drugs prescribed.</td>
</tr>
<tr>
<td>Inappropriate preparation of drugs.</td>
<td>Drugs prepared only in aseptic unit of Pharmacy except in emergencies when they may be prepared in a suitable area at ward level.</td>
</tr>
<tr>
<td>Consent not obtained</td>
<td>Medical staff to ensure that informed consent is obtained before proceeding with treatment.</td>
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<tr>
<th>Treatment delivery Failures</th>
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<tbody>
<tr>
<td>Chemotherapy given to wrong patient.</td>
<td>Chemotherapy must be checked as stated in 2.14 of this protocol.</td>
</tr>
<tr>
<td>Chemotherapy spillage occurs</td>
<td>Chemotherapy to be handled according to Trust Guidelines and Salisbury NHS Foundation Trust Oncology and Haematology Handbook. Training to address safe handling. Spillage kits are located on the inpatient cancer unit, haematology oncology day case unit, the emergency drug cupboard and Pharmacy.</td>
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<th>Patient Characteristics</th>
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<tr>
<td>Patient anxious about procedure</td>
<td>Counselling required, e.g., by doctor, nurse or counsellor.</td>
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5 Evidence Base

5.1 Sources of information


4. Frequently asked questions and further information relating to HSC 2001/022, April 2002.

5.2 Summary of literature review and recommendations

5.2.1 In order to prevent the inadvertent administration of vinca alkaloids by the intrathecal route practices should be established to maintain the separation of vinca alkaloids and intrathecal
chemotherapy at all times. Staff training should include the consequences of such inadvertent administration.

5.2.2 All steps from prescribing through administration of cytotoxic intrathecal chemotherapy should be documented. Only designated personnel who are trained and authorised should be involved with cytotoxic intrathecal chemotherapy. In addition, doses of vinca alkaloids should be diluted to standardised volumes to reduce the chance of administration by a route other than intravenous.

5.3 Evidence review

5.3.1 The information contained in this protocol is based on previous and updated national guidance and previous Trust protocols (Intrathecal2.doc to Intrathecal13.doc).

Author: DLN Robertson, Oncology Pharmacist

Protocol Approved by:

<table>
<thead>
<tr>
<th></th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Director</td>
<td></td>
<td></td>
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<tr>
<td>Director of Nursing</td>
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<td></td>
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<tr>
<td>Chief Pharmacist</td>
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<tr>
<td>Directorate Manager for Medicine</td>
<td></td>
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<tr>
<td>ITC Lead</td>
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</tr>
</tbody>
</table>

Review Date: 31.01.15
FLOW CHART FOR INTRATHECAL CHEMOTHERAPY DOSES

PRESCRIPTION FOR ANY INTRAVENOUS DOSES SENT TO PHARMACY

PHARMACY CHECK PRESCRIPTION AND PREPARE INTRAVENOUS DOSES

INTRAVENOUS DOSES PACKED IN BLUE or CLEAR or BLACK PLASTIC WRAPPING IN DEDICATED ENVOPACK
Phone clinical area to collect
Or put in chemo dedicated pneumatic tube

NURSES CHECK THAT PACKAGE IS WRAPPED IN BLUE or CLEAR or BLACK PLASTIC CHECK SYRINGE LABEL and CHECK DRUG IS BEING GIVEN TO CORRECT PATIENT
TWO CHEMOTHERAPY TRAINED NURSES MUST CHECK PATIENT & DRUGS (OR ADMINISTERING DOCTOR AND CHEMOTHERAPY TRAINED NURSE)
SIGN PRESCRIPTION AFTER GIVING DOSES

PRESCRIPTION FOR INTRATHECAL DOSE (S) ON INTRATHECAL CHEMOTHERAPY CHART SENT TO PHARMACY WITH CHART FOR INTRAVENOUS DOSES

PHARMACY CHECK THAT INTRAVENOUS DOSES HAVE BEEN GIVEN BEFORE PROCEEDING PHARMACY CHECK PRESCRIPTION AND PREPARE INTRATHECAL DOSE
Dose prepared on day of administration

INTRATHECAL SYRINGE WRAPPED IN RED PLASTIC WRAPPING AND PACKED IN A DEDICATED ENVOPACK
Doctor bleeped to collect
And take to Designated area

DOCTOR CHECKS THAT PACKAGE IS WRAPPED IN RED PLASTIC CHECK SYRINGE LABEL and CHECK DRUG IS BEING GIVEN TO CORRECT PATIENT
DO NOT ADMINISTER IF VOLUME IS MORE THAN 5ml
DOCTOR PERFORMING PROCEDURE & CHEMOTHERAPY TRAINED NURSE ON INTRATHECAL REGISTER MUST CHECK PATIENTS & DRUGS. SIGN PRESCRIPTION AFTER GIVING DOSE
**Appendix 1 Register of Designated Personnel**

**REGISTER OF DESIGNATED PERSONNEL INVOLVED WITH INTRATHecal CHEMOTHERAPY**

Copies of this register are kept in the following areas: Pembroke unit and Pharmacy.

[View current register](#)

**Doctors** who have been assessed as competent to **prescribe, administer** and **distribute** (deliver) intrathecal chemotherapy:

<table>
<thead>
<tr>
<th>Name</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Authorised by:………………………………… Date:  
Medical Director

---

This document is cancelled on 31.01.2015.
REGISTER OF DESIGNATED PERSONNEL INVOLVED WITH INTRATHECAL CHEMOTHERAPY

**Nurses** who have been assessed as competent to **check** the administration of intrathecal chemotherapy:

<table>
<thead>
<tr>
<th>Name</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

Authorised by: ..................................        Date:

Director of Nursing
**REGISTER OF DESIGNATED PERSONNEL INVOLVED WITH INTRATHecal CHEMOTHERAPY**

**Oncology Pharmacy staff** who have been assessed as competent to **dispense** (prepare and label) intrathecal chemotherapy:

<table>
<thead>
<tr>
<th>Name</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Authorised by:………………………………… Date:
Chief Pharmacist

**Oncology Pharmacy staff** who have been assessed as competent to **clinically verify and issue** (label, release and package) intrathecal chemotherapy:

<table>
<thead>
<tr>
<th>Name</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Authorised by:………………………………… Date:
Chief Pharmacist

**Oncology Pharmacy staff** who have been assessed as competent to **distribute** (deliver) intrathecal chemotherapy:

<table>
<thead>
<tr>
<th>Name</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Authorised by:………………………………… Date:
Chief Pharmacist
On call Pharmacy staff who have been assessed as competent to clinically verify and dispense (label, release, package and deliver) 'Intrathecal kits' out of hours.

<table>
<thead>
<tr>
<th>Name</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Authorised by:_____________________________  Date:__________________________

Chief Pharmacist
RECORD OF RECEIPT OF DOCUMENTS ABOUT INTRATHECAL CHEMOTHERAPY

On receipt and reading of all of the following documents please sign and date the table below.
Documents:

3. Protocol for the Safe Administration of Intrathecal and Intraventricular Chemotherapy, SFT. Please indicate which version you have received.

Either:

☐ February 2014 version Intrathecal14.doc,
Or

☐ January 2013 version Intrathecal13.doc and a summary of changes memo data 24th September as there are no significant changes in version 14.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

Please retain a copy of this form in your professional development file (or portfolio), your personnel file held by your manager and forward a copy to your professional lead (Dr Cullis for doctors, Belinda Mills for nurses and Debra Robertson for pharmacy staff).
### ASSESSMENT OF COMPETENCY FOR INTRATHECAL CHEMOTHERAPY

I certify that I have assessed that

<table>
<thead>
<tr>
<th>Duty</th>
<th>Initial and Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribe (Doctor)</td>
<td></td>
</tr>
<tr>
<td>Administer (Doctor)</td>
<td></td>
</tr>
<tr>
<td>Check (Nurse)</td>
<td></td>
</tr>
<tr>
<td>Dispense syringes (prepare + label) (Pharmacy)</td>
<td></td>
</tr>
<tr>
<td>Issue syringes (label, release + package) and</td>
<td></td>
</tr>
<tr>
<td>clinically verify (Pharmacist)</td>
<td></td>
</tr>
<tr>
<td>Distribute syringes (Pharmacy or Doctor)</td>
<td></td>
</tr>
<tr>
<td>Dispense ‘Intrathecal kits’</td>
<td></td>
</tr>
<tr>
<td>(label+release+package+deliver) and clinically</td>
<td></td>
</tr>
<tr>
<td>verify (Pharmacist)</td>
<td></td>
</tr>
</tbody>
</table>

Assessed by: Date:

Trained by: Date:

Assessee: Date:

Just an Ordinary Day - Safe Administration of Intrathecal Chemotherapy training film parts 1 and 2 (version 2003) viewed on…………………………………………………………..(insert date)

By……………………………………………………..(Signature of assessee)

Please retain a copy of this form in your professional development file (or portfolio), your personnel file held by your manager and forward a copy to your professional lead (Dr Cullis for doctors, Belinda Mills for nurses and Debra Robertson for pharmacy staff).

Valid from 31.01.14 or date assessed until 31.01.15
Appendix 4 Roles and Responsibilities

Roles and Responsibilities of Staff

All staff
- Ensure that this protocol is followed.
- Challenge colleagues not adhering to this protocol or if actions of an individual may cause potential risk to a patient.

Chief Executive
- Hold overall responsibility for ensuring compliance with the National guidance

Medical Director
- Ensure that the register of medical staff is maintained and kept up to date.
- Invited to attend annual protocol review meeting.

Director of Nursing
- Ensure that the register of nursing staff is maintained and kept up to date.
- Nominate the lead nurse for intrathecal chemotherapy as the Lead Chemotherapy Nurse.
- Invited to attend annual protocol review meeting.

Chief Pharmacist –
- Ensure that the register of pharmacy staff is maintained and kept up to date.
- Nominate the lead pharmacist for intrathecal chemotherapy as Debra Robertson.
- Ensure that new members of pharmacy staff who will be involved with the ITC service are provided with a formal induction by the lead pharmacist that includes either the distribution of copies of both this protocol and current national guidance.
- Invited to attend annual protocol review meeting.

ITC Lead and Lead Doctor
- Identified by the Chief Executive (CE) as the designated lead to oversee compliance with the national guidance and accountable to the CE on this subject.
- Lead doctor for intrathecal chemotherapy.
- Nominate the Lead Oncology Pharmacist as the ITC Lead Trainer.
- Nominate the following competency assessors: Lead Medical Assessor – Dr Grand, Lead Nurse Assessor – Lead ITC Nurse, Lead Pharmacy Assessor – Aseptic Services Manager.
- Ensure that all medical staff working in Haematology who will be involved with the ITC service are provided with a formal documented induction that includes the distribution of copies of both this protocol and current national guidance.
- Train all doctors working within adult medicine (consultants and haematology ST3/SpR) who are involved in intrathecal chemotherapy in the local protocol and procedures for safe administration of intrathecal chemotherapy in SFT.
- Ensure that all records of such training are maintained in accordance with this protocol.
- Keep copies of the receipt of document and assessment forms for all doctors with the Register of designated personnel and ensure that copies are placed in the individual’s personnel file.
- Maintain the register of designated medical personnel and keep it up to date.
- Ensure that all 'adult' medical staff on the register of designated personnel receive regular updates about the practical administration of intravenous
and intrathecal chemotherapy as part of their continuing professional education.

- Forward copies of ALL receipt of documents forms and assessment forms for medical staff to the ITC Lead Trainer.
- Must attend annual protocol review meeting.
- The ITC Lead must ensure that they maintain their knowledge through active participation in the annual protocol review meeting, reviewing the annual training package produced by the ITC Lead Trainer, linking to Cancer Network ITC training activities and through practical administration of intrathecal chemotherapy. Assessment of the ITC Lead by the Lead assessor for medical staff will be based on these activities.

Lead assessor for medical staff

- Conduct formal, documented assessment of all Consultants and Haematology ST3/SpR involved with intrathecal chemotherapy.
- Forward completed assessment forms to the ITC Lead in order that the register of designated personnel may be maintained.
- Invited to attend annual protocol review meeting.
- The lead medical assessor must demonstrate their competency in this practice through the development of the assessment tool for medical staff, practical administration of intrathecal chemotherapy and annual retraining by the ITC Lead. Assessment of the Lead assessor for medical staff by the ITC Lead will be based on these activities.

Lead Nurse Assessor

- Lead nurse for intrathecal chemotherapy.
- Ensure that all nursing staff who will be involved with the ITC service are provided with a formal documented induction that includes the distribution of copies of both this protocol and current national guidance.
- Conduct formal, documented assessment of all nurses involved in intrathecal chemotherapy.
- Keep copies of the receipt of document and assessment forms for all nurses with the register of designated personnel and ensure that copies are placed in the individual’s personnel file.
- Maintain the register of designated nursing personnel and keep it up to date.
- Ensure that all nursing staff on the register of designated personnel receive regular updates about the practical administration of intravenous and intrathecal chemotherapy as part of their continuing professional education.
- Forward copies of ALL receipt of documents forms and assessment forms for nursing staff to the ITC Lead Trainer.
- Must attend annual protocol review meeting.
- The lead nursing assessor must demonstrate their competency in this practice through the development of the assessment tool for nursing staff, active participation of the annual protocol review meeting, practical checking of intrathecal chemotherapy and annual retraining by the ITC Lead Trainer. Assessment of the Lead nurse assessor will be based on these activities.

ITC Lead Trainer and Lead Oncology Pharmacist

- ITC Lead Trainer for the Trust.
- Nominate responsibilities for training and induction of medical staff to Lead Doctor.
- Nominate responsibility for induction of nursing staff to Lead Nurse Assessor.
- Lead pharmacist for intrathecal chemotherapy.
- Ensure that this protocol is reviewed and updated on an annual basis.
- Train all nurses and pharmacy staff involved in intrathecal chemotherapy.
- Ensure that all pharmacy and nursing staff on the register of designated personnel receive regular updates about the practical administration of intravenous and intrathecal chemotherapy as part of their continuing professional education.

Salisbury NHS Foundation Trust
Protocol for the Safe Administration of Intrathecal and Intraventricular Chemotherapy

24 | Page
v14.1.docx
Salisbury NHS Foundation Trust
Protocol for the Safe Administration of Intrathecal and Intraventricular Chemotherapy

This document is cancelled on 31.01.2015

Professional education.

- Keep copies of the receipt of document and assessment forms for all pharmacy staff with the register of designated personnel and ensure that copies are placed in the individual’s personnel file.
- Maintain the register of designated pharmacy personnel and keep it up to date.
- Keep copies of ALL receipt and assessment forms for medical, nursing and pharmacy staff included on the register of designated personnel.
- Ensure that all pharmacy staff who will be involved with the ITC service are provided with a formal documented induction that includes the distribution of copies of both this protocol and current national guidance.
- Ensure that new members of nursing and medical staff who will be involved with the ITC service are provided with a formal induction by the lead nurse and lead doctor respectively that includes the distribution of copies of both this protocol and current national guidance.
- Must attend annual protocol review meeting.
- The ITC Lead Trainer must ensure that they maintain their knowledge through active participation in the annual protocol review meeting, reviewing this protocol, producing the annual training package, checking the nursing and pharmacy assessment tools, linking to Cancer Network ITC training activities and through practical involvement in intrathecal chemotherapy. Annual assessment of the ITC Lead Trainer will be based on these activities.

Aseptic services manager and Lead Pharmacy Assessor

- Conduct formal, documented assessment of all pharmacy staff involved with intrathecal chemotherapy.
- Forward completed assessment forms to the ITC Lead Trainer in order that the register of designated personnel may be maintained.
- Invited to attend annual protocol review meeting.
- The lead pharmacy assessor must demonstrate their competency in this practice through the development of the assessment tool for pharmacy staff, practical involvement in intrathecal chemotherapy and annual retraining by the ITC Lead Trainer. Assessment of the Lead Pharmacy assessor will be based on these activities.

Named staff

- Ensure that the yellow intrathecal chemotherapy files are maintained and there contents are up to date at all times.
- The following people are responsible for these files in their designated areas: Belinda Mills (Pembroke Unit 2 folders) and Debra Robertson (Pharmacy 1 folder).

All prescribers

- Ensure that the doctor administering intrathecal chemotherapy has been appropriately trained and is on the register of designated personnel.

All doctors administering ITC

- Ensure that the person assisting them with the ITC procedure, including the formal checking procedure, is on the register of designated personnel.
Appendix 5 Intrathecal Chemotherapy Prescription and Checklist

Intrathecal Chemotherapy (ITC) Prescription and Checklist

This prescription is to be used on only one occasion. All sections of the checklist must be completed

Section I: Please fill in before prescribing

<table>
<thead>
<tr>
<th>Addressograph label</th>
<th>Ward</th>
<th>Consultant</th>
<th>Protocol:</th>
<th>Clinical Pharmacy Verification:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section II: Prescribe intrathecal drugs and strike through lines not being used, then complete the first of the checklists over the page

<table>
<thead>
<tr>
<th>Date</th>
<th>Drug</th>
<th>Route</th>
<th>Dose</th>
<th>Prescribers signature</th>
<th>Batch No.</th>
<th>Pharmacy Release by</th>
<th>Handed out By</th>
<th>Accepted By</th>
<th>Checked By</th>
<th>Given By</th>
<th>Date &amp; Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Intrathecal Only</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3</td>
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</tr>
</tbody>
</table>

Checking Procedure:
1. Explain the nature of the procedure, the route of administration and the drug(s) to be administered to the patient, or their guardian.
2. All intravenous chemotherapy apart from continuous infusions should have been completed before this chart is sent to pharmacy.
3. The only other IVs that can be in progress during an ITC procedure are non-cytotoxics such as IV hydration or Rituximab.
4. Ask the patient to confirm their name, date of birth and consent to treatment.
5. Check the patient details on this prescription against patient’s name band
6. Then check the following details on the prescription against the chemotherapy syringe
   Route of administration, drug name, dose, volume, expiry, patient name and patient hospital number.
7. Sign, using full signature, the appropriate sections of the prescription.
8. Once completed please photocopy this prescription, send the copy to the lead oncology pharmacist and file the original in the patient’s notes.
**Intrathecal Chemotherapy (ITC) Prescription and Checklist**

**Appendix 5 contd.**

**Section III:** Must be completed by the prescriber before the chart is sent to pharmacy

<table>
<thead>
<tr>
<th>Question</th>
<th>YES/NO</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the procedure, drug(s), and route of administration, <strong>all</strong> been explained to the patient?</td>
<td>YES/NO</td>
<td>If NO, please state reason</td>
</tr>
<tr>
<td>Is the patient fit to receive Intrathecal chemotherapy?</td>
<td>YES/NO</td>
<td>If NO, please state reason</td>
</tr>
</tbody>
</table>

**Section IV:** Please fill in before ITC administration and after checking the patients details

<table>
<thead>
<tr>
<th>Question</th>
<th>YES/NO</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the patient given either verbal or written consent?</td>
<td>YES/NO</td>
<td>If NO, please state reason</td>
</tr>
<tr>
<td>Is the patient in a designated ITC administration place? Please record bed/room number</td>
<td>YES/NO</td>
<td>Room/bed no:..................</td>
</tr>
<tr>
<td>Are any other IV medications in progress?</td>
<td>YES/NO</td>
<td>If YES What</td>
</tr>
<tr>
<td>Have all the patient’s bolus and short infusion chemotherapy doses been completed for today?</td>
<td>YES/NO</td>
<td>If NO, please state reason</td>
</tr>
<tr>
<td>Details checked with patient?</td>
<td>YES/NO</td>
<td>If NO, then reason</td>
</tr>
</tbody>
</table>

**Section V:** Must be completed by the prescriber before the ITC is administered

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the treatment wrapped in RED or BLUE or CLEAR or BLACK plastic?</td>
<td>RED</td>
<td>ITC can be given</td>
</tr>
<tr>
<td><em>(please circle)</em></td>
<td>BLUE or CLEAR or BLACK</td>
<td>If BLUE or CLEAR or BLACK <strong>do not</strong> give, return it to pharmacy</td>
</tr>
<tr>
<td>Is the treatment one of the following? <em>Methotrexate, Cytarabine or Hydrocortisone</em></td>
<td>YES/NO</td>
<td>If NO <strong>do not give</strong>, return to pharmacy</td>
</tr>
<tr>
<td>Is the date of preparation and administration the same?</td>
<td>YES/NO</td>
<td>If NO <strong>do not give</strong>, return it to pharmacy</td>
</tr>
<tr>
<td>Is the volume &gt;5ml?</td>
<td>YES/NO</td>
<td>If YES <strong>do not give</strong>, return it to pharmacy</td>
</tr>
<tr>
<td>Is the checking nurse on the current ITC register? The current register must be checked.</td>
<td>YES/NO</td>
<td></td>
</tr>
</tbody>
</table>

**Section VI:** Must be completed by the prescriber after the ITC has been administered

<table>
<thead>
<tr>
<th>Question</th>
<th>YES/NO</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbar puncture and treatment successfully administered</td>
<td>YES/NO</td>
<td>If NO, please state reason</td>
</tr>
<tr>
<td>Was the ITC returned to Pharmacy?</td>
<td>YES/NO</td>
<td></td>
</tr>
</tbody>
</table>

**Additional comments**
Appendix 6: Procedure for Out of Hours

Procedure for Out of hours intrathecal chemotherapy doses

1. ‘Intrathecal chemotherapy kits’ are only to be used in emergency situations when the aseptics section of Pharmacy is closed. Only doses of 12.5mg intrathecal methotrexate may be prepared and administered out of hours.

2. Contents of ‘Intrathecal chemotherapy kit’

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 vial</td>
<td>Methotrexate 50mg in 2ml suitable for intrathecal use (or 200mg in 8ml)</td>
</tr>
<tr>
<td>1</td>
<td>3ml Leur lock syringe</td>
</tr>
<tr>
<td>1</td>
<td>Needle 19g (white)</td>
</tr>
<tr>
<td>1</td>
<td>Vent filter needle</td>
</tr>
<tr>
<td>1</td>
<td>Pair size 8 1/2 chemo gloves</td>
</tr>
<tr>
<td>1</td>
<td>Green apron</td>
</tr>
<tr>
<td>1</td>
<td>Chemotherapy mat</td>
</tr>
<tr>
<td>2</td>
<td>Pairs of safety goggles</td>
</tr>
<tr>
<td>2</td>
<td>Masks</td>
</tr>
<tr>
<td>2</td>
<td>Pairs large nitrile gloves</td>
</tr>
<tr>
<td>1</td>
<td>Helapet wipe</td>
</tr>
<tr>
<td>1</td>
<td>Alcowipe</td>
</tr>
</tbody>
</table>

One ‘intrathecal chemotherapy kit’ will be prepared by the aseptics section of Pharmacy. A batch number and expiry will be assigned to each kit.

3. Issuing of ‘Intrathecal chemotherapy kit’

The administering Haematology Consultant or Haematology ST3/SpR should contact the on call pharmacist. The need to use the emergency kit must be authorised by a consultant haematologist on the ITC register of designated personnel. The names of both doctors must be recorded by the pharmacist. The on call pharmacist should collect the ‘intrathecal chemotherapy kit’ from within Pharmacy and take it to the administration area.

The on call pharmacist must check the prescription. The prescription chart used must be a dedicated intrathecal chart shown in Appendix 5, it must have written on it the patient name, hospital number, date, drug name (methotrexate only administered out of hours), dose (standard dose of 12.5 mg only out of hours) and be signed by the administering consultant.

Both the administering doctor and the oncall pharmacist must be on the register of designated personnel. The methotrexate vial in the kit must be checked to ensure that it is in date and is labelled as suitable for intrathecal use. The Pharmacist must endorse the prescription chart with the batch numbers of both the methotrexate vial plus intrathecal chemotherapy kit and sign both the ‘Pharmacy release by’ and ‘Handed out by’ sections of the chart. The doctor must sign the ‘Accepted by’ section in the presence of the pharmacist.
4. **Preparation of the intrathecal dose**

Only the administering Haematology Consultant or Haematology ST3/SpR on the register of designated personnel should prepare intrathecal methotrexate outside of Pharmacy. The intrathecal syringe must be prepared in the presence of the checking chemotherapy trained nurse.

i. Both the nurse and doctor must check the vial of methotrexate to ensure that it is in date, is suitable for intrathecal use and has the batch number written on the prescription. The drug name and strength should also be checked.

ii. Both the nurse and doctor should independently calculate the volume of injection that corresponds to a dose of 12.5mg, the volume should be 0.5ml.

iii. Prepare a dressings trolley for use.

iv. Take out the contents of the 'Intrathecal chemotherapy kit'.

v. The doctor should put on the green apron, one large pair of nitrile gloves, safety goggles and lastly the pair of chemotherapy gloves. The nurse should put on the nitrile gloves and safety goggles.

vi. Unwrap the chemotherapy mat and Helapet wipe, and place both on the top of the dressings trolley.

vii. Flip the top off the methotrexate vial and swab the vial bung using the Alcowipe. Allow alcohol to dry.

viii. Vent the vial using the vent filter needle provided.

ix. Draw up the required volume of methotrexate from the vial and withdraw the needle from the vial.

x. Remove excess air from the syringe and if necessary inject any excess methotrexate back into the vial.

NB when using a vent filter needle ensure that the needle of the vent is in an air space if pushing fluid or air back into the vial. If the tip of the vent is instead in the fluid then methotrexate may flow out of the top of the vent.

5. **Checking procedure**

Both the administering doctor and the checking nurse should follow the checking procedure outlined below:

i. Check the volume of methotrexate in the syringe corresponds to the calculated dose.

ii. Recheck that the vial of methotrexate is in date, suitable for intrathecal use and that its batch number has been recorded.

iii. Check the following details against both the prescription and patient (name band): route of administration, drug name, dose, patient name and hospital number.

iv. Explain the nature of the procedure, the route of administration and the drug to be administered to the patient.

v. Ask the patient to confirm their name, date of birth and consent to treatment.

vi. Sign the checked by section of the prescription.
Appendix 7 Policy for the Preparation and Labelling of High Risk Drugs

Policy for the preparation and labelling of High Risk drugs for intravenous use (Vinca Alkaloids)

1. Dilution of drugs for intravenous use

Adult patient (or adolescent patients treated by Haematologists)

To avoid the inadvertent administration of vinca alkaloids by routes other than intravenous, these drugs must be diluted. All vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) MUST be aseptically dispensed and administered in 50 ml bags sodium chloride 0.9% for intravenous infusion. Due to compatibility/stability issues some brands of vinorelbine can instead be presented in 50 ml bags containing glucose 5%. All minibags are infused over 5 to 10 minutes and monitored for signs of extravasation.

Where the vinca alkaloid eg vincristine, is dispensed as part of the VAD regimen the dose is presented in a CADD pump or elastomeric infusor. The dilution is determined by the device used.

Paediatric or adolescent patients treated by Paediatricians

All doses of the vinca alkaloids vincristine, vinblastine, vindesine and vinorelbine aseptically dispensed and administered to patients treated by the paediatric oncology service will be diluted to at least 10 ml with sodium chloride 0.9% and presented in a syringe. The volume will be determined by the age of the patient and the drug prepared as outlined below.

Children under the age of 10 years: (present in syringe)
- Vincristine doses are diluted to 10 ml
- Vinblastine doses are diluted to 10 ml
- Vindesine doses are diluted to at least 10 ml
- Vinorelbine doses are diluted to at least 10 ml

Children aged 10 years or older: (present in syringe)
- Vincristine doses are diluted to 20 ml
- Vinblastine doses are diluted to 20 ml
- Vindesine doses are diluted to at least 20 ml
- Vinorelbine doses are diluted to at least 20 ml

2. Labelling/Packaging

All devices containing vinca alkaloids are labelled ‘Warning: Vin…… For intravenous use only. FATAL if administered by other routes.’

The outer wrapper is labelled ‘Do not remove this outer covering until the moment of injection. For intravenous use only. Potentially fatal if administered by any other route.’

All minibags (adult patients) and syringes (paediatric patients) containing vinca alkaloids will be wrapped in black plastic.

Pump devices containing vinca alkaloids as part of the VAD regimen will be labelled and packaged as outlined above.
Protocol agreed by:

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<thead>
<tr>
<th>Role</th>
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<tbody>
<tr>
<td>Lead Oncology Pharmacist</td>
<td></td>
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<tr>
<td>Head of Adult Chemotherapy Service</td>
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<tr>
<td>Head(s) of Paediatric Chemotherapy Service</td>
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<tr>
<td>Designated Paediatric Pharmacist</td>
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Written by DLN Robertson, Lead Oncology Pharmacist 24.09.11
Review due 31st January 2015
Appendix 8 Patient information leaflet: Information about Intrathecal Chemotherapy
Can be found here