# Safe Administration of Intrathecal Chemotherapy Policy

**Reference Number:** 
NHSCT/11/458  

**Target audience:** 
This policy applies to staff involved in one or more of the following tasks: the prescribing, dispensing, issuing, checking and administering of intrathecal chemotherapy in NHSCT.

**Sources of advice in relation to this document:** 
Ewan McGrattan, Principal Pharmacist  
Pat McClelland, General Manager Cancer Services  
Eileen Deery, Lead Nurse Cancer  
Peter Flanagan, Director of Medical Services

**Replaces (if appropriate):** 
Any legacy policies on the Safe Administration of Intrathecal Chemotherapy

**Type of Document:** 
Trust Wide

**Approved by:** 
Policy, Standards and Guidelines Committee

**Date Approved:** 
17 November 2011

**Date Issued by Policy Unit:** 
14 December 2011

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**NHSCT Mission Statement**
To provide for all the quality of services we would expect for our families and ourselves
Safe Administration of Intrathecal Chemotherapy Policy

November 2011
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Safe Administration of Intrathecal Chemotherapy Policy

1: Introduction

This policy predominantly relates to treatment, for adults, given by lumbar puncture (i.e. via spinal injection) but is also relevant to intraventricular chemotherapy (i.e. via injection into the ventricles of the brain).

No provision has been made in the NHSCT for the administration of Intrathecal Chemotherapy to children.

The Chief Executive will need to ensure that a risk assessment of the Trust in relation to volume of service is performed and reviewed annually. This risk assessment should be performed by the “designated lead” and should be reported to the Chief Executive and to the Medicines Governance Committee. (Reference to paragraph 19 of National guidance in relation to Low Volume Providers i.e. 10 procedures or less per annum).

2: Background

A major patient safety issue is the danger to patients if intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are injected intrathecally (via spinal or intraventricular injections) during the chemotherapy treatment of a cancer patient. Vinca alkaloids are intended for intravenous use only. If injected intrathecally they cause paralysis almost always followed by death. The World Health Organisation has identified 55 intrathecal chemotherapy incidents worldwide.

A number of the reported incidents took place in England, the most recent, in January 2001, following which the Government agreed a target to reduce the number of patients dying or being paralysed by maladministered spinal injections to zero by the end of 2001.

3: Aim

This policy aims to comply with National Guidance and to provide direction to staff on the safe administration of intrathecal chemotherapy.

4: Scope / Target Audience

This policy applies to staff involved in one or more of the following tasks: the prescribing, dispensing, issuing, checking and administering of intrathecal chemotherapy in NHSCT.
5: Policy Compliance

This policy complies with and reflects the contents of the updated National Guidance on the Safe Administration of Intrathecal Chemotherapy HSC 2008/01, and HSC (SQSD) 61/2008 from DHSSPSNI.

The National Patient Safety Agency (NPSA) also issued a rapid response report NPSA/2008/RRR004 and supporting information on Using Vinca Alkaloid Minibags (Adult/Adolescent Units) which should be read in conjunction with this guidance.

Hard copies of the Trust policy, national guidance, Trust register and other related documents are held in Pharmacy at Laurel house, Chemotherapy Unit at Laurel House and on Ward A3 in Antrim Hospital.

6: Roles and responsibilities

The Chief Executive, who has overall responsibility for ensuring compliance with the National Guidance, should identify a “designated lead” to oversee compliance within the Trust.

In the NHSCT, the “designated lead” is the Medical Director. The designated lead is accountable to the Chief Executive for ensuring the service provided in the NHSCT is in compliance with the National Guidance.

The “designated lead” for the Trust has overall responsibility for holding the register and ensuring that it is maintained and kept up to date. (Example of register at Appendix 1). The “designated lead” should also perform the annual risk assessment relating to volume of service.

The Medical Director, Director of Nursing and the Head of Pharmacy and Medicines Management are responsible for ensuring staff, from the respective disciplines, under their control, are deemed competent to perform the tasks indicated on the Trust register.

The ‘designated lead’ has responsibility for ensuring induction, training and continuing professional development related to intrathecal chemotherapy.

Responsibility for delivering the training is designated to senior members of staff as “Lead Trainers”

Lead Trainers in the Trust for Medical, Nursing and Pharmacy staff are the Medical Director, Trust Lead Nurse for Cancer and Principal Pharmacist, Specialist Services, respectively.

Roles and tasks that should be undertaken by the “lead trainers” are outlined in Appendix 2.

Only staff named on the register should perform the identified tasks.
It is the responsibility of those individuals on the register to ensure that any colleagues they involve in this process are on the register for the task in question.

7: Register of Designated Personnel for Intrathecal Chemotherapy

The Trust maintains a Register of Designated Personnel (Appendix 1) who have been trained and are competent in one or more of the following tasks: prescribing, dispensing, issuing, checking and administering of intrathecal chemotherapy. Only personnel named on the Register are authorised to undertake these tasks relating to intrathecal chemotherapy within the Trust.

Annual reviews of competency must be undertaken and confirmed in writing. It is the responsibility of the lead professional (i.e. Medical Director, Head of Pharmacy and Medicines Management and Director of Nursing) to ensure that documentary evidence of competency is available and retained in personal training files for those staff on the register of designated personnel.

Staff already on an Intrathecal Chemotherapy Register in another Trust who move to the NHSCT are not automatically included on the NHSCT Register. They must be assessed as competent by the relevant lead professional and formally proposed to the Designated lead for inclusion on the register.

The Register will be reviewed annually by the Principal Pharmacist, Specialist Services (as lead cancer pharmacist) and following changes in the designated personnel.

The Register is signed by the Medical Director, Director of Nursing and Head of Pharmacy and Medicines Management.

The original Register is held in Pharmacy at Laurel House. Copies of the Register are held in the Chemotherapy Unit at Laurel House and in Ward A3, Antrim Hospital.

It is the responsibility of staff on the Trust register to ensure they only involve others in the process who are also on the Trust register for relevant tasks.

8: Induction and Training

Lead trainers (i.e. Lead Cancer Nurse, Lead Cancer Pharmacist, Medical Director) must ensure that all relevant new staff are provided with a formal period of induction, including provision of copies of the current National Guidance, the Trust’s treatment protocol(s) and guidelines relevant to prescribing, dispensing, issuing, checking and administering intrathecal chemotherapy. Documentary evidence of this training is required. These staff are required to sign a written confirmation indicating that they have read and understood this documentation before being allowed to practice their respective roles. This signed confirmation should be updated annually.
Copies of policy, protocol and all other relevant guidelines are held Pharmacy at Laurel House, the Chemotherapy Unit Laurel House and in Ward A3, Antrim Hospital.

**NO** member of staff is permitted to perform an activity relating to the prescribing, dispensing, issuing, checking and administering of intrathecal chemotherapy until they have completed the NHSCT training and their name has been added to the NHSCT register.

There is to be **no** automatic inclusion of staff on the NHSCT register as a resulting of training or registration with another Trust.

### 9: Patient consent

Full patient consent (See “Reference Guide to Consent for Examination or Treatment” at [www.dh.gov.uk/consent](http://www.dh.gov.uk/consent)) is required for a course of chemotherapy rather than each dose within the course. However, when attending for each dose, patients should be explicitly told the nature of the procedure, the route of administration, and the drug to be administered.

### 10: Prescribing

**Only Consultant Haematologists** will be included on the Register of doctors authorised to prescribe intrathecal chemotherapy.

FT and ST grades of medical staff **must not** prescribe or administer intrathecal chemotherapy.

Intrathecal chemotherapy must only be prescribed on a purpose designed intrathecal chemotherapy prescription chart.

### 11: Preparation and Dispensing

Only designated Specialist Services Pharmacy staff included on the register will prepare and dispense intrathecal chemotherapy.

Intrathecal chemotherapy must only be prepared immediately prior to use.

Labels added in pharmacy should read clearly ‘**For Intrathecal Use Only**’

### 12: Issuing of Drugs

Drugs for intrathecal chemotherapy will only be issued by Pharmacy to the designated Consultant (named on the Trust register) administering the intrathecal chemotherapy. The drug will be taken to the ward/unit by an authorised designated member of Pharmacy staff.
Intrathecal chemotherapy will only be issued following written confirmation that any intravenous chemotherapy drugs for the named patient for that day have already been administered.

Intrathecal chemotherapy will be packed and transported separately from treatments for administration by other routes.

13: Storage

Intrathcal chemotherapy is for immediate use and must not be stored on the ward.

On delivery and issue to the designated area the intrathecal preparation must remain under the personal control of the consultant who signed as ‘collecting’ the dose and who will be administering the dose.

If administration is going to be delayed or the patient/nurse/consultant is not ready to proceed with the administration, the intrathecal chemotherapy must be returned to the pharmacy at Laurel House and stored in the designated lockable fridge by an authorised Pharmacist only.

14: Checking and Administration of Drugs

The Consultant on the Trust register of designated personnel who will be administering the intrathecal chemotherapy must review the patient before intrathecal chemotherapy is administered. This is to ensure that the patient is fit for treatment, the correct tests have been conducted, the correct chemotherapy has been prescribed and that arrangements have been clearly made for the intrathecal chemotherapy to be administered by the appropriate member of staff.

As part of this planning review, all participants who plan to be involved in the procedure should assemble prior to administration to confirm the date, time and location for administration of the dose. A check should be performed to verify that each participant is approved for their respective role on the current trust register. Confirmation that the review has taken place should be written in the patient’s medical notes.

Intrathecal chemotherapy will be administered in a designated area where no other chemotherapy drugs are being given or stored. The designated area should be a separate room with walls and a door. In the NHSCT this may only be a consulting room in Laurel house or side room on Ward A3, Antrim Hospital.

This area should be designated for the administration of Intrathecal chemotherapy for the entire session even if only one such procedure is to take place in that session.

Under no circumstances should any other form of chemotherapy take place in this area during this session.
Intrathecal chemotherapy must only be administered after intravenous chemotherapy drugs.

Intrathecal chemotherapy must only be administered by a Consultant haematologist named on the Trust register as being competent to perform this task.

Medical and nursing staff must use a formal checking procedure (in accordance with the NHSCT procedure) before administering the treatment to ensure that the right drug and the right dose is given by the right route to the right patient.

This includes checking for the correct:
- drug name,
- drug dosage,
- date of expiry,
- date to be administered,
- route of administration,
- patient’s name and unit number against the prescription sheet and the actual preparation

As a further check, staff may find it helpful to bear in mind that Methotrexate, the drug most commonly given intrathecally, is yellow.

The checking procedure must be confirmed and signed by a chemotherapy trained nurse who is named on the Trust register.

As part of this pre-administration review, the consultant should check that any staff present and assisting in the procedure, are on the register for the task they are carrying out.

The checking procedure must not be conducted by two doctors.

If a designated nurse is not available the intrathecal procedure must be postponed.

The patient and if appropriate, a relative or guardian should be enabled to check the details on the label with the prescription chart if they so wish.

The Consultant Haematologist administering the intrathecal chemotherapy should explain to the patient the nature of the procedure, the drug that is to be administered and the route of administration.

A record of all checks and administration must be made in the appropriate section on the intrathecal chemotherapy chart.

Intrathecal chemotherapy should only be administered within normal working hours.
Trust procedures for the safe handling and administration of hazardous drugs should be followed at all times.

15: Completion of signatures

The prescription is supported by an administration record. Each step must be completed in turn and must be signed by the relevant member of staff who completed the activity.

Only staff members on the Trust Intrathecal chemotherapy register may sign the administration record.

A full and identifiable signature must be signed by the staff member. The original administration record should be retained in the patient’s notes. A copy should be retained by pharmacy with the patient’s records.

16: Patient safety and Incident reporting

All staff involved with the care of patients receiving intrathecal chemotherapy are encouraged to challenge non-adherence to policy and protocols or individual actions which incur potential risk to patients. Such challenges should not be perceived as adversarial, but rather as an additional check to maintain patient safety. Individuals who are so challenged must accept that a discussion is required to investigate the issue in the interests of patient safety.

Any protocol violations, incidents or near misses should be reported as clinical incidents on the Trust’s Near miss and incident reporting forms to the Medical Director, as designated lead, for action.

17: Equality, Human Rights and DDA

The policy is purely clinical/technical in nature and will have no bearing in terms of its likely impact on equality of opportunity or good relations for people within the equality and good relations categories.

18: Alternative Formats

This document can be made available on request on disc, larger font, Braille, audio-cassette and in other minority languages to meet the needs of those who are not fluent in English.

19: Sources of Advice in relation to this document

The Policy Author, responsible Assistant Director or Director as detailed on the policy title page should be contacted with regard to any queries on the content of this policy.
### INTRATHECAL CHEMOTHERAPY REGISTER OF DESIGNATED PERSONNEL

This Register complies with HSS 2008/001. Only staff listed below are authorised to prescribe, dispense, issue, check or administer intrathecal chemotherapy appropriate to their area of competency.

<table>
<thead>
<tr>
<th>Name</th>
<th>Grade</th>
<th>Signature</th>
<th>Areas of Competency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Staff</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff Name</td>
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<tr>
<td></td>
<td></td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Nursing Staff</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff Name</td>
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</tr>
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<tr>
<td><strong>Pharmacy Staff</strong></td>
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</tr>
<tr>
<td>Staff Name</td>
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<tr>
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<tr>
<td></td>
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<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**AUTHORISED BY:**

- MEDICAL DIRECTOR
- DIRECTOR OF NURSING
- HEAD OF PHARMACY AND MEDICINES MANAGEMENT

Date of last review of register __________________ Date __________________

Register valid until __________________
Appendix 2

Roles and tasks that should be undertaken by the “lead trainer(s)”

include ensuring that:

- a formal induction course is available and attended by staff (nursing, pharmacy and medical - including consultants new to the hospital) appropriate to their proposed role in the intrathecal chemotherapy service i.e. prescribing, dispensing, issuing, checking and administration;

- the induction covers: all potential clinical hazards associated with intrathecal chemotherapy including the danger posed to patients if intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are accidentally administered intrathecally; and new safer practice recommendations from the NPSA on the presentation of intravenous vinca alkaloids for adults and for young people in an adult or dedicated teenage setting (para 65);

- 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 prescribing, dispensing, issuing, checking or administering intrathecal chemotherapy read the national guidance and associated local protocols as part of the induction. These staff, including consultants, should be required to sign a written confirmation that they have read and understood these documents before being allowed to practice their respective roles. This signed confirmation should be updated annually;

- all staff on the register are able to demonstrate that they are competent for the roles they will be expected to undertake in providing an intrathecal chemotherapy service and that this competence is reviewed annually alongside how often staff carry out this procedure for ITC;

- staff should receive a certificate, or other written confirmation, that they have completed the training (or annual refresher training) and are competent/remain competent to be included on the register for the designated task(s);

- 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. It is the responsibility of those individuals on the register to ensure that any colleagues they involve in this process are on the register for the task in question.
Appendix 3

Intrathecal Chemotherapy Administration:
Protocol for Designated Nursing Staff

This protocol must be read in conjunction with the Trust Policy for Safe Administration of Intrathecal Chemotherapy. It complies with the National Guidance on the Safe Administration of Intrathecal Cytotoxic Chemotherapy HSC 2008/001. Attainment of level three chemotherapy competence is a pre requisite to training and subsequent entry onto the register as a designated nurse to check Intrathecal Chemotherapy.

Nurse’s role: The chemotherapy nurse plays an important role in patient care during the administration of intrathecal chemotherapy. The nurse should consider the patient holistically, mindful that he/she will require information, support and reassurance. A critical component of patient safety is the key role the nurse plays in checking that the correct drug and dosage are administered to the correct patient. Only those nurses on the intrathecal chemotherapy register must be involved in the checking process. If the nurse does not have a certificate and his/her name is not on the live intrathecal register he/she must not be involved in any aspect of intrathecal cytotoxic chemotherapy.

Prescribing: Intrathecal chemotherapy must only be prescribed Consultant Haematologists included in the register of designated medical staff authorised to prescribe and administer intrathecal chemotherapy.

Administration: Intrathecal chemotherapy must only be administered Consultant Haematologist included in the register of designated medical personnel authorised to administer intrathecal chemotherapy.

Intrathecal chemotherapy must only be administered in the designated areas – A Side room on ward A3 in Antrim Hospital, or a Consulting Exam room in Laurel House. It is not permissible to administer intrathecal cytotoxic chemotherapy in any other location. It is not permissible to administer intrathecal cytotoxic chemotherapy at any location used for intravenous cytotoxic chemotherapy.

The administration must be conducted within normal working hours of 9.00am–5.00pm, Monday - Friday.

Indications: Prophylaxis or treatment of central nervous system (CNS) involvement:
- Acute lymphoblastic leukaemia
- Burkitt’s lymphoma
- Diffuse large B cell lymphoma with oropharyngeal, bone marrow or testicular infiltration
- Other leukaemias / lymphomas with documented CNS infiltration
Contraindications:
- Raised intracranial pressure
- Local sepsis at injection site
- Allergy to the intrathecal drug

Drugs and dosage:
- Methotrexate 10 mg/m² – maximum 15 mg per dose. Standard dose is 12.5 mg.
- Cytarabine 30 mg/m² – maximum 100 mg per dose
- Thiotepa – maximum 10 mg per dose
- Hydrocortisone 15 mg/m² maximum 20mg per dose

Staff may find it helpful to bear in mind that Methotrexate, the drug most commonly given intrathecally, is yellow.

Single agent, double and triple therapy protocols are available. For intrathecal use, preservative-free formulations of these drugs are dispensed by pharmacy, as preservatives can cause arachnoiditis.

Side effects:
- Cerebrospinal fluid (CSF) leak and lumbar puncture headache
- Sepsis
- Methotrexate-induced neurotoxicity: Chemical arachnoiditis
  Seizures
  Leucoencephalopathy
- Systemic methotrexate effect - prolongation of cytopenias and stomatitis. Consider folinic acid rescue.

Patient Assessment. It is the nurse responsibility to:
- Confirm the identity of the patient by asking their name, date of birth and address, and check the hospital number on his/her wrist band.
- Be vigilant as to any potential signs/symptoms of raised intracranial pressure (ICP) and to ensure that he/she is otherwise fit for lumbar puncture. Report any anomalies to the administering consultant promptly.
- Potential indications of raised ICP may include:- Widening blood pressure (systolic rising and diastolic falling), bradycardia, nausea and vomiting, confusion, altered level of consciousness, abnormal respiratory pattern, headache, pupil dilation, seizures.
- Ensure the administering doctor has reviewed the patient and documented this in the medical notes.
- Check that all staff involved in the administration of the intrathecal chemotherapy are on the live intrathecal register
- Check relevant blood counts. If the platelet count is less than 5 x 10^9/L platelets should be given as prescribed before proceeding.
• Check that a recent height and weight has been recorded.
• If necessary reinforce the administering consultant’s explanation to the patient regarding the nature of the procedure, the drug(s) and method of administration to the patient and relative/guardian.
• Ensure signed, informed consent has been obtained.
• After the drug(s) have been issued to the Consultant and before the patient is placed into position for the procedure, the nurse checks the drugs, route, dosage, expiry, and patient identification against the prescription.
• Before the patient is placed into position a second check must be done independently by the consultant administering the drugs, whose name appears on the current register of personnel authorised.
• Both the nurse and administering consultant should confirm with each other that they are both satisfied that they are preparing to administer the correct drug(s), with the correct route, dosage, expiry, and patient identification against the prescription.
• If a designated nurse is not available the procedure must be postponed
• These double checks must not be done by two doctors.
• Facilitate the patient or a relative/guardian to see the prescription and the syringe labelling if they so wish, or verbally ascertain that they are aware that intrathecal chemotherapy is to be given during the lumbar puncture
• The designated nurse must remain present for the entire process of the intrathecal chemotherapy administration

Administration:
• Assist the patient into a comfortable foetal position
• Assist with a standard lumbar puncture at L3/4 or standard Omaya reservoir access.
• Ensure Lidocaine 1% is used as the local anaesthetic.
• Assist the doctor to collect 2-5 ml CSF for cytopsin and routine microbiology.
• Remain present during the administration of the intrathecal cytotoxic drug(s) by slow intrathecal push and reassure the patient.
• Provide a sterile dressing to cover the puncture site with.
• After the procedure is complete allow the patient to mobilise cautiously. There is no evidence that prolonged supine posture reduces the risk of lumbar puncture headache.
• Check the puncture site dressing for any signs of haemorrhage or CSF leak post procedure
• Monitor the patient's observations before and after procedure as per Trust policy, particularly the respiration rate, if the patient has received sedation during the procedure.
• Patient to stay a minimum of 30 mins after procedure but may stay up to 4 hours if unstable or has had sedation.
• Ensure the puncture site is checked and the dressing applied.
• Lumbar puncture dressing can be removed after 24 hours on ward or at home by patient/carer. If there are any problems patient/carer can contact Laurel House or Ward B1.

Handling cytotoxic drugs:
• Since intravenous and intrathecal drugs may be prescribed on the same day it is imperative that routes of administration are not confused. Vinca alkaloids must be administered only by the intravenous route\(^1\). They cause universally fatal encephalopathy if inadvertently administered by the intrathecal route.
• Intrathecal chemotherapy may only be stored in the Pharmacy at Laurel House and must be returned by the delivering pharmacist or administering doctor if it cannot be administered to the patient immediately.
• Intravenous drugs must not be held in the designated treatment room reserved for intrathecal administration.
• Intravenous drugs scheduled for the same day must be administered before intrathecal chemotherapy.
• Pharmacy will dispense intrathecal drugs only after seeing written confirmation of the completed intravenous administration for that day.
• If the chemotherapy regimen includes a continuous intravenous infusion, pharmacy will dispense intrathecal drugs only after seeing written confirmation that the infusion is running.

Documentation:
• The drug(s) for intrathecal administration will be delivered by a pharmacist designated to do so on the Trust register (issuer).
• The doctor administering the drug(s) must receive them directly from a designated pharmacist from the Pharmacy at Laurel House. The prescription sheet must be signed to indicate that the doctor has received the drug(s) (collector).
• The intrathecal drugs must remain in the administering consultant’s possession until administered.
• The administering consultant and the designated nurse who checks the drugs against the prescription must sign the prescription sheet in the appropriate sections.
• After the procedure the completed prescription sheet is returned to pharmacy at laurel house for copying. The original will then be filed in the patient’s note.
• Document the procedure in the nursing notes.

\(^1\) From 06 October 2008 vinca alkaloids will be administered only in 50ml of 0.9% sodium chloride by minibag iv infusion over 5-10 minutes.
Intrathecal Chemotherapy Administration:
Protocol for Designated Medical Staff

This protocol must be read in conjunction with the Trust Policy for Safe Administration of Intrathecal Chemotherapy. It complies with the National Guidance on the Safe Administration of Intrathecal Cytotoxic Chemotherapy HSC 2008/001.

Prescribing: Intrathecal chemotherapy must only be prescribed consultant haematologists included in the register of designated medical staff authorised to prescribe and administer intrathecal chemotherapy.

Administration: Intrathecal chemotherapy must only be administered by consultant haematologists included in the register of designated medical personnel authorised to administer intrathecal chemotherapy.

Intrathecal chemotherapy must only be administered in the designated areas – A Side room on ward A3 in Antrim Hospital, or a Consulting Exam room in Laurel House. It is not permissible to administer intrathecal cytotoxic chemotherapy in any other location. It is not permissible to administer intrathecal cytotoxic chemotherapy at any location used for intravenous cytotoxic chemotherapy.

The administration must be conducted within normal working hours of 9.00am–5.00pm, Monday - Friday.

Indications: Prophylaxis or treatment of CNS involvement:
- Acute lymphoblastic leukaemia
- Burkitt’s lymphoma
- Diffuse large B cell lymphoma with oropharyngeal, bone marrow or testicular infiltration
- Other leukaemias/ lymphomas with documented CNS infiltration

Contraindications:
- Raised intracranial pressure
- Local sepsis at injection site
- Allergy to the intrathecal drug

Drugs and dosage:
- Methotrexate 10 mg/m\(^2\) – maximum 15 mg per dose. Standard dose is 12.5 mg.
- Cytarabine 30 mg/m\(^2\) – maximum 100 mg per dose
- Thiotepa – up to 10 mg per dose
- Hydrocortisone 15 mg/m\(^2\) - maximum 20mg per dose
Staff may find it helpful to bear in mind that Methotrexate, the drug most commonly given intrathecally, is yellow. Single agent, double and triple therapy protocols are available. For intrathecal use, **preservative-free** formulations of these drugs are dispensed by pharmacy, as preservatives can cause arachnoiditis.

**Side effects:**
- Cerebrospinal fluid (CSF) leak and lumbar puncture headache
- Sepsis
- Methotrexate-induced neurotoxicity:
  - Chemical arachnoiditis
  - Seizures
  - Leucoencephalopathy
- Systemic methotrexate effect - prolongation of cytopenias and stomatitis. Consider folinic acid rescue.

**Patient Assessment:**
- Confirm the identity of the patient by asking their name, DOB and address, and check the hospital number on his/her wrist band.
- Examine the patient to exclude raised intracranial pressure and to ensure that he/she is otherwise fit for lumbar puncture.
- Check relevant blood counts. If the platelet count is less than $50 \times 10^9/L$ platelets should be given before proceeding.
- Explain the nature of the procedure, the drug(s) and method of administration to the patient and relative/guardian.
- Obtain signed, informed consent.
- After the drug(s) have been issued by pharmacy and before the patient is placed into position, a second check of the drugs, dosage, expiry, and patient identification against the prescription must be undertaken.
- The second check must be done independently by a designated chemotherapy nurse whose name appears on the current register of personnel authorised to check intrathecal chemotherapy.
- Both the nurse and administering consultant should confirm with each other that they are both satisfied that they are preparing to administer the correct drug(s), with the correct route, dosage, expiry, and patient identification against the prescription.
- If a designated nurse is not available postpone the procedure
- These double checks must not be done by two doctors.
- The patient or a relative/guardian may wish to see the prescription and the syringe labelling.
- The designated nurse must remain present for the entire process of the intrathecal chemotherapy administration.
Administration:
- Proceed with a standard lumbar puncture at L3/4 or standard Omaya reservoir access.
- Lidocaine 1% must be used as the local anaesthetic.
- Collect 2-5 ml CSF for cytospin and routine microbiology.
- Administer intrathecal cytotoxic drug(s) by slow intrathecal push.
- Remove the needle and cover the puncture site with a sterile dressing.
- After the procedure is complete allow the patient to mobilise cautiously.
- There is no evidence that prolonged supine posture reduces the risk of lumbar puncture headache.
- Patient to stay a minimum of 30 mins after procedure but may stay up to 4 hours if unstable or has had sedation.

Handling cytotoxic drugs:
- Since intravenous and intrathecal drugs may be prescribed on the same day it is imperative that routes of administration are not confused. Vinca alkaloids must be administered only by the intravenous route. They cause universally fatal encephalopathy if inadvertently administered by the intrathecal route.
- Intrathecal chemotherapy may only be stored in the Pharmacy at Laurel House and must be returned by the delivering pharmacist or administering doctor if it cannot be administered to the patient immediately.
- Intravenous drugs must not be brought to the designated area reserved for intrathecal administration.
- Intravenous drugs scheduled for the same day must be administered before intrathecal chemotherapy.
- Pharmacy will dispense intrathecal drugs only after seeing written confirmation of the completed intravenous administration for that day.
- If the chemotherapy regimen includes a continuous intravenous infusion, pharmacy will dispense intrathecal drugs only after seeing written confirmation that the infusion is running.

Documentation:
- The drug(s) for intrathecal administration will be delivered by a pharmacist designated to do so on the Trust register (issuer).
  
  The doctor administering the drug(s) must receive them directly from a designated pharmacist from the Pharmacy at Laurel House. The prescription sheet must be signed to indicate that the doctor has received the drug(s) (collector)
- The intrathecal drugs must remain in your possession until administered. If the procedure can not take place or is to be delayed, the drugs must be return to pharmacy Laurel.

2 From 06 October 2008 vinca alkaloids will be administered only in 50ml of 0.9% sodium chloride by minibag iv infusion over 5-10 minutes.
They may only be stored in the pharmacy at Laurel House in a designated refrigerator.

- The administering consultant and the designated nurse who check the drugs against the prescription must sign the prescription sheet in the appropriate sections.
- After the procedure the completed prescription sheet is returned to pharmacy at laurel house for copying. The original will then be filed in the patient’s note.

**Protocol Violation:**
All staff involved with the care of patients receiving cytotoxic chemotherapy including intrathecal chemotherapy are encouraged to challenge non-adherence to protocols or individual actions which incur potential risk to patients. Such challenges should not be perceived as adversarial, but rather as an additional check to maintain patient safety. Individuals who are so challenged must accept that a discussion is required to investigate the issue in the interests of patient safety. Any protocol violations or near misses should be reported as clinical incidents on the Trust’s incident report form and the designated lead clinician (Medical Director) must be informed.
Appendix 5

Intrathecal Chemotherapy Administration:
Protocol for Pharmacy Staff

This protocol must be read in conjunction with the Trust Policy for Safe Administration of Intrathecal Chemotherapy. It complies with the National Guidance on the Safe Administration of Intrathecal Cytotoxic Chemotherapy HSC 2008/001.

**Pharmacist’s role:** The Pharmacist must be named on the NHSCT register to perform the tasks required for intrathecal chemotherapy. The pharmacist is required to clinically verify the therapy requested, other chemotherapy that may be part of the overall treatment plan, the sequencing of administration, verify written confirmation that IV therapies have been given(commenced) and the patients blood values are acceptable. The Pharmacist is also required to ensure that the dose is prepared, packaged and issued safely from pharmacy in Laurel House in accordance with local aseptic procedures. The pharmacist will deliver the dose (issue) directly to the consultant haematologist performing the procedure, at the designated time and location.

**Technician’s role:** The technician must be named on the NHSCT register to perform the tasks required for intrathecal chemotherapy. The technician will prepare the dose in accordance with local pharmacy aseptic procedures and leave the dose to be checked, labelled and packaged by the pharmacist. Technicians are **not permitted to issue** intrathecal chemotherapy doses.

**Prescribing:** Intrathecal chemotherapy must only be prescribed by consultant haematologists included in the register of designated medical staff authorised to prescribe and administer intrathecal chemotherapy.

**Administration:** Intrathecal chemotherapy must only be administered by consultants haematologists included in the register of designated medical personnel authorised to administer intrathecal chemotherapy.

Intrathecal chemotherapy must only be administered in the designated areas - A Side room on ward A3 in Antrim Hospital, or a Consulting Exam room in Laurel House. It is not permissible to administer intrathecal cytotoxic chemotherapy in any other location. It is not permissible to administer intrathecal cytotoxic chemotherapy at any location used for intravenous cytotoxic chemotherapy.

The administration must be conducted within normal working hours of 9.00am–5.00pm, Monday - Friday.

**Indications: Prophylaxis or treatment of CNS involvement:**
Acute lymphoblastic leukaemia
Burkitt’s lymphoma
Diffuse large B cell lymphoma with oropharyngeal, bone marrow or testicular infiltration
Other leukaemias/ lymphomas with documented CNS infiltration

Contraindications:
Raised intracranial pressure
Local sepsis at injection site
Allergy to the intrathecal drug

Drugs and dosage:
- Methotrexate 10 mg/m² – maximum 15 mg per dose. Standard dose is 12.5 mg.
- Cytarabine 30 mg/m² – maximum 100 mg per dose
- Thiotepa – up to 10 mg per dose
- Hydrocortisone 15 mg/m² - maximum 20mg per dose

Staff may find it helpful to bear in mind that Methotrexate, the drug most commonly given intrathecally, is yellow.

Single agent, double and triple therapy protocols are available. For intrathecal use, preservative-free formulations of these drugs are dispensed by pharmacy, as preservatives can cause arachnoiditis.

Side effects:
- Cerebrospinal fluid (CSF) leak and lumbar puncture headache
- Sepsis
- Methotrexate-induced neurotoxicity: Chemical arachnoiditis
- Seizures
- Leucoencephalopathy
- Systemic methotrexate effect - prolongation of cytopenias and stomatitis. Consider folinic acid rescue.

Dispensing:
Dispensing is the activity of preparing the dose, filling the syringe and placing the syringe in the packaging for transport.

Only Pharmacists and technicians named on the Trust register may perform the required tasks for dispensing.

Pharmacist must ensure that preservative-free preparations are used.

The dose must be labelled in pharmacy indicating the route of administration. This must be printed clearly in the largest font size possible and embolded e.g. ‘For intrathecal Use Only’

If storage is required between dispensing and issuing, intrathecal chemotherapy drugs should be stored in a dedicated lockable container/fridge in the pharmacy at Laurel House. This facility should never be used to store intravenous drugs.
Intrathecal chemotherapy drugs should always be packed and transported separately from treatments for administration by other routes. Intrathecal chemotherapy drugs should be transported in a distinctive bag/container that is not used for any other purpose, as per local pharmacy procedure.

**Issuing:**
The intrathecal chemotherapy should only be issued from the pharmacy by a pharmacist on the Trust register (issuer), and delivered to the designated location and handed directly to the consultant performing the administration (collector). Pharmacist must confirm that they are issuing the correct drug, dose and route for the correct patient. Both the issue and collection must be signed for by the pharmacist and consultant respectively on the chemotherapy chart. Intrathecal chemotherapy drugs should be issued at a different time from drugs for intravenous chemotherapy. Intravenous chemotherapy should be issued first. **Only following written confirmation that any intravenous chemotherapy drugs for the named patient for that day have already been administered should the intrathecal chemotherapy drugs be issued by the pharmacy**

Intrathecal chemotherapy preparations must never be stored anywhere outside of pharmacy, Laurel house.

**Patient Assessment: (For reference only– Nurse and Consultant role)**
Confirm the identity of the patient by asking their name, DOB and address, and check the hospital number on his/her wrist band. Examine the patient to exclude raised intracranial pressure and to ensure that he/she is otherwise fit for lumbar puncture. Check relevant blood counts. If the platelet count is less than $50 \times 10^9 /L$ platelets should be given before proceeding. Explain the nature of the procedure, the drug(s) and method of administration to the patient and relative/guardian. Obtain signed, informed consent. After the drug(s) have been issued by pharmacy and before the patient is placed into position, a second check of the drugs, dosage, expiry, and patient identification against the prescription must be undertaken. The second check must be done independently by a designated chemotherapy nurse whose name appears on the current register of personnel authorised to check intrathecal chemotherapy. Both the nurse and administering consultant should confirm with each other that they are both satisfied that they are preparing to administer the correct drug(s), with the correct route, dosage, expiry, and patient identification against the prescription. If a designated nurse is not available postpone the procedure.
These double checks must not be done by two doctors.
The patient or a relative/guardian may wish to see the prescription and the syringe labelling.
The designated nurse must remain present for the entire process of the intrathecal chemotherapy administration

**Administration: (For reference only. Performed by Consultant, assisted by Nurse)**
Proceed with a standard lumbar puncture at L3/4 or standard Omaya reservoir access.
Lidocaine 1% must be used as the local anaesthetic.
Collect 2-5 ml CSF for cytospin and routine microbiology.
Administer intrathecal cytotoxic drug(s) by slow intrathecal push.
Remove the needle and cover the puncture site with a sterile dressing.
After the procedure is complete allow the patient to mobilise cautiously.
There is no evidence that prolonged supine posture reduces the risk of lumbar puncture headache.

**Handling cytotoxic drugs:**
Since intravenous and intrathecal drugs may be prescribed on the same day it is imperative that routes of administration are not confused. Vinca alkaloids must be administered only by the intravenous route. They cause universally fatal encephalopathy if inadvertently administered by the intrathecal route.
Intrathecal chemotherapy may only be stored in the Pharmacy, Laurel House and must be returned by the delivering pharmacist or administering doctor if it cannot be administered to the patient immediately.
Intravenous drugs must not be brought to the designated area reserved for intrathecal administration.
Intravenous drugs scheduled for the same day must be administered before intrathecal chemotherapy.
Pharmacy will dispense intrathecal drugs only after seeing written confirmation of the completed intravenous administration for that day.
If the chemotherapy regimen includes a continuous intravenous infusion, pharmacy will dispense intrathecal drugs only after seeing written confirmation that the infusion is running.

**Documentation:**
The drug(s) for intrathecal administration will be delivered by a pharmacist designated to do so on the Trust register (issuer).
The doctor administering the drug(s) must receive them directly from a designated pharmacist from the Pharmacy at Laurel House. The prescription sheet must be signed to indicate that the doctor has received the drug(s) (collector)

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From 06 October 2008 vinca alkaloids will be administered only in 50ml of 0.9% sodium chloride by minibag iv infusion over 5-10 minutes.
The intrathecal drugs must remain in the Consultants possession until administered. If the procedure can not take place or is to be delayed, the drugs must be return to pharmacy Laurel house. They may only be stored in pharmacy Laurel House in a designated refrigerator. The administering doctor and the designated nurse who checks the drugs against the prescription must sign the prescription sheet in the appropriate sections. After the procedure the completed prescription sheet is returned to pharmacy at laurel house for copying. The original will then be filed in the patient's note.

**Protocol Violation:**
All staff involved with the care of patients receiving cytotoxic chemotherapy including intrathecal chemotherapy are encouraged to challenge non-adherence to protocols or individual actions which incur potential risk to patients. Such challenges should not be perceived as adversarial, but rather as an additional check to maintain patient safety. Individuals who are so challenged must accept that a discussion is required to investigate the issue in the interests of patient safety. Any protocol violations or near misses should be reported as clinical incidents on the Trust's incident report form and the designated lead clinician (Medical Director) must be informed.