

**Standards and Guidelines Committee**

**Policy for Safe Administration of Intrathecal Cytotoxic Chemotherapy**

<b>Summary</b>	This policy applies to the use of intrathecal cytotoxic chemotherapy agents in paediatric, adolescent and adult patients throughout the BHSCT: specifically to the dispensing, issuing, prescribing, checking and administration of intrathecal cytotoxic chemotherapy.
<b>Purpose</b>	To comply with national guidance on the Safe Administration of Intrathecal Chemotherapy - HSC 2008/001.
<b>Operational date</b>	April 2011
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<b>Version Number</b>	V 1
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<b>Reference Number</b>	SG 19/11
<b>Supersedes</b>	Legacy policies

**Version Record**

<b>Date</b>	<b>Version</b>	<b>Author</b>	<b>Comments</b>
27 May 2010	V 0.1	CA Macartney	Initial draft
June 2010	V 0.2	JR Johnston	Reformatting: plus compliance with document changes.
July 2010	V 0.3	JR Johnston	Andrew Brown comments
28 July 2010	V 0.4	CA Macartney	Further changes
23/03/2011	V 0.5	CA Macartney	Further changes
25/03/2011	V 0.6	JRJ	Addition of final appendices
04/04/2011	V 0.7	CAM	Minor changes after D&T 1/4/2011
23/05/2011	V0.8	CAM	Minor changes to Appendix 2

**Policy Record**

		<b>Date</b>	<b>Version</b>
Author (s)	Approval		
Director Responsible	Approval		

**Approval Process – Clinical Standards and Guidelines**

D&T	Approval	01/04/2011	V0.6
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Policy Committee	Approval	16/05/2011	V0.7
Executive Team	Authorise	23/05/2011	V0.8
Appropriate Director	Sign Off	24/05/2011	V0.8

## **Full Description**

Reference No: SG 19/11

### **Policy for Safe Administration of Intrathecal Cytotoxic Chemotherapy**

**2. Introduction:**

In 2008 the National Patient Safety Agency (NPSA) and the UK Department of Health (DoH) reported fatal and serious incidents from hospitals in which doses of vinca alkaloids intended for intravenous administration have been administered by the intrathecal (spinal) route in error.

In November 2008, the DHSSPSNI issued circular HSC(SQSD) 61/2008 which required trusts to implement both the NPSA/2008/RRR004 "Using Vinca Alkaloid Minibags (Adult / Adolescent Units)" and HSC 2008/001 "Updated national guidance on the safe administration of intrathecal chemotherapy" from the DoH (UK). This policy outlines the processes and procedures of the BHSC to comply with these recommendations.

**3. Purpose:**

To comply with national guidance on the Safe Administration of Intrathecal Chemotherapy - HSC 2008/001 and the NPSA/2008/RRR004.

**4. The scope:**

This policy applies to staff involved in one or more of the following tasks: the dispensing, issuing, prescribing, checking and administering of intrathecal cytotoxic chemotherapy - in the adolescent and adult haematology services at Belfast City Hospital (BCH) and Royal Belfast Hospital for Sick Children (RBHSC).

Guidance is also included regarding the regulations for intravenous chemotherapy.

**5. Objectives:**

To describe the policy for the following facets of intrathecal cytotoxic chemotherapy administration:

- Induction and training
- Registration of designated trained personnel
- Prescribing
- Preparation, dispensing, issuing, storage and issue
- Checking and administration
- Protocol violation

**6. Roles and Responsibilities:**

Dr C A Macartney (Royal Belfast Hospital for Sick Children) is the designated lead clinician with responsibility for induction, training and continuing professional development related to intrathecal chemotherapy within the Trust.

Dr RJG Cuthbert (Belfast City Hospital) is the deputy lead clinician.

Dr Macartney and Dr Cuthbert take direct responsibility for these activities for medical staff.

The following lead trainers have delegated responsibility within their disciplines:

- Maurice Regan for pharmacy staff (BCH)
- Anne Simpson for pharmacy staff (RBHSC)

- Caroline McCaughey for nursing staff (BCH)
- Bernie McShane for nursing staff (RBHSC)

Formal induction programmes and annual review of staff competence are conducted in the three disciplines, and written confirmation of staff competence is recorded for the relevant designated task(s).

## 7. **The definition and background of the policy:**

At least 55 incidents are known to have occurred around the world where the intravenous vinca alkaloids have been inadvertently injected intrathecally during the treatment of cancer patients. These incidents have resulted in the paralysis or death of all the patients involved.

The UK Department of Health agreed a target to reduce the number of patients dying or being paralysed by maladministered spinal injections to zero by the end of 2001 and National Guidance was issued in 2001 (HSC 2001/022) to support this. The guidance was updated in 2003 (HSC 2003/010), and in August 2008 (HSC 2008/001).

## 8. **Policy description and statements:**

8.1 This policy complies with the recommendations of

- HSC 2008/001 "*Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy*"
- NPSA/2008/RRR004 "*Using Vinca Alkaloid Minibags (Adult / Adolescent Units)*".
- HSC(SQSD) 61/2008 from DHSSPSNI.

## 8.2 **Register of Designated Personnel:**

The hospital maintains a register of designated personnel who have been trained and hold certification of competency in one or more of the following procedures:

- Prescribing and administration of intrathecal chemotherapy.
- Dispensing and issuing of intrathecal chemotherapy from pharmacy.
- Checking the drugs and prescription before administration.

Personnel on the register are the only members of staff authorised to participate in tasks related to intrathecal chemotherapy.

The register is held on the NI Cancer Centre pharmacy website:

<http://hpssweb.n-i.nhs.uk/niccpharmacy/index.html> - access is available via the Belfast Trust website. Hard copies of the register will be kept in the Satellite Pharmacy BCH and Haematology/Oncology outpatient area (RBHSC).

The Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy HSC 2008/001 and this policy are held in the following areas: Ward 10 North, Bridgewater Suite Day Ward, Satellite Pharmacy and Main Pharmacy (Belfast City Hospital) and Children's Haematology Unit, Haematology/Oncology outpatient area and Satellite Pharmacy (RBHSC).

## 8.3 **Induction and Training:**

8.3.1 All new staff, even if they have had training elsewhere, must undergo a formal induction and training programme appropriate for their role in prescribing, dispensing, issuing, checking or administration of intrathecal chemotherapy.

Induction includes highlighting potential hazards associated with chemotherapy, and

in particular, the dangers of accidental intrathecal administration of vinca alkaloids (vincristine, vinblastine, vindesine, vinorelbine).

- 8.3.2 Health care staff not involved in providing the intrathecal chemotherapy service, but working in areas where it is undertaken, must **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.

- 8.3.3 Medical staff must **not** prescribe or administer intrathecal chemotherapy until completion of appropriate induction and training, and have had their competency assessed and documented.

The prescription and administration of intrathecal chemotherapy is restricted to medical staff in the following grades: SpR, ST3 and above, associate specialists and consultants.

It is not appropriate for junior grades to administer intrathecal chemotherapy. ST1 and ST2 grades may only in exceptional circumstances be deemed competent and included on the register to administer intrathecal chemotherapy. In this instance a **waiver** to the national policy will need to be signed off by the chief executive, the medical director, nurse director and chief pharmacist.

Medical staff who are training to undertake intrathecal chemotherapy procedures must be supervised by a designated doctor whose name is on the current register.

The supervising doctor must take ultimate responsibility for the patient assessment, drug checking and administration procedures, but should ensure that the trainee is undertaking these procedures correctly.

- 8.3.4 Nursing and pharmacy staff are provided with induction and training programme appropriate to their role in the safe handling, dispensing, storage, and checking of intrathecal cytotoxic drugs.

When individuals have completed their training and assessment they are given a certificate of competency, and their names are added to the register of personnel designated to participate in tasks related to intrathecal chemotherapy. They must sign a written confirmation that they have read and understood this policy. This training and assessment should be updated annually as annual refresher training is required to remain on the register.

#### 8.4 **Prescribing:**

- 8.4.1 Only those designated consultants, associate specialists, SpR's and grades ST3 and above whose names appear on the register are authorised to prescribe intrathecal chemotherapy.

Staff grades, SHO's, FT1, FT2, ST1, & ST2 doctors are **not** authorised to prescribe intrathecal chemotherapy.

- 8.4.2 Intrathecal chemotherapy must be prescribed on the separate intrathecal chemotherapy prescription chart which cannot be used for any other cytotoxic agents.

The chart includes the drug name, dose, route of administration and signatures of

the prescriber, dispenser, pharmacy issuer, collector, nurse checker, and administering doctor.

Intrathecal cytotoxic drugs must be issued or received only by designated staff.

BCH only (adult intrathecal chemotherapy chart)

A new chart must be completed for each episode of intrathecal chemotherapy administered to any individual patient i.e. more than one chemotherapy drug may be prescribed on the same chart only if to be administered at the same procedure.

RBHSC only (paediatric intrathecal chemotherapy chart)

A new chart must be completed for each separate intrathecal chemotherapy drug being administered i.e. only one drug may be prescribed on each prescription sheet.

**8.5 Preparation, Storage and Issue:**

8.5.1 Intrathecal cytotoxic drugs are prepared only in the

- Satellite Pharmacy on C-floor (BCH),
- Satellite Pharmacy (RBHSC)
- Main Pharmacy (Royal Victoria Hospital).

They must be packed and transported separately from drugs administered by other routes.

8.5.2 Labels added in pharmacy should have the route of administration printed clearly in the largest font size possible and emboldened:

### **For Intrathecal Use Only**

Negative labelling, i.e. *“Not for ..... Use”* must **not** be used.

8.5.3 Intrathecal cytotoxic drugs must be stored in each of the Satellite Pharmacies in a dedicated, locked container kept in the refrigerator, or in the locked refrigerator reserved for intrathecal chemotherapy on Ward 10 North (BCH) or Haematology/Oncology outpatient area (RBHSC).

Intrathecal cytotoxic drugs must be issued from Satellite Pharmacy **directly** to the doctor carrying out the intrathecal procedure, or taken to the ward by a designated member of the pharmacy staff. Intrathecal therapy delivered to the ward must be either issued directly to the doctor carrying out the intrathecal procedure or placed in the designated refrigerator.

In both instances the pharmacy staff member must sign the release of the drugs and record to whom they were released or record placement in the designated refrigerator. Only the doctor who is to administer the intrathecal cytotoxic drugs may remove them from the refrigerator, and must then check them.

**N.B.** Liposomal cytarabine for intrathecal use (Depocyte) must be stored at room temperature. Therefore, the doctor carrying out the intrathecal administration must collect it directly from pharmacy just before the procedure, and it must not be stored in the designated ward refrigerator.

8.5.4 **Timing of issue of non-intrathecal chemotherapy from Pharmacy**  
**BCH only**

Intrathecal cytotoxic drugs must be issued from Satellite Pharmacy at a different time

from drugs for intravenous chemotherapy. Where a patient's treatment requires intravenous chemotherapy to be administered on the same day as intrathecal chemotherapy, the intravenous chemotherapy should be prescribed and issued first. The intrathecal drug should **only** be issued after written confirmation of administration of the intravenous cytotoxic drugs is returned to the Satellite Pharmacy.

When a regimen involves a continuous intravenous regimen combined with intrathecal chemotherapy, it is only acceptable to issue and administer intrathecal chemotherapy after receiving written confirmation that the intravenous infusion has started.

### **RBHSC**

In RBHSC intrathecal chemotherapy is delivered under general anaesthesia. Therefore in RBHSC only, the intrathecal chemotherapy will be administered first, and the intravenous chemotherapy will **only** be issued after the pharmacy staff have received written confirmation that the intrathecal chemotherapy has been administered.

If the intravenous chemotherapy is scheduled for twice daily administration on the same day as intrathecal chemotherapy, the intrathecal chemotherapy will only be released after written confirmation that the first intravenous dose has been administered.

When a regimen involves a continuous intravenous regimen combined with intrathecal chemotherapy, it is only acceptable to issue and administer intrathecal chemotherapy after receiving written confirmation that the intravenous infusion has started.

## **8.6. Checking & Administration:**

- 8.6.1 Intrathecal chemotherapy must be administered only in the designated areas -
- Ward 10 North Side B Treatment Room (Belfast City Hospital)
  - Bridgewater Suite Procedure Room 3 (Belfast City Hospital)
  - Surgical Day Unit or Main Theatre (RBHSC).

Intravenous chemotherapy must **not** be administered in these areas under any circumstances.

- 8.6.2 Except in exceptional circumstances, the administration must be conducted within normal working hours of 9.00am – 5.00pm, Monday - Friday.
- 8.6.3 The administering doctor must review the patient clinically to ensure that he/she is fit for treatment, the correct tests have been done, and the correct chemotherapy has been prescribed. Confirmation that the review has taken place must be written in the patient's medical notes.
- 8.6.4 The doctor must use a formal checking procedure before administration of intrathecal chemotherapy. This includes checking the:-
- 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 syringe/minibag.

8.6.5 The checking procedure must be confirmed and signed by a designated haematology nurse.

The checking procedure must **not** be conducted by two doctors.

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

As part of the review, the member of staff should check that any staff assisting in the procedure are on the register for the task they are carrying out.

8.6.6 At the end of the procedure the prescription sheet completed with the appropriate signatures must be returned to pharmacy for registration \*\*, before ultimately being filed in the patient's notes. (\*\*Filed directly in patients notes in RBHSC).

8.6.7 The patient, or a relative or guardian, should be given the opportunity to participate in the checking procedure if they so wish. In any case the patient's identity must be confirmed, and purpose of the procedure, its method of conduct, and details of the drug being administered must be explained to the patient and/or guardian. Signed consent must be obtained before proceeding.

## 8.7 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 clinicians (CAM or RJGC) must be informed.

## 8.8 Vinca alkaloids for intravenous use

**To comply with the NPSA Rapid Response Report NPSA/2008/RRR004:**

### 8.8.1 Adults/Adolescents in BCH

Minibags are to be used for the intravenous administration of vinca alkaloids in adult and teenage patients who are treated in adult and adolescent units. When vinca alkaloids are prescribed, dispensed or administered in adult or adolescent units, syringes should **NOT** be used. The prescribed vinca alkaloid should be supplied from the hospital pharmacy ready to administer in a 50ml minibag of sodium chloride 0.9%. (For some brands of vinorelbine glucose 5% solution for injection may be used instead).

### 8.8.2 Children and adolescents treated in RBHSC

#### 1. Children < 10yrs:

- Intravenous vinca alkaloids can be given at higher concentrations.
- Currently vincristine is given at 1mg/ml concentration.

#### 2. Children > 10yrs:

- The volume of vincristine must be diluted to a maximum concentration of 0.1mg/ml.

- The volume of vinblastine, vindesine and vinorelbine must be diluted to a minimum volume of 20ml.

3. For patients >10yrs with poor veins and where peripheral administration of larger volumes of vinca alkaloids poses an increased risk of extravasation injury, then the consultant haematologist/oncologist can request in writing that these doses are presented in their undiluted form. This is local practice and not taken from the national policy document.
4. Intravenous vinca alkaloids are not routinely administered on the same day for the same patient as intrathecal chemotherapy at RBHSC. However in rare circumstances it may be necessary to administer a vinca alkaloid on the same day as intrathecal chemotherapy. In this case the signed intrathecal prescription chart will be used as confirmation that the intrathecal procedure has been completed prior to the intravenous vinca alkaloid being released from pharmacy. The vinca alkaloid must only be administered in either the Haematology Outpatient area or ward.

**11. Implementation / Resource requirements:**

As for legacy trusts.

**12. Source(s) / Evidence Base:**

This policy complies with the recommendations of the Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy HSC 2008/001.

**13. References, including relevant external guidelines:**

1. [Department of Health. Health Service Circular 2008/001](#) Updated national guidelines on the safe administration of intrathecal chemotherapy. London. DOH.
2. National Health Service National Patient Safety Agency (2008) [Rapid Response Report NPSA/2008/RRR004](#) "Using Vinca Alkaloid Minibags (Adult / Adolescent Units)".
3. [HSC\(SQSD\) 61/2008](#) - NPSA RRR: Using Vinca Alkaloid Minibags (Adult/Adolescent Units) and HSC 2008/001 updated national guidance on the safe administration of intrathecal chemotherapy - 25 November 2008.

**14. Consultation Process:**

The consultation process included:

- Consultant haematologists
- Satellite Pharmacy staff
- Oncology / Haematology nurse managers
- Haematology ward and team Leaders (nursing)
- Haematology educational facilitator (nursing)
- Oncology clinical leaders
- Infusional Services

**Equality and Human Rights screening carried out:**

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, the Belfast Trust has carried out an initial screening exercise to ascertain if this policy should be subject to a full impact assessment.

15.  Screening completed  Full impact assessment to be carried out.  
No action required.

**Procedures:**

This policy should be read in conjunction with:

Appendix 1 = BCH protocol for designated medical staff involved in prescribing and administering intrathecal chemotherapy. (2008)

Appendix 2 = BCH protocol for designated nursing staff involved in checking intrathecal chemotherapy prior to its administration (2008)

Appendix 3 = RBHSC protocol for designated nursing staff involved in checking intrathecal chemotherapy prior to its administration (2008)

Appendix 4 = Pharmacy Policy for the Management of Intrathecal Chemotherapy (BCH)

Appendix 5 = Pharmacy Policy for the Management of Intrathecal Chemotherapy (RBHSC)

Appendix 6 = BCH intrathecal chemotherapy chart

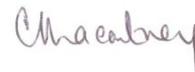
Appendix 7 = RBHSC intrathecal chemotherapy chart



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**Director Jennifer Welsh**

**Date: May 2011**



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**Author Dr CA McCartney**

**Date: May 2011**

**Department of Haematology - Belfast City Hospital**
**Intrathecal Cytotoxic Chemotherapy Administration:  
Protocol for Designated Medical Staff**

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

**Prescribing:** Intrathecal chemotherapy must be prescribed only by consultants, SpR's or grade ST3 and above, whose names are included in the register of designated medical staff authorised to prescribe and administer intrathecal chemotherapy.

**Administration:** Intrathecal chemotherapy must be administered only by consultants, SpR's or grade ST3 and above, included in the register of designated medical personnel authorised to administer intrathecal chemotherapy.

Intrathecal chemotherapy must be administered only in the designated areas - Ward 10 North Side B Treatment Room or Bridgewater Suite Procedure Room 3. It is not permissible to administer intrathecal cytotoxic chemotherapy at any site 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<sup>2</sup> – maximum 15 mg per dose. Standard dose is 12.5 mg.
- Cytarabine 30 mg/m<sup>2</sup> – maximum 100 mg per dose
- Thiotepa – up to 10 mg per dose
- Hydrocortisone 15 mg/m<sup>2</sup> - maximum 20mg per dose

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:**

- CSF leak and lumbar puncture headache
- Sepsis
- Methotrexate-induced neurotoxicity: Chemical arachnoiditis  
Seizures  
Leucoencephalopathy
- Systemic methotrexate effect - prolongation of cytopenias. 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.
- Check the drugs, dosage, expiry, and patient identification against the prescription.
- A cross check must be done independently by a designated haematology nurse whose name appears on the current register of personnel authorised to check intrathecal chemotherapy.
- If a designated nurse is not available postpone the procedure
- The cross check must not be done by another doctor.
- The patient or a relative/guardian may wish to see the prescription and the syringe labelling.

**Administration:**

- Proceed with a standard lumbar puncture at L3/4 or standard Omayya 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<sup>1</sup>. They cause universally fatal encephalopathy if inadvertently administered by the intrathecal route.
- In Ward 10 North intrathecal drugs must be stored in the locked refrigerator reserved for this purpose.
- Intravenous drugs must never be brought to the side ward 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 doctor administering the drug(s) must receive them directly from a designated pharmacist in Satellite Pharmacy, or from the designated refrigerator on Ward 10 North. In both situations the prescription sheet must be signed to indicate that the doctor has received the drug(s).
- For outpatients the drugs must be collected directly from Satellite Pharmacy.
- The intrathecal drugs must remain in your possession until administered, or locked in the designated refrigerator on Ward 10 North.
- 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 send the completed prescription sheet back to pharmacy for registration. It 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 (IR Clinical), and the designated lead clinician (RJGC) must be informed.

**RJG Cuthbert**

Updated to comply with HSC/2008/001 – August 2008

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<sup>1</sup> 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.



**Department of Haematology - Belfast City Hospital**

**Intrathecal Cytotoxic Chemotherapy Administration:  
Protocol for Designated Nursing Staff**

This protocol must be read in conjunction with the Policy for Safe Administration of Intrathecal Cytotoxic 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 haematology 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. 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 be prescribed only by consultants, SpR's or grade ST3 doctors and above, whose names are included in the register of designated medical staff authorised to prescribe and administer intrathecal chemotherapy.

**Administration:** Intrathecal chemotherapy must be administered only by consultants, SpR's or grade ST3 doctors and above, included in the register of designated medical personnel authorised to administer intrathecal chemotherapy. Intrathecal chemotherapy must be administered only in the designated areas - Ward 10 North Side B Treatment Room or Bridgewater Suite Procedure Room 3. It is not permissible to administer intrathecal cytotoxic chemotherapy in any other location. It is not permissible to administer intrathecal cytotoxic chemotherapy at any site used for intravenous cytotoxic chemotherapy. The administration must be conducted within normal working hours of 9.00am–5.00pm.

**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/m<sup>2</sup> – maximum 15 mg per dose. Standard dose is 12.5 mg.
- Cytarabine 30 mg/m<sup>2</sup> – maximum 100 mg per dose
- Thiotepa – maximum 10 mg per dose
- Hydrocortisone 15 mg/m<sup>2</sup> – maximum 20mg per dose

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 doctor 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 50 x 10<sup>9</sup>/L platelets should be given as prescribed before proceeding.
- If necessary reinforce the administering doctor's explanation 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.
- Check the drugs, route, dosage, expiry, and patient identification against the prescription.

- Carry out the cross check which must be done independently by the designated haematology nurse whose name appears on the current register of personnel authorised to check intrathecal chemotherapy and the administering doctor.
- If a designated nurse is not available the procedure must be postponed
- The cross check must not be done by another doctor.
- 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 nurse must remain present for the entire process of the intrathecal chemotherapy administration
- If the prescribed intrathecal chemotherapy is for any reason not successfully administered, the patient's consultant and Dr Cuthbert should be informed.

#### **Administration:**

- Assist the patient into a comfortable foetal position
- Assist with a standard lumbar puncture at L3/4 or standard Omayra 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, as a *minimum* pre procedure and once post procedure, or as dictated by the clinical condition of the patient and in particular the respiration rate, if the patient has received sedation during the procedure
- In the day care context, if the procedure is performed without complication, the patient should be allowed home within 30-60minutes, depending on ascertaining that he/she is safely ambulant.
- Ensure the puncture site is checked and the dressing removed 24 hours post procedure

#### **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<sup>2</sup>. They

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<sup>2</sup> 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.

cause universally fatal encephalopathy if inadvertently administered by the intrathecal route.

- In Ward 10 North intrathecal drugs must be stored in the locked refrigerator reserved for this purpose.
- Intrathecal chemotherapy cannot be stored in the Bridgewater Suite and must be returned to satellite pharmacy by the administering doctor if it cannot be administered to the patient immediately.
- Intravenous drugs must never be found in the 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 doctor administering the drug(s) must receive them directly from a designated pharmacist in Satellite Pharmacy, or from the designated refrigerator on Ward 10 North. In both situations the prescription sheet must be signed to indicate that the doctor has received the drug(s).
- For Bridgewater Suite outpatients, the drugs must be collected directly from Satellite Pharmacy.
- The intrathecal drugs must remain in the administering doctor's possession until administered, or locked in the designated refrigerator on Ward 10 North.
- 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 should be sent back to pharmacy for registration. It will then be filed in the patient's notes.
- Document the procedure in the nursing notes

**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 (IR Clinical), and the designated lead clinician (RJGC) must be informed.

**RJG Cuthbert**

Updated to comply with HSC/2008/001 – August 2008

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**Children's Haematology unit  
Royal Belfast Hospital for Sick Children**

**Intrathecal Cytotoxic Chemotherapy Administration:  
Protocol for Designated Nursing Staff**

This protocol must be read in conjunction with the Policy for Safe Administration of Intrathecal Cytotoxic 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 haematology 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. 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 be prescribed only by consultants, associate specialists, SpR's or grade ST3 doctors and above, whose names are included in the register of designated medical staff authorised to prescribe and administer intrathecal chemotherapy.

**Administration:** Intrathecal chemotherapy must be administered only by consultants, associate specialists, SpR's or grade ST3 doctors and above, included in the register of designated medical personnel authorised to administer intrathecal chemotherapy.

Intrathecal chemotherapy must be administered only in the designated areas – surgical day theatre or main theatre. It is not permissible to administer intrathecal cytotoxic chemotherapy in any other location. It is not permissible to administer intrathecal cytotoxic chemotherapy at any site used for intravenous cytotoxic chemotherapy. The administration must be conducted within normal working hours of 9.00am–5.00pm. Only in exceptional circumstances should administration occur outside of these times.

**Indications: Prophylaxis or treatment of central nervous system (CNS) involvement:**

- Acute lymphoblastic leukaemia
- Burkitt's lymphoma
- Other leukaemias / lymphomas
- Some brain tumours

**Contraindications:**

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

**Drugs and dosage:**

Dosage varies according to the patient's age and treatment regimen.

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 checking 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 doctor 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  $50 \times 10^9/L$  platelets should be given as prescribed before proceeding.
- If necessary reinforce the administering doctor's explanation regarding the nature of the procedure, the drug(s) and method of administration to the patient and/or relative/guardian.
- Ensure signed, informed consent has been obtained.
- Check the drugs, route, dosage, expiry, and patient identification against the prescription.
- Carry out the cross check which must be done independently by the designated haematology nurse whose name appears on the current register of personnel authorised to check intrathecal chemotherapy and the administering doctor.
- If a designated nurse is not available the procedure must be postponed
- The cross check must not be done by another doctor.

- 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 nurse must remain present for the entire process of the intrathecal chemotherapy administration
- If the prescribed intrathecal chemotherapy is for any reason not successfully administered, the patient's consultant should be informed.

**Administration:**

- Most children will have this performed under general anaesthesia
- Assist the patient into a comfortable foetal position
- Assist with a standard lumbar puncture at L3/4 or standard Omayya reservoir access.
- Assist the doctor to collect 10-15 drops of CSF for cytopsin, and routine microbiology if indicated.
- Remain present during the administration of the intrathecal cytotoxic drug(s) by slow intrathecal push.
- Provide a sterile dressing to cover the puncture site with.
- After the procedure is complete the patient will be transferred to recover from the general anaesthetic.
- Check the puncture site dressing for any signs of haemorrhage or CSF leak post procedure
- Monitor the patient's observations, particularly the respiration rate, if the patient has received sedation during the procedure.
- Ensure the puncture site is checked and the dressing removed 24 hours post procedure

**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<sup>3</sup>. They cause universally fatal encephalopathy if inadvertently administered by the intrathecal route.
- In RBHSC intrathecal drugs must be stored in the locked refrigerator in the haematology/oncology outpatient area reserved for this purpose, or collected from pharmacy by the doctor administering the intrathecal chemotherapy.
- Intrathecal chemotherapy cannot be stored in the Childrens haematology ward and must be returned to satellite pharmacy by the administering doctor if it cannot be administered to the patient immediately. If not administered, sign the appropriate area on the prescription sheet.
- Intravenous chemotherapy drugs must never be found in the treatment areas reserved for intrathecal administration.

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<sup>3</sup> 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.

- Intravenous chemotherapy drugs scheduled for the same day must be administered after intrathecal chemotherapy.
- Pharmacy will dispense intravenous drugs only after receiving confirmation of the completed intravenous administration for that day from the doctor administering the intrathecal chemotherapy.
- If the chemotherapy regimen includes a continuous intravenous infusion, pharmacy will dispense intrathecal drugs only after receiving medical staff confirmation that the infusion is running.

**Documentation:**

- The doctor administering the drug(s) must receive them directly from a designated pharmacist in Satellite Pharmacy, or from the designated refrigerator in the haematology/oncology outpatient area. In both situations the prescription sheet must be signed to indicate that the doctor has received the drug(s).
- The intrathecal drugs must remain in the administering doctor's possession until administered, or locked in the designated refrigerator in the haematology/oncology outpatient area.
- 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 should be filed in the patient's notes.
- Document the procedure in the medical and nursing notes

**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 (IR Clinical), and the designated lead clinician (C Macartney) must be informed.

**CA Macartney**

Updated to comply with HSC/2008/001 – August 2008

## Belfast City Hospital

# Satellite Pharmacy Policy for the Management of Intrathecal Chemotherapy

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### General

1. Intrathecal chemotherapy is managed in accordance with the updated National Guidance on the Safe Administration of Intrathecal Chemotherapy (HSC 2008/001), the recommendations of the National Patient Safety Agency regarding the presentation of intravenous vinca alkaloids (NPSA/2008/RRR004), and the Belfast Trust Policy.
2. This Policy must be read in conjunction with the updated national guidance, the NPSA recommendations and the Belfast Trust Policy.

### Registers

1. An up-to-date copy of the register of designated personnel who have been trained and certified competent in the prescribing, dispensing, issuing, checking (prior to administration) and administering of intrathecal chemotherapy is held in the Satellite Pharmacy. An electronic version is available at <http://hpssweb.n-i.nhs.uk/niccpharmacy/index.html>
2. **Registered individuals are responsible for ensuring that any colleagues that they involve in the intrathecal chemotherapy process are registered to undertake the relevant task.**
3. A copy of the Trust's waiver to the national policy (if applicable), signed by the Chief Executive, the Medical Director, the Nurse Director and the Chief Pharmacist, allowing competent ST1 and ST2 grades to be registered to administer intrathecal chemotherapy, must be held in the Satellite Pharmacy.

### Training

1. Staff must be provided with formal induction training appropriate to their role in the intrathecal chemotherapy service.
2. The induction training must cover all of the potential clinical hazards associated with intrathecal chemotherapy, the danger posed to patients if vinca alkaloids are accidentally administered intrathecally, and the NPSA

safer practice recommendations on the presentation of intravenous vinca alkaloids.

3. Trainers must ensure that it is made clear to staff that they should challenge colleagues if they believe that protocols are not being adhered to or if the actions of an individual may cause risk to a patient receiving intrathecal chemotherapy.
4. Staff must undergo formal assessment of their understanding of the protocols and guidelines before they commence their practice with intrathecal chemotherapy.
5. Registered staff must undertake (annually) update training and sign a declaration that they have re-read the updated National Guidance, NPSA/2008/RRR004, the local guidance and tutorial, and re-watched the NHS video "Safe Administration of Intrathecal Chemotherapy Training Film Parts 1 & 2".
6. Staff must be given written confirmation (e.g. a certificate) that they have completed training / annual refresher training and are competent / remain competent to be included on the register for the designated task.

#### **Prescribing**

1. Intrathecal chemotherapy may only be prescribed by members of staff who have been designated, trained, certified competent and registered to prescribe intrathecal chemotherapy by the hospital.
2. Intrathecal chemotherapy must be prescribed on a purpose-designed intrathecal chemotherapy prescription chart. The drug and route of administration must be written clearly and in full. The chart must have space to record the full signature of the prescriber, issuer, collector, checker and the person who administers the intrathecal chemotherapy.

#### **Administering**

1. Intrathecal chemotherapy may only be administered by members of staff who have been designated, trained, certified competent and registered to administer intrathecal chemotherapy by the hospital.
2. Intrathecal chemotherapy must be administered in a designated area. No other cytotoxic drugs may be stored or administered in this area.

### **Dispensing**

1. Intrathecal chemotherapy may only be dispensed by members of staff who have been designated, trained, certified competent and registered to dispense intrathecal chemotherapy by the hospital.
2. Labels added in Pharmacy must state the route of administration "For Intrathecal Use Only".
3. Negative labelling "Not for ..." must NOT be used.
4. Dispensed intrathecal and intravenous drugs must be stored in different locations.
5. Between dispensing and issuing, intrathecal chemotherapy must be stored in the pharmacy in a dedicated lockable container/refrigerator. This dedicated lockable facility must never be used to store intravenous drugs.
6. When vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are prescribed, dispensed or administered the prescribed dose should be supplied from the hospital pharmacy ready to administer in a 50mL minibag of sodium chloride 0.9%. (For some brands of vinorelbine glucose 5% solution for injection may be used instead).
7. *Vinca alkaloids* (and other drugs with similar life-threatening consequences) must be labelled "For Intravenous Use Only – Fatal if Administered by Other Routes".
8. Intrathecal chemotherapy must be packed separately from other treatments for administration by other routes and transported in a distinctive bag/container not used for any other purpose.
9. Chemotherapy preparation services are not available outside normal hours.

### **Issuing**

1. Intrathecal chemotherapy may only be issued by members of staff who have been designated, trained, certified competent and registered to issue intrathecal chemotherapy by the hospital.
2. Intrathecal drugs must only be issued when written proof has been provided that all intravenous drugs (for that patient that day) have been administered.

3. Where intrathecal chemotherapy is to be given in combination with continuous intravenous chemotherapy, intrathecal chemotherapy must only be issued when written proof has been provided that the intravenous infusion has begun.
4. Intrathecal drugs should be issued by registered Pharmacy staff directly to the registered administering doctor at the Pharmacy (collection). No other drugs may be supplied at this time.
5. Intrathecal drugs may be issued by registered Pharmacy staff directly to the registered administering doctor on the ward (delivery). No other drugs may be supplied at this time.
6. The issuer must sign the intrathecal chemotherapy prescription chart and record the identity of the administering doctor.
7. The administering doctor (collector) must sign the intrathecal chemotherapy prescription chart.
8. A registered member of pharmacy staff (the issuer) may take the intrathecal chemotherapy directly to the ward. In the absence of the administering doctor, the issuer may place the intrathecal chemotherapy in a designated, dedicated, lockable container/refrigerator. The container / refrigerator must be locked at all times and the key kept by the member of staff-in-charge of the ward. In this case the issuer must sign the intrathecal chemotherapy prescription chart and identify that the drugs have been lodged in the relevant container/refrigerator. Only the registered administering doctor may collect the intrathecal drugs from the container/ refrigerator when they must check the drugs and sign for their collection.



**Belfast Health and  
Social Care Trust**

**BELFAST HEALTH & SOCIAL CARE TRUST****ROYAL GROUP OF HOSPITALS  
ASEPTIC DISPENSARY****Standard Operating Procedure No. SOP 66A****TITLE: PHARMACY INTRATHECAL POLICY**

Prepared by:- Barbara Jackson Date:- 01/10/10	Approved by:- Nan Simpson Date:- 28/02/11 Review Date: 01/02/2012	Reviewed by:- Date:-
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**Pharmacy Policy for the Safe Management of Intrathecal Therapy  
(RBHSC Site)****Background**

Since 1985 at least 13 patients have died or been paralysed as a result of the accidental intrathecal administration of Vinca alkaloids which was intended for intravenous administration.

In November 2001, the Department of Health in England issued National Guidance on the Safe Administration of Intrathecal Chemotherapy. The Guidance was updated in 2003 and again in 2008 (HSC 2008/001). In 2008 the National Patient Safety Agency issued a report regarding the presentation of intravenous vinca alkaloids (NPSA/2008/RRR004). The DHSSPNI have endorsed these recommendations and each Trust must comply fully with them.

A register of designated personnel who have undergone training and been certified competent in the prescribing, dispensing, issuing, checking and administering of intrathecal chemotherapy must be maintained by the Trust and up-to-date copies of this should be kept at all relevant locations. The register is also held electronically on the NI Cancer Centre pharmacy website:

<http://hpssweb.n-i.nhs.uk/niccpharmacy/index.html>

**This Pharmacy Policy must be read in conjunction with HSC 2008/001, NPSA/2008/RRR004 and the Trust's Policy for Safe Administration of Intrathecal Cytotoxic Chemotherapy and all relevant pharmacy SOPs.**

## **Training**

1. Nan Simpson is the designated Intrathecal Chemotherapy Lead Trainer for pharmacy staff covering the RBHSC satellite pharmacy unit.
2. Training at an appropriate level will be given to all individuals involved in the preparation, delivery and storage of intrathecal chemotherapy.
3. The training will include:
  - a) A talk on Intrathecal Chemotherapy and the associated hazards.
  - b) Watching the DVD produced by the DoH on the Safe Administration of Intrathecal Chemotherapy.
  - c) \*Reading the current National guidance on the Safe Administration of Intrathecal Chemotherapy and the NPSA Report "Using Vinca Alkaloid Minibags (Adult/Adolescent Units)".
  - d) \*Reading the Trust policy and protocol on the Safe Administration of Intrathecal Chemotherapy.
  - e) \*Reading the pharmacy policy/procedures on the Safe Handling of Intrathecal Chemotherapy.
  - f) Supervised training in the appropriate role.
  - g) \*Assessment (MCQ).
4. The Trainer and Trainee must sign the Intrathecal Chemotherapy Training and Assessment Form.
5. After the assessment, a certificate of competence will be issued by the Head of Pharmacy RVH and the name of that individual added to the relevant register.
6. Training must be repeated (\*) at least every year. This refresher training must be documented.
7. In the event that a Pharmacist or Technician works infrequently in the unit then the pharmacy policy/procedures should be read each time intrathecal chemotherapy is prepared.
8. Any additions or deletions to the register must be forwarded to Dr. Christine McCartney in CHU RBHSC (Intrathecal Chemotherapy Lead for the Trust).

**Only those members of staff who have received training, are deemed competent and whose name appear on the Intrathecal Register may undertake any duties relating to intrathecal chemotherapy.**

### **Checking/Dispensing/Issuing Intrathecal Chemotherapy**

1. Intrathecal chemotherapy must be ordered on one of the designated Intrathecal Prescription Templates. No other drugs can be ordered on these prescriptions. These prescriptions have space to record the full signatures of the prescriber, issuer, collector, checkers and person who administers the intrathecal chemotherapy.
2. The Intrathecal Chemotherapy Prescription must be signed only by a doctor on the current IT Register.
3. Only pharmacy staff whose name appear on the current IT register may clinically check, dispense, release and deliver intrathecal chemotherapy.
4. The Pharmacist must follow the SOP for checking a chemotherapy prescription and must sign the IT prescription.
5. A worksheet must be completed as per SOP for each intrathecal dose for each patient.
6. Intrathecal chemotherapy **must** be prepared **separately** from all other chemotherapy.
7. All doses of a specific drug for intrathecal administration should be prepared together. Dispensing of one drug must be completed and checked before a second drug for intrathecal administration is prepared.
8. All intrathecal drugs will have a maximum expiry of 24 hours.
9. All intrathecal drugs should be clearly labelled "**FOR INTRATHECAL USE ONLY**".
10. The Pharmacist checking and releasing the intrathecal chemotherapy must sign the IT prescription.
11. Intrathecal chemotherapy must be delivered separately from all other treatments and stored in the designated IT fridge in the Haematology Clinic. This is a lockable fridge reserved for this purpose **alone**. No other drugs can be stored in this fridge.
12. The authorised member of pharmacy staff delivering the drugs must sign that they have delivered the drugs to the administering doctor or sign that they have placed them in the designated IT fridge in the Haematology Clinic.
13. In RBHSC intrathecal chemotherapy is delivered under general anaesthesia. Therefore in RBHSC only, the intrathecal chemotherapy will be administered first, and the intravenous chemotherapy will **only** be issued after the pharmacy staff have received written confirmation that the intrathecal chemotherapy has been administered.

If the intravenous chemotherapy is scheduled for twice daily administration on the same day as an intrathecal chemotherapy, the intrathecal chemotherapy will only be released after written confirmation that the first intravenous dose has been administered.

When a regimen involves a continuous intravenous regimen combined with intrathecal chemotherapy, it is only acceptable to issue and administer intrathecal chemotherapy after receiving written confirmation that the intravenous infusion has started.

### **Presentation of Vinca Alkaloids for Intravenous Administration**

5. In 2008 the National Patient Safety Agency issued a report regarding the presentation of intravenous vinca alkaloids ([NPSA/2008/RRR004](#)). This report supported the use of minibags in adult and adolescent units. It was acknowledged that in paediatric units, vinca alkaloid doses could continue to be presented in a syringe ie. no change to current practice.
6. Children < 10yrs:
  - Intravenous vinca alkaloids can be given at higher concentrations.
  - Currently vincristine is given at 1mg/ml concentration.
7. Children > 10yrs:
  - The volume of vincristine must be diluted to a maximum concentration of 0.1mg/ml.
  - The volume of vinblastine, vindesine and vinorelbine must be diluted to a minimum volume of 20ml.
8. For patients >10yrs with poor veins and where peripheral administration of larger volumes of vinca alkaloids poses an increased risk of extravasation injury, then the consultant haematologist/oncologist can request in writing that these doses are presented in their undiluted form. This is local practice rather and not taken from the national policy document.
9. Intravenous vinca alkaloids are not routinely administered on the same day for the same patient as intrathecal chemotherapy at RBHSC. However in rare circumstances it may be necessary to administer a vinca alkaloid on the same day as intrathecal chemotherapy. In this case the signed intrathecal prescription chart will be used as confirmation that the intrathecal procedure has been completed prior to the intravenous vinca alkaloid being released from pharmacy. The vinca alkaloid must only be administered in either the Haematology Outpatient area or ward.

Belfast City Hospital - BLANK INTRATHECAL Medication Prescription Chart

Name:	Regimen :	Height		CM
Hosp. No:	Diagnosis :	Weight		KG
Ward:	Consultant:	Surface area		M <sup>2</sup>
D.O.B:	Administered by: Lumbar puncture / Ommaya reservoir (delete one)			
Regimen Approved By:				

Drugs	Actual Dose	Fluids or Bolus	DATE OF INJECTION	Route	GENERAL INSTRUCTIONS
1.		Bolus		INTRATHECAL	<u>BLOOD TESTS :</u> FULL BLOOD COUNT.  <b>Use this chart to prescribe INTRATHECAL chemotherapy <u>only</u>.</b>  <u>Use only preservative free products</u> For Methotrexate use 25mg/ml (DBL Brand) For Cytarabine use 20mg/ml (DBL Brand)
2.		Bolus		INTRATHECAL	
3.		Bolus		INTRATHECAL	
Hospital INTRATHECAL policies must be adhered to:					For Hydrocortisone use Solu-Cortef  <b>Consultant or Specialist Registrar Only</b> <u>Prescribers Name</u> .....  <u>Prescribers Signature</u> .....  Date:                      Bleep:

PAEDIATRIC ONCOLOGY AND HAEMATOLOGY  
CHILDRENS HAEMATOLOGY UNIT RBHSC

Appendix 7

**INTRATHECAL METHOTREXATE PRESCRIPTION**

Patient Name:

Hospital Number:

Date of Birth:

Protocol Name:

DATE	DRUG	ROUTE	DOSE	TIME DUE
		INTRATHECAL		

<i>Prescribed by</i> Consultant/Specialist Registrar Signature	<input type="text"/>	Date-	<input type="text"/>
<i>Checked by</i> Clinical Pharmacists Signature	<input type="text"/>	Date	<input type="text"/>
<i>Checked and released by</i> Pharmacists Signature	<input type="text"/>	Date	<input type="text"/>
<i>Delivered by</i> Pharmacy Staff Member Signature	<input type="text"/>	Date	<input type="text"/>
<i>* Received by</i> Consultant/Specialist Registrar/Clinical Medical Officer Signature	<input type="text"/>	Date	<input type="text"/>
<i>Pre-administration check</i> Consultant/Specialist Registrar/ Clinical Medical Officer Chemotherapy trained Nurse Signature	<input type="text"/>	Date	<input type="text"/>
<i>Administered by</i> Consultant/Specialist Registrar/Clinical Medical Officer Signature	<input type="text"/>	Date	<input type="text"/>
		Time given	<input type="text"/>

\* This must be the Doctor who is administering the intrathecal drug. If this Doctor is unavailable please sign below that the drug has been placed in the **designated refrigerator** for intrathecal drugs

I have placed the intrathecal drug in the designated refrigerator Pharmacy Staff Member's Signature	Date	<input type="text"/>	Time	<input type="text"/>
<input type="text"/>				
Intrathecal drug removed from refrigerator Consultant/Specialist Registrar/Clinical Medical Officer Signature	Date	<input type="text"/>	Time	<input type="text"/>
<input type="text"/>				

Intrathecal drug not administered Disposed of by: Doctor or Nurse's Signature	Date	<input type="text"/>
<input type="text"/>		