Trust Policy

University Hospitals Plymouth NHS Trust

Intrathecal Chemotherapy Policy

Issue Date	Review Date	Version
November 2019	November 2021	4

Purpose

To ensure the safe prescribing, dispensing, and administration of cytotoxic drugs by the Intrathecal route.

Who should read this document?

All doctors, nurses and pharmacists involved in the prescribing, dispensing, and administration of Intrathecal cytotoxic chemotherapy drugs.

Key Messages

- The overall responsibility for the safe prescribing, dispensing and administration of cytotoxic drugs rests with Trust Lead for Intrathecal chemotherapy.
- Only those members of staff who have been trained, and are present on the Intrathecal register can take part in the process.

Presence on the register requires annual re training and competency assessment.

Core accountabilities	
Owner	David Lewis
Review	Chemotherapy Operations Group, Medicines Governance Group
Ratification	Ian Higginson, Care Group Clinical Director for Medicine
Dissemination (Raising Awareness)	Trust Intrathecal Chemotherapy Lead
Compliance	Trust Intrathecal Chemotherapy Lead

Links to other policies and procedures

- Medicines Management Policy
- Trust Chemotherapy Operations Policy
- Injectable Drug Administration policy

Version History		
1	July 2010	Approved by the Chemotherapy User Group
2	February 2012	Link to Pharmacy SOP included, training syllabus and policy added.
3	March 2014	Reference to NHS/PSA/2014/002 Non-luer spinal (intrathecal) devices for chemotherapy
4	November 2019	Addition of mandatory use of ARIA e-chemo prescribing system, administration of intraventicular methotrexate

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available in the Document Library. Larger text, Braille and Audio versions can be made available upon request.

Contents

1 Introduction

This policy outlines the procedures for the safe prescribing, dispensing and administration of chemotherapy drugs by the intrathecal route. The policy also outlines the procedures that have been implemented to **avoid** the accidental administration of vincristine and vinca alkaloids intrathecally. These procedures **MUST** be followed by all staff concerned to ensure the safety of the patient.

Only the intrathecal lead or single named person with responsibility delegated by the intrathecal lead for a specified part of the register, can authorise the entry or removal there of an eligible person onto that part of the register for that respective task.

2 Purpose

- Updated National guidance on the safe administration of intrathecal chemotherapy HSC 2008/001[1]
- NPSA Rapid Response report NPSA/2008/RRR004 Using Vinca Alkaloid Minibags (Adult/Adolescent units)[2]
- NHS/PSA/2014/002 Non -luer spinal (intrathecal) devices for chemotherapy

3 Definitions

Intrathecal Route – administration of a medication via lumber puncture into the spinal canal

Cytotoxic – Chemotherapeutic agent given with the intent to treat a malignant neoplastic disease.

ITC – Intrathecal Chemotherapy

4 Duties

- The Trust Lead for Intrathecal chemotherapy is responsible for the production and implementation of this policy.
- The Trust Intrathecal chemotherapy trainers are responsible for the training of staff within their areas according to the Intrathecal chemotherapy training syllabus.
- All staff on the Intrathecal chemotherapy register are responsible for ensuring the staff not on the register take no part in the process of the prescription, dispensing or administration of Intrathecal chemotherapy.
- All staff are responsible for reporting adverse events to the trust lead for Intrathecal chemotherapy.

5 Prescription and administration of intrathecal chemotherapy

a) The prescription for intrathecal chemotherapy will be completed by the following, all of which are included on the Trust's register of designated personnel for intrathecal chemotherapy;
   i. Consultant in Haematology or Consultant Paediatrician with Oncological Responsibilities
   ii. Specialist Registrar or ST3/or above in Haematology, or specialist registrar/ST3 or above / Associate Specialist working with the consultant paediatrician with oncological responsibilities.
   iii. Other appropriate named individuals listed on the Signed Waiver to National Protocol on the Safe Administration of Intrathecal chemotherapy.

b) FT1/FT2/ST1/ST2/SHOs must **NEVER** prescribe intrathecal chemotherapy.

c) New medical staff must not prescribe intrathecal chemotherapy until they have;
   i. received appropriate training
   ii. had their competency agreed and documented by Trust Intrathecal chemotherapy lead (and lead trainer) or member of the list of ITC trainers.
   iii. been included in the Trust's Register of designated personnel.

d) Intrathecal chemotherapy should be electronically prescribed. Adult patients' prescriptions should be prescribed on ARIA.

e) In exceptional circumstances, intrathecal drug(s) can be prescribed on a a designated intrathecal prescription, which has spaces for the FULL signatures of the prescriber, check prescriber, issuer, collector, nurse checker, and administrator. This should be discussed with the intrathecal lead.

f) A permanent Specialist Pharmacist on the register must screen the prescription.

Dispensing of intrathecal chemotherapy

a) Dispensing of intrathecal cytotoxics will be carried out in the Pharmacy Technical Services department by designated personnel included in the Trust's Register.

b) Drugs for intrathecal use will be prepared in the isolator first of any given session. In an emergency a new session will be started before preparing the intrathecal.

c) If intrathecal cytarabine or methotrexate is required, no other cytotoxic drugs will be present in the preparation area at the same time.

d) The intrathecal drug will be labelled: "FOR INTRATHECAL USE ONLY".

Please refer to Pharmacy SOP – CH2 Vs10 for the process of manufacture and control within pharmacy.

Distribution of intrathecal chemotherapy

a) Drugs for intrathecal administration will be packed and distributed separately in sealed designated boxes that are not used for any other purpose.

b) If storage is required between dispensing and issuing, ITC should be stored in a

lockable container/refrigerator within pharmacy. This container/refrigerator should **NEVER** be used for intravenous drugs.

c) For patients prescribed intrathecal therapy, pharmacy will issue the intrathecal therapy directly to the ward via a trained senior member of staff. The dispenser and the nurse or doctor accepting the intrathecal drug into the designated fridge must both be on the Register and must confirm the dose is correct against the current prescription on Aria..

d) If intrathecal drugs are to be stored on the ward prior to administration they must be locked in the designated intrathecal drugs refrigerator, and not stored with any other chemotherapy. The key must be kept with the nurse in charge.

Timing/sequencing of intrathecal chemotherapy

a) If intravenous chemotherapy is prescribed for the **same day** as intrathecal chemotherapy, the intravenous chemotherapy must be given first. The intrathecal chemotherapy will be retained in the pharmacy and only issued once administration of the intravenous chemotherapy has been confirmed on Aria or via receipt of the signed paper prescription

Rarely protocols, or the need for a general anaesthetic in paediatric practice, may require ITC to be given before intravenous chemotherapy. In this case and ONLY after discussion with the ITC lead, intrathecal chemotherapy may be administered as long as the intravenous chemotherapy is retained in pharmacy and only dispensed on confirmation of administration of the ITC as above.

b) Where a regimen involves ITC given during continuous Intravenous chemotherapy, it is only acceptable to administer the ITC once the intravenous infusions have begun. The intrathecal chemotherapy will be retained in the pharmacy and only issued on confirmation that the intravenous chemotherapy for that day has begun as above.

c) These procedures for retaining and releasing intrathecal and intravenous chemotherapy will be applied to any chemotherapy prescribed **within 72 hours** of an intrathecal.

ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY

a) From August 2014 the delivery of Intrathecal chemotherapy will be using Non – Luer lock devices – (needles and syringes)

b) Cytotoxic drugs must only be administered by specialist staff, that have received appropriate training and accreditation (see section 9 Injectable drug administration policy). Documentation confirming this should be retained on the appropriate unit.

c) All staff involved with the administration of cytotoxic intrathecal drugs must have read the reports by Brian Toft[3] and Kent Woods[4], and the National Guidance on the Safe Administration of Intrathecal Chemotherapy HSC2008/001[1]. These reports will be kept alongside the local policy, and the Trust Register in the intrathecal chemotherapy file on the appropriate units: -

- Birch Ward
- Plym Day Case Theatre

- Bracken ward (Trust policy and register only)
- Wildgoose Ward (Trust policy and register only)
- Brent Ward (Trust policy and Register only)
- Oncology Outpatients (Trust policy and Register only)
- Pharmacy

d) Intrathecal drugs must only be administered by;

- Consultant in Haematology or Consultant Paediatrician with Oncological Responsibilities
- Specialist Registrar/ST3 or above in Haematology, or specialist registrar or ST3 or above / Associate Specialist working with the consultant paediatrician with oncological responsibilities.
- Other appropriate named individuals listed on the Signed Waiver to National Protocol on the Safe Administration of Intrathecal chemotherapy. (Currently not applicable.)

e) FT1/FT2/ST1/ST2/SHO's must **NEVER** administer intrathecal chemotherapy.

f) The nursing staff assisting the doctor must be experienced, competent and suitably trained with the administration of intrathecal drugs and must be included on the Trust register. Documentation confirming this should be retained on the appropriate unit.

g) Intrathecal drugs must be administered in the designated intrathecal treatment rooms.

h) If administration is to take place in any other areas e.g. Intensive Care/Xray/Operating theatres then the intrathecal chemotherapy file must be taken from the relevant area and the procedure adhered to at all times. A member of staff helping to site a difficult lumber puncture e.g. Radiologist may NOT administer the ITC.

i) No other cytotoxics other than intrathecal chemotherapy must be delivered to or stored in the designated intrathecal treatment room. The ITC should be delivered immediately prior to administration.

j) All other cytotoxics must be given in a separate room.

k) Intrathecal drugs must be administered within normal working hours (Monday to Friday 0800-1800hrs), with authorised personnel present. Only in the most exceptional circumstances (determined by the Consultant Haematologist or Consultant Paediatrician with Oncological responsibilities) should intrathecal chemotherapy be administered **out of hours**. The designated lead must be informed that the procedure has had to take place at the earliest opportunity – enclosed in the ITC Silver folders are forms for this purpose (see Appendix 1, Out of hours administration of intrathecal chemotherapy)

l) A doctor who is on the register of designated staff must review the patient before ITC administration. This ensures that the patient is fit for treatment, the relevant tests have been performed e.g. Full blood count, clotting screen, the patient has received any blood products which may be required, and that the correct chemotherapy has been prescribed.

m) The patient/ relative or guardian should be involved in the administration process (check) where appropriate.

n) The drug will be removed from the container. The nurse and doctor carrying out the administration will cross reference the prescription, the drug label and the following checklist to ensure the safe administration of the drug

   a. Patient name
   b. Hospital number
   c. Drug
   d. Dose
   e. Date
   f. Expiry date
   g. Route of administration - For Intrathecal Use
   h. If intrathecal Methotrexate – solution is yellow

o) Once the above procedure has been carried out then it is safe to proceed with the administration of the drug. If at any stage of the process any of the individuals involved have any concerns then the procedure must be stopped pending investigation of the problem.

p) If additional chemotherapy is required to be given on the specified date it will be given at a separate time in another area.

q) At the end of the procedure those persons administering and checking the ITC drug must sign and date the ITC administration-monitoring book.

r) The administering doctor and checking nurse must electronically sign that the drug has been checked and administered.

Administration of intraventricular methotrexate via Omaya reservoir

On a named patient basis in exceptional circumstances intraventricular chemotherapy may be given via an Omaya reservoir

Methotrexate 6mg is made up to 2.5ml in a luer lock syring in this instance

Safe administration of vinca alkaloids by the intravenous route

To avoid the accidental administration of vincristine and other vinca alkaloids (Vinblastine, Vindesine, Vinorelbine) by the intrathecal route and in light of the National patient safety agency rapid response report NPSA/2008/RRR004:

1. For adults and adolescents vinca doses in syringes should no longer be used.

2. The prescribed dose should be supplied from pharmacy ready to administer in a 50 ml minibag of 0.9% sodium chloride (for some brands of vinorelbine glucose 5% for injection may be used instead of sodium chloride).

3. For children vinca alkaloid may still be given in a syringe. For patients receiving less than or equal to 1 mg the vincristine must be diluted to 10ml. For patients receiving >1mg the vincristine must be diluted to at least 0.1mg/ml to a maximum of 2mg in 20ml.

4. For children under the age of 1 years the vincristine can be undiluted if necessary at a concentration of 1mg/ml but it is presented in a 10 ml syringe.

5. Labels on individual doses of Vinca alkaloids (Vincristine, Vinblastine, Vinorelbine,

Vindesine) must clearly show the patient's name and the name of the product and the sole route of administration.

6. All vinca alkaloids (Vincristine, Vinblastine, Vinorelbine, Vindesine) must be labelled: Warning: Vin……(drug name): FOR INTRAVENOUS USE ONLY.

7. The outer wrapper must be labeled. "Warning: Remove only at time of injection. For intravenous use only. Fatal if given by any other route".

8. The vinca minibag should be infused over 5-10 minutes and the patient closely monitored for signs of extravasation. Incidents of extravasation should be shared via the National Extravasation Information service www.extravasation.org.uk

9. Vinca alkaloids will not be kept as stock on any ward or department.

10. The minimum syringe size for all vinca alkaloids will be 10ml.

Responsibility of Designated Deputy for Paediatric ITC

- To provide training in accordance with the agreed course syllabus for Trust Intrathecal Chemotherapy.
- To provide an induction programme for Intrathecal Policy awareness for all staff in the relevant staff group and keep a written record of this.
- To provide training for staff who will be undertaking roles relevant to intrathecal chemotherapy following competency assessment.
- To assess the competence of staff in the staff group.
- To notify the Trust Intrathecal Lead of staff deemed competent in the assessed component of the intrathecal chemotherapy process for inclusion on the relevant Trust register.
- To provide an update and reassessment of competence on an annual basis, and to notify the Trust Intrathecal Lead accordingly. Annual reconfirmation includes there being written confirmation that the staff member has read the ITC national guidance & associated local protocols. Assessment of competence will be based on documented evidence from the Paediatric ITC administration monitor book
- To inform the Trust Intrathecal Lead of any failure in competency assessment and reasons for staff to be removed from register, as noted above.

Maintaining the intrathecal register

a) Only the Intrathecal chemotherapy lead for the Trust can authorise the entry of an eligible person onto that part of the register for their respective task.

b) No provisional entry is allowed.

c) Staff moving from one hospital trust to PHNT may bring with them a record of their competency but automatic inclusion on the register does not occur. Formal training must take place.

d) There will be a compulsory annual review of competency for all members on the register. The trust intrathecal lead and lead trainer is responsible for the annual update

of all trainers who are then responsible for the annual update and review of competency of their designated areas.

e) At annual review of competence, the ITC lead is authorized to delete a staff member from the register, if they have been assessed by the ITC lead as performing their registered task(s) insufficiently to maintain competence. For Plymouth Hospitals NHS Trust this is defined as having taken part in the ITC process at least once over a one-year period. The ITC administration monitoring books for both Adult and Paediatric services will be used for this purpose.

Responsibilities of intrathecal chemotherapy trainers

- To provide training in accordance with the agreed course syllabus for Trust Intrathecal Chemotherapy.
- To provide an induction programme for Intrathecal Policy awareness for all staff in the relevant staff group and keep a written record of this.
- To provide training for staff who will be undertaking roles relevant to intrathecal chemotherapy following competency assessment.
- To assess the competence of staff in the staff group.
- To notify the Trust Intrathecal Lead of staff deemed competent in the assessed component of the intrathecal chemotherapy process for inclusion on the relevant Trust register.
- To provide an update and reassessment of competence on an annual basis, and to notify the Trust Intrathecal Lead accordingly. Annual reconfirmation includes there being written confirmation that the staff member has read the ITC national guidance & associated local protocols.
- To inform the Trust Intrathecal Lead of any failure in competency assessment and reasons for staff to be removed from register.

Intrathecal chemotherapy training

Objectives for participants

- To understand the rationale for intrathecal chemotherapy, the drugs used and conditions treated
- To have an awareness of the historical backdrop to national intrathecal policy
- To have detailed working knowledge of the National Intrathecal Guidance **HSC** 2008/001
- To have detailed working knowledge of the Local Intrathecal Policy
- To understand the roles and responsibilities for staff on the intrathecal register
- To understand the clinical risks associated with intrathecal chemotherapy

Syllabus for Intrathecal chemotherapy training -

- National Guidelines for the Safe Administration of Intrathecal Chemotherapy (2008) – In induction pack and discussed.

- Plymouth Hospital NHS Trust Intrathecal Chemotherapy Policy – In induction pack and discussed.
- In most cases individual doctors (Consultants, Associate Specialists and SpR's only), will act as non-participating observers of the intrathecal process at least once. Similarly, all nursing staff entering the register will undergo a period of non-participating observation prior to formal assessment.
- **Previous inclusion on a register in another Trust does not result in automatic inclusion on the Plymouth Hospital NHS Trust register.**
- Lumbar puncture and intrathecal chemotherapy procedure performed in presence of:
    - Registered Intrathecal chemotherapy Trainer (Not participating in procedure otherwise).
    - Nurse on Intrathecal chemotherapy register (Doctor assessment)
    - Doctor on Intrathecal register (Nurse assessment)
- Induction questionnaire (required score is 100%).
- Receive certificate of competence to prescribe and administer intrathecal chemotherapy (Doctors), or competence in the care of patients receiving intrathecal chemotherapy (Nursing Staff).
- Annual update to remain on Intrathecal register (applies to all), to include:
    - Powerpoint slides with any additional updates to National or local policy.
    - Question and answer session (required score is 100%).
    - Confirm inclusion on updated intrathecal register.

Individuals who have not participated in the intrathecal process at least once during the previous year, may be removed from the register.

6 Overall Responsibility for the Document

Trust Intrathecal Chemotherapy Lead for Production and compliance

Overall responsibility for the Safe administration of Intrathecal chemotherapy rests with the Trusts' Chief Executive.

7 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of two years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Chemotherapy Operations Group and ratified by the Chair.

Non-significant amendments to this document may be made, under delegated authority from the Chair, by the nominated owner. These must be ratified by the Chair.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

8 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document with the named Chair and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

9 Monitoring Compliance and Effectiveness

The intrathecal chemotherapy policy will be reviewed every 2 years by the Trust lead for Intrathecal chemotherapy within the setting of the Chemotherapy Operations group. The review will include a review of any new clinical data and published government guidelines.

Deviation from this policy are reported via the Trust Incident reporting system, collated by the Chemotherapy pharmacists, discussed at the monthly Chemotherapy Operation group meetings and reviewed by the Medicines Governance Committee on a monthly basis. The Medicines Governance Committee will then nominate a committee member to resolve any identified issues

10 References and Associated Documentation

1. Updated National guidance on the safe administration of intrathecal chemotherapy HSC 2008/001
2. NPSA Rapid Response report NPSA/2008/RRR004 Using Vinca Alkaoid Minibags (Adult/Adolescent units)
3. Toft B. (2001) External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham, Department of Health.
4. Woods K. (2001) The Prevention of Intrathecal Medication Errors - A report to the Chief Medical Officer; Department of Health

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan			
Document Title	Intrathecal Chemotherapy Policy		
Date Finalised	October 2019		
Previous Documents			
Action to retrieve old copies	Removal from shared drive		
Dissemination Plan			
Recipient(s)	**When**	**How**	**Responsibility**
All Trust staff	November 2019	Vital Signs	Information Governance Team
All Trust staff	November 2019	Trust Documents	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Y
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Y
	Does the style & format comply?	Y
Rationale	Are reasons for development of the document stated?	Y
Development Process	Is the method described in brief?	Y
	Are people involved in the development identified?	Y
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Y
	Is there evidence of consultation with stakeholders and users?	Y
Content	Is the objective of the document clear?	Y
	Is the target population clear and unambiguous?	Y
	Are the intended outcomes described?	Y
	Are the statements clear and unambiguous?	Y
Evidence Base	Is the type of evidence to support the document identified explicitly?	Y
	Are key references cited and in full?	Y
	Are supporting documents referenced?	Y
Approval	Does the document identify which committee/group will review it?	Y
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A
	Does the document identify which Executive Director will ratify it?	N/A
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Y
	Does the plan include the necessary training/support to ensure compliance?	Y
Document Control	Does the document identify where it will be held?	Y
	Have archiving arrangements for superseded documents been addressed?	Y
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y
	Is there a plan to review or audit compliance with the document?	Y
Review Date	Is the review date identified?	Y
	Is the frequency of review identified? If so is it acceptable?	Y
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	October 2019
Title	Intrathecal Chemotherapy Policy
What are the aims, objectives & projected outcomes?	The safe prescribing, dispensing and administration of chemotherapy drugs by the intrathecal route, and the procedures that have been implemented to avoid the accidental administration of vincristine and vinca alkaloids intrathecally. The projected outcomes are that only suitably qualified and registered staff will administer this systemic anti-cancer therapy.
Scope of the assessment	
Staff and patient groups affected (i.e., Medics of appropriate grade, nurses of appropriate grade, specialist pharmacists, patients with Haematological Malignancy).	
Collecting data	
Race	No
Religion	No
Disability	Yes
Sex	Yes
Gender Identity	No
Sexual Orientation	No
Age	Yes
Socio-Economic	No
Human Rights	No
What are the overall trends/patterns in the above data?	Where identified above the data collected is only used to support treatment decisions, e.g., dosing of systemic anti-cancer therapy, access, etc.
Specific issues and data gaps that may need to be addressed through consultation or further research	None identified.

Involving and consulting stakeholders	
Internal involvement and consultation	Medical staff, nursing team, pharmacy.
External involvement and consultation	None
Impact Assessment	
Overall assessment and analysis of the evidence	This policy will not impede or hinder equality or the rights of its users or intended recipients.

Action Plan

Action	Owner	Risks	Completion Date	Progress update
None				