

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Safe Use of Non-Cytotoxic Intrathecal and Intraventricular injections (in Adults and Children)

Version No:	1.1
Effective From:	19 January 2016
Expiry Date:	19 January 2019
Date Ratified:	14 October 2015
Ratified By:	Medicines Management Committee

1 Introduction

The preparation and administration of all intrathecal and intraventricular injections are high risk processes and potentially associated with serious safety risks.

The intrathecal and intraventricular route should only be used where there is clear evidence of efficacy.

The administration of intrathecal and intraventricular (see 'Definitions') drugs must only be undertaken by staff that have undergone appropriate training and are assessed competent to participate in the process by the nominated lead.

2 Policy scope

This policy applies to all members of staff working within The Newcastle upon Tyne Hospitals NHS Foundation Trust who are involved in prescribing, preparation, supply and administration of non-cytotoxic intrathecal and intraventricular injections. This includes infusions for refilling implantable pumps.

This policy does not cover routine intrathecal spinal anaesthesia and analgesia.

This policy does not cover cytotoxic intrathecal chemotherapy.

This policy should be read in conjunction with other Injectable Medicines Policy and the Medicine Policy.

3 Aim of policy

To minimise the risks associated with the prescribing, preparation, supply and administration of non-cytotoxic intrathecal and intraventricular injections.

4 Roles and Responsibilities

Roles	Responsibilities
Medicine Management Committee	<ul style="list-style-type: none">■ Trust lead for policy.■ Responsible for reviewing and updating the policy

Roles	Responsibilities
Clinical Directors	<ul style="list-style-type: none"> ■ Responsible for ensuring all staff involved in the prescribing, preparation, supply and administration are suitably trained, and aware of relevant Trust guidelines. ■ Appoint Nominated Lead Individual(s) in the specialist areas and ensure this list is readily available.
Nominated Lead Individual	<ul style="list-style-type: none"> ■ Ensures appropriate local guidelines and standard operating procedures exist (and are available) within their designated speciality area. ■ Ensures appropriate competency training for staff in their area.
All staff	<ul style="list-style-type: none"> ■ Responsible for following the policy ■ Ensuring their training is up to date

5 Definitions

Non- cytotoxic intrathecal injection - an injection of a non-cytotoxic drug into the intrathecal space surrounding the spinal cord (also known as a "spinal" within anaesthesia)

Non-cytotoxic intraventricular injection -an injection of a non-cytotoxic drug for diffusion throughout the ventricular and subarachnoid space by means of a ventricular puncture.

Non-cytotoxic intrathecal infusion - an infusion of a drug into the intrathecal space via an infusion device, either external or implanted.

All references to an intrathecal medicines/route in the following paragraphs should be read as equally applicable to intraventricular medicines/route.

6 The Prescribing, Preparation, Supply and Administration of non- cytotoxic intrathecal

6.1 Prescribing

- Intrathecal and intraventricular medication must be prescribed only by a Consultant or Specialist Registrar.
- The word "intrathecal" or "intraventricular" must be written in full on the drug chart, anaesthetic chart or highlighted on e-record and must not be abbreviated.

6.2 Intrathecal doses should be prescribed to be administered at distinctly different times from other concomitant medication.

Preparation

- Risks associated with the intrathecal route of administration should be considered when deciding the most appropriate location for preparation.
 - Preparation in the Pharmacy Production Unit will be the most appropriate location for preparation in the majority of cases
- i) Pharmacy Production Unit
- All infusions for refilling implantable pumps must be made by the Pharmacy Production Unit.
 - Preparation of non-cytotoxic intrathecal bolus injections whenever possible should be by the Pharmacy Production Unit.
 - All bespoke requests for non-cytotoxic intrathecal infusions should be received in pharmacy 96hours in advance for planned procedures e.g. pump refills (unless exceptional circumstances) and 48 hours in advance for others unless in exceptional circumstances
 - All requests should be on Pharmacy-approved request forms which must include the following details:
 - Patient name and Hospital Number
 - Drug / preparation required
 - Route of administration
 - Diluent (if applicable)
 - Total volume of infusion
 - Dose / infusion rate
 - Total dose (using words and figures for controlled drugs where required)
 - Ward
 - Date and time required
 - Doctors signature and contact number
 - Clinical and compatibility checks should be performed for all bespoke requests before preparation. Clinical check, by the ward pharmacist and compatibility check by pharmacy production team.
 - Non-cytotoxic intrathecal medicines prepared by pharmacy will be pre-filtered and in a "ready to administer" form. They should not be tampered with.
 - If intrathecal and non-intrathecal injections are prepared in the pharmacy for the same patient, they must be prepared and issued from the pharmacy at different times.
- ii) Clinical Area
- On the rare occasions where a preparation of an intrathecal bolus injection within the clinical area has been deemed necessary the preparation and administration must always be performed by or under the direct supervision of a consultant / specialist registrar who is competent in the technique.

- Preparation of injectable medicines in clinical areas is covered in Section 7 of the [Injectable Medicines Policy-Supporting Information](#). In addition to the requirements stated in this policy for intrathecal injections the materials should be preservative free and the solution should be filtered using a 0.2micron filter.

6.3 Labelling

- Labels on individual doses of intrathecal medication must show clearly the:
 - Patient's name and hospital number (or date of birth)
 - Name of the product
 - Dose
 - The route of administration clearly printed in the largest font size possible and in bold. "FOR INTRATHECAL USE ONLY"
 - The words 'Store in a separate area to other injectables'
- Negative labelling must never be used.
- The outer wrapper should not be removed until immediately prior to administration.

6.4 Packing

- Non-cytotoxic intrathecal medication must be packed and transported separately from treatments which are to be administered by other routes.

6.5 Issuing

- All bespoke non-cytotoxic intrathecal medication must be issued and collected from pharmacy by a member of pharmacy and ward staff, respectively
- The member of pharmacy staff issuing the intrathecal medicine from pharmacy must sign the request form when issuing the dose and the receiving member of ward staff must sign for receipt.

6.6 Transportation and Storage

- Intrathecal medication should be transported from pharmacy in sealed bags/containers which are distinct from bags/containers used for any other purposes.
- All bespoke non-cytotoxic intrathecal medication received on the ward should ideally be used immediately.
- If the non-cytotoxic intrathecal drugs unavoidably requires storage for a short period this should be done within the outer plastic bag and kept in a separate designated area.

6.7 Administration

- Only specialist Consultants and specialist registrars (or a trainee under direct supervision) may administer a non-cytotoxic intrathecal injection. Nurse Practitioners who have been appropriately trained and have had approval from the Clinical Role Development Group may refill an intrathecal drug pump reservoir.
- The healthcare professional preparing to administer a non-cytotoxic intrathecal must verify details to ensure that the correct medicine and the correct dose are given to the correct patient by the correct route at the

- correct date and time.
- The details must be verified by an appropriate second person and checks must be recorded (this includes checking the setting of the refill programmer for intrathecal pumps)
- When refilling pumps print a copy of programming details and place in the patients records
- Administration of non-cytotoxic should, whenever possible, be in designated areas where staff is routinely involved in the administration of drugs by the intrathecal route.
- Currently these are -
 - RVI Wards 15,16 and 43
 - RVI Ward 1b
 - Theatres
 - Critical Care areas
 - Child development centre and in children's outpatients
- DAN non-cytotoxic intrathecal medication must be administered at a distinctly different time to that of other concomitant injectable medication.
- Whenever possible non-cytotoxic intrathecal must be prepared and administered within normal working hours.
- Individual departmental procedures must be followed (e.g. for refill of pumps)
- The NPSA has issued a Patient Safety Alert (Part A) which required that from 1 April 2011 all spinal (intrathecal) bolus doses are performed using syringes, needles and other devices with connectors that do not also connect with intravenous Luer connectors - this will be introduced as equipment becomes available from manufacturers).

7 Education and Training

All staff involved in the prescribing, preparation, supply, collection and administration of non-cytotoxic intrathecal medication must be suitably trained and deemed competent to carry out the relevant task

7.1 Education and Training

- Directorate-specific guidelines must be produced for the use of non-cytotoxic intrathecal. The local guideline should be readily accessible for all healthcare professionals involved in the process.
- Medical, nursing, pharmacy and other relevant staff must receive appropriate training to their level of involvement in the process
- Staff programming and or checking the intrathecal pump programmer must ensure they have undergone the relevant training for the device used
- Training for all professionals involved will be coordinated by the Nominated Lead individual for each clinical area.
- All staff transferring to the Trust must be inducted and assessed as competent by the appropriate nominated lead individual(s).
- It is the responsibility of each practitioner to ensure that as part of their Continuing Professional Development they maintain practical experience.
- All near-misses and incidents relating to non cytotoxic intrathecal must be recorded via the Trust's DATIX system.

8 Equality and diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds.

9 Monitoring Compliance with the Policy

Process	Monitoring and Auditing			
	Method	By	Committee	Frequency
Datix incidents	Analyse individual reports	Datix investigator		
SOPs	Check in place	CGARD/Pharmacy	MMC	Every two years
Prescribing limited to appropriate SPR & Consultants	Review 5 prescriptions to check prescribing limited to appropriate staff	Pharmacy	MMC	Every two years

10 Consultation and review

Consultation Group

Neurosciences

Dr Gholkar - Clinical Director, Neurosciences

Dr Duddy - Consultant Neurologist Ms Claire Nicholson - Consultant

Neurosurgeon Paula Coulson - Matron Neurosciences

Russell Mills - Specialist Nurse Practitioner

Priti Sharma - Lead Pharmacist Neurosciences

Pre-Operative & Critical Care

Will Wight - Clinical Director Peri-operative & Critical Care RVI

Karen Beacham - Clinical Director Peri-operative & Critical Care FRH

Paul Wilkinson - Consultant in Pain Management and Anaesthesia

Gus Vincent - Lead Clinician Critical Care Ward 18

Lesley Scott - Matron, Adult ITU RVI

Nicola Rudall - Senior Lead Clinical Pharmacist

Paediatrics

Dr Rob Forsyth - Consultant Neurologist

Nadia Conway - Nurse Specialist

Helga Charters - Matron for Children's Services

Nicola Vasey - Senior Lead Clinical Pharmacist

Others

Lorna Clark - Assistant Director of Pharmacy

Denise Blake - Senior Lead clinical Pharmacist

John Horncastle - Lead Production Pharmacist

Anne Black - Assistant Director of Pharmacy (Quality Assurance)

Steven Brice - Assistant Director of Pharmacy

Medicines Management Committee 4th July 2012

Review in Sept 2015

Input from each directorate co-ordinated by special pharmacist in each area
Priti Sharma - Lead Pharmacist, Neurosciences
Nicola Rudall - Senior Lead Clinical Pharmacist, Perioperative & Critical Care
Nicola Vasey - Senior Lead Clinical Pharmacist, Paediatrics
John Horncastle - Lead Production Pharmacist

11 Implementation of Policy

An electronic copy of this policy should be distributed to all members of staff involved in the prescribing, checking, preparation, supply and administration of a non-cytotoxic intrathecal.

12 References

The Prevention of Intrathecal Medication Errors - A Report to the Chief Medical Officer - Department of Health 2001

Guidance on the Safe Handling of Intrathecal and Intraventricular injections - HDL (2006) 11 issued by the Scottish Executive Health Department

Safer practice with epidural injections and infusions - National Patient Safety Agency 2007

Intrathecal drug delivery for the management of pain and spasticity in adults; recommendations for best clinical practice - The British Pain Society - August 2008

13 Associated documentation

[Medicines Policy](#) - The Newcastle upon Tyne Hospitals NHS Foundation Trust

[Injectable Medicines Policy - Supporting Information](#) - The Newcastle upon Tyne Hospitals NHS Foundation Trust

[Intrathecal Cytotoxic Chemotherapy \(ITC\) Policy](#) - The Newcastle upon Tyne Hospitals NHS Foundation Trust

10 Acknowledgements

To the consultation group, for their comments and support in producing this new policy.

Equality Analysis Form A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

PART 1

1. **Assessment Date:**
2. **Name of policy / strategy / service:**
3. **Name and designation of Author:**
4. **Names & designations of those involved in the impact analysis screening process:**
5. **Is this a:**
- | | | | | | |
|------------------------|-------------------------------------|---------------|-------------------------------------|-----------------|--------------------------|
| Policy | <input checked="" type="checkbox"/> | Strategy | <input type="checkbox"/> | Service | <input type="checkbox"/> |
| Is this: | New | Revised | <input checked="" type="checkbox"/> | | |
| Who is affected | Employees | Service Users | <input checked="" type="checkbox"/> | Wider Community | <input type="checkbox"/> |
6. **What are the main aims, objectives of the policy, strategy, or service and the intended outcomes?** *(These can be cut and pasted from your policy)*
7. **Does this policy, strategy, or service have any equality implications?** Yes No
- If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:**

8. Summary of evidence related to protected characteristics

Protected Characteristic	Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups	Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address (by whom, completion date and review date)	Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? (by whom, completion date and review date)
Race / Ethnic origin (including gypsies and travellers)	Staff are expected to comply with policy irrespective of their race / ethnic origin.	No	No
Sex (male/ female)	Staff are expected to comply with policy irrespective of their sex.	No	No
Religion and Belief	Staff are expected to comply with policy irrespective of their religion and belief.	No	No
Sexual orientation including lesbian, gay and bisexual people	Staff are expected to comply with policy irrespective of their sexual orientation.	No	No
Age	Staff are expected to comply with policy irrespective of their age.	No	No
Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section	Staff with physical disabilities will be expected to comply with policy. Staff with learning difficulties, sensory impairment and mental health may be excluded from prescribing, preparation, supply and administration of non-cytotoxic intrathecal and intraventricular injections. This is appropriate from a safety and security perspective.	Staff with learning difficulties, sensory impairment and mental health may be excluded from the policy; this is on the grounds of safety and security.	No
Gender Re-assignment	Staff who have had gender re-assignment are expected to comply with policy.	No	No
Marriage and Civil Partnership	Staff are expected to comply with policy whether they are married, in a civil partnership or single.	No	No
Maternity / Pregnancy	Staff are expected to comply with policy when pregnant.	No	No

9. Are there any gaps in the evidence outlined above? If 'yes' how will these be rectified?

No

10. Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any

significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.

Do you require further engagement? Yes No

- 11. Could the policy, strategy or service have a negative impact on human rights? (E.g. the right to respect for private and family life, the right to a fair hearing and the right to education?)**

No.

PART 2

Name:

Steven Brice

Date of completion:

13.1.16

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified, please refer to the Policy Author identified above, together with any suggestions for action required to avoid/reduce the impact.)