Procedure for Intrathecal Injections

Purpose of this procedure:

This procedure is based on the Scottish Government 'Guidance on the safe handling of intrathecal and intraventricular injections' issued as NHS HDL (2006) 11. A copy of this guidance must be available in all areas where intrathecal and intraventricular injections are handled. SE Health Department NHS, MEL

The procedure also considers the requirements of the National Patient Safety Alert NPSA/2024/002/NHSPS – Transition of NRFit™ connectors for intrathecal and epidural procedures, and delivery of regional blocks, which describes the use of non-Luer neuraxial equipment to avoid inadvertent connection and administration of intravenous injections natpsa-2024-002-nhsps.pdf.

- All references to intrathecal medicines in the following paragraphs should be read as equally applicable to intraventricular medicines.
- For guidance specific to intrathecal cytotoxic chemotherapy, refer to the NHS Lothian Guidelines for the Safe Use of Anti-cancer Therapies, Systemic Anticancer Therapy (SACT) (Chemotherapy) and the NHS Lothian Medicines Policy Subcommittee procedure for Cytotoxic Chemotherapy (document under development; refer to the current version in section 16 of NHS Lothian Safe Use of Medicines Procedures (Intranet)).

The Procedure:

1 General good practice

1.1 The intrathecal route should only be used where there is a clear body of evidence of efficacy in the clinical situation.

1.2 Practitioners involved in the prescribing, preparation and administration of intrathecal injections must receive education and training appropriate to their roles. Formal induction programmes for all practitioners must cover, at the very minimum, all potential clinical hazards associated with intrathecal medicines. There should be a formal local competency assessment to ensure that all practitioners, including locums, have read and understood this guideline and all the organisation's relevant guidelines and protocols.

1.3 A written local protocol must be available in each clinical area where intrathecal injections are prescribed, prepared or administered. It must be readily accessible to all practitioners involved in the process. The local protocol should cover training, prescribing, preparation, transportation, storage, checking and administration.

It should include the following local information:

- Defined responsibilities outlining who is authorised to carry out each task
- The specific locations where intrathecal-related activities must take place
- Where to access key documents, including national guidance and local protocols
- A list of medicines and specific formulations licensed to be administered by the intrathecal route including the licensed doses
- Procedures to eliminate or minimise the hazards associated with the preparation and administration of intrathecal injections

1.4 Use of medicines and doses not licensed for intrathecal administration is only permitted with approvals in line with the NHS Lothian procedure for the use of unlicensed and off-label medicines. Procedure for the use of unlicensed medicines or as part of an NHS Lothian approved clinical trial Medicines used in research and clinical trials.

1.5 A system must be in place to ensure that only the current edition of the local protocol is available to staff. Review of protocols should be carried out every two years and documented.

1.6 All practitioners involved with the care and treatment of patients receiving intrathecal injections must be encouraged to challenge colleagues if, in their judgement, protocols are not being adhered to or when the actions of an individual may cause potential risk to a patient. Challenging a colleague should not be seen as adversarial, but as an additional check to improve patient safety and reduce risk.

1.7 Injections must be clearly identifiable at all stages of preparation and administration. This can be achieved through appropriate labelling or by using another locally agreed safe system. For example, if the prepared injection is to remain under continuous supervision from preparation through to the completion of administration, both the original container and the final prepared product may be kept together in an individual tray during this process.

1.8 If labels are added, the route of administration must be printed clearly in the largest font size possible and emboldened. Negative labelling (for example, 'Not for intrathecal use') must never be used.

1.9 Once prepared, intrathecal injections must be kept in designated areas separate from injections that are to be given by a different route. They should never be kept as ward or theatre stock.

2 Arrangements for intrathecal spinal anaesthesia and analgesia in operating departments

Personnel

2.1 Anaesthetists recognised as such by the Royal Colleges of Anaesthetists or equivalent professional regulator, or delegated by the Clinical Director of Anaesthesia, are authorised to prescribe, prepare and administer intrathecal spinal anaesthetics and analgesics in operating departments.

2.2 Practitioners in training under the supervision of an anaesthetist may prepare and administer intrathecal spinal anaesthetics and analgesics when they have achieved a suitable level of skill. The anaesthetist must determine the level of supervision required, depending on the experience of the trainee. The trainee must be familiar with the local protocols relevant to the prescribing, dispensing, checking and administering of intrathecal medicines.

2.3 A local register of trainees that are authorised to prepare and administer intrathecal spinal anaesthetics and analgesics must be held in operating departments where intrathecal injections are prepared and administered. There must be a system in place to ensure that the local register is always up to date.

Preparation and administration

2.4 Intrathecal injections should be prepared and administered by the same person.

2.5 Practitioners preparing to administer an intrathecal injection must verify details to ensure that the correct medicine and the correct dose are given to the correct patient by the correct route.

2.6 Checks must be made at relevant stages throughout the preparation process. The responsibility for checking remains with the anaesthetist or trainee who administers the dose. A second appropriately trained registered healthcare professional must check the ingredients to ensure that they are correct. The NHS Lothian procedure, Practitioners authorised to administer medicines details the responsibilities of a registered professional when providing a second check for medicines administration.

2.7 Intrathecal injections must be administered immediately following preparation.

2.8 Intrathecal injections should be prepared and administered at a different time from injections to be given by the intravenous or other injection route. Where this is not possible, intrathecal injections must be kept clearly separate from injections to be given by a different route to avoid the risk of selecting the wrong preparation.

2.9 Administration of intrathecal injections must be recorded on the anaesthetic record by the anaesthetist who administers the dose.

2.10 Scheduling of administration of intrathecal medicines must take account of the availability of anaesthetists, or trainees named on the local register. The intrathecal procedure must not be undertaken if they are not available.

3 Arrangements for intrathecal injections other than spinal anaesthesia and analgesia

Personnel

3.1 NHS Lothian maintains an intrathecal register containing the names of registered practitioners who have been trained and certified competent in the prescribing, preparation and/or administration of medicines given by the intrathecal route. The register is held on the NHS Lothian Intranet. Intrathecal Register and documentation.

3.2 The register includes, for each individual practitioner, the specific intrathecal medicines, or category of intrathecal medicines where appropriate, and the clinical indication for which they may be prescribed, prepared or administered. The intrathecal register also includes the activity (that is prescribing, preparation or administration), for which the practitioner is authorised.

3.3 Practitioners named on the intrathecal register will have to demonstrate that they are competent to fulfil their designated roles and that they have been certified as such by the appropriate person. The Medical Director, the Director of Nursing and the Director of Pharmacy are responsible for ensuring that there is a system in place to maintain the intrathecal register.

3.4 Practitioners, including locums, moving from one organisation to another must produce proof of their competence before being placed on the NHS Lothian intrathecal register. Appropriate lead professionals must ensure that these practitioners are provided with a formal period of induction. The practitioner must be familiar with and confirm in writing they have read the local protocols relevant to the prescribing, dispensing, checking and administering of intrathecal medicines before being placed on the register.

3.5 In order to remain on the intrathecal register, practitioners must undergo formal documented assessment to demonstrate every two years that they are up to date on

policies and competent in their required skills in relation to the prescribing, preparation and /or administration of intrathecal medicines.

Prescribing

3.6 Intrathecal medicines used for the treatment and diagnostic imaging may only be prescribed by registered prescribers that are named on the intrathecal register.

3.7 Prescribing and administration of intrathecal medicines should be recorded on the main paper or electronic prescription and administration record. However, where it is not possible to record prescribing or administration to the required level of detail on the main prescription, a separate supplementary chart may be used.

3.8 Wherever possible, intrathecal doses should be prescribed and/or administered at different times from intravenous bolus doses. Where this is not possible, intrathecal injections must be kept separate from injections to be given by a different route to avoid the risk of selecting the wrong preparation.

Preparation

3.9 Intrathecal doses of medicines used for treatment and diagnostic imaging must only be prepared in pharmacy aseptic departments.

3.10 Only practitioners named on the intrathecal register, or trainees under the supervision of a person named on the intrathecal register as authorised to prepare, and who have achieved a suitable level of skill, may prepare intrathecal injections.

3.11 An up-to-date copy of the intrathecal register, naming practitioners authorised to prepare intrathecal medicines, and of the local protocol, naming the medicines licensed to be administered by the intrathecal route and the doses to be used, must be held in pharmacies where intrathecal injections are prepared.

3.12 Intrathecal doses prepared in pharmacy will be supplied in NRFit syringes to prevent inadvertent administration by another route.

Issue and transportation from the pharmacy

3.13 Medicines for intrathecal administration must only be issued from the pharmacy by and to practitioners designated in the local protocol. If the medicines are taken to the near-patient area they must be either issued directly to the person who will be administering the intrathecal medicine or placed in the designated area for the storage of intrathecal injections. The pharmacy practitioner must sign for the release of the medicines, identifying to whom the medicines were released or that they have been placed in the designated area. Where the person who will be administering the

intrathecal medicine does not take direct receipt of the medicines, they must check the medicines and sign for them on retrieval from the designated area.

3.14 Intrathecal injections must always be packed and transported separately from treatments for administration by other routes. Intrathecal doses must be packed in such a way as to highlight that the product is different from intravenous drugs. For example, the transport containers could be clearly labelled for intrathecal use. The packaging of intrathecal injections must comply with the manufacturer's recommendations. Colour coding of containers and syringes alone is unreliable and could result in error.

3.15 If injections to be administered by intravenous bolus, and injections to be administered by intrathecal injection are prepared in the pharmacy for the same patient, they must be issued from the pharmacy at different times. Injections to be administered by intravenous bolus must be issued first. The only exception that can be made to the sequencing is when it is essential that intrathecal injections, and injections to be administered by intravenous bolus, are given in one episode of treatment.

3.16 Prepared intrathecal medicines should not be stored in the clinical area. Intrathecal medicines issued from the pharmacy should be delivered immediately before the planned administration time, and those prepared in operating departments should be used immediately following preparation. Where this is not possible, intrathecal injections must be stored in the designated area, separate from injections to be given by a different route, to avoid the risk of selecting the wrong preparation.

3.17 The designated area must be a lockable area. The key must be kept with the nurse-in-charge. The area must be always locked.

3.18 Only a practitioner on the intrathecal register should remove the intrathecal injection from the designated area. Only one dose should ever be removed at any one time.

Administration

3.19 Practitioners preparing to administer an intrathecal injection must verify details to ensure that the correct medicine and the correct dose are given to the correct patient by the correct route. These details must be verified by a second authorised person, and the checks made must be recorded on the paper or electronic prescription and administration record. The NHS Lothian procedure, Practitioners authorised to administer medicines details the responsibilities of a registered professional when providing a second check for medicines administration.

3.20 Intrathecal medicines should be administered at a different time from injections to be given by the intravenous or other injection route. Where this is not possible, intrathecal injections must be kept clearly separate from injections to be given by a different route, to avoid the risk of selecting the wrong preparation. Wherever possible, the intrathecal and the intravenous bolus injection should be administered by different practitioners.

3.21 A technically difficult lumbar puncture may occasionally need the assistance of staff not on the intrathecal register, for example a radiologist to position the needle under imaging control. This is acceptable – however, these staff must never be involved in any other aspect of the process and, specifically, must never administer the intrathecal injection.

3.22 Intrathecal injections must be prepared and administered within normal working hours whenever possible. The intrathecal procedure should not be undertaken if practitioners named on the intrathecal register are not available.

Associated materials/references:

Safe Use of Medicines – Policy

Online SE Health Department

NHS, MEL natpsa-2024-002-

nhsps.pdf

Systemic Anticancer Therapy (SACT) (Chemotherapy)

Cytotoxic Chemotherapy – Document currently in development (refer to current version in section 16 of NHS Lothian Safe Use of Medicines Procedures (Intranet))

Procedure for the use of unlicensed medicines

Medicines used in research and clinical trials

Practitioners authorised to administer medicines