NHS Grampian

Policy For The Safe Administration of Non-Cytotoxic Intrathecal or Intraventricular Injections (other than spinal anaesthesia and analgesia administered in operating theatres) by Staff Working within NHS Grampian

Author:		Approver:
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Signature: 		**Signature:** 

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Policy Statement:
It is the responsibility of all staff to ensure that they are working to the most up to date and relevant guideline, policies, protocols and procedures.

Version 3

Executive Sign-Off

This document has been endorsed by the Director of Pharmacy and Medicines Management

Signature: 

Replaces: NHSG/Policy_Intrathecal/GADTC1135, Version 2

Document application: NHS Grampian Acute

Revision History:

Revision Date	Summary of Changes (Descriptive summary of the changes made)	Changes Marked* (Identify page numbers and section heading)
September 2024	Policy moved to new policy format	
September 2024	Patients receiving epidural administration of medicines	Section 1.5 – page 4
September 2024	Removal of word 'routine' 'patients who are undergoing 'routine' anaesthesia'	Section 1.5 – page 4
September 2024	Reference added for 'ready to administer form'	Page 2 (introduction) P6
September 2024	CEL 21(2009) Safe Administration of Intrathecal Cytotoxic therapy. Replaces HDL(2004) 30	Page 2 (introduction) and reference section
September 2024	New hyperlink added to reference 3	Page 15 reference 3
September 2024	Reference to PAR removed and replaced with HEPMA	Page 8 section 3.2.4
September 2024	Reference to NRFit connectors added	Page 11 section 3.5

Consultative Group

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Policy for the Safe Administration of Non-Cytotoxic Intrathecal or Intraventricular Injections (other than spinal anaesthesia and analgesia administered in operating theatres) by Staff Working within NHS Grampian

1. Introduction

Preparation and administration of intrathecal and intraventricular injections is a potentially hazardous process and is associated with a significant number of potentially serious patient safety risks. The intrathecal or intraventricular route should only be used where there is a clear body of evidence of efficacy.

It is recognised that non-cytotoxic intrathecal and intraventricular injections are most commonly used within **specialist areas where safe systems of use are firmly established and monitored by experienced healthcare professionals to ensure patient safety**.[1]

Non-cytotoxic intrathecal and intraventricular injections raise risk management issues (involving patient safety and quality assurance) which need to be addressed as a matter of high priority. As a result, the Scottish Executive Health Department issued **HDL (2006) 11 – Guidance on the Safe Handling of Intrathecal and Intraventricular Injections**[1] and requested full implementation of this national guidance with immediate effect.

The recommendations contained within this document have numerous implications and build on the recommendations of two previous publications: **Safe Administration of Intrathecal Cytotoxic Chemotherapy CEL 21 (2009)** [2] and the **Clinical Resource and Audit Group (CRAG) Good Practice Statement on the Preparation of Injections in Near-Patient Areas, including Clinical and Home Environments**, **December 2002.**[3]

To ensure the recommendations of this document are addressed and implemented effectively, a co-ordinated, NHS Grampian multidisciplinary approach is essential.

Many areas have been highlighted for attention, such as education and training, labelling, packaging and storage, prescribing, preparation and administration, transportation and personnel involved. It has also been stipulated that, intrathecal injections should be made under aseptic conditions in pharmacy. This is not currently possible in NHS Grampian. However, many of the products intended to be given by the intrathecal/ intraventricular route can be purchased in a 'ready to administer' form.[3]

Adherence to this policy will minimise the risk to patients receiving intrathecal or intraventricular injections within NHS Grampian hospitals.

1.1. Objectives

This is the NHS Grampian policy for prescribing, preparation and administration of non-cytotoxic intrathecal or intraventricular injections by registered healthcare professionals. It does not include spinal anaesthesia and analgesia administered in operating theatres.

The preparation and administration of intrathecal and intraventricular injections are hazardous processes. Suitable and sufficient control measures are necessary to minimise risk.

The policy provides the framework for each speciality or clinical area using non-cytotoxic intrathecal and intraventricular injections and will cover:

- Roles and Responsibilities.
- Who are the nominated leads.
- Who can do what.
- Those included and excluded from the policy.
- Training.
- Guidance on preparation and supply.
- Guidance on delivery, storage, administration and checking.

This policy must be rigidly adhered to at all times, as administration of the wrong drug or dose by the intrathecal or intraventricular route could potentially be fatal.

1.2. Definitions

For the purposes of this policy, the following definitions will be used:

- Intrathecal injection – an injection into the intrathecal space surrounding the spinal cord.
- Intraventricular injection – an injection of a drug for diffusion throughout the ventricular and subarachnoid space by means of ventricular puncture.
- Intrathecal infusion – an infusion into the intrathecal space via an infusion device either external or implanted.

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

Within this document

- “Registered” means trained and certified as competent by NHS Grampian to undertake the appropriate tasks set out within this policy.
- The “register” is the Non-Cytotoxic Intrathecal and Intraventricular Injections Register.
- “In training” means in the process of being trained and certified as competent by and under the supervision of a member of staff named on NHS Grampian register to undertake the appropriate tasks set out within this policy. These

training details will be recorded in the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.
- "An intrathecal" is an intrathecal injection or intrathecal infusion or an intraventricular injection or infusion.
- The Heads of Professions are the Medical Director, the Director of Pharmacy and Medicines Management, the Director of Nursing, and the Head of Clinical Governance.
- The nominated Lead is the person responsible for a designated area, for example speciality or clinical area within NHSG to undertake the appropriate task(s) set out in this policy.

1.3. Clinical Situations

This policy applies to all members of staff working within NHS Grampian who are involved in prescribing, preparation, supply and administration of non-cytotoxic intrathecal and intraventricular injections. The only areas where this policy can be used are:

- Roxburghe House,
- Neurorehabilitation unit at Woodend Hospital,
- RACH HDU and Theatres
- Aberdeen Royal Infirmary in Ward 205, ITU, and Theatre 8.

For the purpose of this policy, Labour ward, Aberdeen Maternity hospital is considered an operating theatre and therefore excluded from this policy.

There is a separate NHS Grampian Policy [4] for Intrathecal use in operating theatres (other than RACH theatre and theatre 8 ARI); this should be referred to where appropriate.

There is a separate NHS Grampian Policy for the Administration of Intrathecal Cytotoxic Chemotherapy [5].

There is a separate NHS Grampian guideline for the use of epidural medicines in Palliative care [6].

1.4. Patient Groups to Which This Document Applies

Patients who require medicines to be administered via the intrathecal or intraventricular route. This includes infusions for refilling implantable pumps.

1.5. Patient Groups to Which This Document Does Not Apply

Patients who are undergoing intrathecal spinal anaesthesia and analgesia. Patients who are to receive cytotoxic medicines by intrathecal or intraventricular route. Those receiving epidural administration of medicines.

2. Evidence Base

Preparation and administration of intrathecal and intraventricular injections is a potentially hazardous process and is associated with a significant number of

potentially serious patient safety risks. The intrathecal or intraventricular route should only be used where there is a clear body of evidence of efficacy. The evidence for the use of intrathecal/intraventricular medications is limited. However, the systematic review by Ng et al concludes that the use of intraventricular vancomycin for the treatment of meningitis, ventriculitis and CNS device-associated infections appears safe and effective.
https://link.springer.com/article/10.1007/s12028-012-9784-z

The use of intrathecal medications for the management of pain and spasticity has a good evidence base with the British Pain Society supporting the use of opioids for chronic non-malignant pain and cancer-related pain, and baclofen for spasticity not controlled by systemic agents or where systemic agents causes intolerable side effects.
https://www.britishpainsociety.org/static/uploads/resources/files/itdd_2015_pro_v3.pdf

3. Process Document Main Components and Recommendations

This policy documents the necessity for the safe management of intrathecal/ intraventricular medications by highlighting the need to adhere to specific guidance when prescribing, ordering, preparing, administering and storing these medicines. It also details the specific training required for medical, nursing and pharmacy staff as well as their addition to the intrathecal register relevant to their role in the management of these medications.

3.1. Personnel/ Intrathecal Register

NHS Grampian must establish and maintain a Non-Cytotoxic Intrathecal and Intraventricular Injections Register that names healthcare professionals who have been trained and certified competent in the prescribing, preparation, checking and/or administration of medicines given by the intrathecal route.

Only healthcare professionals who have completed a competency-based training programme on the relevant aspects of intrathecal use and can demonstrate competency, can be placed on the NHS Grampian register.

Only healthcare professionals named on this register may prescribe, prepare, check or administer intrathecal medicines.

Only healthcare professionals experienced in the field of intrathecal infusion therapy and on the register for this purpose can adjust infusion devices and alter programming.

The register must record for each individual healthcare professional;

a. The specific medicines, or category of medicines where appropriate
b. The clinical indication, for which the medicine may be prescribed, prepared and administered.
c. Each activity for which individuals are authorised for example prescribing, preparation, checking or administration.

d. Where a healthcare professional is named on the register to administer, the exact route must be defined, i.e. intrathecal, intraventricular or intrathecal infusion via an implantable device.

The full register is held by the NHS Grampian Chief Executive and an electronic copy can be accessed by the Medical Director, Director of Pharmacy and Medicines Management and Director of Nursing. The original register should be contained within the Qpulse system.

The Medical Director is responsible for ensuring the register is kept up to date for doctors, the Director of Nursing for nurses, and Director of Pharmacy and Medicines Management for pharmacists and pharmacy technicians.

Each Head of Profession must provide an up-to-date register to the other disciplines.

Healthcare professionals not named on the register may not under normal circumstances prescribe, prepare, check or administer intrathecal medicines.

In exceptional circumstances where there is an identified clinical need for a healthcare professional not named on the register to prescribe, prepare, check or administer intrathecal medicines to any patient in NHS Grampian, such healthcare professional must set out their requirements in writing with supportive evidence. This information will be passed to the Medical Director, the appropriate Clinical Director, Director of Pharmacy and Medicines Management and Director of Nursing. The Clinical Director will liaise with the appropriate Lead Pharmacist to collate all the issues. The Medical Director, working with the Director of Pharmacy and Medicines Management, Director of Nursing and Head of Clinical Governance (or nominated deputies), must give written approval before the treatment is prescribed, supplied, prepared, checked and administered.

In order to remain on the register, healthcare professionals must demonstrate that they are up-to-date on policies and practice for administration of intrathecal medicines every two years.

3.2. Training

Medical, nursing or pharmacy staff, or other relevant healthcare professional group may only train, prescribe, prepare, order, supply, transport, store, check or administer non-cytotoxic intrathecal medication if they are:

- Authorised to do so by their designated lead.
- Trained and certified as competent for the relevant task(s).
- Registered on the non-cytotoxic intrathecal Register.
- Using non-cytotoxic intrathecal/intrathecal injection as per this policy.

A local written protocol and standard operating procedure must be produced for the prescribing, preparation and administration of intrathecal medicines and should be readily accessible for healthcare professionals involved in the process. The local protocol should cover all aspects of the guidance in this policy – from training,

through prescribing, preparation, transportation, storage, checking and administration. It should include the following information:

- Who can do what
- Where things should be done
- Where to find key documents such as national guidance and local protocols
- A list of medicines and specific formulations licensed to be administered by the intrathecal route
- Doses licensed to be used for intrathecal administration
- Procedures to eliminate or minimise the hazards associated with the preparation and administration of intrathecal injections.

Use of medicines and doses not licensed for intrathecal administration should only be permitted in line with the document “Guidance for processing requests to prescribe unlicensed, off-label or non-formulary medicines” approved by the Grampian Medicines Management Group

Medical, pharmacy, nursing and other relevant staff must receive competency-based training appropriate to their level of involvement in the prescribing, verification, preparation, supply and administration of intrathecal medicines. All groups of staff must, at the very minimum, be made aware of all potential clinical hazards associated with, and of the potentially fatal consequences associated with the inadvertent or incorrect administration of intrathecal medicines. Training plans for all professions involved will be held by the Nominated Lead Individual for each clinical area.

Although staff training will be the responsibility of the Nominated Lead Individual for each clinical area, training may be delegated to named medical, nursing and pharmacy trainers.

Trainer and trainee must have a documented training plan. The training will cover theory and practice. Training will be deemed complete when the trainer signs a competency certificate. The trainee’s competency certificate will be sent by the trainer to the relevant Nominated Lead Individual for the clinical area and the Head of Profession for inclusion in the appropriate section of the register. Regular review of competency for staff who have completed the training programme should be carried out by a trainer, nominated by the relevant Nominated Lead Individual for the clinical area.

It is the responsibility of the Nominated Leads to maintain and review the register at least every 6 months and update, where necessary, the list of accredited intrathecal healthcare professionals within their area of responsibility.

The Nominated Lead Individual for each clinical area will make arrangements for the current edition of the register to be sent to the Medical Director, and the Director of Pharmacy and Medicines Management, and the Director of Nursing, and the Chief Operating Officer on at least an annual basis.

Healthcare professionals moving from one hospital to another must take with them their certificate along with their training record as proof of their competence before

being placed on the register at their new location. It is the responsibility of the Nominated Lead to ensure that these healthcare professionals have a formal period of induction and assessment of competency. This should include the provision of copies of the organisation's policy, local protocols, standard operating procedures and guidelines relevant to the prescribing, dispensing, checking and administering of intrathecal medicines. Healthcare professionals should confirm in writing that they have received and read the correct protocols and guidelines before being placed on the register.

3.2.1. Training Medical Staff

- Training will be provided by appropriate, qualified healthcare professionals appointed by the Nominated Lead Individual for each clinical area and registered on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.
- Only medical staff above FY2 grade can be trained to prescribe, aseptically prepare or administer intrathecal medicines.
- Trained members of medical staff named on the register will be authorised to provide a second-check for the administration of an intrathecal medicine.
- The training, approved by the Medical Director, will include theory and practical training.
- Registration of medical staff on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register will be reviewed as part of their annual appraisal and in-service training assessment.
- The medical trainers will send a copy of the trainee's competency certificate to the Nominated Lead Individual for each clinical area for inclusion in the appropriate section of the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.

3.2.2. Training of Pharmacy Staff

- Training will be provided by appropriate, qualified healthcare professionals appointed by pharmacy management within the acute service at Aberdeen Royal Infirmary and registered on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.
- Pharmacy staff will be trained as appropriate to verify, prepare, dispense and issue intrathecal medicines.
- The training, approved by the Director of Pharmacy and Medicines Management (or nominated deputy), will include theory and practical training.
- The pharmacy trainers will send a copy of the trainee's completion certificate to the Director of Pharmacy and Medicines Management (or nominated deputy) for inclusion in the appropriate section of the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.
- Registration of pharmacy staff on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register will be reviewed as part of their annual appraisal and in-service training assessment.

3.2.3. Training of Nursing/ Theatre (RACH/theatre 8 ARI) Staff

- Training will be provided by appropriate, qualified healthcare professionals appointed by the Nominated Lead for the designated clinical area and registered on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.
- Only nursing staff, working within designated areas, can be trained to prescribe, prepare and administer intrathecal medicines. All other nursing staff, working within designated areas, must be familiar with this policy.
- Once trained, staff should be registered on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register,
- Trained members of nursing staff named on the register will be authorised to provide a second-check for the administration of an intrathecal medicine.
- The training, approved by the Director of Nursing (or nominated deputy), will include theory and practical training.
- The nurse trainers will send a copy of the trainee's completion certificate to the nominated lead for the designated clinical area for inclusion in the appropriate section of the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.
- Registration of nursing staff on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register will be reviewed as part of their annual appraisal and in-service training assessment.

3.2.4. Prescribing

Intrathecal drug therapy must be prescribed by a healthcare professional named on the register as a prescriber. Pharmacists must not authorise a prescription unless the prescriber is on the register

The prescription should clearly state the route of administration, i.e. INTRATHECAL and should be written in full. Abbreviations are not acceptable.

All intrathecals need to be prescribed on the intrathecal prescription chart **in addition to** main prescription and administration record (in the Hospital Electronic Prescribing and Administration (HEPMA) system). The HEPMA entry should refer to the intrathecal prescription chart, to show an intrathecal prescription chart is in use.

Whenever 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 **in a locked designated area** separate from injections to be given by a different route to avoid the risk of selecting the wrong preparation.

A clinical pharmacist on the register must verify all doses of intrathecal medicines, and sign the Intrathecal Request Form, prior to its submission to pharmacy for dispensing or supply.

If there is evidence of an intention to use medicines in contravention of the guidance within this policy and the issues cannot be resolved after discussion with the

consultant responsible for the patient, the pharmacist concerned must contact senior pharmacy management. The final decision to supply lies with senior pharmacy management.

For areas with a clinical pharmacist, all intrathecal medicines **prepared in pharmacy** must be verified by a pharmacist named on the register to ensure the prescription details are correct when compared to an approved prescribing protocol and patient's clinical parameters. The clinical pharmacist must sign the Intrathecal Request Form.

For all areas without a clinical pharmacist the request will be technically screened against approved prescribing protocols by a pharmacist on the register. The pharmacist must sign the intrathecal request form.

An intrathecal prescription chart must be used when prescribing and administering intrathecal medicines to out-patients. This chart must not contain any other drug prescription. No amendments are permitted to this prescription.

3.3. Preparation, Packaging, Labelling and Supply from Pharmacy

Intrathecal medicines used for treatment and diagnostic imaging should be outsourced in a ready to administer form, or prepared in pharmacy aseptic departments. It is recognised that this is not feasible in some instances.

3.3.1. Intrathecal injections prepared within aseptic unit of pharmacy

Prior to preparation pharmacy must hold:

- An up to date copy of the Non-Cytotoxic Intrathecal and Intraventricular Injections Register containing the names of pharmacy staff authorised to prepare intrathecal medicines.
- The local protocol naming the medicines administered by the intrathecal route and the doses to be used.
- A copy of the prescription signed by an authorised prescriber who is named on the register.
- The intrathecal request form signed by a pharmacist who is named on the register.

Only pharmacy staff who have achieved a suitable level of skill (signed off by pharmacy management) and are named on the register, or trainees under direct supervision of a person named on the register as authorised to prepare, may prepare intrathecal medicines.

Intrathecal medicines prepared by pharmacy will be pre-filtered and in a "ready to give" form. They should never be altered.

All intrathecal medicines will be labelled with the patient's name, ward, CHI number and date.

All intrathecal medicines must be labelled: "FOR INTRATHECAL USE ONLY" in the largest font size possible and in bold. The syringe should be over-wrapped and

labelled: “FOR INTRATHECAL USE ONLY”. Do not remove outer wrapper until immediately prior to administration.

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 the intrathecal injection and injections to be administered by intravenous bolus are given in one episode of treatment (e.g. patients under anaesthetic).

3.3.2. Packaging

Intrathecal medicines will be supplied in **PURPLE** light protective sealed bags. Intrathecal medicines will be delivered in separate transport containers. The delivery bag/box will be labelled “CONTAINS MEDICINES FOR INTRATHECAL ADMINISTRATION”**.**

3.4. Delivery and Storage

Drugs to be administered via the intrathecal route should not be stored in ward/ theatre areas unless defined below.

The following locations are authorised to maintain small stocks of named preparations for logistical reasons or for emergencies. No other area is authorised to stock any intrathecal injections without application in writing to the Medical Director and the relevant Heads of Profession.

Area	Product Stocked	Quantity
Locked Intrathecal cupboard, Clinical room, Neurorehabilitation unit, Woodend hospital	Baclofen 500microgram/ml (10mg/20ml) Baclofen 2000microgram/ml (40mg/20ml)	1 x 20ml 1 x20ml
Locked Intrathecal cupboard, Clinical area, Neuroradiology, ARI	Iopamidol 300mg/ml (Niopam® 300)	1 x 20mL bottle
Locked Intrathecal/Epidural cupboard or controlled drug cupboard, Clinical area Roxburghe House	Diamorphine Injection (5mg,10mg,30mg and 100mg) Levobupivacaine Injection (0.25%, 0.5%) Clonidine Injection 150mcg/mL	1 box of 5 1 box of 5 (10ml) 1 box of 5 (1ml)

Intrathecal doses should either be issued directly to the named prescriber who will be administering the dose, or alternatively may be taken to the ward by a designated member of nursing or pharmacy staff, whose name appears on the register, and delivered directly to the administering healthcare professional or placed in the designated area for the storage of intrathecal medicines.

The member of pharmacy staff issuing the intrathecal medicine from pharmacy must sign the pharmacy intrathecal request form when releasing the dose(s) and the receiving member of ward staff must sign for receipt.

Intrathecal medicines will not be stored in any clinical area except in the designated area used for intrathecal therapy only. This must be kept locked at all times and the key held by the nurse-in-charge.

Where the person who will be administering the intrathecal medicine does not take direct receipt of the medicines, she/he must check the medicines and sign for them on retrieval from the designated area.

Intrathecal medicines for administration at Woodend will be transported by hospital transport to Woodend hospital pharmacy, for release to the ward.

Intrathecal medicines for administration in Roxburghe House will be transported by hospital transport to Roxburghe House.

3.5. Intrathecal Medicines Requiring Preparation or Manipulation outside of Pharmacy

Intrathecals should be ordered from pharmacy using a copy of the intrathecal request form, which must be signed by a healthcare professional named on the register as a prescriber of the specified medicine.

Drugs to be administered via the intrathecal route should not be stored in ward/theatre areas. Any exceptions must have written approval from Director of Pharmacy and Medicines Management, Medical Director and Nursing Director – see section 3.5.

Intrathecal medicines should be prepared by a member of staff named on the register or in training working under the supervision of someone on the register, adhering to the policy for the prescribing, preparation and administration of intrathecal medicines. The calculations and preparation must be double checked by a second member of staff named on the register for that purpose.

All intrathecal medicines must be administered immediately after preparation.

Transition to NRFit connectors for intrathecal and epidural procedures, and delivery of regional blocks. In 2010, a new international standard for small bore connectors (ISO 80369) was developed. 3 This included a dedicated connector for neuraxial applications (NRFit™ ISO 80369-6) defined as “those for administering medications to neuraxial sites, wound infiltration anaesthesia delivery and other regional anaesthesia procedures, or to monitor or remove cerebrospinal fluid for therapeutic or diagnostic purposes[7].

3.6. Administration and Checking

A member of **clinical** staff on the register must prepare the trolley for administration of the intrathecal medicine.

Healthcare professionals preparing to administer an intrathecal medicine must verify details to ensure that the correct medicine and the correct dose are given to the correct patient by the correct route. The details must be verified by a second person named on the register for that purpose and the checks made must be recorded on the prescription chart.

Patients should only receive intrathecal therapy in designated areas where staff are routinely involved in the administration of drugs by the intrathecal route. These are Roxburghe House, Neurorehabilitation unit at Woodend Hospital, RACH HDU and Theatres, and at Aberdeen Royal Infirmary in Ward 205, ITU, and Theatre 8.

If the Consultant in charge of the patient decides that the patient cannot be moved to one of the above designated areas to continue to receive the intrathecal therapy then this variance must be noted in the patient's case notes. All other aspects of this policy must be adhered to, e.g. only staff registered on the register may prescribe, prepare, administer and check the intrathecal medicines.

Intrathecals should be administered at a different time from injections to be given by the intravenous or other injection route. Where this is not possible, intrathecals must be kept 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 healthcare professionals.

Only a healthcare professional, (or trainee under direct supervision) whose name appears on the register trained to administer, may administer intrathecal medicines. Healthcare professionals not on the register must not administer intrathecal medicines. The register will be available in all areas where intrathecals are administered (except 3.7.4 above).

Scheduling of intrathecal therapy must take into account the availability of the relevant trained staff (see 3.2). If, for any reason, the required trained personnel are unavailable, the administration of intrathecal medicine should be delayed.

In the case of intrathecal baclofen infusion where patients are on long term treatment, the intrathecal **must** be administered, unless deemed clinically inappropriate, by a doctor on the register. Abrupt withdrawal of baclofen treatment is potentially hazardous.

Intrathecals must be prepared and administered within normal working hours whenever possible.

All healthcare professionals 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 individuals 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.

4. Summary of Responsibilities

Chief Executive

- Holds the Non-Cytotoxic Intrathecal and Intraventricular Injections Register for all disciplines.

Medical Director

- Holds (or has access to) a copy of the policy.
- Holds a copy of the Non-Cytotoxic Intrathecal and Intraventricular Injections Register for all disciplines.
- Maintains and keeps register for doctors up to date.
- Working with Directors of Nursing and Pharmacy and Medicines Management makes a decision on whether in exceptional circumstances a healthcare professional not on the register should be permitted to prescribe, prepare, check or administer an intrathecal medicine.
- In collaboration with Directors of Nursing and Pharmacy, appoints a Nominated Lead Individual who is responsible for the prescribing, preparation and administration of intrathecal medicines in a designated area, for example a ward or clinic.

Director of Nursing

- Holds (or has access to) a copy of the policy.
- Holds a copy of the Non-Cytotoxic Intrathecal and Intraventricular Injections Register for all disciplines.
- Maintains and keeps register for nurses up to date.
- Working with Directors of Medicine and Pharmacy and Medicines Management makes a decision on whether in exceptional circumstances a healthcare professional not on the register should be permitted to prescribe, prepare, check or administer an intrathecal medicine.
- In collaboration with Directors of Medicine and Pharmacy, appoints a Nominated Lead Individual who is responsible for the prescribing, preparation and administration of Intrathecal medicines in a designated area, for example a ward or clinic.

Director of Pharmacy and Medicines Management

- Holds (or has access to) a copy of the policy.
- Holds a copy (or has access to an electronic version) of the Non-Cytotoxic Intrathecal and Intraventricular Injections Register for all disciplines.
- Maintains and keeps register for pharmacy staff up to date.
- Makes a decision on whether a supply of an intrathecal should be made if there is evidence of potential non-compliance with the policy.

- Working with Directors of Medicine and Nursing makes a decision on whether in exceptional circumstances a healthcare professional not on the register should be permitted to prescribe, prepare, check or administer an intrathecal medicine.
- In collaboration with Directors of Medicine and Nursing, appoints a Nominated Lead Individual who is responsible for the prescribing, preparation and administration of intrathecal medicines in a designated area, for example a ward or clinic.

Nominated Lead Individual

- Holds (or has access to) a copy of the policy
- Holds a copy of the Non-Cytotoxic Intrathecal Register
- Sends an up to date register for their designated area to the Medical Director, Director of Nursing and the Director of Pharmacy and Medicines Management on an annual basis.
- Maintains training plans for all healthcare professionals practicing according to this policy within their designated area; training may be delegated to named medical, nursing and pharmacy trainers
- Ensures all healthcare professionals practising within their designated area have their competencies re-assessed every 2 years
- Ensures there is a local protocol and appropriate standard operating procedures within their designated area

Nominated Lead for Aseptic Preparation of Medicines

- Holds (or has access to) a copy of the policy
- Holds a copy of the Non-Cytotoxic Intrathecal Register
- Must retain a copy of the prescription and intrathecal request form for medicines prepared in aseptic preparation area of the pharmacy department (according to NHS Grampian Pharmacy Department Retention of Documents Policy).

All healthcare staff involved in the prescribing, preparation and administration of Intrathecals

- Hold (or have access to) a copy of the policy and associated Standard Operating Procedures
- Ensure that the policy is adhered to.
- Hold a current certificate of competence
- Have competence re-assessed every 2 years

5. Distribution

- A copy of this policy should be given to all members of staff involved in the preparation, prescribing, supply and administration of intrathecal medicines and the Heads of Professions. This will be the responsibility of the Nominated Lead Individual for each clinical area. A copy will be kept in all areas where intrathecal medicines are prescribed, prepared, supplied or administered.
- All healthcare professionals including doctors, nurses and pharmacy staff who are involved in the prescribing, dispensing, checking, delivery/storage and

administration of intrathecal medicines must be fully cognisant of this policy and other policies and understand their impact on practice.

Distribution List:

Clinical Leads
Unit Operational Managers
Nurse Managers
Senior pharmacy staff
Professional and Practice Development Unit
Uploaded on NHS Grampian Internet
Uploaded onto QPulse
Distribute via global email

6. References

1. HDL(2006)11 – Guidance on the Safe Handling of Intrathecal and Intraventricular Injections, 16 February 2006, Scottish Executive Health Department http://www.show.scot.nhs.uk/sehd/mels/HDL2006_11.pdf
2. Safe Administration of Intrathecal Cytotoxic Chemotherapy CEL 21 (2009), 19th June 2009. CEL 21 (2009) - Safe administration of intrathecal cytotoxic chemotherapy (scot.nhs.uk)
3. Clinical Resource and Audit Group (CRAG) Good Practice Statement for the Preparation of Injections in Near-Patient Areas, Including Clinical and Home Environments, December 2002, Good Practice Statement for the Preperation of Injections in Near-Patient Areas, including Clinical and Home Environments (nrscotland.gov.uk)
4. Guideline for the safe management of patients following spinal anaesthetic, with or without the administration of Intrathecal (Spinal) Opioids for Aberdeen Royal Infirmary and Woodend General Hospital
5. Administration of Intrathecal Cytotoxic Chemotherapy in NHS Grampian. Administration of Intrathecal Cytotoxic Chemotherapy.pdf
6. Palliative Care Epidural Guidelines.
7. NPSA Safety Alert – Transition to NRFit connectors for intrathecal and epidural procedures, and delivery of regional blocks.

Appendix 1a: Non-Cytotoxic Intrathecal and Intraventricular Injection Register (Wards)

NHS GRAMPIAN
NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS REGISTER
REGISTER OF WARD STAFF AUTHORISED TO
TRAIN, PRESCRIBE, ADMINISTER, CHECK AND/OR RECEIVE/COLLECT
INTRATHECAL AND/OR INTRAVENTRICULAR INJECTIONS

NAME	DESIGNATION	AUTHORISED TO: Please tick appropriate column(s):					COMPETENCY ASSESSED BY*: Include name and designation	DATE ASSESSED:	REASSESS-MENT DATE:
		Train	Prescribe	Administer	Check	Receive/ Collect			

*This person must be named on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injection Register and must themselves be trained and certified competent for the task that they are assessing.

Appendix 1b: Non-Cytotoxic Intrathecal and Intraventricular Injection Register (Pharmacy)

NHS GRAMPIAN
NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS REGISTER
REGISTER OF PHARMACY STAFF AUTHORISED TO
TRAIN, ISSUE, CHECK, PACKAGE, HAND OUT
INTRATHECAL AND/OR INTRAVENTRICULAR INJECTIONS

NAME	DESIGNATION	AUTHORISED TO: Please tick appropriate column(s):					COMPETENCY ASSESSED BY*: Include name and designation	DATE ASSESSED:	REASSESS-MENT DATE:
		Train	Issue	Check	Package	Hand out			

*This person must be named on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injection Register and must themselves be trained and certified competent for the task that they are assessing.

Appendix 2: Certificate of Competency – Prescribers

NHS Grampian
Non-Cytotoxic Intrathecal and Intraventricular Injections
Certificate of Competency – Prescribers

This documentation must be completed by an authorised medical trainer, nominated by the Medical Director (or deputy), that is named and certified competent on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.

Name of Trainee: _____
Grade: _____
Department: _____
Name of Supervisor: _____

I confirm that I have received formal training in the safe handling of non-cytotoxic intrathecal and intraventricular injections. This has included:

- Training on all potential clinical hazards associated with non-cytotoxic intrathecal and intraventricular injections
- Training on all relevant policies relating to non-cytotoxic intrathecal and intraventricular injections
- Demonstration of competency to the required level for the task involved

I am aware that I am now authorised to perform the following tasks **only** (delete tasks not authorised):

- Collection of non-cytotoxic intrathecal and intraventricular injections from the storage area
- Prescribing of non-cytotoxic intrathecal and intraventricular injections
- Preparation of non-cytotoxic intrathecal and intraventricular injections
- Verification of non-cytotoxic intrathecal and intraventricular injections as a second checker for administration
- Administration of non-cytotoxic intrathecal and intraventricular injections

I confirm that I have read and understood all of the relevant guidelines and protocols and that I will comply with the policy.

Signature of Trainee: _____ Date: _____

I am satisfied that the above doctor has read and understood the relevant training and has now been included on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.

Signature of Supervisor: _____ Date: _____

Reassessment of competence is required every 2 years.
Reassessment Date: _____

Appendix 3: Certificate of Competency – Nursing Staff

NHS Grampian
Non-Cytotoxic Intrathecal and Intraventricular Injections
Certificate of Competency – Nursing Staff

This documentation must be completed by an authorised nursing trainer, nominated by the Director of Nursing (or deputy), that is named and certified competent on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.

Name of Trainee: _____
Grade: _____
Department: _____
Name of Supervisor: _____

I confirm that I have received formal training in the safe handling of non-cytotoxic intrathecal and intraventricular injections. This has included:

- Training on all potential clinical hazards associated with non-cytotoxic intrathecal and intraventricular injections
- Training on all relevant policies relating to non-cytotoxic intrathecal and intraventricular injections
- Demonstration of competency to the required level for the task involved

I am aware that I am now authorised to perform the following tasks **only** (delete tasks not authorised):

- Collection of non-cytotoxic intrathecal and intraventricular injections from the storage area
- Prescribing of non-cytotoxic intrathecal and intraventricular injections
- Preparation of non-cytotoxic intrathecal and intraventricular injections
- Verification of non-cytotoxic intrathecal and intraventricular injections as a second checker for administration
- Administration of non-cytotoxic intrathecal and intraventricular injections

I confirm that I have read and understood all of the relevant guidelines and protocols and that I will comply with the policy.

Signature of Trainee: _____ Date: _____

I am satisfied that the above nurse has read and understood the relevant training and has now been included on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.

Signature of Supervisor: _____ Date: _____

Reassessment of competence is required every 2 years.
Reassessment Date: _____

Appendix 4: Certificate of Competency – Pharmacy Staff

NHS Grampian
Non-Cytotoxic Intrathecal and Intraventricular Injections
Certificate of Competency – Pharmacy Staff

This documentation must be completed by an authorised pharmacy trainer, nominated by the Director of Pharmacy (or deputy), that is named and certified competent on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.

Name of Trainee: _____
Grade: _____
Department: _____
Name of Supervisor: _____

I confirm that I have received formal training in the safe handling of non-cytotoxic intrathecal and intraventricular injections. This has included:

- Training on all potential clinical hazards associated with non-cytotoxic intrathecal and intraventricular injections
- Training on all relevant policies relating to non-cytotoxic intrathecal and intraventricular injections
- Completion of an assessment to the required level for the task involved
- Demonstration of competency to the required level for the task involved

I am aware that I am now authorised to perform the following tasks **only** (delete tasks not authorised):

Receipt of stock from wholesaler:
- Receive deliveries of non-cytotoxic intrathecal and intraventricular injections from the wholesaler

Issue from an intrathecal/intraventricular medication request form:
- Issue non-cytotoxic intrathecal and intraventricular injections when ordered on an order form
- Check non-cytotoxic intrathecal and intraventricular injections when ordered on an order form
- Package non-cytotoxic intrathecal and intraventricular injections when ordered on an order form
- Hand out non-cytotoxic intrathecal and intraventricular injections to authorised personnel from pharmacy
- Delivery of non-cytotoxic intrathecal and intraventricular injections to authorised personnel in the relevant clinical area

Issue from a prescription:
- Verify prescriptions for non-cytotoxic intrathecal and intraventricular injections
- Prepare non-cytotoxic intrathecal and intraventricular injections

- Check and release of non-cytotoxic intrathecal and intraventricular injections

In clinical areas:

- Collection of non-cytotoxic intrathecal and intraventricular injections from the storage area
- Prescribing of non-cytotoxic intrathecal and intraventricular injections
- Preparation of non-cytotoxic intrathecal and intraventricular injections
- Verification of non-cytotoxic intrathecal and intraventricular injections as a second checker for administration
- Administration of non-cytotoxic intrathecal and intraventricular injections

I confirm that I have read and understood all of the relevant guidelines and protocols and that I will comply with the policy.

Signature of Trainee: _____ Date: _____

I am satisfied that the above pharmacist/ pharmacy technician has read and understood the relevant training and has now been included on the NHS Grampian Non-Cytotoxic Intrathecal and Intraventricular Injections Register.

Signature of Supervisor: _____ Date: _____

Reassessment of competence is required every 2 years.
Reassessment Date: _____

Appendix 5: Intrathecal/ Intraventricular Antibiotic Prescription and Administration Record

Private & Confidential

Intrathecal/Intraventricular Antibiotic Prescription and Administration Record

NHS Grampian

TO BE COMPLETED IN BLACK INK ONLY

Patient Details		Prescribing / Administration:
Surname	Community Health Index (CHI)	• Only staff registered on the intrathecal/intraventricular register may prescribe, administer and check intrathecal/intraventricular medication
Forename	Date of Admission dd mm yyyy	• Wherever possible, intrathecal/intraventricular doses must be prescribed and administered at different times from all other medication prescribed by injection route, e.g. intravenous bolus doses.
Address	Prescription No	• Scheduling of intrathecal/intraventricular therapy must take into account the availability of relevant, trained staff.
	Date Re-written dd mm yyyy Male ☐ Female ☐	
Postcode	Hospital / Ward / Other	
or affix patient label	Consultant GP	

Allergies • Refer to main Prescription and Administration Record before prescribing and administration of medicines

Indication for Intrathecal/Intraventicular : Duration : or 'Must be reviewed daily'

Date	Time	Medication	Dose	Route	Prescribed by sign and print name	Batch Number / Expiry Date	Date Given	Time Given	Administered by sign and print name	Checked by sign and print name
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	:									
	:									
	:									
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Version 1 — All sections of this record MUST be completed

SAMPLE

Indication for Intrathecal/Intraventicular :						Duration : or 'Must be reviewed daily'				
Date	Time	Medication	Dose	Route	Prescribed by sign and print name	Batch Number / Expiry Date	Date Given	Time Given	Administered by sign and print name	Checked by sign and print name
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Version 1	All sections of this record MUST be completed									

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