NHS GREATER GLASGOW AND CLYDE POLICY FOR THE MANAGEMENT OF NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS

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PREFACE

This policy was produced in response to the NHS HDL (2006) 11 – Guidance on the Safe Handling of Intrathecal and Intraventricular Injections, Scottish Executive Health Department (February 2006) and is based on the NHSGGC Cytotoxic Intrathecal Chemotherapy Policy.

This policy contains information relevant to the implementation of the recommendations of this HDL and was originally produced by a short-life multidisciplinary implementation groups for NHS Greater Glasgow and Clyde (NHSGGC) in 2009. A list of the original contributors can be found at the end of the document.

It is the responsibility of the Designated Lead for each specialty or clinical area to ensure compliance with this policy and to ensure that Registers of Personnel are forwarded to the Heads of Profession annually.

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NHS Greater Glasgow & Clyde Policy for the Management of Non-Cytotoxic Intrathecal and Intraventricular Injections (NCIIIs)

Contents

Additional local information must be readily available for each Specialty or Clinical Area and must include the following:

A Formal Intrathecal and Intraventricular Staff Induction Policy, which must contain:
- All potential clinical hazards associated with intrathecal and intraventricular injections
- A formal local assessment to ensure all relevant staff, including locums, have read and understood this document and other relevant guidelines and protocols

Local Relevant Information on the Use of NCIIIs that contains as a minimum, guidance on:
- Training
- Prescribing
- Preparation
- Transportation
- Storage
- Checking
- Administration
- Monitoring

1. Context

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

The safe use of intrathecal and intraventricular injections is a high priority requiring stringent risk management. As a result, the Scottish Executive Health Department issued **HDL(2006)11 – Guidance on the Safe Handling of Intrathecal and Intraventricular Injections in February 2006** for non-cytotoxic intrathecal and intraventricular injections (NCIIIs) and requested full implementation of this national guidance with immediate effect.[1]

The recommendations contained within this document have numerous implications and build on the recommendations of two previous publications: HDL(2004)30 Guidance on the Safe Administration of Intrathecal Cytotoxic Chemotherapy,[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 Greater Glasgow and Clyde (NHSGGC) 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 where possible, NCIIIs should be made under aseptic conditions in pharmacy. This is not currently possible for many reasons, however work is ongoing to ensure the products associated with the highest risk are outsourced in a ready-to-administer form or made in pharmacy where possible to ensure patient, staff and environmental safety.

Adherence to this document will minimise the risk to patients receiving intrathecal or intraventricular injections within the hospitals of NHSGGC.

References:

1. Scottish Executive Health Department NHS HDL(2006)11 – Guidance on the Safe Handling of Intrathecal and Intraventricular Injections, 16 February 2006, http://www.show.scot.nhs.uk/sehd/mels/HDL2006_11.pdf.
2. Scottish Executive Health Department NHS HDL(2004)30 – Safe Administration of Intrathecal Cytotoxic Chemotherapy, 2 June 2004, http://www.show.scot.nhs.uk/sehd/mels/HDL2004_30.pdf.
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, http://www.scotland.gov.uk/Resource/Doc/46932/0013922.pdf

2. Purpose and Scope

2.1 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 be potentially fatal. It must be read and used in conjunction with the following information sources:

- **HDL(2006)11, Guidance on the Safe Handling of Intrathecal and Intraventricular Injections, 16 February 2006, Scottish Executive Health Department.**
- **Additional local information for each individual specialty or clinical area which covers all additional details and arrangements relevant to the specialty or clinical area, for example, training programmes or details of designated areas where NCIIIs will be administered.**

2.2 **Only specialties or clinical areas within NHSGGC that are authorised to use NCIIIs are listed in Appendix 1. Use of NCIIIs in each specialty or clinical area will be the responsibility of the Designated Lead. This will be the lead consultant for the specialty, service or area, or a nominated deputy who will also be a doctor of consultant grade. Education, training, maintenance of registers of authorised personnel, local policies for the relevant area, and competency checks and reviews, will be the responsibility of the Designated Lead. Nominated leads for pharmacy and nursing may also be named to assist with the implementation, management and monitoring of this policy, and local on-site pharmacy contacts will be listed to assist with local issues.**

2.3 This policy provides a framework for each specialty or clinical area using NCIIIs and will cover:

- Who is the Designated Lead for the specialty or clinical area
- Who are the Nominated Pharmacy and Nursing Leads
- Who can do what
- What specialties and clinical areas are authorised to use NCIIIs in NHSGGC
- What NCIIIs are authorised for use in these specialties and clinical areas, their licensed status, authorised doses and dose ranges (Appendix 1)
- Where NCIIIs can be given
- Key documents such as national guidance and local protocols
- Key requirements, procedures and controls required to eliminate or minimise hazards associated with the use of NCIIIs

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

- Intrathecal injection – an intrathecal injection (often simply called "intrathecal") is an injection into the spinal canal (intrathecal space surrounding the spinal cord), as in a spinal anaesthesia
- Intraventricular injection – an injection of a drug for diffusion throughout the ventricular and subarachnoid space by means of ventricular puncture.
- Licensed medicine – a medicine with a Marketing Authorisation (formerly known as a Product License) granted by the Medicines and Healthcare Products Regulatory Authority (MHRA) which signifies that the medicine meets the appropriate quality standards and is safe and efficacious for its designated use.
- Unlicensed medicine – a medicine with no Marketing Authority for any formulation or indication in the UK.
- Off-label medicine – a licensed medicine used outwith the terms of its Marketing Authorisation.

2.5 Within this document “registered” means being trained, certified competent and authorised by the Designated Lead for the specialty or clinical area within NHSGGC to undertake the appropriate task(s) set out within this policy. “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 the NCIII Register within NHSGGC to undertake the appropriate task(s) set out within this policy. These training details will be recorded on the relevant NCIII Register and Competency Certificates. Sample registers can be found in Appendix 2 and 3 respectively, however some specialist areas may have their own and which may be maintained electronically.

2.6 For the purpose of this policy the Heads of Professions are the Lead Director for Acute Medical Services, Head of Nursing and Head of Pharmacy and Prescribing Support Unit (PPSU).

2.7 **Medical, nursing or pharmacy staff, or other relevant healthcare professional group may only train, prescribe, prepare, order, supply, transport, store, check or administer NCIIIs if they are:**

- **Authorised to do so by their Designated Lead**
- **Trained and certified as competent for the relevant task(s)**
- **Registered on the NCIII Register**
- **Using an NCIII as outlined in Appendix 1**

The information contained within Appendix 1 is <u>not</u> transferable between different specialties or clinical areas ie if you are an authorised prescriber of one NCIII in one specialty/clinical area, you are <u>not</u> automatically authorised for prescribing this agent in another specialty/clinical area.

2.8 Medical, nursing or pharmacy staff, or other relevant healthcare professional group, other than those set out in point 2.7 above, may <u>not</u> under normal circumstances train, prescribe, prepare, order, supply, transport, store, check or administer NCIIIs.

Any practitioner wishing to use an NCIII via the intrathecal or intraventricular route not authorised in Appendix 1, in a dose or in an area not authorised in Appendix 1, must make an application in writing in advance of use – refer to section 3.7 for further information.

2.9 All practitioners must be familiar with the licensed status of the NCIIIs they are authorised to use and comply with the NHSGGC Unlicensed Medicines Policy where applicable (Refer to Staffnet).

2.10 All NCIIIs should be outsourced as a ready-to-administer preparation or be prepared by pharmacy giving appropriate notice in advance, unless they are being prepared in near-patient areas in anaesthetics or in other pre-arranged circumstances. If the NCIIIs are prepared within pharmacy, it must be done by pharmacy staff registered on the NCIII Register.

2.11 If NCIIIs cannot be outsourced as a ready-to-administer preparation or be prepared in pharmacy, then the relevant task(s) ie order, supply, transport, store, prepare, check or administer NCIIIs, must only be undertaken by staff named on the NCIII Register who are trained and certified competent for the task(s) involved.

2.12 Pharmacy will <u>not</u> supply NCIIIs or medicines thought to be given by the intrathecal or intraventricular route if there is evidence of potential non-compliance with this policy or if there is any ambiguity over orders, prescriptions or requests for NCIIIs.

3. Statement of Policy

3.1 General Points

3.1.1 All relevant staff such as medical, pharmacy, nursing, theatre staff and any other staff group involved in any way with the use of NCIIIs, must be aware of this policy and understand its impact on practice.

3.1.2 All staff involved in the use of NCIIIs must receive the appropriate training according to their role, as agreed with the Designated Lead for the specialty or clinical area.

3.1.3 Patients should receive NCIIIs only in agreed designated areas within Operating Theatres, Critical Care Areas and Specialist Units (unless in exceptional circumstances or emergencies) within NHSGGC. If the Consultant in charge of the patient decides that the patient cannot be moved to an agreed designated area to receive the NCIIIs then this variance must be noted in the patient's case notes. All other aspects of this policy must be adhered to eg only staff registered on the NCIII Register may train, prescribe, prepare, order, supply, transport, store, check or administer NCIIIs.

3.1.4 Policies must be readily available at all times to all members of staff involved in the use of NCIIIs and the Heads of Professions. This will be the responsibility of the Designated Lead for each clinical area.

3.2 Education and Training

3.2.1 All medical, pharmacy, nursing and other relevant staff must receive training appropriate to their level of involvement through formal induction programmes. All groups of staff must be made aware at the very minimum of all potential clinical hazards associated with NCIIIs and of the potentially fatal consequences associated with the inadvertent or incorrect administration of NCIIIs.

3.2.2 Although the training of staff will be the responsibility of the Designated Lead for each clinical area, they may delegate the training to named medical, nursing and pharmacy trainers.

3.2.3 Trainer and trainee should formally document the training. The training will cover theory and practice. Training will be deemed complete when the trainer signs a competency certificate (Appendix 3). The trainee's competency certificate will be sent by the trainer to the relevant Designated Lead for the clinical area for inclusion in the appropriate section of the NCIII Register.

3.2.4 The Heads of Profession, or nominated deputy, will have overall responsibility to ensure that the NCIII Register of trained staff for their professional group is maintained.

3.2.5 The Designated Lead for each clinical area will make arrangements for the current version of the NCIII Register to be sent to the Heads of Profession, or nominated deputy, on an annual basis or before if required.

Medical Training

3.2.6 Medical training will be undertaken by practitioners registered on the NCIII Register appointed by the Designated Lead.

3.2.7 Only medical staff above FY2 grade can be trained to train, prescribe, prepare, order, supply, transport, store, check or administer NCIIIs.

3.2.8 The training, approved by the Designated Lead, will include theory and practical training.

3.2.9 Registration on the NCIII Register will be reviewed for medical staff on an annual basis as part of their annual appraisal and in-service training assessment.

3.2.10 The medical trainers will send a copy of the trainee's competency certificate to the Designated Lead for each clinical area for inclusion in the appropriate section of the NCIIIs Register.

Pharmacy Training

3.2.11 Pharmacy training will be undertaken by practitioners registered on the NCIII Register appointed by the Nominated Pharmacy Lead.

3.2.12 Pharmacy staff will be trained as appropriate to train, verify, prepare, dispense, order, supply, transport, store, check or issue NCIIIs.

3.2.13 The training, approved by the Nominated Pharmacy Lead will include theory and practical training.

3.2.14 Registration on the NCIII Register will be reviewed for pharmacy staff on an annual basis as part of their annual appraisal and in-service training assessment.

3.2.15 The pharmacy trainers will send a copy of the trainee's competency certificate to the Nominated Pharmacy Lead for inclusion in the appropriate section of the NCIIIs Register.

Nurse Training

3.2.16 Nurse training will be undertaken by practitioners registered on the NCIII Register appointed by the Nominated Nursing Lead.

3.2.17 Only nursing staff, registered on the NCIII Register, working within designated areas, can be trained to train, prepare, order, supply, transport, store, check or administer NCIIIs. All other nursing staff, working within designated areas, must be familiar with this policy. Medical or nursing staff on the NCIII Register will be authorised to provide an independent double-check for the administration of NCIIIs. In exceptional circumstances only, an independent second-check can be carried out by a qualified senior nurse or member of medical staff of Registrar grade or above.

3.2.18 The training, approved by the Nominated Nursing Lead, will include theory and practical training.

3.2.19 The nurse trainers will send a copy of the trainee's completion certificate to the Nominated Nursing Lead for inclusion in the appropriate section of the NCIII

Register.

3.2.20 Registration on the NCIII Register will be reviewed for nursing staff on an annual basis as part of their annual appraisal and in-service training assessment.

3.3 Prescribing

3.3.1 All prescriptions for NCIIIs must be clearly written or printed in full and signed by a member of medical staff named on the NCIII Register authorised for this task. This includes all medicines used for treatment and diagnostic imaging.

3.3.2 NCIIIs should be prescribed on the patient's main prescription chart. If it is not possible to record prescribing, preparation or administration to the required level of detail on the main prescription chart or the anaesthetic chart, then the agents must be prescribed on an additional pre-printed NCIII prescription chart, which contains no other drug prescriptions and is authorised for use by the Designated Lead, refer to the additional local information for each specialty or clinical area for further details. If NCIIIs are to be prepared in pharmacy, then the agent(s) must be requested on the relevant NCIII Pharmacy Request Form, clearly written or printed in full, and the dose/concentrations required must be clearly stated in words and figures and signed by a member of medical staff named on the NCIII Register. Contact your Nominated Pharmacy Lead for copies of this request form.

3.3.3 The prescription must clearly state the route of administration, ie **INTRATHECAL,** which must be written in full. Abbreviations are <u>not</u> acceptable.

3.3.4 Where possible, NCIIIs must be prescribed at different times to other injections. Where this is not possible, NCIIIs must be kept separate to other injections in a designated locked area to avoid the risk of selecting the wrong preparation.

3.3.5 Only NCIIIs and doses in line with approved local prescribing protocols and authorised in Appendix 1 may be prescribed and used in NHSGGC.

3.3.6 All prescriptions for NCIIIs prepared in pharmacy, must be verified and clinically checked by a pharmacist named on the NCIII Register to ensure the prescription is appropriate, and that the details are correct when compared to the protocol and the patient's clinical parameters. If a clinical pharmacist is not available, the request will be verified and technically checked by a pharmacist on the NCIII Register who must only authorise dispensing and supply if the prescription is appropriate, clear and unambiguous. Extra steps should be taken to confirm the appropriateness for the patient eg check previous dispensing history, check prescribing protocols where available, check local registers of dose/dose ranges for each patient. The pharmacist must sign the NCIII Pharmacy Request Form or prescription.

3.4 Preparation, Issue, Transportation and Storage of NCIIIs from Pharmacy

NCIIIs should be outsourced in a ready-to-administer form or be prepared in pharmacy wherever possible, however it is recognised that this is not feasible in a number of settings and situations.

3.4.1 For NCIIIs Prepared within Pharmacy

3.4.1.1 NCIIIs which require preparation or manipulation on a specific named patient basis must be requested on the NCIII Pharmacy Request Form. If any of the NCIIIs requested on this form are Controlled Drugs, then the Controlled Drug Order Book must also be completed and sent with the NCIII Pharmacy Request Form.* If the authorised signatory for Controlled Drugs is not registered on the NCIII Register, then the Controlled Drug Order Book must also be signed by a named individual on the NCIII Register. **Each order must state that the drug is for INTRATHECAL use.**

*Depends on local policy, some sites may not insist on additionally sending the Controlled Drug Order Book as long as the audit trail can be fully completed by other means.

3.4.1.2 All NCIIIs requested on an NCIII Pharmacy Request Form for Pharmacy Preparation, must be verified by a pharmacist authorised and registered to perform this task (refer to 3.3.6). All calculations must undergo an independent double-check by a second pharmacist authorised for this task and named on the NCIII Register.

3.4.1.3 NCIIIs must be prepared, dispensed or issued from the pharmacy aseptic department by trained pharmacy staff named on the NCIIIs Register.

3.4.1.4 All NCIIIs must be labelled: **"FOR INTRATHECAL USE ONLY" in the largest font sized possible and emboldened.** The syringe should be over-wrapped and labelled: **"FOR INTRATHECAL USE ONLY**. Do not remove outer wrapper until immediately prior to use".

3.4.1.5 All NCIIIs must be contained in primary packing highlighting that the product is different from intravenous or other injectable drugs.

3.4.1.6 Final release of NCIIIs must be performed by an authorised pharmacist named on the NCIIIs Register.

3.4.1.7 If **not** for immediate use, NCIIIs must be stored in pharmacy in a clearly defined, separate location from intravenous or other injectable medicines.

3.4.1.8 NCIIIs should **not** be stored in ward/theatre/clinic areas unless under exceptional circumstances. They may be ordered in advance from pharmacy but will **not** be issued until the day or time that they are required. Any exceptions must have written approval from the Designated Lead.

3.4.1.9 NCIIIs prepared in pharmacy must be issued by a pharmacist named on the NCIIIs Register.

3.4.1.10 Pharmacists will only issue the NCIIIs to a named member of staff that is trained and registered to administer NCIIIs on the NCIII Register. The pharmacist must check the training status of the staff with the register held in the pharmacy before releasing the NCIIIs. Pharmacists issuing the NCIIIs and the staff collecting the NCIIIs must sign the NCIII Pharmacy Request Form.

3.4.1.11 If a member of staff on the NCIII Register cannot collect the NCIIIs, the registered pharmacist issuing the NCIIIs may organise delivery of NCIIIs to the registered doctor or nurse administering the NCIIIs. This must occur just prior to the administration of the NCIII. Under no circumstances can any other medicines be handed over at the same time. The issuing pharmacist must receive a signature from the registered doctor or nurse administering the NCIII. After being issued from pharmacy, NCIIIs must **not** be stored in the ward area and must be used immediately unless authorised to maintain stocks of NCIIIs. Alternatively, the NCIIIs can be delivered by pharmacy portering staff to named healthcare professional on the NCIII Register. A consignment note must be completed and signed by the named individual on the NCIII Register.

3.4.1.12 NCIIIs will not be supplied out-of-hours, unless there is a local agreement to do so. If a local agreement exists or where a potential need for emergency supplies has been identified, then this must be outlined in the supportive local information for the specialty or clinical area and be authorised by the Designated Lead and Nominated Pharmacy and Nursing Leads. NCIIIs can only be supplied by a member of staff on the NCIII register who is authorised to perform the relevant task(s).

3.4.2 For NCIIIs Requiring Preparation or Manipulation in Clinical Areas

3.4.2.1 NCIIIs or medicines to be administered via the intrathecal or intraventricular route, not requiring manipulation in pharmacy, should be ordered from pharmacy using either a Controlled Drug Order Book or a Pharmacy Requisition. This must state clearly that the medicine is for **INTRATHECAL** administration, which must be signed by a member of medical staff named on the NCIII Register and if a Controlled Drug, the Controlled Drug Order Book must be signed by an authorised signatory.

3.4.2.2 NCIIIs to be administered via the intrathecal or intraventricular route must **not** be stored in ward/theatre areas unless authorised to do so in Appendix 1, refer to 3.4.3.

3.4.2.3 NCIIIs should be prepared by a member of staff named on the NCIII Register or be in training working under the supervision of a member of staff authorised and registered to perform the task involved. The calculations and preparation must be **independently double-checked** by a second member of staff named on the NCIII Register. If the NCIII is prepared in the clinical area, it must be prepared and administered by the same person.

3.4.2.4 All NCIIIs must be clearly identifiable at all stages of preparation and administration.

3.4.2.5 Pharmacists will only issue the NCIIIs to a named member of staff that is trained and registered to administer NCIIIs on the NCIII Register. The pharmacist must check the training status of the staff with the register held in the pharmacy before releasing the NCIIIs. Pharmacists issuing the NCIIIs and the staff collecting the NCIIIs must sign NCIII Pharmacy Request Form.

3.4.2.6 All NCIIIs must be administered immediately on receipt unless authorisation has been given to maintain small stocks of NCIIIs within the designated clinical area (see 3.4.3).

3.4.2.7 NCIIIs will not be supplied out-of-hours, unless there is a local agreement to do so. If a local agreement exists or where a potential need for emergency supplies has been identified, then this must be outlined in the additional local information for the specialty or local area and must be authorised by the Designated Lead and Nominated Pharmacy and Nursing Leads. NCIIIs can only be supplied by a member of staff on the NCIII register who is authorised to perform the relevant task(s).

3.4.3 Storage of NCIIIs

A limited number of areas are authorised to maintain small stocks of named preparations for logistical reasons or for emergencies (Appendix 1). This list is not modifiable and no other area is authorised to stock any NCIIIs without application in writing as outlined in section 3.7.

3.5 Administration

3.5.1 A consultant or nominated deputy named on the NCIII Register must review patients before NCIIIs are administered. This is to ensure that the patient is fit for treatment, the correct tests have been conducted, the correct NCIII has been prescribed and that arrangements have been clearly made for the NCIII to be administered by staff named on the NCIII Register.

3.5.2 If technically difficult then another medical practitioner can position the needle in the intrathecal space but the NCIII must be administered by a doctor registered on the NCIII Register to administer.

3.5.3 Scheduling of NCIIIs must take into account the availability of trained and registered staff. Should registered staff be unavailable, the procedure must be delayed.

3.5.4 NCIIIs must be prepared (where applicable) and administered in the designated local areas within NHSGGC.

3.5.5 Whenever possible, outpatient NCIIIs should be administered on a separate visit from administration of other injections. However due to distance some outpatients may be scheduled to receive NCIIIs and other injectable medicines on the same day but there must be significant separation in time between the administrations.

3.5.6 The registered practitioner administering the NCIIIs must explain the nature of the procedure, the route of administration and the drug to be administered to the patient, obtaining the appropriate consent. The registered practitioner administering the NCIII must sign the appropriate section of the prescription chart.

3.5.7 The NCIIIs prescription chart must be present with the NCIIIs at the time of administration.

3.5.8 Two members of staff, one of which must be named on the NCIII Register, ie doctor/doctor or doctor/nurse, must always **independently** double-check the following details of all NCIIIs before administration and record the checks on the NCIIIs prescription chart:

- Patient's name, date of birth and patient unit number
- The drug name
- The drug dose
- The drug volume
- The route of administration (ie intrathecal)
- The drug expiry date

3.5.9 The administering registered practitioner and checker must also sign the "given by/checked by" section of the standard prescribing system.

3.6 Medication Incidents and Local Anaesthetic Toxicity

3.6.1 All medication incidents relating to the use of NCIIIs, which includes medication errors, near-miss events and adverse drug reactions, **MUST** be reported immediately via Datix (available via Staffnet). The Designated Lead must also be informed. If the medication incident is significant, then the NHSGGC Significant Clinical Incident Policy (available via Staffnet) must be followed.

3.6.2 In the rare event that a patient develops local anaesthetic toxicity, guidance is available from The Association of Anaesthetists of Great Britain and Ireland: Guidelines for the Management of Severe Local Anaesthetic Toxicity (available via www.aagbi.org, or http://www.aagbi.org/sites/default/files/la_toxicity_2010_0.pdf and http://www.aagbi.org/sites/default/files/la_toxicity_notes_2010_0.pdf). This guidance should be readily available and supplies of Intralipid® 20% should be maintained as a potential antidote.

3.7 Application to Amend the NHSGGC Authorised List of NCIIIs, Specialties or Clinical Areas, or to Request a New NCIII for Use in NHSGGC

3.7.1 Medical, nursing or pharmacy staff, or other relevant healthcare professional group, other than those set out in point 2.7, may not under normal circumstances train, prescribe, prepare, order, supply, transport, store, check or administer NCIIIs.

Medical, nursing, or pharmacy staff, or other relevant healthcare professional group, other than those set out in point 2.7, who wish to use an NCIII not already authorised in Appendix 1, must submit a request in writing in advance of use, with supporting evidence and with an Unlicensed Medicines Request Form, where appropriate, to the Designated Lead for their specialty or clinical area and the Leads for Implementation (Appendix 1). The Designated Lead should consult with Nominated Pharmacy and Nursing leads before making a decision on whether to approve or not approve any requests. This decision will be formally authorised by the appropriate Clinical Director, who retains overall responsibility; and in the case of a high-cost unlicensed medicine, Directorate approval must also be obtained from the Lead Medical Director and Directorate General Manager (or nominated deputies). Please refer to the Unlicensed Medicines Policy (available via Staffnet), for further information.

This includes, for example:

- use of a new agent via the intrathecal or intraventricular route not already listed and authorised in Appendix 1
- use of an NCIII already listed in Appendix 1 for an additional condition
- use of an NCIII already listed in Appendix 1 but in a different formulation or strength
- use of an NCIII already listed in Appendix 1 at a dose or dose range not already outlined
- use of an NCIII already listed in Appendix 1 but within a different specialty or clinical area
- request maintenance of local stocks of NCIIIs for logistical or emergency purposes

3.8 Conclusions and Professional Responsibilities

3.7.1 The intrathecal or intraventricular administration of NCIIIs is an extremely high-risk procedure. This policy must be adhered to at all times. Deviations from this policy must be relayed to the Designated Lead and the Leads for Implementation:

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3.7.2 If any member of staff has any doubts regarding their responsibility, they should immediately contact their Designated Lead to seek clarification, and if necessary, further training.

3.7.3 Any member of staff who judges that the policy is not being adhered to or who considers that the action of an individual may cause potential risk to a patient, must challenge that individual in order to ensure patient safety. If required the staff member may report their concerns to their line manager and seek clarification before the procedure is undertaken.

3.7.4 The care of patients depends on adherence to this policy and the untiring vigilance of all relevant staff.

4. Roles in the prescribing, supply and administration of NCIIIs in NHSGGC

4.1 Lead Director for Acute Medical Services:

- Implementation and compliance with NHS HDL(2006) 11, Guidance on the Safe Handling of Intrathecal and Intraventricular Injections
- Receive a copy of the local training policy and NCIII Register on at least an annual basis from the Designated Lead for each specialty or clinical area

4.2 Designated Lead for Each Specialty or Clinical Area:

- Implementation and compliance with medical issues within NHS HDL(2006) 11, Guidance on the Safe Handling of Intrathecal and Intraventricular Injections
- Review the content and compliance with the policy, the training and the NCIII Register for medical staff on an annual basis and confirm in writing the conclusions of the review to the Lead Director for Acute Medical Services
- Approve requests, following consultation with Nominated Pharmacy and Nursing leads, for the use of NCIIIs other than those listed within the policy and obtain final authorisation from the Clinical Director
- Provide written approval for the prescribing, preparation or administration of NCIIIs other than those listed within the policy
- Provide written approval for a member of staff other than those listed in the policy to prescribe, prepare or administer NCIIIs
- Provide written approval, following final authorisation from their Clinical Director, for small stocks of NCIIIs to be stored in clinical areas, where appropriate.
- Appoint trainers and approve the content of training
- Maintain the NCIII Register for medical staff
- Arrange for the current version of the NCIII Register to be sent to the Lead Director for Acute Medical Services, the relevant Heads of Professions, the nurse in charge of each designated clinical area and each hospital site Pharmacy Manager on an annual basis

4.3 Head of PPSU (or nominated deputy):

- Implementation and compliance with the pharmacy issues within NHS HDL(2006) 11, Guidance on the Safe Handling of Intrathecal and Intraventricular Injections
- Work with the Lead Director for Acute Medical Services to give approval for the prescribing, preparation, administration or supply of NCIIIs other than those listed in the policy
- Appoint pharmacy trainers and approve the content of pharmacy training
- Maintain the NCIII Register for pharmacy staff
- Review the content and compliance of pharmacy staff with the policy, the pharmacy training and the NCIII Register for pharmacy staff on an annual basis and confirm in writing the conclusions of the review to the Lead Director for Acute Medical Services

4.4 Head of Nursing (or nominated deputy):

- Implementation and compliance with the nursing issues within NHS HDL (2006) 11, Guidance on the Safe Handling of Intrathecal and Intraventricular Injections
- Work with the Lead Director for Acute Medical Services to give approval for nurses to check the administration of NCIIIs
- Work with the Lead Director for Acute Medical Services to give approval for nurses to check the administration of NCIIIs for a Consultant in specialties other than those listed in the policy
- Appoint nurse trainers and approve the content of nurse training
- Maintain the NCIII Register for nursing staff
- Review the content and compliance of nursing staff with the policy, the nurse training and the NCIII Register for nurses on an annual basis and confirm in writing the conclusions of the review to the Lead Director for Acute Medical Services.

4.5 Medical:

- Arrange date of administration.
- Review compliance with the NCIII policy
- Prescribe the NCIII
- Collect or receive the NCIII from the pharmacist (if prepared in pharmacy)
- Prepare the NCIII
- Review patient before the NCIII is administered
- Check NCIII details in accordance with the policy before administration
- Administer the NCIII
- Provide support and education to patients before, during and after administration of NCIII as required

4.6 Pharmacy:

- Verify the NCIII prescription
- Prepare and dispense the NCIII where applicable
- Issue the NCIII
- Provide support and education to patients before, during and after administration of NCIII as required

4.7 Nursing:

- Check NCIII details in accordance with the policy before administration
- Provide support and education to patients before, during and after administration of NCIII as required
- Arrange date of administration
- Collect/receive NCIIIs from pharmacy where applicable
- Prepare NCIII where applicable
- Review patient before the NCIII is administered
- Administer NCIII
- Refer to medical staff if any problems occur

Original Contributors:

Multidisciplinary Short-Life Working Group:	
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Gail Caldwell	Pharmacy Manager GGH and Lead Pharmacist, Specialist Oncology and Cardiorespiratory Services, NHSGGC
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Rakesh Kishore	Senior Clinical Pharmacist, Surgery, GRI
Frances Mann	Aseptic Services Manager, SGH
Carol Mitchell	Specialist Pharmacist, Haemato-Oncology, Paediatrics, Yorkhill Hospitals
Jennifer Murphy	Senior Clinical Pharmacist, Critical Care / Pain Management, VI

Appendix 1

NHSGGC Register of Authorised Specialties/Clinical Areas, NCIIIs, Dose Ranges and Upper Limits

Available via Staffnet:

http://www.ggcmedicines.org.uk/media/uploads/policies/section_11/intrathecal_non-chemo_register_-_2014.pdf

Appendix 2

NHSGGC Registers for Non-Cytotoxic Intrathecal and Intraventricular Injections

- Anaesthetics Medical Staff
- Non-Anaesthetics Medical Staff
- Pharmacy Staff
- Nursing Staff

NHS GREATER GLASGOW AND CLYDE

NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS REGISTER

REGISTER OF ANAESTHETICS MEDICAL STAFF AUTHORISED TO TRAIN, PRESCRIBE, PREPARE AND ADMINISTER 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	PREPARE	ADMINISTER			

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

NHS GREATER GLASGOW AND CLYDE

NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS REGISTER

REGISTER OF MEDICAL STAFF AUTHORISED TO TRAIN, PRESCRIBE, PREPARE AND ADMINISTER INTRATHECAL AND/OR INTRAVENTRICULAR INJECTIONS

NAME & DESIGNATION:	**ASSESSED BY, INCLUDE NAME & DESIGNATION:** This person must be trained and certified competent in the prescribing, preparation and administration of all medicines listed below.
MEDICINES, OR CATEGORY OF MEDICINES COVERED:	**CLINICAL INDICATION FOR MEDICINE, OR CATEGORY OF MEDICINE:**

AUTHORISED TO: Please tick appropriate column(s)				**DATE CERTIFIED:**	**REASSESSMENT DATE:**
TRAIN	**PRESCRIBE**	**PREPARE**	**ADMINISTER**		

NHS GREATER GLASGOW AND CLYDE

NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS REGISTER

REGISTER OF PHARMACY STAFF AUTHORISED TO MANAGE INTRATHECAL AND/OR INTRAVENTRICULAR INJECTIONS

NAME & DESIGNATION:	AUTHORISED TO: Competency assessor please initial appropriate column(s):										COMPETENCY ASSESSED BY*: Include name and designation	DATE ASSESS-ED:	RE-ASSESS-MENT DATE:
	For orders going through distribution:				For orders going through aseptic:								
	Train	Authorise Indent	Enter and Pick	Check and Issue	Train	Verify	Assemble Trays and Labels	Check Tray and Labels	Prepare	Final Check and Issue			

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

NHS GREATER GLASGOW AND CLYDE

NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS REGISTER

REGISTER OF NURSING STAFF AUTHORISED TO RECEIPT, TRAIN, PREPARE AND ADMINISTER 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:
	RECEIPT/ COLLECT	TRAIN	PREPARE/ ADMINISTER	MONITOR			

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

Appendix 3

NHSGGC Certificates of Competency for Non-Cytotoxic Intrathecal and Intraventricular Injections

- Medical Staff
- Pharmacy Staff
- Nursing Staff

NHS GREATER GLASGOW AND CLYDE

NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS

CERTIFICATE OF COMPETENCY – MEDICAL STAFF

This documentation must be completed by an authorised medical trainer, nominated by the Lead Director for Acute Medical Services (or deputy), that is named and certified competent on the NHS Greater Glasgow and Clyde 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
- Receipt of non-cytotoxic intrathecal and intraventricular injections on delivery
- Prescribing of non-cytotoxic intrathecal and intraventricular injections
- Preparation of non-cytotoxic intrathecal and intraventricular injections
- 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 Greater Glasgow and Clyde Non-Cytotoxic Intrathecal and Intraventricular Register.

Signature of Supervisor: _____ Date: _____

Reassessment of competence is required annually. Reassessment Date: _____

NHS GREATER GLASGOW AND CLYDE

NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS

CERTIFICATE OF COMPETENCY – PHARMACY STAFF

This documentation must be completed by an authorised pharmacy trainer, nominated by the Head of Pharmacy and Prescribing Support Unit (or deputy), that is named and certified competent on the NHS Greater Glasgow and Clyde Non-Cytotoxic Intrathecal and Intraventricular Injections Register.

Name of Trainee: _____

Pharmacist ☐ **Technician** ☐ **Assistant** ☐ **Porter** ☐

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 (delete issues not relevant):

- 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:

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

Issue from a pharmacy indent:

- Authorise pharmacy indents for non-cytotoxic intrathecal and intraventricular injections
- Issue non-cytotoxic intrathecal and intraventricular injections when ordered on a pharmacy indent
- Check non-cytotoxic intrathecal and intraventricular injections when ordered on a pharmacy indent
- Issue of non-cytotoxic intrathecal and intraventricular injections from pharmacy to authorised personnel
- 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
- Preparation of non-cytotoxic intrathecal and intraventricular injections
- Check and release of non-cytotoxic intrathecal and intraventricular injections

Deliver:

- Deliver to a nominated and pre-arranged individual that is named on the register.

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 member of staff has read and understood the relevant training and has now been included on the NHS Greater Glasgow and Clyde Non-Cytotoxic Intrathecal and Intraventricular Register for the task(s) listed above.

Signature of Supervisor: _____ Date: _____

Reassessment of competence is required annually. Reassessment Date: _____

NHS GREATER GLASGOW AND CLYDE

NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR INJECTIONS

CERTIFICATE OF COMPETENCY – NURSING STAFF

This documentation must be completed by an authorised nursing trainer, nominated by the Head of Nursing (or deputy), that is named and certified competent on the NHS Greater Glasgow and Clyde 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
- Receipt of non-cytotoxic intrathecal and intraventricular injections on delivery
- Preparation of non-cytotoxic intrathecal and intraventricular injections
- Administration of non-cytotoxic intrathecal and intraventricular injections
- Monitoring non-cytotoxic intrathecal and intraventricular injection sites

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 Greater Glasgow and Clyde Non-Cytotoxic Intrathecal and Intraventricular Register.

Signature of Supervisor: _____ Date: _____

Reassessment of competence is required annually. Reassessment Date: _____