

**GREATER GLASGOW AND CLYDE HOSPITALS
DIVISION (GG&C)**

**POLICY FOR THE
PRESCRIBING, SUPPLY AND
ADMINISTRATION OF
CYTOTOXIC INTRATHECAL
CHEMOTHERAPY**

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Review Date: December 2014

Last Update: December 2011

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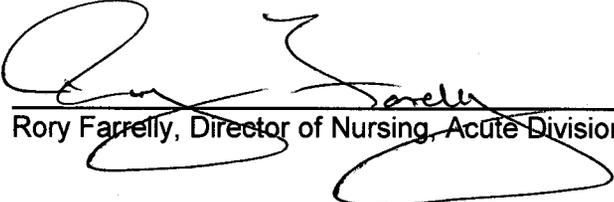
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This policy will be reviewed by the GG&C Cancer Therapeutics Group in 2014.

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The annual checklist has been removed. Please refer to the updated checklist in the most recent CEL http://www.sehd.scot.nhs.uk/mels/CEL2009_21.pdf . This CEL supersedes NHS HDL (2004) 30

1. Context

In the UK, at least 13 patients have died or been paralysed due to errors associated with the inappropriate administration of cytotoxic chemotherapy by the intrathecal route. These errors occurred as a result of a number of failures in the systems associated with the prescribing, supply and administration of cytotoxic chemotherapy.

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

This document complies with the Scottish Government Health Directorates policy document “Safe Administration of Intrathecal Cytotoxic Chemotherapy”, *CEL 21 (2009)*.

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 route is very likely to be fatal.
- 2.2 For the purposes of this policy an intrathecal cytotoxic is an agent given by intrathecal injection as part of an approved cytotoxic chemotherapy protocol (i.e. methotrexate, cytarabine and hydrocortisone). All staff must be aware that there is a risk of confusion between standard cytarabine and liposomal cytarabine (*Depocyte*). See www.npsa.nhs.uk/health/alerts for further information.
- 2.3 Within this document “registered” means being trained and certified as competent by NHSGGC hospitals to undertake the appropriate tasks set out within this policy. These training details will be recorded on the NHSGGC Intrathecal Register (Appendix 1).
- 2.4 For the purpose of this policy the Heads of Professions are the Acute Division Medical Director, the Head of Pharmacy and Prescribing Support Unit (PPSU) and the Acute Division Nurse Director.
- 2.5 Only medical staff who are registered on the NHSGGC Intrathecal Register and are therefore trained and certified competent in intrathecal chemotherapy treatment may prescribe and administer intrathecal chemotherapy.
- 2.6 Other drugs may also be administered intrathecally in the management of CNS infection (gentamicin, flucloxacillin, ampicillin, vancomycin or benzylpenicillin). Intrathecal baclofen is used in the management of spasticity; and opioids +/- adjunctive agents may also be administered intrathecally for pain control. Although this policy does not specifically deal with these other areas, the good practice points stated within should be considered relevant to the prescribing and administration processes involved. Please refer to policies for intrathecal use of non-chemotherapy, see *Staffnet Clinical Guidelines*. Intrathecal use of unlicensed medicines must follow the Board unlicensed medicines policy and be supported by written evidence.
- 2.7 A Consultant in haematology or oncology wishing to prescribe or administer to any patient in NHSGGC any intrathecal chemotherapy other than those set out in point 2.2

above must set out their requirements in writing with supportive evidence. This information will be passed to the Clinical Director (Specialist Oncology Services, SoS) and to the area Lead Clinical Pharmacist (LCP) for Cancer. The Clinical Director will liaise with the LCP to collate all the issues. The NHSGGC Regional Services Directorate (RSD) Associate Medical Director, working with the RSD Lead Directorate Pharmacist and RSD Lead Nurse, must give written approval before the treatment is prescribed, supplied and administered.

- 2.8 Consultants in specialties other than haematology and oncology may not under normal circumstances prescribe intrathecal chemotherapy. If they wish to do so they must set out their requirements in writing, with supportive evidence. This information should be passed to their relevant Clinical Director, Lead Directorate Pharmacist (LDP), Lead Nurse and the Clinical Director (SoS) who will liaise with each other to collate all the issues. The relevant Associate Medical Director, working with their LDP and Lead Nurse, must give written approval before the treatment is prescribed, supplied and administered. Only medical staff registered on the NHSGGC Intrathecal Register may prescribe and administer the intrathecal chemotherapy.
- 2.9 All intrathecal chemotherapy must be prepared and dispensed in pharmacy by pharmacy staff registered on the NHSGGC Intrathecal Register. Pharmacy staff will only issue intrathecal chemotherapy to named medical staff who are on the NHSGGC Intrathecal Register and who is the administering doctor.
- 2.10 Pharmacy will not supply intrathecal chemotherapy if there is evidence of potential non-compliance with this policy.
- 2.11 Compliance with this policy (i.e. completion of the checklist) will be reviewed annually by the Lead Clinical Pharmacists (Cancer Care) and the findings reported in writing to the Heads of Professions and the Associate Medical Director (Regional Services). The content will be reviewed by NHSGGC Cancer Therapeutics Group every 2 years.

3. Statement of policy

3.1 General Points

- 3.1.1 All relevant staff namely, medical, pharmacy, nursing, theatre staff and any other staff group involved in any way with the prescribing, verification, supply and administration of chemotherapy for cancer treatment or intrathecal cytotoxic chemotherapy specifically, must be aware of this policy and understand its impact on practice.
- 3.1.2 All staff involved in the prescribing, verification, supply and administration of intrathecal chemotherapy must receive the appropriate training according to their role, as agreed with their Head of Profession.
- 3.1.3 Patients should receive intrathecal chemotherapy only in designated areas within NHSGGC. The following areas which are designated for intrathecal use should be used whenever possible
 - Intrathecal chemotherapy room, Beatson, WoSCC

- Ward 24 intrathecal chemotherapy treatment room, Southern General Hospital
- Intrathecal chemotherapy room, Clinic P, New Victoria Hospital
- Single room, ward 1, Royal Alexandra Hospital
- Daycare Unit intrathecal chemotherapy room, Yorkhill Hospital
- Schiehallion ward treatment room, Yorkhill Hospital
- Theatre Suite, Yorkhill Hospital

There are occasions when patients require intrathecal chemotherapy to be given out with the areas detailed above. For instance during an anaesthetic, or when radiological assessment is required to aid in needle placement or patients who require specialist nursing such that they may not be moved. It is the responsibility of the Consultant Haematologist or Oncologist to ensure that all staff within the unit are aware of the policy and comply with it. In these instances the following areas within any NHSGGC acute services site may be used.

- Theatre suites
- X ray suites
- ITU suites

In exceptional circumstances after discussion between the Consultant in charge of the patient and the Consultant Haematologist or Oncologist, registered on the NHSGGC Intrathecal Register, it is decided that the patient cannot be moved to one of the above designated areas to receive the intrathecal cytotoxic chemotherapy then this variance must be noted in the patient's case notes. The Associate Medical Director, Regional Services must be informed in writing of this decision. All other aspects of this policy must be adhered to e.g. only staff registered on the NHSGGC Intrathecal Register may administer and check the intrathecal chemotherapy. For example, if the patient has an Ommaya Reservoir in-situ, the administering doctor and registered checker may take the intrathecal drug to the patient's bedside for administration.

3.1.4 This policy will be available to all members of staff involved in the prescribing, verification, supply and administration of intrathecal chemotherapy, the Heads of Professions and the Chief Executive via the *Clinical Guidelines* section on Staffnet. A copy should be kept in all areas where chemotherapy is prescribed, verified, prepared and administered.

3.2 Training

3.2.1 All medical, pharmacy, nursing and other relevant staff must receive training appropriate to their level of involvement in the prescribing, verification, supply and administration of intrathecal chemotherapy. All groups of staff must be made aware of the potentially fatal consequences associated with the inadvertent administration of intravenous chemotherapy via the intrathecal route.

3.2.2 Although the training of staff will be the responsibility of the Heads of Professions, they may delegate the training to named medical, pharmacy and nursing 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 certificate of competence. The trainee's certificate will be sent to the relevant Head of

Profession or deputy by the trainer for inclusion in the appropriate section of the NHSGGC Intrathecal Register.

- 3.2.4 The Heads of Professions or named deputies will maintain the NHSGGC Intrathecal Register of trained staff for their professional group.
- 3.2.5 The Clinical Director (Specialist Oncology Services) will make arrangements for the current version of the NHSGGC Intrathecal Register to be sent to the Chief Executive, the Acute Services Medical Director, the Head of PPSU, the Acute Services Nurse Director, the nurse in charge of each of the administration sites listed in 3.1.3 and the Lead Directorate Pharmacist (Regional Services).

Medical Training

- 3.2.6 Medical training will be undertaken by medical trainers in co-operation with a named Consultant in Haematology or Oncology for each site. The medical trainers will be appointed by the Clinical Director (SoS) and must be on the NHSGGC register.
- 3.2.7 Only consultants, associate specialists, staff grades and specialist trainees in year 3 and above (ST3) in Haematology or Oncology can be trained to prescribe and administer cytotoxic intrathecal chemotherapy. No doctor below the level of haematology/oncology ST3 should be trained to prescribe or administer intrathecal chemotherapy.
- 3.2.8 The training, approved by the Clinical Director (SoS), will include theory and practical training.
- 3.2.9 An individual who has previously been registered with NHSGGC as competent, but has allowed this to lapse will be deemed competent after being supervised placing the LP needle and administering intrathecal chemotherapy on at least one occasion by an individual who is already named on the NHSGGC register. In addition they must score 100% in the MCQs.
- 3.2.10 The medical trainers will send a copy of the trainee's certificate of competence to the Clinical Director (SoS) or nominated deputy for inclusion in the appropriate section of the NHSGGC Intrathecal Register.
- 3.2.11 Trained medical staff must be reassessed every 2 years by registered medical trainers in order to remain on the register. This will include completion of the MCQ's with 100% score and evidence of at least one completed intrathecal procedure. The documentation must be sent to the Clinical Director (SoS) or nominated deputy to indicate compliance.

Pharmacy Training

- 3.2.12 Pharmacy training will be undertaken by pharmacy trainers. The pharmacy trainers will be appointed by the Head of PPSU or deputies (Lead Clinical Pharmacists, Cancer Care). The Lead Clinical Pharmacists will train clinical pharmacists only. All other pharmacy staff and those involved in transport will be trained by the Lead Pharmacist Preparative Services or nominated deputy.
- 3.2.13 Pharmacists and pharmacy technicians will be trained as appropriate to verify, prepare, dispense and issue cytotoxic intrathecal chemotherapy. Only pharmacists may verify intrathecal chemotherapy. Pharmacists and technicians may issue intrathecal chemotherapy to the administering doctor.
- 3.2.14 The training, approved by the Head of PPSU or deputies, will include theory and practical training.
- 3.2.15 The pharmacy trainers will send a copy of the trainee's certificate of competence to the Head of PPSU or deputies for inclusion in the appropriate section of the NHSGGC Intrathecal Register.
- 3.2.16 Trained pharmacy staff will be reassessed every 2 years by registered pharmacy trainers. This will include completion of the MCQ's with 100% score and evidence of one completed intrathecal task appropriate to the staff member. The documentation must be sent to the Lead Clinical Pharmacist for clinical pharmacists or Lead Pharmacist Preparative Services for all other pharmacy staff to indicate compliance.

Nurse Training

- 3.2.17 Nurse training will be undertaken by nurse trainers. Nurse trainers will be appointed by the Directorate Head of Nursing and approved by the Acute Services Nurse Director.
- 3.2.18 All chemotherapy-trained nurses working within those areas identified under 3.1.3 of this policy will be trained to check the administration of cytotoxic intrathecal chemotherapy.
- 3.2.19 The training, approved by the Directorate Head of Nursing, will include theory and practical training.
- 3.2.20 The nurse trainers will send a copy of the trainee's completion certificate to the Acute Services Nurse Director or nominated deputy for inclusion in the appropriate section of the GG&C Intrathecal Register.
- 3.2.21 Trained nursing staff will be reassessed every 2 years by registered trainers. This will include completion of the MCQ's with 100% score and evidence of at least one completed intrathecal checking procedure. The documentation must be sent to the Directorate Head of Nursing to indicate compliance.

3.3 GG&C Intrathecal Register

The Administrator of the register will maintain the register. A copy of the certificate of competence must be sent to the Administrator for new staff and reassessment of existing staff. The certificate must state the date that registration expires.

- 3.3.1 The GG&C register will contain three sections one for each discipline, medical, nursing and pharmacy.
- 3.3.2 It will state the first date that the individual was registered within GG&C and the date that the individual's authorisation to prescribe/verify/prepare/administer etc. expires.
- 3.3.3 An individual whose authorisation has expired will be removed from the register and have to be reassessed.
- 3.3.4 It is the responsibility of the nominated deputy for each professional group on each site to ensure that the register is kept up to date. They must inform the Administrator of the register of any changes.
- 3.3.5 A current copy of the register will be posted on the NHSGGC intranet to ensure that all staff can check to ensure that their own status and that of their colleagues is valid at the time of carrying out the intrathecal procedure.
- 3.3.6 It is the responsibility of each individual to ensure that their details on the register are correct and up to date.

3.4 Prescribing

- 3.4.1 All prescriptions for intrathecal chemotherapy must be clearly written and signed by a consultant, specialist registrar, specialist trainee in year 3 or above (ST3), associate specialist or staff grade in haemato-oncology/oncology named on the NHSGGC Intrathecal Register.
- 3.4.2 Intrathecal drugs must be prescribed on the NHSGGC standardised pre-printed intrathecal drug prescription chart, which contains no other drug prescriptions. Only one dose may be prescribed on each prescription form.
- 3.4.3 Only doses in line with approved NHSGGC chemotherapy prescribing protocols may be prescribed. Copies of all chemotherapy prescribing protocols should be lodged in pharmacy.
- 3.4.4 All prescriptions for intrathecal chemotherapy must be verified by a cancer care clinical pharmacist named on the NHSGGC register to ensure the prescription details are correct when compared to the protocol and patient's clinical parameters. The clinical pharmacist must sign the intrathecal prescription form.

3.5 Preparation and Dispensing

- 3.5.1 Intrathecal chemotherapy must only be prepared in and issued from the pharmacy aseptic department by trained pharmacy staff named on the NHSGGC Intrathecal Register.
- 3.5.2 All intrathecal chemotherapy 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”
- 3.5.3 All intrathecal chemotherapy must be contained in primary packing highlighting that the product is different from intravenous drugs.
- 3.5.4 Final release of intrathecal chemotherapy must be performed by an authorised pharmacist named on the NHSGGC Intrathecal Register.
- 3.5.5 If not for immediate use, intrathecal chemotherapy doses must be stored in a clearly defined, separate location in pharmacy from intravenous doses of chemotherapy according to local procedure. Storage at ward level is not permitted. In exceptional cases intrathecal chemotherapy for paediatric patients may be stored in a locked fridge out with pharmacy which is used for this purpose only. No other drugs may be stored in this fridge. Only staff named on the intrathecal register may have access to this fridge.

3.6 Issue, transportation from pharmacy and storage

- 3.6.1 Intrathecal chemotherapy must only be issued by a pharmacist or technician named on the NHSGGC Intrathecal Register (the *issuer*).
- 3.6.2 Intrathecal chemotherapy will only be issued to doctors trained and registered to administer intrathecal chemotherapy on the NHSGGC Intrathecal Register. The issuer must check the training status of the doctor with the register held in the pharmacy before issuing the intrathecal chemotherapy. Pharmacy staff issuing the intrathecal chemotherapy and the doctor collecting the intrathecal chemotherapy must both sign the intrathecal drug prescription chart.
- 3.6.3 The doctor collecting the chemotherapy can **ONLY** be supplied with the intrathecal chemotherapy. Under **NO** circumstances can any other medicines, in particular chemotherapy, be handed over at the same time even if the medicine is for a different patient.
- 3.6.4 If the administering doctor cannot collect the intrathecal chemotherapy from pharmacy, the registered issuer may deliver the intrathecal chemotherapy directly to the registered doctor administering the intrathecal chemotherapy. They may not carry any

other medicines under any circumstances, in particular chemotherapy. This must occur just prior to the administration of the intrathecal chemotherapy and be taken directly to the designated area for administration. The issuer must receive a signature from the registered doctor administering the intrathecal chemotherapy.

- 3.6.5 At sites where the aseptic unit is remote from the clinical area where administration will take place, arrangements can be made for the transportation of intrathecal chemotherapy to the clinical area by trained pharmacy staff. This must be approved by Head of PPSU. Staff must be trained appropriately for this task and must be signed off as suitable by the registered pharmacy trainer. There must be a SOP for transportation of intrathecal drugs and for dealing with a spillage. Intrathecal chemotherapy must always be transported separately from treatments for administration by other routes. The intrathecal chemotherapy should be transported directly to the clinical area and given only to the doctor who is to administer the drug. The staff member transporting the drug must sign appropriate paperwork and obtain the signature of the doctor on receipt to ensure a full audit trail. The drug will be transported in an outer packaging suitable for the transport of cytotoxics which is different from any container used for other chemotherapy (preferably in both colour and size).

NB Under no circumstances is it permissible to store intrathecal chemotherapy for in the clinical area. If the intrathecal chemotherapy is not going to be used immediately it **MUST** be returned to pharmacy. If the procedure is unsuccessful pharmacy must be informed immediately and arrange removal of the intrathecal dose which must be returned to pharmacy for destruction.

In exceptional circumstances intrathecal chemotherapy for paediatric patients may be stored in a locked fridge reserved solely for this purpose. See section 3.5.5.

3.7 Administration

- 3.7.1 A consultant or nominated deputy named on the NHSGGC Intrathecal Register must review patients before intrathecal chemotherapy is administered. This is to ensure that the patient is fit for treatment, the correct tests have been conducted, the correct chemotherapy regimen has been prescribed and that arrangements have been clearly made for the chemotherapy to be administered by medical staff named on the NHSGGC Intrathecal Register.
- 3.7.2 Only oncology/haemato-oncology consultants, specialist registrars, specialist trainees year 3 and above, associate specialists or staff grades will be trained and registered on the NHSGGC Intrathecal Register to administer intrathecal chemotherapy.
- 3.7.3 If technically difficult then another medical practitioner can position the needle in the intrathecal space but the intrathecal chemotherapy must be administered by a doctor registered on the NHSGGC Intrathecal Register to administer. The doctor administering the intrathecal chemotherapy must be satisfied that the needle is positioned correctly and must be assisted by a nurse also registered on the NHSGGC Intrathecal Register.

- 3.7.4 Scheduling of intrathecal chemotherapy must take into account the availability of trained and registered staff. Should registered staff be unavailable, the intrathecal procedure must be delayed.
- 3.7.5 ONLY in exceptional circumstances should intrathecal chemotherapy be required out-of-hours i.e. after 5pm or at weekends. In this event the Consultant registered on the NHSGGC Intrathecal Register must contact the on-call pharmacist. The on-call pharmacist must arrange for the intrathecal chemotherapy to be verified, prepared and issued by pharmacy staff registered on the NHSGGC Intrathecal Register. The intrathecal chemotherapy must be administered and checked by staff registered on the NHSGGC Intrathecal Register. This should be recorded as a clinical incident.

In paediatric areas routine and planned intrathecal chemotherapy must be administered by 5pm. A local procedure must be in place for returning unused intrathecal chemotherapy if the procedure is unsuccessful.

- 3.7.6 Intrathecal chemotherapy must be administered in the designated areas within NHSGGC as defined in 3.1.3 above.
- 3.7.7 When intrathecal chemotherapy is being administered, the area should not be used for any other purpose. Under no circumstances should any other cytotoxic chemotherapy be stored in this area.
- 3.7.8 For adults, intrathecal chemotherapy and intravenous bolus chemotherapy or vinca alkaloid infusions **MUST** never be administered at the same time. Intrathecal chemotherapy and vinca alkaloid infusions may not be administered to the same patient on the same day. **In-patients** should not be scheduled to receive intravenous bolus chemotherapy and intrathecal chemotherapy on the same day; **out-patients** may be scheduled to receive intravenous and intrathecal chemotherapy on the same day, but pharmacy should only issue the intrathecal dose when they have confirmed from the administration record that the intravenous dose has been administered.

In paediatrics, in exceptional cases, intravenous bolus chemotherapy may be administered before intrathecal chemotherapy. Intrathecal chemotherapy must **NEVER** be administered on the same day as vinca alkaloids.

- 3.7.9 The doctor administering the intrathecal chemotherapy must explain the nature of the procedure, the route of administration and the drug to be administered to the patient. The doctor should take written consent from the patient and document this in the case notes. The administering doctor must sign the appropriate section of the intrathecal prescription chart. The patient should be given an information leaflet.

Example of patient information can be found at:

<http://www.cancerbackup.org.uk/Treatments/Chemotherapy/Lumbarpuncture>

- 3.7.10 The intrathecal prescription chart must be present with the intrathecal chemotherapy at the time of administration.

3.7.11 Two members of staff named on the NHSGGC Intrathecal Register i.e. doctor/doctor or doctor/nurse, must always check the following details of all intrathecal chemotherapy before administration and record these checks on the intrathecal prescription chart:

Patient's name, date of birth and unit number/CHI number

The drug name

The drug dose

The drug volume

The route of administration (i.e. intrathecal)

The drug expiry date.

In addition, the administering doctor and registered checker must record both signatures and printed names on the intrathecal chemotherapy prescription form.

3.7.12 The administering doctor and registered checker named on the NHSGGC Intrathecal Register must also initial the "given by/checked by" section of the standard chemotherapy prescribing system e.g. Kardex.

3.7.13 A copy of every intrathecal chemotherapy prescription form should be stored in pharmacy to allow regular audit of compliance with the policy.

3.8 Conclusions and professional responsibilities

3.8.1 The intrathecal administration of cytotoxic chemotherapy is an extremely high-risk procedure. All staff involved in the care and treatment of patients receiving intrathecal chemotherapy must ensure that this policy is adhered to at all times. Deviations from this policy are not acceptable and may lead to disciplinary action.

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

3.8.3 Any member of staff who judges that this 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.

3.8.4 The care of patients depends on the untiring vigilance of all relevant staff. In all instances, delays are preferable to deviations from this policy. Any deviation from this policy must be reported as a clinical incident.

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

4.1 Chief Executive

- Implementation and compliance with NHS CEL 21 (2009), Safe administration of intrathecal cytotoxic chemotherapy.

4.2 NHSGGC Board Medical Director

- Implementation and compliance with medical issues within NHS CEL 21 (2009), Safe administration of intrathecal cytotoxic chemotherapy.
- Provide written approval for the prescribing or administration of intrathecal chemotherapy not approved by the Cancer Therapeutics Group.
- Provide written approval for a consultant in specialties other than haematology or oncology to request intrathecal chemotherapy.

4.3 Clinical Director (Specialist Oncology Services)

- Appoint medical trainers and approve the content of medical training.
- Appoint a named deputy to maintain the NHSGGC Intrathecal Register for medical staff for each site.
- Arrange for the current version of the NHSGGC Intrathecal Register to be sent to the Chief Executive and the relevant Heads of Professions.

4.4 Head of Pharmacy and Prescribing Support Unit (PPSU)

- Implementation and compliance with the pharmacy issues within NHS CEL 21 (2009), Safe administration of intrathecal cytotoxic chemotherapy.
- Work with the Acute Services Medical Director and relevant members of the review group to give approval for the supply of intrathecal chemotherapy not approved by the Cancer Medicines Group.
- Work with the Acute Services Medical Director and relevant members of the review group to give approval for the supply of intrathecal chemotherapy for a consultant in specialties other than haematology or oncology.
- Appoint named deputies (Lead Pharmacists for Cancer and Preparative Services) as pharmacy trainers and to maintain the NHSGGC Intrathecal Register for pharmacy staff for each site and approve the content of pharmacy training.

4.5 Acute Services Nurse Director

- Implementation and compliance with the nursing issues within NHS CEL 21 (2009), Safe administration of intrathecal cytotoxic chemotherapy.
- Work with the Acute Services Medical Director to give approval for nurses to check the administration of intrathecal chemotherapy not approved by the Cancer Medicines Group.
- Work with the Acute Services Medical Director to give approval for nurses to check the administration of intrathecal chemotherapy for a consultant in specialties other than haematology or oncology.
- Appoint nurse trainers and approve the content of nurse training.
- Appoint a named deputy to maintain the NHSGGC Intrathecal Register for nursing staff for each site.

4.6 Medical staff

- ❑ Arrange date and time of administration.
- ❑ Review compliance with the chemotherapy treatment protocol.
- ❑ Prescribe the intrathecal chemotherapy.
- ❑ Review patient before the intrathecal chemotherapy is administered.
- ❑ Collect or receive the intrathecal chemotherapy from the pharmacy.
- ❑ Take written consent from patient
- ❑ Check intrathecal chemotherapy details with an intrathecal trained nurse/ doctor in accordance with the policy before administration.
- ❑ Administer the intrathecal chemotherapy.
- ❑ Provide support and education to patients before, during and after administration of intrathecal chemotherapy as required.

4.7 Pharmacy staff

- ❑ Verify the intrathecal chemotherapy prescription.
- ❑ Prepare and dispense the intrathecal chemotherapy.
- ❑ Issue the intrathecal chemotherapy.
- ❑ Provide support and education to patients on intrathecal chemotherapy as required.

4.8 Nursing staff

- ❑ Check intrathecal chemotherapy details with an intrathecal trained doctor in accordance with the policy before administration.
- ❑ Provide support and education to patients before, during and after administration of intrathecal chemotherapy as required.

4.9 Administrator of the Register

- ❑ Enter staff details on the electronic register on receipt of a certificate of competence.
- ❑ Maintain the electronic register
- ❑ Issue staff whose registration is due to expire a warning via email 3 months in advance of the expiry date

Appendix 1

NHS Greater Glasgow and Clyde Hospitals Intrathecal Register – Example

GREATER GLASGOW & CLYDE HOSPITALS ACUTE DIVISION

Intrathecal Register-Nursing Staff

Register of nursing staff authorised to train and check the administration of intrathecal chemotherapy.

NAME Surname, forename	Train	Check	Supervisor	First date certified	Expiry date

VALID UNTIL _____ or otherwise superseded (destroy if superseded)

Appendix 2

Medical Training Plan for Intrathecal Chemotherapy Prescribing and Administration

All NHS facilities providing intrathecal chemotherapy treatment must introduce and maintain a register of designated personnel who have been trained and certified competent to prescribe, verify, dispense, check and administer intrathecal chemotherapy. Individuals placed on the register will have to have demonstrated that they are competent to fulfil their designated role, and have been certified as such.

Essential Reading:

- Safe Administration of Intrathecal Cytotoxic Chemotherapy. Scottish Government Health Directorates NHS CEL 21 (2009) http://www.sehd.scot.nhs.uk/mels/CEL2009_21.pdf
- Greater Glasgow and Clyde Policy for Prescribing, Supply and Administration of Cytotoxic Intrathecal Chemotherapy.

Recommended reading:

- The prevention of intrathecal medication errors. (The Kent Woods Report) Department of Health London. <http://www.dh.gov.uk/assetRoot/04/06/50/49/04065049.pdf>
- Report of an Independent Investigation into the Death of a Teenager from an Intrathecal Injection Error at the Queen's Medical Centre, Nottingham. Professor Brian Toft. http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4010064&chk=00u5YE

All new consultants involved with intrathecal chemotherapy, haematology/oncology specialist registrars (SpR), ST3 and above training grades and haematology staff grades who will be involved in the prescribing and/or administration of intrathecal chemotherapy must complete training in intrathecal chemotherapy and be assessed to be competent to fulfil their designated role. Once certified as competent they will be placed on the NHSGGC Intrathecal Register of medical staff competent to prescribe and/or administer intrathecal chemotherapy and may carry out this role when required. All staff on the register must be re-accredited every 2 years.

Training plan

Trainee is defined as a medically qualified individual who is not on the NHSGGC Intrathecal Register and is undergoing training prior to inclusion.

- The trainee must read this policy and complete an assessment with their assigned trainer (a Consultant whose name appears on the intrathecal register).
- All trainees must undergo formal training in the administration of intrathecal chemotherapy and be certified as competent by their trainer.

This will be:

- A minimum of observing one procedure carried out by SpR, staff grade or Consultant
- Carrying out one procedure under supervision of a Consultant to a satisfactory standard
- A score of 100% in the MCQ's (A score <100% requires candidates to repeat the assessment).
- Successful completion of intrathecal administration training.

Ongoing accreditation

- A score of 100% in the MCQs.
- Position the needle and administer the intrathecal chemotherapy on at least one occasion since the last assessment i.e. once every two years.

Appendix 3

Medical Certificate of Competence for Training, Prescribing and Administration of Intrathecal Chemotherapy

Trainee name.....

Grade.....

For new staff, the individual being trained must initially observe at least one intrathecal chemotherapy administration and then, under appropriate supervision, administer at least one intrathecal chemotherapy to a satisfactory standard.

Date	Supervising doctor	Grade	Notes
			First administration - observation only
			Final supervised administration – sign-off

First observation administration can be performed by any trained doctor registered on the GG&C Intrathecal Register, but supervised administration and sign-off must be by a Consultant registered on the GG&C Intrathecal Register.

I(print) Medical Supervisor certify that
.....has achieved the required level of proficiency in the administration of intrathecal chemotherapy and has an understanding of the GG&C Policy for the prescribing, supply and administration of intrathecal chemotherapy.

.....(signature) Medical Supervisor (Consultant)

Date/...../.....

Trainee

I have undertaken the specified training for medical staff for the prescribing and administration of intrathecal chemotherapy and agree to have this training recorded on the GG&C Intrathecal Register held by the Medical Director and for the information to be supplied to other staff groups in accordance with GG&C Intrathecal policy

Name.....

Grade.....

Signature..... **Date**/...../.....

Appendix 4

Pharmacy Training in the Provision of Intrathecal Cytotoxic Chemotherapy

All NHS facilities providing intrathecal chemotherapy treatment must introduce and maintain a register of designated personnel who have been trained and certified competent to prescribe, dispense, check and administer intrathecal chemotherapy. Individuals placed on the register will have to have demonstrated that they are competent to fulfil their designated role, and have been certified as such.

Essential Reading:

- Safe Administration of Intrathecal Cytotoxic Chemotherapy. Scottish Government Health Directorates NHS CEL 21 (2009) http://www.sehd.scot.nhs.uk/mels/CEL2009_21.pdf
- Greater Glasgow and Clyde Policy for Prescribing, Supply and Administration of Cytotoxic Intrathecal Chemotherapy.

Recommended reading:

- The prevention of intrathecal medication errors. (The Kent Woods Report) Department of Health London. <http://www.dh.gov.uk/assetRoot/04/06/50/49/04065049.pdf>
- Report of an Independent Investigation into the Death of a Teenager from an Intrathecal Injection Error at the Queen's Medical Centre, Nottingham. Professor Brian Toft. http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4010064&chk=O0u5YE

Pharmacy staff for entry onto the register will be categorised as follows:

Pharmacy Support Worker: All Pharmacy Support Workers taking part in the preparation of intrathecal chemotherapy where this has been approved.

Pharmacy Technician: All technicians taking part in the preparation and issue of intrathecal chemotherapy.

Authorised Pharmacist: All pharmacists required to release or issue intrathecal chemotherapy.

Clinical Pharmacist: All pharmacists required to verify intrathecal chemotherapy prescriptions.

It should be noted that both Authorised Pharmacist and Clinical Pharmacist may issue intrathecal chemotherapy.

Prior to consideration for intrathecal training the pharmacy staff member must have undergone the following training as appropriate:

Pharmacy Support Worker: completion of local training plan or equivalent

Pharmacy Technician: completion of local training plan or equivalent

Authorised Pharmacist: completion of local aseptic pharmacist training plan

Clinical Pharmacist: completion of local training plan on prescription verification.

All pharmacy staff involved in the provision of the aseptic or cancer clinical pharmacy services will be trained via the pharmacy intrathecal training manual upon completion of the basic training programs.

Appendix 5

Pharmacy Certificate of Competence for the Training, Verification, Preparation, Release and Issue of Intrathecal Chemotherapy

Trainee name.....

Scope of remit (P/T)

Date	Trainer	P/T	Notes
			Demonstrate understanding of policy
			Practical demonstration of task

I(name of registered trainer)

certify thathas demonstrated:

- a satisfactory level of understanding of the GG&C Policy for the Prescribing, Supply and Administration of Intrathecal Chemotherapy and
- is competent to train/verify/prepare/release/issue (delete as appropriate) intrathecal chemotherapy according to the GG&C policy and pharmacy procedures.

.....(signature, trainer)

Date:...../...../.....

Trainee

I have undertaken the specified training for pharmacy staff in training/verification/preparation/ release/issue (delete as appropriate) of intrathecal chemotherapy and agree to have this training recorded on a data base held by the Head of Pharmacy and Prescribing Support Unit (or authorised deputy) and for the information to be supplied to other staff groups in accordance with the NHSGGC Policy

Name.....

Designation.....

Signature.....

Date/...../.....

Appendix 6

Pharmacy Certificate of Competence for the Transport of Intrathecal Chemotherapy

Trainee name.....

Scope of remit.....

Date	Trainer	Grade	Notes
			Demonstrate understanding of SOP
			Practical demonstration of task

I(name of registered trainer)

certify thathas demonstrated:

- a satisfactory level of understanding of the GG&C Policy for the Prescribing, Supply and Administration of Intrathecal Chemotherapy and
- is competent to transport intrathecal chemotherapy according to the GG&C policy and pharmacy procedures.

..... (signature, trainer)

Date:...../...../.....

Trainee

I have undertaken the specified training for pharmacy staff for transport of intrathecal chemotherapy and agree to have this training recorded on a data base held by the Head of Pharmacy and Prescribing Support Unit (or authorised deputy) and for the information to be supplied to other staff groups in accordance with the NHSGGC Policy

Name.....

Designation.....

Signature.....

Date/...../.....

Appendix 7

Final version March 2012

Nurse Training Plan to Check the Administration of Intrathecal Chemotherapy

All NHS facilities providing intrathecal chemotherapy treatment must introduce and maintain a register of designated personnel who have been trained and certified competent to prescribe, dispense, check and administer intrathecal chemotherapy. Individuals placed on the register will have to have demonstrated that they are competent to fulfil their designated role, and have been certified as such.

Essential Reading:

- Safe Administration of Intrathecal Cytotoxic Chemotherapy. Scottish Government Health Directorates NHS CEL 21 (2009) http://www.sehd.scot.nhs.uk/mels/CEL2009_21.pdf
- Greater Glasgow and Clyde Policy for Prescribing, Supply and Administration of Cytotoxic Intrathecal Chemotherapy.

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Recommended reading:

- The prevention of intrathecal medication errors. (The Kent Woods Report) Department of Health London. <http://www.dh.gov.uk/assetRoot/04/06/50/49/04065049.pdf>
- Report of an Independent Investigation into the Death of a Teenager from an Intrathecal Injection Error at the Queen's Medical Centre, Nottingham. Professor Brian Toft. http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4010064&chk=O0u5YE

All chemotherapy trained nursing staff working in a clinical area where intrathecal chemotherapy may be given should complete training in intrathecal chemotherapy and be assessed to be competent to fulfil their designated role according to protocol. Once certified as competent they will be placed on the trust intrathecal register and may carry out their role when required.

All staff on the register must be re-accredited every 2 years.

Training plan:

- All nursing staff will be assigned a trainer, who will be responsible for ensuring they complete the intrathecal training plan. The trainer will be a senior member of nursing staff who has completed intrathecal training, and whose name appears on the NHSGGC intrathecal register.
- All nursing staff must read the above material and complete the assessment questions – both core questions and nurse role-specific questions. A score of 100% will deem them competent to fulfil their role. A score of less than 100% will require them to re-read the supplied material and repeat the assessment.

Appendix 8

Nursing Certificate of Competence to Check the Administration of Intrathecal Chemotherapy

Trainee name.....

Grade.....

Date	Trainer	Grade	Notes
			Demonstrate understanding of policy
			Practical demonstration of task

I (name of registered trainer)

certify thathas demonstrated:

- a satisfactory level of understanding of the NHSGGC Policy for the Prescribing, Supply and Administration of Intrathecal Chemotherapy and
- is competent to check the administration of intrathecal chemotherapy in accordance with the NHSGGC policy

.....(signature registered trainer)

Date: /...../.....

Trainee

I have undertaken the specified training for nursing staff for the administration of intrathecal chemotherapy and agree to have this training recorded on the NHSGGC Intrathecal Register held by the Director of Nursing and for the information to be supplied to other staff groups in accordance with NHSGGC Intrathecal policy

Name.....

Grade.....

Signature.....

Date/...../.....

Appendix 9

Policy for vinca alkaloids

Essential reading http://www.sehd.scot.nhs.uk/mels/CEL2009_22.pdf

Since 1985 at least 13 patients in the UK have died or been paralysed as a result of the accidental intrathecal administration of vincristine which was intended for intravenous administration. **Vinca alkaloids must only be administered intravenously.** Two reports on intrathecal injections errors were published in England and Wales in April 2001. One reported on the investigation into the death of a teenager in Nottingham in 2001 and the other on a review of clinical policy and the prevention of intrathecal cancer chemotherapy errors. Both reports made important recommendations. Since these reports there have been further reports of fatal and serious incidents from outside the UK in which doses of vinca alkaloids, intended for intravenous administration, were administered by the intrathecal route in error.

The new CEL builds on the subsequent advice from the WHO, DH and NPSA and must be implemented by all NHS Boards by December 2009. A key change is the recommendation that all vinca alkaloids are administered by intravenous infusion for all adults and adolescents treated in adult or adolescent units. This must be implemented by all NHS Boards regardless of whether or not intrathecal chemotherapy is administered within the NHS Board.

The practical difficulties of preparing and administering intravenous infusions of vinca alkaloids to treat children outweigh the benefits. For this reason the use of minibags to administer vinca alkaloids to children and adolescents in children's units is NOT recommended. For children and adolescents treated in a children's unit, intravenous vinca alkaloids can be given undiluted. It is however considered good practice, as far as possible, to dilute all vinca alkaloids and dispense in a 10ml or greater syringe size.

When vinca alkaloids are prescribed for administration in adult or adolescent units:

- Doses in syringes should no longer be used.
- The prescribed dose should be supplied from the hospital pharmacy ready to administer in a 50ml minibag of sodium chloride 0.9% or glucose 5% according to stability
- The vinca minibag should be infused intravenously over 5 - 10 minutes and the patient closely monitored for signs of extravasation.
- A full risk assessment should be undertaken locally to determine the method of intravenous infusion
- Chemotherapy protocols, policies and procedures should be amended to reflect these requirements.
- Staff should be alerted and trained to follow the new practice.
- Practice should be audited to ensure compliance with the revised safety procedure.

Solutions of vinca alkaloids dispensed by pharmacy will be labelled: "For intravenous use only. Fatal if given by other routes". The syringe or bag will be over-wrapped and labelled: "Remove only at the time of injection. For intravenous use only. Fatal if given by other routes."

Extravasation and other incidents relating to the administration of vinca alkaloids that occur as a result of this guidance will be collected by the designated NHS Board Lead, summarised into quarterly reports and submitted to the national Chemotherapy Advisory Group.