## Medicines Code: Intrathecal Chemotherapy

**Prescribing, Dispensing, Administration, Checking and Supply**

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<tr>
<td><strong>Author &amp; Title:</strong></td>
<td>Rosie Simpson, Principal Pharmacist Cancer and Aseptic Services</td>
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<td><strong>Review Date:</strong></td>
<td>31 December 2015</td>
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<td><strong>Ratified by:</strong></td>
<td>Francesca Thompson Director of Nursing &amp; Accountable Officer: Controlled Drugs</td>
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<td><strong>Date Ratified:</strong></td>
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**Related Policies & Guidelines:**
- Prescribing, handling and administration of cytotoxic drugs 714
- Trust Medicines Code policies 731
- Consent Policy 728
- Management and disposal of waste 605
17. References  

Appendix 1: Induction course structure  
Appendix 2: Intrathecal chemotherapy training for persons to be entered onto the register  
Appendix 2b: Checklist for Intrathecal Chemotherapy Training  
Appendix 3: Training for specific roles  
Appendix 4: Example of written assessment  
Appendix 5: Certificate on completion of Training  
Appendix 6a: Annual Update  
Appendix 6b: Annual Checklist for Training  
Appendix 7: Intrathecal Chemotherapy Prescription Chart  
Appendix 8: Out of normal working hours  

Document Control Information  
- Ratification Assurance Statement  
- Consultation Schedule  
- Equality Impact: (A) Assessment Screening  
- Equality Impact: (B) Full Analysis  

Amendment History

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<td>18</td>
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<td>Francesca Thompson, Director of Nursing &amp; Accountable Officer, Controlled Drugs</td>
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<td>17</td>
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<td>9 December 2009</td>
<td>Review</td>
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1. Key points

- This Policy reflects the Department of Health Updated National Guidance on safe administration of intrathecal chemotherapy
- All staff involved in intrathecal chemotherapy must have received training appropriate to the role they perform and have demonstrated competency in that role
- Only staff named on the Royal United Hospital Intrathecal Chemotherapy register may participate in the provision of intrathecal chemotherapy

2. Introduction

An adverse incident occurred at the Queen’s Medical Centre in Nottingham on January 4th 2001 where vincristine was accidentally administered intrathecally to a patient with fatal consequences. This was the most recent of a series of similar incidents of maladministration of intrathecal medicines. After a detailed enquiry, the Department of Health (DH) has set out clear recommendations as to how this mistake can be avoided in the future. The DH guidance was updated in August 2008. This document has been written to provide a clear process for the safe prescribing and administration of intrathecal chemotherapy, in order to prevent the reoccurrence of errors resulting in death.

3. Purpose of this policy

The purpose of this policy is to provide guidance for staff within the Royal United Hospital, Bath NHS Trust about the requirements and processes for the prescribing, dispensing and administration of intrathecal chemotherapy. Including staff training requirements and the in process checks which must be carried out. The policy reflects the standards laid out in the Department of Health guidelines on the Safe administration of Intrathecal Chemotherapy.

There are some aspects of this policy that are more stringent that required under the most recent national guidance. This has been discussed at the Oncology Clinical Governance Meeting with agreement to continue with the more stringent controls.

This policy applies to all individuals in the employ of the Royal United Hospital Bath NHS Trust.

Failure to comply with the RUH Intrathecal Policy and Procedure can be regarded as misconduct and dealt in accordance with the Trust's Conduct Procedure. Any death
from intrathecal injection of a vinca alkaloid is likely to be subject to scrutiny under the Corporate Manslaughter & Corporate Homicide Act 2007.
Hard copies of both of these documents are available in the RUH intrathecal chemotherapy files, which are available in William Budd Ward, William Budd Day Care Unit Treatment Room, pharmacy aseptic production unit and the Oncology / Haematology Satellite Pharmacy. Copies are also available in the Oncology Management Guidelines in the Paediatric Unit adolescent treatment room and in the Intrathecal Chemotherapy file in Theatre 11 anaesthetic room this policy is also relevant to intraventricular chemotherapy.

4. Definitions

4.1. Intrathecal

The injection of a therapeutic agent (in this case a chemotherapy agent) into the sheath surrounding the spinal cord.

4.2. Intrathecal Register

An up to date list of persons; Doctors, nurses, pharmacists and pharmacy technicians, who have received training relating to intrathecal chemotherapy and achieved a required levels of competence in their area of practice and so are able to participate in the prescribing, dispensing, checking and administration of intrathecal chemotherapy according to their role.

4.3. Intrathecal Lead

Person responsible for overseeing compliance with the national guidance and the local policy. Accountable to the Chief Executive for this issue.

4.4. Lead trainer for intrathecal chemotherapy

Person/s to whom the designated lead has delegated responsibility for induction, training and continuing professional development related to intrathecal chemotherapy.
5. **Aims and Objectives of this policy**

- By adhering to this policy trust staff will ensure the safe administration of intrathecal chemotherapy.
- Administration errors which could lead to severe patient harm or death should be avoided

6. **Duties / Responsibilities**

All staff must ensure that the principles outlined within this document are universally applied.

All staff involved in the prescribing, dispensing, supply, checking and administration of intrathecal chemotherapy at the Royal United Hospital must be listed on a register to be known as the intrathecal register.

When participating in an intrathecal procedure, all staff are required to check the intrathecal registration of those healthcare professionals they are working alongside.

It is the responsibility of staff on the register to ensure that they only involve others in the process who are also on the register for relevant tasks.

Key organisational duties are identified as follows:

6.1. **Chief Executive**

Overall responsibility for ensuring compliance with the National Guidance

6.2. **Intrathecal Lead**

- Oversee compliance with the national guidance and the local policy
- Holding the intrathecal register and ensuring that it is maintained and kept up to date

6.3. **Lead Trainer for intrathecal chemotherapy**

- Two lead trainers one for the adult chemotherapy service and one for the paediatric service
- Responsible for delivering intrathecal training to all appropriate staff, including induction training, as detailed in this policy
- Approve staff entry onto the intrathecal register
6.4. Updating the intrathecal register

The senior pharmacist responsible for the satellite oncology pharmacy updates the intrathecal register and distributes copies of the updated register.

7. Monitoring Compliance

Any instance of non-compliance with this policy will be reported as a Trust incident and to the intrathecal Lead. All oncology / haematology incidents are routinely discussed at the monthly clinical governance meetings, appropriate investigations carried out and any necessary actions implemented.

Compliance will be externally monitored as part of the Cancer Peer Review Process. Any shortfall identified under this process will be reported to the Trust together with the actions which must be taken to correct the shortfall.

The policy will be audited yearly to ensure compliance by the Intrathecal lead the result of audit and actions taken being reported to Oncology / Haematology Governance committee.

8. Induction, Education and Training

- A formal induction course is provided for all oncology / haematology, nursing, medical and pharmacy staff, appropriate to the roles they will be performing and irrespective of whether that person will be on the intrathecal register or not.

- Induction should take place within the first month of joining the Trust.

- Nursing staff, anaesthetists and operating department assistants who work in Theatre 11 will also receive training regarding the process of administering intrathecal chemotherapy although they will not partake in the administration procedure.

- The structure of the induction course is outlined in Appendix 1. It considers all potential clinical hazards associated with chemotherapy and the danger posed to patients if vinca alkaloids (e.g. vincristine) are accidentally administered intrathecally.

- The induction course will be delivered by a designated lead trainer.
• All staff that are to be entered on the Trust Intrathecal Register must undergo further more detailed training as outlined in appendix 2.

• The Lead Trainer for the adult Intrathecal Chemotherapy service and the Lead trainer for the paediatric Intrathecal Chemotherapy service are responsible for delivering this training. (Appendix 2 Intrathecal training for persons entered on the intrathecal register)

• Staff must also receive training in the technical aspects of the role they are to perform from a person already on the register who carries out the same role and be assessed as competent to perform the role. (Appendix 3)

• While undergoing training, the trainee may sign the relevant sections on the intrathecal documentation (prescription chart, pharmacy worksheet etc) but the trainer, who must be on the register, must countersign all signatures.

• An assessment must be carried out to ensure staff have read and understood all relevant NHS Trust guidelines and protocols before their name can be entered on the register. (Appendix 4)

• All training must be documented on the training checklist. Having received training and achieved the required level of competency to carry out specific tasks, the training checklist will be signed off by the lead trainer. The trainee’s name is entered onto the intrathecal register for the specific tasks they are now authorized to carry out. The signed off check list is kept in the satellite pharmacy as a permanent record. The trainee is issued with a certificate for completing their training. (Appendix 5)

• All staff must have an annual update of training relating to intrathecal chemotherapy and have their competency confirmed if they are to remain on the register. It is the responsibility of each individual that they attend update training. The lead trainers are responsible for providing update training. (Appendix 6 a and b)

• All staff should challenge colleagues if, in their judgment, either protocols are not being adhered to or the actions of an individual may cause potential risk to a patient. Challenging a colleague should not be seen as adversarial, but as an additional check to improve patient safety and reduce risk. Any concerns should be discussed with the Intrathecal Lead for the Trust. The individual involved must be assessed for suitability to remain on the register.

• If a lead trainer is absent from the Trust for an extended period of time such that training is compromised the Intrathecal Lead must be notified.

• The intrathecal lead for the trust is responsible for training the lead trainers and vice versa.
9. Intrathecal Register

- The master copy of the intrathecal register is held in the satellite oncology pharmacy.

- Copies of the register are kept in the pharmacy aseptic production unit, William Budd Day Care Unit Treatment Room and on William Budd ward. They are also available in the Oncology Management Guidelines in the Paediatric Unit adolescent treatment room and in the intrathecal chemotherapy file in theatre 11 anaesthetic room.

- The senior pharmacist in charge of the satellite pharmacy unit co-ordinates the updating of the register and ensures that copies throughout the trust are kept up to date.

- Staff transferring to this hospital from another trust, must be reassessed and demonstrate their competence to this Trust before having their name added to the RUH register.

- Any person who has been removed from the RUH intrathecal register because their training has lapsed, may have their name returned to the register following successful completion of
  - Update training – if less than 3 months since removal from the register
  - Full training –if more than 3 months since removal from the register

- The Lead Trainer for Adult Chemotherapy is responsible for notifying the senior pharmacist of any changes required to the register of medical or nursing personnel responsible for prescribing, checking and administration to adults.

- The Lead Trainer for Paediatric Chemotherapy is responsible for notifying the senior pharmacist of any changes required to the register of medical or nursing personnel responsible for prescribing, checking and administration to children.

- The Lead Trainer for Adult Chemotherapy is responsible for notifying the senior pharmacist of any changes required to the register of pharmacy personnel responsible for dispensing, verifying and issuing intrathecal chemotherapy.

- The Lead trainers are also responsible for informing the senior pharmacist when staff have successfully completed their annual update training.

- To remain on the register a minimum number of one intrathecal chemotherapy operations must be performed in the previous year (see appendix 6)
10. Prescribing of intrathecal chemotherapy

- Intrathecal chemotherapy must only be prescribed by registered medical practitioners who have been assessed as competent and received specific training as per the Trust policy and are on the Trust intrathecal register.

- FT1 and FT2 grades and ST1 and ST2 grades must never prescribe intrathecal chemotherapy. ST3 grades can prescribe intrathecal chemotherapy as long as they have been appropriately trained, deemed competent and their name appears on the intrathecal register for this task.

- All intrathecal chemotherapy must be prescribed on the specific RUH Trust intrathecal prescription sheet (appendix 7).

- Methotrexate, cytarabine and hydrocortisone are the only medicines that can be prescribed for administration intrathecally.

- The word intrathecal must be written in full. The name of the medicine must also be written in full and not abbreviated.

- When a patient is to receive intravenous chemotherapy and intrathecal chemotherapy on the same day, the intravenous chemotherapy must be prescribed such that it must be administered before the intrathecal chemotherapy.

- The only exceptions that can be made to the sequencing of intravenous therapy before intrathecal chemotherapy are:
  - where intrathecal chemotherapy is to be given to children under general anaesthesia; or
  - where the paediatric protocol / regimen requires that intrathecal chemotherapy is given first.

- The prescribing doctor must ensure that appropriate pharmacy and nursing staff i.e. staff on the intrathecal register are available to perform their respective tasks in line with this policy on the date the treatment is required.
11. Prescribing of chemotherapy outside normal working hours

- Paediatric and adult Intrathecal chemotherapy will only be prescribed and administered within normal working hours; from 09.00 to 17.00 hours, Monday to Friday (excluding bank holidays). An earlier start time of 08.30 has been agreed for paediatric patients on Fridays only, to fit with availability of theatre 11. The only exceptions, which may require emergency treatment, are Central Nervous System involvement in acute leukaemia, lymphoma or malignant meningitis. The decision for out of hour’s treatment must only be undertaken by an oncology or haematology consultant directly in charge of the patient and listed on the intrathecal register. There must be a clear clinical need for this procedure to be undertaken urgently in preference to delaying it until the next working day.

- The doctor planning to administer the “outside normal working hours” intrathecal chemotherapy is responsible for ensuring that all the required staff to perform the procedure are available.

- Pharmacists and pharmacy technicians called in to dispense intrathecal chemotherapy outside normal working hours must be authorised to do so and on the Intrathecal register.

- Where a nurse on the intrathecal register is not on duty it is the responsibility of the doctor planning to administer to liaise with the nurse in charge of William Budd Ward who has access to telephone numbers of nurses on the intrathecal register.

- The prescriber must inform the designated lead for intrathecal chemotherapy on the next working day that intrathecal chemotherapy has been administered outside normal working hours and an entry must be made in the medical notes about why the situation had arisen, the actions taken and the outcome.

- It is the responsibility of the Intrathecal chemotherapy lead to keep a record in the intrathecal chemotherapy file in the oncology satellite pharmacy of any intrathecal chemotherapy administered outside normal working hours.
12. Preparation and dispensing of intrathecal chemotherapy

- Only staff that have been appropriately trained, deemed competent and whose name appears on the intrathecal register should dispense intrathecal chemotherapy drugs. For the purpose of this guidance dispensing is the activity of preparing the dose, filling the syringe and placing the syringe in the packaging ready for transport.

- Pharmacists must not authorise the dispensing of a prescription for intrathecal chemotherapy unless it is signed by a doctor authorised to prescribe and listed as such in the register.

- The pharmacist must check that the dose is appropriate in accordance with the treatment protocol.

- All doses of intrathecal medication must be diluted to 5ml with sodium chloride 0.9%, with the exception of dual or triple therapy (methotrexate, cytarabine and hydrocortisone given together) when the total volume must be 5ml.

- All doses of intrathecal medication must be dispensed in 10ml luer-slip syringes and have black blind hubs attached.

- A final check on the preparation is carried out by a pharmacist on the intrathecal register. This may take place in the aseptic unit or in the satellite oncology pharmacy.

- Following dispensing the intrathecal preparation is delivered to the satellite oncology pharmacy in the purple transport bag. It must then be placed in the lockable container under the intrathecal shelf with all the relevant documentation on the shelf to await collection or delivery for immediate administration.
13. Labelling of intrathecal chemotherapy

- Labels affixed to intrathecal preparations in the pharmacy must have contain the patient's name and the name of the product. The route of administration must be printed in bold in the largest font size possible e.g For Intrathecal Use Only

- Negative labelling (e.g."not for..... use") must never be used as this can be misleading.

14. Issuing of intrathecal chemotherapy

14.1. Issuing

- All issues of intrathecal chemotherapy must be recorded and signed for in the ‘intrathecal medicines record book’ held in the satellite pharmacy.

- Intrathecal chemotherapy must only be issued to persons on the register.

- Intrathecal preparations must be issued at different times to medicines intended for intravenous administration. The intravenous chemotherapy drugs must be issued first and administered before the intrathecal is administered. (see exemptions for paediatric patients in section 9)

- If issuing doses for 2 or more patients at the same time, each dose must be signed for separately by the issuer and collector.

- Before the intrathecal preparation is issued, the pharmacy department must see written proof that any intravenous cytotoxic drugs previously dispensed and issued as part of the same treatment cycle for that particular patient, have already been administered. This requires seeing the intravenous chemotherapy prescription. If intravenous chemotherapy is to be given by continuous infusion, the intrathecal chemotherapy must only be issued once written confirmation has been seen that the infusion has started.

14.2. Collection

- Adult intrathecal chemotherapy will be collected by the doctor on the intrathecal register who is to administer the chemotherapy.
• Paediatric intrathecal chemotherapy will be collected by the doctor who is to administer it or will be delivered by a member of the pharmacy staff, who is on the intrathecal register, to the paediatric doctor who is to administer it.

• In exceptional circumstances, when an adult patient is receiving treatment in an area of the hospital other than William Budd Ward day care consulting room eg Radiology a member of the pharmacy staff, who is on the intrathecal register, will deliver the intrathecal chemotherapy to the doctor who is to administer it.

• Release of all intrathecal medicines must be signed for by the member of pharmacy staff and by the doctor receiving the intrathecal medicines in the appropriate section of the intrathecal prescription chart.

14.3. Transporting

• Medicines to be administered by the intrathecal route must always be packed and transported separately from treatments for administration by other route.

• Intrathecal chemotherapy must always be transported from the pharmacy to the place where it is to be administered, in a dedicated intrathecal chemotherapy transport box.

15. Storage

• Intrathecal medication for administration to adults must not be stored outside the satellite pharmacy.

• Intrathecal medication for administration to paediatric patients in Theatre 11 anaesthetic room may be stored during the morning of administration in the designated intrathecal fridge in that room. The fridge must be locked and the key held by the member of staff in charge of the location.

• Intrathecal medication for administration to paediatric patients in the adolescent treatment room on the paediatric unit may be stored during the morning of administration in the designated intrathecal fridge in that room. The fridge must be locked and the key held by the member of staff in charge of the location.

• It is the responsibility of the doctor administering the intrathecal chemotherapy to ensure that any unused doses at the end of the morning are returned to the satellite pharmacy for disposal.
16. Checking and Administration of intrathecal chemotherapy

16.1. Checking and administration

- Intrathecal chemotherapy must only be administered by registered medical practitioners who have been assessed as competent and received specific training as per the Trust policy and are on the intrathecal register

- Intrathecal chemotherapy must only be administered to adult patients in the William Budd day care consulting room. No other patient must be present in the consulting room at the time that the intrathecal chemotherapy is being administered. The William Budd day care consulting room must never be used for the administration of any intravenous chemotherapy.

- For Paediatric patients undergoing general anaesthetic, intrathecal chemotherapy must be administered in Theatre 11 anaesthetic room. No other patient must be present in Theatre 11 at the time that the intrathecal chemotherapy is being administered. Theatre 11 anaesthetic room must never be used for the administration of any intravenous chemotherapy.

- For Paediatric patients not undergoing general anaesthetic, intrathecal chemotherapy must be administered in the paediatric ward adolescent treatment room designated for the administration of intrathecal chemotherapy. This treatment room must never be used for the administration of any intravenous chemotherapy.

- Signs stating ‘Intrathecal Chemotherapy in progress do not enter’ will be placed on the designated room door(s) for the duration of the procedure by the nurse participating in the intrathecal procedure.

- Formal written consent must be obtained from the patient (or guardian / relative, if more appropriate). Consent is required for each course of intrathecal chemotherapy not for each dose. However, when attending for each dose, patients must be told the nature of the procedure, the route of administration and the drug to be administered.

- All patients must be reviewed by a member of staff who is on the register for administration of intrathecal chemotherapy 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 has been prescribed
- that arrangements have been made for the intrathecal chemotherapy to be administered by the appropriate medical staff.

- As part of this review the member of staff should check that any staff assisting in the procedure are also on the register for the task they are carrying out. Confirmation that the review has taken place should be written on the intrathecal prescription.

- Before administering the dose of intrathecal chemotherapy, the authorised doctor must check (verbally) the following with an authorised nurse performing a second check:
  - The patient’s name, hospital number and date of birth
  - The name of the medicine, dose, volume, route of administration and expiry date against the written prescription
  - The patient is fit to receive the treatment, the correct tests have been conducted and the correct medication has been prescribed
  - If applicable, anti-coagulant treatment has been stopped
  - The patient has given her/his consent
  - That the spinal needle is correctly located i.e. there is free flow of CSF out of the needle
  - That there is a tight seal between the syringe and needle.

- A second doctor is not permitted to carry out the checking procedure as agreed at the Oncology / Haematology Governance meeting.

- The nurse who has checked the intrathecal medication (and is on the intrathecal register) must remain with the patient throughout the procedure of administration

- For paediatric patients, the patient or guardian (if more appropriate) may be involved in the checking process as far as they wish; Checking the name, dose and route of the drug written on the chart with those on the label of the syringe If the patient is receiving intrathecal chemotherapy under general anaesthesia, the patient or guardian will not be able to participate in the final checking. In such cases, arrangements should be made for an additional check in theatre to be made by the senior theatre nurse.
For adult patients, the patient or their representative should be involved in the checking process. Checking the name, dose and route of the drug written on the chart with those on the label of the syringe. Should neither of these be appropriate a 3rd person—either a doctor or a nurse who knows the patient—may perform this check.

The doctor administering, the nurse checking and the patient / guardian (or additional checker) must all sign the prescription chart.

The administering doctor must ensure that all the signature sections on both the front and back of the prescription chart have been completed by the relevant professional or patient / representative who participated in the procedure.

16.2. Accessing the Cerebrospinal Cavity / space

- Chloraprep® 0.5% in 70% alcohol is the cleansing agent of choice prior to lumbar puncture.

- Gaining access to the cerebrospinal fluid (CSF) can sometimes be difficult and the assistance of suitably skilled staff e.g. anaesthetists may be requested. Doctors not listed on the intrathecal register are permitted to site the spinal needle but must have no further involvement in the administration of intrathecal chemotherapy. This must be carried out by a doctor authorised to do so.

- When medical devices and pharmaceutical manufacturers supply devices with ‘safer connectors that will not connect to intravenous luer connectors’ that are available via supply chain these will be implemented within the trust in line with National Patient Safety Agency alert issued November 2009.
16.3. Administration of Intrathecal chemotherapy in non-designated areas / location

- In exceptional circumstances, where it is not possible to transfer a patient to William Budd Ward day care consulting room or to the Paediatric ward (e.g. a patient being nursed on the Critical Care Unit or undergoing a general anaesthetic in theatre or in X-Ray), the treatment may be administered outside the designated areas. Extra caution is needed to ensure that no other chemotherapy is in the vicinity at the time of the procedure. This decision must be authorised by the consultant in charge of the patient’s care who must be on the register. The intrathecal chemotherapy must only be prescribed and administered by a doctor authorised to do so. The reason for not transferring the patient to the designated area must be clearly documented in the patient’s notes. An authorised nurse on the register must take a copy of the policy and the register with them to the area of administration and be responsible for checking the intrathecal chemotherapy.

- If for any reason the intrathecal chemotherapy is not administered to the patient, it must be returned immediately to the satellite pharmacy for disposal.

16.4. Patient Monitoring

- The patient will be encouraged to lie flat post lumbar puncture for 1 hour to aid good drug distribution and prevent the patient from developing a headache which can be a side effect of sitting up too quickly following the procedure

In relation to safe handling of cytotoxic drugs, administration, spillage and disposal of cytotoxics please refer to the relevant section of RUH Trust Policy 714 2001 Prescribing, handling and administration of cytotoxic drugs.
17. References

The Department of Health National Guidance on the Safe Administration of Intrathecal Chemotherapy

External enquiry into the adverse event that occurred at the Queen's Medical Centre, Nottingham, January 4th 2001, Professor Brian Toft

The Prevention of Intrathecal Medication Errors, April 2001, Professor Kent Woods

Appendix 1: Induction course structure

Applicable to all staff working in adult & paediatric oncology, haematology, whether nursing, medical or pharmacy staff and irrespective of grade.

Nursing staff, anaesthetists and operating department assistants who work in Theatre 11 will also receive training regarding the process of administering intrathecal chemotherapy although they will not partake in the administration procedure.

Aims of the session

- To highlight the risks involved with intrathecal chemotherapy
- To identify the responsibilities of the individual.

Content

- Discuss the history of the intrathecal chemotherapy issue –including the last incident in Nottingham
- National guidance –issue copies for reading
- Local Intrathecal chemotherapy policy –issue copies for reading
- Talk about individuals role (or lack of a role)
- Questions
- The lead trainers maintain a register of attendees

Induction courses are held on the first Thursday of the month. Unless an intrathecal chemotherapy training course or update course is taking place that day. It is the responsibility of the new member of staff’s line manager to arrange attendance on induction course. If the above date is not suitable then the individual must liaise with the lead trainer and organize a mutually convenient date and time for training.
Appendix 2: Intrathecal chemotherapy training for persons to be entered onto the register

Applicable to all staff working in oncology, haematology and paediatrics whether nursing, medical or pharmacy staff who are to be entered on the Trusts intrathecal register.

Aims of the session

- Multidisciplinary training
- Ensure the individual has a sound understanding of the risks of intrathecal chemotherapy
- Ensure the individual has a sound understanding of the national guidance and local policy and can apply this to practice.

Content

- National guidance – must have read
- Local Intrathecal chemotherapy policy – must have read
- DH intrathecal chemotherapy video
- Exercises to test understanding and knowledge
- Vinca alkaloids policy
- Requirement to challenge poor practice. All staff should challenge colleagues if, in their judgement, either protocols are not being adhered to or the actions of an individual may cause a potential risk to a patient.
- All attendees to sign that have attended and understood the session and their role.
- All attendees understand requirement for annual update, their responsibility for organising this and that will be removed from the register if an update has not been completed by the date when it is due
- The lead trainers maintain a register of attendees

At this session each attendee is given

- An Intrathecal chemotherapy training checklist
- A written intrathecal chemotherapy test. The test must be completed and returned to the lead trainer within 1 week. All questions must be answered correctly (i.e. 100% pass mark). Failure of this test will require the individual to undergo further training with the lead trainer.
# Appendix 2b: Checklist for Intrathecal Chemotherapy Training

## Royal United Hospital NHS Trust

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### INITIAL TRAINING

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<tr>
<th>Applicable to</th>
<th>Signature of trainee</th>
<th>Signature of Accredited trainer</th>
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- **Read and understood the national guidance and RUH policy for the Safe Administration of Intrathecal Chemotherapy.**
  - All: No trainer signature required

- **Attended a Trust intrathecal Chemotherapy training session.**
  - All

- **Passed the trust Intrathecal test**
  - All

- **Completed the Dispensing Accreditation for 3 doses (at least 1 adult and 1 paed)**
  - Technicians
  - Pharmacists
  - Adults
  - Paeds

- **Completed the Intrathecal Clinical Screening accreditation for:**
  - 2 adult intrathecal prescriptions
  - 2 paediatric prescriptions
  - Pharmacists
  - Adults
  - Paeds

- **Completed the Intrathecal Final Checking and Issuing Accreditation for 3 doses (at least 1 adult and 1 paed)**
  - Pharmacists
  - Adults
  - Paeds

- **Observe 1 procedure performed by relevant professional on intrathecal register.**
  - Nurses/Doctors

- **Perform 1 procedure competently performed under the supervision of relevant professional on intrathecal register**
  - Nurses/Doctors

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**Please enter name onto intrathecal register**
- ☐ prescribe
- ☐ administer
- ☐ clinical check
- ☐ dispense
- ☐ final check /issue
- ☐ nurse check

**Do not enter name onto intrathecal register**
- ☐

**Entered on register by**
- (pharmacist responsible for register)

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**Ref.:** 723  
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**Author:** Rosie Simpson  
**Page 22 of 42**
Appendix 3: Training for specific roles

Competency based training for

Prescribing and Administration – Doctors
Clinical check of prescription – Pharmacists
Dispensing – Technicians and Pharmacists
Final Check and Issuing – Pharmacists
Checking – Nursing

All staff that are to be entered on the register need practical training for the role they are to perform in addition to theoretical training relating to the risks involved. Training should be delivered by a person of the same discipline who is already on the register.

Refer to intrathecal chemotherapy folder for latest version of list of approved competency assessors

Medical Staff

Tasks; Prescribing, Collect from pharmacy or accept delivery, Administration.

- Observe a person on the register carrying out the role at least once.
- Perform the task at least once under supervision to required level of competency as defined in the national guidance and local policy. (100% pass rate required, i.e. no errors)
- Both the person being assessed and the assessor must be happy that competence has been achieved. Further supervised tasks must be completed if either party considers it necessary

On completing the above to a satisfactory standard, the assessor who must be on the register, signs and dates the appropriate section of the person’s intrathecal checklist.
Nursing Staff

Nursing staff competent in the administration of intravenous chemotherapy will only undertake intrathecal training to go on the register following permission from the Senior Sister in chemotherapy or Clinical Manager / Matron for Oncology.

Tasks; Checking intrathecal chemotherapy, preparation of the patient and care of the patient before, during and after the procedure.

- Observe a person on the register carrying out the role at least once.
- Perform the task at least once under supervision to required level of competency as defined in the national guidance and local policy. (100% pass rate required, i.e. no errors)
- Both the person being assessed and the assessor must be happy that competence has been achieved. Further supervised tasks must be completed if either party considers it necessary.

On completing the above to a satisfactory standard, the assessor who must be a registered nurse band 6 or above and be on the register, signs and dates the appropriate section of the person’s intrathecal checklist.

Pharmacy Staff

*Note; only pharmacy staff working regularly in oncology / haematology, should be considered for entry on the register*

Tasks; Clinical check of prescription, dispensing, final check, issuing

- Observe a person on the register carrying out the role at least once.
- Perform the task under supervision to required level of competency as defined in the national guidance and local policy. (100% pass rate required, i.e. no errors)

Minimum number required for competency assessment

<table>
<thead>
<tr>
<th>Task</th>
<th>Minimum Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical check</td>
<td>4 prescriptions (2 adult 2 paed)</td>
</tr>
<tr>
<td>Dispensing</td>
<td>3 (at least 1 adult and 1 paed)</td>
</tr>
<tr>
<td>Final check</td>
<td>3 (at least 1 adult and 1 paed)</td>
</tr>
<tr>
<td>Issuing</td>
<td>3 (at least 1 adult and 1 paed)</td>
</tr>
</tbody>
</table>

- Both the person being assessed and the assessor must be happy that competence has been achieved. Further supervised tasks must be completed if either party considers it necessary.

On completing the above to a satisfactory standard, the assessor who must be on the register, signs and dates the appropriate section of the person’s intrathecal checklist.
Appendix 4: Example of written assessment

Intrathecal Policy Assessment

Name ___________________________ Date __________________

Job Title ________________________

Please read the Intrathecal Policy before attempting to answer the following multiple choice and short questions
Please note there may be more than one correct answer

1) All staff involved in prescribing, dispensing, issuing, checking or administering intrathecal chemotherapy must
   a) Work Monday to Friday
   b) Be a member of staff within Oncology who has undertaken intrathecal training
   c) Be on the intrathecal register
   d) Be a member of staff in Paediatrics who has undertaken intrathecal training

2) Formal Intrathecal training for those who are on the intrathecal register in the RUH must be updated
   a) When you move hospitals / trusts
   b) Yearly
   c) When the policy has been changed
   d) Whenever there is a new chief executive

3) Intrathecal chemotherapy must be prescribed by
   a) A registrar
   b) A consultant
   c) An associate specialist
   d) Any of the above providing they are on the intrathecal register

4) Who is ultimately responsible for ensuring all signatures are complete on the intrathecal prescription chart following administration of Intrathecal chemotherapy?
   a) The patient who received the intrathecal chemotherapy
   b) The nurse who performed the intrathecal checks
   c) The doctor who administered the intrathecal chemotherapy
   d) The pharmacist who issued the intrathecal chemotherapy
5) The insertion of the spinal needle prior to the administration of intrathecal chemotherapy can be performed by
a) An associate specialist
b) A radiologist
c) A registrar or Consultant
d) Any of the above
   Explain the rationale for your answer

6) Routine administration of Intrathecal chemotherapy will be undertaken
a) In William Budd Day Care consulting room
b) Within normal working hours
c) In Theatre 11, anaesthetic room
d) All of the above

7) If intrathecal chemotherapy is administered on a Saturday afternoon
a) The need for out of hour’s intrathecal chemotherapy must be decided by the on-call registrar or consultant.
b) The intrathecal chemotherapy will only be prepared in a pharmacy aseptic suite and dispensed by the on-call pharmacist
c) All personnel participating in prescribing, dispensing, issuing, checking and administration of intrathecal chemotherapy and administration must be on the intrathecal registrar for the part of the procedure they are to undertake.
d) Patient must be transferred to Bristol Oncology Centre

8) Intrathecal chemotherapy must be prescribed on
a) Once only section of RUH drug chart
b) Regular side of RUH drug chart
c) Yellow chemotherapy prescription chart
d) Other (please state) _______________________________

9) A pharmacist on the intrathecal register must check the following before dispensing and issuing intrathecal chemotherapy
a) Patient has received all intravenous drugs they were due
b) Patient has received all intravenous chemotherapy drugs due that particular day
c) Patient has received all chemotherapy drugs issued from pharmacy.
d) Prescription has been written by a doctor on the intrathecal register
10) Within the RUH any doctor on the intrathecal register can
   a) Prescribe intrathecal chemotherapy
   b) Check intrathecal chemotherapy
   c) Administer intrathecal chemotherapy
   d) Assess a patient as requiring intrathecal chemotherapy over a weekend

11) Who is the intrathecal lead for the trust _____________________________

12) Name two occasions during the intrathecal procedure when staff must check
    the intrathecal register to ensure the staff they are working with are on the
    intrathecal register and training up to date.

    1. __________________________________________________________
    2. __________________________________________________________

THANK YOU.
Please return completed assessment to your lead trainer

Caroline Gilleece – adults

Allison Richardson - paeds
Appendix 5: Certificate on completion of Training

This is to certify that

___________________________

Has completed the intrathecal chemotherapy training programme

• Has read and understood the policy for Prescribing, Administration, Checking and Supply of Intrathecal Chemotherapy
• Attended an Intrathecal chemotherapy training session
• Successfully passed the written test
• Completed the training for the specific role he/she is to perform

Signature of trainee ___________________________ date ____________

Lead trainer ___________________________ date ____________

Valid until ____________

Please ensure annual update training is booked before date stated above
Appendix 6a: Annual Update

Applicable to all staff working in oncology, haematology and paediatrics currently on the register who wish to remain on the register.

Aims of the session
- To highlight any changes which have been made to the national guidance or the local intrathecal chemotherapy policy
- To remind staff of the risks relating to intrathecal chemotherapy

Session outline
- Discuss any changes made to the national guidance or the local policy and the impact of these changes
- Review number of procedures individuals have performed in the last 12 months
- To allow opportunity for discussion of any issues which may have arisen in the last 12 months
- All attendees to sign that they have attended and understood the session and their role.
- All attendees understand requirement for annual update, their responsibility for organizing this and that will be removed from the register if an update has not been completed by the date when it is due
- The lead trainers maintain a register of attendees

At this session each attendee is given
- An Intrathecal chemotherapy update training checklist
- A written intrathecal chemotherapy test. The test must be completed and returned to the lead trainer within 1 week. All questions must be answered correctly (i.e. 100% pass mark)
### Appendix 6b: Annual Checklist for Training

**Royal United Hospital NHS Trust**  
**Annual Update Checklist for Intrathecal training**

<table>
<thead>
<tr>
<th>Name</th>
<th>Valid Until</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Initials</td>
</tr>
</tbody>
</table>

#### ANNUAL TRAINING

<table>
<thead>
<tr>
<th></th>
<th>Applicable to</th>
<th>Signature of trainee</th>
<th>Signature of Accredited trainer</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number of Intrathecal procedures pertaining to your role undertaken in last 12 months (must perform at least 1 to remain on the register.)</td>
<td>ALL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enter number here</td>
<td>No trainer signature required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Read any updates to National Guidance and local policy.</td>
<td>ALL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Attended update.</td>
<td>ALL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Passed written test 100% pass mark</td>
<td>ALL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Deemed competent to continue on register or Requires reassessment of competence to perform specific role relevant to staff member. <strong>(delete as appropriate)</strong></td>
<td>ALL</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Lead trainer Signature**  
Date

Please update name on intrathecal register  
☐ prescribe  ☐ administer  ☐ clinical check  ☐ dispense  
☐ final check /issue  ☐ nurse check  

Do not update name on intrathecal register  
☐ clinical check  ☐ dispense  

Entered on register by  
(pharmacist responsible for register)  
Date
** Item 5 refers to the person’s ability to carry out the technical aspects of the task they perform. If the accredited trainer (another person who carries out the same task and is on the register) is satisfied the person in question can perform the role, sign –Deemed competent to continue on the register.

If the accredited trainer is unsure, sign the section -Requires reassessment of competence.
### Appendix 7: Intrathecal Chemotherapy Prescription Chart

#### Patient details

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Stage</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regimen</td>
<td>Trial Number</td>
<td>(if applicable)</td>
</tr>
<tr>
<td>Cycle no.</td>
<td>Day no.</td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
<td>Weight (kg)</td>
<td>Surface area (m²)</td>
</tr>
</tbody>
</table>

#### Hospital no.

#### Surname

#### First name

#### Date of birth

#### Consultant

#### Ward

#### Other relevant information

<table>
<thead>
<tr>
<th>Prescription</th>
<th>Pharmacy clinical check</th>
<th>Supply from Pharmacy</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Please sign full names – not just initials</td>
<td>(the signatures below affirm that the checklist overleaf has been completed to everyone’s satisfaction)</td>
<td>(the signatures below affirm that the checklist overleaf has been completed to everyone’s satisfaction)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Drug (do not abbreviate)</th>
<th>Dose</th>
<th>Route</th>
<th>Doctor sig</th>
<th>Pharmacist sig</th>
<th>Pharmacy sig</th>
<th>Doctor sig</th>
<th>Time</th>
<th>Doctor sig</th>
<th>Nurse sig</th>
<th>Patient / other sig</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intrathecal</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Intrathecal</td>
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<tr>
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<tr>
<td></td>
<td>Intrathecal</td>
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</tr>
</tbody>
</table>

*Note if prescribing liposomal cytarabine, you must specify both the generic name and the brand name i.e. liposomal cytarabine, DepoCyte—to avoid confusion*
Reminders:
- Staff prescribing, dispensing, checking or administering intrathecal chemotherapy must have received the relevant training and be registered on the official RUH intrathecal Chemotherapy Register as competent before proceeding - please read the RUH intrathecal chemotherapy policy if you are in any doubt.
- Intrathecal chemotherapy is NOT permitted to be prescribed on the same chart as intravenous chemotherapy.
- Vinca alkaloids to be given at the same stage of the protocol MUST NOT be given on the same day as intrathecal chemotherapy.
- Aim for platelet count > 50 x 10⁹/l before inserting spinal needle.
- Intrathecal Methotrexate must be avoided if patient has recently received high dose IV Methotrexate and is still receiving oral or intravenous Calcium Folinate rescue.
- Once the intrathecal medication has been dispensed it MUST be taken directly to the patient and administered without delay.
- If the patient is unable to participate in the checking procedure then a parent, guardian or close relative (or senior nurse in Theatre or ITU) should sign for the checking procedure on their behalf.
- Please ensure that all signatures have been completed on the front of this prescription form.

---

**CHECKLIST**

- The following must be checked at the time of supply of medication from Pharmacy
  - If applicable, have all *intravenous* cytotoxic drugs that have already been dispensed for this patient been administered? Yes / No / not applicable  
    (Dr's sig) .................. (Pharmacist's sig) ..................  
  - The following must also be checked by the administering doctor and the supplying pharmacist:  
    Doctor's sig  Pharmacist's sig  
    Are the doctor and pharmacist on the RUH intrathecal register and registration is up to date? (check register)  
    Correct patient (check patient name, hosp no. and dob)  
    Correct chemotherapy treatment protocol  
    Timing of intrathecal dose(s) (refer to protocol)  
    Drug name(s), dose(s), volume(s) and expiry date(s)  
    Is the patient on Calcium Folinate? – Yes / No (circle as appropriate)  

- The following must be checked at the time of administration of intrathecal chemotherapy
  Doctor's sig  Nurse's sig  Patient's sig  
  Are the doctor and nurse on the RUH intrathecal register? (Check)  
  Correct patient? (check patient name, hosp no. and dob)  
  Correct timing of intrathecal dose(s)? (refer to protocol)  
  Drug name(s), dose(s), volume(s) and expiry date(s)  
  Is the patient fit to proceed with intrathecal chemotherapy?  
  Is the patient's platelet count >50 x 10⁹/l?  
  (If applicable) Has anticoagulation been stopped?  
  Has the patient given his/her consent?
Appendix 8: Out of normal working hours

The purpose of this appendix is to provide clear guidance for staff involved in the administration of intrathecal chemotherapy outside normal working hours.

Emergency out of hours treatment may be appropriate in the following situations
- Central nervous system (CNS) involvement in acute leukaemia
- CNS involvement in lymphoma
- Leptomeningeal involvement by metastatic solid tumour

Responsibilities
All staff involved in the procedure are individually responsible for their own actions and must act at all times in accordance with the National Guidance and the local policy.

Need for treatment
The consultant responsible for the patient must establish the need for emergency treatment. If that person is not on the intrathecal register, the decision must be made following discussion with a haematology consultant who is on the intrathecal register. The consultant haematologist who agrees with the decision to administer intrathecal chemotherapy can choose whether to convene the relevant nursing and pharmacy staff or to delegate this responsibility to a haematology SPR who is on the register (if a SPR is available).

See below for the staff required for the procedure and how to contact them.

| Doctor to prescribe the intrathecal chemotherapy | -usually the doctor that has established the need for treatment |
| Doctor to administer the intrathecal chemotherapy | Usually the same as the prescriber except in circumstances where the prescriber is unable to administer. It is the prescriber’s responsibility ensure there is a doctor available to administer the intrathecal chemotherapy |
| Pharmacist to provide the intrathecal chemotherapy | Contact the on-call pharmacist via RUH switchboard. The pharmacist will refer the request to a senior oncology pharmacist |
| Nurse to check the intrathecal chemotherapy | Contact details for nursing staff on the intrathecal register are in the off duty file in the William Budd ward office. |
Prescribing
The intrathecal treatment must be prescribed by a doctor on the intrathecal register. Blank intrathecal chemotherapy prescriptions are available in the intrathecal chemotherapy file in William Budd Day Care treatment room.

Dispensing
A pharmacist who is on the intrathecal register should dispense the intrathecal chemotherapy following pharmacy standard operating procedures. The doctor who is to administer the intrathecal chemotherapy must collect the treatment from the satellite pharmacy.

Administration
A doctor who is on the intrathecal register must administer the treatment.

Checking
The second check on the intrathecal chemotherapy prior to administration must be carried out by a nurse who is on the intrathecal chemotherapy.

Documentation
The need for emergency out of hour’s treatment must be documented in the patients notes by the consultant on the intrathecal register who is taking responsibility for this aspect of the patient treatment. The record should include why the treatment was necessary, the treatment given and the outcome. By the end of the next working day the prescriber must inform in writing (or by e-mail) the Trust lead for intrathecal chemotherapy that treatment has been given as an emergency outside normal working hours and the reasons for doing so.

The intrathecal lead for the Trust will keep a record of all such events.
Ratification Assurance Statement

Dear Francesca

Please review the following information to support the ratification of the below named document.

Name of document: Medicines Code: Intrathecal Chemotherapy (Reference 723)

Name of author: Rosie Simpson

Job Title: Principal Pharmacist: Cancer and Aseptic Services

I, the above named author confirm that:

- The Policy presented for ratification meets all legislative, best practice and other guidance issued and known to me at the time of development of the Policy;
- I am not aware of any omissions to the Policy, and I will bring to the attention of the Executive Director any information which may affect the validity of the Policy presented as soon as this becomes known;
- The Policy meets the requirements as outlined in the document entitled Trust-wide Policy for the Development and Management of Policies (v4.0);
- The Policy meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable;
- I have undertaken appropriate and thorough consultation on this Policy and I have documented the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the Policy following consultation;
- I will send the Policy and signed ratification checklist to the Policy Coordinator for publication at my earliest opportunity following ratification;
- I will keep this Policy under review and ensure that it is reviewed prior to the review date.

Signature of Author: ____________________________________________ Date: 14 December 2012

Name of Person Ratifying this policy: Francesca Thompson

Job Title: Director of Nursing & Accountable Officer: Controlled Drugs

Signature: ____________________________________________ Date: 31 December 2012

To the person approving this policy:

Please ensure this page has been completed correctly, then print, sign and post this page only to: The Policy Coordinator, John Apley Building.

The whole policy must be sent electronically to: ruh-tr.policies@nhs.net
## Consultation Schedule

<table>
<thead>
<tr>
<th>Name and Title of Individual</th>
<th>Date Consulted</th>
</tr>
</thead>
<tbody>
<tr>
<td>James Scott, Chief Executive</td>
<td>25/9/2012</td>
</tr>
<tr>
<td>Dr Chris Oakhill Led Clinician Paediatric Oncology</td>
<td>21/9/2012</td>
</tr>
<tr>
<td>Dr Sarah Wexler, Lead Clinician Adults</td>
<td>24/9/2012</td>
</tr>
<tr>
<td>Dr Regina Brophy, Chief Pharmacist</td>
<td>21/9/2012</td>
</tr>
<tr>
<td>Rosie Simpson, Intrathecal Chemotherapy Lead</td>
<td>11/7/2012</td>
</tr>
<tr>
<td>Caroline Gilleece, Lead Trainer Adult</td>
<td>19/9/2012</td>
</tr>
<tr>
<td>Allison Richardson, Lead Trainer Paediatrics</td>
<td>19/9/2012</td>
</tr>
<tr>
<td>Jackie Davies, Pharmacist responsible for updating the intrathecal register</td>
<td>21/9/2012</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Committee</th>
<th>Date of Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology / Haematology Clinical Governance</td>
<td>16/8/2012</td>
</tr>
<tr>
<td>Paediatric Oncology MDT meeting</td>
<td>19/9/2012</td>
</tr>
</tbody>
</table>

The following people have submitted responses to the consultation process:

<table>
<thead>
<tr>
<th>Name and Title of Individual</th>
<th>Date Responded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Chris Oakhill</td>
<td>20/9/2012</td>
</tr>
<tr>
<td>Caroline Gilleece</td>
<td>11/7/2012</td>
</tr>
<tr>
<td>Caroline Gilleece</td>
<td>7/8/2012</td>
</tr>
</tbody>
</table>
Equality Impact: (A) Assessment Screening

To be completed when submitted to the appropriate Executive Director for consideration and approval.

Person responsible for the assessment:
Name: Rosie Simpson  
Job Title: Principal Pharmacist Cancer and Aseptic Services

<table>
<thead>
<tr>
<th>Does the document/guidance affect one group less or more favourably than another on the basis of:</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnic origins (including gypsies and travellers)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nationality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender (including gender reassignment)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Culture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Religion or belief</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual orientation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability (learning disabilities, physical disability, sensory impairment and mental health problems)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there any evidence that some groups are affected differently?</td>
<td>Yes</td>
<td>pregnant women,</td>
</tr>
<tr>
<td>If you have identified potential discrimination, are there any valid exceptions, legal and/or justifiable?</td>
<td>Yes</td>
<td>risk vs benefit of chemotherapy during pregnancy</td>
</tr>
<tr>
<td>Is the impact of the document/guidance likely to be negative?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>If so, can the impact be avoided?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>What alternative is there to achieving the document/guidance without the impact?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Can we reduce the impact by taking different action?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

If you answered NO to all the above questions, the assessment is now complete, and no further action is required.

If you answered YES to any of the above please complete the
Equality Impact: (B) Full Analysis

---

Document name: Medicines Code: Intrathecal Chemotherapy  
Ref.: 723  
Issue date: 10 January 2013  
Status: Approved  
Author: Rosie Simpson  
Page 5 of 42
Equality Impact: (B) Full Analysis

Note:

Only complete this section if you answered YES to any of the questions in the Equality Impact: (A) Screening Assessment

Equality Analysis is a process of systematically analysing a new or existing policy or service to identify what impact or likely impact it will have on different groups within the community. The primary concern is to identify any discriminatory or negative consequences for a particular group or sector of the community. Equality Analysis can be carried out in relation to service delivery as well as employment policies and strategies.

This template has been developed to use as a framework when carrying out an Equality Analysis on a policy, service or function. It is intended that this is used as a working document throughout the process, with a final version including the action plan section being published on the Royal United Hospital, Bath NHS Trust website.

1. Identify the aims of the policy or service and how it is implemented.

<table>
<thead>
<tr>
<th>Key questions</th>
<th>Answers / Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Briefly describe purpose of the service/policy including • How the service/policy is delivered and by whom • If responsibility for its implementation is shared with other departments or organisations • Intended outcomes</td>
<td>This policy sets out the process as to personnel who can participate in the intrathecal chemotherapy procedure i.e. prescribing, dispensing, issuing, checking and administration and the training requirement prior to participating</td>
</tr>
<tr>
<td>1.2 Provide brief details of the scope of the policy or service being reviewed, for example: • Is it a new service/policy or review of an existing one? • Is it a national requirement? • How much room for review is there?</td>
<td>The policy covers all aspects of the intrathecal chemotherapy process for both adult and paediatric patients within the Royal United Hospital</td>
</tr>
<tr>
<td>1.3 Do the aims of this policy link to or conflict with any other policies of the Trust?</td>
<td>No</td>
</tr>
</tbody>
</table>
### 2. Consideration of available data, research and information

Monitoring data and other information should be used to help you analyse whether you are delivering a fair and equal service. Please consider the availability of the following as potential sources:

- **Demographic** data and other statistics, including census findings
- Recent **research** findings (local and national)
- Results from **consultation or engagement** you have undertaken
- Service user **monitoring data** (including ethnicity, gender, disability, religion/belief, sexual orientation and age)
- Information from **relevant groups** or agencies, for example trade unions and voluntary/community organisations
- Analysis of records of enquiries about your service, or **complaints** or **compliments** about them
- Recommendations of **external inspections** or audit reports

<table>
<thead>
<tr>
<th>Key questions</th>
<th>Data, research and information that you can refer to</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.1</strong> What is the equalities profile of the team delivering the service/policy?</td>
<td>The team delivering involves a select group of staff working in adult and paediatric oncology with a similar equalities profile</td>
</tr>
<tr>
<td><strong>2.2</strong> What equalities training have staff received?</td>
<td>RUH Trust equality and diversity training</td>
</tr>
<tr>
<td><strong>2.3</strong> What is the equalities profile of service users?</td>
<td>Male and Female age range children, teenagers and adults who due to their diagnosis and treatment plan require intrathecal chemotherapy to be administered</td>
</tr>
<tr>
<td><strong>2.4</strong> What other data do you have in terms of service users or staff? (e.g results of customer satisfaction surveys, consultation findings). Are there any gaps?</td>
<td>Our patients are surveyed using the National Cancer Patient Survey</td>
</tr>
<tr>
<td><strong>2.5</strong> What engagement or consultation has been undertaken as part of this EIA and with whom? What were the results?</td>
<td>The policy fits with the mandatory National Guidelines for administration of Intrathecal Chemotherapy which are linked to patient safety issues.</td>
</tr>
<tr>
<td><strong>2.6</strong> If you are planning to undertake any consultation in the future regarding this service or policy, how will you include equalities considerations within this?</td>
<td>N/A</td>
</tr>
</tbody>
</table>
3. Assessment of impact: ‘Equality analysis’

Based upon any data you have considered, or the results of consultation or research, use the spaces below to demonstrate you have analysed how the service or policy:

- Meets any particular needs of equalities groups or helps promote equality in some way.
- Could have a negative or adverse impact for any of the equalities groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>Examples of what the service has done to promote equality</th>
<th>Examples of actual or potential negative or adverse impact and what steps have been or could be taken to address this</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Gender</td>
<td>No impact</td>
<td></td>
</tr>
<tr>
<td>3.2 Transgender</td>
<td>No impact</td>
<td></td>
</tr>
<tr>
<td>3.3 Disability</td>
<td>No impact</td>
<td>If a patient has a spinal injury it may not be possible to administer medicines via the intrathecal route. Clinician would need to consider alternative methods of administration</td>
</tr>
<tr>
<td>3.4 Age</td>
<td>No impact</td>
<td></td>
</tr>
<tr>
<td>3.5 Race</td>
<td>Service offered to all ethnic groups</td>
<td></td>
</tr>
<tr>
<td>3.6 Sexual orientation</td>
<td>Service offered to all</td>
<td></td>
</tr>
<tr>
<td>3.7 Religion/belief</td>
<td>Service offered to all</td>
<td></td>
</tr>
<tr>
<td>3.8 Marriage/Civil Partnership</td>
<td>Service offered to all</td>
<td></td>
</tr>
</tbody>
</table>
Examples of what the service has done to promote equality

3.9 Pregnancy/Maternity
Identify the impact/potential impact of the policy
Risk assessment would be required to balance the risks of receiving chemotherapy treatment while pregnant vs. the clinical need and benefits

4. Royal United Hospital, Bath Equality Impact Assessment Improvement Plan

Please list actions that you plan to take as a result of this assessment. These actions should be based upon the analysis of data and engagement, any gaps in the data you have identified, and any steps you will be taking to address any negative impacts or remove barriers. The actions need to be built into your service planning framework. Actions/targets should be measurable, achievable, realistic and time framed.

<table>
<thead>
<tr>
<th>Issues identified</th>
<th>Actions required</th>
<th>Progress milestones</th>
<th>Officer responsible</th>
<th>By when</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Sign off and publishing

Once you have completed this form, it needs to be 'approved' by your Line Manager or their nominated officer. Please ensure that it is submitted to the body ratifying your policy or service change with your report/proposal. Keep a copy for your own records.

Signed off by: Hard copy signed by Dr Knechtli  
Date: 

Document name: Medicines Code: Intrathecal Chemotherpy  
Ref.: 723  
Issue date: 10 January 2013  
Status: Approved  
Author: Rosie Simpson  
Page 9 of 42