

The Policy for Administration of Intrathecal Chemotherapy for Adult Oncology & Haematology Patients

To be read in conjunction with:

- 'HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy'

Date Agreed: April 2017
Version Number: 11
Operational Review Date: March 2019

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 1 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

INDEX

SECTION	PAGE
1 BACKGROUND	3
2 INTRODUCTION	3
3 CLINICAL GOVERNANCE	3 - 5
4 DRUGS FOR INTRATHECAL USE	5 - 6
5 TRUST INTRATHECAL REGISTER	6 - 7
6 TRAINING	8 - 9
7 PRESCRIBING	9
8 CLINICAL CHECKING BY PHARMACIST	9 - 10
9 DISPENSING	10
10 FINAL CHECKING	11
11 ISSUING/TRANSPORTATION AND STORAGE	11 - 12
12 CHECKING AND ADMINISTRATION	12 - 14
13 DOCUMENT CONTROL	15
14 APPROVAL	16
APPENDIX I: List of named individuals with ITC responsibilities	17
APPENDIX II: Trust ITC Policy document history	18 - 19

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 2 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

1. BACKGROUND: INTRATHECAL CHEMOTHERAPY SERVICE AT ROYAL SURREY COUNTY HOSPITAL (RSCH)

- 1.1 To ensure safe administration of appropriate chemotherapy by the intrathecal route this policy states in explicit terms the process for prescribing, supply and administration of intrathecal drugs at the RSCH. The accidental administration of certain cytotoxic drugs by the intrathecal route almost always causes death.
- 1.2 The RSCH is a single site hospital Trust and the intrathecal chemotherapy service is an undivided service across the whole Trust.
- 1.3 At the RSCH a single division Intrathecal Chemotherapy (ITC) Service is provided for:
 - Adult haematology patients
 - Adult oncology patients
- 1.4 Intrathecal Chemotherapy is only administered during normal working hours, i.e. 08:00 to 18:00 hrs Monday to Friday (excluding Bank and Public Holidays).
- 1.5 The designated room where intrathecal chemotherapy is given is the Haematology Room in the Oncology Outpatient Department (Level B St Luke's Cancer Centre). In isolated cases, where lumbar puncture is difficult, the patient may be moved to the Interventional Radiology Room (Room 7 in the Radiology Department) where the needle may be positioned using X-ray screening.
- 1.6 There is no Paediatric Intrathecal Chemotherapy Service at the RSCH.

2. INTRODUCTION

The guidance issued in this document applies to both intrathecal chemotherapy and also to intraventricular chemotherapy (i.e. via injection into the ventricles of the brain) administered to adult haematology and oncology patients at the RSCH. This policy is to be read in conjunction with the 'Policy for prescribing and administration of vinca alkaloids.'

3. CLINICAL GOVERNANCE

- 3.1 The Trust Chief Executive has identified the single Trust ITC Lead to be the Lead Consultant Haematologist. The Trust ITC Lead and staff with delegated ITC responsibilities are named in Appendix I.
- 3.2 The Single Trust Intrathecal Chemotherapy Lead will:**
 - 3.2.1 Be accountable to the Trust Chief Executive for ensuring compliance with the National Guidance (HSC 2008/001).
 - 3.2.2 Have overall responsibility for training (designated Lead Trainer), with regard to intrathecal chemotherapy.
- 3.3 As Lead Trainer, the ITC Lead will:**
 - 3.3.1 Agree responsibilities with the Trust Chief Executive.
 - 3.3.2 Have a Programmed Activity (PA) in his/her job-plan that covers the time requirement to fulfil this responsibility.
 - 3.3.3 Be responsible for the "Royal Surrey County Hospital Intrathecal Chemotherapy Induction" syllabus.
 - 3.3.4 Ensure medical staff proposed for inclusion in the Trust ITC Policy complete the Trust ITC induction and the competency-based programme specific to their proposed role(s).

Reason for Update: Routine review (+ e-Rx and Surety added)	Page 3 of 19
Valid from: April 2017	Review date: March 2019
Version: 11	Supersedes version: 10
Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive	

- 3.3.5 Take responsibility for a competency-based training programme for the prescribing and administration of ITC.
- 3.3.6 Be the training lead and named competency assessor for prescribing and administration of ITC.
- 3.3.7 Ensure staff registered for prescribing and/ or administration of ITC meet the eligibility criteria documented in section 5.2.1 and are trained and competent to prescribe and/or administer ITC.
- 3.3.8 Be responsible for annual re-assessment of staff registered for prescribing and/or administration of ITC. This will include monitoring how often the staff carry out their registered ITC tasks. The outcome of this assessment should be confirmed in writing.
- 3.3.9 Inform the Deputy Chief Pharmacist (CARS) when additions/ re-registrations or removals should be made to the Trust ITC Register for the tasks of prescribing and administration of ITC.
- 3.3.10 Delegate named individuals to be responsible for induction and registration training of nursing and pharmacy staff proposed for inclusion in the Trust ITC Register..
- 3.3.11 Ensure the staff employed into delegated roles are competent to perform their tasks.
- 3.3.12 Agree the registration training syllabus with the delegated competency assessor for each professional group.

3.4 The Delegated Nurse will:

- 3.4.1 Be the Lead Haematology Nurse, following assessment on coming into post.
- 3.4.2 Ensure nursing staff proposed for inclusion in the Trust ITC Register complete the Trust ITC induction and the competency-based programme specific to their proposed role(s).
- 3.4.3 Take responsibility for a competency-based training programme for checking ITC prior to administration.
- 3.4.4 Be the training lead and named competency assessor for checking of ITC prior to administration.
- 3.4.5 Ensure staff who are to be included on the Trust ITC Register for checking ITC prior to administration meet the eligibility criteria documented in section 5.3.1 and are trained and competent to check ITC prior to administration.
- 3.4.6 Be responsible for annual re-assessment of staff registered for checking ITC prior to administration. This will include monitoring how often the staff carry out their registered ITC tasks. The outcome of this assessment should be confirmed in writing.
- 3.4.7 For the Delegated Nurse, the initial competency assessment and subsequent re-assessment of competence will be performed by the job share partner for this post (who will have been assessed as competent in this ITC task and be included on the Trust ITC register for this ITC task).
- 3.4.8 Inform the Deputy Chief Pharmacist (CARS) when additions/ re-registrations or removals should be made to the Trust ITC Register for the task of checking ITC prior to administration.

3.5 The Delegated Clinical Pharmacist will:

- 3.5.1 Be the Deputy Chief Pharmacist Cancer, Aseptic and Research Services (CARS), following assessment on coming into post.
- 3.5.2 Ensure all clinical pharmacy staff proposed for inclusion in the Trust ITC Register complete the Trust ITC induction and the competency-based programme specific to their proposed role(s).

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 4 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

- 3.5.3 Be the named competency assessor for staff performing the clinical check on ITC prescriptions.
 - 3.5.4 Ensure staff who are to be included on the Trust ITC Register for checking ITC prior to administration meet the eligibility criteria documented in section 5.4.1 and are trained and competent to check ITC prior to administration.
 - 3.5.5 Ensure that clinical pharmacy staff on the Trust ITC Register are annually reassessed. This will include monitoring how often the staff carry out their registered ITC task. The outcome of this assessment should be confirmed in writing.
 - 3.5.6 For the Delegated Clinical Pharmacist, the initial competency assessment and subsequent re-assessment of competence will be performed by the Senior Specialist Pharmacist, Oncology and Haemato-Oncology (who will have been assessed as competent in this ITC task and be included on the Trust ITC register for this task).
 - 3.5.7 Ensure that additions/ re-registrations or removals are made to the Trust ITC Register of individuals trained in ITC for the task of clinical checking ITC prescriptions.
 - 3.5.8 Ensure that additions/ re-registrations or removals are made to the Trust ITC Register of individuals trained in ITC as directed by the named competency assessor for all other ITC tasks.
 - 3.5.9 Issue 'Intrathecal Training Certificates' as directed by the named competency assessor for each ITC task. This will be done at the point that the staff member is added to the Trust ITC Register or is re-registered.
 - 3.5.10 Review the Trust ITC Register every three months to ensure all staff hold a current 'Intrathecal Training Certificate' for their registered ITC task(s).
 - 3.5.11 Review the Trust ITC caseload annually. If the caseload falls below ten procedures or less per year the Deputy Chief Pharmacist (CARS) will undertake a risk assessment to ensure the safety of the service and compliance with the National Guidance.
 - 3.5.12 Perform ITC document control as per section 13.
- 3.6 The delegated Pharmacy Aseptic Services Lead will:**
- 3.6.1 Be the Aseptic Services Manager.
 - 3.6.2 Be the named competency assessor for dispensing, final checking and issuing/ transportation of ITC.
 - 3.6.3 Ensure staff who are to be trained on the Trust ITC Register meet the eligibility criteria documented in section 5.5.1 and are trained and competent to perform their designated ITC task(s).
 - 3.6.4 Ensure that staff registered for Pharmacy Aseptic Services Department-based ITC tasks are annually reassessed, and that the outcome of this assessment is confirmed in writing.
 - 3.6.5 For the Delegated Pharmacy Aseptic Services Lead, the initial competency assessment and subsequent re-assessment of competence will be performed by the Deputy Chief Pharmacist (CARS) who will have been assessed as competent in this ITC task and be included on the Trust ITC register for these ITC tasks).
 - 3.6.6 Inform the Deputy Chief Pharmacist (CARS) when additions/ re-registrations or removals should be made to the Trust ITC Register of individuals trained in ITC.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 5 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

4. DRUGS FOR INTRATHECAL USE

The only drugs that can routinely be given by the intrathecal route are:

- Methotrexate
- Cytarabine
- Hydrocortisone sodium succinate

Other intrathecal drug(s) may only be initiated by a Consultant included on the Trust ITC register after discussion with the Trust ITC Lead and completion of a Trust 'Treatment guideline for one-off chemotherapy protocols' green form. The green form must include reference(s) to published evidence demonstrating safety and efficacy of the planned intrathecal treatment. A copy of the green form will be held in the 'Master Intrathecal Chemotherapy File' for future reference.

5. TRUST INTRATHECAL REGISTER

5.1 General

- Only individuals on the Trust ITC Register of designated personnel can take part in ANY part of the intrathecal chemotherapy process at the RSCH.
- Certificates issued at other hospitals are not valid at the RSCH. Individuals must complete training before they will be added to the Trust ITC Register.
- All staff involved in any part in the ITC delivery process must check colleagues also involved are included in the Trust ITC Register.

5.2 Prescribing and administration of ITC

5.2.1 Eligibility

- Only Haematology/Oncology Consultants or ST3 grades and above who are on the Trust ITC Register of authorised personnel are permitted to carry out prescribing and/ or administration of intrathecal chemotherapy.
- FT1 and FT2 grades and ST1 and ST2 grades must not prescribe or administer intrathecal chemotherapy.
- Locum Consultants and ST3 grades and above may only prescribe intrathecal chemotherapy if they have undertaken the RSCH medical training and assessment programme.
- Associate Specialist doctors in this Trust may prescribe or administer intrathecal chemotherapy on completion of the same training and competency assessment required for consultants and specialist registrars.
- Radiologists are not permitted onto the Trust ITC Register. Radiologists may position the lumbar needle but are not permitted to prescribe or administer intrathecal chemotherapy.

5.2.2 Responsibility

- Medical Staff as defined above can be accepted onto the Trust ITC Register only to prescribe or administer intrathecal chemotherapy. Once on the Trust ITC Register, the Doctor takes full responsibility for their registered ITC task(s).
- An exception to this is an ST3 Grade and above or Consultant undergoing training in the procedure. In this case, direct supervision will be given by a Consultant or on the Trust ITC Register.
- The details of the medical responsibility can be found in section 7 'PRESCRIBING' and section 11 'ISSUING/TRANSPORTATION AND STORAGE' and section 12 'CHECKING AND ADMINISTERING.'

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 6 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

5.3 Checking ITC prior to administration

5.3.1 Eligibility

- Nursing staff band 6 or above who completed the 'ITC nursing competency training' and who have been assessed to be competent to perform this task are able to be part of the Trust ITC Register.

5.3.2 Responsibility

- Staff as defined above can be accepted onto the Trust ITC Register to undertake the following role:
 - Check patient identity at the bedside prior to administration.
 - Check ITC drugs prior to administration of intrathecal chemotherapy.
- Full details of this responsibility can be found in section 12: Procedure for Checking and Administration of Intrathecal Chemotherapy.

5.4 Clinical Checking of ITC Prescriptions

5.4.1 Eligibility

- Only Clinical Pharmacists who have completed the 'Clinical checking of intrathecal chemotherapy prescriptions' competency-based training programme and who have been assessed to be competent to perform this task are able to be admitted to this part of the Trust ITC Register.

5.4.2 Responsibility

- Clinical Pharmacy Staff as defined above can be accepted onto the Trust ITC Register to undertake the following roles:
 - Clinical checking

The details of the Clinical Pharmacist's responsibility is detailed in section 8 'Clinical Checking by Pharmacist.'

5.5 Dispensing, Final Checking and Issuing/Transportation of ITC

5.5.1 Eligibility

Dispensing:

- Only Pharmacy staff who have completed section 8 of the RSCH Aseptic Services Training Manual and who have an up-to-date validation in the Cytotoxic Isolator may be admitted to this part of the Trust ITC Register.

Final checking:

- Only Pharmacy staff who have completed section 8 of the RSCH Aseptic Services Training Manual and who have completed the final checking assessment for cytotoxic drugs in accordance with Pharmacy Aseptic Services Department Procedure F.3.8. may be admitted to this part of the Trust ITC Register.

Issuing/transportation

- Only Pharmacy staff who have completed section 8 of the RSCH Aseptic Services Training Manual may be admitted to this part of the Trust ITC Register.

5.5.2 Responsibility

- Aseptic Pharmacy Staff as defined above can be accepted onto the Trust ITC Register to undertake the following roles:
 - Dispensing
 - Final checking
 - Issuing/transportation from pharmacy

The details of the staff member's responsibility for each of these tasks can be found in sections 9-11 and the Pharmacy Aseptic Services Department Procedure G.2.15.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 7 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

5.5 Location of the Trust ITC Register

- The Trust ITC Register will be stored as per section 13.1.2 of this policy and document control will be as per section 13.

5.6 Registration training

- See section 6.2.1 and 6.2.2 for details of initial registration training and annual re-assessment of competence.

6. TRAINING

6.1 Induction training

- 6.1.1 The Trust ITC induction must be undertaken by all clinical staff that are proposed for inclusion in the Trust ITC Register.
- 6.1.2 Responsibility for ensuring this induction takes place lies with the Trust ITC Lead for medical staff, the Delegated Nurse for nursing staff, the Delegated Clinical Pharmacy Staff for Clinical Pharmacists, and the Delegated Pharmacy Aseptic Services Lead for Pharmacy staff working in the Aseptic Unit.
- 6.1.3 Staff will sign a written confirmation that they have undergone the formal induction and are aware of the national ITC guidance and local ITC policy.

6.2 Registration training

6.2.1 Initial registration training

- Before completing mandatory registration training staff will have completed the Trust ITC Induction.
- All staff required to prescribe, clinical check, dispense, final check, issue/transport, check or administer intrathecal chemotherapy MUST be formally trained to do so.
- The training syllabus and programme for each discipline will be approved by the Trust ITC Lead, and held in the ITC Master folder. These will incorporate elements of the ITC training and support toolkit.
- The designated competency-based assessors for each ITC task are listed in section 3 and are named in Appendix I. Only these individuals can authorise entry of eligible staff onto of the Trust ITC Register and only for the ITC task for which they are a designated competency-based assessor.
- Once the trainee has completed the theoretical and practical registration training programme, they will be assessed for competency.
- Successful completion of training and assessment of competence to practice must be documented.
- Once assessed as competent, the named competency-based assessor must ensure that the person is admitted onto the Trust ITC Register under the appropriate section by informing the Deputy Chief Pharmacist (CARS). (Section 13.1.5).
- Upon entry to the register, the Deputy Chief Pharmacist (CARS) will issue an 'Intrathecal Training Certificate' which will be valid for 12 months.
- The Trust competency assessors for each part of the intrathecal chemotherapy process are named in Appendix I.

6.2.2 Reassessment of registration

- Re-assessment of competence will be undertaken on expiry of the 'Intrathecal Training Certificate' to determine whether registration should be i) reconfirmed or ii) refresher training initiated or iii) they are deleted from the register.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 8 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

- The re-assessment should include a signed declaration by the registered staff that they have read the latest version of the national ITC guidance and the Trust ITC Register in the last year.
- At the time of reassessment the member of staff should declare the frequency with which they have performed their registered ITC tasks. If they have not performed any of their registered task(s) within the last two years, refresher training should be initiated for the specific ITC task or they should be deleted from the Trust ITC register.
- If at any point competence is not reconfirmed, refresher training must be initiated and the name removed from the Trust ITC Register until competence is reconfirmed.
- Responsibility for training and maintenance of the Trust ITC Register lies with the delegated lead for each profession. They should inform the delegated pharmacist of any changes necessary to the Trust ITC Register (see section 13).

7. PRESCRIBING OF INTRATHECAL CHEMOTHERAPY

- 7.1. Intrathecal chemotherapy can only be prescribed by those medical staff defined in section 5.2.1
- 7.2. The intrathecal chemotherapy will be prescribed on the electronic prescribing system, ARIA MedOnc Manager. The prescribing doctor will also complete the INTRATHECAL CHEMOTHERAPY QUESTIONNAIRE. The prescription and the questionnaire will NOT be printed by the prescribing doctor – this task is performed by the Clinical Pharmacist once they have clinically checked the prescription (see Section 8). All signatures on the INTRATHECAL CHEMOTHERAPY chemotherapy chart must be full signatures and must be by personnel included on the Trust ITC Register.
- 7.3. The prescribing doctor must declare on the INTRATHECAL CHEMOTHERAPY QUESTIONNAIRE whether any concurrent intravenous cytotoxic chemotherapy is prescribed. At the RSCH the preferred practice is to give intravenous chemotherapy on separate days to intrathecal chemotherapy. If a patient requires intravenous **and** intrathecal chemotherapy, the intravenous chemotherapy should be given first, before the intrathecal chemotherapy. The printed electronic prescription for the intravenous chemotherapy or the paper-based intravenous chemotherapy chart must be faxed to the Pharmacy Aseptic Services Department (extension 4503) with signatures to confirm that the intravenous chemotherapy has been administered (otherwise the intrathecal chemotherapy will not be final checked). See section 10 ‘Final checking.’

8. CLINICAL CHECKING OF INTRATHECAL CHEMOTHERAPY PRESCRIPTIONS BY PHARMACIST

- 8.1 The checking of the electronic prescription chart and the electronic questionnaire can only be undertaken by Clinical Pharmacists defined in section 5.4.1.
- 8.2 The Clinical Pharmacist will not commence the processing of the electronic prescription unless the electronic questionnaire has also been completed.
- 8.3 The route must be specified in full, the doses in accordance with the patient’s treatment protocol unless dose modification has been clearly identified, and in all other respects the prescription is clear and unambiguous.
- 8.4 Blood results are often not available at this stage and thus responsibility for checking blood results lies with the administering doctor.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 9 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

- 8.5 The intravenous chemotherapy declaration on the electronic questionnaire must be checked via Aria MedOnc by reviewing the scheduled dates of any subsequent intravenous chemotherapy treatment.
- 8.6 The Clinical Pharmacist should record the prescription details on the Excel spreadsheet in the following G drive folder (on Trustwide shared drive): G\Shared\TrustWide\Intrathecal Chemotherapy\ITC monitoring. This will provide the basis for monitoring the ITC annual caseload at the RSCH.
- 8.7 All signatures on the INTRATHECAL CHEMOTHERAPY chemotherapy chart must be full signatures (not initials) and must be by personnel included on the Trust ITC Register.
- 8.8 After completion of the clinical check, the Clinical Pharmacist will print the intrathecal chemotherapy prescription and the intrathecal chemotherapy questionnaire on YELLOW card.

9. DISPENSING OF INTRATHECAL CHEMOTHERAPY

- 9.1 The dispensing of intrathecal chemotherapy can only be undertaken by Pharmacy staff as defined in section 5.5.1.
- 9.2 Intrathecal drugs are not batch-dispensed at the RSCH.
- 9.3 The Pharmacy Aseptic Unit will not commence processing of the intrathecal chemotherapy prescription unless a print out of the electronic prescription and the electronic questionnaire on YELLOW card is received. Checks will also be carried out to ensure the prescribing Doctor and the Clinical Pharmacist who has checked the prescription are included in the Trust ITC Register
- 9.5 Pharmacy will not begin dispensing the ITC doses(s) until administration of any concomitant intravenous chemotherapy has been confirmed. The printed electronic prescription for the intravenous chemotherapy or the paper-based intravenous chemotherapy chart must be faxed to the Pharmacy Aseptic Services Department (extension 4503) with signatures to confirm that the intravenous chemotherapy has been administered (otherwise the intrathecal chemotherapy will not be final checked).
- 9.5 Intrathecal chemotherapy can only be dispensed within normal working hours.
- 9.6 Intrathecal chemotherapy will ONLY be dispensed in the Pharmacy Aseptic Services Department by those members of Pharmacy staff on the Trust ITC Register of individuals authorised to dispense intrathecal chemotherapy.
- 9.7 Intrathecal chemotherapy must be dispensed using the following Surety® products:
 - Surety blunt drawing-up needle
 - Surety lock syringe
 - Surety syringe cap
- 9.8 Intrathecal chemotherapy will be clearly labelled with black print on white labels. In addition to the standard labelling information (which includes patient's name, hospital number, date of birth and the name of the product) the label will state "For Intrathecal Use Only" and this will be emboldened.
- 9.9 See Pharmacy Aseptic Services Department Procedure G.2.15 'Supply of drugs for intrathecal use' for details of the full dispensing procedure.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 10 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

10. FINAL CHECKING INTRATHECAL CHEMOTHERAPY

- 10.1 The final check of intrathecal chemotherapy can only be undertaken by Pharmacy staff as defined in section 5.5.1.
- 10.2 The final checker should transfer the name of the dispenser from the worksheet to the intrathecal chemotherapy prescription. The final checker must check the drug chart to see if any concomitant intravenous chemotherapy prescribed. If so, they must ensure that the intravenous chemotherapy has been given before the intrathecal treatment is released by seeing the intravenous chemotherapy chart.
- 10.3 Chemotherapy for Intrathecal administration will be supplied to the ward in a dedicated sealed bag labelled "FOR INTRATHECAL USE".
- 10.4 See Pharmacy Aseptic Services Department Procedure G.2.15 'Supply of drugs for intrathecal use' for details of the full final checking and packaging procedure.
- 10.5 All signatures on the YELLOW INTRATHECAL CHEMOTHERAPY chemotherapy chart must be full signatures and must be by personnel included on the Trust ITC Register.
- 10.6 Once final checked and released by pharmacy staff the ITC drug(s) will be issued/transported immediately.

11. ISSUING/TRANSPORTATION AND STORAGE OF INTRATHECAL CHEMOTHERAPY

- 11.1 Intrathecal chemotherapy may be issued and transported to the designated clinical area by one of the following methods:
 - 11.1.1 A member of the Pharmacy staff registered to issue/transport intrathecal chemotherapy will take the sealed bag and original drug chart to the designated area:
 - Under no circumstances will the member of staff delivering the intrathecal chemotherapy to the designated area, deliver items required for administration by any other route, at the same time.
 - The staff member will sign the 'Issued/transported from Pharmacy by' and 'Stored in designated fridge by' box on the YELLOW intrathecal chemotherapy chart once the intrathecal drug(s) are locked in the designated refrigerator.
 - The duplicate key for the designated refrigerator is kept in the safe in St Luke's pharmacy.
 - The administering doctor will remove the intrathecal chemotherapy from the designated refrigerator and sign the 'Taken out of designated refrigerator by' box on the YELLOW intrathecal chemotherapy chart.
 - THE BAG IS TO REMAIN SEALED UNTIL OPENED BY THE DOCTOR TO PREPARE FOR ADMINISTRATION.
 - 11.1.2 Alternatively, the sealed bag containing intrathecal chemotherapy may be collected directly from the Pharmacy Aseptic Unit by the administering doctor who will sign the YELLOW intrathecal chemotherapy chart on collection. This will be countersigned by a member of Pharmacy staff registered to issue/transport intrathecal chemotherapy. This forms a record of collection of the dose. Under no circumstances can medication required for any other route be collected at the same time as the intrathecal chemotherapy. Nurses and other hospital staff are not allowed to collect intrathecal chemotherapy from the Pharmacy Aseptic Unit.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 11 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

- 11.2 All signatures on the YELLOW INTRATHECAL CHEMOTHERAPY chemotherapy chart must be full signatures and not initials., and must be personnel included on the Trust ITC Register.
- 11.3 Pharmacy responsibilities for issuing/transportation are detailed further in Pharmacy Aseptic Services Department Procedure G.2.15 'Supply of drugs for intrathecal use.'

12. CHECKING AND ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY

- 12.1 Intrathecal chemotherapy must only be administered by Doctors who meet the criteria described in section 5.2.1, and who are authorised to prescribe on the Trust ITC Register.
- 12.2 Radiologists may position lumbar needles but must NOT administer intrathecal chemotherapy or have any further involvement in the intrathecal chemotherapy process.
- 12.3 The National Patient Safety Agency (NPSA) has stated that all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with safer connectors that cannot connect with intravenous Luer connectors:
<http://www.nrls.npsa.nhs.uk/resources/?EntryId45=94529>
 In light of this, the dispensed intrathecal chemotherapy dose will be presented in a Suret[®]y lock syringe. The compatible Vygon NeuraSafe Whitacre 22G L90mm needle must be used for the intrathecal chemotherapy administration procedure. This has the safety feature of a Surety[®] non-Luer connection.
- 12.4 The patient should be explicitly told the nature of the procedure, the route of administration and the drug to be administered. If deemed appropriate by the medical practitioner, the patient will also check that the correct drug labelled for intrathecal use is to be administered, as explained prior to the procedure. This check will be documented in the patient's healthcare record.
- 12.5 It is ultimately the responsibility of the administering doctor to ensure that the correct drug is given.
- 12.6 The intrathecal chemotherapy must be administered in a designated area. The designated room where intrathecal chemotherapy is given is the Haematology Room in the Oncology Outpatient Department (Level B St Luke's Cancer Centre). In isolated cases, where lumbar puncture is difficult, the patient may be moved to the Interventional Radiology Room (Room 7 in the Radiology Department) where the needle may be positioned using X-ray screening.
- 12.7 Should the exceptional occasion arise where intrathecal chemotherapy needs to be administered other than in a designated area (i.e. in Radiology, ITU) full compliance with all areas of the policy MUST occur.
- 12.8 The designated room will be reserved for the purpose of intrathecal administration for the entire session within which the procedure is intended to take place.
- 12.9 Intrathecal Chemotherapy must only be administered during normal working hours, i.e. 0800 to 1800 hrs Monday to Friday (excluding Bank and Public Holidays), at times when a full range of specialist expertise, knowledge and support is readily accessible. Intrathecal chemotherapy will not be administered outside these hours.
- 12.10 Staff in other areas must not be involved in the administration of the intrathecal chemotherapy unless they are on the Trust ITC Register of competent individuals at the RSCH. The reasons why a different area needed to be used for the procedure

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 12 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

must be fully documented in the patient's healthcare record by the doctor administering the intrathecal chemotherapy.

12.11 The bag containing the drug for intrathecal administration must remain sealed and stored in the designated locked refrigerator until opened by the doctor to prepare for administration

12.12 NO DRUGS OTHER THAN THOSE REQUIRED FOR THE PROCEDURE MUST BE TAKEN INTO OR STORED IN THE DESIGNATED ROOM

12.13 Procedure for checking and administration of intrathecal chemotherapy:

- Prior to the commencement of this session the room must be checked for the presence and removal of intravenous chemotherapy before it is used for the administration of intrathecal chemotherapy.
- While intrathecal chemotherapy is being administered, the room will not be used for any other purpose during that session and the outside of the door will be marked "Do not disturb."
- Prior to the procedure, the doctor due to administer the dose will clinically review the patient. This will be documented in the medical notes. They will also check that all the staff involved in the ITC procedure thus far, are included in the Trust ITC Register. They will sign the YELLOW ITC prescription to confirm that the patient review and registration check has taken place.
- The sealed bag containing the intrathecal chemotherapy must remain sealed until the patient is fully prepared for the dose to be administered.
- If subcutaneous lignocaine is to be used as a local anaesthetic prior to this procedure, this must be administered and the syringe disposed of prior to unsealing the final packaging containing the intrathecal chemotherapy.
- The checking of intrathecal chemotherapy and patient identity can only be undertaken by those staff defined in section 5.3.1.
- The member of staff checking the ITC prior to administration must check the intrathecal chemotherapy out of the bag with the consultant or designated ST3 Grade or above.
- Double checking means both staff check all the details independently, and not that the checking procedure is split.
- **Check and confirm the details on the syringe(s) correspond with that on the patient's prescription chart in all respects as follows:**
 - The patient's name, hospital number and date of birth, on the prescription chart and the pharmacy label must be identical.
 - The name of the drug on the prescription chart and the pharmacy label must be identical.
 - The dose on the prescription chart and pharmacy label must be identical.
 - The time and date must be within the expiry date on the pharmacy label.
 - The volume in the syringe must correspond to the volume on the label.
 - The route of administration on the prescription chart corresponds to that on the label of the syringe(s).

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 13 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

- **At the patient's bedside:**
 - Check patient identification by confirming that the patient's identification wrist band detailing full name, date of birth and hospital number corresponds with the prescription chart and the intrathecal drug to be administered.
 - If the patient is able, ask for their full name and date of birth.
 - If deemed appropriate by the medical practitioner, the patient will be offered the opportunity to check that the correct drug labelled for intrathecal use is to be administered, as explained prior to the procedure.
 - The checking member of staff should sign the intrathecal chemotherapy prescription to confirm the intrathecal drug(s) and the patient's identity have been checked.
 - **If at any stage there is the slightest doubt on the part of the doctor or the checking member of staff that the drugs presented are not appropriate for the patient, or the patient identity is incorrect STOP and clarify the situation, DO NOT PROCEED until certain that everything is correct.**
 - Wash hands and wear a plastic apron and gloves before commencing the procedure in a 'no touch' aseptic manner.
 - Perform a lumbar puncture using a Vygon Neurasafe Whitacre needle.
 - Remove a volume of CSF equal to the volume to be injected intrathecally.
 - Send CSF for all relevant diagnostic investigations on the first occasion and for bacteriology and cytology on all occasions.
 - Dispose of local anaesthetic syringe.
 - Remove the outer wrapping of the syringe containing intrathecal chemotherapy.
 - Place the syringe(s) and any equipment on a tray protected with a disposable absorbent dressing towel. Only intrathecal doses should be placed on the tray.
 - Check the contents of the syringe again.
 - Attach the syringe containing the cytotoxic to the Vygon NeuraSafe Whitacre needle. Ensure the needle is still within the CSF and inject the drug slowly. Discontinue if there is any resistance to flow or patient complains of pain.
 - The Doctor who administers the Intrathecal Chemotherapy signs the Intrathecal Chemotherapy prescription chart and records the procedure in the patient's healthcare record.
 - All signatures on the YELLOW INTRATHECAL CHEMOTHERAPY chemotherapy chart must be full signatures and must be personnel included on the Trust ITC Register.
 - Dispose of the syringes directly into the sharps bin and double bag dressing towels, protective clothing and gloves into yellow plastic disposable bags.
 - Finally wash and dry hands.
 - Advise nurses of any technical difficulties that may have occurred during the procedure that may affect the after care of the patient.
 - Nurses must document the procedure in the patient's notes.
 - Nurses must record the administration of the Intrathecal Chemotherapy on the electronic prescribing system, ARIA MedOnc Manager.
 - If any of the intrathecal drug(s) are not administered, the administering Doctor or checking nurse should immediately place the dose(s) in a cytotoxic waste bin.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 14 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

13. DOCUMENT CONTROL

13.1 Hard copy documents:

13.1.1 The following documents are required to be stored in the areas involved in Intrathecal Chemotherapy:

- National ITC Guidance
- Local ITC Policy
- Trust ITC Register

13.1.2 The 'Master Intrathecal Chemotherapy Folder' is kept by the Deputy Chief Pharmacist (CARS). Operational copy folders areas are kept in:

- Haematology Room, St Luke's Outpatient Department – Level B
- Onslow Ward – Level F
- Satellite Pharmacy, St Luke's Cancer Centre – Level B
- Pharmacy Aseptic Services Department – Level B
- Room 7, Radiology Department – Level B

It is the responsibility of the Trust ITC Lead that the local ITC policy should be revised when new national ITC guidance is issued, or every 24 months, whichever is soonest.

13.1.3 It is the responsibility of the Deputy Chief Pharmacist (CARS) that on policy revision new policies are issued with the correct version number, and they are placed in the areas listed above, with previous versions removed and destroyed.

13.1.4 It is the responsibility of each competency-based assessor to inform the Deputy Chief Pharmacist (CARS) of any admissions, re-registrations or removals from the Trust ITC Register.

13.1.5 It is the responsibility of the Deputy Chief Pharmacist (CARS) that when the re-registration, addition or removal of staff from the Trust ITC Register occurs, the Intrathecal folders are updated and previous copies of the Trust ITC Register removed from the folder.

13.1.7 The Trust ITC Registers of competent individuals will be reviewed every three months by the Deputy Chief Pharmacist (CARS).

13.2 Electronic copy documents

13.2.1 Latest versions of the Trust ITC induction and induction signature confirmation letter are stored in PDF form on the G drive (Trust shared drive):

[G\Shared\TrustWide\Intrathecal Chemotherapy\Trust ITC Induction](G:\Shared\TrustWide\Intrathecal Chemotherapy\Trust ITC Induction)

13.2.2 The latest version of the national ITC guidance is stored in PDF form on the G drive:

<G\Shared\TrustWide\Intrathecal Chemotherapy\Current ITC Guidance>

13.2.3 The latest version of the local ITC policy is stored on the St Luke's Cancer Alliance Website:

<http://stlukescanceralliance.co.uk/intrathecal-chemotherapy-policies/>

13.2.4 The ITC caseload monitoring spreadsheet is stored on the G drive:

<G\Shared\TrustWide\Intrathecal Chemotherapy\ITC caseload monitoring>

13.2.5 It is the responsibility of the Deputy Chief Pharmacist (CARS) to move outdated documentation to the archive folder on the G drive:

<G\Shared\TrustWide\Intrathecal Chemotherapy\Archive>

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 15 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

14. APPROVAL of:

Royal Surrey County Hospital NHS Trust “The policy for administration of intrathecal chemotherapy for adult oncology & haematology patients:”

By:

Medical Director, Royal Surrey County Hospital
Dr Christopher Tibbs, Medical Consultant

Signature: C Tibbs Date: 07.04.17.

Head of Service for Chemotherapy, SLCC
Dr Agnieszka Michael, Consultant Medical Oncologist

Signature: A Michael Date: 25.04.17.

Intrathecal Chemotherapy Lead at Royal Surrey County Hospital
Dr John de Vos, Consultant Haemato-Oncologist

Signature: J De Vos Date: 31.03.17.

Deputy Chief Pharmacist, Royal Surrey County Hospital
Sally Seymour

Signature: S Seymour Date: 28.03.17.

Director of Nursing and Patient Experience, Royal Surrey County Hospital
Louise Stead

Signature: L Stead Date: 06.04.17.

Chief Executive Royal Surrey County Hospital
Paula Head

Signature: P Head Date: 04.04.17.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 16 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

Appendix I:

List of names: Named Trust ITC Lead and staff with delegated ITC responsibilities

Single Trust ITC Lead and Lead Trainer:	Dr John de Vos Lead Consultant Haematologist <i>Deputy (who will assess Trust ITC Lead): Dr Louise Hendry Consultant Haematologist</i>
Delegated Nurse:	Sam Darby Lead Haematology Nurse <i>Deputy (who will assess delegated nurse): Sandy Kirk Clinical Nurse Specialist Haemato-Oncology</i>
Delegated Clinical Pharmacist:	Sally Seymour Deputy Chief Pharmacist Cancer, Aseptic and Research Services (CARS) <i>Deputy (who will assess delegated clinical pharmacist): Man-Chie Chow Lead Pharmacist, Haemato-Oncology</i>
Delegated Pharmacy Aseptic Services Lead:	Caroline May Aseptic Services Manager <i>Deputy (who will assess delegated aseptic services lead): Sally Seymour Deputy Chief Pharmacist Cancer, Aseptic and Research Services (CARS)</i>

Reason for Update: Routine review (+ e-Rx and Surety added)	Page 17 of 19
Valid from: April 2017	Review date: March 2019
Version: 11	Supersedes version: 10
Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive	

APPENDIX II

Trust ITC Policy document history:

Policy originally prepared for the RSCH Chemotherapy Working Party by:

- J Turner, SWSH Network Pharmacist
- Dr G Robbins, Trust ITC Lead

Version 5 prepared April 2007 by:

- S Punter, Principal Cancer Services Pharmacist
- C Palles-Clark, Lead Chemotherapy Nurse
- Dr G Robbins, Trust ITC Lead

Version 6 prepared June 2007 by:

- S Punter, Principal Cancer Services Pharmacist
- C Palles-Clark, Lead Chemotherapy Nurse
- Dr G Robbins, Trust ITC Lead

Version 7 prepared December 2008 by:

- S Seymour (ne Punter), Principal Cancer Services Pharmacist
- V Mumford, Lead Chemotherapy Nurse
- Dr G Robbins, Trust ITC Lead

Version 8 prepared December 2010 by:

- S Seymour, Principal Cancer Services Pharmacist
- V Mumford, Lead Chemotherapy Nurse
- Dr G Robbins, Trust ITC Lead

Version 9 prepared November 2011 by:

- S Seymour, Deputy Chief Pharmacist Cancer, Aseptic & Research Services (CARS)
- S Flaherty, Lead Haematology Nurse
- Dr G Robbins, Trust ITC Lead

Version 10 prepared July 2013 by:

- M Chow, Lead pharmacist Haemato-oncology
- R Williams, Deputy Chief Pharmacist Cancer, Aseptic & Research Services (CARS)

Summary of changes:

- Area of administration has been changed to 'designated area'
- Intrathecal chemotherapy is not issued and transported in a box but in a dedicated bag,
- Date of birth is now part of the Intrathecal label
- Routine review, names updated

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 18 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	

Version 11 prepared October 2016 by:

- M Chow, Lead pharmacist Haemato-oncology
- S Seymour, Deputy Chief Pharmacist Cancer, Aseptic & Research Services (CARS)

Summary of changes:

- Routine review, names updated
- Update of procedure whereby intrathecal chemotherapy is prescribed on ARIA MedOnc Manager and an electronic intrathecal chemotherapy questionnaire is also completed by the prescribing doctor – both are printed on yellow card by the Clinical Pharmacist performing the clinical check of the prescription.
- Addition of Surety® system to dispensing and administration procedure.

Reason for Update: Routine review (+ e-Rx and Surety added)		Page 19 of 19
Valid from: April 2017	Review date: March 2019	Distribution: Master folder, Haematology Room, Onslow Ward, SLCC Pharmacy, Aseptic Unit, Radiology, G drive
Version: 11	Supersedes version: 10	