CP52
Intrathecal chemotherapy Policy

CONTENTS

Attachments

1.0 Policy Statement Purpose / Objectives of the policy

The purposes of this policy are to outline the processes for the prescribing; preparing; dispensing; issuing; delivering; checking and administering of Intrathecal chemotherapy and provide guidelines for medical, nursing and pharmacy professionals within RWHT.

2.0 Definitions

Intrathecal chemotherapy - administration involves the injection of chemotherapy drug(s) directly into the Cerebral-Spinal Fluid (CSF) by Lumbar Puncture (LP).

3.0 Accountabilities

3.1 The Chief Executive has overall responsibility for ensuring compliance with National guidance and for appointing a Trust Lead for Intrathecal chemotherapy.

3.2 It is the responsibility of the Trust Lead for Intrathecal chemotherapy to ensure that the policy and procedure is implemented, monitored, reviewed and updated.

3.3 It is the responsibility of the Lead Medical Trainer; Lead Nurse Trainer and Lead Pharmacy Trainer to ensure that all staff involved in the processes receive formal induction and training appropriate to their role in the procedure, along with annual review of competencies.

3.4 Individual staff must adhere to the policy and maintain own competence.

4.0 Policy Detail

4.1 The policy applies to all employees of the Trust who play a part in any element of the process in relation to Intrathecal chemotherapy.

4.2 This policy is supported by the following procedures, protocols and guidelines:

- Register of designated personnel;
- Designated Trust Lead Roles and Responsibilities;
- Staff Induction, Training and Lead Trainer/s roles and responsibilities;
- Prescribing, preparation, storage, issuing of drugs, administration of intrathecal chemotherapy and designation of area;
- Patient consent, reviews and involvement of the patient;
- Reducing the risk of error;
- Location “Intrathecal chemotherapy Policy” Folders and list of designated areas for intrathecal chemotherapy administration;
- Process for entry onto the register;
- Record of out of hours / emergency administration of intrathecal / chemotherapy;
- Emergency preparedness flowchart;
- Procedure for administration of intrathecal chemotherapy;
- Administration checklist;
- Lumbar puncture care standard;

- Medical staff training competencies and assessment record;
- Pharmacy intrathecal chemotherapy training assessment record;
- Nurse intrathecal chemotherapy training assessment record.

4.2 Policy guidelines

Please see Appendix 1 for details

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	Yes – **No**
2	Does the implementation of this policy require additional revenue resources	Yes – **No**
3	Does the implementation of this policy require additional manpower	Yes – **No**
4	Does the implementation of this policy release any manpower costs through a change in practice	Yes – **No**
5	Are there additional staff training costs associated with implementing this policy which can not be delivered through current training programmes or allocated training times for staff.	Yes – **No**
	Other comments	

6.0 Equality Impact Assessment

This policy applies to all employees irrespective of sex, age, race, colour, religion, disability, nationality, ethnic origin, gender, sexual orientation or marital status.

7.0 Maintenance

It is the responsibility of the Trust Lead for Intrathecal chemotherapy to ensure that this policy is kept up to date, implemented and adhered to at RWHT.

8.0 Communication and Training

Directors and managers are responsible for ensuring that all staff are made aware of this policy on local induction and applied to all relevant situations.
Staff with specific roles associated with this policy will receive additional training.
All staff involved with Intrathecal chemotherapy will be recorded on a register of designated personnel.

9.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Committee/ Group
Monitoring of the effectiveness of the policy and adherence of the nursing/medical/ pharmacy staff to the policy (good practice)	Trust Lead for Intrathecal chemotherapy	National Cancer Peer Review assessment of the RWHT's Haematology & Chemotherapy services Haematology/ Oncology Directorate Governance framework – review of clinical incidents (Datix) & complaints	Annual basis 4 weekly	Results presented to Division 2 Governance Committee, Division 2 Core Team and to the QSAG. Clinical incident monitoring presented and discussed at the monthly Haematology/Oncology Directorate Governance meetings
Staff training	Trust Lead for Intrathecal chemotherapy	Monthly review & update of the Trust's Intrathecal training and annual competency register	Monthly	N/A

The above monitoring will be organised by the Trust Lead for Intrathecal chemotherapy on behalf of the Chief Executive.

10.0 References

- Department of Health, Health Service Circular 2008/001 - "Updated National Guidance on the Safe Administration of Intrathecal chemotherapy" 11/08/08 Available at: DRAFT (allcatsrgrey.org.uk) [Accessed 02/10/2023]
- Department of Health Clinical Governance Programme - "An Organisation with a Memory: report of an expert group on learning from adverse events in the NHS" 2000. Available at: An organisation with a memory - PubMed (nih.gov) [Accessed 02/10/2023]
- Department of Health Progress Report - "Building a Safer NHS for Patients" April 2001.
  Available at: 78185- Build Best Cover (nicpld.org) [Accessed 02/10/2023]

- "The Prevention of Intrathecal Medication Errors: A report to the Chief Medical Officer" - Prof Kent Woods, April 2001.
  Available at: The Prevention of Intrathecal Medication Errors: A report to the Chief Medical Officer | Request PDF (researchgate.net) [Accessed 02/10/2023]

- 'The External Enquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham', 4th January 2001,
  External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham, 4th January 2001 (17 April 2001) - Other reports and inquiries - Patient Safety Learning - the hub (pslhub.org) [Accessed 04/10/2023]

- NPSA Rapid Response Report "Using Vinca alkaloid Minibags" NPSA/2008/RRR004. Available at: Details for: NPSA rapid response report on using minibags to administer vinka alkaloids and revised intrathecal chemotherapy (ITC) guidance. › The King's Fund Library catalog (kingsfund.org.uk) [Accessed 04/10/2023]
- BSH Guidelines (2016) for platelet level prior to invasive procedure available at: Use of Platelet Transfusions (b-s-h.org.uk) [Accessed 02/10/2023]

Document Control

Policy number and Policy version: **CP52 V5.0 September 2023**	**Policy Title** **Intrathecal chemotherapy Policy**	**Status:** **Final**		**Author: Trust Medical Lead for Intrathecal chemotherapy** **Director Sponsor: Medical Director**
Version / Amendment History	Version	Date	Author	Reason
	V1 V2 V3 V4	July 09 June 13 July 15 June 19	Trust Lead for Intrathecal chemotherapy	New policy Update Update Update
	V4.1	Sept. 2022	Trust Lead for Intrathecal chemotherapy	Extension
	V4.2	Dec. 2022	Trust Lead for Intrathecal chemotherapy	Extension
	V4.3	Aug. 2023	Trust Lead for Intrathecal chemotherapy	Extension
	V5.0	Sept. 2023	Trust Lead for Intrathecal chemotherapy	Full Review
Intended Recipients: Any medical/nursing/pharmacy professional involved in the preparation and administration of intrathecal chemotherapy				
Consultation Group / Role Titles and Date:. Trust Lead for Intrathecal chemotherapy &Haematologist– September, 2023 Lead Haematology Clinical Nurse Specialist – September, 2023 Lead Oncology Pharmacist – September, 2023 Re-reviewed Apr 2015, Feb 2013 following amendments undertaken as requested by the Policy Committee in Jan 2013 Re-reviewed May 2019 as requested by the Policy Committee in July 2015 Re-reviewed September 2022 as requested by the Policy Committee in August 2022 Re-reviewed September 2023 as requested by the Policy Committee in August 2023				
Name and date of Trust level group where reviewed	Trust Policy Group – October 2023			
Name and date of final approval committee	Trust Management Committee – October 2023			
Date of Policy issue	November 2023			

Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	October 2026 (3 years)
Training and Dissemination: This policy is already widely used and referred to within the Trust's Chemotherapy and Haematology Teams. Following the approval of the updated policy at RWHT's Policy Committee, the policy will be circulated to all the multi-disciplinary members of the Haematology and Chemotherapy Teams, and to the Oncology Pharmacy Team. The responsibility for the dissemination of the updated policy will lie with the Lead Cancer/Chemotherapy Nurse	
To be read in conjunction with: NA	
Initial Equality Impact Assessment (all policies): Completed Yes / No **Impact assessment (as required): Completed Yes / No / NA**	
Monitoring arrangements and Committee	Trust Medical Lead for Intrathecal Chemotherapy – Dr Whitmill
Document summary/key issues covered.	
Key words for intranet searching purposes	Chemotherapy, Haematology • Clinical Haematology Directorate Governance Committee Haematology Team meetings: clinical incident review – Datix

Appendix 1 – Intrathecal chemotherapy Policy details/guidelines

1.1 Register of Designated Personnel.

All NHS facilities providing an intrathecal chemotherapy service will maintain a register of designated personnel who have been trained and certified competent in one or more of the following tasks:

- Prescribing intrathecal chemotherapy;
- Dispensing intrathecal chemotherapy i.e. preparing the dose, filling the syringe, final checking and release of the drug(s), placing it in packaging for transport;
- Issuing intrathecal chemotherapy from the pharmacy i.e. transporting the drug if it is not issued directly to the collector;
- Checking intrathecal chemotherapy drugs prior to administration;
- Administering intrathecal chemotherapy.

The "designated lead" for the Trust has overall responsibility for holding the register and ensuring that it is maintained and kept up to date. He or she may delegate day to day responsibility for maintaining individual aspects of the register to other senior staff, for example the Chief Pharmacist for dispensing / issuing, Intrathecal Nurse Lead or the Lead Cancer Nurse for checking.

A system is in place to ensure that only the latest edition of the register is available to staff. An up to date hard copy of the full register will be available in each location in the Trust where intrathecal chemotherapy is prescribed, dispensed / issued and administered. A copy is also available in the haematology in-patient area, even though intrathecal chemotherapy is never administered in that location.

No form of "provisional" entry onto the register is allowed for any staff.

Individuals named on the register must be able to demonstrate that they are competent to fulfil their designated roles and have been certificated as such. Staff moving from one hospital to another will take with them their certification in their training logbook or other training record. However, automatic inclusion onto the hospital register will not occur. On arrival, individuals will have to demonstrate their competence to the hospitals satisfaction before being added to the register.

1.2 Designated Trust Lead for Intrathecal chemotherapy -Role and Responsibilities:

The Trust Lead for Intrathecal chemotherapy is directly accountable to the Chief Executive for compliance with the National Guidance on Intrathecal chemotherapy and compliance with the Cancer Peer Review Measures, namely:

- Management and Organisation;
- Case Volume and Safety Issues;
- The Local Protocol;
- The Register;
- Induction and Training;
- Managing Intrathecal chemotherapy Drugs;
- The declared divisions of the Intrathecal chemotherapy Service.

The Trust Lead is also responsible for monitoring how often staff on the Register carry out

procedures related to Intrathecal chemotherapy and assessing whether they be permitted to remain on the Register.

The Trust Lead for Intrathecal chemotherapy has overall responsibility for Induction, Training and continuing professional development related to Intrathecal chemotherapy. Within the Wolverhampton NHS Trust there are Lead Trainers designated for each staff discipline involved:

- Medical Lead Trainer;
- Nursing Lead Trainer;
- Pharmacy Lead Trainer.

1.3 Responsibility for staff induction, training and review:

The responsibility for ensuring the ongoing delivery of staff induction and training relating to the safe administration of Intrathecal chemotherapy for all staff lies with the Designated Trust Lead for Intrathecal chemotherapy within the Trust.

In this Trust there are identified Lead Trainers for Medical, Nursing and Pharmacy Personnel.

The Lead Trainer Role and Responsibilities:

- All staff, including Consultants, that are newly appointed to the Trust, or to a relevant ward or department involved in intrathecal chemotherapy administration must be provided with a formal induction and training. They must also read the Trust policy and national guidance.
- There is a formal induction course covering the potential clinical hazards of intrathecal chemotherapy and the danger posed to patients if intravenous Vinca alkaloids (Vincristine, Vinblastine, Vindesine and Vinorelbine) are accidentally administered intrathecally, for all nursing, pharmacy and medical - including consultants – staff new to the hospital, that it is appropriate to their role.
- As part of the induction/training it is made clear to all staff involved with the care and treatment of patients receiving intrathecal chemotherapy that they challenge colleagues if, in their judgement, either protocols are not being adhered to or the actions of an individual may cause potential risk to a patient. Challenging of a colleague must not be seen as adversarial, but as an additional check to improve patient safety and reduce risk.
- Staff that are not involved in providing an Intrathecal chemotherapy Service, but are likely to work in areas where different aspects of the service are provided, must be made aware that there is strict National Guidance and a local Trust “Intrathecal chemotherapy Policy” for this service which prohibits their involvement in any aspect of service delivery.
- All Registered staff, including consultants, must sign a written confirmation that they have read and understood the Trust policy and national guidance. This signed confirmation must be updated annually.
- The practical issues regarding intrathecal chemotherapy from decision to treat onwards are a regular part of continuing professional education for all staff who remain on the Register of Designated Personnel and participation in Intrathecal procedures is closely monitored to ensure that competence is maintained.
- All staff on the Register are able to demonstrate they are competent for the roles that they are expected to undertake in providing an Intrathecal Chemotherapy Service and

this competence is reviewed annually.

- Once staff have been assessed as competent, the Lead Trainer will inform the Trust Lead for intrathecal chemotherapy who will then authorise entry onto the Register of Designated Personnel and arrange for the issue of a Certificate which confirms their designated role.
- Lead Trainers will review the Register on a monthly basis.
- It is the responsibility of the Lead Trainer to check that all staff on the Register undergo Annual Update and Review of Competence and have participated in at least 2 intrathecal chemotherapy procedures in the preceding 12 months.

  Any required additions or alterations to the register will be communicated to the Intrathecal Chemotherapy Lead for authorisation.

  Staff then may:

  - have their competence re-confirmed;
  - receive refresher training;
  - be deleted from the Register.
- Practical experience/training in the delivery of intrathecal chemotherapy takes place as described below.

  Trainees must observe the procedure initially and familiarise themselves with the process involved before undertaking supervised practice.

  Personnel may perform a given registerable task under the direct supervision of (and in the constant presence of) personnel who are currently on the Register of Designated Personnel for the task being undertaken.

  They must then continue to be supervised until they and their assessor feel that they are competent to undertake the task independently. At least 2 procedures must be performed under supervision before independent practice is permitted.

  Agreed written competencies must be completed for all staff and the assessor will then inform the relevant Lead Trainer so that the practitioner can be entered onto the Register.

  The Lead Trainer then informs the Trust Lead for intrathecal chemotherapy who authorises entry onto the Register and arranges for a Certificate which includes confirmation of their role to be issued to the practitioner and the date at which this needs to be reviewed.
- A copy of the competency/assessment record must be kept as evidence by the Lead Trainer and the Trust Lead.

- The Lead Trainers will receive a copy of the assessment document and a copy of the updated Register. It is the responsibility of all Lead Trainers to ensure they have their own folder and copy of the up to date Register.
- Staff who have been removed from the Register, and who are now seeking re-entry onto the Register, must satisfy themselves and their assessor that they are competent by:
  - attendance at a Training Update session;
  - undergoing further Competency assessment and performing at least 2 procedures under supervision;
  - familiarisation with the most recent National Guidance and the local Trust Policy;
  - signing to confirm that they have read and understood both documents.

Induction

All medical, nursing and pharmacy staff working in areas where intrathecal chemotherapy is practised but who are not directly involved in intrathecal administration must have an awareness of and understand the reasons for the strict regulations governing this procedure; they will also have received the appropriate Induction and Training and will be asked to sign to confirm this. All Registered staff will be asked to sign to confirm that they have read and understood the National Guidance Document and the Trust Intrathecal Policy.

- Any member of medical, nursing and pharmacy staff who is temporarily working in the clinical areas where intrathecal chemotherapy is part of routine procedure must be informed regarding the strict regulations that apply. Under no circumstances will they be asked to be involved in any part of the procedure. If they are approached to be involved they must refuse to do so. They must be given the information sheet for temporary staff.
- The Oncology and Haematology Directorate Induction day includes a session on Chemotherapy Awareness and covers the issues relating to intrathecal chemotherapy.
- According to national guidance a formal induction course must be provided for all staff, including designated medical, nursing and pharmacy staff, appropriate to their needs and with regard to their specific role in prescribing, dispensing, issuing, checking and the administration of intrathecal chemotherapy. All Staff involved in the prescription, preparation, dispensing, issue, delivery, checking and administration of intrathecal chemotherapy will receive the appropriate Induction related to their role in this procedure.
- Formal induction covers the potential clinical hazards associated with intrathecal chemotherapy administration and the danger posed to patients if Vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are accidentally administered intrathecally, and newer safer practice recommendations from the NPSA on the presentation and administration of intravenous vinca alkaloids for adults and adolescents.
- It is made clear to all new Consultant medical staff that they must not prescribe or administer intrathecal chemotherapy until they have received the appropriate local induction and training and their competency has been assessed and registered.

Training

Before becoming involved with any aspect of intrathecal chemotherapy, all relevant staff must undergo the required mandatory training.

The mandatory training programme in the Safe Administration of Intrathecal Chemotherapy for medical, nursing and pharmacy staff within the Wolverhampton NHS Trust must include information on the following:

- The rationale for the administration of intrathecal chemotherapy;
- The potential hazards associated with the administration of intrathecal chemotherapy;
- The contents and recommendations of the National Guidance on the safe administration of intrathecal chemotherapy;
- The contents of the Trust Intrathecal Chemotherapy Policy;
- Personnel involved in intrathecal procedures and where and when the procedure can be performed;
- Who is prohibited from taking part in intrathecal procedures;
- The Register of Designated Personnel;
- Drugs that can be given intrathecally;
- Drugs which must never be given intrathecally and the reasons why;
- The prescription, preparation/dispensing, confirmation/check, issue/delivery, transport and storage of intrathecal chemotherapy;
- Patient/carer involvement;
- The procedure, including consent, checking and administration of intrathecal chemotherapy

The mandatory training programmes are supported by the use of the Department of Health

"Intrathecal Chemotherapy Induction and Training Support Toolkit".

Annual Competence Review

Competence Review of staff on the Register must take place annually. Competence will be assessed by:

- Evidence of Annual Update and Formal Assessment by completion of relevant Competencies;
- Evidence of participation in at least 2 procedures per year (staff participation in intrathecal procedures is recorded on record sheets kept on CHU and in the Aseptic Suite in Pharmacy);
- Evidence that each individual has read the National Guidance and the local Trust Policy (as part of their initial intrathecal chemotherapy training, staff must sign the Registered Staff Statement to confirm that they have done this).

1.4 Prescribing, preparation, storage, issuing of drugs, administration of intrathecal/intraventricular chemotherapy and designation of area

Prescription

Within RWT only Consultants and Associate Specialists, whose names appear on the Register of Designated Personnel are permitted to prescribe intrathecal chemotherapy. The dose of intrathecal chemotherapy must be prescribed by a Consultant whose name appears on the Register of Designated Personnel, as per the Trust Chemotherapy Policy.

Within this Trust, only Consultants, Associate Specialists, ST4's or staff grade equivalents, whose names appear on the Register of Designated Personnel are permitted to administer intrathecal chemotherapy.

The purposely designed electronic Intrathecal Chemotherapy Treatment Chart will be used in all instances. The drug and route of administration will be clearly written in full on the chart. The chart will have space to allow for the signatures in full of the prescriber, issuer, delivery staff, nurse checker and administrator of the to enable a clear audit trail. The paper copy of the prescription is scanned to the patient portal record and retrospectively marked as given in the chemotherapy EPMA system by the specialist nursing staff.

Preparation

All intrathecal chemotherapy is prepared in a pharmacy aseptic unit by specifically trained pharmacy staff, that are listed on the Register of Designated Personnel.

Storage

If storage is required between dispensing and issuing, intrathecal chemotherapy drugs are stored in a dedicated lockable refrigerator in the pharmacy aseptic unit. This facility must never be used to store intravenous drugs.

Issuing of drugs

Drugs for intrathecal chemotherapy must only be issued to the doctor who will be administering the drug and taken to the designated administration area by a designated member of pharmacy staff whose name appears on the register. The member of pharmacy staff must sign for the release of the drug(s), and the doctor must sign to receive the drug(s), in the appropriate section of the prescription chart.

Whenever possible, intrathecal and intravenous chemotherapy drugs must not be administered to a patient on the same day. However if this is not possible intrathecal chemotherapy drugs must be issued at a different time from drugs for intravenous administration.

Intravenous chemotherapy drugs must be issued first. Only following written confirmation, (a signed treatment sheet) that any intravenous chemotherapy drugs for the named patient have already been administered will the intrathecal chemotherapy drugs must be issued by pharmacy.

The Pharmacist releasing the intrathecal chemotherapy will sign the intrathecal prescription chart to verify that these checks have been made. This will ensure that the drugs which would

prove fatal if given by other routes will have been used before the intrathecal chemotherapy drugs are issued.

Where a regimen involves intrathecal chemotherapy to be given during continuous intravenous chemotherapy administration, it is only acceptable to administer intrathecal chemotherapy once the intravenous infusion(s) have started. Written confirmation (a signed treatment sheet) that the intravenous infusion(s) have been started must be done prior to the issue of intrathecal chemotherapy drugs from the pharmacy.

Administration

All routine intrathecal chemotherapy is administered in the Angiography Suite or the Screening Room in the Main Radiology Department.

Any urgent intrathecal chemotherapy which is needed to be given on an emergency basis outside of normal working hours will be given in a side room in the Clinical Haematology Unit (CHU).

The area must be designated as ”I.V. FREE‟ for the duration of the procedure, and a sign indicating this must be placed at the entrance to the room.

Appropriate checks must be made to ensure that any intravenous chemotherapy, bolus or infusion, due that day for the patient has already been administered or commenced. If intravenous chemotherapy has been issued but not administered, it must be returned to Pharmacy before the Intrathecal drug(s) is released.

Intravenous chemotherapy must NEVER be stored in the designated area.

NB. If intravenous sedation is required for the procedure, an appropriate member of staff must be designated as responsible for this sole purpose. This must not be the designated Consultant or chemotherapy nurse involved in the intrathecal administration or checking. The designated “IV” person must stay with the patient and take no part in the intrathecal procedure.

In an Emergency “Out of Hours” procedure, a bay in the CHU is designated for the sole purpose of intrathecal chemotherapy administration. The area is designated as “I.V. FREE” and a sign indicating this is placed at the entrance to the room.

If a patient is admitted as an emergency, requiring emergency intrathecal chemotherapy and is currently being nursed in an inappropriate area (AMU or ED) then the patient must be transferred to the CHU as soon as possible. This may necessitate the transfer out of another patient to accommodate the emergency and the reasons for this must be clearly explained to all concerned.

If a patient requiring intrathecal chemotherapy is an in-patient on another ward, he or she must be transferred to an in-patient bed on CHU, or booked in as a Day Case on the Durnall Unit.

Once the procedure has been completed the patient can then be transferred back to their original ward.

Emergency preparedness plan

THE PROCESS TO BE FOLLOWED IN THE EVENT OF THE DESIGNATED AREA BEING UNAVAILABLE IS OUTLINED BELOW.

This is the arrangement for when treatment is essential and the Interventional radiology Suite/Screening room cannot be used.

The following steps must be taken:

- The Consultant responsible for the patient's management must ascertain with the Consultant Radiologist(s) that the Interventional radiology Suite / Screening room is unavailable.
- Permission to proceed with the procedure outside of the designated area must be given by the Trust Lead for Intrathecal Chemotherapy or, in his absence, by the Consultant responsible for the patient's management before the procedure is carried out.
- The reasons for the procedure must be clearly documented in the patient's medical notes.
- A side room on CHU ward must be cleared and made available for the procedure. This may cause inconvenience to other patients and the reasons for this must be clearly explained to all concerned.
- If it is not possible to clear a side room on the CHU, the Consultant attending to the patient must make a decision as to whether transfer to another hospital where treatment can be given is necessary.
- All appropriate staff must be informed as to where the procedure is to take place
    - Designated Consultant
    - Designated Chemotherapy Nurse
    - Assistant Director of pharmacy-Aseptic, Cancer and Clinical Trials Services
    - Drug Delivery personnel
    - Senior Sister/Nurse in charge of the Unit at the time
    - Directorate Manager or Deputy at the time
    - Designated Trust Lead for Intrathecal Chemotherapy. If not available at the time the Trust Lead must be informed as soon as practically possible.
- The side room must be designated "IV Free" and appropriate checks made and documented to ensure that any IV chemotherapy due that day for the patient has already been administered or it must be returned to Pharmacy before the Intrathecal drug / s is issued from Pharmacy.
- All other aspects must be performed as in a routine procedure.
- The Record of "Out-of-Hours or Emergency Administration of Intrathecal Chemotherapy" must be completed.

Out of Hours

- In the event of a Clinical Emergency, e.g. CNS relapse, it may be necessary for the procedure to take place out of hours. In this instance, the Designated Trust Lead for Intrathecal Chemotherapy must be informed, if possible, prior to the procedure being performed. If this is not possible then the Lead must be informed at the earliest available opportunity.

In these circumstances the following procedure must be followed:

- The On-call Consultant must make the clinical decision to proceed.
- The following members of designated staff from the Register of designated personnel must be available:
  - Designated Consultant;
  - Designated Chemotherapy nurse;
  - Designated Cancer Pharmacist and Technician;

  All of the above MUST be on the Register of Designated Personnel.
- In the event of the appropriate personnel not being on-duty or available via the On Call System, every effort must be made to contact other appropriately trained members of staff to ascertain whether they can make themselves available.
- If this fails, the procedure MUST NOT PROCEED. A decision must be made by the attending consultant as to whether the patient needs to be transferred to another hospital to receive the appropriate treatment.
- If all the relevant staff are available then an area must be designated for the purpose of the procedure. The chosen area is a bay in the Clinical Haematology Unit, which although it may be in use out of hours, can be emptied easily and can therefore be designated for the sole purpose of the Intrathecal procedure.
- The area is designated ”IV FREE‟ and the relevant signage is put in place. During this time the area is used for the sole purpose of administration of intrathecal chemotherapy. Once the procedure has been completed the area can be un-designated and signage removed.
- A record must be kept of the procedure specifying why it had to take place out-of-hours, which staff were involved in the procedure and the outcome. The “Out-of-Hours or Emergency Administration of Intrathecal Chemotherapy” record must be completed.

1.5 Patient consent, reviews and involvement of the patient

Patient information

Patient information will be provided prior to obtaining consent. The patient must be informed of the drugs to be administered.

Consent

Consent will be obtained in adherence with Trust policy CP06

Patient Reviews

A member of staff who is on the Register of Designated Personnel who can administer intrathecal chemotherapy will review the patient before the 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 and that arrangements have been clearly made for the intrathecal chemotherapy to be administered by the appropriate member of staff.

As part of the review, this member of staff will 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 will be written in the patient's medical notes / documented on Clinical Web Portal.

1.6 Recommendations to reduce the risk of an error occurring

The placement of an LP needle for the purpose of an injection of intrathecal chemotherapy will usually be done under x-ray guidance by a Consultant Interventional Radiologist. This is because the LP is often technically difficult in these patients. This is acceptable – however the Radiologist must not be involved in any other aspect of the process and must never administer the intrathecal chemotherapy unless they have received the appropriate training, and been determined competent by the designated lead or medical lead trainer/s and their name included on the register of designated personnel for the task in question.

- No one other than the Designated Registered Consultant will prescribe first dose of intrathecal chemotherapy as per Trust Chemotherapy policy. Associate Specialists and haematology trainees at ST4 level or above are allowed to prescribe subsequent Intrathecal drugs in this Trust.
- No one other than the Designated Registered Consultants, Associate Specialists or haematology trainees at ST4 level or above are allowed to administer intrathecal drug(s) in this Trust.
- The checking of intrathecal chemotherapy drugs prior to administration must only be performed by specifically trained chemotherapy nurses. These nurses must have already completed their Intravenous chemotherapy competencies and will have then gone on to complete the specific training and competency assessment related to intrathecal chemotherapy and be named as designated personnel on the Register.

- The intrathecal chemotherapy trained nurse will check the drugs with the administering Consultant immediately prior to the intrathecal chemotherapy administration.
- The patient / carer must be asked if they wish to take part in the checking of the drug / s. If they so wish then this will be facilitated by the intrathecal chemotherapy trained nurse and Consultant.

N.B. two Doctors checking is not an appropriate substitute for an intrathecal chemotherapy nurse taking part in the Checking Procedure.

This process ensures that intrathecal chemotherapy is given in a different area (Radiology Department), by different staff (Consultant Haematologists or Oncologists) who do not normally give intravenous chemotherapy and at a different time, as intravenous chemotherapy is never administered in the Radiology Department.

1.7 Location of the "Intrathecal Chemotherapy Policy" and register of designated staff

- Designated Trust Intrathecal Lead – Master Copy;
- Lead Cancer/Chemotherapy Nurse/Intrathecal Nurse Lead – Master copy of Intrathecal staff register;
- Assistant Director of Pharmacy-Aseptic, Cancer and Clinical Trials Services- Pharmacy Staff Lead Trainer;
- Senior Sister, CHU;
- Radiology Services Manager - Angiography Room;
- Durnall Unit;
- Trust Intranet – policy for reference only.

The current Registers of Designated Personnel permitted to participate in the administration of intrathecal chemotherapy are held by all the above as hard copies in the relevant clinical areas. The Register is updated accordingly by the Trust Lead and circulated to all the above.

All out of date copies of the Register must be destroyed on receipt of a new Register. Only the latest edition of the National guidance, associated local policy and protocols and register will be available for staff. Hard copies will be found in the locations listed above.

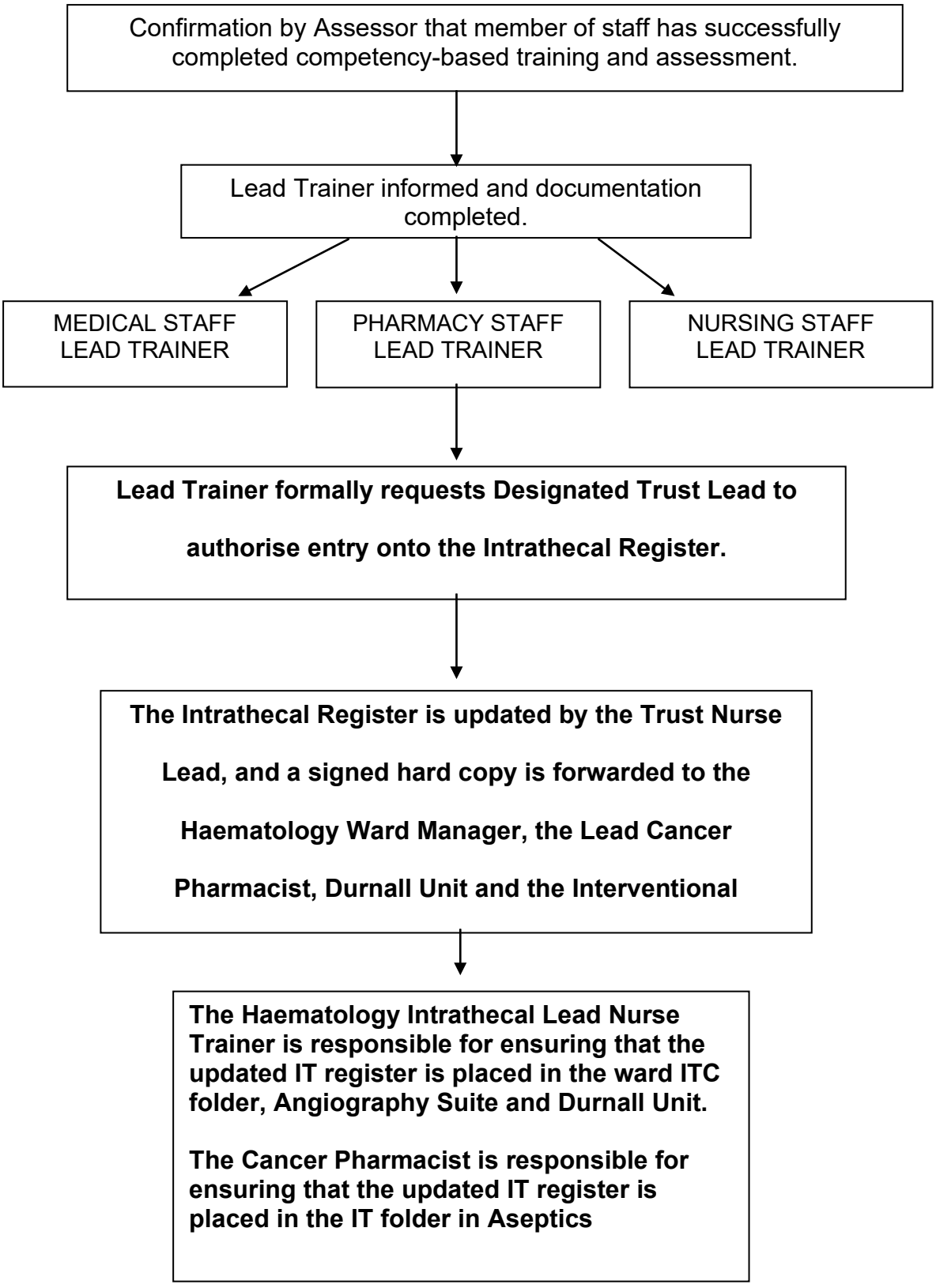
It is the responsibility of the above designated staff to ensure that the IT folders in the relevant areas are kept up to date.

Authorised area for the administration of intrathecal chemotherapy

- Angiography room – Radiology;
- Screening room – Radiology.

1.8 Process for certification and entry onto register

Process for Certification and Entry onto Register



The Royal Wolverhampton NHS Trust

1.9 RECORD OF "OUT-OF-HOURS" or "EMERGENCY" ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY

Date	Patient Name	Hosp.No.	Clinical Indication	Consultant	Nurse	Pharmacist	Trust ITC Lead Informed & date

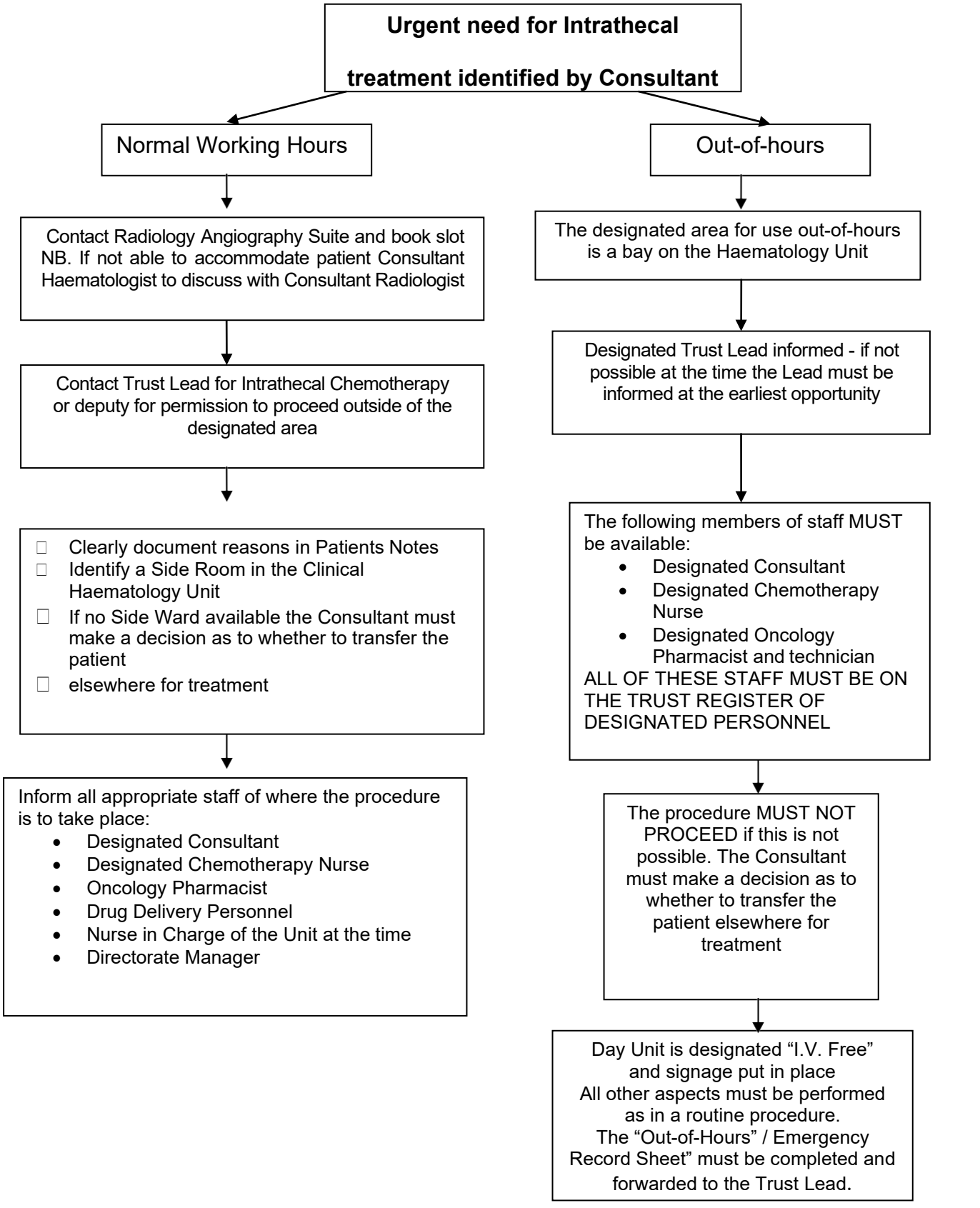
Please document the clinical outcome:

Form completed by:

…… Please print full name
…… Signature
…… GMC/UKCC PIN NO

Date: ……..

1.10 Intrathecal Chemotherapy Administration- *"Emergency Preparedness" Flowchart*



1.11 Procedure For Administration of Intrathecal chemotherapyIntrathecal chemotherapy

PROCEDURE	RATIONALE
1. Designated Consultant, Associate Specialist or haematology trainees at ST4 level or above on the Intrathecal Register make the clinical decision for the patient to receive Intrathecal / Intraventricular chemotherapy.	1. A Designated Consultant, Associate Specialist, or haematology trainees at ST4 level or above on the Intrathecal Register who has received appropriate training makes the decision for treatment.
2. Patient Information Leaflet is given to the patient with explicit information regarding the nature of the procedure, the route, and the name of the drug / s to be administered.	2. To facilitate informed consent and minimise risk by involving patient in the checking procedure.
3. Written Patient consent is gained by a Designated Consultant, Associate Specialist or haematology trainee at ST4 level or above from the Intrathecal Register and includes the name of the drug(s) to be given.	3. Patient is aware of the name of the drug(s) they are to receive and of the procedure.
4. The designated area is identified and made available. • Date/Time • Clarification if MRI/CT required	4. To ensure availability of the designated "IV FREE" area. To ensure that there are no clinical contraindications to the procedure being performed.
5. Prescription is written by Designated Consultant, Associate Specialist or haematology trainee at ST4 level or above. **First doses will only be prescribed by the Haematology Consultant as per Chemotherapy Policy.** • Designated Intrathecal prescription sheet is utilised • Drug name and Intrathecal route are written in full.	5. To reduce ambiguity of prescription and to adhere to guidelines.
6. Designated Consultant, Associate Specialists, haematology trainee at ST4 level or above and Intrathecal Chemotherapy trained nurse are identified to participate in the forthcoming procedure.	6. In accordance with the National Guidance and Nottingham Inquiry recommendations. To comply with Trust Policy

7. Prescription is dispatched to Pharmacy with the administration date / time clearly written.	7. To ensure availability of medication. To facilitate time given for pharmacy to perform preparation and appropriate checks to ensure no IV drugs are due to be given at the same

DAY OF TREATMENT	DAY OF TREATMENT
8. Patient is assessed medically and declared fit for treatment by a Designated Consultant, Associate Specialist or haematology trainee at ST4 level or above : • General health • Peripheral bloods are taken , full blood count and full clotting screen. • Ensure Pregnancy is excluded for all patients who are of childbearing age via urine sampling to microbiology. •	8. To ensure medically fit for treatment and to minimise risk of complications.
9. Patients who attend the Durnall Unit pre procedure • Will have peripheral bloods taken, full blood count and full clotting screen. • Ensure pregnancy is excluded in patients who are of childbearing age via urine sampling to microbiology. • Ensure the allocated nurse on the intrathecal register is aware the patient has arrived. • Allocate the patient a bed • Monitor vital signs, blood pressure, pulse, respirations, oxygen saturations and temperature. Inform clinician of any abnormalities. • Review blood results and inform nurse allocated from the Intrathecal register of any abnormalities. • If patient fit to proceed ensure a wristband is applied and theatre gown worn. • When interventional radiology send for patient, ensure the allocated nurse on the Intrathecal register is informed so they can coordinate chemotherapy delivery and Clinician availability. • Post procedure the patient will be nursed lying flat for two hours. • The puncture site will be observed and if minimal bleeding and feeling	9. To ensure medically fit for treatment and to minimise risk of complications.

well, the patient will be discharged ensuring follow up is in place. • If Fibrinogen below 1.5 and must be undertaken by the appropriate registrar /ST4/Middle Grade and clinical decisions made in conjunction with Haematology Consultant on the Intrathecal register.	
10. The Designated Consultant, Associate Specialist, haematology trainee at ST4 level or above, must check that all staff involved in the procedure are currently on the Register and permitted to participate.	10. To comply with National Guidance.
11. Designated Intrathecal Chemotherapy Trained Nurse accompanies patient in the Radiology Department or to the designated area in a clinical emergency – refer to Out of Hours/Emergency Policy. • Ensuring Vital signs are stable • Blood results are available • platelet/clotting screen • Clinical notes / X-Rays are available • Identification / Consent Form checked	11. To ensure Patient safety and to provide support and reassurance to the patient. To facilitate Medical colleague's role in assessing the patient is fit for the procedure.
12. Designated Cancer Pharmacist dispenses the drug(s) to the designated member of the pharmacy staff who then delivers the drug / s directly to the Designated Consultant, Associate Specialist or haematology trainee at ST4 level or above, and signs as the Issuer. The Designated Consultant, Associate Specialist or haematology trainee at ST4 level or above signs to accept delivery of the drug / s	12. The drug / s are prepared as close to the administration time as possible to minimise the risk of drug deterioration and avoid storage. The drug / s are transported singularly and are clearly marked. The Issuer signs to confirm delivery to the Consultant, Associate Specialist or haematology trainee at ST4 level or above, who checks and signs to accept delivery.
13. The Designated Chemotherapy Trained Nurse and Designated Consultant, Associate Specialist or haematology trainee at ST4 level or above check the patient's identity.	13. The Designated Consultant, Associate Specialist or haematology trainee at ST4 level or above , and the designated chemotherapy trained nurse from the Register check and confirm Patient's identity to ensure that the drug is given to the correct patient.

14. Any anticoagulant drug effects has diminished via calculation of half-life.	
15. Drugs are checked by the Designated Consultant, Associate Specialist or haematology trainee at ST4 level or above and the designated chemotherapy trained nurse: • Name of drug, dose, route, date and time, diluent, volume and expiry time/date. • Patient's name and unit number. • The patient or carer is asked to confirm details / participate in the checking procedure, as appropriate.	15. To confirm that drug is correct. To confirm informed consent. To adhere to Trust Policy re: Intrathecal drug administration. To involve the patient in the checking procedure.
16. Patient is prepared for Lumbar Puncture.	16. L.P. guidelines are adhered to
17. Radiologist performs Lumbar Puncture using X-Ray guidance but takes no further part in the procedure.	17. To maximise ease and correct placement of needle and reduce risk of complications.
18. CSF samples are obtained as required. The designated Consultant, Associate Specialist or haematology trainee at ST4 level or above, administers drug / s according to prescription via spinal needle.	18. To ensure safe administration in accordance with National Guidance and Nottingham Inquiry recommendations. To comply with Trust Policy.
19. Needle is removed and used syringes are discarded into the Cytotoxic Disposal Container. A dressing is applied to the puncture site.	19. Waste is disposed of appropriately according to Trust Policy
20. Patient is repositioned onto back and made comfortable.	20. To facilitate patient comfort.
21. All actions are recorded within the Medical Notes and Nursing Records or Documented on Clinical Web Portal. The treatment sheet is signed by the Designated Consultant , Associate Specialist or haematology trainee at ST4 level or above and checking Chemotherapy Nurse.	21. To ensure an accurate record has been made.
22. Patient is escorted back to the Unit by a trained nurse and advised to lie flat for at least 2 hours post procedure.	22. To maintain patient safety. To minimise side effects / complications. To aid drug distribution.
23. Procedure log is completed with details of patient and staff participating in the procedure.	23. To maintain accurate numbers of procedures and monitor staff participation in procedures.

1.12 – Intrathecal chemotherapy administration checklist

Date of procedure …… INTRATHECAL CHEMOTHERAPY ADMINISTRATION CHECKLIST Once the decision to give intrathecal chemotherapy has been made by a Consultant, Associate Specialist or haematology trainee at ST4 level or above, on the Designated Intrathecal Staff Register, the following checks must be made: Patients Name: Hosp. No:	Tick and sign to confirm action:
1. Discussion with Patient and Patient Information Booklet given. The name of the drug / s to be administered will be clearly written on the sheet.	☐
2. Written consent is obtained by a Consultant, Associate Specialist or haematology trainee at ST4 level or above from the Designated Intrathecal Staff Register.	☐
3. The Prescription is written by a Consultant, Associate Specialist or haematology trainees at ST4 level or above from the Designated Intrathecal Staff Register on dedicated Intrathecal Prescription Sheet. **First intrathecal chemotherapy doses must only be prescribed by the Haematology Consultant on the Intrathecal Register.**	☐
4. Radiology Department informed – date and time of slot agreed. NB. If the Angiography Suite or Screening Room is not to be used, e.g. Out-of-hours or in a Clinical emergency, all appropriate staff must be informed. Refer to "Emergency Preparedness" Procedure and "Out-of-hours Policy"	☐
5. Cancer Pharmacist informed – drugs ordered	☐
6. Appropriate staff from the Designated Intrathecal Staff Register are identified to participate in the procedure and their participation is confirmed on the morning of the procedure.	☐
7. The Patient is assessed by a Consultant, Associate Specialist or haematology trainees at ST4 level or above from the Designated Intrathecal Staff Register and necessary investigations requested and organised. The forms for the CSF investigations are completed.	☐
8. On the day of treatment, the planned time of administration is confirmed with the Radiology Department, Pharmacy, Designated Consultant , Associate Specialist or haematology trainees at ST4 level or above , Designated Chemotherapy Nurse and the patient. NB. Checks are made by Pharmacy to ensure that any Intravenous bolus or Infusional Chemotherapy has been administered prior to	☐

proceeding – this check is documented on the Prescription Sheet.	
9. Review of Patient by Designated Consultant, Associate Specialist or ST4 to confirm patient's fitness to proceed – check that consent has been obtained and that all results of investigations are within the accepted parameters. **Platelet count will be 40 or above prior to procedure. If this is not possible advice will be taken from a haematology Consultant.** Hb…… WCC…… Neut…… Plt……..PT …….. APTT …… Fibrinogen……. Any blood products given: ……. Ensure pregnancy is excluded before administering ITC Yes/No/NA	☐
10. Chemotherapy Nurse from the Designated Intrathecal Staff Register, wearing the Blue Radiation Exposure badge, escorts the patient to the designated area taking the Cytotoxic Waste Sharps Box, completed CSF Investigation forms and sample pots, 4 x Universal Container + if required 1 x Glucose.	☐
11. The area is designated as *"*IV FREE*"* for the duration of the administration procedure. NB. If Intravenous sedation is required for the procedure a member of staff is designated for this sole purpose. This must not be the Chemotherapy Nurse or Consultant, Associate Specialist or haematology trainees at ST4 level or above involved in the Intrathecal checking / administration. This designated person must stay with the patient and take no part in the Intrathecal Procedure.	☐
12. Pharmacy Personnel from the Designated Intrathecal Staff Register deliver the drug and the Designated Consultant, Associate Specialist or haematology trainees at ST4 level or above accepts – both sign to confirm.	☐
13. The Designated Consultant, Associate Specialist or haematology trainees at ST4 level or above must check that all staff assisting in the procedure are also on the Register for the Task, that they are carrying out.	☐
14. The Patient / Relative / Carer is asked if they wish to participate in the following checks, optional.	☐
15. Designated Chemotherapy Nurse and designated Consultant, Associate Specialist or haematology trainees at ST4 level or above confirm the Patient's identity and check the drug / s.	☐
16. Following the administration the procedure is documented: - Prescription Sheet - Medical Notes - Nursing Records	☐

- Scanned/documented on to Clinical Web Portal -mark the cEPMA system as given	
17. The Checklist is filed in the Patient's Medical Notes /scanned on to Clinical Web Portal.	
18. The Procedure Log kept on CHU is completed by the Chemotherapy Nurse, detailing which staff have participated in the procedure.	

[Affix Patient Identification label]

Name of Clinician Giving intrathecal chemotherapy……. GMC No ……..

Signature …… Date

Consultant Supervisor's name ……..

Supervisor's grade ……..

Supervisors signature ……..

Date …….

Chemotherapy Nurse Name ……..

Chemotherapy Nurse grade …….

Date …….

Chemotherapy Nurse Signature …….

Chemotherapy Nurse Supervisor's name ……..

Chemotherapy Nurse Supervisor's signature ……

Chemotherapy Nurse Supervisor's grade ……

Date ……..

1.13 Nursing prodecure for the administration of Intrathecal Chemotherapy

Expected outcome

The patient will be fully informed regarding the procedure, their safety maintained during and after the procedure and possible complications minimised.

The "Administration of Intrathecal Chemotherapy" Flow chart will be followed throughout the Patient Journey thus ensuring compliance with Trust Policy and National Guidance.

Process

1. Explain the procedure to the patient and their relatives, if appropriate, allowing time to ask questions and express any fears. Ensure the patient has received the Patient Information Leaflet for Intrathecal Chemotherapy, which includes the name of the drug(s) to be given.
2. Ensure written informed consent has been obtained, the Consent form has been completed appropriately and signed by the patient and includes the name of the drug(s) to be given.
3. Ensure the designated area and designated personnel are available for the procedure.
4. Ensure that the patient has been declared fit for the procedure by a designated Consultant, Associate Specialist or haematology trainees at ST4 level or above , and that all necessary investigations have been performed, results are available and within accepted parameters.
5. If required administer blood product support, as prescribed, prior to the procedure.
6. Ensure that checks to ensure that any Intravenous or Infusional chemotherapy due the same day has already been administered have been made and that this has been clearly documented.
7. Ensure all equipment required is available and procedure trolley is laid up. The designated area will be declared "IV Free" for the duration of the procedure.
8. Ensure the patient is fully aware of what is required of them so as to allow maximum patient co-operation. Ask the patient / carer if they wish to participate in the checking of the drug / s prior to administration.
9. Assist the patient to lie on their side with knees drawn up and head flexed onto their chest to ensure maximum widening of the intravertebral space and thus ease access to the Intrathecal space.
10. Assist the doctor as required with the lumbar puncture procedure. Reassure and observe the patient throughout the procedure.
11. If patient complains of pain in one leg during the procedure inform the doctor, as the dorsal nerve root may have been touched. Pain will reduce once the needle is moved. Reassure the patient that no damage will have been done.

12. Assist the doctor to collect the required specimens of CSF into numbered sterile containers.
13. Ensure that the drugs are checked by the Designated Consultant, Associate Specialist or haematology trainees at ST4 level or above and designated chemotherapy nurse, according to Trust policy, prior to administration and that they are administered correctly. When the drug / s have been given ensure that the used syringe / s are placed into the cytotoxic disposal container.
14. Ensure that all waste, including sharps, is disposed of according to Trust Policy.
15. When the needle has been removed, apply pressure to the site and then apply a small sterile dressing to the puncture site.
16. Ensure the patient is comfortable. The patient will lie flat, ideally for at least two hours, according to their clinical condition. This helps avoid headache and decreases the possibility of brainstem herniation due to a reduction of CSF pressure. This is uncommon following this particular procedure, as the volume of CSF removed is replaced by the volume of drug administered. There is also evidence that this allows for better distribution of the drug throughout the cerebral-spinal fluid.
17. Record vital signs and neurological observations according to clinical condition. There may be a rise in temperature due to meningeal irritation.
18. Observe the patient for the next 24 hours if remaining as an inpatient for:
    - Alteration in neurological signs;
    - Leaking from the puncture site;
    - Headache / backache may need analgesia;
    - Signs of infection.
19. Report any complications or symptoms to the medical staff immediately.
20. If the patient has been treated as a Day Case ensure that the patient is aware of the possible complications and of how to obtain help / advice.
21. Ensure that an appropriate Follow-up appointment has been arranged.
22. Ensure correct documentation of the procedure.

INTRATHECAL PRE PROCEDURE CHECKLIST

Patient Details

Date ……

Action	Signed /Stamp
1. Patient arrives on Durnall and has an URGENT peripheral • Full Blood Count • Full Clotting Screen • U and E"s • LFT"s	
2. Patient is checked to make sure no anticoagulation has been taken	
3. CHU is contacted by the nurse on Durnall who has been allocated the patient to ensure a nurse and a medical practitioner on the intrathecal register is available to attend procedure.	
4. Angio suite ext. 6344 is contacted to confirm procedure is booked and to establish time of procedure.	
5. Blood results are reviewed Wcc Neuts Hb Plts PT PTT	
6.Observations are recorded. • Blood pressure ……/….. • Pulse …… • Temperature ……. • Oxygen Saturations …….. Any abnormalities are reported to the clinician covering Durnall.	
7. Patient is allocated a bed.	

8. Patient is given a wristband.	
9. Patient is dressed in a theatre gown.	
10. Intrathecal Nurse is contacted when the patient leaves Durnall for Intrathecal procedure.	
11. On returning to Durnall post procedure the patient lies flat for 2 hours.	
12. The puncture site is observed for signs of bleeding. The dressing stays in situ for 24hours.	
13. If minimal bleeding, the patient is discharged home ensuring follow up appointments are in situ including consultant follow up.	

1.14 Medical Staff Training Competencies and Assessment Record for Participation in the Administration of Intrathecal Chemotherapy Procedures:

Medical Staff Training Competencies and Assessment Record for Participation in the Administration of Intrathecal Chemotherapy Procedures

Date of Intrathecal Assessment ……

Name: …….

GMC No ……..

Grade: CONSULTANT, Associate Specialist or ST4

Assessment completed by: ……

GMC NO …….

Grade: CONSULTANT

Objectives:

The aim of this manual is to provide written and verbal guidance for the training and update of Consultant medical staff for participation in the prescription and administration of intrathecal chemotherapy procedures.

This manual will provide evidence of achievement/maintenance of individual competencies and comply with National Guidance on the Safe Administration of Intrathecal Chemotherapy.

By the end of the training period / update the practitioner will be expected:

1. To have read and understood the National Guidance and local Trust Policy on the Safe Administration of Intrathecal Chemotherapy and to sign to verify this;
2. To have a sound understanding on the prescribing and administration processes for intrathecal chemotherapy;
3. To be competent in the prescription and administration of intrathecal chemotherapy as per Trust / National Guidance.

After evidence of successful completion of this Assessment Record has been submitted by the Assessor, the Designated Trust Intrathecal Chemotherapy Lead will authorise entry onto the Register of Designated Personnel and a certificate of competence will be issued to this effect Medical Staff will then be expected to maintain their competence by participation in at least 2 Intrathecal procedures per year and by attendance at an Annual Update session.

OBJECTIVE ONE

To have knowledge and understanding of the Trust Policy on the Prescription, Preparation, Dispensing, Issue, Checking and Administration of Intrathecal Chemotherapy.

Competency Criteria:	**Trainee to sign to confirm**	**Trainee Competent**	**Assessed by Sign & date**
1.1 Demonstrates an expert knowledge regarding the contents of the DOH National Intrathecal Chemotherapy Guidance. Demonstrates an understanding of the contents of the RWT Intrathecal Chemotherapy Policy			
1.2 Is able to list the indications for ITC administration Is able to explain the instances where the administration of ITC on an emergency is required			
1.3 Is able to explain the rationale for the need to ensure that all intravenous chemotherapy, bolus or infusional, for the patient that day is given before starting the intrathecal chemotherapy procedure.			
1.4 Is able to describe the procedure for the registration of personnel onto the ITC register, and is able to explain the reasons why those not listed on the ITC register may not participate in ITC procedures			

1.5 Is familiar with the current intrathecal chemotherapy prescription chart.			
1.6 Is able to explain the consent process for ITC Is able to list the pre-treatment investigations required prior to proceeding with an ITC procedure Is able to list the results parameters required for an ITC procedure to be undertaken.			
1.7 Is able to explain the ITC procedure & the rationale for this, e.g. assistance in the procedure by a chemotherapy nurse on the Register of Designated Personnel - A second doctor cannot be a substitute for the nurse.			
1.8 Is able to explain with rationale the following: A. The need for the person administering the Chemotherapy to accept delivery of the drug / s direct from the pharmacy staff member responsible for delivery immediately prior to the procedure. B. The need to sign the prescription chart on acceptance of delivery. C. Colour coding of packaging of Intrathecal drugs.			

1.9 Is able to describe with rationale the checking process prior to starting the LP			
1.10 Is able to describe with rationale the need to involve the patient in the checking process, and is able to provide examples of how this might be achieved.			
1.11 Is able to describe with rationale the need for a second check immediately prior to instilling the intrathecal chemotherapy, and is able to describe precisely what this check entails.			
1.12 Is able to describe the arrangements for ITC administration and to provide the rationale for this. E.G. intrathecal chemotherapy will only be given during normal working hours Monday to Friday 9am-5pm and what action is to be taken if it needs to be given outside normal working hours.			

OBJECTIVE TWO

Is knowledge regarding the circumstances in which it is safe to proceed with lumbar puncture and any complications that might be caused.

Competency Criteria:	**Trainee to sign to confirm**	**Trainee competent**	**Assessed by sign**
2.1 Is able to list and explain the criteria to be met regarding blood count and coagulation prior to proceeding with LP and administration of intrathecal chemotherapy and is able to demonstrate the rationale for these parameters.	Write parameters		
2.2 Is able to explain the contraindications to lumbar puncture and the rationale for this.			
2.3 Indicate if previous experience of intrathecal chemotherapy administration number of years	Initial training only Assessor to be satisfied at least 2 procedures		
2.4 Is able to demonstrate awareness that the Consultant Radiologist placing the lumbar puncture needle must take no further part in the procedure.			
2.5 Is able to explain the common complications of lumbar puncture and how these can be managed and avoided.			

Date of Assessment …../…../…..

Practitioner Name…….

Practitioner Signature ……

Grade: Consultant Associate Specialist or ST4

GMC No……

Assessors name: ……

Assessors signature: ……..

Grade: Consultant

GMC No ……..

COMPLETION of ASSESSMENT:

Has the Practitioner passed all areas of assessment? Yes / No

*If YES then further assessment / update and validation is not required for a further 12 months.

*If NO then further training and re-assessment will be required.

Date for Re-assessment: ….. / ….. / …..

Please give brief details of those areas requiring further training.

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Signature: …… Date: ……

Post Held: Consultant

This form will now be forwarded to the Designated Trust Lead for Intrathecal Chemotherapy for action:

- Authorisation of entry onto the Register of Designated Personnel ☐
- A copy of this form will be kept as evidence for compliance and a copy will be returned to the practitioner and their Lead Trainer ☐

1.15 Pharmacy intrathecal chemotherapy training assessment record

PHARMACY INTRATHECAL CHEMOTHERAPY TRAINING ASSESSMENT RECORD	
Agreed by: Pharmacy Lead Trainer for Intrathecal Chemotherapy	Agreed by: Designated Trust Lead for Intrathecal Chemotherapy

Name: Designation:

The aim of this document is to provide guidance for the training and update of Pharmacy staff for participation in the provision of intrathecal chemotherapy service.

This document will provide evidence of achievement/maintenance of individual competencies and comply with the National Guidance on the Safe Administration of Intrathecal Chemotherapy.

By the end of the training period/update the pharmacy staff is expected:

1 To have read and understood the:-

- The National Guidance on the Administration of Intrathecal Chemotherapy;
- Trust Policy on the administration of Intrathecal Chemotherapy;
- Pharmacy Procedures on Intrathecal Chemotherapy

  – Supply of intrathecal chemotherapy;

  Delivery of intrathecal chemotherapy;

  Intrathecal chemotherapy training for Pharmacy Personnel

2 To have participated in an Intrathecal training / update session

3 To have a sound understanding on the role of pharmacy staff in the provision of an Intrathecal Chemotherapy Service.

4 To be competent in the supply of intrathecal chemotherapy as per Trust / National Guidance. After evidence of successful completion of this assessment, the Pharmacy Lead Trainer for Intrathecal Chemotherapy will inform the Trust Lead for Intrathecal Chemotherapy who will authorise entry into the register of designated personnel and arrange for issue of certification and confirmation of the designated role.

Pharmacy staff are expected to maintain their competence by participation in at least 2 Intrathecal procedures per year and by attendance at an Annual Update session.

Objective One

Competency Criteria	Trainee to sign to confirm	Trainee Competent	Assessed by	Comments
Has participated in an Intrathecal chemotherapy training / update session	Date:			
Has read: • The National Guidance on the administration of intrathecal chemotherapy • Trust Policy on the administration of intrathecal chemotherapy	Indicate when read			
• Has read: • Pharmacy Procedures on intrathecal chemotherapy: • Supply of intrathecal chemotherapy • Delivery of intrathecal chemotherapy • Intrathecal Chemotherapy Training for Pharmacy Personnel	Indicate when read			
• To have watched the NHS Intrathecal Training Video	Date:			
• Is aware of the need to ensure that all intravenous chemotherapy, bolus or infusional, for the patient that day is given before starting the intrathecal chemotherapy procedure. • Is aware of the Register of Designated Personnel for the prescription, preparation, dispensing, issue, checking & administration of intrathecal chemotherapy.				
• Is aware that persons not on the above register must not be involved in intrathecal chemotherapy procedures.				
• Is familiar with the current Intrathecal prescription chart.				

Objective Two
Questions 3, 9, 10 and 11 are not applicable to trainee whose only designated role is the issue of intrathecal chemotherapy.

Assessment Question	Answer	Competent / Comments	Trainee's Signature	Assessor's Signature
1. What is an Intrathecal drug?				
2. Give examples of chemotherapy drugs including the strength that can be administered intrathecally.				
3. Describe the reconstitution process involved in the preparation of intrathecal chemotherapy.				
4. What is the procedure for the transportation of Intrathecal drugs?				
5. What grade of medical staff can administer intrathecal chemotherapy in this Trust?				
6. List the locations where you would expect intrathecal chemotherapy to be administered.				
7. What class of drug will never be administered via the intrathecal route?				
8. Give an example of a vinca alkaloid.				

9. Describe the reconstitution process for vincristine injections.				
10. List the signs and symptoms of inadvertent administration of vincristine intrathecally.				
11. Where would you find the information for the procedure to follow if a vinca alkaloid drug is administered intrathecally?				

Date of Assessment: ……..

Name of Trainee ……..

Signature of Trainee: ……

Assessors Name …….

Assessors Signature …….

For staff undergoing an intrathecal chemotherapy update training only -

Indicate the number of intrathecal chemotherapy undertaken in the Trust in last year

Completion of Assessment:

Has the trainee passed all areas of assessment? Yes / No

*If YES then further assessment/update and validation is not required for a further 12 months.

*If NO then further training and re-assessment will be required.

Date for Re-assessment: …../…../…..

Please give brief details of those areas requiring further training.

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Trainee Signed off by: …..... Date: ……..

Designation: Pharmacy Training Lead for Intrathecal Chemotherapy

This form will now be incorporated into the trainee's training file and a copy of this form will be forwarded to the Designated Lead for Intrathecal Chemotherapy for authorisation of entry onto the Register of Designated Personnel

1.16 Nurse intrathecal chemotherapy training assessment record

The Royal Wolverhampton NHS Trust

NURSE INTRATHECAL CHEMOTHERAPY TRAINING ASSESSMENT RECORD

Date of assessment ……..

Name ……

Designation ……

UKCC PIN NO ……..

Name of Assessor ……..

Designation of Assessor ……..

UKCC PIN NO ……

The aim of this document is to provide guidance for the training and update of nursing staff for participation in the provision of intrathecal chemotherapy service.

This document will provide evidence of achievement/maintenance of individual competencies and comply with the National Guidance on the Safe Administration of Intrathecal Chemotherapy

By the end of the training period / update the nursing staff are expected:

1. To have read and understood the :-
   - The National Guidance on the administration of intrathecal chemotherapy
   - Trust Policy on the administration of intrathecal chemotherapy
2. To have participated in an intrathecal training / update session
3. To have a sound understanding on the role of nursing staff in the provision of an intrathecal chemotherapy service.
4. To be competent in supporting the administration of intrathecal chemotherapy as per Trust / National Guidance.

After evidence of successful completion of this Assessment, the Nurse lead trainer for Intrathecal chemotherapy Intrathecal chemotherapy will inform the Trust lead for intrathecal chemotherapy Intrathecal chemotherapy who will authorise entry into the register of designated personnel and arrange for issue of certification and confirmation of their designated role.

Nursing Staff are expected to maintain their competence by participation in at least 2 Intrathecal procedures per year and by attendance at an Annual Update session.

Management and Administration of Intrathecal Chemotherapy The practitioner will be able to:	**Dependent**	**Marginal**	**Assisted**	**Supervised**	**Independent**	**Self Assessment**
	(D a t e & S i g n a t u r e)					
Demonstrate an awareness of the content of the Trust Policy for "The Administration of Intrathecal Chemotherapy".						
Demonstrate knowledge of the National Guidance and recommendations for the safe administration of intrathecal chemotherapy.						
Outline the major points in these documents, and state the location of the Trust Policy.						
Demonstrate an understanding of the rationale for the administration of intrathecal chemotherapy.						
Name the drugs that can be administered intrathecally.						
Demonstrate knowledge of which drugs must never be given intrathecally and why.						
Describe the side effects of the drugs discussed.						
Demonstrate knowledge of the procedure of Lumbar Puncture and injection of intrathecal chemotherapy to include explanation of procedure and possible complications to patient.						

• Consent to procedure.						
• Positioning of patient.						
• The performance of the lumbar puncture and obtaining samples of CSF.						
• Checking of the drugs and administration of intrathecal chemotherapy, including patient/carer involvement.						
• Safe disposal of waste.						
• Care of the patient following procedure and any possible side effects or complications.						
• Demonstrate knowledge regarding the prescription, preparation, supply, transport and storage of cytotoxic drugs for intrathecal use.						
COMMENTS:						

Date of Assessment ……

Signature of Trainee ……

Signature of Assessor …….

For staff undergoing an intrathecal chemotherapy update training only-

Indicate the number of intrathecal

chemotherapy undertaken in the

Trust in last year: COMPLETION of

ASSESSMENT

Has the trainee passed all areas of assessment? Yes / No

*If YES then further assessment / update and validation is not required for a further 12 months.

*If NO then further training and re-assessment will be required.

Date for Re-assessment ……../……./…….

Please give brief details of those areas requiring further training.

……
……
……
……
……
……

Trainee Signed off by …… Date ……..

Designation: Nurse Training Lead for Intrathecal Chemotherapy

This form will now be incorporated into the trainee's training file and a copy of this

form will be forwarded to the Designated Lead for Intrathecal Chemotherapy for

authorisation of entry onto the Register of Designated Personnel