University Hospitals of Leicester NHS
NHS Trust

Intrathecal Chemotherapy UHL Policy

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

V9 – Update to previous version includes:

- **Change towards single written consent for repeated lumbar puncture with intrathecal chemotherapy then verbal consent subsequent occasions with review of initial written consent form**
- **No requirement for pharmacy to witness disposal of unused intrathecal SACT**
- **An electronic annotation must be made on ChemoCare when intrathecal SACT is allocated**
- **A concession can be approved by any member of the Intrathecal Management Group**
- **Intrathecal procedures for children performed outside the designated area and done in main theatre under the same GA/sedation as other procedures is not a concession but should be recorded**
- **For the ward 27 list, if there is long delay for one patient to start intravenous methotrexate due to suboptimal urine pH/urine output, intrathecal methotrexate can be released and given before IV methotrexate commenced providing IV methotrexate is kept in pharmacy until electronic confirmation that intrathecal has been given. The Trust Lead must be informed about these occurrences so they are reviewed in the Management Group meetings**

KEY WORDS Intrathecal, intraventricular, SACT, chemotherapy, oncology, haematology, cytotoxic

1 INTRODUCTION

1.1 Intrathecal chemotherapy administration refers to the administration of a cytotoxic drug into the cerebral spinal fluid either via a lumbar puncture or through an intraventricular route.

1.2 This policy predominantly applies and refers to chemotherapy but is also relevant to other systemic anti-cancer therapy (SACT) e.g. monoclonal antibodies, targeted immune therapies.

1.3 The administration of intrathecal drugs is potentially dangerous and must only be undertaken by staff who have undergone appropriate training and are certified as competent to participate in the process (section 7). There is generalised agreement that clinical errors have occurred because rules written into policies have not been followed. All hospitals in the UK where intrathecal chemotherapy is administered must have a written policy.

1.4 This policy must be read in conjunction with the chemotherapy administration procedures as written in the East Midlands Region Systemic Anti-Cancer Therapy (SACT) Policy and the Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy [HSC 2008/001]

HSC (2008) 001 Updated national guidance on the safe administration of intrathecal chemotherapy (allcatsrgrey.org.uk)

1.5 The Updated National Guidance must also be read in conjunction with the NPSA alert Safer Spinal (intrathecal), epidural and regional devices. This alert states that all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with connectors that cannot connect with intravenous Luer connectors. In UHL specified intrathecal needles have been introduced so that intrathecal chemotherapy must be prepared in the Pharmacy in 'ready to use' intrathecal syringes and only this system may be used for the administration of intrathecal chemotherapy.

NHS England » Patient safety alert on non-Luer spinal (intrathecal) devices for chemotherapy

1.6 Vinca alkaloids: - Vincristine, Vinblastine, Vinorelbine, and Vindesine are all fatal if administered intrathecally. **They must only be given intravenously**. Administration must be compliant with the NPSA Rapid Response Report [NPSA/2008/RRR04] on vinca alkaloid administration.

[ARCHIVED CONTENT] Using Vinca Alkaloid Minibags (nationalarchives.gov.uk)

1.7 Sodium chloride 0.9% 50ml minibags will be used for all patients receiving vinca alkaloids in adult areas of LRI. For patients, aged 16-24, treated on the Teenage & Young Adult (TYA) Unit on Ward 27 vinca alkaloids will be administered via 50ml mini- bags but children <16 years treated on Ward 27 or within the Children's Hospital will continue to receive vinca alkaloids in syringes made up to 20ml in volume with sodium chloride 0.9%. Children who turn 16 years of age during their treatment will be switched over from 20 ml syringes to 50ml mini-bags during their 16th year. UHL takes note of the guidance in NPSA/2008/RRR04 regarding treatment of children and TYA in the same area but a Risk Assessment has been performed.

1.8 This policy only applies to SACT for cancer patients.

1.9 No intravenous SACT will be present in the designated intrathecal treatment areas at any time.

1.10 For the purposes of the management of intrathecal chemotherapy, the University Hospitals of Leicester NHS Trust has two relevant CMGs (Clinical Management Groups). These two CMGS are:

- CHUGGS (Cancer, Haematology, Urology, Gastroenterology and General Surgery) which includes adult oncology, haematology and palliative care

- Womens and Childrens which includes paediatric haematology and oncology as well as TYA patients being managed in the TYA unit on Ward 27.

Both CMGs follow the same policy and protocols.

1.11 Administration of intrathecal chemotherapy must be in accordance with this policy and attached Standard Operating Procedure (SOP):

SOP: Procedure for Patients Receiving Intrathecal Chemotherapy - Adult and Paediatric [Appendix 1]

1.12 This policy must be compliant with the Updated National Guidance on the Safe Administration of Intrathecal Therapy, HSC 2008/001.

1.13 This policy will be assessed as part of the Cancer Peer Review Process and must be 100% compliant

1.14 This policy and the associated standard operating procedures form the Local Safety Standards for Invasive Procedures (LocSSIP) documentation for intrathecal chemotherapy. This has been developed in line with the National Safety Standards for Invasive Procedures (NatSSIPs) available here: https://www.england.nhs.uk/patientsafety/never-events/natssips/ .

2 POLICY AIMS

2.1 The aim of this policy is to ensure the safe administration of intrathecal chemotherapy by:

a) Setting the standards for education and training that all staff must adhere to

b) Maintaining a register of authorised professionals able to undertake this skill

c) Providing clear procedures and processes for prescribing, consenting, preparing, delivering and administering intrathecal chemotherapy which comply with National and Peer Review Standards

3 POLICY SCOPE

3.1 This policy applies to members of the UHL NHS Trust who have been trained and assessed as competent to be involved in the Intrathecal Chemotherapy process (or who are in training toward achieving competency in this procedure).

3.2 This policy applies to all patients (adult and children) who require intrathecal chemotherapy, either as a planned or emergency procedure.

4 DEFINITIONS

4.1 Intrathecal Chemotherapy

a) The administration of any chemotherapy drug into the intrathecal space used as part of the chemotherapy treatment of the patient. This is generally administered via lumbar puncture.

4.2 Intraventricular Chemotherapy

a) The administration of any chemotherapy drug into the intraventricular space, usually via an Ommaya reservoir, used as part of the chemotherapy treatment of a patient.

4.3 Systemic Anti-Cancer Therapy (SACT)

a) Describes treatment for all solid and haematological cancers and includes chemotherapy, targeted immune therapies and antibody therapies

4.4 Definition of Teenage and Young Adult Patient Group (TYA)

a) The Department of Health document 'Improving outcomes in children and young people with cancer: guidance on commissioning services for young people', published date: 8 September 2008 (Gateway reference: 10393) states that all patients aged from 13-24 years must be offered care in a Principal Treatment Centre with specific age appropriate facilities for this age group.

b) In the Leicester Royal Infirmary an age specific facility exists on Ward 27 with an adjacent Day Case Unit and Theatre. Patients aged 0-18 years inclusive being treated at UHL must receive all their oncology care on Ward 27.

c) Patients aged 19-24 years at diagnosis are given the choice of where they wish to be treated for their cancer and may be managed either on Ward 27 TYA unit or in the Osborne Building, Wards 39-41.

d) The management of TYA patients is described in APPENDIX 1 and care is offered in the appropriate chosen setting.

e) For the purposes of this Policy the age for defining the TYA population will start at 16 years.

5 ROLES AND RESPONSIBILITIES

In order to comply with the revised and Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy [August 2008], there are key personnel identified within this policy with specific responsibilities. The named individuals responsible are listed on the Authorised Register.

These personnel conduct their role[s] with the designated authority of the Chief Executive via the Designated Trust Lead and Deputy Designated Trust Lead. Each of these individuals must have their role within the Intrathecal Policy reflected in their job description and the appraisal process. The Medical Director is the Executive Lead for the policy and has approved this list of responsibilities.

They are as follows:

5.1 Designated Trust Lead / Lead Medical Trainer

a) Has the overall responsibility for intrathecal practices and adherence to the Intrathecal Policy / National Guidance and Peer Review in UHL.

b) Overall responsibility for holding the register and ensuring it is maintained and kept up-to-date.

c) Lead trainer in Intrathecal Policy for Medical Staff

d) Responsible for induction, training and continuing professional development related to intrathecal chemotherapy.

e) Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks. Will delegate these responsibilities appropriately to the Lead Trainers.

f) Responsible for ensuring the Lead Trainers have this role recognised in their job description and appraisal process.

g) Responsible for assessing any variances, deviations or incidents from this policy in either service.

h) Responsible for collating all emergency procedures performed outside the designated lists and recording out of hours procedures.

i) Responsible for informing the Medical Director and Chief Executive of incidents, unplanned deviations or other issues related to the policy.

5.2 Designated Deputy Lead / Lead Medical Trainer [Adult]

a) Oversees adherence to the Intrathecal Policy / National Guidance within Adult Haematology, CHUGGS CMG.

b) Responsible for reporting any variances from the Intrathecal Policy to the Designated Trust Lead.

c) Lead Trainer for Medical Staff in Adult Haematology, CHUGGS CMG, including TYA patients under the care of the adult team.

d) Responsible for induction, training and continuing professional development related to intrathecal chemotherapy for Medical Staff in Adult Haematology, CHUGGS CMG.

e) Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks.

5.3 Designated Lead Medical Trainer [Paediatric Staff]

a) Oversees adherence to the Intrathecal Policy / National Guidance within the Children's Hospital, Women's and Children's CMG.

b) Responsible for reporting any variances from the Intrathecal Policy to the Designated Trust Lead

c) Lead Trainer for Medical Staff in Children's Hospital, Women's and Childrens' CMG.

d) Responsible for induction, training and continuing professional development related to Intrathecal chemotherapy for medical staff in Children's Services, Women's and Children's CMG.

e) Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks

5.4 Designated Lead Nursing Trainer [Adult Staff]

a) Acts as Lead Trainer for Nursing Staff in Adult Haematology, CHUGGS CMG.

b) Ensures adherence to Intrathecal Policy from a nursing perspective

c) Responsible for induction, training and continuing professional development related to intrathecal chemotherapy for Nursing Staff in Adult Haematology, CHUGGS CMG.

d) Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks.

5.5 Designated Lead Nursing Trainer [Paediatric Staff]

a) Acts as Lead Trainer for Nursing Staff in Children's Services, Women's and Children's CMG. This includes TYA patients diagnosed before the age of 25 years.

b) Ensures adherence to Intrathecal Policy from a nursing perspective

c) Responsible for induction, training and continuing professional development related to intrathecal chemotherapy for Nursing Staff in Children's Services, Women's and Children's CMG.

d) Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks.

5.6 Designated Lead Pharmacy Trainer

a) Acts as Lead Trainer for Pharmacy Staff.

b) Responsible for ensuring adherence to the Intrathecal Policy within the pharmacy setting.

c) Responsible for induction, training and continuing professional development related to intrathecal chemotherapy within the Pharmacy Department.

d) Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks.

The **Intrathecal Management Group** consists of the designated leads listed above as representation of all teams involved with intrathecal chemotherapy in the Trust. The group will meet at a minimum of every 3 months and review intrathecal activity, the authorised register, risk management and incident reporting (see section 6.2), quality improvement and audit. The group will report to the CMG Quality and Safety Boards and the Medical Director.

Additional staff not listed in the National Guidance on the Safe Administration of Intrathecal Chemotherapy have the following responsibilities:

5.7 Staff on the Authorised Register for Intrathecal Chemotherapy Administration

a) Must have successfully completed the training required to fulfil their role in the Intrathecal Chemotherapy process as detailed in section 7 of this policy.

b) To ensure that their certificate of competency is kept up-to-date and their name is on the authorised register.

c) To adhere to the procedures detailed within this policy.

d) Only involve other staff, who are on the authorised register in any part of the process.

e) To report any deviations from the policy to the Designated Trust Lead.

f) Must be trained in the use of ChemoCare and have a valid password.

5.8 Staff not on the Authorised Register for Intrathecal Chemotherapy Administration

a) When a patient is under general anaesthetic and cannot participate in the checking process a staff member not on the Authorised Register may act as a third checker on the patient's behalf in line with the National Guidance.

b) Except under the circumstances listed in 5.8a **no member of staff not on the Authorised Register may assist in any part of the procedure under ANY circumstances**

6 POLICY STATEMENTS AND PROCEDURES

6.1 Authorised Register

a) For the purposes of this document "trained" refers to any completed training received relating to the safe administration of intrathecal chemotherapy.

b) **Only staff on the Authorised Register are permitted to have any part in the process of prescribing, consenting, dispensing, checking or administering intrathecal chemotherapy.** Locum and bank staff who have completed the UHL Intrathecal Chemotherapy Training package and have been assessed as competent by an authorised trainer may be issued with a certificate of competency, be placed on the Authorised Register and participate in those areas of the process they are certificated for. The same standards apply to all staff on the Authorised Register.

c) The hospital will keep an up-to-date register of all staff who are designated competent for part or all of the intrathecal process. These individuals will have been issued with a certificate of competency which must be in date and the register will list the area of competency for each individual on the list. The Designated Trust Lead is responsible for the register.

d) The Certificate of competency will be divided into competencies related to Adults managed in the Osborne Building and Paediatrics managed on Ward 27. The management of TYA patients is outlined in APPENDIX 1.

e) An electronic copy of the Authorised Register is available on the UHL Intranet Site. This register is reviewed every 3 months. More frequent amendments will be made if personnel change; this will be completed by the holder of the authorised register and communicated by the designated Leads for each Professional Group. Entry onto the authorised list is only permitted upon production of a valid certificate of competence being signed by a designated trainer.

f) A hard copy of the register is also available in the following locations:-

Osborne Day Care Procedure Room

Ward 39 (Oncology)

Ward 40 (Oncology)

Ward 41 (Haematology)

Bone Marrow Transplant Unit

Ward 27 Theatre, LRI

Ward 27

Aseptic Unit – Pharmacy

Chemotherapy Suite - Osborne

Hope Unit, LRI

6.2 Concessions, Variances and Breaches from the UHL Intrathecal Policy

a) A **concession** describes approved deviation from the management of patients receiving intrathecal chemotherapy policy [Appendix 1]. This approval must be given prior to the concession taking place. This approval requires completion of a Concession Form [Appendix 5] and approval can only be given by the members of the Intrathecal Management Group..

b) A **variance** describes an omission/variation, which is then picked up through the intrathecal process but does not present any potential harm to the patient. All variations must be discussed with the Designated Trust Lead and within the Intrathecal Management Group. If the Designated Trust Lead or Intrathecal Management Group decide the magnitude of the event is deemed sufficiently significant, the episode will be escalated to a breach and reported as a prevented patient safety incident in accordance with the Trust's Policy A10/2002. The incident will be reported on Datix Web and copied to the Designated Trust Lead.

c) A **breach** describes any event where the intrathecal process is not performed in line with the Intrathecal Systemic Anti-Cancer Therapy (SACT) Policy and the Designated Trust Lead and Intrathecal Management Group deem this to represent a patient/policy risk. All breaches must be reported as a patient safety incident in accordance with the Trust's Policy A10/2002. The incident will be reported on Datix Web and copied to the Designated Trust Lead.

d) All breaches will be reported to the Medical Director and escalated accordingly.

e) All concessions, variances and breaches will be discussed and reviewed by the designated leads at the Intrathecal Management Group meetings, which will occur at a minimum of 3 monthly intervals. The CMG Quality and Safety Boards and Medical Director will be kept informed of the issues discussed at each meeting.

6.3 Risk Assessment

Within Peer Review there is a requirement for annual Risk assessments to be done to ensure there is capacity to provide a safe service. Ongoing review is a feature of the process looking at compliance, deviations and applications for variance from the Policy. This will be co-ordinated by the relevant Lead Clinician

in conjunction with the Corporate Risk Team. Risk assessments will be reviewed annually by the relevant staff within the two CMGs.

6.3.1 Capacity Risk Assessment

a) Both adult and paediatric areas have conducted multi-disciplinary risk assessments regarding safe capacity for their intrathecal list. The maximum number of patients on each session list is:

Paediatrics 8 (including TYA patients) Adult

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b) In the event of more patients than the maximum number (as stated above) requiring intrathecal chemotherapy, a review of the patients on the list must be undertaken involving all relevant clinical staff.

c) This may result in patients being deferred to another scheduled list if clinically appropriate. The agreed maximum number of patients can only be exceeded if all relevant clinical and support staff agree and a formal risk assessment has been completed.

d) The completed risk assessment form and associated documentation (contained in the risk assessment form) of this agreement must be retained for future review by the National Peer Review Team, as well as for local audit purposes.

e) A quarterly report of the number of intrathecal procedures will be reviewed for each intrathecal area at the intrathecal management group meetings. If it is projected that the number of procedures will exceed 500 per year, a risk assessment will be undertaken as per the National Guidance.

6.4 Administration on a site that does not usually provide an Intrathecal Service

a) If a patient who is an inpatient on another site (other than the LRI) requires intrathecal chemotherapy and it is deemed inappropriate to move them, for example if they are too ill, the following procedure will apply:

b) A discussion will take place with the Designated Trust Lead or their deputy to agree that intrathecal chemotherapy is clinically required and that the patient cannot be moved.

c) The exceptional circumstances part of the protocol (see Appendix 1, section 7) will come into force with the addition that staff from the Authorised Register who are conducting the procedure will travel to that site to perform the procedure. Intrathecal chemotherapy is stable for transfer at room temperature.

6.5 Intraventricular Chemotherapy – see also Appendix 6

a) Occasionally there is a requirement for SACT to be administered by the intraventricular route via a reservoir.

b) Intrathecal policy details must be followed for patients receiving intraventricular chemotherapy except for the specific points below:

- The route of the drug allocated on ChemoCare and generated on the intrathecal paper prescription must state intraventricular.
- All intraventricular SACT must be clearly labelled ‘For Intraventricular use only’
- Doses are usually less than intrathecal doses. If an intraventricular dose is not stated in the patient’s treatment protocol, allocate 50% of the intrathecal dose.
- Individual doctors administering intraventricular chemotherapy must have

received specific training in this technique

6.6 Location

6.6.1 Adults

a) Except in exceptional circumstances for adults, all intrathecal chemotherapy will be administered in the Osborne Day Care Treatment Room (second floor).

b) There is a Thursday morning list between 10:00am and 2:00pm. A second list can be held on a Monday afternoon between 1:00pm and 4:00pm.

c) This area will not be used for the administration of any other SACT during these periods of time and no SACT should ever be stored in this area even when the area is not being used for intrathecal chemotherapy administration.

6.6.2 Paediatric

a) Except in exceptional circumstances for paediatrics, all intrathecal chemotherapy will be administered in the Ward 27 Theatre.

b) There is a Tuesday and Thursday morning list between 9:00am and 2:00pm.

c) This area will not be used for the administration of any other SACT during these periods of time and no chemotherapy should ever be stored in this area even when the area is not being used for intrathecal chemotherapy administration.

d) It must be noted that some children and young people requiring a general anaesthetic for intrathecal chemotherapy also require diagnostic bone marrow aspirates and/or trephines at the same time. In addition, at the start of treatment children who will require a central line insertion, diagnostic bone marrow and lumbar puncture with instillation of chemotherapy should not expect to receive more than one general anaesthetic and these procedures may be combined in main theatres. These episodes do not require a concession but should be recorded.

6.6.3 TYA

TYA patients being treated within CHUGGS CMG will receive their intrathecal chemotherapy during the Adult Thursday or Monday lists. TYA patients treated within Women's and Children's CMG in the TYA unit on Ward 27, will receive their intrathecal chemotherapy on Tuesday or Thursday morning lists.

6.6.4 Exceptional Circumstances

a) Exceptional circumstances fall into 2 categories. Those patients who require urgent treatment outside the normal designated times or those who cannot be treated in the designated location either because they are too ill such as being managed on the ITU or due to difficulties with placement of the needle they need to be treated in radiology. These circumstances are covered in Section 7.

6.7 Intrathecal Referral Form and Procedure Safety Checklist [APPENDIX 3]

a) This form reflects the Local Safety Standards for Invasive Procedures (LocSSIPs) relevant to intrathecal chemotherapy and must be completed for every single patient undergoing lumbar puncture and administration of intrathecal chemotherapy.

b) It should be commenced by the doctor allocating the intrathecal chemotherapy and

include any extra information which will be relevant to the day of procedure such as:

a. Diagnosis/indication for intrathecal chemotherapy
b. Treatment protocol being used and if any deviation
c. If the patient requires a translator
d. If any intravenous chemotherapy/injectable SACT is due
e. If patient is on anticoagulation and when stopped
f. If patient is likely to require transfusion support
g. If any concerns regarding raised intracranial pressure
h. Number of samples requested
i. If patient requires any extra procedures e.g. bone marrow, NG tube
j. If patient may need longer spinal needle

c) Prior to intrathecal chemotherapy administration a team safety briefing [Appendix 4] needs to be done and for each individual patient the 'sign in and time out' section fully completed. The team briefing should consist of the doctor and nurse involved in checking and administrating the intrathecal chemotherapy. In Ward 27 theatre, as general anaesthetic/sedation is frequently used the team briefing should also involve the anaesthetist, operating department practitioner (ODP) and recovery nurse.

d) Following completion of intrathecal chemotherapy administration, the 'sign out' section must be fully completed.

6.8 Disposal of Waste

a) The UHL Trust policy for the Disposal of Waste [A15/2002] must be followed.

b) Syringes and lumbar puncture needles must be disposed of into a cytotoxic sharps bin.

c) All other waste must be placed into a heavy duty yellow bag.

7 EDUCATION AND TRAINING REQUIREMENTS

7.1 The prescribing, consenting, dispensing, checking and administering of intrathecal chemotherapy requires specific training. This policy sets out the authorised trainers for each professional group. These individuals are responsible for ensuring that staff whom are added to the authorised register have successfully completed the relevant training package and are deemed to be competent to carry out their designated role. This training is updated on an annual basis.

7.2 Within the National Guidance two people deemed competent must check the intrathecal drugs prior to administration.

7.3 Any member of staff whose certificate has lapsed will have their name removed from the UHL Authorised Register by the Designated Trust Lead / register holder until the training update has been successfully completed.

7.4 The Designated Training Leads for Adult and Paediatric medical and nursing staff and pharmacy will nominate an individual from the Authorised Register to review their competency on an annual basis, following which a new certificate will be issued.

7.5 The emphasis and responsibility is on staff who appear on the Intrathecal Register

to only involve other staff members who are also on the Authorised Register. No staff should be asked to be involved unless this forms part of the training for entry onto the register. It is the responsibility of those on the register to ensure any colleague they involve in this process is on the register and listed as competent for the task in question.

7.6 Medical staff

a) Must receive theoretical and practical training on the indications and safe administration of intrathecal chemotherapy.

b) They must fully read the UHL Intrathecal SACT Policy even if they are only involved in one patient group. This must be followed by an assessment of competency.

c) Doctors deemed competent in the process will be issued with a certificate valid for one year. This certificate will list the areas within the process in which they are competent to practice.

d) The areas of competency for medical staff are prescribing, consenting, checking chemotherapy and administration.

e) Consultant medical staff may also be listed as competent to train and assess competency levels. Certification will be followed by entry of the individual's name onto the UHL Authorised Register. The certificate is valid for only one year and must be renewed annually following a refresher training session.

f) The training of Specialist Registrars at ST3 level or above in the administration of intrathecal chemotherapy must only be undertaken by consultants who are listed as competent to deliver training and assess competency in the relevant section of the Authorised Register. All practical training must be given during the routine weekly list and never during an emergency list.

7.7 Nurses

a) Must receive theoretical training on the use of intrathecal chemotherapy and the Intrathecal SACT Policy. This must be followed by an assessment of competency.

b) Nursing staff deemed competent in the process will be issued with a certificate valid for one year. This certificate will list the areas within the process in which they are competent to practice.

c) The area of competency for nursing staff is checking chemotherapy and assisting at administration. Certification will be followed by entry of the individual's name onto the UHL Authorised Register. The certificate is valid for only one year and must be renewed annually following a refresher training session.

d) Nursing staff may also be listed as competent to train and assess competency levels of other nursing staff.

7.8 Pharmacy Staff

a) All new staff working in the Aseptic services department, during their induction, must read and understand this Policy. They must also understand that they may not participate in the Intrathecal Chemotherapy process unless on the Authorised Register.

b) The areas of competency for Pharmacy staff are Compounding, Checking, Issuing and Delivery.

a. Compounding: aseptically preparing intrathecal chemotherapy
b. Checking: checking compounded intrathecal drugs and ensuring they are placed in the locked container awaiting final release. This may be undertaken by a Pharmacist competent to check aseptic products
c. Issuing: Releasing the intrathecal drugs from the Pharmacy to the Clinical areas or handing the drugs to a doctor on the Authorised Register.
d. Delivery: transporting intrathecal chemotherapy to the Ward 27 Theatre and Osborne Daycare Treatment room Refrigerators used for storing Intrathecal chemotherapy just prior to each list commencing.

c) Competency in one area does not confer competency in another.
d) Pharmacy staff including locum and bank staff must undergo training and assessment prior to being allowed to participate in any part of the intrathecal chemotherapy process.
e) Staff who have completed the training package and passed the assessment process will be issued with a certificate of competency and their name placed on the Authorised Register. They may then participate in the areas for which they hold the certificate of competency. Certification will be valid for one year.
f) Pharmacy staff may also be listed as competent to train and assess competency levels of other pharmacy staff.

8 PROCESS FOR MONITORING COMPLIANCE

8.1 Adherence to the National Guidance encapsulated within this policy will be audited as part of a National Cancer Peer Review Process.

8.2 CHUGGS CMG and Women's and Children's CMG are committed to conducting an annual audit of compliance with this Policy, incorporating Pharmacy. This will form part of both services' audit programmes.

Element to be monitored	Lead	Tool	Frequency	Reporting arrangement	Lead(s) for acting on recommendations	Change in practice and lessons to be shared
Number of Procedures performed	Designated Trust Lead Chemo Care System Manager		3 months	To Designated Trust Lead	Designated Trust Lead	>500 procedures requires risk assessment and declaration to NHS England
Compliance with Policy	Designated Trust Lead And Intrathecal Management Group		Yearly	To all individuals on Register	Designated Trust Lead	
Completion of referral form/procedure safety checklist	Designated Lead Nurse Trainers and Intrathecal Management Group		6 monthly	To CMG Quality & Safety Board	Designated Trust Lead	
Peer Review Compliance	Lead Clinician	Peer Review Standards	Yearly	Via Peer Review process and To Chemotherapy Group	Designated Trust Lead	

9 EQUALITY IMPACT ASSESSMENT

9.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

9.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

10 LEGAL LIABILITY

The Trust will generally assume vicarious liability for the acts of its staff, including those on honorary contract. However, it is incumbent on staff to ensure that they:

- Have undergone any suitable training identified as necessary under the terms of this policy or otherwise.
- Have been fully authorised by their line manager and their CMG to undertake the activity.
- Fully comply with the terms of any relevant Trust policies and/or procedures at all

times.

- Only depart from any relevant Trust guidelines providing always that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible clinician it is fully appropriate and justifiable - such decision to be fully recorded in the patient's notes.

It is recommended that staff have Professional Indemnity Insurance cover in place for their own protection in respect of those circumstances where the Trust does not automatically assume vicarious liability and where Trust support is not generally available. Such circumstances will include Samaritan acts and criminal investigations against the staff member concerned.

Suitable Professional Indemnity Insurance Cover is generally available from the various Royal Colleges and Professional Institutions and Bodies. For further advice contact: Head of Legal Services on 0116 258 8960.

11 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

Key Documents	Location
East Midlands Region Systemic Anti Cancer Therapy (SACT) Policy	http://www.eastmidlandscanceralliance.nhs.uk/cancer/chemotherapy
Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy (HSC 2008/001)	HSC (2008) 001 Updated national guidance on the safe administration of intrathecal chemotherapy (allcatsrgrey.org.uk)
NPSA Safer Spinal (intrathecal), epidural and regional devices (NPSA/2011/PSA001)	NHS England » Patient safety alert on non-Luer spinal (intrathecal) devices for chemotherapy
NPSA Rapid Response Report (NPSA/2008/RRR04) Using Vinca Alkaloid Minibags	[ARCHIVED CONTENT] Using Vinca Alkaloid Minibags (nationalarchives.gov.uk)
National Safety Standards for Invasive Procedures	https://www.england.nhs.uk/patientsafety/never- events/natssips/
UHL Incident and Accident Reporting Policy (A10/2002)	UHL Intranet site
Authorised Intrathecal Register UHL NHS Trust Intrathecal Systemic Anti-Cancer Therapy Policy Paediatrics; A2/2003.	UHL Intranet Site Osborne Day Care Procedure Room Ward 39 (Oncology) Ward 40 (Oncology) Ward 41 (Haematology) Bone Marrow Transplant Unit Ward 27 Theatre,LRI Ward 27 Aseptic Unit – Pharmacy Chemotherapy Suite, Osborne Hope Unit, LRI

Other Documentation:

Authorised Intrathecal Register [Appendix 2]

Intrathecal Referral Form & Procedure Safety Checklist [Appendix 3]

Intrathecal Chemotherapy Safety Team Brief [Appendix 4]

Concession Form [Appendix 5]

Intraventricular Chemotherapy [Appendix 6]

UHL Consent to Examination or Treatment Policy [Trust ref: A16/2002]

12 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

12.1 This policy has been developed by a multi-disciplinary working group with the specific purpose of reviewing and updating the existing policy to reflect current practice whilst complying with National Guidance. Agreement has been provided by lead clinicians, pharmacy representation and senior nursing staff.

12.2 This policy has been discussed and agreed by the relevant Management Board Meetings. Once the CMGs have agreed the policy it is forwarded to the Trust's Policies and Guidelines Committee for final approval. Once this is granted this document will be uploaded onto SharePoint and available for access by Staff through INsite. It will be stored and archived through this system.

12.3 This Policy will be reviewed every three years or sooner in response to newly published national guidance or identified risk issues.

All staff involved at any stage with this procedure may withdraw and refuse to proceed if they feel that the Policy has not been adhered to or the practice is incorrect in any way. Such action should be notified to the Lead Clinician immediately and this will be urgently reviewed with the Intrathecal Management Group. All breaches will require a Patient Safety Incident Form on Datix Web to be completed.

1 Booking Patients for Intrathecal Therapy

1.1 Patients requiring intrathecal therapy must undergo treatment at LRI in the Osborne Day Care Treatment Room or Ward 27 Theatre except in exceptional circumstances. See section A7.

1.2 A routine list will be held in each area.
Osborne Daycare Treatment Room: Thursday morning between 10:00am and 2:00pm. When a second intrathecal list is required it will take place on Mondays between 1:00pm and 4:00pm. The list on a Monday must be agreed in advance with the individuals involved with that particular intrathecal session.
Ward 27 (LRI) Theatre lists will be held each Tuesday and Thursday morning between 9:00am and 2:00pm. A Paediatric Anaesthetist is available for these children and young people.
The final patient receiving intrathecal chemotherapy on each procedure list, needs to be inside the designated treatment room before the end time of the routine list.

1.3 Patients requiring intrathecal chemotherapy must be booked in advance.
Patients will be booked in advance using the Intrathecal Referral Form & Procedure Safety Checklist [Appendix 3]. For the adult list this should be given to the Osborne Day Care Sister or her deputy. For the paediatric/TYA list this should be given to the Ward 27 Day Care Sister or her deputy. A list will be automatically generated of any patients who have been allocated intrathecal chemotherapy before 3pm the day before the scheduled routine list. For the adult intrathecal session on Monday afternoons, this patient list will be generated at 3pm the Friday before.

If a patient is allocated intrathecal chemotherapy after 3pm the day before the routine list, it is the responsibility of the prescribing clinician to communicate directly with the relevant treatment area and pharmacy.

1.4 In addition to the Intrathecal Referral Form & Procedure Safety Checklist, the doctor responsible for the intrathecal session must be informed by the referring doctor about any patients to be treated, whether they are Oncology or Haematology patients. The Sister or her deputy will discuss the patients with the doctor responsible for the session. The booking clinician must make all the relevant clinical findings known at the time of referral including:-

- Indication for intrathecal chemotherapy

- Treatment schedule/protocol
- Any deviation from standard treatment schedule
- Any injectable SACT due that day
- Any anticoagulation
- Any concern of raised intracranial pressure

1.5 Patients must have had a full blood count (and INR if clinically indicated) within one week prior to the procedure. Patients on intensive chemotherapy such as during induction and delayed intensification cycles, when they might be expected to have low platelet counts or abnormal coagulation, should have these tests performed within 2 days.

If the platelet count is <40 x 10^9/l the following should be considered and discussed with the doctor responsible for the list and the patient's Consultant team:

- One therapeutic dose of platelets to be administered immediately prior to the procedure in patients who are not refractory to platelet transfusions.
- HLA matched or two random adult therapeutic doses of platelets for refractory patients.
- If the INR is >1.3 this MUST be discussed with the Consultant in charge of the list.

1.6 The scheduling of intrathecal therapy must take into account the availability of the staff required. This is a minimum of one nurse, one doctor, one pharmacist and one pharmacy compounder from the Authorised Register. If any of these staff are not available, the procedure must be re-scheduled. If a list needs to be cancelled, the Designated Trust Lead and Pharmacy must be informed.

2 Prescribing

2.1 Only methotrexate, cytarabine and hydrocortisone are regularly being given intrathecally. Any other SACT which is being considered to be given intrathecally/intraventricular to a patient has to be discussed with the Trust Lead and within the Intrathecal Management Group. It is acknowledged for neuro-oncology patients other intrathecal/intraventricular SACT may be administered.

2.2 Allocation

Drugs to be given intrathecally must only be prescribed (allocated on ChemoCare) by medical staff who appear on the UHL Authorised Register. SHO's [FY1/2 and ST1/2] are not allowed to prescribe chemotherapy and do not have access to do so on ChemoCare. Several cycles of intrathecal chemotherapy may be allocated at a time. The dose prescribed is age related and varies for different diseases and trial protocols. The dose must be checked against the patient's treatment protocol and medical notes. **A record must be made in the electronic ChemoCare notes of:**

- Indication for intrathecal chemotherapy
- Named treatment schedule or protocol
- Any deviation from standard schedule or protocol. The decision to administer intrathecal chemotherapy outside of a protocol should only be made by a Consultant and must be clearly documented in the notes. The drug and dosage must be clearly stated.

2.3 Confirmation

The allocated intrathecal chemotherapy prescription must be checked against the

protocol, notes or previous treatment schedules by a pharmacist and confirmed. Only a pharmacist can complete this stage but they do not need to be on the authorised intrathecal register.

24 Authorisation

The prescription must be authorised by a doctor on the authorised register once the decision to proceed has been made. **The prescription must be authorised within 8 days of the date of administration. Once the prescription is authorised the doctor must not print the prescription** – this step will be performed by a pharmacist on the authorised register.

25 Final Pre-dispensing Check

A pharmacist on the UHL Authorised Register must check:

- The prescription elements are complete
- The electronic signatories of the individuals allocating, compounding/dispensing, issuing and authorising the intrathecal chemotherapy prescription are all on the authorised intrathecal register and in date.
- The authorisation date is within 8 days of the date of administration.

They then complete the "pharmacy check". The prescription will now have 4 electronic signatures. The prescription will be printed by a Pharmacist on the authorised register, automatically generating two copies - one of which will be destroyed. The remaining copy will be used to document issue, delivery/collection and administration. The paper chart will be signed in ink by the Pharmacist and will form an audit trial for the procedure. If in the event of treatment deferral or other printing issues and a reprint is required (watermarked "Reprint") the reason for reprinting will be documented on the prescription and signed.

3 Preparation Issue Delivery Collection and Storage

Intrathecal chemotherapy may be prepared (but not issued) against a ChemoCare pre-empt list. Intrathecal chemotherapy must be prepared on an individual basis and not as a batch.

3.1 Intrathecal chemotherapy must be prepared in the Pharmacy in 'ready to use' intrathecal syringes. The outside of the syringes, whilst clean, will not be sterile. Intrathecal syringes which connect to specific intrathecal needles to prevent maladministration must be used.

3.2 Pharmacy staff who have completed the knowledge and competency assessment may aseptically prepare intrathecal chemotherapy. Pharmacists working in the lab who have passed their competencies for checking aseptic products may check intrathecal drugs and ensure they are placed in the locked container awaiting final release by a pharmacist on the authorised register.

Only pharmacists who are on the UHL Authorised Register can be involved in the issue of intrathecal chemotherapy. An up-to-date copy of the UHL Authorised Register of designated staff must be kept in the Pharmacy Department.

3.3 Intrathecal chemotherapy is never to be kept as ward stock, but prepared on an individual basis and must only be used for the patient it is labelled for.

3.4 Syringes must be clearly labelled FOR INTRATHECAL USE ONLY. Abbreviations must not be used.

3.5 If the patient is scheduled to receive any injectable SACT on the same morning as intrathecal chemotherapy, the injectable SACT must be issued and administered prior to the beginning of the intrathecal list.

3.6 For children and young people, if there is the potential that a drug reaction e.g. asparginase allergy, monoclonal antibody reaction may be masked whilst the child is receiving sedation/general anaesthetic, it is appropriate to give these SACT agents after the intrathecal chemotherapy but the SACT drug must be removed from the ward area and stored in pharmacy until the intrathecal drug is given and a concession must be requested first.

3.7 For the ward 27 list, if there is a delay to a child or young person commencing intravenous methotrexate before 11:00am due to incorrect urine pH/suboptimal urine output, knowing they are scheduled for sedation/general anaesthetic, the intrathecal drug can be released and given before the intravenous methotrexate is commenced. This can only happen if the IV methotrexate is stored in pharmacy until the intrathecal drug is given electronically on ChemoCare. A concession is not required for this specific circumstance but the Trust Lead should be notified after the event, so these episodes can be documented in the Management Group meetings.

3.8 Any SACT supplied for a patient on the list prior to releasing intrathecal chemotherapy must either:-

a) have been fully administered
   or
b) the infusion must have been started and there must be no other chemotherapy remaining on the ward not being infused
   or
c) returned to Pharmacy if it cannot be given or is not required and unreleased on ChemoCare.

3.9 Only when the authorised Pharmacist is satisfied that:

a) there are no injectable SACT preparations awaiting administration for the individual patients on the list
b) they have electronic or hard copy confirmation that, for all patients on the intrathecal list, injectable SACT drugs have been administered or they have seen signed confirmation that, for patients on the intrathecal list, on continuous intravenous SACT therapy, treatment has commenced.
c) the treatment area and designated intrathecal fridge are clear of any IV or other SACT

will they issue the intrathecal chemotherapy for the patients named on the list.

3.10 Only when the authorised Pharmacist is satisfied that injectable SACT drugs have been administered or that the intravenous SACT infusion has begun, will they sign Part A of the prescription and issue the intrathecal chemotherapy and indicate this

by completing the “drug dispensed by” section on ChemoCare. An authorised member of pharmacy staff will release the drugs to a doctor or deliver and complete Part B as appropriate.

Release from Pharmacy and Acceptance in Clinical Area **Chart Id.:**

Part A (NB Both sections below must be completed before Intrathecal admin chemotherapy can be released)

Is IV/SC/IM chemotherapy due to be given prior to todays Intrathecal admin dose(s)?	Yes/No/NA	Sign
Has pharmacist seen evidence that the IV/SC/IM chemotherapy has been administered?	Yes/No/NA	Sign

Part B (NB One of the sections below must be fully completed before administration can proceed)

Either 1	Issued from pharmacy by authorised member of pharmacy staff (signature):	Sign	Print Name	Date	Time
	Received by authorised doctor (signature):	Sign	Print Name	Date	Time
Or 2	Delivered to designated area and stored as defined in local policy by authorised member of pharmacy staff (signature):	Sign	Print Name	Date	Time
	Retrieved from designated storage area as defined in local policy, by authorised doctor (signature):	Sign	Print Name	Date	Time
Or 3	Delivered to designated area by authorised member of pharmacy staff and issued directly to authorised doctor by (signature) :	Sign	Print Name	Date	Time
	Received by authorised doctor (signature):	Sign	Print Name	Date	Time

NB Only staff who have been trained and whose name is listed on the relevant registers for Intrathecal admin chemotherapy may prescribe prepare, issue, deliver, check and administer Intrathecal admin chemotherapy

3.11 **Intrathecal chemotherapy for each patient must be released in an individual red box used for intrathecal chemotherapy only and never together with any drug for administration by any other route.** Under no circumstances must intravenous and intrathecal drugs be transported in the same container.

3.12 Once the intrathecal chemotherapy has been issued to a treatment area, no other injectable S A C T will be issued for patients on the list. If further injectable SACT is required after the list (bd, sequential, other exception) then this will not be released until intrathecal prescription charts have been signed and the pharmacist can confirm this by viewing the patient record to see intrathecal drugs have been “given” on the electronic record. Where in exceptional circumstances it is not possible to “give” on the system the completed hard copy prescription or a faxed copy must be seen.

3.13 Intrathecal injections must be collected by the doctor performing the lumbar puncture or delivered directly and locked in the intrathecal refrigerator by authorised pharmacy staff. The intrathecal refrigerator must only be used for the storage of intrathecal drugs. Under no circumstances must any other drugs be stored in the intrathecal refrigerator.
NO OTHER STAFF ARE ALLOWED TO COLLECT INTRATHECAL DRUGS FROM PHARMACY.

Osborne Day Care Treatment Room: The Intrathecal refrigerator is located in the Osborne Day Care Treatment Room. The prescription will be signed and annotated accordingly and given to the Sister or their deputy. No other SACT must be stored or administered in Osborne Daycare Treatment Room.

Ward 27 Theatre: The Intrathecal refrigerator is located in Ward 27 Theatre. The prescription will be signed and annotated accordingly and placed in the folder on top of the intrathecal refrigerator. No other S A C T must be stored or administered in Ward 27 Theatre.

3.14 **The drugs must only be collected/delivered just prior to the commencement of the lumbar puncture list, except when to be given under exceptional circumstances** (see section 7).
Osborne Day Care Treatment Room may have drugs collected/delivered Thursday morning & Monday Afternoon.
Ward 27 Theatre may have drugs collected/delivered Tuesday and Thursday mornings.

3.15 There are two sets of keys to the intrathecal refrigerator in each Designated Treatment area. One set will be stored in pharmacy and used by the authorised pharmacy staff. The other set is stored in the drug cupboard in Osborne Day Care or Ward 27 theatre and is the responsibility of the authorised nurse in charge of the list.

4 Consent

4.1 **Written informed consent must be obtained for the first intrathecal/intraventricular procedure for each patient. This first consent form should state it is for repeated lumbar puncture and administration of intrathecal chemotherapy or administration of intraventricular chemotherapy.**

4.2 Consent for a child can be given by a parent or guardian. The child can give consent if considered to be Gillick competent as per UHL policy. Risks/side effects from the procedure include headache, bleeding/bruising, infection and toxicity from intrathecal chemotherapy such as encephalopathy and nerve damage.

4.3 For subsequent treatments, verbal consent must be obtained and the initial written consent form reviewed.

4.4 The verbal consent must be obtained by the doctor responsible for administering the intrathecal chemotherapy and he/she must ensure the initial written consent form has been reviewed before the procedure begins.

4.5 A copy of the original written consent form should be made and kept in the relevant designated treatment area.

4.6 The consent form must state the drug(s) to be administered and the procedure of lumbar puncture.

5 Administration: Routine

FY1/2 and ST1/2 ARE <u>NOT</u> AUTHORISED TO ADMINISTER INTRATHECAL OR INTRAVENTRICULAR CHEMOTHERAPY EVEN UNDER SUPERVISION.

5.1 All lumbar puncture sessions will be the responsibility of a Consultant on the Authorised Register. The lumbar puncture, checking and administration of chemotherapy may be delegated to a Specialist Registrar who holds a valid competency certificate and is on the Authorised Register. Specified intrathecal needles are now used for administering intrathecal chemotherapy. Under no circumstances may chemotherapy be transferred to standard Luer lock syringes to enable standard needles to be used.

5.2 The procedure must take place in either:
Osborne Day Care Treatment Room during the allocated list (see section 1.2), except under exceptional circumstances (see section 7).
OR
Ward 27 Theatre LRI during the allocated list (see section 1.2), except under exceptional circumstances (see section 7).

5.3 **If the patient is scheduled to receive any injectable SACT on the same morning as intrathecal chemotherapy, the injectable SACT drugs must be issued and administered prior to the beginning of the intrathecal list.** If a patient requires BD chemotherapy, sequential or another exception then this chemotherapy will not be released until the intrathecal list is completed.

5.4 A member of staff who is on the register of designated personnel who can administer intrathecal chemotherapy will review patients before intrathecal chemotherapy is administered. This is to ensure that:

a) the patient is fit for treatment
b) the correct tests have been conducted and the results checked
c) the correct chemotherapy has been prescribed

Confirmation that the review has taken place will be checked as part of the Intrathecal Referral & Patient Safety Checklist [Appendix 3] and will also be documented in the medical notes.

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5.5 The appropriateness of proceeding with the procedure should be discussed by the patient's Consultant and the administrating doctor under the following circumstances:

- If there have been any major changes in the patient's condition, for example sepsis, or a change in remission status
- Problems during or following previous lumbar punctures
- The presence of infection near the lumbar puncture site

5.6 A register of all staff authorised is located in each area (see section 11). This must be used during the procedure to confirm that staff asked to assist with the procedure are competent to do so. A record of the personnel involved will be kept for each list by the Day Ward Nurse Practitioner or deputy.

5.7 Only one patient receiving intrathecal chemotherapy may be in the Treatment Area at any one time. The patient must be accompanied by their medical notes. Only one patient's notes must be in treatment room/theatre at any one time. The next patient must not be brought into the designated room until the previous patient is in recovery, and their samples labelled.

5.8 **Under no circumstances must other SACT agents be taken into the Treatment Room/Theatre unless already part of a previously commenced continuous intravenous infusion**.

5.9 The key to the designated refrigerator must be held by the Sister or their deputy. The drugs must be removed by the doctor who will be administering them immediately prior to the procedure. Only one patient's drugs must be removed at a time. The doctor must sign to say they have removed the drugs from the refrigerator.

5.10 Prior to commencing each intrathecal procedure, a team safety briefing must be done [Appendix 4] and the 'sign in and time out' section of the Intrathecal Referral

Form & Patient Safety Checklist [Appendix 3] completed to ensure all aspects of the process are within the policy, including that all staff involved are on the authorised register including themselves. In Osborne Day Care Treatment room the safety briefing will be done by the doctor and nurse performing the intrathecal list. In Ward 27 theatre, the safety briefing will be attended by the doctor and nurse performing the intrathecal list, as well as the Anaesthetist, Operating Department Practitioner (ODP) and Recovery Nurse when general anaesthetic is planned.

5.11 Prior to lumbar puncture the doctor administering the intrathecal chemotherapy must verify the identity of the patient. For adult patients this will be done verbally with the patient and via a wristband. Where intrathecal chemotherapy is being given under general anaesthesia the patient/ parent/guardian will not be able to participate in the final checking. In such cases the additional check will be undertaken by the attending ODP or healthcare assistant who will also confirm the identity of the patient. The doctor must also verify it is the appropriate drug, dose, route of administration and expiry date. These details must be checked against the prescription, the consent form and the medical notes (and trial protocol if appropriate). These details must be checked with another authorised member of staff (see Authorised Register). The prescription chart must be signed by both administering doctor and checker.

5.12 Osborne Day Case Treatment Room: The procedure will be done under local anaesthesia using an Aseptic technique according to the accepted standard of medical practice. Intravenous sedation is not given. A small minority of anxious patients may require Entonox or oral benzodiazepine, but should be discussed with the doctor performing the list beforehand.
Ward 27 Theatre: The procedure may be done under sedation/general anaesthetic or local anaesthetic, with or without Entonox using an aseptic technique according to the accepted standard of medical practice.

5.13 CSF samples should be taken prior to injecting chemotherapy each time a lumbar puncture is performed. CSF samples should be sent in sterile universal containers for cytospin. Other samples may be required according to the clinical need, for example biochemistry and microbiology, immunophenotyping or pcr investigation.

5.14 When intrathecal chemotherapy is to be administered in the presence of a low platelet count (less than 40 x 10^9/l) please follow advice in section 1.5.

5.15 If there are problems in inserting the needle, a clinician with more technical expertise may be consulted. This may be an anaesthetist. The Haematologist/ Paediatric Oncologist responsible for the session must be present during this procedure in the Osborne Day Care Treatment Room/ Ward 27 Theatre.

In such circumstances **THE ROLE OF THE ANAESTHETIST IS ONLY THE PLACEMENT OF THE NEEDLE. THE DOCTOR FROM THE UHL AUTHORISED REGISTER MUST BE THE ONE TO ADMINISTER THE CHEMOTHERAPY. UNDER NO CIRCUMSTANCES MUST THE ANAESTHETIST OR OTHER UNTRAINED CLINICIAN ADMINISTER THE CHEMOTHERAPY.**

If the needle still cannot be inserted, it may be placed by a Radiologist under imaging guidance. This results in the patient being moved and the intrathecal chemotherapy being administered in another location and so becomes subject to

the exceptional circumstances protocol (see section 7).

5.16 At the completion of each individual procedure administration will be signed for both on the hard copy and electronically on ChemoCare.

5.17 At the completion of each individual procedure, the staff involved in the safety briefing must complete the 'sign out' section of the Intrathecal Referral Form & Patient Safety Checklist [APPENDIX 3].

5.18 In the case of unused intrathecal chemotherapy:

- The intrathecal drug should be disposed of in the designated area by the authorised doctor and nurse. This applies whether the drug is still sleeved or un-sleeved and the pharmacist does not need to witness disposal.
- The paper intrathecal prescription should be completed with 'Not given' clearly documented and signed.
- The named pharmacist from the authorised register who released and delivered the intrathecal chemotherapy must be informed the drug was not given and was disposed of.
- ChemoCare records must be updated either by deferring the treatment scheduled or deleting it if no longer required but putting a note on ChemoCare stating not given on particular date. Until this is completed and the intrathecal treatment unreleased on ChemoCare, the Pharmacy will not release other injectable SACT for this patient to the Ward. If treatment is deferred the chemotherapy must be un-authorised to ensure when re- authorised the date of authorisation is within 8 days of the proposed new treatment date. The confirmation and re-authorisation will then follow section 2 Prescribing.

6 Care of Teenage and Young Adults

Patients aged 19-24 years may be cared for within the Adult or Paediatric (TYA) units. When intrathecal chemotherapy is administered in the Adult unit the process will not vary from that set out for all adults. When intrathecal chemotherapy is administered in the Paediatric (TYA) unit a Paediatric Oncologist/Haematologist or an Adult Haematologist on the Authorised Register may perform the lumbar puncture and administer the drug. The procedure will be assisted by a member of the Ward 27 nursing staff who is on the Authorised Register. The lumbar puncture may be performed under local or general anaesthetic and the Ward 27 Theatre process will be adhered to.

7 Administration: Exceptional Circumstances

7.1 Intrathecal chemotherapy must, wherever possible, be administered on the routine lists as outlined above. Administration in all other circumstances will be labelled as exceptional circumstances. Most mistakes have been made under these circumstances. Special care is therefore required to ensure such situations are as safe as possible.

The exceptional circumstances fall into three categories:

a. Treatment must be given in another place.
b. Treatment can be given in the usual place but not during the routine list.
    b.1 This may be within normal working hours (9.00am -5:30pm, Monday to Friday).
    b.2 Treatment is to be given outside normal working hours, i.e. between 5:30pm and 9.00am or at a weekend or bank holiday.
c. A combination of both categories exists.

7.2 Only in the most exceptional circumstances (such as CNS disease requiring emergency treatment) should intrathecal chemotherapy be given out of hours. The reason for emergency administration needs to be clearly documented in the patient's notes.

For all intrathecal chemotherapy administration outside the routine list, the following protocol must be adhered to.

7.3 **Any decision to administer intrathecal chemotherapy outside the routine list must be made by a Consultant on the Authorised Register.** The Consultant will review the patient, prescribe the chemotherapy and arrange for the chemotherapy to be administered by members of staff on the Authorised Register. The Consultant will document the reason for treatment and the exceptional circumstances.

7.4 **These exceptional cases must not be used as training procedures for any member of staff.**

7.5 Wherever possible such therapy should be given in Osborne Day Care Treatment Room or Ward 27 Theatre as appropriate. If an alternative location must be used, then only medical and nursing staff on the Authorised Register will undertake the procedure.

7.6 Medical staff must liaise with other authorised staff and pharmacy staff to ensure the availability of a member staff on the Authorised Register to assist in the compounding, issue and checking of the intrathecal chemotherapy drugs as there is not an out of hours on call rota.

7.7 Outside of scheduled list times (see section 1.2) but during the working day (Monday to Friday, 9.00am - 5.30pm), a supply of intrathecal chemotherapy must be requested by the authorised Consultant contacting an authorised Pharmacist. The intrathecal chemotherapy may either be collected by the authorised administering doctor or delivered to the Doctor by an authorised member of the pharmacy staff.

7.8 Out of hours (outside of Monday to Friday, 9.00am - 5.30pm) intrathecal chemotherapy must be requested from the on-call Pharmacist by the authorised Consultant. Prior to issue of intrathecal chemotherapy the on-call Pharmacist will contact an authorised Pharmacist. Intrathecal drugs will only be issued by an authorised Pharmacist with a ChemoCare prescription signed electronically by an authorised Consultant. The intrathecal therapy will be prepared within the Aseptic Unit. The prescription will be processed as usual with an electronic pharmacy check. The pharmacist issuing intrathecal Chemotherapy must complete Part A of the prescription. The pharmacist will issue directly to the doctor and complete Part B section 1 or 1& 3 as appropriate.

Release from Pharmacy and Acceptance in Clinical Area **Chart Id.:**

Part A (NB Both sections below must be completed before Intrathecal admin chemotherapy can be released)

Is IV/SC/IM chemotherapy due to be given prior to todays Intrathecal admin dose(s)?	Yes/No/NA	Sign
Has pharmacist seen evidence that the IV/SC/IM chemotherapy has been administered?	Yes/No/NA	Sign

Part B (NB One of the sections below must be fully completed before administration can proceed)

Either 1	Issued from pharmacy by authorised member of pharmacy staff (signature):	Sign	Print Name	Date	Time
	Received by authorised doctor (signature):	Sign	Print Name	Date	Time
Or 2	Delivered to designated area and stored as defined in local policy by authorised member of pharmacy staff (signature):	Sign	Print Name	Date	Time
	Retrieved from designated storage area as defined in local policy, by authorised doctor (signature):	Sign	Print Name	Date	Time
Or 3	Delivered to designated area by authorised member of pharmacy staff and issued directly to authorised doctor by (signature) :	Sign	Print Name	Date	Time
	Received by authorised doctor (signature):	Sign	Print Name	Date	Time

NB Only staff who have been trained and whose name is listed on the relevant registers for Intrathecal admin chemotherapy may prescribe prepare, issue, deliver, check and administer Intrathecal admin chemotherapy

7.9 INTRATHECAL DRUGS MUST NOT BE STORED ON THE WARD UNDER ANY CIRCUMSTANCES.

7.10 The same procedures for taking consent from the patient, checking the drugs etc. must be followed as previously stated in routine cases (see sections 4 & 5).

7.11 In some circumstances intrathecal chemotherapy needs to be given in other locations, such as Main Theatres, Intensive Care or Radiology. In these circumstances the need to deviate from the normal policy must be clearly documented in the patient's electronic notes on ChemoCare by the Consultant Haematologist/Paediatric Oncologist responsible for the chemotherapy the patient is receiving.

7.12 In most settings the Haematologist/ Oncologist will perform the lumbar puncture and administer the chemotherapy. In the X-ray Department it may be more appropriate for the Radiologist to perform the lumbar puncture. An authorised doctor must stay to administer the chemotherapy, checked by another individual, who must also be on the Authorised Register.

7.13 If there is unused intrathecal chemotherapy, in an exceptional circumstance outside the designated treatment room, it is not necessary for the pharmacist to witness disposal as long as the authorised doctor and nurse dispose of the intrathecal SACT at the time.

7.14 A Senior Pharmacist will inform the Designated Trust Lead each time intrathecal chemotherapy is prepared for a patient out of hours or outside a scheduled list time. This may be done retrospectively.

8 Management of Problems During Administration of Intrathecal Chemotherapy

8.1 Intrathecal chemotherapy should only be administered following a clean tap.

8.2 If the CSF is heavily blood stained, chemotherapy should NOT be administered.

8.3 If the CSF does not flow freely, chemotherapy should NOT be administered.

8.4 The administration of intrathecal chemotherapy under local anaesthetic, should not be painful.

8.5 If the patient complains of severe pain down the leg, the chemotherapy MUST NOT be administered and the needle re-sited.

8.6 If the patient complains of pain immediately on injecting chemotherapy, STOP and check the drug. If the pain stops immediately, consider injecting the chemotherapy more slowly or re-siting the needle.

8.7 If the pain persists or is clearly severe, STOP injecting and allow CSF to flow out freely from the needle. Seek further advice from appropriate Designated Lead Trainer.

APPENDIX 2 **EXAMPLE ONLY**

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
AUTHORISED INTRATHECAL CHEMOTHERAPY REGISTER
AS AT [date]

Trust Lead & Lead Medical Trainer is: Dr Kaljit Bhuller
Deputy Trust Lead is: Dr Constantine Balotis
Lead Medical Trainer (Adults) is: Dr Constantine Balotis
Lead Medical Trainer (Paediatrics) is: Dr Kaljit Bhuller
Lead Nursing Trainer (Adults) is: Sister Charlie Oliver
Lead Nursing Trainer (Paediatrics) is: Sister Hannah Smith
Lead Pharmacy Trainer is: Marie Watson

CHILDREN'S SERVICES – PAEDIATRIC ONCOLOGY/HAEMATOLOGY UNIT AND TYA SERVICE

The following staff, through professional experience and training, hold a valid certificate which authorises them to **SUPERVISE TRAINING, ASSESS COMPETENCY, CONSENT, PRESCRIBE, CHECK & ADMINISTER:**

The following staff, through professional experience and training, hold a valid certificate which authorises them to **CONSENT, PRESCRIBE, CHECK & ADMINISTER:**

Nurses authorised to **TRAIN, ASSESS, COMPETENCY** and **CHECK** intrathecal chemotherapy with an authorised Consultant / Specialist Registrar:

Nurses authorised to **CHECK** intrathecal chemotherapy with an authorised Consultant / Specialist Registrar:

ADULT CLINICAL HAEMATOLOGY SERVICES AND TYA SERVICE

The following staff, through professional experience and training, hold a valid certificate which authorises them to **SUPERVISE TRAINING, ASSESS COMPETENCY, CONSENT, PRESCRIBE, CHECK & ADMINISTER:**

The following staff, through professional experience and training, hold a valid certificate which authorises them to **CONSENT , PRESCRIBE, CHECK, & ADMINISTER:**

Specialist Registrars:

The following staff, through professional experience and training, are authorised to **PRESCRIBE ONLY:**

Consultants:

Nurses authorised to **TRAIN, ASSESS COMPETENCY** and **CHECK** intrathecal chemotherapy with an authorised Consultant / Specialist Registrar:

Nurses authorised to **CHECK** intrathecal chemotherapy with an authorised Consultant / Specialist Registrar:

PHARMACY DEPARTMENT

The following staff, through professional experience and training, hold a valid certificate which authorises them to **ISSUE, DELIVER, TRAIN & ASSESS COMPETENCY in Pharmacy:**

Pharmacists authorised to ISSUE and DELIVER Intrathecal Chemotherapy:

Other Pharmacy Staff authorised to DELIVER Intrathecal Chemotherapy:

Pharmacy Staff authorised to COMPOUND / DISPENSE Intrathecal Chemotherapy within the Aseptic Unit:

Register authorised by: Dr K Bhuller, Consultant Haematologist

This register will be reviewed and updated every 3 months or sooner if necessary.

APPENDIX 3 – Intrathecal Referral Form & Procedure Safety Checklist (LocSSIPs)

Patient ID Label *or write name and number*

Hospital No.:

Name:

Address:

D.O.B.: Sex:

Telephone No. 1:

Telephone No. 2:

STOP THE LINE

Safer Surgery Checklist

Intrathecal Chemotherapy & Bone Marrow Biopsy

LocSSIPs

NHS
University Hospitals of Leicester
NHS Trust

Referrer:

Date of Procedure:

Room:

How to fill in this checklist – put a tick in the box to confirm check has been done. Record anything unexpected, notable or a deviation from normal in the comments column

Diagnosis:	Procedure detail:	Samples Required:	Is any IV chemotherapy due?
Treatment protocol:			Name of doctor checking
			Name of nurse checking

SIGN IN & TIME OUT		COMMENTS
		Record anything notable:
Team safety briefing done	Yes ☐ No ☐ N/A ☐	
Consent form signed	Yes ☐ No ☐ N/A ☐	
Confirm with patient against wristband, consent & notes:		
- Their name, DOB and hospital number (Patient, notes, referral form, prescription & syringe)	Yes ☐ No ☐ N/A ☐	
- Site, side and procedure they are expecting (Any extra procedure e.g. bone marrow, NG tube)	Yes ☐ No ☐ N/A ☐	
- Bloods & anticoagulant check (Platelets >40, INR <1.4, no anticoagulant)	Yes ☐ No ☐ N/A ☐	
- Intrathecal chemotherapy/register checked (Doctor, nurse & pharmacist on register in date)	Yes ☐ No ☐ N/A ☐	
- Equipment checked (Spinal needle size, sample pots, local anaesthetic, GA equipment)	Yes ☐ No ☐ N/A ☐	
- Samples to collect confirmed (Cytospin +/- transfix, MC&S, protein, virology, PCR)	Yes ☐ No ☐ N/A ☐	
- Mediastinal mass or raised ICP (Chest x-ray or CT head performed)	Yes ☐ No ☐ N/A ☐	
Patient allergies	Yes ☐ No ☐ N/A ☐	
Any medication due before procedure	Yes ☐ No ☐ N/A ☐	
Required monitoring in place	Yes ☐ No ☐ N/A ☐	
Read out by: (PRINT)		
Signed:	Date:	

SIGN OUT	COMMENTS
	Record anything notable:
Specimens labelled and checked against patient's wristband by 2 staff members Yes ☐ No ☐ N/A ☐	
Number of specimens and type:	
1	
2	
3	
4	
5	
6	
Intrathecal process complete Yes ☐ No ☐ N/A ☐ (Prescription signed, documented in notes, documented on ChemoCare)	
Confirm & document procedure done and needles removed Yes ☐ No ☐ N/A ☐	
Any equipment issues Yes ☐ No ☐ N/A ☐	
Concerns for recovery, handover to ward Yes ☐ No ☐ N/A ☐ (Recovery from GA, period of bedrest)	
Patient given post-op care instructions Yes ☐ No ☐ N/A ☐ (advice about headache, contact details if problems)	
Read out by: (PRINT)	
Signed:	Date:

1231394SafeSurgeryChecklist

Intrathecal Chemotherapy UHL Policy (LocSSIPs)
Approved by Safe Surgery Board March 2023

APPENDIX 4 – Intrathecal Chemotherapy Safety Debrief

STOP THE LINE

Team Brief Checklist

Intrathecal Chemotherapy & Bone Marrow Biopsy

LocSSIPs

NHS
University Hospitals of Leicester
NHS Trust

Theatre/Procedure Room Site: .....

Named Consultant: .....

Clinicians: .....

Date: .....

This checklist MUST be filed in the Intrathecal Brief folder

1. TEAM BRIEF

At the beginning of the list to discuss all cases, led by the operator

All team members have introduced themselves by name & role ☐	Are the patients where the list says they are ☐
Issues resolved from last debrief ☐	Any latex allergies ☐
Any outstanding investigations ☐	

Patient Name/ Number/ Procedure/Site/ Protocol	Any extra procedures	All equipment available	Samples required	Platelet count	INR	Concerns: raised ICP or mediastinal mass	All IV Chemo Given?	Consent?	Expected deviations from protocol
1									
2									
3									
4									
5									
6									
7									

TEAM DEBRIEF:

Post op debrief performed Yes ☐ No ☐	Team name:	Designation:
Any issues arising that need to be addressed Yes ☐ No ☐	Time:	Date:
If 'Yes', is Debrief Action Log complete (see reverse) Yes ☐ No ☐		

1231394/TeamBriefChecklist

APPENDIX 4 – Intrathecal Chemotherapy Safety Debrief

STOP THE LINE

Team Debrief Checklist

Intrathecal Chemotherapy & Bone Marrow Biopsy

LocSSIPs

NHS
University Hospitals of Leicester
NHS Trust

Date:

This checklist **MUST** be filed in the Intrathecal Debrief folder

Issue noted	Action Required	Responsible Person	Due Date	Comments

Team Signature:	Designation:
Print name:	Time: Date:

123139497TeamBriefChecklist

APPENDIX 5 CONCESSION FORM

Requested by……. Date……

Name and Code of Document / Process
UHL Management of Intrathecal Chemotherapy Policy

Details of Concession Requested

Limitations to Concession	Expiry Date

Comments at Intrathecal Management Review

Concession granted by …… Date granted ……

Date reviewed at Management Review ……

Trust ITC Lead/Deputy Lead signature after review ……

APPENDIX 6

INTRAVENTRICULAR CHEMOTHERAPY

Definitions:

Intraventricular administration refers to administration into the cerebrospinal fluid (CSF) through a subcutaneous implantable device (an Ommaya reservoir) that provides drug delivery into ventricles of the brain.

Intraventricular chemotherapy:
Occasionally cytotoxic drugs are administered by the intraventricular route using an implanted Ommaya reservoir. In these circumstances the Intrathecal Systemic Anti-Cancer Therapy Policy must be followed except:

- The route of the drug on ChemoCare, intrathecal paper prescription and on drug syringe sticker should all state 'Intraventricular'
- The dose being given should be 50% of the dose which would be given intrathecally unless an intraventricular dose is stated in the patient's treatment protocol

The sequence of intravenous chemotherapy before intraventricular chemotherapy is the same, it should be scheduled during routine intrathecal list times in the designated intrathecal areas and only those on the authorised intrathecal register can be involved in this process. The intrathecal procedure checklist and safety debrief should be followed.

Procedure:

1. Administrator should wash hands, put on additional protective clothing if preferred and a pair of sterile disposable gloves prior to handling syringes containing cytotoxic drugs.
2. Nurse and doctor both on authorised intrathecal register to check drug against prescription chart checking patient name, hospital number, date of birth, drug, dose, volume, expiry date and route of administration 'for intraventricular use'. This should include cytotoxic drug/s and 0.9% normal saline in separate non-Luer syringes.
3. Only drugs for intraventricular administration must be present on or near the sterile field until intraventricular drug administration has been completed.
4. Ametop/EMLA cream can be applied to the dome 30-60 minutes before access. Ensure the skin site is free of hair and there is no redness to suggest infection/inflammation.
5. Clean the site using clear Chlorhexidine gluconate 2% w/v Isopropyl alcohol 70% v/v/solution (Chlorprep) and allow to dry.
6. With the patient sitting, use an aseptic technique to access the dome with an NRFit compatible 25G butterfly needle and syringe. Try to avoid inserting the needle through the same puncture site used previously. Aspirate 5ml of CSF taking samples as required.
7. Avoiding air leaks, switch to intraventricular drug syringe and slowly inject drug. Flush dead space of butterfly needle using 5ml 0.9% N. Saline in syringe ensuring total volume injected equals volume CSF removed.
8. Multiple drugs are administered one after the other and not flushed in between.
9. When completed remove the butterfly needle and apply pressure to the puncture site for up to 5 minutes and then apply a taped dressing.

Advice for the patient:
The risks to the patient are the same as that for administration of intrathecal chemotherapy and include infection, bleeding/bruising, headache and encephalopathy/nerve damage.

Patients should be advised if they develop redness/pain at the site, headache, neck stiffness or any neurological symptoms they must be seen urgently and to call:

- Paediatric/TYA patients treated on ward 27 phone
    - Ward 27 daycare (Monday to Friday working hours) 0116 204 7801
    - Ward 27 (outside of daycare hours including overnight & weekends) 0116 258 5959
- Adult patients treated in Osborne building phone
    - Haematology helpline 24 hours 7 days a week 0808 178 2212

If patients attend hospital with fever and/or unwell it is imperative they inform the health care team that they have an Ommaya reservoir so that any additional measures to treat infection can be taken.