Policy	NHS Worcestershire Acute Hospitals NHS Trust

POLICY AND PROCEDURES FOR ADULT INTRATHECAL CYTOTOXIC CHEMOTHERAPY

Department / Service:	Haematology, Pharmacy
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Accountable Director:	Chief Executive
Approved by:	Haematology Governance – 2nd Sept 2024 Medicines Safety Committee – 11th Sept 2024
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Target staff categories	Medical staff, Nursing staff, Pharmacy staff

Policy Overview:
This policy encompasses, or refers to, all parts of the process that must be followed when intrathecal cytotoxic chemotherapy is prescribed, dispensed, issued, checked and administered. This document covers all adult patients requiring intrathecal cytotoxic chemotherapy (ITC) within the Worcestershire Acute Hospitals NHS Trust.

Key amendments to this Document:

Date	Amendment	By:
Sep 2010	Reformat in line with Trust Policy for Key Documents. Reformat approved by Nick Hubbard, Chairman of Medicines Safety Committee 8/9/10	Alison Smith
Aug 2011	Addition of authorisation to store ITC in designated cupboard on Laurel 3 (section 5.3) to comply with National Guidance 2008	Heather Perry
July 2012	1.Addition of Dr S Shafeek is Deputy ITC Lead for the Trust in the absence of Dr J Mills (section 4) 2. Update of CE name	Heather Perry
Sept 2012	Risk of maladministration of bortezomib. Addition to Policy ITC must be on a different day to any bortezomib injection	Heather Perry
Oct 2014	Use of non-Luer devices with Surety design of connectors to be used to comply with Patient Safety Alert 2013 (NHS England)	Heather Perry
April 2016	1. Update of Lead Nurse and Lead medical trainer (section 4.0) 2. Added detail on different day as any other *small volume IV or SC injection.* (section 5.1) as per Trust Risk Services agreement 3. Inclusion of Interventional Radiology (section 5.4)	Heather Perry / Dr J Mills/ A Hawkes
May 2016	Approval of minor amendments to policy by Accountable Director - Interim CEO	Chris Tidman
Sept 2017	Document extended for 3 months as per TMC paper approved 22nd July 2015	TMC
Oct 2017	Document review with no changes	Dr S Shafeek

July 2018	Change from Surety design to NRFit™ design of connectors to comply with Patient Safety Alert NHS/PSA/RE/2017/004[11]	Heather Perry/ Dr J Mills
Oct 2020	Document extended for 3 months with additional encouragement from MSC to get document reviewed and approved	MSC
Feb 2021	Document extended as per Trust agreement 11.02.2021.	
March 2021	Removal of trainer names, removal Depocyte™ (discontinued product), removal of detail referencing'SHA', added hard copies of ITC Policies to 'oncology inpatient area as per National Guidance.	Heather Perry
August 2024	Trust Lead is Dr S. Hebballi	H. Perry
Dec 2025	Change Trust Lead, updated to include manufacture of ITC at Alexandra Hospital Pharmacy	H. Perry
Dec 2025	Medicines Safety Committee 10/12/2025 Approval of technical amendment to reflect urgent site move for aseptic preparation from WRH to AH and change of Trust ITC Lead	Alison Smith

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1. Introduction

- Patient safety is a key strategic objective for the Department of Health. The work began with the publication "An Organisation with a Memory"[1] in 2000 and its recommendations became policy through the NHS Plan.
- To date the World Health Organisation has identified 55 intrathecal incidents worldwide, a number of the reported incidents took place in England. The most recent was in 2001. Intrathecal incidents involved the intravenous vinca alkaloid drug vincristine being incorrectly injected intrathecally (via spinal injections) during chemotherapy treatment of a cancer patient. Vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are intended for intravenous use only. If injected intrathecally they cause paralysis and almost always followed by death.
- In 2001 the Department of Health set a target of reducing to zero the number of patients dying or being paralysed by mal-administered spinal injections by the end of 2001 and established a working party to develop a national guidance.
- "The National Guidance on the Safe Administration on Intrathecal Chemotherapy" (referred to as National Guidance in this Policy) was first issued 2001, reviewed and reissued in 2003[4], and in August 2008 (**HSC 2008/001**). This document (HSC 2008/001) supersedes all other national guidance on safe administration of intrathecal chemotherapy documents. The Trust Local Policy is based on this latest document. The National Patient Safety Agency (NPSA) rapid response report NPSA/2008/RRR004[5] and supporting information on Using Vinca Alkaloid Minibags (Adult / Adolescent Units) should be read in conjunction with the current National Guidance[6] and this local Trust Policy (WAHT-HAE-004).
- Only methotrexate, cytosine arabinoside (cytarabine), or hydrocortisone (as sodium succinate) may be given by the intrathecal route.
- **The mal administration of vinca alkaloids via the intrathecal route is LETHAL.**
- In January 2012 the European Medicines Agency (EMA) issued a document[8] advising that there had been 3 fatal cases, within the European Union, of administration errors, that occurred with bortezomib, where the medicine was given accidentally intrathecally instead of intravenously. The document was issued to remind healthcare professionals to take precautionary measures to prevent further administration errors from occurring.
- In November 2014 Patient Safety Alert (NHS/PSA/D/2014/002) was issued to recommend all bolus doses of chemotherapy should be performed using syringes, needles and devices with non-Luer connectors that cannot connect to intravenous devices, the Surety™ connection was introduced.
- In 2015 Surety™ brand was discontinued and the recommendation (NHS/PSA/W/2015/004) was to transition to the NRfit™ connection which is an ISO compliant device.

2. Scope of this document

This policy encompasses, or refers to, all parts of the process that must be followed when intrathecal cytotoxic chemotherapy is prescribed, dispensed, issued, checked and administered.

This document covers all adult patients requiring intrathecal cytotoxic chemotherapy (ITC) within the Worcestershire Acute Hospitals NHS Trust.

3. Definitions

ITC is treatment in which anticancer drugs are injected into the fluid-filled space between the thin layers of tissue that cover the brain and spinal cord.

4. Responsibility and Duties

The Chief Executive of the Trust has overall responsibility for ensuring compliance with the updated National Guidance on the Safe Administration of Intrathecal Chemotherapy.
The Chief Executive has named an "intrathecal chemotherapy lead" (ITC Lead) to oversee compliance within the Trust. The named ITC Lead for the Trust is Dr S. Chauhan (Consultant Haematologist)

The ITC Lead has overall responsibility within the Trust for induction, training, and continuing professional development related to ITC.
The ITC Lead has formally delegated the responsibility of "Lead Trainers" for medical staff, nursing and pharmacy staff to nominated named staff within their specialities. Copies of these documents are held in the ITC Lead Folder held in pharmacy.

Only personnel on the ITC Register can be involved with ITC within the Trust
(see section 6.3 of this Policy)

5. POLICY AND PROCEDURES FOR ADULT INTRATHECAL CYTOTOXIC CHEMOTHERAPY

5.1 Prescribing ITC:

- The actual ITC prescription must be sent to pharmacy before medication can be dispensed. A photocopy will not be accepted on any occasion. The prescription must be clearly written and complete.

- The ITC prescription must only be signed by staff appropriately trained, and deemed competent by the designated Lead Trainer for medical staff or Designated Lead for the Trust and whose names appear on the ITC Register for prescribing.

- At Worcestershire Acute Hospitals NHS Trust, FT1, FT2, ST1 and ST2 Grade doctors are NOT permitted to prescribe ITC under any circumstance. A waiver is not acceptable for this task.

- ST3 Grades and Specialty Doctors can prescribe ITC as long as they have been appropriately trained, deemed competent by the Lead Trainer for medical staff and their names appear on the ITC Register for prescribing.

- **Charts:**
  ITC must always be prescribed on a separate prescription sheet specifically designed for that purpose. (Appendix 1, 2, and 3). On these prescriptions the drug name is written in full and "Intrathecal injection" is clearly and legibly printed and written in full on the prescription. Full signatures should be used at all times to enable an audit trail.

- Wherever possible the intrathecal cytotoxic chemotherapy should be prescribed for administration on a different day to any intravenous cytotoxic chemotherapy for the named patient. *As an extra safety measure in WAH NHS Trust, when a patient is prescribed BOTH intrathecal cytotoxic chemotherapy and IV vinca alkaloid (or any other small volume IV or SC drug e.g. SC or IV bortezomib) as part of the chemotherapy protocol,* ***the Intrathecal must always be administered on different day to vinca alkaloid (or small volume IV or SC injection, small volume is classed as 10ml or less).***

- ***Prescribing Intraventricular Chemotherapy (Ommaya reservoir)***
  Please refer to current clinical trial or guideline carefully for chemotherapy doses recommended.

5.2 Dispensing, Packaging, and Storage in Pharmacy:

- The preparation of all ITC will take place in a controlled environment within the pharmacy department by staff appropriately trained, deemed competent by the Lead Trainer for pharmacy and whose names appear on the IT Register for dispensing.

- Dispensing is the activity of **preparing the dose, filling the syringe, and placing the syringe in packaging for transport. It also includes transportation to the ward if the drug is not issued directly to the collector in pharmacy**.

- All ITC doses must be dispensed using syringes and needles that cannot connect with intravenous devices. In the Trust "NRFit" syringes, needles and devices are used.

- Labels added to the finished ITC product in the pharmacy must **clearly show the patient's name and NHS hospital number, the name of the product and have the route of administration printed in the largest font size and emboldened** e.g. "For Intrathecal Use only". Negative labelling is never used.

- Pharmacy must always package and transport ITC in a separate cytotoxic transit bag that is colour coded to indicate its specific use. These bags should not be used for any other purpose and will be transported separately from treatments for administration by other routes.

- In pharmacy after dispensing but before issuing, ITC must be stored in the ITC labelled lockable storage box and kept in the pharmacy aseptic suite. This box must never be used for any other purpose.

5.3 Issuing from Pharmacy:

- ITC must only be issued by pharmacy staff whose names are on the ITC Register for issuing intrathecal chemotherapy.

- For an individual patient, intrathecal chemotherapy drugs must be issued at a different time from drugs for intravenous chemotherapy. **Intravenous drugs should be issued first**.

- Only following written confirmation in writing by the administering doctor (by full signature in the appropriate section on the original prescription sheet) that the patient is not having/ has already had intravenous cytotoxic chemotherapy administered that day, or, in the case of continuous intravenous infusion, that the infusion has already begun, may intrathecal cytotoxic chemotherapy be issued from the pharmacy.

- The authorised member of pharmacy staff may either issue directly from the pharmacy or take the ITC to the ward and must only issue **directly to the doctor who will be administering the ITC (the collector).**

- The issuer and collector must both sign the intrathecal prescription chart with full signatures, and the names of both must be clearly written on the prescription. (Refer to Appendices 1, 2, 3 for sections which must be completed on the prescription sheet)

- **STORAGE OF ITC on the ward**.

  As per the National Guidance 2008 (Para 44-45) it is not desirable to store ITC drugs outside the pharmacy between issuing and administration and emergency stocks should never be held on the ward. However, if the ITC drugs have to be issued and there will be a short delay before administration they should be stored in a dedicated container reserved for this purpose alone. **The lockable cupboard reserved for this purpose is situated in the ITC haematology treatment room on Laurel 3 and is labelled accordingly.**

  The cupboard must be lockable and the key is kept with the nurse in charge of the ward. It should be locked at all times unless an authorised member of staff is collecting drugs. Only the member of staff on the register who is designated to administer ITC should remove intrathecal chemotherapy drugs from this ITC cupboard (or pharmacy staff if retrieving the medication for destruction purposes).

5.4 Patient consent, reviews, location, checks and administration to patients:

Patient consent

- Full patient consent is required for a course of ITC rather than each individual dose within the course. However, when attending for each dose, patients should be explicitly told the nature of the procedure, the route of administration and name of the ITC drug to be administered.

Patient reviews

- On every occasion, before ITC is administered, the administering doctor must make a series of formal checks. The doctor must review the patient to ensure that the patient is fit for treatment, the correct tests have been conducted, the correct chemotherapy drug has been prescribed at the correct dose and arrangements have been clearly made for chemotherapy to be administered by the appropriate medical staff. **In addition the administering doctor must check that the nurse who will be involved in the checking task is on the ITC Register for checking.**

Location of Administration:

Intrathecal chemotherapy should be administered in an area where no other chemotherapy drugs are given or stored.

The “designated area” should be a separate room (i.e. with walls and a door)**, a curtained off area with a sign is NOT a suitable alternative.**
On rare occasions, the patient may be in an operating theatre, interventional radiology suite or on ITU, when the ITC is being administered. In these situations, extra caution will be needed to ensure that no other form of chemotherapy is in the vicinity at the time of the procedure and the correct drug is administered intrathecally (See detail in the National Guidance para 49)

Routinely the designated room for ITC administration within the Trust is Laurel 3 Haematology Treatment Room No: GM025.

The designated area should be for administration of intrathecal chemotherapy for the **entire session*** even if only one such procedure is to take place in that session.

On all occasions, **when** ITC is being administered, the designated area should not be used for any other purpose. **Under no circumstances** should any other form of chemotherapy take place in this area **during this session***. Chemotherapy drugs for intravenous use must never be stored in this area, even when the area is not in use.

(NOTE * One session is defined as a period of one hour)

Checking Process:

- When preparing to treat a patient with intrathecal chemotherapy the ITC registered administering doctor should use a formal checking procedure to ensure the correct drug and correct dose is given by the correct route to the correct patient.

- In addition the **administering doctor** has the responsibility of ensuring a trained nurse who is on the ITC Register for checking also carries out the same checks.

- Where possible the patient, and if appropriate a relative or guardian, should also be encouraged to check the details on the chart with the details on the label on the syringe. This does not remove the responsibility of clinicians for ensuring that the patient receives the required treatment, but rather adds another safety check to the process. If appropriate, as a minimum requirement, the administering doctor should confirm the following details with the patient and relative or guardian:
    1. Patient's identity, (name, date of birth and NHS number)
    2. Explain the nature of the procedure
    3. Drug Name
    4. Route of administration
    5. Expiry date and time on the injection label

  NB: It is accepted that a patient in theatre will not be able participate in the final checking, therefore the "patient's extra check" should be undertaken in theatre by another member of staff e.g. senior theatre nurse, to act on behalf of the patient/ relative.

  All checks made should be recorded on the prescription sheet with full signatures.

Administration of Intrathecal Chemotherapy:

Only methotrexate, cytosine arabinoside (cytarabine), or hydrocortisone (as sodium succinate) may be given by the intrathecal route.

- **Wherever possible ITC is administered on a different day to any intravenous chemotherapy.**

- *When a patient is prescribed BOTH intrathecal cytotoxic chemotherapy pus an intravenous vinca alkaloid (or other small volume IV or SC injection), they **must always** be administered **on different days.***

- Administration of ITC should only be undertaken by staff appropriately trained and deemed competent by the Lead Trainer for medical staff and whose name is on the ITC Register.

- At Worcestershire Acute Hospitals NHS Trust, for safety reasons it is **not permitted** for junior grades of doctors to administer ITC (this includes FT1, FT2, ST1 and ST2 grades).
  (NB Please refer to The National Guidance for details of "waivers" for ST1 and ST2 grades)

- **ST3 grade and Specialty Doctors,** if after suitable training, being deemed competent by the Lead Trainer for medical staff and having their name placed on the ITC Register for administration, are permitted to administer ITC. A waiver is not needed for ST3 grade and Specialty Doctors.

  On occasions it may be necessary to enlist the help of an anaesthetist or radiologist to position the needle for a technically difficult lumbar puncture. The anaesthetist/ radiologist should play no further part in the procedure once the needle has been correctly positioned and should never administer the intrathecal chemotherapy unless they have been appropriately trained, been deemed competent by the Lead Trainer for medical staff, and their name is on the ITC Register for administration of intrathecal chemotherapy.

Administration Procedure:

1. Before the procedure takes place, the administering doctor must perform a series of checks (see above).

2. Place the NRFit syringe containing the cytotoxic intrathecal injection and any other equipment required on a clean trolley protected by a sterile dressing towel.

3. Position patient in preparation for the procedure.

4. Put on plastic apron, wash hands, and put on sterile disposable gloves.

5. Perform lumbar puncture using 18 to 22G NRFit lumbar puncture needle.

6. Drain a volume of CSF equal to the volume to be injected (2 – 5 ml).

7. Send CSF for all relevant diagnostic investigations on the first occasion and to haematology laboratory for cytospin if relevant on subsequent occasions.

8. Attach NRFit syringe containing cytotoxic intrathecal injection to NRFit lumbar puncture needle. Do not draw back on the syringe before injecting. Inject the drug slowly. Discontinue if there is any resistance to flow or if the patient complains of pain.

9. Remove the needle complete with attached syringe once the injection has been completed.

10. Dispose of syringe and needles directly into the cytotoxic sharps bin.

11. Double bag dressing towels, protective clothing with yellow plastic clinical waste bags.

12. Wash and dry hands.

13. Record details of administration on prescription chart and in patient's medical records.

5.5 Timing of Administration and Out of Hours:

- **Routinely, ITC should only be administered during normal working hours when a full range of specialist expertise, knowledge and support is readily accessible. This would normally be 08:30 – 17:00 Monday to Friday, and the labelling of the product from pharmacy will reflect this information.**

  Out of hours, any decisions must be made at the highest possible level, the decision to treat out of hours would have to be agreed by the on call haematologist plus a second haematology consultant or the ITC Lead.

  Only in exceptional circumstances, (such as CNS relapse of leukaemia or lymphoma requiring emergency treatment) should administration occur "out of hours".

  In these circumstances, there should be clear medical need for the procedure to be undertaken without delaying until the next working day.

  If such a medical case can be made, ***only an ITC registered doctor for prescribing and administration can undertake the prescribing, and administration*** *in accordance with the relevant sections of this protocol.*

  Although ***not part of the pharmacy on call service****, in the first instance the on call pharmacist would need to be contacted, and the case discussed with a senior pharmacist. If appropriate to do so, the senior pharmacist would attempt to arrange for ITC registered members of pharmacy staff to dispense the prescription. (NB in the absence of ITC registered trained pharmacy staff able to dispense or issue or ITC registered trained nurses being available to check, refer to section "sickness or absence of staff" in this protocol).*

- The ITC Lead for the Trust would need to be notified that such a procedure had had to take place out of hours and there would need to be clear documentation about why this situation had arisen, actions taken and outcome.

- The ITC Lead must keep a record of the number of times this procedure has taken place outside of normal working hours.

- A record of out of hours decisions must be written in full in the patient's medical notes on every occasion.

Sickness or Absence of Staff:

In the event of none of the trained staff on the ITC Register being able to carry out any of the designated tasks (prescribing, dispensing, issuing, checking or administering), then medication MUST be delayed until an appropriately trained person is available.

5.6 Disposal of unused <u>issued</u> cytotoxic chemotherapy:

- In the event of the issued ITC not being administered to the patient, the administering doctor must cross through the prescription and endorse "not given, returned to pharmacy / disposed of on ward" and sign and date the endorsement.

- The administering doctor must then either immediately return the ITC injection to pharmacy for disposal or personally dispose of the injection in a sharps bin on the ward.

5.7 NHS organisations that do not provide an intrathecal chemotherapy service:

An emergency requiring intrathecal chemotherapy to be carried out in a "non-intrathecal chemotherapy hospital" should be a very rare occurrence.
Should this situation arise, the procedure should only take place following discussions escalated to the highest level within the Trust (including the Chief Pharmacist, Medical Director and the Chief Executive, plus the Medical Director and Chief Executive of the host NHS Trust).
To comply with the current Trust Incident Reporting Policy, the 'serious managed incident' must also be formally escalated to the CCG.
Additionally, there must be clear documentation in the patient's medical records recording why the situation had arisen, all actions taken and outcome.
(Refer to the National Guidance for more detail).

The procedure would be supervised by staff from the ITC Register of authorised personnel from WRH.

5.8 Management and reporting of Incidents and Near Misses

- *Unless discussed and documented beforehand*, any ITC event that does not fully comply with the Trust Policy will be classed as a "Near Miss" or "Clinical Incident".

- On every occasion the detail of an ITC near miss or incident MUST be brought to the IMMEDIATE ATTENTION of the ITC Lead or the on call consultant haematologist at the time.

- Any event or near miss must be documented in the patient's medical notes and reported using the Trust Clinical Incident Reporting Procedure.

- A register held by the ITC Lead must be maintained of all near misses, clinical incidents or events which did not fully comply with the Trust Policy for ITC.

5.9 Minibags and dilutions of Intravenous Vinca Alkaloids:

A Rapid Response Report on the dilution and method of administration of vinca alkaloids has been issued by NPSA. It is essential that this report NPSA/2008/RRR004 is read in conjunction with this guidance. It can be found at
http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/rapidrr

6. Implementation of key document

6.1 Implementation of the Policy and Procedures for adult intrathecal cytotoxic chemotherapy is led by the Lead ITC and Lead Trainers (see section 4 of this Policy)

6.2 Dissemination - An electronic version of the current Local ITC Policy WAHT-HAE-004 is available on the Trust Intranet. This includes a link to the current National Guidance. Lead Pharmacist or the Lead Nurse will liaise with the Clinical Governance Team regarding the Local ITC Policy on the Trust Intranet.

Please note that HSC 2008 / 001 'Updated National guidance on the safe administration of Intrathecal chemotherapy' states that:

> "up to date **hard copies** of the N**ational Guidance** and **associated local protocols** should be lodged, as a minimum, in each location in a Trust **where intrathecal chemotherapy is dispensed, issued and administered**. This should include the oncology in-patient area, **even if intrathecal chemotherapy is never administered in that location**".

In order to comply with this detail, folders containing a hard copy of the current National Guidance and current Local Trust ITC Policy are located in the following areas:

1. Laurel 3 WRH - inpatient haematology ward
2. Laurel 2 WRH - inpatient oncology ward
3. Pharmacy Aseptic Suite Worcestershire Royal Hospital
4. Pharmacy Aseptic Suite Alexandra Hospital

An **annual review** of the ITC folders will be co-ordinated by the Lead ITC Pharmacist with Lead ITC Haematology Nurse to ensure only the most up to date versions of the Local Policy and National Guidance are available to staff.

6.3 Training and awareness

Induction, Training, Re-Training and Assessment

The ITC Lead has overall responsibility for induction, training, and continuing professional development related to ITC

The ITC Lead has formally delegated responsibility of "Lead Trainer" for training, assessing and re-assessing to named medical, nursing and pharmacy staff. The detail of the named staff is held within the Lead ITC Folder in pharmacy WRH.

In the event of prolonged staff absence of the above lead roles, an appropriate deputy must be nominated which must be approved by the Trust ITC Lead.

The "Lead trainers" are accountable for ensuring the roles and tasks below take place:

- A **formal induction course** appropriate to their role in ITC provision must be available and attended by all staff (nursing, pharmacy and medical new to the hospital) i.e. prescribing, dispensing, issuing, checking and administration.
- The induction will include the following:

1. All clinical hazards associated with ITC including the danger posed to patients of mal-administration of vinca alkaloids; and new safer practice recommendations from the NPSA[5] on the presentation of vinca alkaloids for adults.
2. Explanation to all staff involved with the care and treatment of patients receiving chemotherapy that they should challenge their 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 a colleague should not be seen as adversarial, but as an additional check to improve patient safety and reduce risk.
3. All staff involved in the ITC process must read **both** the current National Guidance on the Safe Administration of Intrathecal Chemotherapy **and** the Local Trust Policy as part of the induction training and they must sign to confirm the documents have been read and they have understood the documents before being able to practise their respective roles. This signed confirmation should be updated annually.
4. All staff on the ITC Register must demonstrate that they are competent for the roles they are expected to undertake in the ITC process. This competence is reviewed annually by the Lead Trainers alongside how often staff carry out this procedure.
5. The Lead Trainer for the speciality will issue staff with a certificate to confirm that they have completed induction training or annual refresher training and are competent/ remain competent to be included on the register for the designated task.
6. Only staff on the ITC Register must be involved in the ITC service, **it is the responsibility of staff on the ITC Register to ensure that any colleagues they involve in the process are on the ITC Register for the task in question.**
7. To support the induction and training programme in the safe administration of ITC which all staff should be encouraged to view the support training film which demonstrates the general messages of the guidance.
8. **Staff in training**, **having refresher training, or having a competency review, of any task for which they require registration** must perform the task **only** if under the direct and constant supervision of a member of staff on the ITC Register for that task.

6.4 Registers of Designated Personnel

- The Trust Intrathecal Register (ITC Register) is a list of designated staff working in the Trust who have been trained and are certified competent in one or more of the following ITC tasks: prescribing chemotherapy, dispensing, issuing from the pharmacy, checking prior to administration and administering.

- Only personnel on the ITC Register can be involved with ITC within the Trust

- The ITC Lead for the Trust has overall responsibility for the ITC Register and ensuring it is maintained and kept up to date.

- There is **one single ITC Register** for the Trust, the location of the ITC Register is in the Aseptic Suite, in pharmacy WRH. Only copies of the latest edition of the ITC Register are available to staff at all times.

- **Copies of the ITC Register** are located in the following places:
  Trust Lead's office, (policies folder) at WRH
  Pharmacy WRH Aseptic Suite notice board
  Pharmacy Alexandra Aseptic suite support room
  Haematology Ward Laurel 3 (WRH) on the ITC treatment room notice board
  Haematology Ward Laurel 3 (WRH) in the policies folder

- The ITC Register is made up of 3 main sections, the ITC Lead has delegated the responsibility of the maintenance of the separate sections to the "Lead Trainers" as detailed section 6.3

- Only the ITC Lead or these delegated Trainers are authorised to add or remove personnel from the section of the ITC Register of which they are responsible.

- For entry onto a section of the ITC Register, individuals will have to demonstrate to the relevant Lead Trainer that they are competent to fulfil their designated roles. Once an individual has been issued with a certificate of competence, the Lead Trainer can add the individual to the relevant section of the ITC Register.

- On at least an **annual basis,** in order to remain on the ITC Register, every individual named on the ITC Register will have to re-demonstrate to the relevant Lead Trainer that they remain competent. Once competence has been confirmed the Lead Trainer will re-certificate, which will confirm the individual may remain on the ITC Register for one more year.

- Lead Trainers will monitor how often staff on their relevant section of the ITC Register carry out procedures related to intrathecal chemotherapy. The Lead Trainers have the responsibility to assess if an individual does not perform the registered task sufficiently often to maintain competence. Mandatory further competency assessments may need to be undertaken before a person can remain on the register. The **ITC Lead** also has the authority to remove individuals from the ITC Register if he believes an individual is not performing the task often enough to maintain competence.

- The ITC Register will be reviewed and updated on at least an annual basis by the Lead Trainers, even if all the individuals remain the same.

- To ensure only the latest edition of the ITC Register is available to staff, the Lead Haematology Nurse and / or the Lead Pharmacist, on issue of a new ITC Register will be responsible for removal of the superseded version and replacement with the new version in the relevant folders and locations.

7. Monitoring and compliance

STANDARDS	%	Clinical Exceptions
All IT chemotherapy is prepared in designated area	100%	None
All IT chemotherapy is stored in designated area	100%	None
All IT chemotherapy is administered in designated area	100%	None
All staff will have relevant training	100%	None
All staff will have annual validation of training	100%	None

Lead Trainers will monitor how often staff on their relevant section of the ITC Register carry out procedures related to intrathecal chemotherapy. The Lead Trainers have the responsibility to assess if an individual does not perform the registered task sufficiently often to maintain competence. Mandatory further competency assessments may need to be undertaken before a person can remain on the register. The **ITC Lead** also has the authority to remove individuals from the ITC Register if he believes an individual is not performing the task often enough to maintain competence.

8. Policy review

This Policy and Procedures will be reviewed every 3 years. An interim review will automatically be triggered by an Clinical Incident or the publication of any new National Guidance and/ or national alerts requiring action.

9. References

1. Department of Health (2000) “An Organisation with a Memory”.

2. “Building a Safer NHS for Patients” April 2001

3. “Safety First: A Report for patients, clinicians and healthcare managers” December 2006

4. Department Of Health HSC2003/010, Updated National Guidance On The Safe Administration Of Intrathecal Chemotherapy.

5. THE NATIONAL PATIENT SAFETY AGENCY (NPSA) RAPID RESPONSE REPORT NPSA/2008/RRR004

6. Website for the current Updated National Guidance on the Safe Administration of Intrathecal chemotherapy issued 7th January 2008 is: http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_086870

7. THE NATIONAL PATIENT SAFETY AGENCY (NPSA) RAPID RESPONSE REPORT NPSA/2007/ RRR001 (LIPOSOMAL CYTARABINE)

8. European Medicines Agency, Recommendations to prevent administration errors with Velcade (bortezomib) 19 January 2012, EMA/34910/2012, EMEA/H/C/000539

9. Patient Safety Alert “Non-Luer Spinal (Intrathecal) devices for Chemotherapy and Lumbar puncture” November 2013

10. Patient Safety Alert: Stage three Directive “Non-Luer Spinal (Intrathecal) devices for Chemotherapy and puncture” February 2014 NHS/PSA/D/2014/002 https://www.england.nhs.uk/wp-content/uploads/2014/02/non-Luer-spinal-alert.pdf

11. Patient Safety Alert: Resources to support safe transition from Luer connector to NRFit ™ for intrathecal and epidural procedures, and delivery of regional blocks. NHS/PSA/RE/2017/004

10. Background

10.1 Equality Impact Assessment

The Policy and Procedures for adult intrathecal cytotoxic chemotherapy have been assessed by the Medicines Safety Committee as having NO IMPACT on equality and diversity on the grounds of race, religion/belief, or disability and NO IMPACT on Race Relations.

10.2 Financial Risk Assessment

The Policy and Procedures for adult intrathecal cytotoxic chemotherapy have been assessed by the Clinical Director of Pharmacy and the Medicines Safety Committee as requiring no financial support that is additional to that already in place.

10.3 Consultation Process

Reviewed Document (March 2021) has been circulated to the following for approval

Name	Designation

10.4 Approval process

The Policy and Procedures for adult intrathecal cytotoxic chemotherapy are formally approved by the Medicines Safety Committee.

Appendix 1

Worcestershire Royal Hospital

Worcestershire NHS Acute Hospitals NHS Trust

INTRATHECAL METHOTREXATE CHEMOTHERAPY

Patient name……
Address……
……
Hosp Number……
Date of Birth……

Consultant Name…… .

Course no:……

Ward for administration……

Day No:	Date	Time Due	Drug	Dose	Total Vol	Prescribed by (signature in full)	Prescriber's printed name	Dispensed by (signature in full)
			INTRATHECAL Methotrexate					

Checklist for administration	Check (Tick)	Checked and Administered by: (Authorised Dr)	Check (Tick)	Checked by: (Authorised Staff Nurse only)	Check (Tick)	Checked by Patient:
Patient Fit for treatment & Consent obtained		Print name……		Print name……		Signature……
Platelet count and clotting screen had been checked if appropriate						
Patient name		Signature (in full) ……		Signature (in full) ……		
Date of birth						
Hosp Number						
Drug name		Time given……				
Drug dose						
Route of administration						
Expiry date & time						
Area IV- free						

Checklist for Issuing	Authorised staff names and signatures
I confirm that this Patient: 1) Is not having any other IV chemotherapy today 2) Has had all IV chemotherapy today 3) Is having continuous IV chemotherapy today and is already connected to the infusion	Dr Name…… Signature (in full) ……
Issuing from pharmacy Syringe issued to Dr……(print name)	Pharmacy staff name…… Signature (in full) ……
Syringe received by authorised administering doctor	Dr Name…… Signature (in full) ……

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Appendix 2

Worcestershire Royal Hospital

Worcestershire NHS Acute Hospitals NHS Trust

INTRATHECAL CYTARABINE (CYTOSINE) CHEMOTHERAPY

Patient name……
Address……
……
Hosp Number……
Date of Birth……

Consultant Name……
Course no: ……
Ward for administration……

Day No:	Date	Time Due	Drug	Dose	Total Volume	Prescribed by (signature in full)	Prescriber's printed name	Dispensed by (signature in full)
			INTRATHECAL Cytarabine					

Checklist for administration	Check (Tick)	Checked and Administered by: (Authorised Dr)	Check (Tick)	Checked by: (Authorised Staff Nurse only)	Check (Tick)	Checked by Patient:
Patient Fit for treatment & Consent obtained		Print name……		Print name……		Signature……
Platelet count and clotting screen had been checked if appropriate						
Patient name		Signature (in full) ……		Signature (in full) ……		
Date of birth						
Hosp Number						
Drug name		Time given……				
Drug dose						
Route of administration						
Expiry date & time						
Area IV- free						

Checklist for Issuing	Authorised staff names and signatures
I confirm that this Patient: 1) Is not having any other IV chemotherapy today 2) Has had all IV chemotherapy today 3) Is having continuous IV chemotherapy today and is already connected to the infusion	Dr Name…… Signature (in full) ……
Issuing from pharmacy Syringe issued to Dr……(print name)	Pharmacy staff name…… Signature (in full) ……
Syringe received by authorised administering doctor	Dr Name…… Signature (in full) ……

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Appendix 3

Worcestershire Royal Hospital

Worcestershire NHS Acute Hospitals NHS Trust

INTRATHECAL HYDROCORTISONE CHEMOTHERAPY

Patient name……
Address……
……
Consultant Name……
Hosp Number……DOB……
Course no:……
Ward for administration……

Day No:	Date	Time Due	Drug	Dose	Total Vol	Prescribed by (signature in full)	Prescriber's printed name	Dispensed by (signature in full)
			INTRATHECAL Hydrocortisone (as Sodium Succinate)					

Checklist for administration	Check (Tick)	Checked and Administered by: (Authorised Dr)	Check (Tick)	Checked by: (Authorised Staff Nurse only)	Check (Tick)	Checked by Patient:
Patient Fit for treatment & Consent obtained						
Platelet count and clotting screen had been checked if appropriate		Print name……		Print name……		Signature……
Patient name		Signature (in full) ……		Signature (in full) ……		
Date of birth						
Hosp Number						
Drug name		Time given……				
Drug dose						
Route of administration						
Expiry date & time						
Area IV- free						

Checklist for Issuing	Authorised staff names and signatures
I confirm that this Patient: 1) Is not having any other IV chemotherapy today 2) Has had all IV chemotherapy today 3) Is having continuous IV chemotherapy today and is already connected to the infusion	Dr Name…… Signature (in full) ……
Issuing from pharmacy Syringe issued to Dr……(print name)	Pharmacy staff name…… Signature (in full) ……
Syringe received by authorised administering doctor	Dr Name…… Signature (in full) ……

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