

Intrathecal Chemotherapy Procedure

Key Points

- The only medications that should EVER be given intrathecally are cytarabine (including liposomal form), methotrexate or hydrocortisone.
- Intrathecal chemotherapy can only be prescribed by a named consultant on the intrathecal chemotherapy register
- Intrathecal chemotherapy can only be prepared, checked and issued by a named pharmacist on the intrathecal chemotherapy register
- Intrathecal chemotherapy can only be administered by a named doctor on the intrathecal chemotherapy register in the presence of a nurse on the same register.
- Intrathecal chemotherapy must be given at designated sites, and during working hours

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Abbreviations

IT	Intrathecal
ITC	Intrathecal chemotherapy
ITU	Intensive Therapy Unit

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1. Purpose of the Procedure

- 1.1 The purpose of this procedure is to ensure patient safety and prevent inadvertent intrathecal administration of vinca alkaloid drugs and other agents which cannot be given by the intrathecal route, e.g., bortezomib. Vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine), which are intended for intravenous use only. If injected intrathecally these drugs cause paralysis almost always followed by death.
- 1.2 If the number of administrations of intrathecal (IT) chemotherapy at either site falls below 10 per year (averaged over 2 years) or exceeds 500 per year, a risk assessment of the service will be carried out and agreed with the Chief Executive.
- 1.3 This procedure must be read in conjunction with the policy section of Cytotoxic Chemotherapy Guideline for Frimley Health.

The Procedure

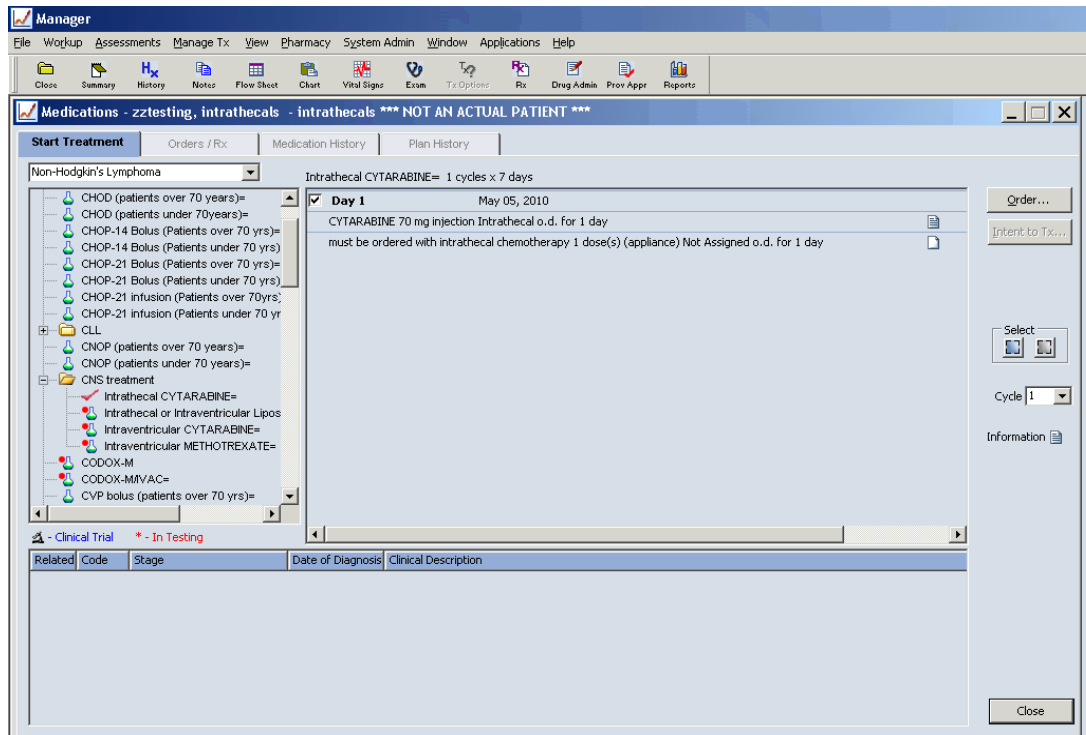
2. Designated Areas

- 2.1 Intrathecal chemotherapy may only be administered in the following designated areas:
 - Intrathecal chemotherapy room, Eden Unit, Wexham Park
 - Treatment room, G1 day unit, Frimley Park
 - Exceptionally in the radiology departments at Wexham Park or Frimley Park if technical difficulties in performing the lumbar puncture require this procedure to be carried out with imaging guidance.
 - Exceptionally in the Intensive Care Unit at Wexham Park Hospital or Frimley Park.
 - Exceptionally (e.g., during pandemic) in any room so designated by ITC Lead or Chemotherapy Lead on any site.
- 2.2 The regulations for checking and administration of intrathecal chemotherapy apply equally to these designated areas.
- 2.3 If IT chemotherapy is given in exceptional areas as above (radiology, ITU), an Exceptional Circumstances – Area of Administration form must be completed forthwith and forwarded to the ITC Clinical Lead (see Appendix F)

3. Prescribing Intrathecal Chemotherapy

- 3.1 To prescribe intrathecal chemotherapy electronically on Aria, you must be on the intrathecal register for your Trust as an authorised prescriber. If the patient is on no other chemotherapy regimen, prescribe intrathecal chemotherapy as usual under the treatment tab (Figure 1). You will find intrathecal chemotherapy under leukaemia and then the sub folder of CNS treatment.

Figure 1



- 3.2 If the patient requires intravenous chemotherapy plus intrathecal chemotherapy, e.g., R-CHOP + intrathecal methotrexate, prescribe the iv chemo and then add in the appropriate support regimen of intrathecal chemotherapy, which can be found in the intrathecal folder in the support regimens (Figure 2).

Figure 2

- 3.3 The agent 'must be ordered with intrathecal chemotherapy' must be prescribed to allow the pharmacist to "pharmacy approve" the intrathecal prescription – please do not remove this line from the prescription (Figure 3).

Figure 3

- 3.4 Once the prescription has been prescribed and approved by the prescriber the pharmacist can approve the prescription as per normal procedure.

- 3.5 Once reviewed and approved the pharmacist must print off the intrathecal prescription in the following way (Figure 4).

Figure 4

Manager

File Workup Assessments Manage Tx View Pharmacy System Admin Window Applications Help

Close Summary History Notes Flow Sheet Chart Vital Signs Exam Tx Options Rx Drug Admin Prov Appr Reports

Review Prescription Details - zztesting, intrathecal - intrathecal * NOT AN ACTUAL PATIENT *****

Order / Rx Medications Cum. Dose Alerts Allergies/Adverse Reactions ☐ R-CHOP bolus (Patients under 70yrs)=

Ordered by VMS, MD on May 05, 2010 at 10:02 ☒ Completed

Order ID 105200001 Start on 05/MAY/2010 APPROVED on May 05, 2010 at 10:11

Internal

Administration Start Date May 05, 2010 R-CHOP bolus (Patients under 70yrs)= - Cycle 1 Day 1

1 SODIUM CHLORIDE 500 ml (of 0.9 %) infusion Intravenous once	Plan - Opt 100 % Admin Instructions	☐ Dose Mod. Reason
2 PREDNISOLONE 70 mg (at 40 mg/m2) (of 5 mg) tablet Oral once	Plan - Opt 100 % Admin Instructions	☐ Dose Mod. Reason
3 PARACETAMOL 1,000 mg (of 500 mg) tablet Oral once	Plan - Opt 100 % Admin Instructions	☐ Dose Mod. Reason
4 CHLORPHENAMINE 10 mg injection Intravenous once bolus	Plan - Opt 100 % Admin Instructions	☐ Dose Mod. Reason
5 RITUXIMAB 600 mg (at 375 mg/m2) preservative free infusion Intravenous once in sodium chloride 0.9% w/v 500 ml (1)	Plan - Opt 100 % Admin Instructions	☐ Dose Mod. Reason
6 DOXORUBICIN 85 mg (at 50 mg/m2) injection Intravenous once bolus	Plan - Opt 100 % Admin Instructions	☐ Dose Mod. Reason

* Additional administration instructions have been entered

Print... OK Cancel

- 3.6 From this page (figure 4) press print on the bottom left of the screen, you will then get the pop up shown in Figure 5 (overleaf).

Figure 5

Manager

File Workup Assessments Manage Tx View Pharmacy System Admin Window Applications Help

Close Summary History Notes Flow Sheet Chart Vital Signs Exam Tx Options Rx Drug Admin Prov Appr Reports

Review Prescription Details - zztesting, intrathecal

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* Additional administration instructions have been entered

Print... OK Cancel

Rx Choices

Prescription Types # Prints

☐ Internal

☒ Pickup - External

☐ Pickup - Internal

☐ Print Selected Drugs Only

☐ Print UPIN and DEA Numbers

☐ Print UPIN Number

☒ Print DEA Number

☐ N/A

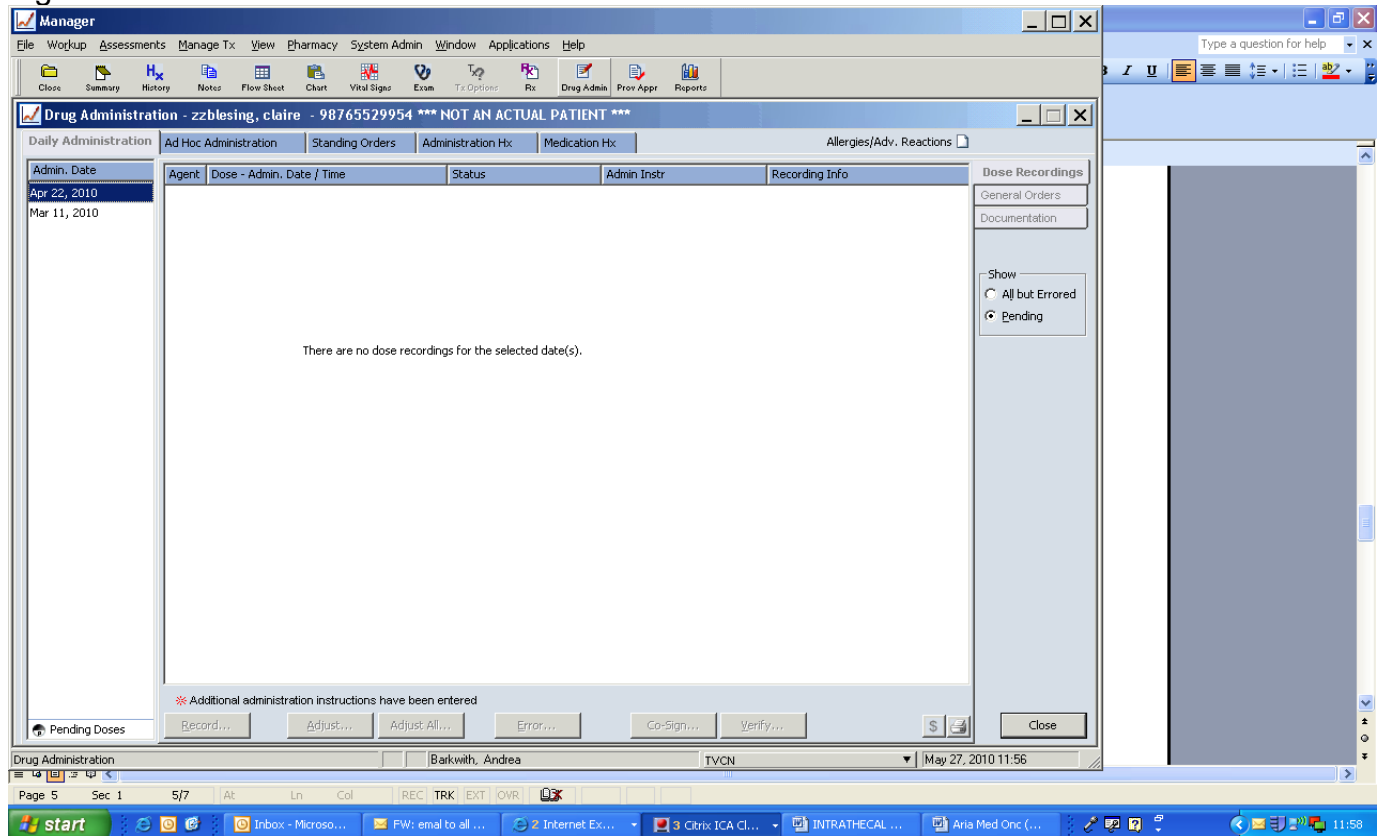
☒ Print Administration Instructions

☐ Print One Drug Per Page

OK Cancel

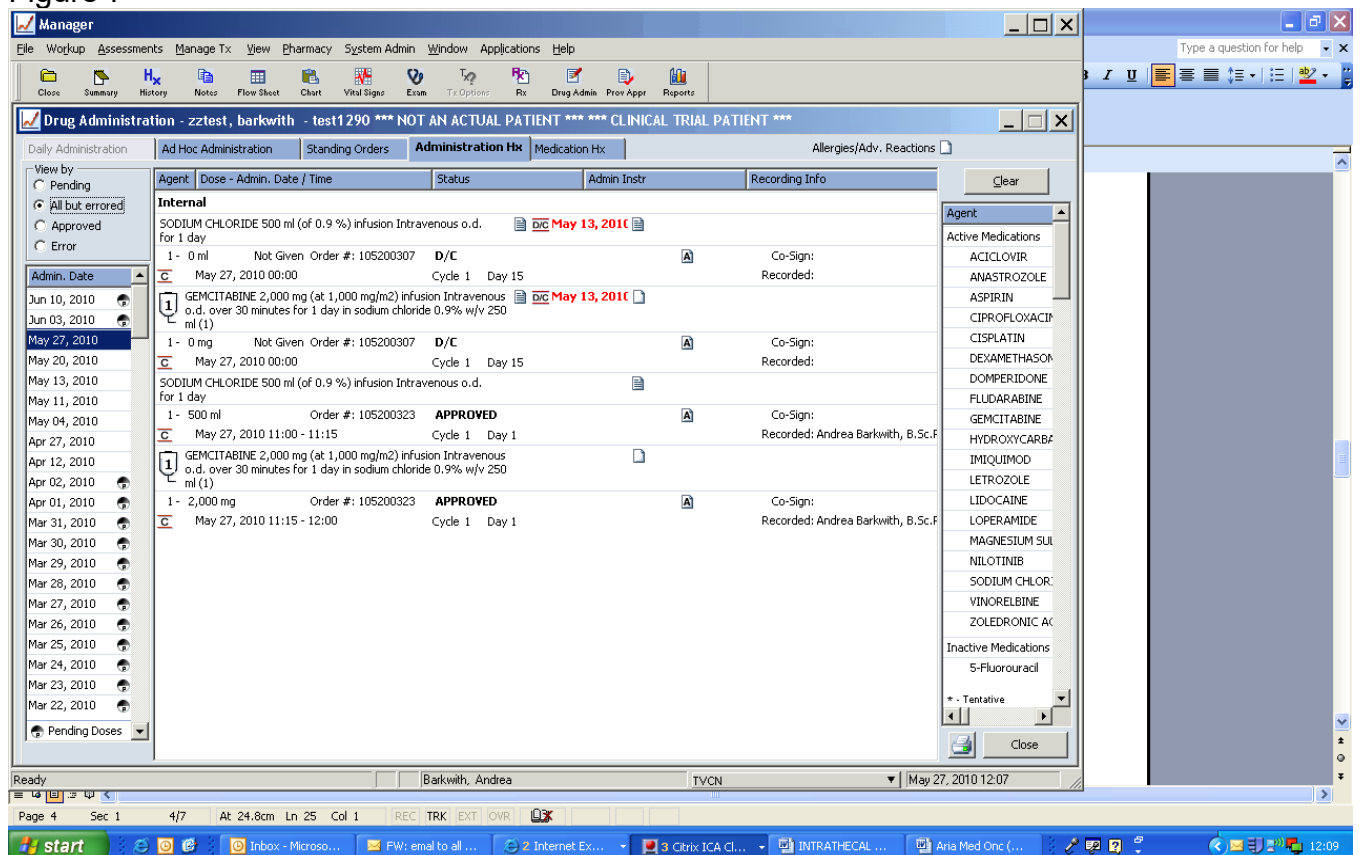
- 3.7 Tick the 'Pick up – External' option only and then click OK.
- 3.8 The prescription along with the intrathecal sign off sheet must then print to the default printer in Wexham Park aseptic unit.
- 3.9 The printed prescription must be stored in the pharmacy ready for collection with the injection for doses to be administered at Wexham Park Hospital; and transported with the intrathecal chemotherapy, for doses to be administered at Frimley Park Hospital.
- 3.10 The doctor who is going to administer the intrathecal injection will collect the injection (prepared in a non-Luer lock NRFit™ISO 80369-6) syringe), non-Luer lock (NRFit™ISO 80369-6) needle and the printed prescription (which also contains the sign off sheet). The doctor must be on the register of authorised people for administration of intrathecal chemotherapy.
- 3.11 Before issuing the prescription the pharmacist must see proof that any Intravenous chemotherapy the patient is due has been administered. This will be either by looking on the Aria system and seeing that the administration has been recorded electronically or by the doctor bringing the paper prescription that has the nurses' record of administration signed.
- 3.12 At Wexham Park Hospital (WPH), send the prescription and intrathecal sign off sheet to the default printer in the aseptic unit. The printed prescription must be stored in the pharmacy ready for collection with the injection.
- 3.13 At Frimley Park Hospital, the printed prescription must be transported with the intrathecal chemotherapy.
- 3.14 If there is no Intravenous chemotherapy due this can be seen on Aria also by the registered issuer. The administration can be checked on Aria by clicking the drug admin tab (Figure 6).

Figure 6



3.15 Then select the admin history tab (Figure 7)

Figure 7



- 3.16 You will then see what has been administered or waiting to be administered for the day selected on the right hand side
- 3.17 The sign off sheet must be completed and filed in the patient's notes, and the administration of the intrathecal chemotherapy recorded electronically on Aria (**Appendix B**).

4. Preparation & Dispensing of Intrathecal Chemotherapy Doses

- 4.1 The intrathecal chemotherapy prescription is received in the pharmacy chemotherapy aseptic unit. The prescription is validated by an authorised pharmacist. The dose is prepared as per pharmacy aseptic procedures in a non-Luer lock (NRFit™ ISO 80369-6) syringe, ensuring that the dose will be in date at the time of administration.
- 4.2 The checking pharmacist in the pharmacy chemotherapy unit must (in addition to the usual checking procedures) ensure that the intrathecal drug label contains the words "INTRATHECAL" and "FOR INTRATHECAL USE ONLY" and is packed separately from all other drugs. The label must clearly show the patient's name and name of product. Negative labelling must never be used.
- 4.3 The checking pharmacist in the pharmacy chemotherapy unit must follow the process above.
- 4.4 The intrathecal chemotherapy for patients in Frimley Park Hospital must be transported in a chemotherapy cool box with no other chemotherapy doses in the box via the regular hospital transport.
- 4.5 Upon receipt at Frimley Park Hospital (FPH) the pharmacist will check the intrathecal chemotherapy against the prescription attached. This should then be stored in the red intrathecal chemotherapy box and locked with an envopak seal until the administering doctor arrives for collection.
- 4.6 The member of pharmacy staff, before issuing any intrathecal doses, must confirm with the administering doctor that any intravenous drugs the patient is due to receive that day have already been given.
- 4.7 Intrathecal chemotherapy doses must be administered between 0900 and 1700 hours on weekdays only; otherwise, the intrathecal chemotherapy administration must be delayed until the next day, and pharmacy informed of the delay.
- 4.7.1 Out of Hours administration – special authorisation procedure
- 4.7.1.1 The decision to administer Intrathecal chemotherapy out of hours in an emergency situation can only be made by the on-call consultant haematologist for clinical emergencies. It can only take place if all members of the ITC team are available i.e. prescribing doctor, pharmacist to validate and release, pharmacy technician to prepare, administering doctor and checking nurse who are all named on the ITC register and it takes place at a location stated in the policy. If a complete team is not available, then the patient must either be transferred to another unit or their treatment deferred until the next working day depending upon clinical need.

4.7.1.2 The Consultant wishing to carry out the procedure is responsible for:

- ensuring that the ITC team is available
- emailing the Lead Clinician for Chemotherapy and the Lead Clinician for Intrathecal Chemotherapy to inform them that this event has taken place out-of-hours, at the time of the event
- prescribing the dose using ARIA (or dedicated ITC chart if Aria not available)

4.7.1.3 The on-call pharmacist should be contacted. He or she will try to arrange for a pharmacy technician and pharmacist who are named on ITC register to come in within 24 hours, to prepare and check the dose. The on-call pharmacist should try to contact the Chief Pharmacist (or Deputy if unavailable) to inform them of the event.

4.7.1.4 The nurse in charge of the in-patient ward should be contacted to try to identify a nurse on the ITC register who is available to check the ITC dose prior to its administration.

4.7.1.5 The procedure must be carried out with strict adherence to the Trust's intrathecal procedure. The administering doctor should document clearly in the patient's notes why the situation had arisen, actions taken and the outcome. The Consultant must complete an Exceptional Circumstances – Out of Hours ITC Administration form (see Appendix F) and email this forthwith to the ITC Lead Clinician.

4.7.1.6 The ITC lead on the next working day should inform the Trust Senior Management of the exceptional event and it should be minuted at the next DTC and CCSG meeting. The ITC lead should keep a record of how many times this procedure has taken place out of hours per year for review at Annual Steering Group meeting.

4.8 If intrathecal drugs are issued but not given, they must be returned to pharmacy immediately for destruction. Intrathecal chemotherapy has a maximum assigned stability of 24 hours.

4.9 For any patient receiving an intravenous vinca alkaloid, the checking pharmacist must ensure that:

- The label must state "INTRAVENOUS" and "FOR INTRAVENOUS USE ONLY. FATAL IF ADMINISTERED BY OTHER ROUTES". Any labels where this is not clear and ambiguous must be returned for re-labelling. The label must clearly show the patient's name and the name of the product. Negative labelling must never be used.
- For adults, all vinca alkaloids should be prepared in a 50mL bag of sodium chloride 0.9% to be administered as an intravenous infusion.

4.10 Neither WPH nor FPH is designated to administer intrathecal chemotherapy to children.

5. Distribution & Storage of Prepared Intrathecal Doses

- 5.1 Pharmacy staff listed on the “Register of Authorised Staff” who are to issue intrathecal chemotherapy doses from the Pharmacy Department must have undergone training and be deemed competent to fulfil this role. Pharmacy intrathecal training takes place annually in April and is valid for 12 months. Any new staff will receive training within the first few weeks of their role. In some cases, a staff member may be validated twice in the same 12 month period, so that all annual training can be aligned.'
- 5.2 At the beginning of the day, the pharmacist in the pharmacy chemotherapy unit must check if any patients are to receive intravenous chemotherapy and intrathecal chemotherapy.
- 5.3 When the intrathecal chemotherapy dose(s) has been final checked by a pharmacist, a member of staff must contact the administering doctor stating that the dose is ready for collection. Intrathecal chemotherapy doses for FPH patients will be transported via the hospital chemotherapy transport driver.
- 5.4 If there is a delay between the dose being ready for release from pharmacy and when it will be required by the doctor, the dose must be placed in a separate area of the pharmacy chemotherapy fridge in its red outer packaging.
- 5.5 The administering doctor will come to pharmacy to collect the intrathecal dose, non-Luer lock (NRFit™ ISO 80369-6) needle and the prescription. These will be issued by a member of pharmacy staff on the intrathecal register.
- 5.6 Intrathecal chemotherapy doses being collected by the administering doctor must be packed and transported separately from any other drug. The administering doctor must sign the prescription to confirm that any intravenous doses of chemotherapy have already been administered or commenced and that there is no further intravenous chemotherapy prescribed for the patient for that day. The pharmacy staff member will sign the prescription as issued and the administering doctor will sign the prescription to confirm that the dose has been transferred to his or her care.

6. Administration of Intrathecal Chemotherapy

- 6.1 Medical staff must have received training on the administration of intrathecal chemotherapy.
- 6.2 A register of staff authorised to administer intrathecal chemotherapy will be kept. This will be the responsibility of the consultant lead for intrathecal chemotherapy and the register and guideline will be kept in all relevant clinical areas where intrathecal chemotherapy is administered and in the pharmacy.
- 6.3 Intrathecal chemotherapy must be administered to patients in the designated ITC Room on Eden Unit, WPH or the G1 day unit treatment room, FPH where no other cytotoxic drugs are being given or stored, and no other clinical procedures are to be carried out during the same session. No Luer lock spinal needles are to be stored in this area.

- 6.4 The following steps for intrathecal chemotherapy must be followed by all staff involved in the administration process:
- The doctor must inform nursing staff of the intention to administer intrathecal chemotherapy and request assistance from a member of the nursing staff (who must be chemotherapy trained and must be named on the intrathecal chemotherapy register as a designated nurse checker) at a mutually convenient time.
 - The doctor must be familiar with the Trust's guidelines on the safe handling of cytotoxic drugs.
 - The doctor must prescribe the intrathecal dose.
 - The administering doctor (who must be on the Register for Administration but is not necessarily the doctor who has prescribed the ITC) must ensure that:
 - The patient's written consent for cytotoxic administration has been obtained.
 - The patient has no known allergy to either the cytotoxic drug or any anaesthetic or sedative drug to be given.
 - The patient's platelet count is $>50 \times 10^9/L$ and clotting is within normal limits (if not, these parameters must be corrected before the lumbar puncture is performed), or these results are within the chosen Chemotherapy protocol parameters.
 - The chemotherapy pharmacist must then be contacted and asked if the intrathecal dose is ready for collection by the administering doctor. At this time, the ward pharmacist must check the "Intrathecal Chemotherapy Prescription Sheet(s)" to ensure correct patient, drug(s), dose(s), route and date of administration have been stated. The pharmacist must then sign on the "Intrathecal Chemotherapy Prescription Sheet(s)" to indicate that the intrathecal dose(s) has been issued. The administering doctor must also sign to confirm receipt of the drug.
 - Intrathecal drugs are not stored in any location outside of the designated area in pharmacy. ITC drugs are collected and transported directly to the appropriate administration area and administered immediately without local storage. Time of arrival of the ITC in the ITC room and time of its administration are recorded in the ITC Room Log; if there is any delay in administration of the drug, it is returned to pharmacy for storage. No ITC drugs are stored in the ITC Room.
 - The intrathecal drug must not be removed from its packaging until immediately prior to its administration.
- 6.5 The following process must be checked off in writing on the "Checklist for Administration of Intrathecal Chemotherapy" (**Appendix C**) and signed on completion by both the administering doctor and the nurse checking the administration. If more than one intrathecal drug is to be given, only one checklist need be completed:
- The authorised intrathecal chemotherapy trained nurse and the administering doctor will check that:
 - the correct drug, dosage and route of administration have been prescribed according to the treatment protocol.

- the cytotoxic drug in the syringe and its dosage corresponds to the “Intrathecal Chemotherapy Prescription Sheet”.
- the syringe label states “INTRATHECAL”.
- The needle is non-Luer lock (NRFit™ ISO 80369-6) as is the syringe containing the IT chemotherapy.
- the drug is to be used before the expiry time/date.
- Both the checking nurse and the doctor will confirm the identity of the patient against the prescription sheet before administration of the intrathecal drug as per the Trust’s medicines administration policy.
- The administering doctor will ensure that he/she has explained the nature of the procedure to the patient (or designated relative/guardian).
- The patient (or designated relative/guardian) may be invited to check that the correct patient name, the name of the intrathecal drug(s) and the route of administration printed on the injection label corresponds with the “Intrathecal Chemotherapy Prescription Sheet(s)”. The patient (or designated relative/guardian) may then sign on the checklist to confirm these checks.
- The administering doctor must ensure the patient is fit for treatment with the correct tests conducted and these checks documented on the chemotherapy review sheet. Sections 1 to 6 of the Intrathecal Chemotherapy Checklist are required to be confirmed and signed prior to administration.
- The doctor will administer the drug intrathecally slowly over 20-30 seconds (for liposomal cytarabine 1-5 minutes), in the presence of the checking nurse. (Two doctors may not check each other.)
- The administering doctor and checking nurse must then sign and write the time given on the “Intrathecal Chemotherapy Prescription Sheet(s)”.
- The process above must be completed for each intrathecal drug to be administered for patients receiving more than one intrathecal drug.
- The administering doctor and checking nurse must sign sections 8 to 10 of the Intrathecal Chemotherapy Checklist.
- Only those staff members named on the Trust’s own register for a given task in the ITC process are permitted to perform that task in the trust, except for the sole condition specified under the next bullet point.
- Personnel may perform a given task under constant direct supervision of personnel who are agreed as trust competency assessors for that task, when it is being performed as part of the trust ITC registration training programme, competency review or refresher training.
- Only those staff members who have been trained and assessed as competent in that task, according to the trust’s ITC training procedure, are eligible to be registered for that task.

- Only medical staff in the following categories (following training and the attainment of competence) are eligible to be registered for **prescribing ITC**; Consultants. Individual Specialist Registrars (ST3), Associate Specialists. Staff Grade doctors can also (following training and the attainment of competence) prescribe ITC if they have been named, and given personal written permission, by the Trust CE.
- Only medical staff in the following categories (following training and attainment of competence) are eligible to be registered to **administer ITC**: Consultants, Specialist Registrars (ST3), Associate Specialists, and Staff Grade doctors.
- **Note**
 - *FY1 and FY2 medical staff should never administer ITC.*
 - *ST1 and ST2 medical staff can only be registered to **administer** ITC (following training and attainment of competence) if the trust has fulfilled the ST1/ST2 waiver measure.*
 - *ST1/ST2 can never be registered to **prescribe** ITC.*
 - *Radiologists who position lumbar puncture needles are not permitted to perform any other part of the ITC process or procedure.*
- The registration status of any registered staff member never lasts for more than one year. Their name is deleted from the register unless their competence is reviewed and re-certified within that time. Re-certification may be dependent on refresher training.
- All staff should have the frequency with which they perform the registered tasks monitored and their competency reviewed annually by a named competency assessor.
- Only the ITC lead or the named persons with responsibility delegated by the ITC lead for a specified part of the register (see Appendix A), can authorise the entry of an eligible person onto that part of the register for that respective task.
- The people delegated to have responsibility for authorising entry onto the register for specified tasks are named in Appendix A.
- At their annual review of competence, or at any other time, the ITC lead or a delegated person is authorised to delete a staff member from the register, if they are assessed as performing their registered task(s) insufficiently often to maintain competence.
- The initial assessment of competence and its annual reconfirmation includes written confirmation that the staff member has read the ITC national guidance and associated local protocols.

7. Training & Accreditation

- 7.1 Any member of staff being trained in any task concerning intrathecal chemotherapy must be under direct supervision and in the constant presence of the relevant assessors (see Appendix A) for that task.
- 7.2 Training of medical staff shall cover:
- all potential clinical hazards associated with intrathecal chemotherapy
 - the dangers posed if vinca alkaloids (or other agents) are accidentally administered intrathecally
 - the Intrathecal Chemotherapy Procedure particularly emphasising all aspects relevant to medical staff who may prescribe and administer intrathecal chemotherapy.
 - relevant national & local policies and procedures relating to cytotoxic chemotherapy
- 7.3 To allow designated pharmacists to fulfil their duties in dispensing, distributing and storing intrathecal chemotherapy, they must undergo the Frimley Health NHS Foundation Trust Intrathecal Chemotherapy Training Programme which will cover all aspects of dispensing, distributing and storing intrathecal chemotherapy.
- 7.4 To allow nursing staff to fulfil their duties in checking the administration of intrathecal chemotherapy, they must undergo Frimley Health Hospitals NHS Foundation Trust Intrathecal training programme and hold an accredited chemotherapy qualification.
- 7.5 The programme shall cover all aspects of nurse checking of the administration of intrathecal chemotherapy as previously described.
- 7.6 A haematology or oncology doctor will have their name added to the “Register of Authorised Staff” (**Appendix D**) authorised to prescribe or administer intrathecal chemotherapy if that doctor has:
- completed the Frimley Health NHS Foundation Trust Intrathecal Chemotherapy Training Programme.
 - acknowledged their completion of the programme in writing.
- 7.7 The clinical lead for intrathecal chemotherapy, who shall be responsible for the Intrathecal Chemotherapy Training Programme, shall add the name of the doctor to the “Register of Authorised Staff” (Register 1 and/or 8) and will sign to confirm the doctor’s completion of the Intrathecal Chemotherapy Training Programme.
- 7.8 A pharmacy member of staff’s name will be added to the “Register of Authorised Staff” (**Appendix D**) authorised to dispense, distribute or store intrathecal chemotherapy if that pharmacist has:
- completed the Frimley Health NHS Foundation Trust training Programme
 - acknowledged completion of the programme in writing
- 7.9 The Lead Chemotherapy Pharmacist, delegated by the ITC Lead Clinician to be responsible for the pharmacy element of the Intrathecal Chemotherapy Training

Programme, shall add the name of the pharmacist to the “Register of Authorised Staff” and update all copies of the Register accordingly. The updated “Register of Authorised Staff” (Registers 1-9) is to be signed by the Chief Pharmacist, who must confirm the pharmacist’s completion of the programme with the Lead Chemotherapy Pharmacist.

- 7.10 A nurse’s name will be added to the “Register of Authorised Staff” authorised to check the administration of intrathecal chemotherapy if that nurse:
- is a chemotherapy trained nurse on the chemotherapy register
 - has successfully completed an annual assessment of chemotherapy competency
- 7.11 The Haematology Advanced Nurse Practitioner, delegated by the ITC Lead Clinician to be responsible for the nursing element of the Intrathecal Training programme, shall add the name of the nurse to the “Register of Authorised Staff” and update all copies of the Register accordingly.
- 7.12 All staff involved in intrathecal chemotherapy will undergo annual refresher training.

8. Process for Monitoring Compliance with this Guideline / Procedure

- 8.1 These guidelines will be reviewed annually by the Trust’s Chemotherapy Working Group as part of peer review cycle and are endorsed by the Frimley Health NHS Foundation Trust Management Team.
- 8.2 Areas designated for the administration of cytotoxic drugs will have access to all relevant guideline and protocol documents. These will be checked for currency and availability annually.
- 8.3 The area will also have an annual risk assessment undertaken to ensure fitness for purpose, in line with the recommendations of NPSA alert promoting the use of Injectable medicines, 2007/20. This assessment should encompass an Equality Impact Assessment. Checks of medical equipment used within the area must be undertaken on an annual basis.

9. References

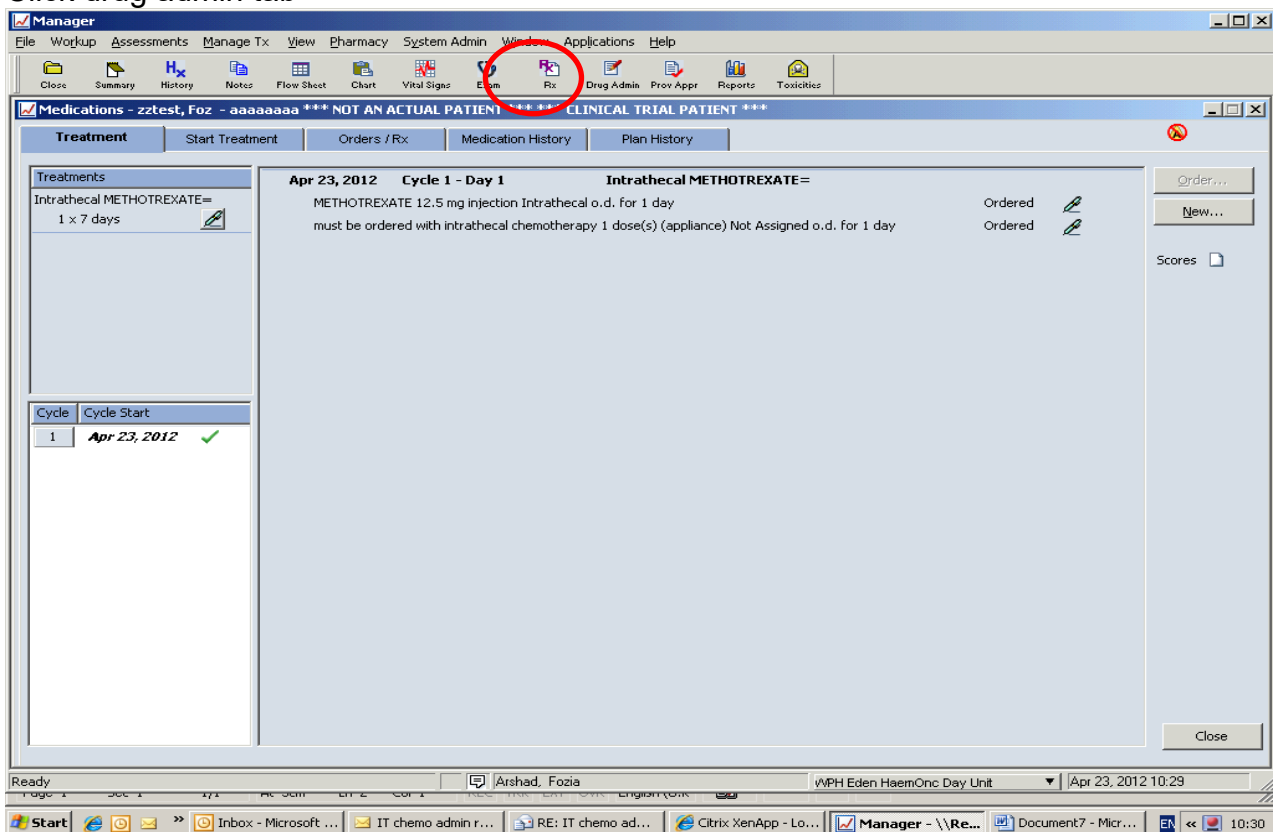
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Appendix A - Named Staff in ITC Service

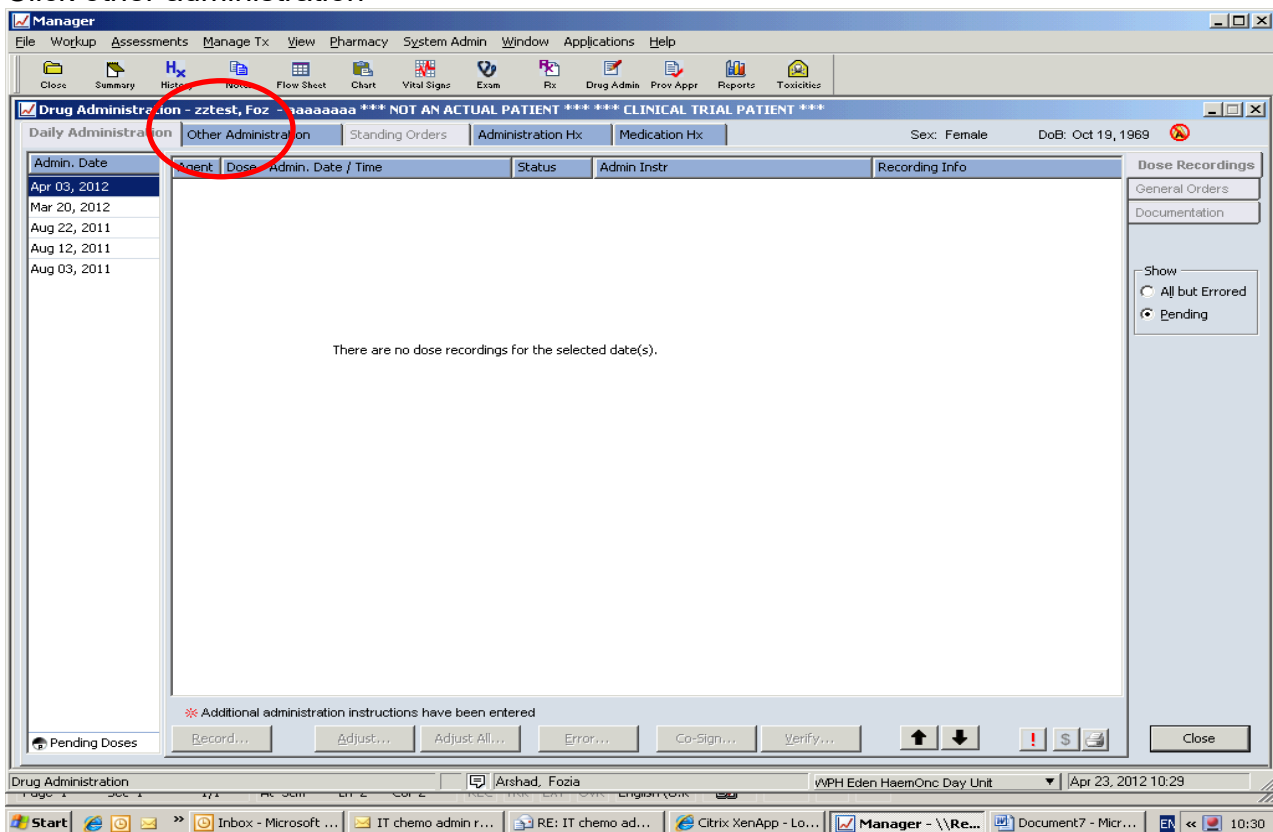
Name	Role
Dr John Willan	Lead ITC Clinician Designated Lead Trainer, Competency Assessor for Medical Staff (WPH)
Dr Edward Renaudon-Smith	Designated Trainer, Competency Assessor for Medical Staff (FPH)
Sr Kathryn Kensey	Designated Nurse ITC Trainer, Competency Assessor for Nursing Staff
Dee Kriel	Designated Pharmacy Trainer, Competency Assessor for Pharmacy Staff

Appendix B – Drug Administration

Click drug admin tab



Click other administration



Select the appropriate drug from the list and click record

Manager

File Workup Assessments Manage Tx View Pharmacy System Admin Window Applications Help

Close Summary History Notes Flow Sheet Chart Vital Signs Exam Rx Drug Admin Prov Appr Reports Toxicities

Drug Administration - zztest, Foz - aaaaaaa * NOT AN ACTUAL PATIENT *** CLINICAL TRIAL PATIENT *****

Daily Administration **Other Administration** Standing Orders Administration Hx Medication Hx Sex: Female DoB: Oct 19, 1969

Ad Hoc Administration

Agent	Admin Instr	Admin Start Date	Quantity	Date of Last Dose
METHOTREXATE 12.5 mg injection Intrathecal o.d. for 1 day (Pickup - External)		Apr 23, 2012		
must be ordered with intrathecal chemotherapy 1 dose(s) (appliance) Not Assigned o.d. for 1 day (Pickup - Internal)				
ACICLOVIR 200 mg tablet Oral t.d.s. for 2 weeks (Pickup - Internal)		Dec 06, 2011	42	

Record... Stop Recording...

Agent Level Recording

Agent	Dose - Admin. Date / Time	Status	Admin Instr	Recording Info
No agents exist for which agent level dose recordings can be created.				

Record... Error... View... Show: All Pending Date Range: 26/10/2011 23/04/2012 All Dates Refresh

Additional administration instructions have been entered

Close

Drug Administration Page 1 Doc 1 174 Arshad, Fozia WPH Eden HaemOnc Day Unit Apr 23, 2012 10:30

Start Inbox - Microsoft ... IT chemo admin r... RE: IT chemo ad... Citrix XenApp - Lo... Manager - \\Re... Document7 - Mic... 10:30

Enter password and click APPROVE

Manager

File Workup Assessments Manage Tx View Pharmacy System Admin Window Applications Help

Close Summary History Notes Flow Sheet Chart Vital Signs Exam Rx Drug Admin Prov Appr Reports Toxicities

Dose Recording - zztest, Foz - aaaaaaa * NOT AN ACTUAL PATIENT *** CLINICAL TRIAL PATIENT *****

METHOTREXATE Order # 105200078 Tx Optional

12.5 mg injection Intrathecal o.d. for 1 day

Dose Seq.	Admin. Date/Time	# Doses	Amt. Received	Duration	Prep Wastage
Dose 1 of 1	Expected 23/04/2012 00:00	1	Detailed Recording		mg
PENDING	Actual 23/04/2012 00:00	1	12.5 mg		Drug Lot #:
	End 23/04/2012 00:00		Not Given		

Recorded As Per: Clinic / Hospital Patient Agency

Ad Hoc Recordings: Add Remove

Adverse Reaction: Add

Record... Stop Recording... Record... Error... View... Show: All Pending Date Range: 26/10/2011 23/04/2012 All Dates Refresh

Additional administration instructions have been entered

Co-Signed by

Approve OK Cancel

Close

Drug Administration Page 2 Doc 1 174 Arshad, Fozia WPH Eden HaemOnc Day Unit Apr 23, 2012 10:30

Start Inbox - Microsoft ... IT chemo admin r... RE: IT chemo ad... Citrix XenApp - Lo... Manager - \\Re... Document7 - Mic... 10:31

In the event of electronic systems failure

Intrathecal chemotherapy must be prescribed on a prescription sheet designated for intrathecal chemotherapy.

If more than one intrathecal chemotherapy drug is to be administered, then each drug must be prescribed on a separate sheet.

Under route for administration, the word INTRATHECAL must be written in full (on the “Intrathecal Chemotherapy Prescription Sheet” (**Appendix E**), this is pre-printed).

Intrathecal Chemotherapy may only be prescribed by a doctor who is listed on the Register of Persons Authorised to Prescribe Intrathecal Chemotherapy (**Appendix D**).

The doctor completing the prescription must:

- (a) clearly state the patient’s full name, hospital number, date of birth and address (patient addressograph label is acceptable).
- (b) state in which clinical area the patient is to receive the Intrathecal drug(s).
- (c) clearly state (in block capitals) drug name(s) and dose(s).
- (d) state date that Intrathecal injection(s) are required.
- (e) sign prescription where indicated.

Medical Staff listed in the “Register of Authorised Staff” who are authorised to order intrathecal chemotherapy must have been trained to do so.

No drugs by routes of administration other than intrathecal should be written on the same prescription.

Prescriptions for intrathecal chemotherapy must be received by pharmacy at least the day before the dose(s) are required **UNLESS** specifically requested by the patient’s consultant, and after discussion with the chemotherapy pharmacist.

Appendix C – Checklist for the Administration of Intrathecal Chemotherapy

To be filed in patient's medical notes when completed

Name of patient: _____

Hospital No: _____

Consultant: _____

D.O.B.: _____

Name(s) and Dose(s) of Intrathecal Cytotoxic Drug(s) _____

CHECKLIST (Doctor (Dr) and Nurse (Nu) to initial box when completed)		Dr	Nu
1	Confirm that clinical review has been undertaken and documented in notes		
2	Correct intrathecal drug and dosage on specific intrathecal Prescription sheet /ARIA (according to protocol)?		
3	Route of administration ("INTRATHECAL") stated in full?		
4	Label on syringe corresponds to prescription (patient name, hospital number, name of drug, dosage, route of administration) and is to be given prior to expiry time/date?		
5	Identity of patient confirmed against prescription chart?		
6	Confirm nurse Checker is on current Intrathecal register		
7	Patient/relative/guardian statement (<i>not mandatory</i>) <i>I confirm that I have had the procedure explained to me, have checked that the name of the drug on the injection is the same as on the chart and that the injection is labelled with my name/the patient's name and states that it is for intrathecal injection.</i> Name of patient/relative/guardian _____ Signature of patient / relative / guardian _____		
8	Have the intrathecal chemotherapy dose(s) been administered?		
9	Intrathecal Prescription sheet(s) administration recorded signed, and including time of administration?		

10	Print name of doctor (ON REGISTER) completing checklist and administering drug Doctor's signature _____ Print name of nurse (ON REGISTER) _____ checking / witnessing administration Nurse's signature _____ Date: _____
----	---

Appendix D – Registers of Authorised Staff

REGISTERS OF AUTHORISED STAFF TO PRESCRIBE, DISPENSE, CHECK AND ADMINISTER INTRATHECAL CHEMOTHERAPY

CONTENTS OF INTRATHECAL CHEMOTHERAPY REGISTER

REGISTER 1	Doctors authorised to prescribe intrathecal chemotherapy
REGISTER 2	Pharmacy staff authorised to prepare worksheets and labels and to assemble intrathecal injections
REGISTER 3	Pharmacy staff authorised to perform transcription and pre-checking of worksheets and labels for intrathecal injections
REGISTER 4	Pharmacy staff authorised to volume check and label intrathecal injections
REGISTER 5	Pharmacy staff authorised to manufacture intrathecal injections
REGISTER 6	Pharmacy staff authorised to screen and final check intrathecal chemotherapy
REGISTER 7	Pharmacy staff authorised to issue intrathecal chemotherapy to the administering authorised doctor
REGISTER 8	Doctors authorised to administer intrathecal chemotherapy
REGISTER 9	Nursing staff authorised to check/witness intrathecal chemotherapy

Current copies of these registers will be displayed in the chemotherapy aseptic suite in pharmacy, the Eden Day Unit ITC room at WPH; and the G1 Day Unit Treatment Room and pharmacy chemo corner at FPH.

A copy is also displayed in the Chief Pharmacist's office at both WPH and FPH.

Person responsible for co-ordinating training/competency assessment of listed members of staff is the Nurse Consultant-lead Cancer Nurse:

Those responsible for assessing individual staff groups and authorising entry onto the appropriate register(s) (as authorised by the Lead Clinician for Intrathecal Chemotherapy) are as follows:

Medical Staff	(Registers 1 and 8)	Lead Clinician for Intrathecal Chemotherapy
Nursing Staff	(Register 9)	Designated nurse ITC trainer
Pharmacy Staff	(Registers 2-7)	Designated pharmacy trainer

The names of the individuals are shown in Appendix A.

Appendix E – Intrathecal Chemotherapy Prescription Sheet (Emergency Use Only)

INTRATHECAL CHEMOTHERAPY PRESCRIPTION SHEET (only use if electronic systems fail)

Separate Prescription sheet for each drug to be given

Date of Administration _____
Site of Administration Eden Unit

Patient Addressograph

Drug name	Dose	Route	Signature of doctor administering	Signature of nurse checking	Time given
		INTRATHECAL			

Name of administering Doctor (name MUST appear on register 8)

Signature of prescribing doctor

On collection of intrathecal chemotherapy dose, the administering doctor must **sign** to confirm that:

Either 1) Intravenous chemotherapy drugs due on the same day
have already been given

Or 2) No intravenous chemotherapy drugs
are due on the same day

and confirm recent platelet count $>50 \times 10^9/L$

Intrathecal dose issued by:	Print name	_____
	Signature	_____
	Time / Date	_____
Intrathecal dose received by:	Print name	_____
	Signature	_____

Example Electronic Intrathecal Chemotherapy Prescription Sheet

WPH Eden HaemOnc Day Unit - TEST

Printed: Jan 22, 2012 14:30

Consultant: Moule, Dr. Simon P

, United Kingdom 00000

Phone: (000) 00-0-0000

Fax:

Patient Name: zzdummy, hwphdummyitc

a) NHS#: 78945313733

HWPH - MRN: 8899889988998

Address:

, Oxfordshire

Date of Birth: Mar 10, 1950

Age: 61

Sex:

Order #: 105200002

M

Home:

Bus: Ext:

Allergies: -

Administration Start Date: Jan 22, 2012

Prescription

METHOTREXATE 12.5 mg injection Intrathecal o.d. for 1 day

THIS IS INTRATHECAL CHEMOTHERAPY

Ensure all intravenous chemotherapy has been administered prior to the release and administration of intrathecal chemotherapy.

Expiry Date:

Batch Number:

No Refills Permitted

Dispense as written:

Substitutions Allowed

Ordered By: Simon P Moule, F.R.C.Path., M.A.,
M.B.B.S., M.R.C.P.

Date: Jan 22, 2012 14:29

Pharmacist Approved By:

Date:

Record of Administration of Intrathecal Chemotherapy:

Drug Name	Dose (mg)	Route	CHECKED BY:	GIVEN BY:
METHOTREXATE	12.50	INTRATHECAL	DOCTOR SIGN & PRINT:	DOCTOR SIGN & PRINT:
Cycle 1 Day 1 of Drug:			NURSE SIGN & PRINT:	Witnessed By: NURSE SIGN & PRINT:
Date:			PATIENT SIGN: (optional)	
Time of Administration:				

Nurse & Doctor:

Please also record Drug Administration electronically on Aria.

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

WPH Eden HaemOnc Day Unit - TEST

Printed: Jan 22, 2012 14:30

Consultant: Moule, Dr. Simon P

, United Kingdom 00000

Phone: (000) 00-0-0000

Fax:

Patient Name: zzdummy, hwphdummyitc

a) NHS#: 78945313733

HWPH - MRN: 8899889988998

INTRATHECAL CHEMOTHERAPY SIGNATURE SHEET.

TO BE PRINTED OFF AND SIGNED IN CONJUNCTION WITH THE ARIA PRESCRIPTION.

Release from Pharmacy and Acceptance in Clinical Area**Part A**

Both sections below must be completed before intrathecal chemotherapy can be released)

Is IV chemotherapy due to be given prior to today's intrathecal dose(s)?	Yes/No/NA	Sign & print
Has pharmacist seen evidence that the IV chemotherapy has been administered?	Yes/No/NA	Sign & print

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 placed in "Intrathecal Fridge" by authorised member of pharmacy staff (signature) :	Sign	Print Name	Date	Time
	Retrieved from designated area "intrathecal" storage fridge 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

Appendix F – Exceptional Circumstances Forms

In exceptional circumstances, it may be necessary to treat the patient in a location other than the designated ward or area; or outside normal working hours. In either of these events, the treating clinician must complete the appropriate form, scan it and upload it to the patient's notes on the Epic EPR system. The original paper form must be forwarded to the Lead Clinician for ITC.

These forms are provided on the following pages:

Exceptional Circumstances Form: Administration of Intrathecal Chemotherapy on a non-designated Ward/Area

Exceptional Circumstances Form: Administration of Intrathecal Chemotherapy Out of Hours

EXCEPTIONAL CIRCUMSTANCES FORM: ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY ON A NON-DESIGNATED WARD/AREA

The designated areas for administration of Intrathecal Chemotherapy (ITC) at Frimley Health NHS Foundation Trust are:

- ITC Room, Eden Unit (WPH) and Treatment Room, G1 Day Unit (FPH)

In exceptional circumstances (see section 2) where a patient requiring ITC cannot be transferred to the designated area (e.g., ITU patient) or if the lumbar puncture needle needs to be placed in radiology, ITC accredited staff *only* may carry out the procedure in ITU or in Radiology department.

- This form must be completed and brought to ITC lead pharmacist.
- *ITC for administration on a non-designated ward will not be released without this form.*
- This form must be scanned and uploaded to the patient's notes.

Patient Name:

Hospital Number

DoB

Consultant

Name of non-designated ward where ITC procedure is to take place:

Reason for Exceptional Circumstance:

Form completed by (Name)

Position

Consultant signature

Date

Please scan and upload the form to the patient's notes and forward the original completed form to the Lead Clinician for ITC, Dr John Willan, Department of Haematology, Wexham Park Hospital.

EXCEPTIONAL CIRCUMSTANCES FORM: ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY OUT OF HOURS

Intrathecal Chemotherapy should be administered within normal working hours. The normal working hours for intrathecal chemotherapy administration at Frimley Health NHS Foundation Trust are

Mondays – Fridays 9.00am – 5.00pm (excluding Bank Holidays).

In exceptional circumstances, where a patient requires ITC in an emergency:

- Section 4.8.1 of the Intrathecal Chemotherapy Procedure must be followed
- The Lead Clinician for Chemotherapy and the Lead Clinician for ITC must be contacted and informed that this procedure is having to take place out of hours
- This form must be completed, scanned and uploaded to the patient's notes.

Patient Name:

Hospital Number:

DoB:

Consultant:

Reason for Exceptional Circumstance (include any action taken and outcome):

Designated Intrathecal Lead and Chemotherapy Lead Contacted: Yes / No

Designated Intrathecal Lead and Chemotherapy Lead contacted by (name/position):

Date & Time:

Form completed by:

Position:

Please scan and upload the form to the patient's notes and forward the original completed form to the Lead Clinician for ITC, Dr John Willan, Department of Haematology, Wexham Park Hospital.

Full version control record

Version:	3.0
Guidelines Lead(s):	Dr John Willan, Consultant Haematologist and ITC Lead for Frimley Health NHS Foundation Trust
Contributor(s):	Dee Kriel, Preparative Services Pharmacy Manager
Lead Director / Chief of Service:	Dr. Jonathan Macintyre
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Date Issued:	27 November 2023
Review Date:	November 2026
Pharmaceutical dosing advice and formulary compliance checked by:	Dee Kriel, Preparative Services Pharmacy Manager, 13 September 2023
Key words:	Intrathecal, chemotherapy

This guideline has been registered with the trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt, contact a senior colleague or expert. Caution is advised when using guidelines after the review date.

This guideline is for use in Frimley Health Trust hospitals only. Any use outside this location will not be supported by the Trust and will be at the risk of the individual using it.

Version History

Version	Date	Guideline Lead(s)	Status	Comment
1.0	March 2019	Intrathecal Chemotherapy Lead Clinician	Final	Merged WPH and FPH Chemotherapy guidelines.
1.1	April 2020	Intrathecal Chemotherapy Lead Clinician	Interim	Update to enable change of designated treatment location (Section 2.1) during Covid-19 pandemic.
2.0	Sept 2021	Intrathecal Chemotherapy Lead Clinician	Final	Scheduled review.
3.0	Nov 2023	Intrathecal Chemotherapy Lead Clinician	Final	Scheduled review.
3.1	May 2024	Intrathecal Chemotherapy Lead Clinician	Interim	Added NREIT™ ISO 80369-6 after the words non-Luer lock throughout document. Correction made to warning label in point 4.7 and to Appendix D, register 4.

Related Documents

Document Type	Document Name
Trust Policy	Medicines Policy (2023), see: https://ourplace.xfph-tr.nhs.uk/media/31124/medicines-policy-v20.pdf
Trust Guidelines	https://guidelines.fhft.nhs.uk – see Haematology and VTE set