

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Intrathecal Cytotoxic Chemotherapy (ITC) Policy

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1. Introduction

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.

The administration of intrathecal drugs is potentially dangerous and must only be undertaken by staff that have undergone appropriate training and are certified as competent to participate in the process.

The administration of certain cytotoxic chemotherapy drugs, such as Vincristine, via the intrathecal route is almost always fatal (DoH 2008). Although the most recent National guidance relaxed some of the requirements compared to previous versions (DoH 2003) the Trust intrathecal chemotherapy group made the decision to keep these unchanged.

Vinca alkaloids: - Vincristine, Vinblastine & Vinorelbine and Vindesine are all fatal if administered intrathecally. They **MUST** only be given INTRAVENOUSLY. This must be compliant with the NPSA Rapid Response Report (NPSA/2008/RRR04) on vinca alkaloid administration. For further details see Appendix 5

This policy should be read in conjunction with other Trust policies, procedures and guidelines including those pertaining to consent, cytotoxic chemotherapy, administration of medicines and sedation.

The key recommendations outlined within this document are as follows:

- ITC can only be administered to adult and paediatric oncology patients at designated times and in designated areas within the Trust.
- Clinical staff who wish to be included on the [Trust ITC Register](#) must undertake appropriate training and demonstrate competence in their registered task prior to inclusion on the Trust ITC Register.
- Only competent and designated personnel, whose names are recorded on the Trust ITC Register, are authorised to prescribe, verify, dispense, issue, check or administer ITC.
- A competent Consultant, Specialist Registrar or Speciality Doctor, listed on the Trust ITC Register, **MUST** prescribe ITC. The drugs covered by the policy are and Methotrexate, Cytarabine, Hydrocortisone and Liposomal Cytarabine (DepoCyte) . In exceptional circumstances other cytotoxic drugs may need to

- be prescribed refer to section 6.6.
- Prescription must be via ChemoCare or in exceptional circumstances using a designated ITC prescription chart,
 - ITC drugs can only be issued and received by designated staff, listed on the Trust ITC Register, and ITC drugs MUST be kept in a designated, lockable refrigerator/container when they cannot be administered immediately.
 - Intravenous cytotoxic chemotherapy must be administered BEFORE ITC drugs are issued (Section 6.10.1).
 - All spinal (intrathecal and intraventricular) chemotherapy doses must be performed using syringes and needles and other devices with non-Luer connectors that cannot connect with intravenous devices.
 - Checks must be made by medical, nursing and pharmacy staff at relevant stages throughout the ITC process.

2. Scope

This policy applies only to members of the Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) 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].

This policy applies to all patients [adult and children] who require intrathecal chemotherapy, either as an emergency or planned procedure.

3. Aims

The aim of this policy is to ensure that Intrathecal chemotherapy is carried out safely and in accordance with National guidance and to minimise the risks associated with the prescribing, preparation, supply and administration of cytotoxic intrathecal and intraventricular injections.

4. Duties (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.

They are as follows:

Designated Lead / Lead Adult Trainer [Medical & Nursing Staff]

- Has the overall responsibility for intrathecal practices and adherence to the Intrathecal Policy / National Guidance in NuTH.
- Overall responsibility for holding the register and ensuring it is maintained and kept up-to-date.
- Lead trainer in Intrathecal policy for Medical and Nursing Staff in Adult Haematology. Responsible for induction, training and continuing professional development related to intrathecal chemotherapy.

- Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks. Monitors the frequency staff perform the registered tasks. Will delegate these responsibilities appropriately to the Lead Trainers.
- Monitors the number of intrathecal chemotherapy administrations per year across NuTH.
- Responsible for ensuring the Lead Trainers have this role recognised in their job description and appraisal process.
- Responsible for assessing any variances, deviations or incidents from this policy in either service.
- Responsible for monitoring the number of intrathecal administrations per year
- Responsible for collating all emergency procedures performed outside the designated lists and recording out of hours procedures.
- Responsible for informing the Medical Director and Chief Executive of incidents, unplanned deviations or other issues related to the policy.

Deputy Designated Lead / Lead Paediatric Trainer [Medical & Nursing Staff]

- Oversees adherence to the Intrathecal Policy / National Guidance within the Great North Children's Hospital.
- Responsible for reporting any variances from the Intrathecal Policy to the Designated Lead.
- Lead trainer in Intrathecal policy for Medical and Nursing Staff in the Great North Children's Hospital.
- Responsible for induction, training and continuing professional development related to intrathecal chemotherapy for medical staff in the Directorate of Children's Services.
- Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks.

Designated Lead Trainer Pharmacy Staff

- Acts as Lead Trainer for Pharmacy Staff.
- Responsible for ensuring adherence to the Intrathecal Policy within the pharmacy setting.
- Responsible for induction, training and continuing professional development related to intrathecal chemotherapy within the Pharmacy Department.
- Responsible for reviewing competencies annually and issuing written confirmation of competence for designated tasks
- Maintains the NuTH Authorised Intrathecal Register and keeps a copy of all competency certificates.
- Responsible for ensuring an up-to-date copy of the register is available on the Trust Intranet and copies circulated to the appropriate clinical areas.

N.B. Although the ITC Lead is accountable to the Trust Chief Executive for compliance with the National ITC guidance every member of staff is accountable for their own individual actions and must adhere to the Trust ITC policy.

5. Definitions

ITC	Intrathecal Chemotherapy
NPSA	National Patient Safety Agency
CSF	Cerebrospinal fluid

6. Intrathecal Cytotoxic Chemotherapy (ITC) Policy

6.1. The ITC Division

The Newcastle Hospitals NHS Trust has two divisions for the purposes of the management of intrathecal chemotherapy. These two divisions are Adult Haematology/Oncology and Paediatric Oncology. Administration of intrathecal therapy must be in accordance with the relevant section of this policy:

- Patients who are under the care of Adult Haematology/Oncology
- Patients who are under the care of Paediatric Oncology Services

The routine administration of ITC is only permitted in the following designated areas within the Royal Victoria Infirmary (RVI) and the Freeman Hospital (FRH) during normal working hours, i.e. between 9.00am and 5.30pm, Monday to Friday, excluding Bank Holidays.

Adult Haemato-oncology / Oncology

- Ward 33 FRH (Intrathecal Chemotherapy Room)
- Ward 36 FRH (Intrathecal Chemotherapy Room)

Paediatric Oncology

- Children's Theatres – New Victoria Wing RVI (20 or 21-25) (irrespective of the need for anaesthetic)

N.B. Under routine circumstances ITC can **NOT** be administered in any other area within the Trust.

Dispensing and issuing of ITC for the two divisions will take place from the following pharmacy locations:

- Dispensing Pharmacy Production Unit RVI
 NCCC Cytotoxic Dispensing Unit FRH
- Issuing Pharmacy Production Unit RVI
 Pharmacy New Victoria Wing RVI
 NCCC Cytotoxic Dispensing Unit FRH
 NCCC Clinical Trials Pharmacy FRH
 Children's Theatres RVI

6.2. Variations and Deviation from the NuTH Intrathecal Policy

Any unauthorised deviation from this policy is not acceptable and therefore must be reported as a patient safety incident in accordance with the [Management and Reporting of Accidents and Incidents Policy](#) (2015)

Such incidents must be reported on Datix Web and copied to the Designated Lead Clinician. All such incidents will be reported to the Medical Director.

In exceptional circumstances a variation to the policy may be requested. This MUST be discussed with the Lead Clinician for Intrathecal Chemotherapy (or deputy) and documented as such in the patients medical notes prior to the variation. At the discretion of the Lead Clinician for Intrathecal Chemotherapy [or their deputy] the variation should be escalated to the Medical Director.

6.3. Education, Training and competency assessment.

6.3.1. Induction

All nursing, medical and pharmacy staff who are new to wards / departments within the ITC Division and pharmacy are advised that they MUST NOT be involved in any task associated with intravenous cytotoxic chemotherapy or ITC until they have received appropriate training and their competency has been assessed. A copy of Appendix 2 should be given to each new member of staff to read during their induction period.

6.3.2. Training procedure for staff wishing to be included on the Trust ITC register.

Only those members of staff who have been trained and assessed as competent in an ITC task are eligible to be registered for that task. The training and assessment will consist of:

- successful completion of the ITC e-learning package,
- acquisition of clinical competence
- a competency assessment.

The ITC e-learning package comprises of the following core syllabus:

- The potential clinical hazards associated with ITC, including the life threatening consequences associated with accidentally administering Vinca Alkaloids via the ITC route. Viewing and discussion of the issues highlighted in the DoH ITC video / DVD).
- The key requirements outlined within the National ITC guidance and implications for local practice i.e. details of the Trust ITC policy.
- The rationale, advantages, disadvantages and potential side effects associated with ITC.
- ITC administration processes to include associated documentation.
- Details pertaining to the process for acquiring / maintaining clinical competence and registration where appropriate.
- The key requirements outlined in NPSA/2008/RRR004 - Using Vinca Alkaloid Minibags (Adult/Adolescent Units)

6.3.3. Acquiring Clinical Competence

Competency criteria:

- Observe practice of the specific ITC task in which the staff member is seeking registration.
- Perform the specific ITC task under the direct supervision of, and in the constant presence when performing it, of personnel who are deemed

competent and are included on the Trust ITC Register.

Competency Assessment

The Lead Adult, Paediatric and Pharmacy trainer / assessors are responsible for assessing the competence of ALL ITC registered clinical staff, with the assessment of nurse's competencies being performed in collaboration with Lead ITC nurses. Although assessment will invariably reflect the requirements of the registerable ITC task, all staff, irrespective of the proposed registerable task, will be expected to:

- Complete the ITC e-learning package.
- Demonstrate an underlying knowledge of ITC including rationale, process, potential side effects and potential clinical hazards / dangers.
- Demonstrate theoretical and practical understanding relevant to the specific ITC task.
- Demonstrate clinical competence in performing the expected registerable ITC task.
- Demonstrate awareness of significant local and national policies, procedures and guidelines supporting clinical practice e.g. consent, pharmacy Standard Operating Procedures (SOPs), accident and incident reporting, performing a lumbar puncture etc.
- Have read and critically analysed the National ITC guidance, NPSA/2008/RRR004 and Local ITC policy.
- Demonstrate an awareness of the holistic, individual needs of patients and relatives / guardians.

Only those clinical staff who have been assessed and deemed to be competent will receive a certificate and be included on the Trust ITC Register. In order to maintain their position on the Trust ITC Register, staff MUST:

- Have their competence re-confirmed annually, in writing via a certificate.
- Perform their registered ITC task sufficiently often to maintain their competence. The Trust ITC group has defined the minimum number of procedures that should be performed or checked by each person on the register per annum as being
 - Adults 5
 - Paediatrics 5

N.B. The assessment of the 3 ITC lead trainer / assessors will be undertaken via colleague peer review.

Clinical staff that are not involved in providing an Intrathecal chemotherapy service (i.e. not on one of the ITC registers), but who are likely to work in areas where different aspects of the ITC service are provided should not take part, or be asked to take part, in any part of this process.

It is the responsibility of those individuals on the ITC register to ensure that any colleagues they involve in this process are on the ITC register for the task in question.

6.3.4. Continuing Professional Development

It is the responsibility of each registered practitioner to ensure that as part of their Continuing Professional Development they maintain practical experience within their registered ITC task/s.

Chemotherapy and ITC education and training must also feature annually within the Continuing Professional Development of all clinical staff who wish to remain on the Trust ITC Register. Each member of staff is personally responsible for maintaining an up to date record of their Continuing Professional Development.

6.3.5. Staff transferring to the NuTH NHS Foundation Trust

All clinical staff transferring to the NuTH NHS Foundation Trust must be inducted and assessed as competent in line with the Newcastle Trust's protocol.

6.4. Register of designated personnel

Unique lists of registered ITC personal, whose names appear on the Trust ITC Register, are available within all areas of the ITC Division and on the Trust intranet. The Trust ITC Register identifies which designated personnel have been trained and certified competent in one or more of the following ITC tasks:

Task		Staff Group
Prescribing	Writing of prescription	Consultants, ST3s and above, Speciality Doctors
	Patient review / consent	Consultants, ST3s and above, Speciality Doctors
Verification of prescriptions	Pharmacist clinical check	Oncology pharmacists
Dispensing and checking drugs in pharmacy	Worksheet and in-process checks	Production pharmacists and accredited production checking technicians
	Dispense and in-process checks	production technicians
	Final check	Production pharmacists
Issuing ITC drugs from the pharmacy		Oncology pharmacists
Checking ITC drugs prior to administration		Chemotherapy trained nurses
Administering the ITC.		Consultants, ST3 and above, Speciality Doctors

For an individual's name to appear on the Trust's ITC Register they must have demonstrated, to their designated lead trainer / assessor (Adult, Paediatric or Pharmacy), that they are competent to fulfil their designated role/s and be certified competent. It is the responsibility of their lead trainer / assessor to complete a competency certificate and forward this to the ITC administrator. The ITC administrator logs the certificate in the ITC Master File, identifying additions / amendments, and the Trust ITC Lead authorises inclusion on the part/s of the Trust ITC Register. The ITC administrator is responsible for maintaining the ITC Master File / Register and updating ALL unique lists of registered ITC personnel within the ITC Division. The ITC administrator will update the Trust ITC Register and unique lists during the first week of each month and as required.

The ITC administrator will notify the Adult and Paediatric Head of ITC services and the Lead Adult and paediatric ITC nurses, approximately 4 weeks in advance, of personnel whose competencies are due to expire. Individuals who fail to maintain their annual competence or perform their registered task(s) insufficiently often to maintain competence will be removed from the Trust ITC Register.

The ITC administrator will keep expired copies of staff's competency certificates for 2 years prior to the current year of registration.

N.B. Inclusion or deletion of staff from a part of the Trust ITC Register can only be undertaken by the ITC administrator with the authorisation of the ITC lead.

The ITC administrator will forward a copy of the ITC register each time it is updated to the Clinical Governance and Risk Department as well as designated members of staff working in each of the areas named in Appendix 1. It is the responsibility of the designated lead in each area to ensure a hard copy is available in the relevant clinical areas alongside the latest National and NuTH intrathecal policies, and that previous versions are destroyed. This should usually be the ward/department manager in all areas.

6.5. Distribution of Trust policy and registers

Only the latest editions of clinical policies, procedures and guidelines are available for reference by any member of staff involved in handling cytotoxic chemotherapy.

To ensure ease of access for consultation, hard copies of the Trust ITC policy, the National ITC guidance (2008), NPSA/2008/RRR004 Using Vinca Alkaloid Minibags (Adult/Adolescent Units) and up to date hard copies of the unique lists of registered ITC personnel can be found in all areas within the ITC Division and in designated inpatient wards and day case areas where oncology / haemato-oncology patients are admitted (Appendix 1). Electronic copies of all of these documents are also available on the Trust intranet.

6.6. Prescribing responsibilities

Only competent Consultants, ST3s or above and Speciality Doctors, whose names appear on the Trust ITC Register, are able to prescribe or administer ITC.

All intrathecal chemotherapy must be prescribed using the computerised

chemotherapy prescribing system, Chemocare. In rare situations where it is not possible to access the computerised prescribing system, then the Trust Intrathecal Chemotherapy Prescription Chart (Appendix 3) can be used for prescribing Intrathecal chemotherapy.

The prescription will be completed by designated medical staff based on a treatment plan authorised by the responsible consultant. Only authorised medical staff may prescribe intrathecal chemotherapy.

All data entry of the chemotherapy protocols on the chemocare system, including course set up and intrathecal drug doses, must be checked and approved by a pharmacist and a consultant.

Only the following drugs can be prescribed:

- Methotrexate
- Cytarabine
- Hydrocortisone
- Liposomal Cytarabine (DepoCyte)

Methotrexate and both formulations of Cytarabine clearly state on the manufacturer's vial that they can be administered via the Intrathecal route. Hydrocortisone sodium succinate (Solu-Cortef) is used intrathecally, as it is preservative free.

In exceptional circumstances other cytotoxic drugs not listed above or monoclonal antibodies may need to be prescribed and administered to a patient being treated for a malignancy. Each case needs to be discussed and agreed by the Trust Lead Clinician for Intrathecal Chemotherapy (or deputy) and the Lead and documented as such in the patients' medical notes prior to the variation.

Documentation must include the rationale for the treatment choice, details of the planned dose, formulation to be used and the names of the individuals involved in the decision.

. Unless there is a clinical emergency all Intrathecal prescriptions must be received in pharmacy by 10:30hrs on the day of treatment.

6.6.1 Prescribing on ChemoCare

A prescription chart for intrathecal chemotherapy will be produced for each individual patient requiring such treatment..

An Intrathecal chemotherapy prescription chart will only contain details of drugs to be administered into the CSF.

Intravenous drugs must be prescribed on a separate chart.

Intrathecal chemotherapy prescription charts should be kept separately from intravenous prescription charts and will be supplied to the clinical area with the

intrathecal drug.

Prescription charts must state the route for administration “Intrathecal” in full. Abbreviations are not acceptable.

The prescription must be completed in full.

The prescriber must sign and print name on the prescription chart. Prescribing of intrathecal chemotherapy should comply with the prescribing standards in the NuTH Medicines Policy.

Prescriptions for intrathecal chemotherapy, which are not fully completed, or contravene this policy will not be made up in or dispensed.

The drug and dose details must not be amended. If alterations are required a new prescription chart must be generated.

Intrathecal doses prescribed on ChemoCare should only be deferred by a Doctor on the ITC register.

6.6.2 Prescribing using the ITC Prescription Chart

A specific NuTH NHS Foundation Trust ITC Prescription Chart should be used only if ChemoCare is unavailable.

ITC drugs must be clearly written, in full, on the ITC Prescription Chart and the prescription must clearly and unambiguously, in the space provided, state the intended route of administration as “Intrathecal”. All 3 layers of the ITC Prescription Chart must then be submitted to the pharmacy.

6.7. Preparation and Dispensing

Cytotoxic chemotherapy (including ITC) can only be dispensed from pharmacy cytotoxic dispensing areas, by designated competent oncology pharmacy staff, during normal working hours i.e. between 9:00am and 5:00pm, Monday to Friday, excluding Bank Holidays.

ITC can only be dispensed by designated competent oncology pharmacy staff who are included on the Trust ITC Register. An up to date list of registered designated ITC pharmacy staff is available in those areas outlined in Appendix 1.

Specific Standard Operating Procedures (SOPs) pertaining to the pharmaceutical management of ITC, prefixed CYT22, can be found within each pharmacy preparation unit within the ITC Division and these must be implemented in conjunction with the general SOPs pertaining to cytotoxic chemotherapy. There are specific ITC SOPs pertaining to the following:

- Clinical Checking of Prescriptions
- Aseptic Dispensing
- Distribution

- Storage

N.B. ITC and cytotoxic chemotherapy should **NEVER** be prepared in ward areas.

6.8. Labelling and Packaging

ALL pharmacy labels for cytotoxic chemotherapy and ITC **MUST** contain the following information:

- Patient's full name and hospital number.
- Name of product and dose.
- Total volume.
- Batch number.
- Expiry date.
- Route of administration (For ITC this **MUST** be printed clearly in **BOLD** and in the largest font size possible).

N.B. Negative expressions (e.g. "Not for Intrathecal Use") must **NEVER** be used on any pharmacy labels.

6.9. Packaging and Transportation

ITC is packed in a clear zip-locked bag and transported in a designated ITC cool box. ITC **MUST** always be packed and transported separately from treatment for administration via any other route.

N.B. Although a group of paediatric ITC's can be transported and stored collectively, each ITC is prepared, packed, issued, checked and recorded individually.

The pharmacist handing over the ITC drugs should print off a copy of the authorised prescription from ChemoCare and ensure it accompanies the intrathecal drugs to the point of administration.

6.10. Issuing ITC

Only designated members of pharmacy staff, can issue ITC to a competent doctor. Both names must appear on the Trust ITC Register. (The pharmacist is referred to as 'the issuer' and the doctor is referred to as 'the collector').

ITC drugs are issued as follows:

- In pharmacy, 'the issuer' physically hands over the ITC to 'the collector' who will be administering the ITC in the designated area.
- 'The issuer' takes the ITC to the designated area where the ITC will be administered and physically hands the ITC over to 'the collector' who will be administering the ITC.

'The issuer' must sign release of the ITC in the allocated section of the ITC Prescription Chart. 'The collector' must also sign in the allocated section of the ITC prescription to confirm receipt of the ITC.

The ChemoCare Intrathecal Chemotherapy prescription chart records release from pharmacy and acceptance in the clinical area.

- Part A records if intravenous chemotherapy is due prior to the prescribed Intrathecal dose and whether evidence of these doses being administered has been recorded by the pharmacist.
- Part B records issue, delivery and retrieval of the Intrathecal product and must be completed before administration can proceed. Within NuTH only option 1 or 3 are acceptable i.e ITC is issued from pharmacy by an authorised member of pharmacy staff or delivered to a designated area and issued directly to an authorised doctor.

The Intrathecal Chemotherapy prescription chart is designed to record details of the individuals involved in each stage of the movement of intrathecal products within the hospital. This will ensure only appropriately trained staff handle intrathecal products.

N.B. When a number of paediatric ITCs are issued collectively each ITC must be released and received individually.

6.10.1. Timing of Issuing ITC

Although, in ideal circumstances, ITC should **NOT** be given on the same day as intravenous cytotoxic chemotherapy, it is acknowledged that the Trust manages patients from across the Northern Region. In instances when ITC is administered on the same day as intravenous cytotoxic chemotherapy the following safeguards **MUST** be enforced:

- Intravenous cytotoxic chemotherapy **MUST** be issued and administered **FIRST**.
- ITC can only be issued following written confirmation that the intravenous cytotoxic chemotherapy, for the named patient, for that day, has already been administered i.e. by checking the patient's medicine chart/ chemotherapy administration chart.

Those patients who are in the middle of an intravenous cytotoxic chemotherapy infusion, which has been started elsewhere, may continue their treatment providing:

- There is written confirmation that the intravenous infusion(s) has started before the ITC is issued from the pharmacy
- That the closed system is maintained and the infusion bag is not changed during the ITC procedure.

Children & adolescents scheduled to receive both intravenous and intrathecal chemotherapy on the same day should have early appointment times for clinic, to ensure all IV bolus chemotherapy is given on the ward or day unit before the ITC general anaesthetics list starts in theatres. If the IV chemotherapy has not been administered by 12:45 hrs the ITC will be cancelled.

'The issuer' must make the following checks, **BEFORE** delivering the ITC and signing the ITC Prescription Chart:

- That ITC and intravenous cytotoxic chemotherapy have not been supplied together, by mistake.
- That any intravenous cytotoxic chemotherapy, prescribed for administration on the same day, has already been administered .
- That there are no IV drugs available in the ward drug fridges for any patient due an intrathecal.

Intravenous chemotherapy for subsequent days for patients due an intrathecal will be returned to pharmacy to be quarantined during the intrathecal procedure. This can only be released by an authorised pharmacist following written confirmation that the ITC has been administered.

There should be no delivery of IV chemotherapy to the paediatric oncology ward or day unit for patients due an intrathecal between 12 noon until all of the patients have returned from theatre.

6.11. Interim Storage

Once dispensed, ITC and intravenous cytotoxic chemotherapy must be distributed and stored in accordance with relevant SOPs, Trust policies, procedures and guidelines (NuTH NHS Trust 2010).

If interim storage of prepared ITC is required then 'the collector' will be responsible for placing the ITC into the dedicated facility i.e. the appropriately labelled and locked ITC refrigerator, which is reserved for that purpose alone. No other drugs can ever be stored in the ITC refrigerator, even when it is not in use. ITC refrigerators are located in the following areas in the RVI:

- Ward 33 FRH.
- Ward 36 (Day Unit) FRH (Intrathecal Chemotherapy Room).
- Pharmacy New Victoria Wing RVI
- Children's Theatres – New Victoria Wing RVI (Theatre 25).

The dedicated ITC refrigerators can only be used to store ITC between issuing and administration. The nurse in charge will keep the key for the ITC refrigerator and the refrigerator can only be unlocked when ITC is being deposited or withdrawn. Only competent doctors or individuals whose names appear on the Trust ITC Register, are able to remove ITC from the ITC fridge.

N.B. When a number of paediatric ITCs are stored collectively, each dose of ITC must be removed from the locked refrigerator on an individual, named and patient number, basis. Once an ITC is withdrawn from the ITC refrigerator it must be re-locked.

All unused doses of intrathecal chemotherapy must be destroyed by placing in the cytotoxic bin in theatre and writing "Destroyed" across the prescription by the Doctor to whom they were issued. The prescription should be returned to pharmacy to enable records to be updated

6.12. Patient Review

A competent Consultant ST3 or above and Speciality Doctors, whose name appears on the Trust ITC Register, **MUST** have reviewed every patient before ITC is administered, ensuring that:

- Consent has been acquired (DoH 2001)
- The patient has been explicitly told the nature of the procedure, the route of administration, and the drug to be administered. This includes providing communication support for the patient where required
- The appropriate tests have been conducted, results reviewed and documented in the patient's medical notes i.e. establishing that the patient is fit for treatment.
- The correct ITC has been prescribed i.e. drug, dose and route, and is authorised on ChemoCare
- Members of staff assisting in the procedure are on the register for the task they are carrying out

Confirmation that the review has taken place should be written in the patient's medical notes

6.13. Checking and Administration

ITC **MUST** only be administered by a competent Consultant, ST3 or above or Speciality Doctor, whose name appears on the Trust ITC Register, during normal working hours, i.e. between 9:00am and 5:30pm, Monday to Friday, excluding Bank Holidays.

ST1 & ST2 **ARE NOT** permitted to prescribe or administer ITC within the NuTH NHS Foundation Trust.

ITC can only be administered to a patient in a designated area, during a predetermined time that has been negotiated by the clinical team in collaboration with the patient / relatives (during normal working hours). ITC can only be administered in designated areas when no other cytotoxic chemotherapy drugs are currently being administered or stored. When ITC is being administered, the designated area **MUST NOT** be used for any other purpose.

6.13.1. Checking

The checking process prior to administration is vital in ensuring that the correct drug and dose is being given to the correct patient, via the correct administration route. The following individuals must be involved in the checking process:

- The competent Doctor, whose name appears on the Trust ITC Register, who will be responsible for administering the ITC.
- An ITC Paediatric oncology / Adult haemato-oncology trained nurse, whose name appears on the Trust ITC Register.
- One of the following:
 - The patient.
 - A theatre nurse or Operating Theatre Practitioner, if the procedure is performed under general anaesthesia, or a chemotherapy nurse.
 - A relative or guardian.

In order for a patient, relative or guardian to actively participate in the checking process, if they so desire, they must be well informed regarding the nature of the procedure, the route of administration and the drug to be administered.

The following checks MUST be made and documented PRIOR to the administration of ITC, and if the ITC is given under a general anaesthetic prior to the patient being anaesthetised.

A competent doctor and a nurse, whose names appears on the Trust ITC Register, when preparing to treat a patient with ITC, must ensure:

- The drugs are checked against the prescription ensuring the following are correct: drug, age appropriate dose, route, volume and expiry and are correct for the patient name and hospital number. NB If the label has become completely detached from the syringe. The procedure must not go ahead)
- Where the intrathecal is given under general anaesthetic the above checks must be made before the patient is brought into the anaesthetic room.
- The ITC prescription is confirmed against the patient's consent form and chemotherapy flowsheet within the patient's medical notes.
- The identity of the patient must be checked via their patient identity band (wrist band).

The senior theatre nurse or patient / relative or guardian is also responsible for confirming the patients identity and that they are due to receive intrathecal chemotherapy.

N.B. Within NuTH a second doctor cannot substitute for a competent ITC Paediatric oncology nurse / Adult haemato-oncology nurse, taking part in the checking process.

6.13.2. Administration

ITC is administered in accordance with Trust procedures ([Injectable Medicines policy](#) and Appendix 4a, 4b) and may require general anaesthetic, sedation or local anaesthetic. The competent Consultant / ST3/ Speciality doctor, whose name appears on the Trust ITC Register, who is responsible for administering the ITC MUST, be present when the ITC is administered. In a situation where there is difficulty in performing the lumbar puncture another doctor may insert the needle but ITC must still be given by, or under the direct supervision of, a competent Consultant, whose name appears on the Trust ITC Register. The latter only applies when an ITC registered Consultant is training / assessing a colleague for entry onto the Trust ITC Register.

The following information MUST be recorded on the ITC Prescription Chart:

- Date and time.
- Name and signature of the Consultant / ST3 administering the ITC.
- Name and signatures of the two checkers.

N.B. The full signatures of **ALL** clinical staff involved in prescribing, dispensing, collecting, checking and administering ITC **MUST** be recorded in the allocated section of the ITC Prescription Chart.

6.14. Workload

The maximum number of children undergoing ITC under general anaesthetic in one operating session is twelve, unless exceptional circumstances prevail. The competent Consultant in charge of the operating list, whose name appears on the Trust ITC Register, must perform a risk assessment and document instances when this number is exceeded.

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. 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. 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.

An annual review of the number of intrathecal procedures will be undertaken by the ITC Lead. If it is projected that the number of procedures will exceed 500 per year, a risk assessment will be undertaken as per National Guidance

6.15. Out of Hours

If a patient is late for their appointment, but their arrival is within normal working hours, there must be sufficient flexibility in the designated area's working arrangements to enable their treatment to proceed. However, if a patient arrives for their planned ITC outside normal working hours i.e. between 9.00am and 5.30pm, Monday to Friday, excluding Bank Holidays then a new appointment must be made.

Only in the most exceptional circumstances e.g. the urgent treatment of central nervous system (CNS) leukaemia requiring emergency treatment, can ITC be given outside normal working hours. In these instances:

- There must be a clear clinical need for the procedure to be undertaken immediately and in these circumstances a Consultant, whose name appears on the Trust ITC Register, must clearly document in the patient's medical notes the risk / benefit analysis that has led to their decision to treat the patient out of hours / outside a designated area.
- Methotrexate maximum dose 12mg is the **ONLY** preparation that can be prescribed and administered by an **ITC Consultant** outside normal working hours.
- A pharmacist, whose name appears on the Trust ITC register, must speak directly to the ITC Consultant ordering and administering the ITC, establishing that there is an absolute clinical need and ensuring that all details are completed on the ITC Prescription Chart. The pharmacist will then facilitate and document the supply of ITC using the cytotoxic chemotherapy on-call guidance documentation and the appropriate ITC SOPs.

- In instances when ITC is administered on the same day as intravenous cytotoxic chemotherapy the pharmacist **MUST** confirm that any intravenous cytotoxic chemotherapy, for the named patient, for that day, has already been administered i.e. by checking the patient's medicine chart / chemotherapy administration chart..
- Duplicate copies of the ITC Prescription Chart **MUST** be kept in pharmacy, in line with standard procedure. On the next working day, the emergency duty pharmacist will inform the Intrathecal Chemotherapy Pharmacist or the ITC Senior Pharmacy Technician that an emergency intrathecal Methotrexate syringe has been issued. The ITC pharmacist or the ITC Senior Pharmacy Technician will ascertain if the ITC was administered and then verbally, or via Trust e-mail, notify the ITC lead of ITC administered outside normal working hours.
- The ITC will be delivered to the designated ITC administration point by the ITC Consultant and the administration of ITC **MUST** be supported by a competent Paediatric oncology / Adult haemato-oncology nurse, whose name appears on the Trust ITC Register. Although administration will be in accordance with the Trust ITC Policy, all Health Care Professionals involved in dispensing, checking and administering ITC outside normal working hours **MUST** also confirm that the drug details on the manufactured drug label correspond to those on the dispensing label. N.B. Following issue from pharmacy, the expiry date will only facilitate administration, provided it is stored in accordance with the Trust ITC Policy.
- The ITC Consultant **MUST** notify the ITC Lead, in writing, of the details pertaining to the requirement for administration outside normal working hours, including the actions taken and the outcome within 24 hours. A copy letter is sent to the ITC pharmacist, who logs the letter in the ITC Master File. The ITC pharmacist and ITC Lead are responsible for monitoring the frequency of out of hours ITC administrations.

6.16. Giving an intrathecal in a non-designated area

ITC must only be administered with the designated areas which are

Adult Haemato-oncology / Oncology

Ward 33 FRH (Intrathecal Chemotherapy Room)

Ward 36 FRH (Intrathecal Chemotherapy Room)

Paediatric Oncology

Children's Theatres – New Victoria Wing RVI (20 or 21-25) (irrespective of the need for anaesthetic)

Only in exceptional circumstances may they be given outwith a designated area (eg ICU or radiology). This must be a clear decision that to move the patient or prolong anaesthetic for transfer would increase the risk to the patient

There must be a clear clinical need for the procedure to be undertaken immediately and in these circumstances a Consultant, whose name appears on the Trust ITC Register, must clearly document in the patient's medical notes the risk / benefit analysis that has led to their decision to treat the patient outside a designated area

- The ITC must be administered by an **ITC Consultant** and supported by a nurse

on the ITC checker and a third checker who is experienced in doing this (senior theatre nurse)

- The ITC Consultant **MUST** notify the ITC Lead, in writing, of the details pertaining to the requirement for administration outside of designated area, including the actions taken and the outcome within 24 hours. A copy letter is sent to the ITC pharmacist, who logs the letter in the ITC Master File. The ITC pharmacist and ITC Lead are responsible for monitoring the frequency using a non-designated area

6.17. Being prepared to challenge

All staff involved with the management of patients receiving ITC are actively encouraged to challenge colleagues, irrespective of their seniority, if:

Policies and procedures are not being followed.

The actions of an individual could increase the potential risk to a patient.

Challenging a colleague is not viewed adversely, but as an additional check to improve patient safety and reduce potential risks.

6.18. Error / Incident reporting

The ITC Lead Clinician and ITC pharmacist must be notified immediately of any error, incident or near miss associated with the prescribing, dispensing, checking or administration of ITC. These individuals are then responsible for:

- Undertaking a root cause analysis
- Recommending any changes necessary
- Oversee the implementation of any changes

N.B. ALL errors, incidents or near misses must be reported in line with Trust procedures (NuTH NHS Trust 2010b).

7. Training

Refer to section 6.3 on Education, Training and competency assessment

8. Equality and diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This policy has been appropriately assessed.

9. Monitoring Compliance

The Trust ITC lead is responsible for initiating the review of the Trust ITC Policy, which reflects the National ITC guidance. The Trust ITC policy will be reviewed bi-annually or more regularly if required. The Trust Lead Chemotherapy nurse, in collaboration with the Matrons, is responsible for ensuring that hard copies of the National ITC Guidelines and the Trust ITC Policy are kept up to date in all wards / departments (Section 2 & Appendix 1). An audit of documentation will be carried out during the life of this policy.

N.B The ITC pharmacist is responsible for co-ordinating the review and authorisation of

all additional documentation that supports the administration of ITC within the Trust.

Standard / process / issue	Monitoring and audit			
	Method	By	Committee	Frequency
Number of ITC doses administered by each division	Pharmacy workload records.	Lead ITC pharmacist	Chemotherapy ITC	Annually
Number of procedures carried out by each member of staff on the individual ITC registers	Pharmacy records. Nursing and medical records of ITC doses given.	Training lead for each area	Chemotherapy ITC	Annually
Completeness of ITC records filed in patients notes	Review of 75% of notes of patients who received ITC	Trust ITC lead	Chemotherapy ITC	Bi-annually
Availability of up-to-date hard copies of register at involved locations.	Review of involved locations.	Lead ITC pharmacist	Chemotherapy ITC	Bi-annually
Frequency of ITC doses administered out-of hour	Out of hours chemotherapy records	Trust ITC lead	Chemotherapy ITC	Annually

10. Consultation and review

This policy has been produced by the Directorate of Pharmacy and Medicines Management in consultation with the Trust Intrathecal Chemotherapy designated lead/.

11. Implementation (including raising awareness)

The ITC Lead Clinician and the main author of this policy will ensure that all staff working within Adult haematology and Paediatric Oncology are aware of this policy and liaise, as required, with the relevant individuals to ensure implementation.

12. References

Department of Health (HSC 2008/001) *Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy*. Department of Health. London.

National Patient Safety Agency (2008) Rapid Response Report NPSA/2008/RRR004 – Using Vinca Alkaloid Minibags (Adult/Adolescent Units)

NHS England Patient Safety Alert, Stage Three: Directive non-Luer Spinal (Intrathecal) devices for chemotherapy. February 2014

Department of Health (2001) *Reference guide to consent for examination or treatment*. <http://www.dh.gov.uk/assetRoot/04/01/90/79/04019079.pdf>

NuTH NHS Trust (2017) *Anticancer Medicines Policy AND Guidance on the Management of Patients receiving Cytotoxic Chemotherapy for Non Malignant Conditions* <http://intranet/Policies/drugs/AnticancerMeds201006.pdf>

NuTH NHS Trust (2012) [Management and Reporting of Accidents and Incidents](#)

13. Associated documentation

Department of Health (2011) *Manual of Cancer Services*. Department of Health. London.

Nursing & Midwifery Council (2004) *Guidelines for the administration of medicines*. NMC. London.

Nursing and Midwifery Council (2002) *Guidelines for Records and Record Keeping*. NMC London.

NuTH NHS Trust (2012) [Injectable Medicines Policy](#)

NuTH NHS Trust (2012). [Medical Device Management Policy](#)

NuTH NHS Trust (2013) [Purple book Procedures for the prescribing, recording and administration of medicines.](#)

NuTH NHS Trust (2013) [Medicine Policy - The Newcastle upon Tyne Hospitals NHS Foundation Trust](#)

Royal College of Nursing (1998) *The administration of cytotoxic chemotherapy: recommendations*. RCN. London.

Appendix 1

Areas where hard copies of the Trust ITC policy and National Guidance can be found

Adult Haematology/Oncology

- Ward 33 FRH
- Ward 36 (Day unit) FRH
- Ward 34 FRH
- Ward 35 FRH
- Bobby Robson Clinical Trials Unit

Paediatric Oncology.

- Children's Theatres – New Victoria Wing RVI
- Ward 4 GNCH
- Ward 14 Paediatric Oncology Day Unit GNCH

Pharmacy

- Pharmacy Production Unit RVI
- Pharmacy New Victoria Wing RVI (in cool store next to IT locker)
- NCCC Cytotoxic Dispensing Unit

Appendix 2

ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY

Information for all staff working on Ward 33 FH, Ward 34 FH, Ward 36 FH, Ward 4 GNCH RVI, Ward 14 Day Unit GNCH Children's Theaters New Victoria Wing RVI

As you will be aware, these are specialist areas that administer different types of chemotherapy via various routes. Due to the specialist nature of these clinical areas your involvement with chemotherapy will be minimal unless you have undertaken specialist training

This Trust has strict policies to adhere to regarding the administration of Intrathecal chemotherapy.

The Administration of Intrathecal Drugs is a procedure that is performed in these specialist areas on a regular basis. There is a Trust policy relating to this procedure that is available in the Intrathecal Resource File held in the designated treatment rooms/theatres.

Under no circumstances will you be asked to perform any part of this procedure unless you have undertaken specialist training deemed competent and appear on the Trust ITC Register

If you are asked to accept delivery of an Intrathecal drug from the pharmacy staff – you must refuse. Drugs may only be accepted for delivery by a competent doctor whose name appears on the Trust ITC Register.

If you are asked to check an Intrathecal drug with a doctor – you must refuse.

If you are unsure about what to do please ask a member of the Nursing Team and they will be happy to help you.

Only competent nurses whose name appears on the Trust ITC Register will be able to check intrathecal drugs with a competent doctor. These nurses are listed on a register in the designated treatment rooms / theatres and on the Trust intranet.

Appendix 3 Copy of ITC prescription

Please write prescription in ball-point pen on a firm surface

THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST INTRATHECAL CHEMOTHERAPY PRESCRIPTION CHART

Name			Protocol		
Hospital No.			Ward		
Date of Birth			Date & Time Required *		
Drug Prescribed by (Consultant/Specialist Registrar)	Signature	Print Name	Date		

In the event of the non-administration of any prescribed dose, enter an X in the 'drug administered by' column. The reason should be specified in the Administration Comments section						
Drug Name	Dose	Route	Batch Number	Expiry	Administration Comments	Time & Date
Confirmation that IV cytotoxic drugs prescribed for above date* have been administered: (Doctor, Pharmacist)						
Drug released from pharmacy by: (Pharmacist/Technician)						
Drug accepted for delivery by: (Consultant or Specialist Registrar)						
Administration checked by: (Trained chemotherapy nurse/Senior theatre nurse)		Chemotherapy Nurse			Chemotherapy Nurse	
		Theatre Nurse			Theatre Nurse	
Drug administered by: (Consultant or Specialist Registrar)						
Administration checked by patient or their representative (Not applicable if administered in Theatre)						

* This prescription chart is designed to comply with National Guidance on the safe administration of intrathecal chemotherapy and must be used in conjunction with local Trust policy on safe administration of intrathecal chemotherapy

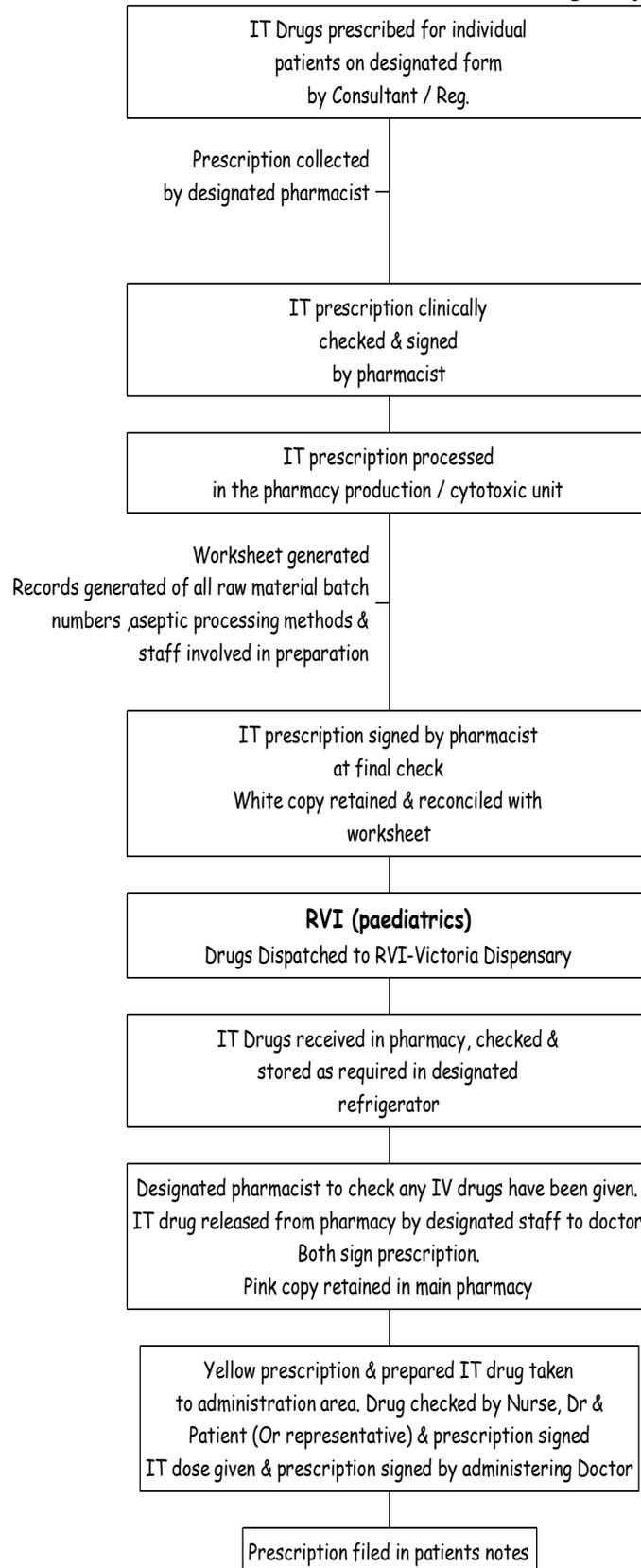
Yellow = Administration Sheet

Pink = Pharmacy Dispatch Record

White = Cytotoxic Dispensing Unit Record

Appendix 4 ITC Prescription Chart life cycle flow diagram

Do we need to retain this? If so to be amended once policy finalised



Appendix 4

Appendix 4a

ITC Administration Procedure (Lumbar Puncture)

- Small Dressing Pack
- Sterile gloves
- Lumbar puncture needle (22G; 1.5 inches, 2.5 inches or 3.5 inches depending on patient size)
- X 1 green needle
- X 1 orange needle
- X1 10 ml non- luer lock syringe
- Sterile sample pot
- Mediwipes
- Sharps box
- Sterile towel
- Liquid soap / Handrub
- Intrathecal chemotherapy
- Betadine (Antiseptic solution, povidone-iodine 10% in aqueous solution)
- Elastoplast or OP-site spray and a small piece of cotton wool.

For procedures performed under local anaesthetic - 1% Lidocaine 10 ml

- 1 Remove watch and rings and wash hands and forearms thoroughly for one minute.
- 2 Dry hands on sterile paper towel.
- 3 Assistant to clean work surface / tray with Mediwipes and open dressing pack without touching the inside and place it onto the work surface.
- 4 Don sterile gloves being careful not to touch the outer part of gloves with your ungloved hand.
- 5 Assistant to open syringe and needles onto the sterile sheet and place Betadine in the container provided (for skin preparation).
- 6 Check that the patient is due for ITC chemotherapy by cross-checking against the patient's treatment protocol / flowsheet in the medical notes.
- 7 Open ITC from its pharmacy packet and place on sterile sheet. Check ITC drug and dosage to be given from the ITC prescription chart and check the labelled syringe containing the ITC (Section 15 Trust ITC Policy). This must be checked by the Registered ITC Consultant / ST3 administering the chemotherapy together with the Registered Paediatric oncology / Adult haemato-oncology nurse and the senior theatre nurse, patient, relative or guardian.
- 8 Place the syringe containing the ITC on the sterile sheet.
- 9 When the patient is in the lateral supine position with the legs appropriately

positioned and the patient is ready for the procedure, (confirmed by the anaesthetist if the patient is under a general anaesthetic); clean the skin twice with the sterile gauze and Betadine from the dressing pack.

- 10 Clean excess Betadine from the patient's skin.
- 11 Place a sterile towel or piece of gauze over the anterior superior iliac spine and select the intravertebral disc that is perpendicular to the anterior superior iliac spine.
- 12 If the patient is NOT having a general anaesthetic infiltrate the skin and disc space with 1% Lidocaine.
- 13 Insert the lumbar puncture needle in this disc space until it is in the cerebrospinal fluid (CSF) space.
- 14 Withdraw the stylet.
- 15 If CSF flows freely then have the assistant catch eleven drops in a sterile universal container (sterile sample pot) for cytospin analysis.
- 16 If the CSF does not flow, or flows with difficulty, reinsert the stylet and adjust the lumbar puncture needle until the CSF flow is satisfactory.
- 17 Connect the syringe containing the ITC onto the end of the lumbar puncture needle.
- 18 If the patient is under the influence of a general anaesthetic check with the anaesthetist that they are happy for you to proceed with an injection of ITC.
- 19 Inject the ITC slowly into the CSF via the lumbar puncture needle.
- 20 After completion, withdraw the needle with syringe attached and have the assistant straighten the patient's legs. If appropriate, spray the skin with OP-site spray and place a small piece of cotton wool over the site to minimise leakage, or apply a dressing.
- 21 Dispose of the sharps from the work surface in the appropriate sharps bin/s and clean the work surface.
- 22 The Registered ITC Consultant / ST3 must sign and date the ITC Prescription Chart to confirm that the ITC has been given. The nurse checker and second checker MUST also sign and date the ITC Prescription Chart to confirm their role in the procedure (Section 15 Trust ITC Policy).
- 23 The Registered ITC Consultant / ST3 must write in the patient's notes describing the procedure performed and confirming the time and date.
- 24 Dispose of equipment in line with Trust guidelines / procedures (NuTH NHS Trust 2010)

Appendix 4b

ITC Administration Procedure (Intraventricular (Ommaya) Reservoir)

- Small Dressing Pack
- Sterile gloves
- 25 gauge butterfly needle (e.g. 20 mm: 0.75 inch needle)
- X 1 green needle
- X1 10 ml non-luer lock syringe
- X1 10ml sodium Chloride 0.9% for injection
- Sterile sample pot
- Mediwipes
- Sharps box
- Sterile towel
- Liquid soap / Handrub
- Intrathecal chemotherapy
- Betadine (Antiseptic solution, povidone-iodine 10% in aqueous solution)
- Elastoplast or OP-site spray and a small piece of cotton wool.

For intraventricular procedure EMLA cream may be applied at reservoir site one hour prior to procedure

1. Remove watch and rings and wash hands and forearms thoroughly for one minute.
2. Dry hands on sterile paper towel.
3. Assistant to clean work surface / tray with Mediwipes and open dressing pack without touching the inside and place it onto the work surface.
4. Don sterile gloves being careful not to touch the outer part of gloves with your ungloved hand.
5. Assistant to open syringe and needles onto the sterile sheet and place Betadine in the container provided (for skin preparation).
6. Draw up 2ml Sodium Chloride 0.9% for injection, remove green needle. Dispose of green needle in sharps box.
7. Check that the patient is due for ITC chemotherapy by cross-checking against the patient's treatment protocol / flowsheet in the medical notes.
8. Open ITC from its pharmacy packet and place on sterile sheet. Check ITC drug and dosage to be given from the ITC prescription chart and check the labeled syringe containing the ITC (Section 15 Trust ITC Policy). This must be checked by the Registered ITC Consultant / ST3 administering the chemotherapy together with the Registered Paediatric oncology / Adult haemato-oncology nurse and the senior theatre nurse, patient, relative or guardian.
9. Place the syringe containing the ITC on the sterile sheet.

10. When the patient is positioned appropriately, and the patient is ready for the procedure, remove EMLA cream if used; clean the skin twice with the sterile gauze and Betadine from the dressing pack.
11. Clean excess Betadine from the patient's scalp.
12. Place a sterile towel or piece of gauze below the site of the Ommaya reservoir.
13. Using a 25-gauge butterfly needle insert the needle in to the centre of the reservoir. Ideally, the precise position of entry should be varied between successive punctures
14. Using a 10ml syringe withdraw the volume of fluid to be injected into the reservoir (i.e. total volume of drug/s plus 2ml Sodium Chloride 0.9% for injection flush), slowly from the reservoir, over 2 minutes prior to drug/s administration. In total no more than 10ml of CSF should be removed at any one procedure.
15. Eleven drops of CSF should be collected in a sterile universal container (sterile sample pot) for cytospin analysis.
16. Connect the syringe containing the ITC onto the end of the butterfly needle. ITC is administered over 30 seconds to 60 seconds (depending on volume). When more than one ITC is given during the same procedure (e.g. when using triple therapy) no flush is required between ITC.
17. When all required ITC have been delivered, flush the reservoir with 2ml of Sodium Chloride 0.9% for injection to ensure ITC has reached the ventricles
18. While the Sodium Chloride 0.9% is being injected and near completion withdraw the butterfly needle with syringe attached. If appropriate, spray the skin with OP-site spray or apply a dressing.
19. Dispose of the sharps in the appropriate sharps bin/s and clean the work surface.
20. The Registered ITC Consultant / ST3 must sign and date the ITC Prescription Chart to confirm that the ITC has been given. The nurse checker and second checker MUST also sign and date the ITC Prescription Chart to confirm their role in the procedure (Section 15 Trust ITC Policy).
21. The Registered ITC Consultant / ST3 must write in the patient's notes describing the procedure performed and confirming the time and date.
22. Dispose of equipment in line with Trust guidelines / procedures (NuTH NHS Trust 2010)

APPENDIX 5

Dilution and labelling of Vinca Alkaloids for intravenous use

Dilution

To reduce the risk of inappropriately administering Vincristine and other Vinca Alkaloids via the intrathecal route, and in order to comply with current National ITC guidelines the following rules apply:

Ward	Presentation of Vinca alkaloids
Ward 4 RVI Paediatric Oncology Day Unit (PODU/14DU)	Vincristine Doses equal to or less than 1mg diluted to a 0.1mg/ml (100micrograms/ml) solution, or to a final volume of 10ml, presented in a syringe. Doses greater than 1mg diluted to a final volume of 20ml presented, in a syringe. Vinblastine, Vindesine and Vinorelbine Diluted to a final volume of 20ml presented in a syringe.
Ward 33 FRH	Doses of Vincristine, Vinblastine, Vindesine and Vinorelbine must always be added to a 50ml minibag of Sodium Chloride 0.9% Injection
Ward 34 FRH	
Ward 35 FRH	
Ward 36 FRH	
Bobby Robson Clinical Trials Unit	

Note: The recommended presentation of vinca alkaloid treatment is not based on the age of the patient, but on where treatment is given. This may result in some patients having vinca alkaloids diluted in different ways on some occasions.

Labelling

The labels for Vinca Alkaloids and drugs with similar life threatening consequences, MUST also clearly warn of the consequences of administration by other routes e.g. "For Intravenous Use Only - fatal if given by other routes".

Exception: Presentation of Vinca alkaloids outwith National ITC Guidelines

The only exceptions to the above presentation requirements is where :

1. Combination chemotherapy of doxorubicin/vincristine is required in a number of regimes for example VAD, EPOCH and C-VAD.

Doxorubicin and vincristine will be combined and presented in an elastomeric infusion for intravenous administration. The required dose/volume of each drug will be further diluted with glucose 5% or sodium chloride 0.9% and the elastomeric infusion will contain a final volume of 48ml to be administered intravenously over 96 hours.

2. Vincristine is given as an infusion over 24 – 96 hours as required within specific protocols.

Register of Those Accredited for Pharmacy Aspects of Intrathecal Chemotherapy

NAME		POSITION	PHARMACIST CLINICAL CHECK	WORKSHEET & IN- PROCESS CHECKS	TECHNICIAN DISPENSE & IN-PROCESS CHECKS	TRANSPORT & ISSUE	REVIEW DATE	ASSESSOR
CLINICAL PHARMACISTS								
Susan	Firbank	Clinical Pharmacist	√	X	X	√	Feb-20	Sumantha Gabriel
Sumantha	Gabriel	Clinical Pharmacist	√	X	X	√	Apr-19	Denise Blake
Emma	Groves	Clinical Pharmacist	√	X	X	√	Jul-19	Sumantha Gabriel
Elizabeth	Reay	Clinical Pharmacist	√	X	X	√	Nov-19	Sumantha Gabriel
Tom	Thornton	Clinical Pharmacist	√	X	X	√	Oct-19	Sumantha Gabriel

√ = authorised, X = not authorised

Register Created By: Sumantha Gabriel, ITC Pharmacist

Register Authorised By:



PRODUCTION PHARMACISTS

Register of Those Accredited for Pharmacy Aspects of Intrathecal Chemotherapy

NAME		POSITION	PHARMACIST CLINICAL CHECK	WORKSHEET & IN- PROCESS CHECKS	TECHNICIAN DISPENSE & IN-PROCESS CHECKS	TRANSPORT & ISSUE	REVIEW DATE	ASSESSOR
Callum	Brown	Production Pharmacist	X	√	X	X	May-19	Christine Middleton
Ahmed	Cader	Production Pharmacist	X	√	X	X	Nov-19	Louise Horncastle
John	Horncastle	Pharmacist	X	√	X	X	Oct-19	Christine Middleton
Karen	Kerton	Production Pharmacist	X	√	X	X	Nov-19	Louise Horncastle
Paul	Lobb	Production Pharmacist	X	√	X	X	Apr-19	Christine Middleton
Nicole	McIntyre	Production Pharmacist	X	√	X	X	Aug-19	Louise Horncastle
Sophie	Thompson	Production Pharmacist	X	√	X	X	Sep-19	Christine Middleton

√ = authorised, X = not authorised

Register Created By: Sumantha Gabriel, ITC Pharmacist

Register Authorised By:



Register of Those Accredited for Pharmacy Aspects of Intrathecal Chemotherapy

NAME		POSITION	PHARMACIST CLINICAL CHECK	WORKSHEET & IN- PROCESS CHECKS	TECHNICIAN DISPENSE & IN-PROCESS CHECKS	TRANSPORT & ISSUE	REVIEW DATE	ASSESSOR
PHARMACY TECHNICIANS								
Aaron	Dickinson	Production Technician	X	X	√	X	Jan-20	Christine Middleton
Paul	Blackwell	Production Technician	X	X	√	X	May-19	Christine Middleton
Marc	Holbrow	Production Technician	X	X	√	X	Jan-20	Christine Middleton
Joyce	Kirton	Production Technician	X	X	√	X	Oct-19	Christine Middleton
David	Martin	Production Technician	X	X	√	X	Nov-19	Christine Middleton
Helen	McLeod	Production Technician	X	X	√	X	Feb-20	Christine Middleton
Louise	McKernan	Production Technician	X	X	√	X	Apr-19	Christine Middleton
Christine	Middleton	Production Technician	X	√	X	X	Jan-20	Nicholas Moyse
Paul	Murphy	Production Technician	X	X	√	X	May-19	Christine Middleton

√ = authorised, X = not authorised

Register Created By: Sumantha Gabriel, ITC Pharmacist

Register Authorised By:



Register of Those Accredited for Medical Aspects of Intrathecal Chemotherapy

NAME		POSITION	PRESCRIBE	ADMINISTER	PATIENT REVIEW / CONSENT	REVIEW DATE	ASSESSOR
MEDICAL STAFF (PAEDS)							
Tasmin	Arif	Trust Doctor	√	√	√	Oct-19	Prof Simon Bailey
Simon	Bailey	Consultant Paed. Onc.	√	√	√	May-19	Dr Peter Carey
Peter	Carey	Consultant Paed. Onc.	√	√	√	Oct-19	Prof Simon Bailey
Sunita	Dhir	Specialty Doctor	√	√	√	Sep-19	Dr Geoff Shenton
Miriam	Munoz	Trust Doctor	√	√	√	Nov-19	Dr Geoff Shenton
Aqeela	Rashid	SpR	√	√	√	Jul-19	Prof Simon Bailey
Christine	Rawlings	Trust Doctor	√	√	√	Nov-19	Dr Geoff Shenton
Wing	Roberts	SpR	√	√	√	Oct-19	Prof Simon Bailey
Geoff	Shenton	Consultant Paed. Onc.	√	√	√	Sep-19	Dr Peter Carey
Frederik	Van Delft	Consultant Paed. Onc.	√	√	√	Apr-19	Dr Peter Carey

√ = authorised, X = not authorised

Register Created By: Sumantha Gabriel, ITC Pharmacist

Register Authorised By:



Register of Those Accredited for Medical Aspects of Intrathecal Chemotherapy

NAME		POSITION	PRESCRIBE	ADMINISTER	PATIENT REVIEW / CONSENT	REVIEW DATE	ASSESSOR
MEDICAL STAFF (ADULT HAEM)							
Michelle	Lannon	Consultant Haematologist	√	√	√	Feb-20	Dr Gail Jones
Gail	Jones	Consultant Haematologist	√	√	√	Jun-19	Prof Graham Jackson
Tobias	Menne	Consultant Haematologist	√	√	√	Jun-19	Prof Graham Jackson
Nitha	Ramachandran	SpR	√	√	√	Feb-20	Dr Gail Jones
Jennifer	Swieton	SPR	√	√	√	May-19	Prof Graham Jackson
Luke	Winn	SpR	√	√	√	May-19	Prof Graham Jackson
Emily	Watts	SpR	√	√	√	Jan-20	Dr Gail Jones
Rebecca	Walker	SpR	√	√	√	Oct-19	Prof Graham Jackson

√ = authorised, X = not authorised

* SpR also on the register for Paediatric oncology between the following dates:

Register Created By: Sumantha Gabriel, ITC Pharmacist

Register Authorised By:



Register of Those Accredited for Nursing Aspects of Intrathecal Chemotherapy

NAME	POSITION	CHEMO NURSE CHECK 1	REVIEW DATE	ASSESSOR	
CHEMOTHERAPY NURSE CHECKERS (Paeds)					
Emma	Castonguay	Sister	√	Feb-20	Geoff Shenton
Linda	Coates	Staff Nurse	√	Jul-19	Dr Peter Carey
Bethany	Ewen	Staff Nurse	√	Nov-19	Dr Peter Carey
Laura	Keen	Staff Nurse	√	Jul-19	Dr Peter Carey
Georgina	Mellor	Staff Nurse	√	Feb-20	Prof S Bailey
Sharon	Phillipson	Staff Nurse	√	Aug-19	Dr Peter Carey
Christina	Johnson	Staff Nurse	√	Jun-19	Dr Simon Bailey

√ = authorised, X = not authorised

Register Created By: Sumantha Gabriel, ITC Pharmacist



Register Authorised By:

Register of Those Accredited for Nursing Aspects of Intrathecal Chemotherapy

NAME	POSITION	CHEMO NURSE CHECK 1	REVIEW DATE	ASSESSOR	
CHEMOTHERAPY NURSE CHECKERS (ADULT HAEM)					
Girlie-May	Bencito	Staff Nurse	√	Jul-19	Prof Graham Jackson
Zoe	Collins	Sister	√	Mar-20	Prof Graham Jackson
Jane	Aston	Staff Nurse	√	Oct-19	Prof Graham Jackson
Karen	Kerby	Staff Nurse	√	Apr-19	Prof Graham Jackson
Hazel	Mason	Staff Nurse	√	Apr-19	Prof Graham Jackson
Joan	Rodham	Staff Nurse	√	Jun-19	Prof Graham Jackson
Dot	Chiltern	Staff Nurse	√	Jun-19	Prof Graham Jackson
Amanda	Henderson	Staff Nurse	√	Jun-19	Prof Graham Jackson
Kathryn	McRae	Staff Nurse	√	Jun-19	Prof Graham Jackson
Nikki	Shepard	Staff Nurse	√	Apr-19	Prof Graham Jackson
Katherine	Wight	Nurse Specialist	√	Apr-19	Prof Graham Jackson
Claire	Wilson	Sister	√	May-19	Prof Graham Jackson

√ = authorised, X = not authorised

Register Created By: Sumantha Gabriel, ITC Pharmacist



Register Authorised By:

Equality Analysis Form A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

PART 1

1. **Assessment Date:**
2. **Name of policy / strategy / service:**
3. **Name and designation of Author:**
4. **Names & designations of those involved in the impact analysis screening process:**
5. **Is this a:** Policy Strategy Service
Is this: New Revised
Who is affected Employees Service Users Wider Community
6. **What are the main aims, objectives of the policy, strategy, or service and the intended outcomes?** *(These can be cut and pasted from your policy)*
7. **Does this policy, strategy, or service have any equality implications?** Yes No
- If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:**

8. Summary of evidence related to protected characteristics

Protected Characteristic	Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups	Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address (<i>by whom, completion date and review date</i>)	Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? (<i>by whom, completion date and review date</i>)
Race / Ethnic origin (including gypsies and travellers)	No reference is made within the policy to any particular racial group		
Sex (male/ female)	No reference is made within the policy to any particular sex		
Religion and Belief	No reference is made within the policy to any particular religion or belief		
Sexual orientation including lesbian, gay and bisexual people	No reference is made within the policy to any particular sexual orientation		
Age	No reference is made within the policy to any particular age		
Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section	No reference is made within the policy to any particular disability		
Gender Re-assignment	No reference is made within the policy to Gender Re-assignment		
Marriage and Civil Partnership	No reference is made within the policy to Marriage and Civil Partnership		
Maternity / Pregnancy	No reference is made within the policy to Maternity / Pregnancy		

9. Are there any gaps in the evidence outlined above? If ‘yes’ how will these be rectified?

No

10. Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.