INTRATHECAL AND INTRAVENTRICULAR CYTOTOXIC CHEMOTHERAPY IN ADULTS AT KMH – SAFE ADMINISTRATION POLICY

POLICY

Reference	CPG-TW-MM-ICCinA
Approving Body	Joint Drugs and Therapeutics/Medicines Optimisation Committee
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Version	17.0
Summary of Changes from Previous Version	Added a statement regarding our new online intrathecal register
Supersedes	v16.0, issued 28th December 2018 to Review Date December 2019
Document Category	• Clinical
Consultation Undertaken	• Steve Jones, Consultant Haematologist • Tim Moorby, Consultant Haematologist • Suzanne Corney, Lead AOS nurse specialist • Julie Binney, Senior technician Pharmacy Aseptic Dispensing Unit (ADU) • Joint Drugs and Therapeutics/Medicines Optimisation Committee
Date of Completion of Equality Impact Assessment	December 2019
Date of Environmental Impact Assessment (if applicable)	December 2019
Legal and/or Accreditation Implications	This Policy provides for local interpretation and implementation of the HSC 2008/001 - National Guidance on the Safe Administration of intrathecal cytotoxic chemotherapy, NPSA/2008/RRR004 - Using vinca alkaloid minibags and NPSA/2011/PSA001 Safer spinal (intrathecal), epidural and regional devices.
Target Audience	Pharmacy aseptic unit (All members of staff whose names appear on the intrathecal register) Haematology department (Consultants and nurses whose names appear on the intrathecal register)
Review Date	March 2022 (ext[1] agreed via chemo meeting 051120, ext[2] due to meeting dates)
Sponsor (Position)	Dr Steve Jones (Lead Haematology Consultant)
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Lead Division/ Directorate	Diagnostics & Outpatients
Lead Specialty/ Service/ Department	Medicines Management (Pharmacy)
Position of Person able to provide Further Guidance/Information	Dr Steve Jones (Consultant Haematologist)

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
1. Screening chemotherapy (Pharmacy) 2. Preparation of Intrathecal products (Pharmacy)	Dec 2019 Dec 2019

CONTENTS

1.0 INTRODUCTION

1.1. Within Sherwood Forest Hospitals NHS Foundation Trust intrathecal cytotoxic chemotherapy is only administered to adults and may only be **prescribed** by a Consultant Haematologist whose name appears on the designated register. It may be administered by either a Consultant Haematologist or a Haematology Specialty Doctor whose name appears on the designated register. This policy also applies to intraventricular cytotoxic chemotherapy.

1.2. This policy is issued and maintained by the INTRATHECAL CYTOTOXIC CHEMOTHERAPY Lead on behalf of the Trust, at the issue defined on the front sheet, which supersedes and replaces all previous versions.

2.0 POLICY STATEMENT

2.1. The purpose of the policy is to ensure compliance with HSC 2008/001 National Guidance on the Safe Administration of intrathecal cytotoxic chemotherapy.

3.0 DEFINITIONS/ ABBREVIATIONS

The Trust:	means the Sherwood Forest Hospitals NHS Foundation Trust
Staff:	means all employees of the Trust including those managed by a third party organisation on behalf of the Trust.
The Local Policy:	This policy
WTC:	Welcome Treatment Centre
ADU:	Aseptic Dispensing Unit
ChemoCare:	KMH e-prescribing system for prescribing chemotherapy for cancer treatment

4.0. ROLES AND RESPONSIBILITIES

4.1 The Chief Pharmacist is the designated Trust Lead for Intrathecal Cytotoxic Chemotherapy and carries responsibility for ensuring compliance with National intrathecal cytotoxic chemotherapy guidance and relevant measures relating to cancer unit accreditation.

4.2 There is no sub-division of the intrathecal cytotoxic chemotherapy service and therefore the Trust Lead takes responsibility for the whole service.

4.3 The Lead Consultant for Malignant Haematology has the overall responsibility for the education and training of the staff within the intrathecal cytotoxic chemotherapy service. He/She ensures the induction training and annual updates are undertaken and an appropriate number of competent staff are on the intrathecal register at all times. This responsibility is delegated to the Lead Clinical Oncology and Nutritional Services Advanced Pharmacist for the Pharmacy staff.

4.4 Responsibilities of each individual authorised to handle intrathecal chemotherapy, i.e. Haematology specialist consultants and staff doctors, Chemotherapy nurses, Pharmacists, Pharmacy technicians and assistants registered on the intrathacal register, will be explained within the bulk of the policy narrative.

5.0. APPROVAL

Joint Drugs and Therapeutics/Medicines Optimisation Committee

6.0. DOCUMENT REQUIREMENTS (NARRATIVE)

6.1 Distribution

6.1.1 Copies of this Policy, the Register and the National Guidance are held in the following locations:

- WTC – Haematology Handbook
- Haematology Department – Lead Consultant for Malignant Haematology
- Pharmacy – Aseptic Dispensing Unit

6.1.2 A copy of this policy and the National guidance is also available on the Trust's intranet

6.1.3 The Trust's policy will be reviewed at least annually and/or following changes to National guidance.

6.1.4 The Chief Pharmacist will co-ordinate the annual review of the Trust's policy

6.1.5 A document control policy is used to ensure only current versions of the policy are distributed and published on the Trust intranet.

6.1.6 The 'designated Trust Lead' will be responsible for ensuring updated copies of National and local guidelines are issued to Lead Pharmacist Clinical Oncology & Nutrition and Lead Chemotherapy Nurse who will be responsible for replacing copies within their respective areas.

6.1.7 Details of this policy will be communicated during training and updating of all staff on the intrathecal cytotoxic chemotherapy registers.

6.2 Intrathecal Cytotoxic Chemotherapy Register

6.2.1 There will be THREE registers of designated personnel (pharmacy, nursing, medical) who have been trained and certified competent in the area within their profession following tasks with respect to intrathecal cytotoxic chemotherapy:

- Medical staff register
  - Prescribing
  - Check (with nurse)
  - Administration

- Pharmacy staff register
  - Dispensing:
    - Clinical check of the prescription (verification)
    - Check assembly of ingredients
    - Preparation
    - In-process check
    - Final check/release
  - Transportation

- Nursing staff register
  - Check (with doctor)

6.2.2 The competency assessment for each of the registers is performed by the following:

- Medical staff register – Lead Consultant for Malignant Haematology
- Pharmacy staff register – Lead Pharmacist Clinical Oncology & Nutrition
- Nursing staff register – Lead Consultant for Malignant Haematology

6.2.3 The Chief Pharmacist as designated Trust Lead has overall responsibility for holding and approving staff on the register.

The master copy of the register is held in Pharmacy (within the Aseptic Dispensing Unit (ADU)). Hard copies of the registers will be kept in Pharmacy ADU. The Lead Consultant for Malignant Haematology will send an updated copy of the register to pharmacy every time a member of staff (nurse or doctor) is up dated. Old master copies of the register will be kept in Pharmacy for FIVE years.

An electronic copy of the list of everyone (Pharmacy staff, Nurses, Doctors) on the intrathecal register and the dates by which they need an update is produced, posted on the trust intranet and kept up to date by the Lead Pharmacist Clinical Oncology & Nutrition.

6.2.4 The frequency that staff perform their designated functions must be monitored and staff competency assessed with regards to whether they should remain on the register.

Individuals responsible for training staff (Lead Consultant for Malignant Haematology, Lead Pharmacist Clinical Oncology & Nutrition) must notify the Chief Pharmacist of any staff changes to the register. In the absence of the Chief Pharmacist, the Medical Director may sign the register.

6.3 Medical Staff Register

6.3.1 Only Consultant Haematologists will be registered to prescribe and administer intrathecal cytotoxic medicines. A Haematology Specialty Doctor may be registered to administer but **not** prescribe intrathecal cytotoxic medicines.

6.3.2 A suitably experienced doctor who is not on the register may perform the lumbar puncture under the supervision of a Consultant Haematologist, **but only the Consultant or Haematology Specialty Doctor whose name appears on the register will instil the cytotoxic medication intrathecally.**

6.4 Nursing Staff Register

Only nurses who have been assessed as competent to administer Cytotoxic Chemotherapy should check cytotoxic medicines for intrathecal administration. Any nurse who carries out the check must appear on the register.

6.5 Pharmacy Staff Register

Only Aseptic Dispensing Unit (ADU) staff will be registered to clinically check, dispense and transport intrathecal cytotoxic chemotherapy.

6.6 Prescribing

6.6.1 The plan for intrathecal treatment must be recorded by the Consultant Haematologist in the medical notes as well as a 'treatment note' on ChemoCare.

6.6.2 Only Consultant Haematologists will be registered to prescribe. A Haematology Specialty Doctor may be registered to administer but **not** prescribe intrathecal cytotoxic medicines.

6.6.3 Intrathecal cytotoxic chemotherapy must be prescribed on ChemoCare. It should be confirmed/authorised on ChemoCare as per the procedure for any other chemotherapy regimen only by a Consultant Haematologist whose name appears on the intrathecal cytotoxic chemotherapy register.

NB. The prescribers are not required to print off the prescription and sign their names in ink.

6.7 Pharmacist Clinical check:

6.7.1 Only a Pharmacist whose name appears on the intrathecal cytotoxic chemotherapy register will perform the clinical check of the prescription.

6.7.2 The Pharmacist has to ensure the Consultant prescriber is on the current intrathecal register. (A Haematology Specialty Doctor may be registered to administer but not prescribe intrathecal cytotoxic medicines.)

6.7.3 The protocol reference for clinical check of the intrathecal chemotherapy is available on the intranet similar along with other chemotherapy protocols.

6.7.4 Once the clinical check has been completed, the prescription must be signed on ChemoCare before printing so the Pharmacist's name appears clearly on the print off. The prescription will be printed at Pharmacy ADU on green paper to distinguish it from other chemotherapy prescriptions. The Pharmacists will then sign their names in ink next to their printed names in "Checked by" box on the printed-off prescription.

Any concerns at any stage of the process above must be discussed with the Lead Clinical Oncology Pharmacist. If unsatisfied with their response or in their absence, the Lead Consultant for Malignant Haematology or Chief Pharmacist must be contacted.

6.8 Pharmacist Approval of preparation:

Pharmacist approval is always required **before** ADU staff start the preparation process (i.e. formula checking the worksheet). Approval happens no earlier than the afternoon previous to the treatment day. This is **a separate stage** to the Pharmacist clinical check as explained above.

6.8.1 Only a Pharmacist whose name appears on the intrathecal cytotoxic chemotherapy register can approve start of the preparation process. This could be a different Pharmacist to the one who has already clinically checked the prescription.

6.8.2 The Pharmacist is responsible for ensuring that the ADU staff who will be involved in the preparation and check of the intrathecal item are on the current intrathecal chemotherapy register.

6.8.3 In order to approve the preparation of the intrathecal medicine, the pharmacist will need to complete and sign the "Release from Pharmacy and Acceptance in Clinical Area, Part A" (see below). This is to ensure that all other parenteral chemotherapy for this patient "authorised" within SEVEN days prior to the intrathecal administration day has been "completed" at the time of arrival of the intrathecal to the clinic. (i.e. the answers to questions below must either be "Yes" for both or "No" for the first question and "NA" for the second).

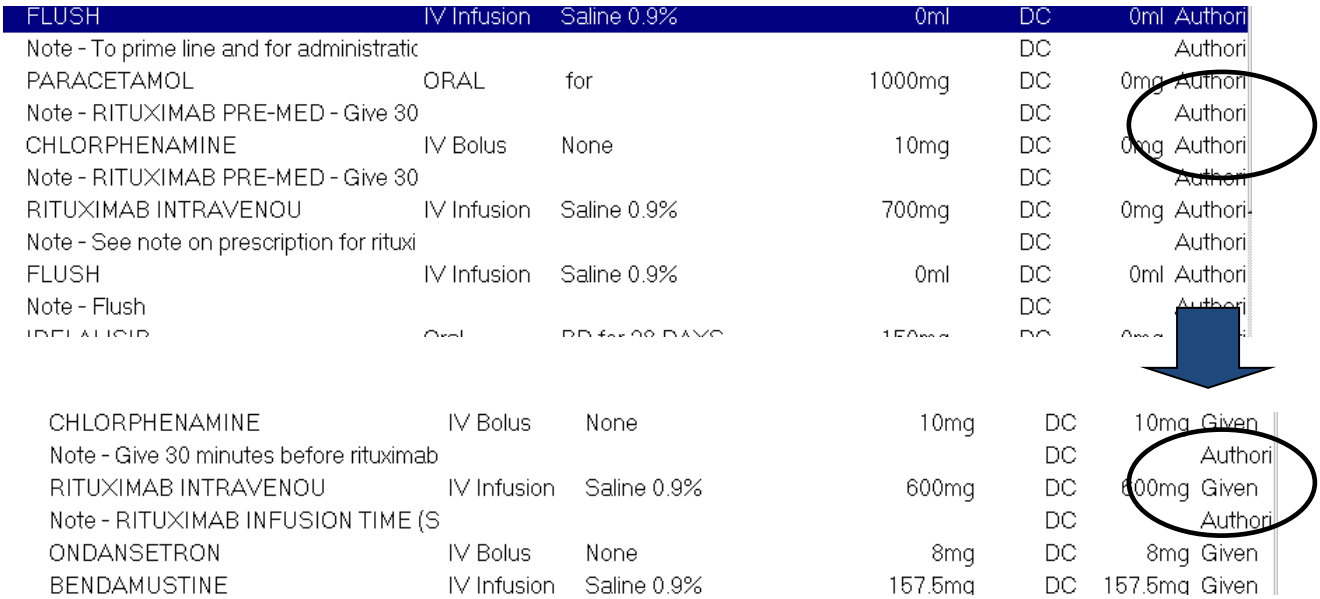
Release from Pharmacy and Acceptance in Clinical Area Chart Id.:319415

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

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

The steps below must be followed by the Pharmacist to establish this:

6.8.3.1 Check on ChemoCare to ensure all other parenteral chemotherapies within SEVEN days prior to the intrathecal are signed as "given" by the chemotherapy nurses. Once an item has been signed as "given" on ChemoCare, the status is locked on the system and cannot be changed by any user.



6.8.3.2 If there is any parenteral chemotherapy other than the intrathecal chemotherapy still showing as "authorised", it could be because they have either been (i) cancelled or (ii) administered and completed, but not signed off by the Nurses or (iii) administration has not been completed. In this

situation the pharmacist must call the Chemotherapy Nurses and investigate.

6.8.3.3 If the nurses confirm that the "authorised" parenteral chemotherapy other than the intrathecal chemotherapy has indeed been cancelled, the Chemotherapy Nurse, the Pharmacist or the Doctor must "unauthorise" the prescription on ChemoCare and defer it to a future date after the intrathecal day on the system. The intrathecal injection cannot be released until this amendment has been made on ChemoCare.

6.8.3.4 If the nurses confirm that the parenteral chemotherapy other than the intrathecal injection was administered, but not signed as "given" or is in the process of administration, the pharmacist has to wait until the Nurse signs them all as "given" on ChemoCare before instructing the ADU staff to start the intrathecal preparation.

6.8.3.5 In the rare event of ChemoCare being down, the Pharmacist must check the ADU batch list and "Dave" (ADU daily work diary) and talk to the Chemotherapy Nurses to ensure that no parenteral chemotherapy other than the intrathecal injection for this patient has been supplied to the patient for the past SEVEN days. The paper copy of the parenteral chemotherapy prescription (all injections other than the intrathecal chemotherapy) within the past SEVEN days, signed by the Nurses as administered must be seen by the Pharmacist before the intrathecal preparation starts in ADU.

6.8.3.6 Any concerns at any stage of the process above must be discussed with the Lead Clinical Oncology Pharmacist. If unsatisfied with their response or in their absence, the Lead Consultant for Malignant Haematology or Chief Pharmacist must be contacted.

6.9 Preparation Procedure:

Only a Pharmacy ADU Technician or Senior Assistant whose name appears on the current intrathecal cytotoxic chemotherapy register will:

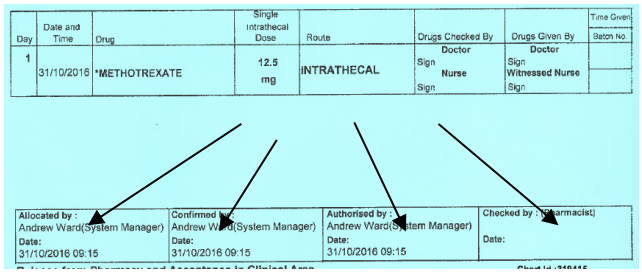
- Formula check the worksheets written for intrathecal chemotherapy (validated Technicians only)
- Assemble the necessary ingredients for preparation of the injection
- Check the assembly of the necessary ingredients and sundries (validated Technicians only)
- Prepare the intrathecal chemotherapy
- Carry out the in-process checks during the preparation of the injection (validated Technicians only)

6.9.1 Ensuring the preparation of the intrathecal is approved before formula checking the worksheet:

Preparation can only happen upon receipt of the print-off of the ChemoCare intrathecal prescription. Before the start of the preparation process (formula checking the worksheets), the ADU-validated Technician must check that the prescription has been:

- "Allocated", "confirmed" and "authorised" by a **Consultant Haematologist** whose name appears on the intrathecal register. The Consultant's printed name is mandatory on the prescription but their signature in ink is **NOT** essential.

- "Clinically checked" by a Pharmacist whose name appears on the intrathecal register. The Pharmacist's printed name in the "checked by" box and their signature **in ink** are both mandatory.



Day	Date and Time	Drug	Single Intrathecal Dose	Route	Drugs Checked By	Drugs Given By	Time Given / Batch No.
1	31/10/2016	*METHOTREXATE	12.5 mg	INTRATHECAL	Doctor Sign / Nurse Sign	Doctor Sign / Witnessed Nurse Sign	

Allocated by :	Confirmed by :	Authorised by :	Checked by : [Pharmacist]
Andrew Ward(System Manager) Date: 31/10/2016 09:15	Andrew Ward(System Manager) Date: 31/10/2016 09:15	Andrew Ward(System Manager) Date: 31/10/2016 09:15	Date:

- Signed at "**Release from Pharmacy and Acceptance in Clinical Area, Part A**" in ink by a Pharmacist whose name appears on the intrathecal register. (This is to ensure once prepared, the product is clear to be released as ADU Pharmacy cannot store the intrathecal in Pharmacy for any reason).

Release from Pharmacy and Acceptance in Clinical Area Chart Id.:319415

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

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

(The answers to questions above must either be "Yes" for both or "No" for the first question and "NA" for the second).

6.9.2 Preparation and Labelling:

6.9.2.1 Intrathecal chemotherapy is prepared in Pharmacy ADU as explained in "Preparation of Intrathecal products" procedure SP.03.32v1.0.

6.9.2.2 ChemoCare-produced validated and approved worksheets or ADU manually written intrathecal worksheets can be used to prepare intrathecal chemotherapy.

6.9.2.3 Only devices with safer connectors (i.e. not compatible with standard Luer connectors) will be used for the dispensing of intrathecal chemotherapy in line with the NPSA alert **(NPSA/2011/PSA001).**

6.9.2.4 Labelling of all medicines intended for intrathecal administration must clearly show the patient's name, and the name of the product. The route of administration must be printed in the largest font size possible and emboldened. Negative labelling is not permitted (i.e. "Not for… use"). It is always labelled 'FOR INTRATHECAL USE ONLY'.

6.9.2.5 In addition to the usual heat-sealed pharmacy packaging, intrathecal chemotherapy will be packaged in an outer bag with printed warnings regarding administration. The heat-sealed bag should be placed in the outer bag so that all labels are clearly visible through the clear reverse side of the bags.

6.9.2.6 In the event that intrathecal cytotoxic chemotherapy has to be bought in from an external supplier, the labelling and packaging may differ from that outlined above, but will still comply with the minimum standards required.

6.9.2.7 ADU always adheres to the strict labelling and packaging requirement for vinca alkaloids infusion bags in accordance with the NPSA alert (NPSA/2008/RRR004, August 2008). They are prepared in 50ml sodium chloride 0.9% bags to be infused over 10 minutes. They are labelled: "For intravenous use only – fatal if given by other routes". The bag is packaged in another clear outer bag through which all labels are clearly visible.

6.9.2.8 If the vinca alkaloids have to be bought in from an external supplier the labelling and packaging may differ from that outlined above, but will still comply with the minimum standards required for vinca alkaloids.

6.10 Pharmacist final release

6.10.1 Only an ADU Pharmacist whose name appears on the intrathecal cytotoxic chemotherapy register will final release the intrathecal product.

6.10.2 Before releasing the product, the releasing Pharmacist must ensure the prescription has been "allocated", "confirmed" and "authorised" by a **Haematology Consultant** (Haematology Specialty Doctors on the register cannot prescribe intrathecal chemotherapy) and "clinically checked" by a Pharmacist both on the current intrathecal register. The Pharmacist must ensure that all ADU staff involved in the preparation of the intrathecal product are on the current intrathecal register.

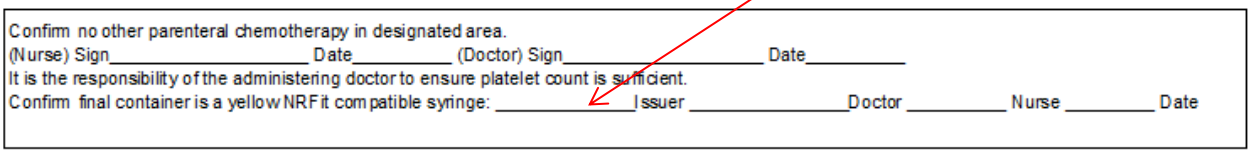
6.10.3 The releasing Pharmacist must follow the procedure under section "4.8.3" above. He/she must ensure all other parenteral chemotherapy within SEVEN days prior to the intrathecal has been administered and completed and the "Release from Pharmacy and Acceptance in Clinical Area, Part A" is signed by an intrathecal registered Pharmacist. (The answers to questions must either be "Yes" for both or "No" for first question and "NA" for the second.)

6.10.4 The releasing Pharmacist must ensure a member of ADU staff on the intrathecal register is available to transport the item to WTC immediately after release. If nobody is available, the Pharmacist has to transport the intrathecal to WTC in person.

6.10.5 The releasing Pharmacist will have to sign the worksheet and the batch book in ADU similar to any other chemotherapy released from ADU. No Pharmacist signature is required on the prescription at this stage.

6.10.6 The pharmacist releasing the product must sign the top section on the prescription confirming the correct syringe is being checked and released:

Additional Notes for Intrathecal


Confirm no other parenteral chemotherapy in designated area.
(Nurse) Sign_____ Date_____ (Doctor) Sign_____ Date_____
It is the responsibility of the administering doctor to ensure platelet count is sufficient.
Confirm final container is a yellow NRFit compatible syringe: _____Issuer _____Doctor _____ Nurse _____ Date

6.10.7 Any concerns or issues at any stage of the process above must be discussed with the ADU manager (or a senior ADU technician in their absence) and Lead Clinical Oncology Pharmacist. If unsatisfied with their responses or in their absence, the Lead Consultant for Malignant Haematology or Chief Pharmacist must be contacted.

6.11 Transportation and delivery to the Welcome Treatment Centre (WTC)

6.11.1 The designated refrigerator used solely for the storage of intrathecal cytotoxic chemotherapy is sited on the WTC. There is no designated intrathecal cytotoxic chemotherapy refrigerator in the ADU so any intrathecal medicines prepared in ADU must be transferred to WTC immediately.

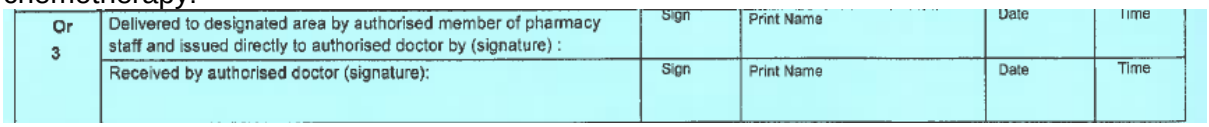
6.11.2 Only a member of Pharmacy staff whose name appears on the intrathecal register may undertake this task. Pharmacy porters must never be involved in transporting intrathecal cytotoxic chemotherapy.

6.11.3 Intrathecal cytotoxic chemotherapy must be transported separately from medicines intended for administration via other routes for the same patient or others. The intrathecal item is placed in a sealed yellow "Envopak" bag, used solely for the purpose of transporting intrathecal cytotoxic chemotherapy.

6.11.4 Intrathecal cytotoxic chemotherapy will be delivered in two scenarios:

Directly to the Consultant Haematologist or Haematology Specialty Doctor who will be administering the intrathecal cytotoxic chemotherapy

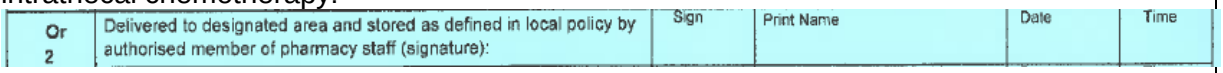
If delivered to the Consultant Haematologist or Haematology Specialty Doctor performing the procedure, "Part B, section 3" on the intrathecal prescription must be completed by the **designated Pharmacy staff** delivering the intrathecal and the **consultant Haematologist or Haematology Specialty Doctor** who will administer the intrathecal cytotoxic chemotherapy:



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

Delivered to the designated intrathecal refrigerator in intrathecal administration room on WTC.

If not the scenario above, the item must be placed in the designated intrathecal fridge on WTC and locked by the WTC staff. Once completed, "Part B, section 2" on the intrathecal prescription must be completed by the **designated Pharmacy staff member** delivering the intrathecal chemotherapy:



Or 2	Delivered to designated area and stored as defined in local policy by authorised member of pharmacy staff (signature):	Sign	Print Name	Date	Time

NB. The intrathecal designated fridge is always locked and a member of WTC staff will usually have to be present to unlock but their signature is not required on the prescription upon delivery.

6.11.5 Only the Consultant Haematologist, or Haematology Specialty Doctor on the register may remove the intrathecal chemotherapy from the refrigerator before start of the procedure.

6.12 Checks before administration

6.12.1 A Consultant Haematologist (or Haematology Specialty Doctor) and a Registered Nurse whose names appear on the intrathecal cytotoxic chemotherapy register will use a formal checking procedure (WHO procedure) immediately prior to administration of intrathecal cytotoxic chemotherapy. All checks will be undertaken in accordance with the Medicines Policy. The patient must be wearing a patient identity bracelet. **It is NOT acceptable for two DOCTORS to check medication to be administered intrathecally.**

6.12.2 The Doctor and the Nurse will check that a written and signed consent has already been obtained from the patient for the administration of the intrathecal chemotherapy. They will review the patient and blood results to ensure he/she is fit for treatment. The patient must be told the nature of the procedure, the route of administration and the medicine to be administered on every episode of intrathecal administration, before the procedure is performed. This will all be recorded in the patient's clinical notes.

6.12.3 A patient information leaflet will have been offered to the patient explaining the nature of this treatment at the time of consenting.

6.12.4 The Haematologist who will administer the intrathecal chemotherapy will check the ChemoCare live system to ensure that all other parenteral chemotherapy other than the intrathecal item "authorised" **within SEVEN days** prior to the intrathecal administration day has been "completed" (i.e. administered).

6.12.5 The Haematologist who will administer the intrathecal chemotherapy must check the ChemoCare live system and ensure no discrepancies exist between the hard copy of the intrathecal prescription (sent by pharmacy ADU with the intrathecal injection) and the existing version on ChemoCare. The prescription must show as "authorised" by the appropriate Haematologist on the live system.

6.12.6 The Haematologist who will administer the intrathecal chemotherapy must check that the Nurse assisting in the procedure is on the intrathecal cytotoxic chemotherapy register.

6.12.7 Within the WTC, a dedicated room is provided for the administration of intrathecal cytotoxic chemotherapy. When intrathecal cytotoxic chemotherapy is being administered, the designated room must not be used for any other purpose for the whole session (i.e. a whole morning or afternoon) even if only one such procedure is to take place during that session.

6.12.8 The Haematologist who will administer the intrathecal chemotherapy and the Nurse assisting will complete a formal check to ensure the designated intrathecal room is clear of all other medicines and syringes not required for that procedure. The intrathecal prescription must then be signed by the doctor and the Nurse under "Additional notes section" :

Additional Notes for Intrathecal

Confirm no other parenteral chemotherapy in designated area.
(Nurse) Sign_____ Date_____ (Doctor) Sign_____ Date_____
It is the responsibility of the administering doctor to ensure platelet count is sufficient.
Confirm final container is a yellow NRFit compatible syringe: _____Issuer _____Doctor _____ Nurse _____ Date

6.12.9 The intrathecal chemotherapy can now be removed from the intrathecal fridge. Only the Consultant Haematologist, or Haematology Specialty Doctor, on the register may remove the intrathecal chemotherapy from the refrigerator for the purpose of administration. The doctor will need to sign "Part B, Section 2" on the intrathecal prescription:

	Sign	Print Name	Date	Time
Retrieved from designated storage area as defined in local policy, by authorised doctor (signature):				

6.12.10 The patient's identity will be formally checked and confirmed against both the intrathecal prescription and the labelling on the intrathecal chemotherapy supplied by pharmacy ADU. Once the patient's identity has been confirmed as correct, the "ID check" box at the top right of the intrathecal prescription must be signed and dated by the Doctor and the Nurse:

Patient ID checked by
Doctor / Nurse
Sign .....
Print .....
Date .....

(If appropriate a relative could be involved in the checking process.)

6.13 Administration

6.13.1 Intrathecal cytotoxic chemotherapy may only be administered by a Consultant Haematologist or Haematology Specialty Doctor whose name appears on the intrathecal cytotoxic chemotherapy register.

6.13.2 Administration of intrathecal chemotherapy will use only devices with safer connectors (i.e. not compatible with standard Luer connectors) in line with the NPSA alert (**NPSA/2011/PSA001**).

6.13.3 Once the intrathecal chemotherapy has been administered, the hard copy of the prescription must be signed by the Doctor and the Nurse who have been involved in the procedure:

Drug	Single Intrathecal Dose	Route	Drugs Checked By	Drugs Given By	Time Given / Baton No.
*METHOTREXATE	12.5 mg	INTRATHECAL	Doctor Sign Nurse Sign	Doctor Sign Witnessed Nurse Sign	

6.13.4 Once administration is complete, the prescription must also be signed as "given" on ChemoCare by the Doctor who performed the procedure in accordance with the "ChemoCare Standard Operating Procedure for prescribing/administration of intrathecal chemotherapy".

6.13.5 The Doctor and the Nurse need to ensure the prescription is filed in the patient's active set of notes.

6.14 Disposal of Unused intrathecal cytotoxic chemotherapy

6.14.1 In the event of a failed or cancelled procedure, the Doctor or Nurse involved in the procedure may dispose of the unused intrathecal cytotoxic chemotherapy within the WTC by placing within a suitable 'Cin bin' held for the purpose of disposing of cytotoxic waste. A Nurse on the register may remove unused intrathecal injection from the dedicated fridge solely for the purpose of disposal.

6.14.2 Once confirmed that an intrathecal procedure has been cancelled, the prescription must be "unauthorised" immediately on ChemoCare by the Haematologist involved in the procedure. Detailed annotations explaining the reason for cancellation must be recorded on ChemoCare and in the patient's notes by the Doctor.

6.14.3 Where an intrathecal dose has not been administered, but instead destroyed, the hard copy of the ChemoCare prescription must be rendered obsolete by striking a line through by the Haematologist involved in the procedure. This copy MUST NOT BE DESTROYED but filed in patient's notes.

6.15 Out-of-hours procedure

6.15.1 Under normal circumstances intrathecal cytotoxic chemotherapy will only be administered **within normal working hours (Mon-Fri 9am-5pm)**. In the unlikely event that it were necessary to administer intrathecal cytotoxic chemotherapy out of hours, the Lead Consultant for Malignant Haematology should be contacted. A Consultant Haematologist and a Nurse whose names appear on the register would need to be available in order for the procedure to go ahead. If the Lead Consultant for Malignant Haematology is in agreement that the out of hours intrathecal cytotoxic chemotherapy is essential then the on-call Pharmacist should be contacted. The on-call Pharmacist will attempt to contact appropriate Pharmacy staff on the register to prepare the parenteral. There is no agreed provision for this service and it will only be possible if the necessary people on the register are able and willing to come in. In the event that the appropriate staff were not available then the patient would have to be transferred to another hospital for treatment.

6.15.2 The 'designated Trust Lead' (Chief Pharmacist) would need to be notified that such a procedure had taken place. An incident form must be completed with clear documentation as to why this situation had arisen, actions taken and outcome. A record should be maintained of the number of times this procedure takes place out of hours.

7.0. MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Assessment of the consultants and nursing staff involved in intrathecal administration intrathecal to ensure their competency and knowledge of this policy to renew their registration on the trust intrathecal register	The Lead Consultant for Malignant Haematology	Reading the relevant national documents and the trust intrathecal policy and completing a procedure while observed by the lead consultant	Annual	Steve May (Chief Pharmacist)
Assessment of pharmacy staff involved in intrathecal preparation to ensure their competency and knowledge of this policy to renew their registration on the trust intrathecal register	The Lead Pharmacist Clinical Oncology & Nutrition and the ADU Lab Manager	Reading the relevant national documents and the trust intrathecal policy and completing a questionnaire and a short discussion with the lead pharmacist. ADU technicians and assistants' preparation skills are assessed by observation by the lead ADU lab manager	Annual	Steve May (Chief Pharmacist)

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Assessment to ensure the whole of intrathecal cytotoxic chemotherapy service is operating in compliance with the national and trust intrathecal policies	Internal or external quality surveillance by another hospital as decided and organised by East Midland Cancer Surveillance group	Audit	Annual	SFH Oncology strategy group
Assessment to ensure the pharmacy cytotoxic chemotherapy service is operating in compliance with the national and trust intrathecal policies	Regional quality controller	Onsite inspection of the pharmacy ADU lab, review of procedures and random recent examples of documents for recent patients	12-18 months	Steve May (Chief Pharmacist)
Patient safety incidents associated with the intrathecal chemotherapy services	The Lead Consultant for Malignant Haematology ort Pharmacist Clinical Oncology & Nutrition and the ADU Lab Manager depending on the type of incident	Review of patient safety Datix incident reports	Monthly	Divisional Governance Forum / escalation to Patient Safety & Quality Group

8.0. TRAINING AND IMPLEMENTATION

8.1 The responsibility for education and training is delegated to the Lead Clinician for Malignant Haematology, who has remit to ensure that induction training and annual updates are undertaken. Specific responsibility for training and assessment in the different specialities, as agreed by the Lead Trainer, is delegated to

- Medical Staff: Lead Consultant for Malignant Haematology
- Nursing Staff: Lead Consultant for Malignant Haematology
- Pharmacy Staff: Lead Clinical Oncology and Nutritional Services Advanced pharmacist

8.2 Medical, Nursing and Pharmacy staff may perform their given registered task as part of the training programme, competency review or refresher training and only when they are directly and continually supervised by a named competency assessor for that task.

8.3 All staff who appear on a register must undertake an annual review of their competence to perform that task.

8.4 At annual review if a member of staff is not deemed competent to perform their allotted task they will be deleted from the relevant register.

8.5 All staff associated with intrathecal cytotoxic chemotherapy will sign annually a declaration that they have read and understood the most up to date national guidance and this Policy.

8.6 Induction and Training of Medical Staff

8.6.1 Induction

All new medical staff, including consultants and locums, that will work within Haematology will complete an induction programme, which includes the Trust Policy for safe Administration of intrathecal cytotoxic chemotherapy and the current National Guidelines. The local policy states that only Consultant Haematologists whose names appear on the register may prescribe intrathecal cytotoxic chemotherapy and only Haematology Consultants or Speciality Doctors whose names appear on the register may administer intrathecal cytotoxic chemotherapy.

8.6.2 Training

All Haematology medical staff will be made aware of the Haematology Guidelines and are required to sign that they have read and understood the guidelines. Copies of the Local and National Guidelines for the Administration of intrathecal cytotoxic chemotherapy are kept within this file.

8.6.3 Competency

The Lead Consultant for Malignant Haematology will be responsible for ensuring the competency of Consultant colleagues and any new medical appointee with regards to intrathecal therapy.

8.6.4 Updating Medical Staff

All staff who have an annual update must sign to acknowledge they have read and understood the local and national guidelines for the safe administration of intrathecal cytotoxic chemotherapy. Competency must also be assessed as part of the annual update. Copies of induction and update certificates are to be forwarded to the Lead Trainer for intrathecal cytotoxic chemotherapy.

8.7 Induction and Training of Pharmacy Staff

8.7.1 Pharmacy ADU staff induction and training

Pharmacists rotating in ADU go through a regimented general validation programme in order to be able to clinical check chemotherapy prescriptions, worksheet check and final release any chemotherapy prepared in ADU. ADU Technicians (rotational and permanent) and Assistants complete an in-depth training in handling and preparation (Technicians and Assistants), ingredient and volume checking (Technicians only) and worksheet checking (Senior Technicians only) for all parenteral chemotherapy.

All staff will complete several validations for each task successfully before handling any chemotherapy in ADU.

Upon completion of these training and validations, the staff above will have an induction which makes their roles and responsibilities with regard to the clinical check, preparation, release or transportation of intrathecal cytotoxic chemotherapy clear.

In order to be added on the intrathecal register, the staff will complete the “Intrathecal training pack” and discuss the contents of the pack with the Lead Clinical Oncology Pharmacist during a one-to-one tutorial session. Technicians and assistants go through individual practical observations and assessments under direct supervision of the ADU Lab Manager for tasks related to intrathecal ingredient assembly and checking, volume checking and product preparation. The staff will sign against each policy read and understood within the pack and successfully complete a questionnaire. Once the pack completed and deemed competent by the Lead Clinical Oncology Pharmacist and the ADU Lab Manager, an intrathecal certificate is signed by both the member of the staff and the Lead Clinical Oncology Pharmacist. These documents are filed within the staff training records in Pharmacy ADU, their name is added to the Intrathecal register and is signed by the Lead Clinical Oncology and Chief Pharmacists.

8.7.2 Updating pharmacy ADU Staff

Updating is undertaken annually. Pharmacy staff will complete the “intrathecal training pack”. They will sign against each policy and guidelines read and understood within the pack and successfully complete a questionnaire. They discuss any queries with the Lead Clinical Oncology Pharmacist and the ADU Lab Manager.

ADU technicians and assistants will have a review of their competency in preparation and other lab-related tasks for the intrathecals by the ADU Lab Manager.

All documents are filed within the staff training records in Pharmacy ADU and their name is re-instated on the register.

8.8 Induction and Training of Nursing Staff

8.8.1 Nursing staff induction

All registered nursing staff and health care assistants new to the WTC will have an induction which makes their roles and responsibilities with regard to the administration of intrathecal cytotoxic chemotherapy clear. Written information will be provided and a certificate signed to verify receipt. A copy of the induction certificate will be retained by the individual nurse. A database of all staff who have induction training and chemotherapy annual update training is maintained by the Lead Chemotherapy Nurse.

8.8.2 Intrathecal Cytotoxic Chemotherapy Training of Nursing Staff

8.8.2.1 Training for nursing staff on the WTC is delivered by the Lead Consultant for Malignant Haematology and specifically identifies the role of the nurse in relation to checking medicines for intrathecal administration. Assessment of knowledge base is integrated within the training.

8.8.2.2 The training is recorded. Copies are held by the individual nurse, the Lead Chemotherapy Nurse (in the individual's training file) and the Lead Consultant for Malignant Haematology.

8.8.2.3 Only those nurses who have undertaken this training will be included in the register.

8.8.2.4 Copies of training records will be sent to relevant nurse managers for information.

8.8.3 Updating of Nursing Staff

Updating will be undertaken by the Lead Consultant for Malignant Haematology. Those updated must read and sign to acknowledge they have read and understood the local and national guidelines. Competency must also be assessed. This will include a theoretical and practical assessment.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality and Environmental Impact Assessment, see completed form at Appendix B
- This document has been subject to an Environmental Impact Assessment, see completed form at Appendix C.

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:
This Policy provides for local interpretation and implementation of the HSC 2008/001 - National Guidance on the Safe Administration of intrathecal cytotoxic chemotherapy, NPSA/2008/RRR004 - Using vinca alkaloid minibags and NPSA/2017/PSA001 Safer spinal (intrathecal), epidural and regional devices.

Related SFHFT Documents:
Pharmacy aseptic dispensing unit SP03.32.V2.0 Preparation of Intrathecal Products

11.0 KEYWORDS

methotrexate; vincristine; haematology; cancer Guideline; vinca alkaloid; cytarabine; for; of; KMH

12.0 APPENDICES

- Appendix A – Sample Intrathecal Prescription Produced on ChemoCare
- Appendix B – Equality Impact Assessment
- Appendix C – Environmental Impact Assessment

Appendix A – Sample Intrathecal Prescription Produced on ChemoCare

Intrathecal Chemotherapy Prescription Chart

Patient Details

Forename	Surname	Ward	SA (m²)	Patient ID checked by Doctor / Nurse
KMH2	TEST		1.81	Sign ..... Print ..... Date .....

DOB	Patient NO	Local No.	Consultant
01/01/1980	KMH2222222		Test Consultant

NHS No

Address

Diagnosis: Adult T-ALL

Course Name: Intrathecal Methotrexate 12.5mg (1)

Protocol

Treatment Location: NUH

Pharmacy Location: NUH

Additional Notes for Intrathecal

Confirm no other parenteral chemotherapy in designated area. (Nurse) Sign_____ Date_____
All intrathecal and intraventricular injections must be prepared and administered according to local policy and national guidelines.
It is the responsibility of the administering doctor to ensure platelet count is sufficient.
Intrathecal chemotherapy must be prescribed according to a recognised protocol or documented treatment plan.

Day	Date and Time	Drug	Single intrathecal Dose	Route	Drugs Checked By	Drugs Given By	Time Given / Batch No.
1	31/10/2016	*METHOTREXATE	12.5 mg	INTRATHECAL	Doctor Sign Nurse Sign	Doctor Sign Witnessed Nurse Sign	

Allocated by :	Confirmed by :	Authorised by :	Checked by : (Pharmacist)
Andrew Ward(System Manager) Date: 31/10/2016 09:15	Andrew Ward(System Manager) Date: 31/10/2016 09:15	Andrew Ward(System Manager) Date: 31/10/2016 09:15	Date:

Release from Pharmacy and Acceptance in Clinical Area **Chart Id.:319415**

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

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

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

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

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

APPENDIX B – EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Intrathecal and Intraventricular Cytotoxic Chemotherapy in Adults at KMH – Safe Administration Policy			
New or existing service/policy/procedure: Existing			
Date of Assessment: December 2019			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	None	NA	NA
Gender	None	NA	NA
Age	None	NA	NA
Religion	None	NA	NA
Disability	None	NA	NA
Sexuality	None	NA	NA
Pregnancy and Maternity	Administration is contraindicated during pregnancy. Pregnant staff are prohibited from any engagement for preparation or administration of these cytotoxic medications	NA	NA
Gender Reassignment	None	NA	NA

Marriage and Civil Partnership	None	NA	NA
Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	None	NA	NA

What consultation with protected characteristic groups including patient groups have you carried out?

- **NA**

What data or information did you use in support of this EqIA?

- **Blank**

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- **None**

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

- Low Level of Impact

Name of Responsible Person undertaking this assessment:

Signature:

Date: Dec 2019

APPENDIX C – ENVIRONMENTAL IMPACT ASSESSMENT

The purpose of an environmental impact assessment is to identify the environmental impact, assess the significance of the consequences and, if required, reduce and mitigate the effect by either, a) amend the policy b) implement mitigating actions.

Area of impact	Environmental Risk/Impacts to consider	Yes/No	Action Taken (where necessary)
Waste and materials	• Is the policy encouraging using more materials/supplies? • Is the policy likely to increase the waste produced? • Does the policy fail to utilise opportunities for introduction/replacement of materials that can be recycled?	No	
Soil/Land	• Is the policy likely to promote the use of substances dangerous to the land if released? (e.g. lubricants, liquid chemicals) • Does the policy fail to consider the need to provide adequate containment for these substances? (For example bunded containers, etc.)	yes	Chemotherapy agent will be discarded per trust policy for discarding cytotoxics.
Water	• Is the policy likely to result in an increase of water usage? (estimate quantities) • Is the policy likely to result in water being polluted? (e.g. dangerous chemicals being introduced in the water) • Does the policy fail to include a mitigating procedure? (e.g. modify procedure to prevent water from being polluted; polluted water containment for adequate disposal)	No	
Air	• Is the policy likely to result in the introduction of procedures and equipment with resulting emissions to air? (For example use of a furnaces; combustion of fuels, emission or particles to the atmosphere, etc.) • Does the policy fail to include a procedure to mitigate the effects? • Does the policy fail to require compliance with the limits of emission imposed by the relevant regulations?	No	
Energy	• Does the policy result in an increase in energy consumption levels in the Trust? (estimate quantities)	No	
Nuisances	• Would the policy result in the creation of nuisances such as noise or odour (for staff, patients, visitors, neighbours and other relevant stakeholders)?	No	