NHS
University Hospitals Sussex
NHS Foundation Trust
St Richards, Worthing & Southlands Hospitals

Intramuscular Methotrexate Clinical SOP and Competency Document for Medical Management of Ectopic Pregnancy or Persistent Gestational Trophoblastic Disease

Summary statement: How does the document support patient care?	To ensure that Methotrexate (via intramuscular injection (IM)) for the management of ectopic pregnancies and persistent gestational trophoblastic disease is administered safely.
Staff/stakeholders involved in development:	Gynaecology Matrons
Division:	Women and Children's
Department:	Gynaecology
Responsible Person:	Chief of Service
Author:	Gynaecology Matrons
For use by:	Gynaecology Nursing Staff
Purpose:	The purpose of this competency is to ensure that staff who are administering Methotrexate (via intramuscular injection (IM)) have sufficient knowledge and competence in order to do so safely.
This document supports:	UHS Standard Infection Prevention and Control Precautions V5, 2018. uhsic002-standard-infection-prevention-control-precautions UHS Waste Management Policy, V4, 2021. uhsfe006-waste-management
Key related documents:	UH Sussex (SRH&WH) CG12018 Ectopic Pregnancy
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Version	Date	Author	Status	Comment
1.0	October 2022	J Birrell and J Chrimes Gynaecology Matrons	Live	New SOP for UH Sussex (SRH&WH)
2.0				

The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician.
If in doubt contact a senior colleague or expert.

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Intramuscular Methotrexate Clinical SOP and Competency Document for Medical Management of Ectopic Pregnancy or Persistent Gestational Trophoblastic Disease

(following referral from Charing Cross Hospital)

1.0 Introduction

The purpose of this competency is to ensure that staff who are administering Methotrexate (via intramuscular injection (IM)) have sufficient knowledge and competence in order to do so safely.

Methotrexate is a type of medicine called an immunosuppressant. It slows down the body's immune system and helps reduce inflammation.

It is used to treat many conditions such as:

- Rheumatoid Arthritis
- Psoriasis (including psoriatic arthritis)
- Crohn's Disease
- Sarcoidosis

It is also used to medically resolve an ectopic pregnancy and as a treatment regime for patients with persistent trophoblastic disease following diagnosis of a molar pregnancy.

It works by destroying rapidly dividing cells such as cancer cells or trophoblastic tissue cells.

2.0 Rationale and background

2.1 Ectopic Pregnancy

Methotrexate is only prescribed following discussion with a Consultant following diagnosis of an ectopic pregnancy or persistent pregnancy of unknown location (PUL). There is a clear criteria for patient selection to ensure patient safety. The Methotrexate dosage is calculated on body surface area and prescribed as 50 mgs per m^2, therefore height and weight must be taken within the clinic to support accurate dosage. Please refer to the Standard Operating Procedure for "The Administration of Intra Muscular Methotrexate for the management of Ectopic Pregnancy and Persistent Gestational Trophoblastic Disease".

2.2 Persistent Gestational Trophoblastic Disease (PGTD)

Patients that have been diagnosed with a molar pregnancy are referred to Charing Cross Gestational Trophoblastic Disease Service (CXH) for follow up and ongoing monitoring.

Partial molar pregnancies usually resolve spontaneously, however in 0.5% of these cases malignant disease will develop and require chemotherapy.

Complete molar pregnancy patients usually have their bloods monitored for 6 months and then following any subsequent pregnancies.

In contrast to a partial molar pregnancy a complete molar pregnancy frequently proceeds to invasive disease with 8-20% of these patients requiring chemotherapy.

Occasionally these patients require ongoing management with chemotherapy (Methotrexate) and a smaller minority of these patients may require a regime which following initial management at CXH is then continued at the patient's local hospital.

3.0 Responsibilities

Departmental Matrons have a responsibility to:

- Ensure the operation and implementation of this competency.
- Ensure that all nurses to who will be required to administer IM Methotrexate have adequate training made available and undergo an appropriate assessment to gain competency.

Clinical Staff have a responsibility to:

- Clinical staff are responsible for ensuring they have read, understood and are capable of discussing and implementing the Standard Operating Procedure for "The Administration of Intra Muscular Methotrexate for the management of Ectopic Pregnancy and Persistent Gestational Trophoblastic Disease".
- Clinical staff are responsible and accountable for their own actions and must ensure that they exercise their own professional judgement in the administration of IM Methotrexate.
- Clinical staff must ensure that they are competent to carry out the administration and disposal of IM Methotrexate prior to taking on the task.
- Deviations to the agreed policy and competency must be rationalised and accurately recorded.

4.0 Abbreviations used within this document

IM Intramuscular injection	**PUL** Pregnancy of unknown location
CXH Charing Cross Gestational Trophoblastic Disease Service	**PGTD or GTD** Persistent Gestational Trophoblastic Disease

5.0 Principles

Patients must be provided with adequate information and time to review this information prior to providing informed consent for the administration of IM Methotrexate.

5.1 Ectopic Pregnancy

IM Methotrexate will be obtained from Pharmacy following its prescription prior to its administration. This will need to be ordered by the nursing or medical team following documentation of a discussion with the consultant and confirmation that the patient will be able to adhere to the monitoring and treatment plan which can continue for several weeks.

5.2 Persistent Gestational Trophoblastic Disease

Patients will be discharged from CXH with a full treatment course of Methotrexate injections, along with sharps bins and a cytotoxic spill kit. Prior to accepting patients, CXH should send through patient information, administration booklets, treatment plan and signed prescriptions.

The administrating team should then ensure that the Methotrexate prescription is photocopied and a copy is retained:

- Within the patients' medical records
- By the patient

so that it is evident to teams outside of the Gynaecology department should the patient present in an emergency. (Both copies require signing on administration).

- IM Methotrexate is to be administered in accordance with the Trust Injectable Medicines Policy and the *Trust Chemotherapy Policy* further information can be found at 12009-injectable-medicines-policy.
- Sharps must be handled and disposed of in accordance with the Trust Standard Infection Prevention and Control Precautions uhsic002-standard-infection-prevention-control-precautions.
- Methotrexate needles and syringes must be disposed of in the purple top Sharps Bins uhsfe006-waste-management.
- Methotrexate is usually given for a set period of time in line with rationale for treatment.

5.3 Authority to proceed

- Patients must have been given adequate information during consultation to allow them to provide informed consent.
- A clear and accurate prescription (or equivalent outpatient documentation) with a documented rationale is required prior to the administration of IM Methotrexate.
- The patients' blood results have been checked are within the appropriate margins for administration of Methotrexate. Any concerns must be discussed with a Consultant.
- The administration of IM Methotrexate may only be performed by a trained member of the clinical staff who has been deemed competent (Appendix 1 & 2).

5.4 Contraindications

- Patients with a known allergy or hypersensitivity to any of the components of a Methotrexate injection should not receive a dose.
- Patients with significant pain/bleeding with a known ectopic pregnancy should be further reviewed.
- Patients with abnormal renal and liver function tests. These patients require a senior review. Those being treated for GTD by CXH will need to be discussed with them.

5.5 Special warnings and precautions for use

- Staff administering Methotrexate should not be pregnant or considering trying for a pregnancy. Should a member of staff fit one of these categories, this should discreetly be discussed with a line manager.
- All Methotrexate injections should be disposed of in a purple lidded (cytotoxic) sharps bin.
- A Cytotoxic spill kit must be available at all times in areas where cytotoxic medication is being prepared and administered.
- The 'Z' tracking technique should be used for the administration of Methotrexate (Appendix 3).

5.6 Undesirable effects of Methotrexate

- The most commonly observed adverse reactions include injection site reactions, lip and gum ulceration, vaginal bleeding, eye reactions and photo-sensitivity.
- If a patient has concerns they should be discussed with the prescribing clinician.

6.0 Monitoring and audit

- Numbers of trained staff within the gynaecology areas should be monitored to ensure adequate staff are available with the skills to administer IM Methotrexate.
- Staff who have undergone training are expected to complete their IM Methotrexate competency document within 6 months of commencement within the service, however it is accepted that there may not always be adequate patient numbers to enable this.
- Incidents relating to IM Methotrexate administration will be monitored through the Trust incident reporting (Datix) database and appropriate actions will then be put in place.

References

WSHT Injectable Medicines Policy V6, 2020. p12009-injectable-medicines-policy

UHS Standard Infection Prevention and Control Precautions V5, 2018. uhsic002-standard-infection-prevention-control-precautions

UHS Waste Management Policy, V4, 2021. uhsfe006-waste-management

Appendix 1: Competency framework for the safe administration of IM Methotrexate

Aim:

This competency will be completed through self-assessment and discussion with a recognised competent supervising practitioner.

"I the qualified healthcare professional can confirm that I have read and understood the Standard Operating Procedure and Competency for the Administration and disposal of Intramuscular Methotrexate. I can confirm that I understand the rationale for treatment, preparation, administration and disposal of IM Methotrexate injections." ***I have read the Trust Policies related the aforementioned documents.***	
Practitioner Name	
Practitioner Signature	
Date	

	Competency	**Assessment and evidence of discussion for competencies**	**Date**	**Supervisor Signed**	**Practitioner Signed**
	The supervising practitioner must be confident that the individual has an adequate understanding of the theory and rationale behind administration. Additional observations can be assessed as required.				
1.	Understanding of the theory and rationale behind the administration of IM Methotrexate including: • Indications (Ectopic or PGTD) • Effect of Methotrexate on the body				
2.	Demonstrates an understanding of the rationale behind giving Methotrexate.				
3.	Demonstrates an understanding of the contra-indications of Methotrexate.				
4.	Ensures patients have adequate knowledge regarding rationale for				

	administration of Methotrexate thereby able to provide informed consent.				
5.	Checks patients understanding regarding ongoing treatment plans following administration of Methotrexate.				
6.	Informs patients about the side effects/adverse reactions associated with Methotrexate.				
7	Demonstrates knowledge of appropriate administration sites and techniques.				
8.	Understands there is a need for continued monitoring and treatment.				
9.	Prepares appropriately for the administration of Methotrexate.				
10.	Checks recent blood results and confirmation (for PGTD patients from CXH) for patients to continue with treatment.				
11.	Advises patient as appropriate on use of barrier contraception				
12.	Carries out the patient safety checks according to the Trust's medication administration policy.				
13.	Administers (using Z Track technique) and disposes of the Methotrexate syringe in a purple lidded sharps bin.				
14.	Described/demonstrates the use of a Cytotoxic spill kit.				
14.	Records the administration of Methotrexate.				
15.	Ensure patient aware of any necessary follow up.				

	_____ has demonstrated an Understanding of the rationale, preparation, administration and disposal of IM Methotrexate Injections. They have read and understood the standard operating procedure for the administration and disposal of IM Methotrexate Injections, including the associated Trust Policies and have been deemed as competent.		
	Comments:		
	Supervisor Name and Signature		**Date:**
	Practitioner Name and Signature		**Date:**

A copy of this competency should be kept in the practitioner's competency folder and a copy should be retained by the Departmental Manager or Practice Development Nurse.

Appendix 2: Equipment and procedure for the administration of IM Methotrexate

Equipment

- Prescription or documented evidence of rationale for administration
- Prescribed Methotrexate
- 70% Alcohol swab
- Needle – length 25mm (21G although 23G may be used on a thin patient)
- Syringe containing prepared intramuscular (IM) medication
- Non-sterile gloves
- Plastic Apron
- Small plaster
- Cytotoxic sharps bin
- Cytotoxic spill kit
- Clinical tray or receiver containing the prepared drug

Pre-procedure

- Introduce yourself to the patient, explain and discuss the procedure with them and gain their consent to proceed.
- Before administration check the following in line with the prescription chart:
  - Patient details
  - Drug
  - Dose
  - Date, time and route of administration
  - Validity of prescription
  - The prescription is legible
  - Signature of the prescriber

Procedure/Administration of Methotrexate

1. Apply apron and gloves, close curtains or door, assist patient to lay on the left or right lateral side in order to administer into the gluteus maximus muscle.
2. Expose the injection site.
3. Assess the injection site for inflammation, infection, oedema and skin lesions.
4. Clean the injection site for 30 seconds and allow to dry for 30 seconds.
5. With the non-dominant hand, pull the skin 2-3 cm sideways or downwards from the injection site (Z-track) and insert the needle.
6. Pull back the plunger, if no blood is aspirated, depress the plunger at approx. 1 ml every 10 seconds and inject the drug slowly. If blood appears, withdraw the needle completely, replace it and begin again. Explain to the patient what has happened.
7. Wait 10 seconds before withdrawing the needle.
8. Withdraw the needle the needle rapidly and release the tension on the skin but do not massage the site.

9. Apply gentle pressure to any bleeding point and then apply a small plaster over the picture site.

Post-procedure

- Ensure that all sharps and non-sharps waste are disposed of safely in a cytotoxic sharps bin.
- Record administration on appropriate charts.

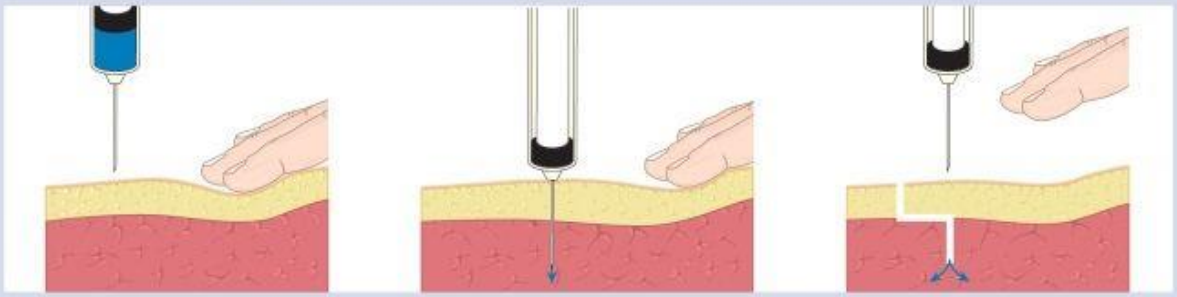
Accidental Spillage

In the event of an accidental spillage:

- Use the cytotoxic spillage kit.
- Wear polyvinyl gloves.
- Place paper towels over the liquid to blot up as much of the drug as possible avoid spreading the methotrexate to a larger area.
- Clean the area with additional paper towels. Work from the outside to the middle.
- Wash the area with plenty of detergent and water.
- Dispose of plastic gloves and any used paper towels in the cytotoxic waste bin.

Appendix 3: Z-track technique

Fig 2. **Z-track technique**



2a. Pull the skin by about 2.5-3.75cm (Malkin, 2008) to displace the underlying tissue

2b. While holding the skin, adminster the injection

2c. Allow the skin to return to its normal position, trapping the drug in the muscle

(nursingtimes.net/clinical-archive/assessment-skills/injection-technique)