Family Nursing & Home Care

Policy and Standard Operating Procedures for Administration of Subcutaneous Methotrexate for Inflammatory Arthritis in Adults

4 August 2021

Document Profile

Document Registration	Added following ratification
Type	Policy / SOP
Title	Policy and Standard Operating Procedures for the Administration of Subcutaneous Methotrexate for Inflammatory Arthritis in Adults
Author	Mo de Gruchy
Category clinical / corporate / education / Health & Safety / HR / Info Governance	Clinical
Description	To provide guidance and SOPs related to the Administration of Subcutaneous Methotrexate for Inflammatory Arthritis in Adults, to ensure staff and patient safety
Approval Route	Organisational Governance Approval Group
Approved by	Bronwen Whittaker
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Document Status	This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet.

Version control / changes made

Date	Version	Summary of changes made	Author
May 2021	2	Previous document transferred to new policy template Roles and Responsibilities defined All information reviewed and updated using latest evidence-based guidance from the RCN (2016) and Health & Community Services Rheumatology Department (2020)	Mo de Gruchy

CONTENTS

1. INTRODUCTION

1.1 Rationale

Methotrexate is recognised as the most effective of the traditional (non-biologic) disease-modifying anti-rheumatic drugs (DMARDs) in current use for inflammatory arthritis. It is seen as the gold standard for treating people with rheumatoid conditions (RCN 2016).

Methotrexate is an anti-metabolite cytotoxic agent that competitively restricts/inhibits the action of an enzyme necessary for the synthesis of DNA and thus cell replication. The mode of action of methotrexate is immunosuppressive, the precise action is unclear but it is believed that the production of lymphocytes is inhibited thus restricting the amount of inflammation the body can produce.

Family Nursing & Home Care (FNHC) recognises the potential legal and clinical obligations of their staff's involvement in the administration of subcutaneous methotrexate and adheres to the Royal College of Nursing's (RCN) guidelines on administering subcutaneous methotrexate for inflammatory arthritis (RCN 2016). FNHC believes that all patients should receive the same standard of care regardless of who is administering the subcutaneous methotrexate. Care should be based on current best practice and patient safety should be maintained at all times.

This policy and standard operating procedures have been developed to aid FNHC Nurses in the safe and effective administration of subcutaneous methotrexate injections and to enable them to support patients and/or their carers to administer treatment at home.

1.2 Scope

This policy and Standard Operating Procedures (SOPs) applies to Registered Nurses employed by FNHC who may be required to administer subcutaneous methotrexate or support patients and/or carers to administer this medication. It applies only to adult patients.

1.3 Role and Responsibilities

Chief Executive Officer

The Chief Executive Officer has ultimate responsibility for ensuring that FNHC has robust governance measures in place to support the safety of patients related to the administration of subcutaneous methotrexate.

Head of Quality Governance and Care

The Head of Quality Governance and Care is responsible for ensuring that FNHC has evidence based procedural documents available to ensure safe administration of subcutaneous methotrexate and that these are reviewed at appropriate intervals. They are also responsible for monitoring any incidents relating to this practice and the implementation of any action required to prevent reoccurrence of untoward incidents.

Operational Leads

Operational leads are responsible for ensuring that their teams have access to this policy/SOPs and for overseeing the monitoring of staff competence and attendance at any training. They also have a responsibility to ensure that any untoward incidents are investigated and action taken as necessary to mitigate risk.

Registered Nurses

Registered Nurses involved in the administration of subcutaneous methotrexate have a responsibility to adhere to this policy/SOPs and other relevant FNHC procedural documents and to report any untoward events related to this practice.

2 POLICY

2.1 Administration of Methotrexate

Parenteral methotrexate can be given by intravenous, intramuscular or subcutaneous injection. Subcutaneous methotrexate in a pre-dosed, auto injector device is now licensed for the treatment of rheumatoid conditions. Subcutaneous injecting is usually less painful than intramuscular administration and allows patients to self-administer this weekly therapy.

Family Nursing & Home Care endorses the Royal College of Nursing's (2016) recommendation to use the licensed pre-filled methotrexate PENs e.g. Metoject®, over pre-filled methotrexate syringes and, in particular, unlicensed pharmacy prepared pre-filled syringes.

Therefore, unless otherwise indicated, this is the recommended mode of administration and will be the mode of administration referred to in this document.

2.2 Drug Interactions

A number of drugs have the potential to interact with and enhance the action of methotrexate or reduce its excretion and thus increase its toxicity. Drugs known to do this, for example, are salicylates, hypoglycaemics, sulphonamides, co-trimoxazole, probenecid, some diuretics, phenytoin and trimethoprim (Medac 2020). Non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids are often used concomitantly and can potentially increase the risk of toxicity; so extra vigilance with blood monitoring is essential.

2.3 Side Effects

Methotrexate is fertility impairing and embryotoxic (causing abortion and foetal defects) therefore, it is essential that men and women of childbearing age use an effective contraceptive during treatment and for at least 6 months after treatment cessation.

Most serious adverse reactions of methotrexate include bone marrow suppression, pulmonary toxicity, hepatotoxicity, renal toxicity, neurotoxicity, thromboembolic events, anaphylactic shock and Stevens-Johnson syndrome.

Most frequently (very common) observed adverse reactions of methotrexate include gastrointestinal disorders e.g. stomatitis, dyspepsia, abdominal pain, nausea, loss of appetite and abnormal liver function tests e.g. increased ALAT, ASAT, bilirubin, alkaline phosphatase.

Other frequently (common) occurring adverse reactions are leukopenia, anaemia, thrombocytopenia, headache, tiredness, drowsiness, pneumonia, interstitial alveolitis/pneumonitis often associated with eosinophilia, oral ulcers, diarrhoea, exanthema, erythema and pruritus.

2.4 Contraindications

- hypersensitivity to the active substance or to any of the excipients
- severe liver impairment
- alcohol abuse,
- severe renal impairment
- pre-existing blood dyscrasias, such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anaemia,
- serious, acute or chronic infections such as tuberculosis, HIV or other immunodeficiency syndromes,
- ulcers of the oral cavity and known active gastrointestinal ulcer disease,
- pregnancy and breast-feeding
- concurrent vaccination with live vaccines.

2.5 Dosage

Methotrexate must only be given in the exact dose as prescribed by the Rheumatologist or General Practitioner (GP). It is given as a single injection once a week on the same day each week. The prescribing of folic acid supplementation is recognised as standard practice to reduce the risk or severity of any mucosal or gastrointestinal side effects (RCN 2016).

When converting from oral to parenteral methotrexate, the oral medication must be stopped for 7 full days prior to the first injection. Please note, the change from oral to parenteral methotrexate is classed as a dose increase due to increased bioavailability.

2.6 Monitoring

Patients receiving methotrexate must have regular monitoring of their bloods. Monitoring guidelines should be provided by the clinician who refers the patient to FNHC. If it is not provided, a request for this information must be made. Where a self-referral has been made, the monitoring regime must be requested from the patient's responsible physician.

Patients may be monitored by either the Consultant Rheumatologist or their General Practitioner (GP). FNHC Nurses must be aware of which clinician has medical

responsibility for the patient and must inform them of their involvement in the patient's care through a liaison letter. The Rheumatology Clinical Nurse Specialists (CNS) must also be informed as they will copy FNHC in to all relevant patient correspondence.

Current local monitoring guidelines should be known to FNHC Nurses and prior to administering subcutaneous methotrexate, said staff must confirm that the patient has had the appropriate tests undertaken at the recommended intervals and that there is no indication to withhold the administration of the subcutaneous methotrexate. This includes when supervising self-administration.

If the responsible physician does not advise FNHC Nurses of the test results, the **methotrexate must not be administered**. FNHC Nurses must contact the responsible physician (GP or Consultant Rheumatologist) for this information.

In addition to confirming the test results, should the patient present with any of the following signs/symptoms, the **methotrexate must be withheld and advice must be sought** from the responsible physician:

- Severe sore throat or mouth
- Abnormal bleeding tendency e.g. excessive bruising, blood spots, blisters on the skin or mouth
- Rash
- Mouth ulcers
- Breathlessness or dry cough
- Symptoms of shingles or chicken pox
- An infection that is not improving
- Pregnancy

A document is available to record pre-administration checks (Appendix 1).

2.7 Patient/Carer Training

In the event of the patient self-administering subcutaneous methotrexate or the family/carer administering to the patient, a competency based training/education programme will need to be undertaken. The initial training/education of patients/ carers to administer subcutaneous methotrexate is not within the scope of this guideline and should not be undertaken by FNHC Nurses.

However, in the event that the patient/carer has undertaken a comprehensive, training/education programme and there is evidence of successful completion of such a programme, FNHC Nurses can support the patient/carer's practice, until such time as they are confident to safely administer the subcutaneous methotrexate alone.

The Rheumatology CNS provides training locally in the administration of subcutaneous methotrexate. On completion of this training, recipients are issued with the following documents:

- Training checklist for home administration of subcutaneous methotrexate by a patient/carer (Appendix 2)

- Competency Agreement for the home administration of subcutaneous methotrexate by patient/carer (Appendix 3)

When supporting the patient/ /carer to administer subcutaneous methotrexate, the FNHC Nurse must confirm that they are aware that they must:

- **stop methotrexate and contact the Rheumatology Consultant/GP if any of the following develop:**

  - severe sore throat or mouth
  - abnormal bleeding tendency (excessive bruising, blood spots or blisters on the skin or in the mouth)
  - rash
  - mouth ulcers
  - breathlessness or dry cough
  - symptoms of shingles or chicken pox
  - an infection which is not improving

- not take any new medication without checking with their Consultant/GP
- only have alcohol in strict moderation due to the potential combined liver toxicity.
- not handle or administer subcutaneous methotrexate if they are pregnant or pregnancy is suspected
- not administer subcutaneous methotrexate to anyone who is pregnant or thinks they may be pregnant .
- contact their Rheumatologist or GP urgently if they have contact with someone with either chicken pox or shingles. **N.B.** unless the patient has definitely had chicken pox/shingles or is known to be immune from prior immunology, they need urgent (same day) varicella zoster serology carried out. If not immune, the on call Rheumatologist or GP must be contacted.

Where indicated, if the FNHC Nurse is administering subcutaneous methotrexate to the patient, they must discuss any side effects, either observed or brought to their attention, with the relevant physician in a timely manner. Side effects should be documented in the patient's nursing records.

To minimise reactions and promote and maintain good injection technique, practitioners should routinely ask patients/carers if they are experiencing any problems.

If, at any time the FNHC Nurse deems that the patient/carer's practice falls below an expected level of competence, they should discuss this immediately with the physician responsible for the patient's care and/or the Rheumatology CNS responsible for training. This approach will help maintain a thorough audit trail and ensure the maintenance of safe practice by patients/carers (RCN 2016).

2.8 Storage

Methotrexate is a yellowish, transparent solution and must be stored out of direct sunlight in a safe place within the home, out of the reach and sight of vulnerable adults, children and pets.

The storage of subcutaneous methotrexate should be in accordance with the manufacturer's instructions as the shelf-life and storage conditions may vary between manufacturers.

FNHC Nurses administering subcutaneous methotrexate should enquire as to how the medication has been stored whilst in the care of the patient/ carer, prior to administration of the drug.

Administration of the drug should not take place if there is concern about its storage conditions. Instead, additional advice from the supplying pharmacy should be sought and/or an alternative supply should be obtained.

2.9 Sharps Injury

If, during the administration of subcutaneous methotrexate, a sharps injury is sustained, staff should follow the FNHC Sharps Injury and/or Blood or Body Fluid Exposure Procedure.

2.10 Special Precautions

Due to the cytotoxic properties of this medication, all staff should be aware of potential hazards and how to reduce risk of harm when handling /administering this medication.

Those staff who are pregnant, particularly in the first trimester, should not handle or administer methotrexate (RCN 2016).

3 STANDARD OPERATING PROCEDURES

3.1 Communication with other Relevant Healthcare Professionals in Subcutaneous Methotrexate Administration

Purpose

To enable all relevant healthcare professionals to be aware of the involvement of FNHC in the administration of subcutaneous methotrexate, so relevant information is shared appropriately and in a timely manner.

Scope

All staff required to administer subcutaneous methotrexate or supporting others to do this.

Core Requirements

The majority of patients are commenced on subcutaneous methotrexate by the Rheumatology Consultant, who issues the initial prescription. Thereafter, care is usually shared with the GP who then takes over the prescribing of the subcutaneous methotrexate.

Patients/carers are responsible for obtaining their own supplies of methotrexate in the form of a pre-filled auto injector device.

If at this stage the patient requires FNHC Nurses to administer the methotrexate injection, a referral will be sent by the Rheumatology Department detailing the patient's individual blood and urine monitoring regime, and written authorisation to medicate will be provided on the FNHC 'Medication Record and Authorisation Sheet', as per the FNHC Medicines Policy.

Regardless of the origin of the referral, when a patient is accepted for the administration of subcutaneous methotrexate or support with the administration of subcutaneous methotrexate, both the GP and the responsible physician (if different) must be informed by means of a liaison letter. The Rheumatology CNS must also receive a copy of the liaison letter. This will alert them to copy FNHC in to all relevant patient correspondence e.g. re a dose increase and increased monitoring.

Where timely confirmation of satisfactory test results is not received from the responsible physician, the FNHC Nurse must contact this person ahead of the day they are due to see the patient. Should this not be forthcoming, the FNHC Nurse must advise the responsible physician that they will not be able to administer/support the administration of the subcutaneous methotrexate. This action should be undertaken following discussion with the appropriate Operational Lead.

Subsequently, if the dose is increased at any time by the Rheumatology Consultant, the Rheumatology Department will send the patient a letter confirming this and blood forms for increased monitoring. Where it is known to the Rheumatology Department that FNHC Nurses are involved with the patient's methotrexate administration, they will copy them into this letter.

Where contraindications to the administration of subcutaneous methotrexate are identified, the responsible physician must be informed immediately and arrangements made for the patient to be reviewed by them. This should be followed up by a liaison letter to the responsible physician.

3.2 Preparing for the Administration of Subcutaneous Methotrexate

Purpose

To ensure that FNHC Nurses are appropriately prepared ahead of administering the injection and contraindications to the administration of subcutaneous methotrexate are identified and appropriate action taken

Scope

All FNHC Nurses required to administer subcutaneous methotrexate or supporting others to do this. **Those who are pregnant, particularly in the first trimester, should not handle or administer methotrexate (RCN 2016)**

Core Requirements

The RCN's 2016 guidelines state that "No specialist training is required for the administration of subcutaneous methotrexate by practitioners" (p 12). However, FNHC Nurses should be competent in the safe use of the auto-injector device which is used for subcutaneous methotrexate administration and in the subcutaneous injection technique.

To develop their practice relating to the administration of subcutaneous methotrexate, FNHC Nurses should complete the educational competencies programme (Appendix 4).

Ensure that the procedure can be carried out with no interruptions or distractions

Ensure the following equipment is available and ready to use:

- Written authorisation from a Registered Prescriber to administer subcutaneous methotrexate
- Subcutaneous Methotrexate Administration Checklist (Appendix 1)
- Methotrexate pre-dosed, pre-filled auto-injector device (Metoject® range)
- Cytotoxic sharps bin (obtained from the Stores Department)
- Disposable gloves (ideally latex free) and apron
- Gauze swabs or tissues
- Spill kit (ideally)

Healthcare professionals or non-patient injectors must wear gloves and an apron however, patients injecting themselves are not required to wear personal protective equipment.

Confirm that the medication had been stored appropriately

Nursing staff must have written authorisation from a Registered Prescriber prior to administering subcutaneous methotrexate. Complete the pre-administration checklist (Appendix 1).

In addition, check and confirm that no changes have been made to the dosage.

Where any discrepancy is found, immediate advice must be sought from the responsible physician.

3.3 Giving the Injection - Metoject® auto-injector

Purpose

To enable the safe administration of subcutaneous methotrexate

Scope

All FNHC Nurses administering subcutaneous methotrexate or supporting others to do this. **Those who are pregnant, particularly in the first trimester, should not handle or administer methotrexate (RCN 2016).**

Core Requirements

- Wash and dry hands thoroughly.
- Put on the gloves and apron (patients who self-administer are not required to wear gloves or apron)
- Check the following: Patient's name on pharmacy label, drug name, dose, route, expiry date and the colour of the liquid in the device (it should be yellow but transparent). Check details against the drug chart. Also check that the medication has been stored appropriately. If there is a discrepancy, do not proceed and contact the dispensing pharmacy.
- Remove Metoject® PEN device from the packaging. The packaging can go in the normal household waste.
- Check that the device is undamaged. An air bubble MAY be visible in the PEN. This is purposefully present, harmless and absorbed easily, therefore do not attempt to eject it.
- Identify the site you are to inject remembering to ensure site rotation each week. Appropriate sites to use are the standard subcutaneous sites; abdomen, thighs and upper arms. Upper arms location is **not** for self-administration and then **only** if there is a sufficient subcutaneous layer. If the abdomen is used avoid the 5cm diameter around the umbilicus (tummy button). Injection sites should be rotated and a record kept of sites used.
- Ensure the skin is clean and dry at the site you are about to inject (alcohol swabbing is not essential if skin is socially clean)
- **Do not remove the yellow protection cap until you are ready to administer the injection**
- Remove the yellow protection cap by pulling it downwards. This will reveal the needle shield. Do not twist or bend the protection cap
- Gently grip the skin at the injection site using your thumb and index finger and maintain throughout the injection process. Ensure that the surface of the skin is firm. (Alternative injection techniques can be considered as per specific brand recommendations).
- Place device at a 90 degree angle to the skin and push firmly against the skin until the needle shield slides fully into the viewing window. This action will then unlock the yellow release button.

- To start the injection, press the yellow release button with your thumb. A clicking sound will then be heard.
- Wait five seconds until all the medicine is injected (observe this through the viewing window) – **Do not move the device during injection**.
- Once the device is empty, release the skin and remove the device.
- Put the device directly into the cytotoxic sharps bin.
- If there is a small amount of leakage from the injection site, dab with cotton wool/swab/tissue.
- Gloves and apron worn during the procedure should be disposed of in the sharps bin along with the cotton wool/swab/tissue.
- Wash and dry hands thoroughly.

3.4 Disposal of Equipment Following Administration of Subcutaneous Methotrexate

Purpose

To enable the safe disposal of equipment used in the administration of subcutaneous methotrexate

Scope

All FNHC Nurses administering subcutaneous methotrexate or supporting others to do this.

Core Requirements

With the exception of the outer packaging of the auto-injector device, all materials used during the administration should be disposed of in the cytotoxic sharps bin.

The FNHC Nurse administering the cytotoxic medication will be responsible for the removal from the patient's home of the sharps bins used. These should be returned to Le Bas Centre

If the patient or carer are administering the medication, they should be encouraged to follow the procedure for disposal of equipment that was agreed during their training.

3.5 Recording the Administration of Subcutaneous Methotrexate

Purpose

To enable the administration of subcutaneous methotrexate to be recorded in line with the FNHC Medicines Policy and FNHC Record Keeping Policy.

Scope

All FNHC Nurses administering subcutaneous methotrexate or supporting others to do this.

Core Requirements

The administration of subcutaneous methotrexate, as prescribed by the responsible physician, must be documented in the appropriate FNHC Medication Administration Record.

3.6 Spillage of Subcutaneous Methotrexate

Purpose

To enable FNHC staff to safely deal with a spillage of subcutaneous methotrexate.

Scope

All FNHC staff required to deal with a spillage of subcutaneous methotrexate or supporting others to do this.

Core Requirements

Although spillage is unlikely when using pre-filled PENs, patients and carers should also be aware of what to do in case of spillage.

Liquid spillage on clothing

Wear protective gloves and blot dry with a paper towel or kitchen roll. As a precaution, clothing should be removed immediately and washed separately from other items. Wash hands thoroughly.

Liquid spillage directly onto the skin

If methotrexate is accidentally spilt onto the skin, the area should be washed ‘liberally with soap and cold water’ Methotrexate is not a vesicant (blister agent).

Liquid spillage directly into the eye

The eye should be washed out using plenty of water for a few minutes. If available, use an eye wash kit. A doctor should be contacted if any side effects are experienced.

Liquid spillage on floors or work surfaces

Wearing gloves, cover the spillage with absorbent paper and clean with soap and water and dry with paper tissue

Dispose of all paper towels, gloves and other materials used to deal with the spillage in the cytotoxic sharps bin.

Wash hands thoroughly after you have dealt with the spillage.

NB The spillage must be reported using the ‘Assure’ incident reporting system.

4 CONSULTATION PROCESS

Name	Title	Date
Judy Foglia	Director of Governance Regulation and Care	15.06.2021
Tia Hall	Operational Lead Adult Services	14.04.2021 & 15.06.21
Elspeth Snowie	Clinical Effectiveness Facilitator	02.06.2021
Justine Bell	Education and Practice Development Nurse	15.06.2021
Jane Abraham (HCS)	Rheumatology Clinical Nurse Specialist	13.04.2021

5 IMPLEMENTATION PLAN

Action	Responsible Person	Planned timeline
Email to all staff	Secretary/Administration Assistant (Quality and Governance Team)	Within 2 weeks following ratification
Policy to be placed on the organisation's Procedural Document Library	Secretary/Administration Assistant (Quality and Governance Team)	Within 2 weeks following ratification

6 MONITORING COMPLIANCE

Compliance with this guidelines/SOPs policy should be monitored by Team Leaders as part of their oversight of patient care. Incident and near miss reporting using Assure will inform learning and potential reviews associated with medicines management.

7 EQUALITY IMPACT STATEMENT

Family Nursing & Home Care is committed to ensuring that, as far as is reasonably practicable, the way services are provided to the public and the way staff are treated reflects their individual needs and does not discriminate against individuals or groups on any grounds.

This policy document forms part of a commitment to create a positive culture of respect for all individuals including staff, patients, their families and carers as well as community partners. The intention is to identify, remove or minimise discriminatory practice in the areas of race, disability, gender, sexual orientation, age and 'religion, belief, faith and spirituality' as well as to promote positive practice and value the diversity of all individuals and communities.

The Family Nursing & Home Care values underpin everything done in the name of the organisation. They are manifest in the behaviours employees display. The organisation is committed to promoting a culture founded on these values.

Always:

- ✓ Putting patients first
- ✓ Keeping people safe
- ✓ Have courage and commitment to do the right thing
- ✓ Be accountable, take responsibility and own your actions
- ✓ Listen actively
- ✓ Check for understanding when you communicate
- ✓ Be respectful and treat people with dignity
- ✓ Work as a team

This policy should be read and implemented with the Organisational Values in mind at all times. The Equality Impact Assessment for this policy can be found at appendix 5.

8 GLOSSARY

Not applicable

9 REFERENCES

Government of Jersey (2019) *Health and Community Services Administering Subcutaneous Methotrexate: Guide for patients* Available at: https://soj/depts/HSS/Registered%20Documents/ID%20Administering%20Subcutaneous%20Methotrexate%20Leaflet.pdf#search=methotrexate Last accessed 15th April 2021

Medac GmbH (2020) *Metoject PEN solution for injection in pre-filled pen; Summary of Product Characteristics.* Available at https://www.medicines.org.uk/emc/product/11351/smpc Last accessed 14th April 2021

RCN (2016) *Administering subcutaneous methotrexate for inflammatory arthritis RCN guidance (Third edition)* https://www.rcn.org.uk/professional-development/publications/pub-005564 last accessed 14th April 2021

10 APPENDIX

Appendix 1
Subcutaneous Methotrexate Administration Checklist

Patient name:……. **D.O.B:……..** **URN:……** **Or affix patient label**	**Sheet Number:**

Has a competency-based education/training programme been undertaken by the patient/carer/parent? Yes / No (delete as applicable)	**Is a copy of the education programme available in the patient's records?** Yes / No (delete as applicable) If 'No' request this from the referrer
Who delivered this programme?	**Date programme completed:**

*If no educational/training programme has been undertaken, the patient must be referred back to the referrer for this to happen.
It is not the responsibility of FNHC Nurses to deliver this training programme

*If the answer to any of the following questions is 'No'
DO NOT ADMINISTER methotrexate – seek medical advice *

Date					
Blood monitoring tests checked and results confirmed to be within acceptable parameters ……Yes/No					
If test results are not within acceptable parameters, advice has been sought from the responsible clinician and documented in the patient's notes……. Yes/No/N/A					
Agreement from clinician to proceed given …… ….. Yes/No					

Continued on next page

The patient is free of the following signs/symptoms: • Severe sore throat or mouth • Abnormal bleeding tendency • Skin rash • Mouth ulceration • Breathlessness or dry cough • Symptoms of/contact with shingles or chickenpox • an infection that is not improving ……. Yes/No					
Is the patient pregnant? Yes/No If this answer is Yes **do not proceed***					
Written authorisation to medicate available and the dosage confirmed as unchanged? Yes/No					
Correct medication available and in date Yes/No					
Medication has been stored appropriately Yes/No					
All necessary equipment available Yes/No					
Consent reaffirmed Yes/No					
Checklist completed by: **Initials**					

Appendix 2

Training checklist for home administration of subcutaneous methotrexate by a patient or carer/parent.

To be completed by staff member delivering the training.

Patient name and URN :	
Person trained:	
Trainer:	
Date:	

Skill	**Shown/discussed with Patient or carer /parent**
Understands verbal and written information given on subcutaneous Methotrexate, including potential complications/side effects. Can discuss why it's given.	
Patient aware to use Contraception as methotrexate is contraindicated in pregnancy.	
Knows how to acquire the Pens.	
Understands storage requirements.	
Knows how to check the equipment and drug.	
Knows the correct hand washing techniques .	
Knows how to deal with a needle stick injury.	
Can give the subcutaneous Methotrexate injection using a safe technique and can identify where the injection can be given.	
Knows how to deal with spillage on surfaces, skin and eyes.	
Knows how to dispose of used sharps, and any unused methotrexate.	
Can discuss instances when not to give the injections i.e. infections/signs of neutropenia.	
Knows who to contact in case of any problems.	
Can discuss the rationale and arrangements for blood monitoring while on methotrexate therapy.	
Knows that Co-Trimoxazole (Septrin) and Trimethoprim must not be taken with Methotrexate.	
Knows what to do when traveling with Methotrexate and that a supporting letter may be given if required.	
Aware not to have Live Vaccinations	
Methotrexate card given	

Appendix 3

Competency Agreement for the home administration of subcutaneous methotrexate by patient or patient's carer

Patient name **Address**	*Or affix Patient label*
Telephone number	

This is to certify that I have received teaching about subcutaneous Methotrexate and how to give the injections. I now feel confident and competent in administering the injectable treatment at home. I understand what problems may arise and what to do if they occur.

Patient/Carer name	
Signature	
Date	
Assessor name	
Assessor signature	
Date	

If the patient is competent at self-administration of injections, the above checklist can be completed by telephone consultation. This should be documented by the assessor.

Appendix 4

Family Nursing & Home Care

Staff Competencies Programme

Name of Practitioner.....

Name of Supervisor.....

Element of Competence to be achieved	Date of achievement	Signature of Practitioner	Signature of Supervisor
Discuss the rationale for the use of subcutaneous methotrexate in rheumatic conditions			
Describe the physiological effects of methotrexate			
Discuss potential issues related to treatment including: *screening of patients *possible side effects or adverse events *drug interactions *contraindications to methotrexate therapy			
Discuss the circumstances when subcutaneous methotrexate should not be administered			
Describe interventions required to alleviate methotrexate induced side effects			
Discuss the process for assessing the patient's suitability for methotrexate therapy e.g. medical history, concomitant medications, allergies, level of disease activity, dexterity and attitude to treatment			
Demonstrate the ability to check the validity of the current prescription, including expiry date, dose, route by which the drug is to be administered and the checking of the patient identification			
Describe sites on the body that would be appropriate for subcutaneous methotrexate injection			

Continued on next page

Describe local health and safety guidelines and risk assessment required for providing a subcutaneous methotrexate service in the patient's home with particular relevance to: *safe storage and handling *handwashing *dealing with spillage and disposal of cytotoxic waste *the use of protective clothing *ensuring a quiet and safe environment *preventing unnecessary exposure to other people *travelling and transporting methotrexate			
Discuss the information/educational needs of the patient/carer in support of home administration of subcutaneous methotrexate therapy			
Discuss action to be taken if patient, parent/carer does not meet expected competencies level, when self-administering			
Demonstrate the ability to maintain concise and accurate patient documentation and audit. These should include: *nursing records *medicine prescription/administration sheet *helpline/follow up			
Demonstrate an understanding of the local monitoring requirements and follow up arrangements for subcutaneous methotrexate therapy and the actions that must be taken in the event of a blood dyscrasia			
Discuss accountability in relation to the administration of subcutaneous methotrexate			
Identify the ways of maintaining current competency			

This programme was adapted from the Royal College of Nursing (2016) guidance document 'Administering subcutaneous methotrexate for inflammatory arthritis'

Appendix 5 Equality Impact Screening Tool

Stage 1 - Screening			
Title of Procedural Document: Administration of Subcutaneous Methotrexate for Inflammatory Arthritis in Adults			
Date of Assessment	16th April 2021	Responsible Department	Clinical
Name of person completing assessment	Mo de Gruchy	Job Title	Quality Performance and Development Nurse

Does the policy/function affect one group less or more favourably than another on the basis of :	**Yes/No**	**Comments**
• Age	No	
• Disability Learning disability; physical disability; sensory impairment and/or mental health problems e.g. dementia	No	
• Ethnic Origin (including hard to reach groups)	No	
• Gender reassignment	No	
• Pregnancy or Maternity	No	
• Race	No	
• Sex	No	
• Religion and Belief	No	
• Sexual Orientation	No	
If the answer to all of the above questions is NO, the EIA is complete. If YES, a full impact assessment is required: go on to stage 2, page 2		

Stage 2 – Full Impact Assessment			
What is the impact	**Level of Impact**	**Mitigating Actions** (what needs to be done to minimise / remove the impact)	**Responsible Officer**

Monitoring of Actions
The monitoring of actions to mitigate any impact will be undertaken at the appropriate level