

**Standard Operating Procedures**

Administration of Subcutaneous Methotrexate for Inflammatory Arthritis in Adults

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# Introduction

Methotrexate, developed in the 1940s as a folic acid antagonist, is a cytotoxic drug that, in low weekly doses, has become the cornerstone of arthritis management over the past 30 years. Early and rapid dose escalation is essential to achieve optimal disease control, and it is considered a first-line treatment for inflammatory conditions unless contraindicated. While debate exists over its cytotoxic nature at low doses, it is widely recognised as safe, well-tolerated, and effective, with strong evidence demonstrating its ability to slow disease progression, preserve function, and enhance outcomes when used in combination with other Disease-Modifying Antirheumatic Drugs (DMARDs) or biologic therapies. (Royal College of Nursing 2021)

Family Nursing & Home Care (FNHC) acknowledges the responsibilities associated with the administration of subcutaneous methotrexate. FNHC adheres to the Royal College of Nursing’s (RCN) guidelines to ensure that all patients receive care that aligns with current best practices while prioritising patient safety. This SOP document provides a structured framework to assist FNHC Nurses in the safe and effective administration of subcutaneous methotrexate injections. It also supports nurses in empowering patients and/or their carers to administer the medication at home confidently and safely.

This SOP document applies to Registered Nurses employed by FNHC who may be required to administer subcutaneous methotrexate or support patients/carers in doing so. It is specifically intended for adult patients receiving this treatment.

# SOP 1 Communication with Relevant Healthcare Professionals

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| ***Purpose*** |

Ensure all relevant healthcare professionals are informed about the administration of subcutaneous methotrexate to ensure seamless patient care.

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| ***Scope*** |

Applies to all nurses and healthcare professionals involved in the administration or support of subcutaneous methotrexate.

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| ***Core Requirements/Procedure*** |

Patients are typically started on subcutaneous methotrexate by the Rheumatology Consultant, who issues the initial prescription.

Following initiation, care is generally shared with the General Practitioner (GP), who assumes responsibility for ongoing prescribing of subcutaneous methotrexate.

Patients or their carers are responsible for obtaining supplies of methotrexate in the form of pre-filled auto-injector devices.

If the patient requires FNHC Nurses to administer the methotrexate injection:

* A referral will be made by the Rheumatology Department, detailing the patient’s specific blood and urine monitoring regime.
* Written authorisation for medication administration will be provided on the FNHC ‘Medication Record and Authorisation Sheet’, in accordance with the [FNHC Medicines Policy](https://www.fnhc.org.je/wp-content/uploads/2024/12/Medicines-Policy-2023.pdf).

Upon accepting a patient for subcutaneous methotrexate administration or support:

* Both the GP and the responsible physician (if different) must be informed via a liaison letter.
* The Rheumatology Clinical Nurse Specialist (CNS) must also receive a copy of this liaison letter to ensure FNHC is copied into relevant patient correspondence, such as notifications of dose increases or adjustments to monitoring requirements.

If timely confirmation of satisfactory test results is not received from the responsible physician:

* The FNHC Nurse must contact the responsible physician prior to the scheduled appointment with the patient.
* Should confirmation not be provided, the FNHC Nurse must notify the responsible physician that administration/support cannot proceed. This decision should be made in consultation with the appropriate Operational Lead.

In cases where the dose is increased by the Rheumatology Consultant:

* The Rheumatology Department will issue a confirmation letter to the patient, along with blood forms for updated monitoring requirements.
* If FNHC Nurses are involved, the Rheumatology Department will ensure they are copied into this correspondence.

If any contraindications to subcutaneous methotrexate administration are identified:

* The responsible physician must be notified immediately.
* Arrangements should be made for the patient to be reviewed.
* This communication should be followed up with a formal liaison letter to the responsible physician.

# SOP 2 Preparing for the Administration

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| ***Purpose*** |

To ensure the safe and effective preparation for the administration of subcutaneous methotrexate, minimising risks to patients and healthcare practitioners while adhering to best practices.

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| ***Scope*** |

Applies to all nurses administering or supporting methotrexate injections.

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| ***Core Requirements/Procedure*** |

**Practitioner Competency**

FNHC Nurses must be competent in subcutaneous injection techniques and the safe use of an auto-injector device.

Completion of the Competency Checklist ([Appendix 1](#_Appendix_1._)).

No specialist training is required as per the RCN’s 2021 guidelines, but practitioners should maintain ongoing professional development.

**Preparation**

Ensure the procedure can be carried out without interruptions or distractions.

Gather and verify the following equipment:

* Written authorisation from a Registered Prescriber to administer methotrexate.
* Subcutaneous Methotrexate Administration Checklist ([Appendix 2](#_Appendix_2._)).
* Pre-dosed, pre-filled auto-injector device (e.g., Metoject®).
* Cytotoxic sharps bin (available from the Stores Department).
* Disposable gloves (latex-free preferred) and apron.
* Gauze swabs or tissues.
* Spill kit (if available).

**Personal Protective Equipment (PPE)**

Gloves (latex-free, ideally) are recommended for practitioners; aprons are optional but encouraged for standard clinical practice.

For patient self-administration, PPE is not required.

Full PPE (e.g., masks, goggles, armlets) is not necessary when using pre-filled auto-injectors due to the low cytotoxic risk.

**Spillage Awareness**

While the risk of spillage with pre-filled auto-injectors is negligible, practitioners and carers should:

* Be aware of local policies for cytotoxic spillage.
* Have access to spillage kits where locally agreed.
* Provide patients/carers with guidance on dealing with accidental spills at home.

**Pre-Administration Checks**

Confirm that the methotrexate has been stored appropriately.

Complete the Subcutaneous Methotrexate Administration Checklist ([Appendix 2](#_Appendix_2._)).

Verify the dosage and ensure no changes have been made since the last prescription.

If any discrepancies are found, immediately seek advice from the responsible physician.

**Documentation**

Document all preparation steps and confirm the patient/carer is aware of the risks associated with handling methotrexate.

Ensure informed consent is obtained and recorded.

# SOP 3 Administering methotrexate using autoinjector pre-filled PENs

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| ***Purpose*** |

The latest guidance from the RCN strongly supports and recommends the use of licensed methotrexate via the subcutaneous route, for instance, an autoinjector pre-filled PEN or a pre-filled injector device, NOT the pre-filled syringes or vials. The purpose of this SOP is to enable safe and effective administration of methotrexate using a pre-filled device.

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| ***Scope*** |

Applies to all nurses involved in methotrexate administration.

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| ***Core Requirements/Procedure*** |

**Preparation**

Wash and dry hands thoroughly.

Wear gloves and an apron. (Note: Patients who self-administer are not required to wear gloves or an apron.)

**Medication and Equipment Check**

Verify the following details against the pharmacy label and drug chart:

* Patient’s name.
* Drug name, dose, route, and expiry date.
* Colour of the liquid in the device (should be yellow and transparent).

Ensure the medication has been stored appropriately.

If there are any discrepancies, do not proceed and contact the dispensing pharmacy.

**Device Preparation**

Remove the Metoject® PEN device from its packaging. Dispose of the packaging in household waste.

Inspect the device for damage. Do not proceed if the device is damaged.

Note: An air bubble in the PEN is normal and should not be removed.

**Site Selection and Preparation**

Identify the injection site, ensuring site rotation each week. Suitable sites include:

* Abdomen (avoiding a 5cm diameter around the umbilicus).
* Thighs.
* Upper arms (not for self-administration unless a sufficient subcutaneous layer exists).
* Ensure the skin is clean and dry. Alcohol swabbing is unnecessary if the skin is socially clean.

**Injection Process**

Do not remove the yellow protection cap until ready to administer.

Remove the yellow protection cap by pulling it downwards, revealing the needle shield. Do not twist or bend the cap.

Gently pinch the skin at the injection site using your thumb and index finger to create a firm surface.

Position the device at a 90-degree angle to the skin and press firmly until the needle shield slides fully into the viewing window, unlocking the yellow release button.

Press the yellow release button with your thumb to start the injection. A clicking sound will confirm the injection has started.

Hold the device in place for 5 seconds to ensure the medicine is fully injected.

**Post-Injection Steps**

Release the skin and remove the device.

Dispose of the used device directly into a cytotoxic sharps bin.

Dab any leakage at the injection site with cotton wool, a swab, or tissue.

Dispose of gloves, the apron, and any used swabs/tissues in the sharps bin.

**Final Steps**

Wash and dry hands thoroughly.

# SOP 4 Disposal of equipment following administration of subcutaneous methotrexate

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| ***Purpose*** |

Ensure safe disposal of all materials used in methotrexate administration.

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| ***Scope*** |

Applies to all personnel administering or supporting the administration of methotrexate.

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| ***Core Requirements/Procedure*** |

Practitioners should be up to date on policies in relation to dealing with hazardous waste and sharps safety.

Refer to the [FNHC Waste Management Policy](https://www.fnhc.org.je/wp-content/uploads/2023/12/Waste-Management-Policy-2021-updated.pdf) and [Sharps Safety Policy](https://www.fnhc.org.je/wp-content/uploads/2022/03/sharps-safety-policy-final-v2.pdf) regarding the storage, collection, handling and disposal of cytotoxic clinical waste / sharps.

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

The FNHC Nurse administering the cytotoxic medication is responsible for the removal of used sharps bins from the patient’s home. 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.

# SOP 5 Dealing with Spillage

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| ***Purpose*** |

Enable safe handling of methotrexate spillage.

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| ***Scope*** |

Applies to all staff managing methotrexate spillage incidents.

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| ***Core Requirements/Procedure*** |

Refer to the [FNHC Waste Management Policy](https://www.fnhc.org.je/wp-content/uploads/2023/12/Waste-Management-Policy-2021-updated.pdf), including procedures for dealing with accidental spillages in relevant settings.

When methotrexate is administered using a licensed autoinjector pre-filled PEN or pre-filled injector device (not a syringe), the risk of spillage and exposure is minimal.

A spillage kit is generally not necessary but may be provided to the patient if deemed appropriate. Refer to local policies for specific guidance.

Patients and carers should be informed of the appropriate actions to take in case of a spillage.

**Spillage on Clothing**

* Wear protective gloves and blot the affected area with a paper towel or kitchen roll. Dispose of the material in a cytotoxic bin.
* Remove the contaminated clothing immediately as a precaution and wash it separately from other items.
* Wash hands thoroughly after handling the spillage.

**Spillage on Skin**

* Methotrexate has poor dermal absorption, but if it comes into contact with skin, wash the area thoroughly with soap and cold water.
* Methotrexate is not a vesicant and does not cause blistering, but prompt washing is recommended.

**Spillage in the Eye**

* Rinse the eye with plenty of water for several minutes.
* If any side effects occur, contact a doctor immediately.
* Some care settings may provide an eye wash kit if required.

**Spillage on Floors or Work Surfaces**

* Wear gloves and cover the spillage with absorbent paper.
* Clean the area with soap and water, then dry with paper tissue.
* Dispose of used materials in a cytotoxic bin.

Wash hands thoroughly after dealing with the spillage.

**The spillage must be reported using the “Assure” incident reporting system.**

# SOP 6 Recording the administration of subcutaneous methotrexate

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| ***Purpose*** |

To enable the administration of subcutaneous methotrexate to be recorded in line with the current version of the [FNHC Medicines Policy](https://www.fnhc.org.je/wp-content/uploads/2024/12/Medicines-Policy-2023.pdf) and [FNHC Record Keeping Policy](https://www.fnhc.org.je/wp-content/uploads/2023/08/v3.2-Record-Keeping-Policy-Final.pdf).

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| ***Scope*** |

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

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| ***Core Requirements/Procedure*** |

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

# References

[FNHC (2021) Record Keeping Policy](https://www.fnhc.org.je/wp-content/uploads/2023/08/v3.2-Record-Keeping-Policy-Final.pdf)

[FNHC (2023) Medicines Policy](https://www.fnhc.org.je/wp-content/uploads/2024/12/Medicines-Policy-2023.pdf)

[FNHC (2023) Waste Management Policy, including procedures for dealing with accidental spillages in relevant settings](https://www.fnhc.org.je/wp-content/uploads/2023/12/Waste-Management-Policy-2021-updated.pdf)

[FNHC (2021) Sharps Safety Policy](https://www.fnhc.org.je/wp-content/uploads/2022/03/sharps-safety-policy-final-v2.pdf)

[FNHC (2023) Injectable Medicines Policy](https://www.fnhc.org.je/wp-content/uploads/2023/08/Injectable-Medicines-Policy-approved-2.08.23.pdf)

Royal College of Nursing (2021) Administering Subcutaneous Methotrexate for Inflammatory Arthritis – Clinical Professional Resource. Fourth edition. Accessible via: <https://www.rcn.org.uk/professional-development/publications/administering-subcutaneous-methotrexate-for-inflammatory-arthritis-uk-pub-009-675>

# Appendix 1. Practitioner Competency Checklist - Methotrexate

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| --- | --- |
| Name of Practitioner |  |
| Name of Supervisor |  |

| Element of competence to be achieved | Date of achievement | Practitioner signature | Supervisor signature |
| --- | --- | --- | --- |
| Discuss the rationale for the use of subcutaneous methotrexate in rheumatic conditions. |  |  |  |
| 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. For example, 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. This includes expiry date, dose, route by which the drug is to be administered and the checking of the patient identification. |  |  |  |
| Demonstrate the ability to teach a patient/carer how to administer subcutaneous methotrexate. |  |  |  |
| Demonstrate the ability to assess a patient’s/carer’s suitability for home administration of subcutaneous methotrexate. |  |  |  |
| Describe local health and safety guidelines and risk assessment required for providing a subcutaneous methotrexate service in hospital and in the patient’s home. With particular relevance to: • safe storage and handling • dealing with disposal and rare situation of spillage • ensuring a quiet and safe environment • preventing unnecessary exposure to other people • travelling and transporting methotrexate. |  |  |  |
| Demonstrate the ability to discuss the information/educational needs of the patient/carer in relation to home administration of subcutaneous methotrexate therapy. |  |  |  |
| Demonstrate the ability to provide the patient/carer with information about the treatment in order that they can give informed consent (written/verbal – in line with local guidelines). |  |  |  |
| Describe sites on the body that would be appropriate for subcutaneous methotrexate injection. |  |  |  |
| Demonstrate the ability to maintain concise and accurate patient documentation and audit. |  |  |  |
| Describe 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. |  |  |  |
| Describe the rationale for the use of folic acid supplementation in patients receiving subcutaneous methotrexate. |  |  |  |
| Identify the ways of maintaining current competency. |  |  |  |

*Adapted from RCN (2021) Guidance Document “Administering Subcutaneous Methotrexate for Inflammatory Arthritis”*

# Appendix 2. Subcutaneous Methotrexate Administration Checklist

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| **Patient name:…………………………………………………….**  **D.O.B:……………………………………………………………..**  **EMIS:………………………………………………………………**  **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:** | |

Please Note: 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 \* | **Yes / No** | **Date** | **Yes / No** | **Date** | **Yes / No** | **Date** | **Yes / No** | **Date** | **Yes / No** | **Date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Blood monitoring tests checked, and results confirmed to be within acceptable parameters? |  |  |  |  |  |  |  |  |  |  |
| If test results are not within acceptable parameters, advice has been sought from the responsible clinician and documented in the patient’s notes? |  |  |  |  |  |  |  |  |  |  |
| Agreement from clinician to proceed given? |  |  |  |  |  |  |  |  |  |  |
| 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 |  |  |  |  |  |  |  |  |  |  |
| Is the patient pregnant?  If this answer is Yes do not proceed |  |  |  |  |  |  |  |  |  |  |
| Written authorisation to medicate available and the dosage confirmed as unchanged? |  |  |  |  |  |  |  |  |  |  |
| Correct medication available and in date? |  |  |  |  |  |  |  |  |  |  |
| Medication has been stored appropriately? |  |  |  |  |  |  |  |  |  |  |
| All necessary equipment available? |  |  |  |  |  |  |  |  |  |  |
| Consent reaffirmed? |  |  |  |  |  |  |  |  |  |  |
| **Checklist completed by: (enter initials)** |  |  |  |  |  |  |  |  |  |  |