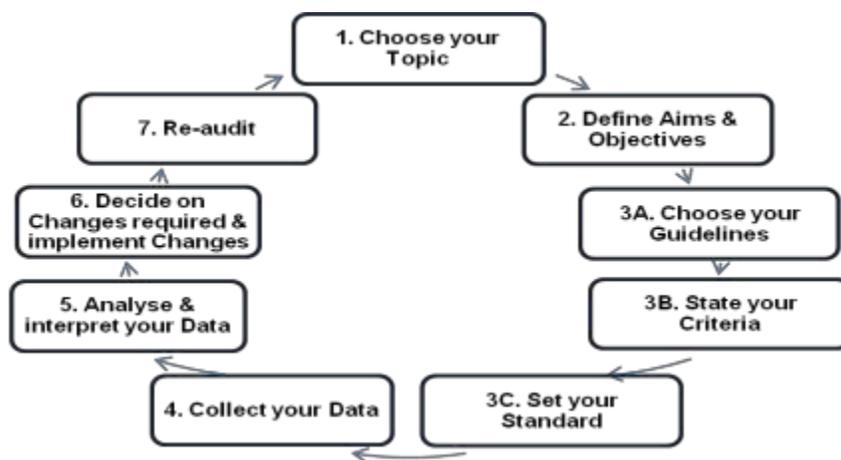




Methotrexate in General Practice Audit



Methotrexate:

Using audit to enhance safer use of potentially toxic medication

Good for patients, Good for doctors.

AUTHORS

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Reviewed August 2019
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Purpose of ICGP sample audits on specific topics

The purpose of the ICGP sample audit for each topic area is to provide practitioners with audit topic proposals and related tools in order to aid them in carrying out a clinical audit in this topic area. For each topic, a specific guideline is chosen which identifies best practice for the relevant topic. Following this, examples of the elements of care or activity that could be measured are provided – these are referred to as “criteria”.

Finally, examples of the type of data that is required in order to audit the sample criteria are provided. A separate document, the ICGP Audit Toolkit, provides detailed generic instructions on how to carry out and report your audit.

Sample Audit Topic:	Methotrexate / Medication Safety
Professional Competence Domains:	Clinical Skills
	Management
	Patient Safety and Quality of Care

In all instances where ‘your patients’ are referred to, this can be taken to mean the patients you see. Where ‘your practice’ is mentioned, this refers to the work you do, not necessarily that you need to be based in one particular practice.”

Original Publication: 2014

Date reviewed: August 2019

Date of next review: 2022

Aims & Objectives:

Errors in prescribing, dispensing, and especially incorrect methotrexate dosing (with daily instead of weekly) continue to cause serious patient harm and deaths. Recent [European medicine safety committee](#) draft recommendations outline new measures to avoid methotrexate-related patient harm.

This audit will help establish the current standard of care provided to your patients taking Methotrexate. Undertake changes where necessary and improve patient safety. An excellent brief synopsis of safe use of oral methotrexate in primary care is available from HSE Medicines Management Programme: <https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/oral-methotrexate-in-primary-care.pdf>

Useful Hints:

- 1. This audit can be readily amended to permit simultaneous audit of patients taking Lithium. Suboptimal monitoring of patients taking lithium therapy is well documented. Serious patient harm may readily result from Lithium toxicity.*
- 2. Methotrexate is mostly prescribed for psoriasis and Rheumatoid arthritis. We use the phrase “**No blood test, no prescription, no exceptions**” to enhance patient attendance for methotrexate blood tests. (This approach is clearly inappropriate for patients taking lithium)*
- 3. Are you compliant with new European draft recommendations for methotrexate?*

European measures (draft) to help prevent methotrexate dosing errors

- Only doctors with expertise in using methotrexate should prescribe methotrexate (GP registrars take note)
- Doctors should ensure that patients/carers *'are able to follow the once weekly dosing schedule'*
- Patient card emphasising the weekly dosing for methotrexate to be provided (see Appendix 1 for template)
- Doctors to be provided with educational materials for methotrexate and to counsel patients accordingly.

Sample Criteria (preferably audit all 4 domains below: see audit template at end of document)

1. **Blood tests:** Patients **stabilised** on an effective dose of methotrexate (As per current BNF standard) should have blood tests every 2-3 months. (Important note: when methotrexate is initiated and following dose increases, blood testing every 1-2 weeks is recommended, see BNF).
2. **Prescription:** Prescriptions for methotrexate should specify once weekly, and state the exact day of week (i.e. *'take once a week on Monday'*) and tablet strength (*'dispense 2.5mg tablets only'*) (2012 IMB guideline).
3. **Vaccinations:** Patients taking Methotrexate should be offered flu vaccine annually and pneumococcal vaccine as appropriate, as per national immunisation [guidelines](#) for immunocompromised patients.
4. **Patient education:** Documented in record: once weekly dosing and outlining symptoms and signs of toxicity/overdose (Please see Criterion 4 below).

Choose the criteria from the above on which to conduct your audit and then set your standard (sometimes known as your target). This is your desired level of performance and is usually stated as a percentage. Avoid setting standards of 100%; standards should be realistic for your practice (perfection may not be possible).

The sample should include current/recent patients. In general, the number of patients taking methotrexate is small. Ideally assess all four above criteria for your patients. You might consider undertaking a similar audit for patients taking Lithium (and omit vaccination domain).

The **Data Collection tool** simplifies data collection for your audit:

Data Collection Tools

<p>Criterion 1:</p> <p>Patients stabilised on an effective dose of methotrexate (As per current BNF standard) should have blood tests every 2-3 months. (Important note: when methotrexate is initiated and following dose increases, blood testing every 1-2 weeks is recommended).</p> <p>Data collection tool:</p> <p>For each patient taking Methotrexate (computer drug search).</p> <ul style="list-style-type: none">- Assess number of blood tests (FBC and LFTs) in previous 13 months for each patient.- Number of patients compliant with guidelines.- Compliance is defined as 4-6 tests in previous 13 months.
<p>Criterion 2:</p> <p>Prescriptions for methotrexate should specify both exact day of week and tablet strength (2012 IMB guideline).</p> <p>Data collection tool:</p> <p>For each patient taking Methotrexate:</p> <ul style="list-style-type: none">- Assess number of patients with correct prescriptions.- Compliance defined as full, partial or not compliant.
<p>Criterion 3:</p> <p>Patients taking Methotrexate should have influenza vaccination annually and pneumococcal vaccination as appropriate (once off or in the past 5 years), as per national immunisation guidelines for immunocompromised patients.</p> <p>Data collection tool:</p> <p>For each patient taking Methotrexate:</p> <ul style="list-style-type: none">- Assess who received influenza vaccine in current season.- Assess who received pneumococcal vaccine.- Compliance is full, partial or not compliant.
<p>Criterion 4:</p> <p>Patient education (regarding once weekly dosing, symptoms and signs of methotrexate toxicity/overdose) should be given and documented (IMB & European guideline).</p> <p>Data collection tool:</p> <p>For each patient taking Methotrexate</p>

- Assess if the clinical record clearly documents patient education, including weekly dosing, signs and symptoms of toxicity, and appropriate action
- **Practical suggestion:** Consider 'free-texting' a patient safety message onto your prescription. This will auto populate every subsequent prescription. The pharmacist will reiterate the patient safety message with every dispensing. Suggested free text:
*"Methotrexate suppresses your immune system. Methotrexate should be taken **once a week**, and on the same day every week. If you are unwell, have sore throat or other infection, fever, chills, shivering, mouth ulcer, easy bruising or bleeding (nosebleeds/bleeding gums), or diarrhoea, vomiting, unexplained rash, breathlessness or persistent dry cough, please seek urgent medical attention. Tell the doctor you are taking methotrexate and request an urgent blood test"*

Next steps:

- Analyse your data and compare with your targets (consider using the accompanying Spreadsheet to simplify repeat data collection).
- Identify and implement necessary Quality Improvement changes.
- Re-audit your (individual) practice to 'complete the audit cycle'.
- Celebrate success and share your audit outcomes with colleagues

A detailed explanation can be found in the ICGP Audit Toolkit on www.icgp.ie/audit

Evidence:

1. **Irish Medicines Board Guidance** – IMB, Drug Safety Newsletter, 47th edition. "Oral Methotrexate – Risk of unintentional overdose due to medication errors". Drug Safety – April 2012 – Issue Number 47, <http://www.hpra.ie/docs/default-source/publications-forms/newsletters/drug-safety-newsletter-issue-no-47-april-2012.pdf>
2. **National Immunisation Guidelines** - see www.immunisation.ie
3. **Medicines.ie** – see <https://www.medicines.ie/medicines/methotrexate-2-5mg-tablet-32838/smpc>
4. **British National Formulary (BNF) Guidance on Methotrexate**
5. European Medicines Agency: "New measures to avoid dosing errors with methotrexate" <https://www.ema.europa.eu/en/news/prac-recommends-new-measures-avoid-dosing-errors-methotrexate>

Useful links:

- [Oral Methotrexate in Primary Care](#) (HSE)
- [Methotrexate 2.5mg tablets](#)
- IMSN methotrexate [safety alert](#)
- HPRA drug safety newsletter ([edition 71](#))
- Drug safety newsletter ([issue 47](#), April 2012)

Criterion	Patient 1		Patient 2-10,	
	before audit	after QI	before audit	after QI
Blood tests: 4-6 in 13 months	Yes/No	Yes/No	Yes/No	Yes/No
Prescription; Specify once weekly	Yes/No	Yes/No	Yes/No	Yes/No
Prescription; Specify day of week?	Yes/No	Yes/No	Yes/No	Yes/No
Prescription; Specify 2.5mg?	Yes/No	Yes/No	Yes/No	Yes/No
Vaccines: influenza	Yes/No	Yes/No	Yes/No	Yes/No
Vaccines: Pneumococcal	Yes/No	Yes/No	Yes/No	Yes/No
Pnt educ-n: S/S of Mtx toxicity?	Yes/No	Yes/No	Yes/No	Yes/No
Patient educ-n: Weekly dosing?	Yes/No	Yes/No	Yes/No	Yes/No
Clinical record: Summary	Yes/No	Yes/No	Yes/No	Yes/No
Clinical record: "Pop-Up Alert"?	Yes/No	Yes/No	Yes/No	Yes/No

Disclaimer:

Whilst every effort has been made to ensure the accuracy of the information and material contained in this document, errors may occur in the content. This audit clinical support does not override the individual responsibility of the healthcare professionals to make decisions that are appropriate to the circumstances of individual patients in consultation with the patient and / or guardian or carer.

Appendix 1 – Patient Alert Card Template (2 pages)

Surname
Forename
Address

GP
Consultant
Pharmacist
Date

Clinical **DIAGNOSIS;**
Immune-suppressant;

1.
2.
3.
Talk to your GP about
Flu, Varicella &
Pneumococcal vaccines

ALERT

This patient is currently on
**IMMUNO SUPPRESSING
DRUG TREATMENT.**

If you feel unwell, or have a
fever, sore throat, easy
bruising, cough, bleeding,
mouth ulcers, shivering see a
doctor **urgently** & request an
urgent blood test. Consider

NEUTROPENIC

SEPSIS (See overleaf for
details)

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SEPSIS (See overleaf for
details)

If the patient has received **IMMUNOSUPPRESSANT drug treatment within the past 28 days and has ANY ONE OR MORE of the following:**

Fevers or hypothermia, Rigors, shaking or chills.
Unexplained tachycardia, hypotension or tachypnoea.
Any indwelling vascular access device.
Feels unwell.
(Signs/Symptoms may be minimal especially if taking corticosteroids)

If the patient has received **IMMUNOSUPPRESSANT drug treatment within the past 28 days and has ANY ONE OR MORE of the following:**

Fevers or hypothermia, Rigors, shaking or chills.
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Consider Neutropenic Sepsis; Treat as an EMERGENCY

If neutropenic sepsis is suspected **Admit to hospital & treat IMMEDIATELY** with broad spectrum intravenous antibiotic **Contact their treating hospital for further advice.**

ACTION-Neutropenic Sepsis;

Urgent IV antibiotics.

Urgent FBC. Temp, pulse, BP, SpO₂

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Urgent FBC. Temp, pulse, BP, SpO₂

Blood cultures

(peripherally and from each lumen of VAD)

Benefits & risks of immunosuppressant medication explained by doctor/nurse; signature
Emergency Contact Details
Hospital Tel No;
Out of hours (6pm-8.30am); and ask for;
"On Call _____ - _____ Dr"

Blood cultures

(peripherally and from each lumen of VAD)

Benefits & risks of immunosuppressant medication explained by doctor/nurse; signature
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