Methotrexate in General Practice Audit

Methotrexate:
Using audit to enhance safer use of potentially toxic medication
Good for patients, Good for doctors.

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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.”

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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:

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**

<table>
<thead>
<tr>
<th>Criterion 1:</th>
<th>Patients <strong>stabilised</strong> 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).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data collection tool:</strong></td>
<td>For each patient taking Methotrexate (computer drug search).</td>
</tr>
<tr>
<td>- Assess number of blood tests (FBC and LFTs) in previous 13 months for each patient.</td>
<td>- Number of patients compliant with guidelines.</td>
</tr>
<tr>
<td>- Compliance is defined as 4-6 tests in previous 13 months.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criterion 2:</th>
<th>Prescriptions for methotrexate should specify <strong>both</strong> exact day of week and tablet strength (2012 IMB guideline).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data collection tool:</strong></td>
<td>For each patient taking Methotrexate:</td>
</tr>
<tr>
<td>- Assess number of patients with correct prescriptions.</td>
<td>- Compliance defined as full, partial or not compliant.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criterion 3:</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data collection tool:</strong></td>
<td>For each patient taking Methotrexate:</td>
</tr>
<tr>
<td>- Assess who received influenza vaccine in current season.</td>
<td>- Assess who received pneumococcal vaccine.</td>
</tr>
<tr>
<td>- Compliance is full, partial or not compliant.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criterion 4:</th>
<th>Patient education (regarding once weekly dosing, symptoms and signs of methotrexate toxicity/overdose) should be given and documented (IMB &amp; European guideline).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data collection tool:</strong></td>
<td>For each patient taking Methotrexate</td>
</tr>
</tbody>
</table>
- 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](http://www.icgp.ie/audit)

**Evidence:**

2. **National Immunisation Guidelines** - see [www.immunisation.ie](http://www.immunisation.ie)
3. **Medicines.ie** – see [https://www.medicines.ie/medicines/methotrexate-2-5mg-tablet-32838/smpc](https://www.medicines.ie/medicines/methotrexate-2-5mg-tablet-32838/smpc)
4. **British National Formulary (BNF) Guidance on Methotrexate**

**Useful links:**

- [Oral Methotrexate in Primary Care](http://www.hse.ie) (HSE)
- [Methotrexate 2.5mg tablets](http://www.hse.ie)
- IMSN methotrexate [safety alert](http://www.hse.ie)
- HPRA drug safety newsletter ([edition 71](http://www.hse.ie))
- Drug safety newsletter ([issue 47](http://www.hse.ie), April 2012)
### ICGP Methotrexate Sample Audit

#### Criterion

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Patient 1 before audit</th>
<th>after QI</th>
<th>Patient 2-10, before audit</th>
<th>after QI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood tests: 4-6 in 13 months</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Prescription; Specify once weekly</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Prescription; Specify day of week?</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Prescription; Specify 2.5mg?</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Vaccines: influenza</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Vaccines: Pneumococcal</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Pnt educ-n: S/S of Mtx toxicity?</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Patient educ-n: Weekly dosing?</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Clinical record: Summary</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Clinical record: &quot;Pop-Up Alert&quot;?</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
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**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)

<table>
<thead>
<tr>
<th>Surname</th>
<th>Forename</th>
<th>Address</th>
<th>GP</th>
<th>Consultant</th>
<th>Pharmacist</th>
<th>Date</th>
</tr>
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### 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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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)

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

Blood cultures
(periherally 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”

Additional Sections

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