

CLINICAL AUDIT

The safe and effective use of  
**Methotrexate**



Valid to October 2019

## Background

Methotrexate is an immunosuppressant used in the treatment of rheumatoid arthritis, severe psoriasis and some cancers. It is principally prescribed for rheumatoid arthritis as one of a number of possible Disease Modifying Anti-Rheumatic Drugs (DMARDs), and is a preferred option due to its low cost, predictable adverse effect profile, and effectiveness. However, it can also be highly toxic and even fatal. Although toxicity is more likely to occur in patients taking high doses, any dosing regimen may induce toxicity.

Adverse effects of methotrexate can occur even at therapeutic levels and include gastrointestinal symptoms such as nausea, dyspepsia, diarrhoea, mouth ulceration and hepatotoxicity. Being an immunosuppressant, methotrexate commonly results in bone marrow suppression which increases the risk of infections and viral illnesses. Another particular concern is the possibility of methotrexate-induced pneumonia, which should be considered if a patient taking methotrexate presents with a dry, persistent cough. Methotrexate can also cause liver cirrhosis and gastrointestinal bleeding that can have severe consequences. Folic acid prescribed on a once weekly basis can reduce the risk of adverse effects.

There have been numerous documented patient deaths attributable to methotrexate use in New Zealand and around the world. These have often involved patients taking methotrexate as a daily, rather than weekly dose due to error on the part of the clinician, the pharmacist or the patient.

Methotrexate is usually initiated in secondary care, however, many patients taking methotrexate will be monitored by their general practitioner, and receive repeat prescriptions in primary care. General practitioners therefore need to be aware of strategies for safe prescribing of this high risk medicine and of the potential signs of methotrexate toxicity. Accurate and complete recording of patient information means that any prescriber is able to easily access key information about the patient's management. This information should be immediately obvious to anyone accessing the notes, i.e. a locum or practice nurse. This can be done in several ways in most practice management software, e.g. using a "screening" entry in Medtech which makes the information easier to find rather than identifying it from a number of consultation notes.

To ensure the safety of patients taking methotrexate it is recommended that there is a systematic, practice-wide approach to prescribing this medicine. Safe prescribing

means that all necessary information is available to the pharmacist on the prescription and also to the patient (on the medicine label). There are a few common sense steps that can be implemented to minimise the risk of methotrexate toxicity and potential accidental overdose.

Common protocols should cover:

1. Accurate prescribing of methotrexate. Be as clear as you can with your prescription instructions:
  - a. To ensure that methotrexate is only ever prescribed on a once weekly basis write the day that the medicine is to be taken in full on the prescription
  - b. Ensure the correct weekly dose is written and give the specific dose in milligrams. If there is a change in dose, ensure that the patient is aware of this, especially if there is a change in the tablet size, e.g. a reduction from one 10 mg tablet per week to three 2.5mg tablets per week
  - c. Check the prescription when it is written and check again when it is printed
2. Check that the patient is also being prescribed weekly folic acid. A simple mnemonic tool as a means of ensuring once weekly dosing for each medicine on different days is 'Methotrexate for Monday', 'Folic acid for Friday'
3. Ensure that there is a standard method of recording that a patient is taking methotrexate, e.g. utilisation of functions within the PMS system such as patient alerts, so that all members of the primary care team are able to easily identify patients on methotrexate
4. Provide patient education regarding the safe use of methotrexate including the use of appropriate written material. The patient should be informed about the potential serious adverse effects associated with methotrexate and should understand when and what action(s) should be taken if these occur
5. Educate clinic staff about the signs of methotrexate toxicity, significant adverse effects and increase awareness of potential medicine interactions.
6. Ensure that there are systems in place so that any concerns about a patient taking methotrexate are communicated to the clinician or that other appropriate action is taken
7. Ensure regular laboratory monitoring of patients on methotrexate treatment

For further information, see: "Methotrexate: potentially fatal in overdose", BPJ 64 (Oct, 2014).

## Audit plan

All patients in the practice who are currently being treated with methotrexate can be audited to assess whether they have been prescribed methotrexate safely. The following information should be readily available in their patient record or in the patient's notes:

1. All necessary information regarding a patient's methotrexate treatment
2. Information regarding the patient's last laboratory test results and when their next laboratory tests are due
3. Information about any adverse effects

### Criteria for a positive result

For a patient to be considered a positive result for the audit, their notes should contain all of the following information:

- That the patient is taking methotrexate
- The condition they take it for
- Their current weekly dose
- The day of the week when they take their methotrexate
- That they are also prescribed weekly folic acid
- That the patient is asked on a regular basis about the presence of any adverse effects
- That appropriate laboratory monitoring is undertaken (past results available, date of next tests noted)

### Recommended audit standards

Given the level of risk of serious adverse effects including death associated with methotrexate use, the standard for this audit should ideally be high. A recommended standard would be for 90% of patients to have all the required information recorded in the patient notes. In addition, there should ideally be an improvement in the achieved percentage between the first and second audit cycles.

## Data

### Eligible people

All patients within the practice currently prescribed methotrexate are eligible for this audit.

### Identifying patients

You will need to have a system in place that allows you to identify these eligible patients. Many practices will be able to identify patients by running a "query" through their PMS system. Identify all patients who have had a prescription for methotrexate.

### Sample size

The number of eligible patients will vary according to your practice demographic. If you identify a large number of patients, take a random sample of 10 – 20 patients whose notes you will audit (the first 10 – 20 results returned is sufficiently random for the purposes of this audit).

### Data analysis

Use the data sheet provided to record your data.

A positive result is any patient who has a tick in each of the "Patient notes" columns. The percentage achievement can be calculated by dividing the number of patients with a positive result by the total number of patients audited.

## Identifying opportunities for CQI

### Taking action

The first step to improving medical practice is to identify where gaps exist between expected and actual performance and then to decide how to change practice.

Decide on a set of priorities for change and develop an action plan to implement any changes.

It may be useful to consider the following points when developing a plan for action.

### Problem solving process

- What is the problem or underlying problem(s)?
- Change it to an aim
- What are the solutions or options?
- What are the barriers?
- How can you overcome them?

### Overcoming barriers to promote change

- What is achievable – find out what the external pressures on the practice are and discuss ways of dealing with them in the practice setting
- Identify the barriers
- Develop a priority list
- Choose one or two achievable goals

### Effective interventions

- No single strategy or intervention is more effective than another, and sometimes a variety of methods are needed to bring about lasting change

- Interventions should be directed at existing barriers or problems, knowledge, skills and attitudes, as well as performance and behaviour

## Review

### Monitoring change and progress

It is important to review the action plan at regular intervals. It may be helpful to review the following questions:

- Is the process working?
- Are the goals for improvement being achieved?
- Are the goals still appropriate?
- Do you need to develop new tools to achieve the goals you have set?

Following the completion of the first cycle, it is recommended that practitioners complete the first part of the CQI activity summary sheet (Appendix 1).

### Undertaking a second cycle

In addition to regular reviews of progress, a second audit cycle should be completed in order to quantify progress on closing the gaps in performance.

It is recommended that the second cycle be completed within 12 months of completing the first cycle. The second cycle should begin at the data collection stage. Following the completion of the second cycle it is recommended that practitioners complete the remainder of the CQI activity summary sheet.



The Royal New Zealand  
College of General Practitioners

### Claiming MOPS credits

This audit has been endorsed by the RNZCGP as a CQI Activity for allocation of MOPS credits; **10 credits** for a first cycle and **10 credits** for a second cycle. General practitioners taking part in this audit can claim credits in accordance with the current MOPS programme. This status will remain in place until **October, 2019**.

To claim points go to the RNZCGP website:  
[www.rnzcgp.org.nz](http://www.rnzcgp.org.nz)

Record your completion of the audit on the **MOPS Online credit summary**, under the **Continuous Quality Improvement/Audit of Medical Practice** section. From the drop down menu, select the audit from the list or select "Approved practice/PHO audit" and record the name in the notes. 'MOPS online' can be completed by vocationally registered doctors or 'CPD online' for general registrants. Alternatively MOPS participants can indicate completion of the audit on the annual credit summary sheet which is available from the College on request.

As the RNZCGP frequently audit claims you should retain the following documentation, in order to provide adequate evidence of participation in this audit:

1. A summary of the data collected
2. An Audit of Medical Practice (CQI Activity) summary sheet (included as Appendix 1).

**bpac<sup>nz</sup>**

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[www.bpac.org.nz/audits](http://www.bpac.org.nz/audits)

# Data sheet – cycle 1 The safe and effective use of Methotrexate

Patient	The patient's note or record includes the following information: (tick if information is present)							
	Patient is on methotrexate	Indication for methotrexate	Weekly dose	Day of the week taken	Weekly folic acid	Query re adverse effects	Appropriate laboratory monitoring	A positive audit result? <small>(a tick in each column)</small>
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<b>Total % of audited patients with a positive result</b>								

Please retain this sheet for your records to provide evidence of participation in this audit.

## Data sheet – cycle 2 The safe and effective use of Methotrexate

Patient	The patient's note or record includes the following information: (tick if information is present)							
	Patient is on methotrexate	Indication for methotrexate	Weekly dose	Day of the week taken	Weekly folic acid	Query re adverse effects	Appropriate laboratory monitoring	A positive audit result? <small>(a tick in each column)</small>
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<b>Total % of audited patients with a positive result</b>								

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## Audit of Medical Practice (CQI activity) Summary Sheet

Topic: **The safe and effective use of Methotrexate**

The activity was designed by  
(name of organisation if relevant): **Bpac<sup>nz</sup>**

Doctors Name:

### FIRST CYCLE

<b>DATA:</b>	Date of data collection:
<b>CHECK:</b>	Describe any areas targeted for improvement as a result of analysing the data collected.
<b>ACTION:</b>	Describe how these improvements will be implemented.
<b>MONITOR:</b>	Describe how well the process is working. When will you undertake a second cycle?

## SECOND CYCLE

<b>DATA:</b>	Date of data collection:
<b>CHECK:</b>	Describe any areas targeted for improvement as a result of analysing the data collected.
<b>ACTION:</b>	Describe how these improvements will be implemented.
<b>MONITOR:</b>	Describe how well the process is working.
<b>COMMENTS:</b>	