safety IN PRACTICE

General Practice DMARDs Clinical Module 2020-21

Every patient, every time

AUCKLAND DISTRICT HEALTH BOARD Te Toka Tumai

Waitematā District Health Board

Best Care for Everyone

ALLIANCE HEALTH+ Inspiring Health Transformation

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1.1 Background

DMARDs (disease-modifying anti-rheumatic drugs) such as methotrexate are often used for a number of rheumatologic diseases as well as severe psoriasis. These medicines are effective, have predictable adverse effect profiles and are low cost. However, they can also be highly toxic and even fatal, at any dosing regimen.[1] While usually initiated by a specialist in secondary care, many patients will be monitored and receive repeat prescriptions in primary care. In 2017, 23.6 prescriptions for DMARDs were dispensed per 1000 patients registered in General Practice in New Zealand.[2] Therefore a practice with 4,000 enrolled patients may be issuing around 100 prescriptions per year. General practitioners need to be aware of safe prescribing strategies and monitoring requirements, along with symptoms and signs of methotrexate toxicity for this potentially toxic medication.

Azathioprine is usually reserved for patients who do not respond adequately to other DMARDs due to the increased risk of adverse effects including nephrotoxicity[3]. It is also used in some other inflammatory gastrointestinal conditions.

This module will help your practice focus on two DMARDs as a way of ensuring that systems are in place to ensure safe monitoring and prescribing for these medicines.

1.2 Aim

100% of patients prescribed the Disease Modifying Anti-Rheumatic Drugs (DMARDs), specifically methotrexate and azathioprine, have these medicines safely prescribed and reliably monitored by June 2021.

1.3 Equity

Reducing inequity in outcomes between Māori and other high needs groups compared to the general population is a priority at all levels of the health system, including Auckland and Waitematā DHBs.[4]

It is well recognised that for those groups who are already experiencing poorer health outcomes, the very reasons that contribute to this also could make them more at risk of errors, oversights, miscommunications and receiving care that is less able to meet their needs. Working on processes to improve patient safety overall would be expected to have particular benefit for reducing risk for these groups, which would contribute to reducing inequity.

In the audit practices will report the ethnicity of each patient.

Practices can focus their work to look at specific higher risk groups using an equity lens.
Some examples might be:

- Selecting eligible patients only for particular groups and then selecting the sample of 10 patients randomly from these. Dr Info and Mohio both allow either selection by Māori, or by high needs, or ordering them according to ethnicity.
- Specifically seeking patient input on their experience of the practice's DMARD monitoring processes, and how they might be improved from the patient interaction point of view.

1.4 Measures & rationale

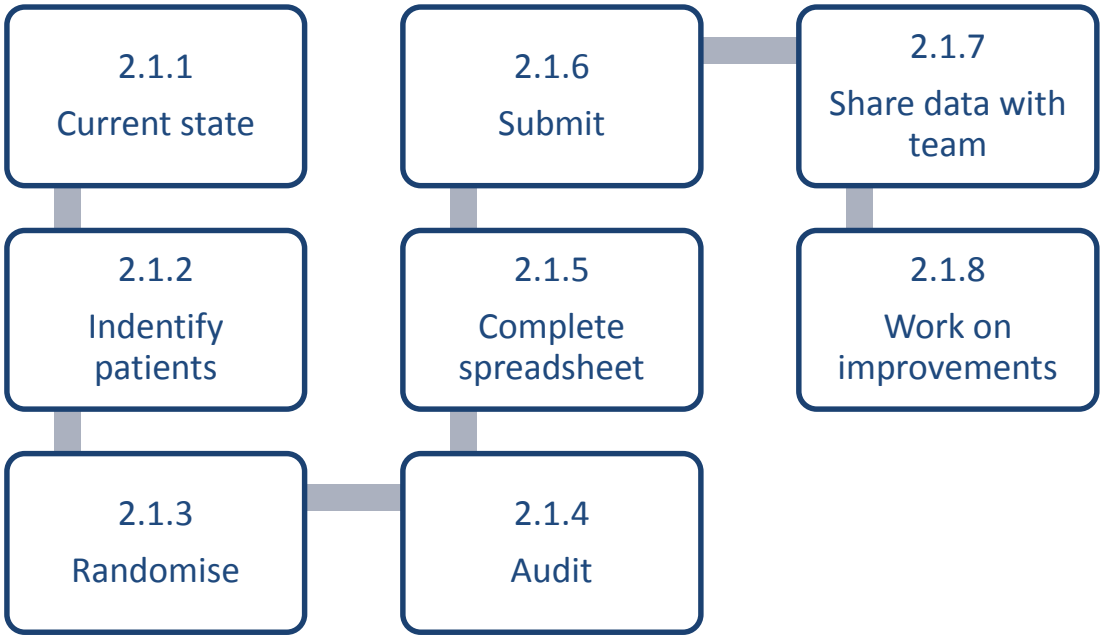
Measure 1: Has there been a full blood count in the past 3 months?
Rationale • Bone marrow suppression is an uncommon but possible important cause of mortality for patients taking methotrexate which can lead to multiple organ failure and gastro-intestinal bleeding. • Blood test monitoring interval should be no longer than every 3 months once established on the medication.
Sources BPAC, 2014. Safer prescribing of high-risk medicines Methotrexate Best Practice Journal 64 Available at: http://www.bpac.org.nz/BPJ/2014/October/safer-prescribing.aspx Auckland Regional Health Pathways, 2018. Methotrexate Shared Care Guidance (localised July 2018) Available at: https://aucklandregion.healthpathways.org.nz/ Auckland Regional Health Pathways, 2018. Azathioprine Shared Care Guidance (localised November 2018) Available at: https://aucklandregion.healthpathways.org.nz/ New Zealand Formulary, Version 74. 2018. Azathioprine. Available at: http://nzf.org.nz/nzf_4729
Measure 2 If any abnormal blood results have been received in the previous 3 months (WBC <3.5 x 10^9/L, neutrophils <2.0 x 10^9/L, platelets <150 x 10^9/L, ALT >x2 upper limit (>60) has action been recorded in the consultation record?

Rationale
• Effective monitoring entails significant results being appropriately actioned, including communication of said action with the patient.
• Long-term liver injury can result in hepatic fibrosis, normally accompanied by elevations of ALT and AST,
• Bone marrow suppression is an uncommon but possible important cause of mortality for patients taking methotrexate which can lead to multiple organ failure and gastro-intestinal bleeding.
• Patient review and action will usually involve the patient's relevant specialist.
• Take action per guidelines if:
  ○ WBC <3.5x10_9/l
  ○ Neutrophils <2.0x10_9/l (if <1.0 DMARD should be stopped immediately and discussion undertaken with specialist)
  ○ Platelets <150x10_9/l (if <50 DMARD should be immediately stopped immediately and discussion undertaken with specialist)
  ○ ALT > x2 upper limit of normal

Sources • BPAC, 2014. Safer prescribing of high-risk medicines Methotrexate Best Practice Journal 64 Available at: http://www.bpac.org.nz/BPJ/2014/October/safer-prescribing.aspx • Methotrexate Shared Care Guidance (localised July 2018)

Azathioprine Shared Care Guidance (localised November 2018) https://aucklandregion.healthpathways.org.nz/ • See table in SafeRX bulletin with actions to be taken: www.saferx.co.nz/full/methotrexate.pdf • BPAC, 2008. Methotrexate. Available at: www.bpac.org.nz/BPJ/2008/October/dmards.aspx
Measure 3 Is there a documented review of blood tests prior to issue of the last prescription?
Rationale No patient should have a repeat prescription if the monitoring has been inadequate.
Sources As above
Measure 4 Has the patient had or declined an influenza vaccine in the last 12 months?
Rationale • Methotrexate is an immunosuppressant and increases the risk of infections, even with a normal blood count. • It is recommended that patients should have annual influenza immunisation which is funded. • It is recommended patients should have pneumococcal vaccine every 5 years, although this is currently not funded.
Sources As above
Measure 5 Is it documented that the patient been asked within the last 3 months about any side effects, e.g. nausea, mouth ulcers, fever, sore throat, shortness of breath, diarrhoea?
Rationale • Patients prescribed DMARDs require close monitoring for adverse effects. These may manifest as symptoms or biochemical abnormalities. • Any of the above symptoms may represent significant side effects. Patients should understand the need to report such symptoms.
Sources As above
Measure 6 Has the patient been given written information about the DMARD that they are taking within the last 12 months?
Rationale • Written information, including the importance and frequency of monitoring, side effects and action if experiencing side effects, should be routinely given to the patient regularly. • Suitable sources of patient information include via the Auckland Regional Health Pathways, SaferRx and Health Navigator.
Sources As above

2.1 Collect your baseline data



2.1.1 Current state

To assess your processes you will collect data from 10 *random* patients every month. As a team, you will then reflect on your results, look for opportunities for improvement and use PDSA cycles (Plan, Do, Study, Act)
Your first set of data (baseline data) is relating to the month of August and is due on September 10th.
Note: we expect low scores for the baseline, or 'Current State' August data.

2.1.2 Identify patients

On the day of the data collection each month, run the query related to your module, available to download from http://www.safetyinpractice.co.nz in the Resources section.
Refer to "Finding your patients" document on website.

2.1.3 Randomise

From the list generated in step 2.1.1 it is essential to **RANDOMLY SELECT** your sample of 10 patients to audit. An online random number generator can be used. Note Safety in Practice does not endorse advertising associated with such tools.

2.1.4 Audit

Review each of your 10 selected records against the following criteria. You can use the Paper Form provided on the resources section of our website to keep track or simply enter records directly onto the audit spread sheet.

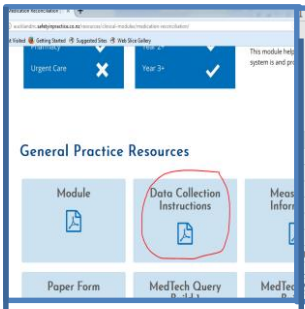
2.1.4.1 Measures & guidance

Measure 1: Has there been a full blood count in the past 3 months?
Guidance Record YES if there is a FBC done in the last 3 months. Record NO if there is not – TestSafe should be checked if there is no record in the notes.
Measure 2 If any abnormal blood results have been received in the previous 3 months (WBC <3.5 x 10^9/L, neutrophils <2.0 x 10^9/L, platelets <150 x 10^9/L, ALT >x2 upper limit (>60) has action been recorded in the consultation record?
Guidance If there has been an abnormal result and the actions from this have been recorded mark as YES and if there has been an abnormal result and actions have not been recorded then mark as NO. If there have not been any abnormal results as above then mark as N/A.
Measure 3 Is there a documented review of blood tests prior to issue of the last prescription?
Guidance If it is clear from the record that the blood tests have been reviewed prior to the prescription being repeated then mark as YES, if not then mark as NO.
Measure 4 Has the patient had or declined an influenza vaccine in the last 12 months?
Guidance Mark as YES if it is documented that they have be offered the influenza vaccination and NO if they have not had the vaccination or had it documented that they have been offered this.
Measure 5 Is it documented that the patient been asked within the last 3 months about any side effects, e.g. nausea, mouth ulcers, fever, sore throat, shortness of breath, diarrhoea?
Mark as YES if it is documented that they have been asked about these side effects and NO if there is not documentation that they have been asked about these side effects.
Measure 6 Has the patient been given written information about the DMARD that they are taking within the last 12 months?
Guidance Mark as YES if it is clear that written information has been given and NO if there is not any record of this.

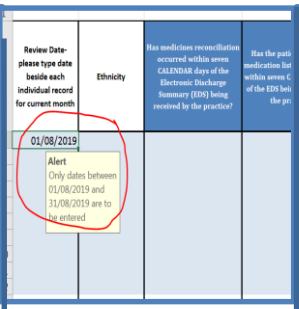
2.1.5 Complete the spreadsheet

Tip: Your first set of data (baseline data) is relating to the month of August so this is due on September 10th.

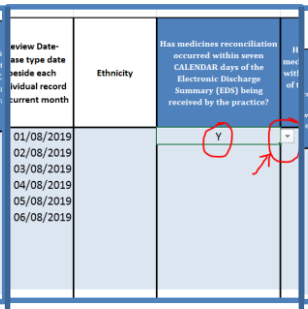
Please note: we expect low scores for the baseline August 2020 data, prior to the Safety in Practice programme beginning



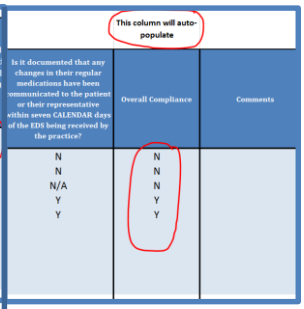
Download the spread sheet for your module in the Resources section of www.safetyinpractice.co.nz



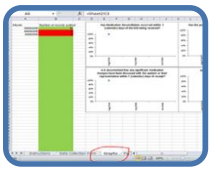
Record the month **the data relates** to in a DD/MM/YY format in the left column (Alert boxes in yellow will guide you). For your first data set collected in September this is 1/8/20



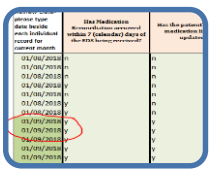
Mark Y, N or N/A by clicking on the dropdown menu, against for each measure and each patient according to your findings in the previous section.



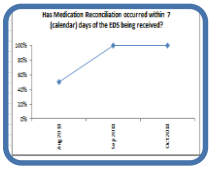
The final measure "Overall compliance" will auto-populate.



Graphs will be automatically generated in the next tab in the spread sheet.



Next month add your data to the same spread sheet.



This means you can track your progress over time.

2.1.6 Submit

Submit your data on the 10th of each month to audit@safetyinpractice.co.nz and your PHO facilitator.

> Tip: Please ensure all data sent to Safety in Practice in anonymised

2.1.7 Share data with your team

Safety in Practice works when all team members take part. Make the data available for everyone to see. Print the graphs and put them up in the tea room so the whole team can see the progress being made and have the opportunity to make suggestions on how to improve.

2.1.8 Work on improvements

As a team, look for opportunities for improvement and use PDSA cycles (Plan, Do, Study, Act). Refer to the Quality Improvement Workbook for other quality improvement tools.

2.2 Change idea examples

The following ideas have been tested and implemented in previous SiP teams

General	• Have a doctor and nurse champion in the practice
Practice processes	• Ensure a robust recall systems so patients return to have their blood test taken • Ensuring patients are invited for influenza and pneumococcal immunisations • Trying various ways for ensuring patients have the regular blood tests e.g. letters, texting, emailing • Develop a policy and process for monitoring DMARDs for the practice so that new staff and locums can use the same process
Recording process in patient management system	• Creation of screening template for recording of review prior to prescription
Practice team roles and responsibilities	• Training health care assistants to ask about side effects of DMARDs • Discuss with specialists around the GP role in education and monitoring and how fits in with their responsibilities
Patient education	• Using patient information leaflets from SafeRx or www.healthnavigator.org.nz • Recording the date that written education given in the screening template
Patient involvement	• Involving patients in the change process – provide good feedback on what they think works best from their perspective

2.3 Previous teams' experiences

Benefits	Challenges
•Increased GP awareness around DMARD monitoring •Improved communication with specialists •Embedding system to improve safety •Better systems for recalling patients. •Improved recording of review of blood test results prior to issuing prescription. •Patients better informed of risks and need for monitoring. •Patients highlighting significant side effects earlier. •More patients being immunized appropriately. •Greater consistency for when patients are expected to have blood test taken.	•Not many patients on Methotrexate but applying the systems to patients on other drugs needing monitoring. •Getting buy-in from colleagues •Inconsistencies between specialists •Lack of documentation from specialists •Adjustments required to the query-build

3.1 Patient engagement

SafeRx Patient Information can be found at: http://www.saferx.co.nz/methotrexate-patient-guide.pdf
Patient information education can also be found by going through the Auckland Regional Health Pathways links or www.healthnavigator.org.nz

3.2 Additional Resources

Template & searches

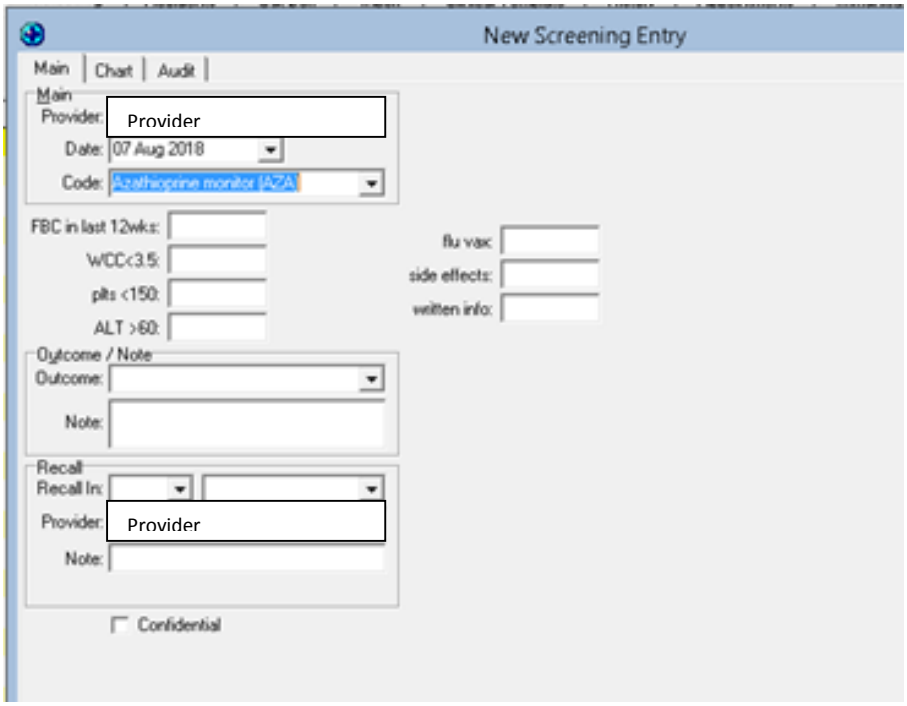
A generic template to help with managing patients being prescribed Methotrexate and Azathioprine could be developed together with your team.

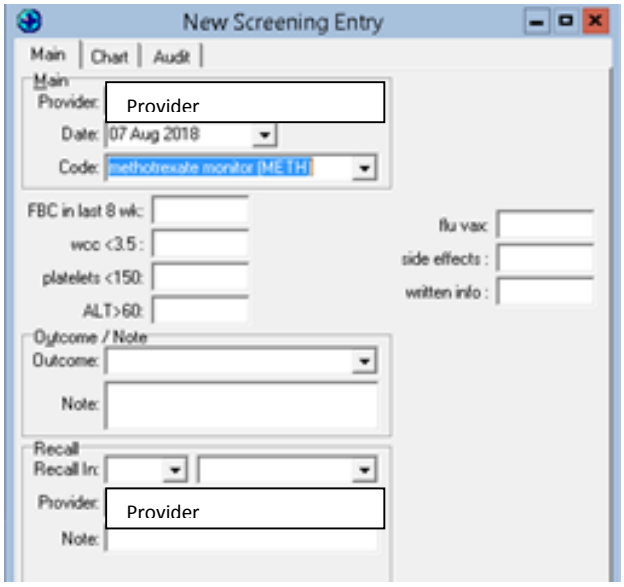
Monitoring Search Dr Info has also developed searches to help practices identify patients who are prescribed Methotrexate or Azathioprine in the past 3 months and:

- No full blood count tests done in the last 4 months.
- No Liver function in the last 4 months.

These searches can be found under the Safety tab in Dr Info.

Example Template





Prescriber Guidance

- BPAC guidance can be found at: www.bpac.org.nz/BPJ/2008/October/dmards.aspx
- Health Pathway guidance can be found at: https://aucklandregion.healthpathways.org.nz
- SafeRX Methotrexate Bulletin Safe Prescribing, once a week: www.saferx.co.nz/full/methotrexate.pdf

3.3 Connections to other parts of Safety in Practice programme

Prescribing Indicators

As a high risk medicine, methotrexate is also included in the prescribing safety indicator group called High Risk Medicines where the practice receives a report each month of patients who have experienced potentially high risk prescribing based on the criteria below. This group of prescribing indicators could be chosen in the same year as the DMARDs clinical module to provide insight into practices which complement this work.

Measure 1 Prescription of Sodium Valproate to a woman of child bearing potential (10-49 years) *(going to get added in if they have NOT had a hysterectomy)*
Measure 2 Prescription of warfarin in the last month to a patient without a record of INR having been measured within the previous 9 weeks (excluding patients who self-monitor)
Measure 3 Prescription of methotrexate in the last month without a record of a full blood count and liver function test within the previous 4 months
Measure 4 Prescription of Methotrexate in the last month without prescription of Folic Acid in the last 4 months
Measure 5 Amiodarone prescribed in the last month without record of thyroid function (TSH) and liver function (LFT) done in the last 7 months

3.4 Glossary

ADE	Adverse Drug Event
ADHB	Auckland District Health Board
ALT	Alanine aminotransferase, a marker of liver function.
AST	Aspartate aminotransferase, a marker of liver function.
Bundle	Each of the areas identified as presenting the highest risk to patients within the community have been developed into modules. Each module is structured to include a change package and a bundle.
CARM	Centre for Adverse Reaction Monitoring New Zealand
Change package	A ccollection of change ideas known to produce a desired outcome in a process or system.
Cytotoxic	A drug that is toxic to living cells.
Dr Info	A clinical information platform used by general practices. Data is extracted and analysed from practices PMS'.
DMARDs	Disease modifying anti-rheumatic drugs. These medications are used in auto-immune diseases such as rheumatoid arthritis.
eGFR	Estimated glomerular filtration rate, renal function test
FBC	Full blood count
GI	Gastro-intestinal
IHI	Institute of Healthcare Improvement
HQSC	Health Quality & Safety Commission of New Zealand
LFTs	Liver function tests
Module	A structured way of improving the processes around patient care: a small, straightforward set of evidence-based practices, generally three to five, that, when performed collectively and reliably, have been proven to improve outcomes.
Mohio	A clinical information platform used by general practices. Data is extracted and analysed from practices PMS'.
PMS	Patient management system e.g. MedTech, MyPractice, ToniQ
PHO	Primary health Organisation e.g Auckland, Alliance Health Plus, Comprehensive Care, East Health Trust, Total Healthcare, National Hauora Coalition, Procare
RNZCGP	Royal New Zealand College of General Practitioners
WBC	White blood cells. Used as a marker of infection and immune system functioning.
WDHB	Waitemata District Health Board
SIP	Safety in Practice

3.5 References

1. Kivity S, Zafrir Y, Loebstein R, et al. Clinical characteristics and risk factors for low dose methotrexate toxicity: A cohort of 28 patients. Autoimmun Rev 2014;[Epub ahead of print].
2. BPAC$_{nz}$. Annual Practice Report, 2017. Available from: https://bpac.org.nz/report/2017/AnnualReport2017_SamplePracticeReport.pdf
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9. BPAC, 2011. Methotrexate. Best Practice Journal Available at http://www.bpac.org.nz/BPJ/2011/february/docs/bpj_34_methotrexate_pages_16-17.pdf
10. https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=121