



General Practice DMARDs Clinical Module 2018-19

Every patient, every time



Adapted with permission



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Section 1: Introduction

1.1 Background

DMARDs such as methotrexate, are often used for a number of rheumatologic diseases as well as severe psoriasis. These medications 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 2013 23.3 prescriptions 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 nephrotoxicity³. It is also used in some other inflammatory GI conditions.

This module will help your practice focus on two DMARD drugs as a way of ensuring that systems in place to ensure safe monitoring and prescribing for these types of medications.

1.2 Aim

100% of patients on Disease Modifying Anti-Rheumatics Drugs (DMARDs), particularly methotrexate and azathioprine, have their drugs safely prescribed and reliably monitored.

1.3 Equity

Reducing inequalities in outcomes between Maori and other high needs groups compared to the general population is a priority at all levels of the health system, including Auckland and Waitemata DHB's.⁴

While Safety in Practice is not a programme specifically focused on equity issues, 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.

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 Maori, or by high needs, or ordering them according to ethnicity.
- Specifically seeking input from patients from these groups on their experience of the practice's opioid management 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 important cause of mortality for patients on methotrexate that can lead to multiple organ failure and gastro-intestinal bleeding.
- Blood test monitoring interval should be a MAXIMUM of 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) Available at: <https://aucklandregion.healthpathways.org.nz/>

Auckland Regional Health Pathways, 2018. Azathioprine Shared Care Guidance (not yet localised) 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 results in the previous 3 months (WBC <3.5 x 10⁹/L, neutrophils <2.0 x 10⁹/L, platelets <150 x 10⁹/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, normally accompanied by elevations of ALT and AST, can result in hepatic fibrosis.
- Bone marrow suppression is an uncommon but important cause of mortality for patients on methotrexate that 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 <3.5x10⁹/l
 - Neutrophils <2.0x10⁹/l (if <1.0 drug should be stopped immediately and discussion undertaken with specialist)
 - Platelets <150x10⁹/l (if <50 drug 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 (not yet localised)

<p>https://aucklandregion.healthpathways.org.nz/</p> <ul style="list-style-type: none"> See table in SafeRx bulletin page 4 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?
<p>Rationale</p> <p>No patient should have a repeat prescription if the monitoring has been inadequate.</p>
<p>Sources</p> <p>As above</p>
Measure 4 Has the patient had or declined an influenza vaccine in the last 12 months?
<p>Rationale</p> <ul style="list-style-type: none"> 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.
<p>Sources</p> <p>As above</p>
Measure 5 Has 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?
<p>Rationale</p> <ul style="list-style-type: none"> 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.
<p>Sources</p> <p>As above</p>
Measure 6 Has the patient been given written information about the DMARD that they are taking within the last 12 months?
<p>Rationale</p> <ul style="list-style-type: none"> 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.
<p>Sources</p> <p>As above</p>

Section 2: Instructions

2.1 Collect your baseline data



2.1.1 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.

2.1.2 Randomise

From the list generated in step 2.1.1 it is important to select a **random sample of 10 patients to audit**.

For sample sizes up to 10

1. Audit all 10 patients.

For sample sizes of 11 - 28

1. Select a random number between 1 and 10 by picking pieces of paper out of a hat.
2. If you select an odd number audit every other patient starting at 1 e.g. 1st, 3rd, 5th, 7th etc.
If you select an even number audit every other patient starting with the second patient e.g. 2nd, 4th, 6th, 8th etc.

For sample sizes 29+

1. Select a random number between 1 and 10 by picking pieces of paper out of a hat.
2. Audit every other patient starting at this number e.g. if 6 is drawn audit the 6th, 8th, 10th patient etc.

2.1.3 Audit

Review each of your 10 selected records against the following criteria. You can use the Paper Form provided in Section 3.1 to keep track or simply enter records directly onto the audit spread sheet.

2.1.3.1 Measures & guidance

Measure 1 Has there been a full blood count in the past 3 months as per local guidance?
Guidance Record YES if there is a FBC done in the last 3 months. Record NO if there is not – Testsafe should be checked also for this if there is no record in the notes.
Measure 2 If any abnormal results 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 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 they have and NO if they have not had or been offered this.
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.

2.1.4 Complete the spread sheet

Tip: Your first set of data is relating to the month of August so this is due on September 10th. For this data set record "August" in the first column.

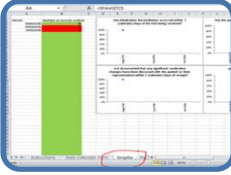
Download the spread sheet for your module in the Resources section of www.safetyinpractice.co.nz

Record the month **the data relates to** in a DD/MM/YY format left column. For your first data set collected in September this is 1/8/18,

Mark y, n or n/a against for each measure and each patient according to your findings in the previous section.

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

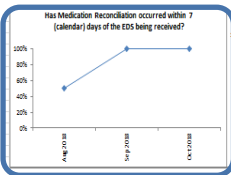
Tip: Please don't audit more than 10 patient for a given month or add or remove rows from the spread sheet as this will disrupt the formulas and cause the graphs to break.



Graphs will be automatically generated in the next tab in the spreadsheet.

Referral type (from service) Each individual provided for current month	Has Medication Reconciliation occurred within 7 (calendar) days of the EDs being received?	Has the patient medication be reconciled?
01/08/2018	n	n
01/08/2018	n	n
01/08/2018	n	n
01/08/2018	n	n
01/08/2018	n	n
01/08/2018	n	n
01/08/2018	y	y
01/08/2018	y	y
01/08/2018	y	y
01/08/2018	y	y

Next month add your data to the same spreadsheet.



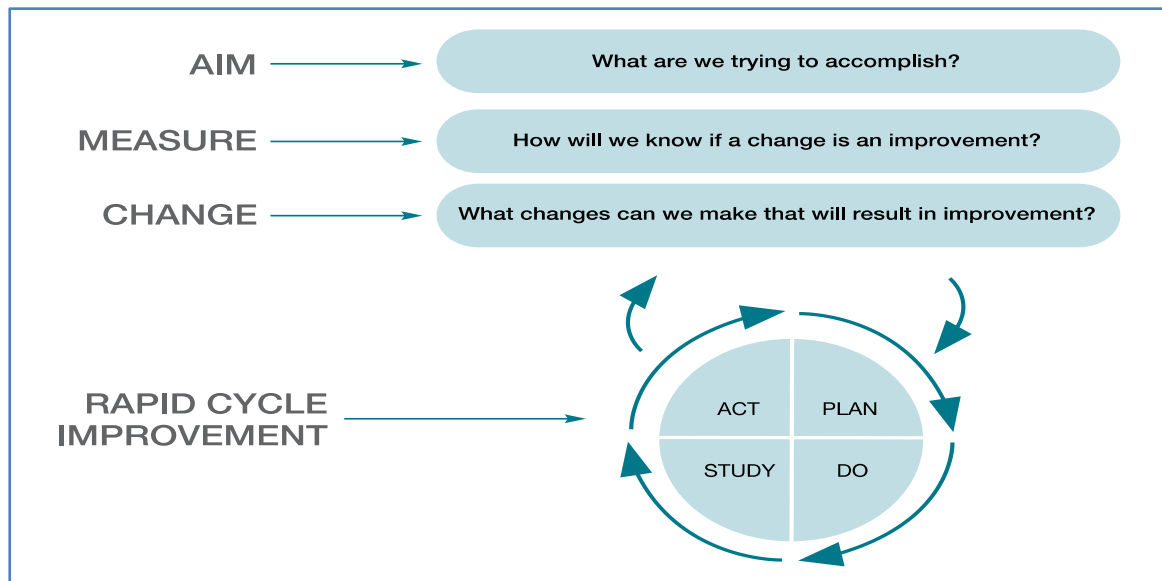
This means you can track your progress over time.

2.1.5 Submit

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

Tip: Please ensure all data sent to Safety in Practice is anonymized

Creating Change – Getting started



Before you start your plan phase:

- Bring together your team – these people will work with you to plan and carry out the test of change
- Select the process you wish to change

As a team answer the 3 questions above:

1. What are we trying to accomplish? (write an objective for this PDSA cycle)
2. How will we know if a change is an improvement?
3. What changes can we make that will result in improvement?

2.2 Plan stage

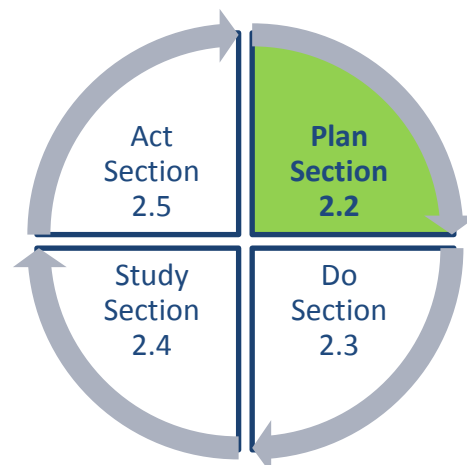
Plan how the changes will happen – ask yourselves and write down the following:

- What will we do?
- Who will carry out the plan?
- When will it take place?
- Where will it happen
- What data and information will we collect – i.e. what will help us determine if the change is an improvement?
- Do we need training or materials?

Make predictions –what do you think will happen when you test the change and why?

Ask yourself:

- What do we hope to learn by



testing the change?

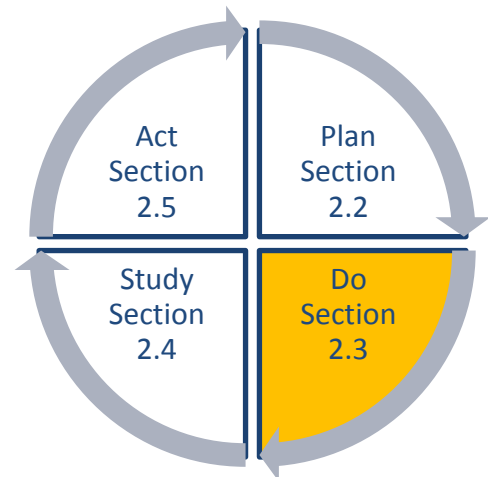
- What will happen when we test the change?
- How will the change be carried out?

2.2.1 Change ideas

General	<ul style="list-style-type: none"> • Have a doctor and nurse champion in the practice
Practice processes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Creation of screening template for recording of review prior to prescription
Practice team roles and responsibilities	<ul style="list-style-type: none"> • Training health care assistants to ask about side effects of the drugs • Discuss with specialists around the GP role in education and monitoring and how fits in with their responsibilities
Patient education	<ul style="list-style-type: none"> • Using patient information leaflets fro SafeRx • Recording the date that written education given in the screening template
Patient involvement	<ul style="list-style-type: none"> • Involving patients in the change process – provide good feedback on what they think works best from their perspective

2.3 Do

- Prepare to test; gather resources
- Try out your change idea – it's usually best to try it out on a small sample or area of your practice. Starting on a small scale might mean 1 or 2 patients – that way if it doesn't work it's easier to remove the step or process
- While you are testing keep track of what happens in real time – don't wait to write it up

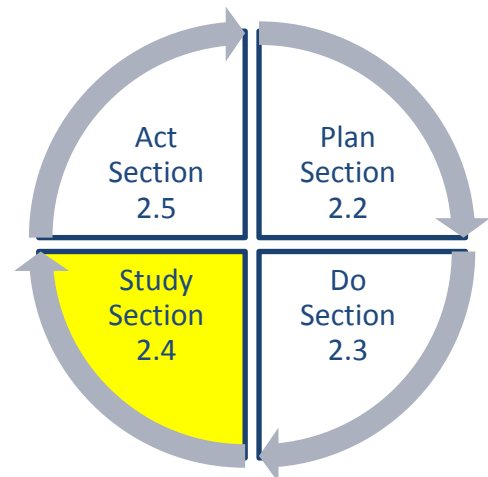


2.4 Study

Complete the analysis of the data.

Ask yourself:

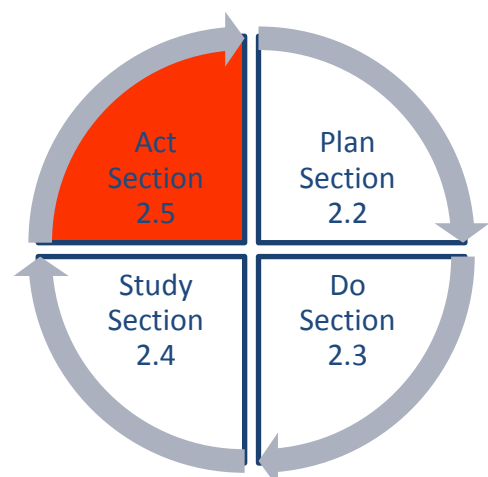
- What has changed
- Who was affected
- Are the effects positive or negative
- Are they worth keeping or removing, adapting or developing



Compare the data to your predictions.

2.5 Act

- Summarise and reflect on what was learned.
- Refine the change based on what was learned.
- Are you going to adopt the change, adapt and retest, or abandon?
- Prepare a plan for your next PDSA cycle – back to step 2.2 Plan for your next cycle!



Previous teams' experiences

Benefits

- 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.

Challenges

- 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

Section 3: Resources

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

3.2 Additional Resource

Template & searches

A generic template to help with managing patients being prescribed Methotrexate and Azathioprine could be developed with you and the 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 3 months.
- No Liver function in the last 3 months.

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

Example Template

New Screening Entry

Main | Chart | Audit

Main

Provider:

Date:

Code:

FBC in last 12wks: ☐

WCC < 3.5: ☐

pils < 150: ☐

ALT > 60: ☐

flu vac: ☐

side effects: ☐

written info: ☐

Outcome / Note

Outcome:

Note:

Recall

Recall In:

Provider:

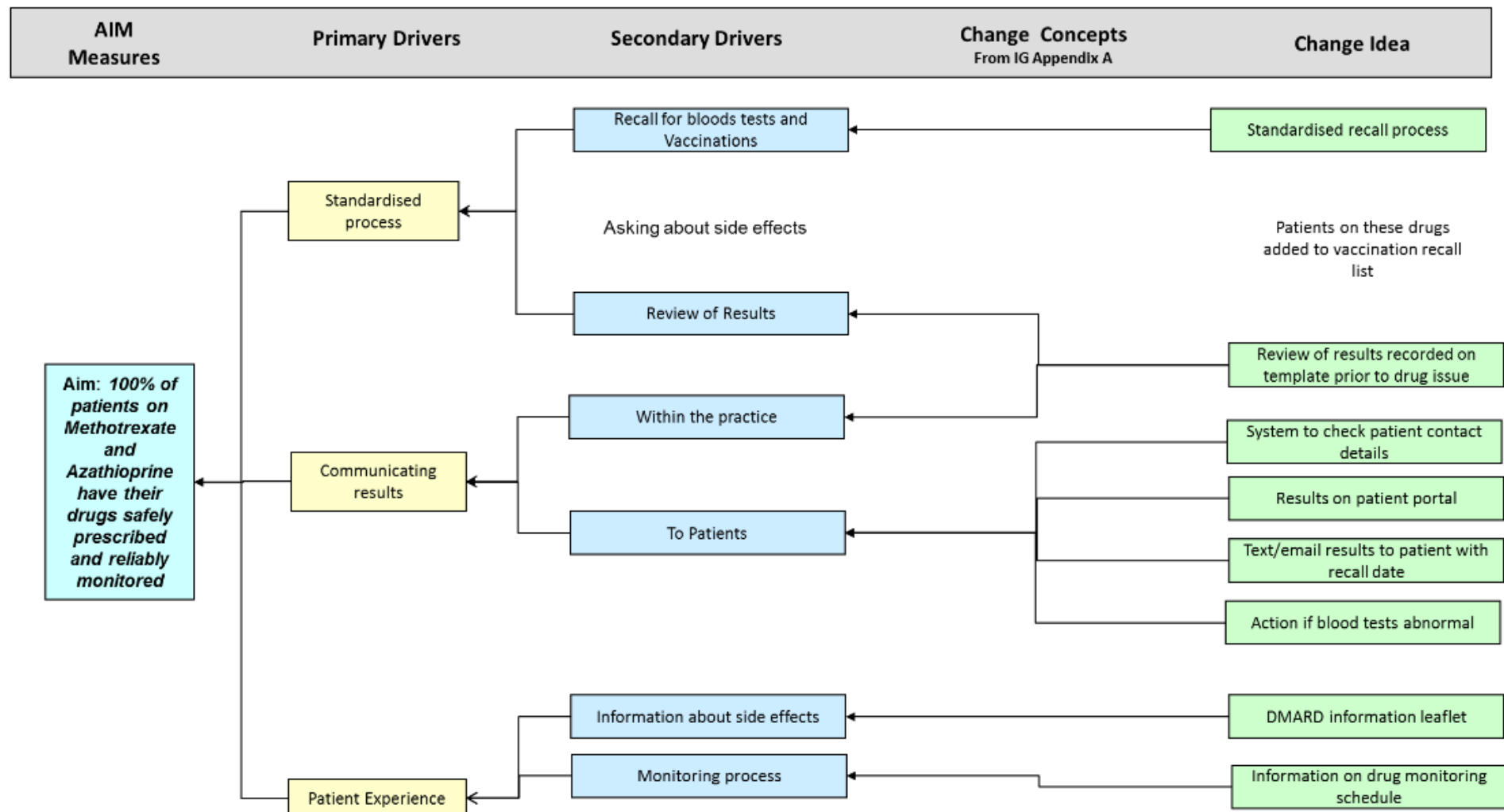
Note:

☐ Confidential

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. May 2014:
www.saferx.co.nz/full/methotrexate.pdf

3.3 Theory of improvement



3.4 Glossary

ACE-inhibitor	Angiotensin converting enzyme inhibitor such as lisinopril. An anti-hypertensive medication.
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.
ARB	Angiotensin receptor blocker such as candesartan. An anti-hypertensive.
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
CoX-2 inhibitors	A form of NSAID that, unlike e.g. ibuprofen, only works on the CoX-2 enzyme.
CPAMS	Community Pharmacy Anticoagulation Monitoring Service
CKD	Chronic kidney disease
Change package	A collection 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 autoimmune diseases such as rheumatoid arthritis.
EDS	Electronic Discharge Summary
eGFR	Estimated glomerular filtration rate, renal function test
FBC	Full blood count
GI	Gastro-intestinal
IHI	Institute of Health Improvement
INR	International Normalised Ratio. This is a marker of coagulability in the blood used to guide warfarin dosage.
H2 antagonists	Gastro-intestinal protective medication
HQSC	Health Quality & Safety Commission of New Zealand
LFTs	Liver function tests
Medication Reconciliation	The process of collecting, comparing, and communicating the 'most accurate' list of medicines that a patient is taking, together with details of any allergies and/or adverse drug reactions (ADRs), with the outcome of providing correct medicines for a given time period
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'.

NSAIDs	Non-steroidal anti-inflammatory drugs used for pain and inflammation. Examples include ibuprofen, naproxen and diclofenac.
Opioids	Strong pain medications such as codeine, morphine and fentanyl.
OTC	Over the counter
PPI	Proton pump inhibitor such as omeprazole. These medicines reduce stomach acid.
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, Procure
TFTs	Thyroid function tests
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. Annual Practice Report, 2013. Available from:
www.bpac.org.nz/Report/2013/November/2013PracticeReportSample.pdf
3. BPAC, 2008. DMARDS Best Practice Journal Available at
<https://bpac.org.nz/BPJ/2008/October/dmards.aspx>
4. Waitemata and Auckland District Health Boards, 2017. 2017/18 Annual Plan.
5. 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>
6. Auckland Regional Health Pathways, 2018. Methotrexate Shared Care Guidance (localised) Available at: <https://aucklandregion.healthpathways.org.nz/>
7. Auckland Regional Health Pathways, 2018. Azathioprine Shared Care Guidance (not yet localised) Available at: <https://aucklandregion.healthpathways.org.nz/>
8. New Zealand Formulary, Version 74. 2018. Azathioprine. Available at:
http://nzf.org.nz/nzf_4729
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>