Submission for medicine reclassification for consideration by the Medicines Classification Committee

Introduction

Gout is the most common inflammatory arthritis[1] and it happens when monosodium urate crystals deposit in and around joints and in other tissues. Gout flares are caused by these crystals, presenting as acute inflammatory episodes that are recurrent and self-limiting. Urate lowering therapy is needed so that the crystals can dissolve. In New Zealand the target is < 0.36 mmol/L for most people and < 0.30 mmol/L where there are tophi[2]. Internationally gout is suboptimally treated[1].

Gout has long been under-treated in New Zealand in terms of prophylaxis[3]. Allopurinol, a xanthine oxidase inhibitor, is the main preventor for gout in New Zealand and by far the most commonly used internationally[1], but it needs to be started at a low dose and titrated to the appropriate level for the patient. The person needs to present to a prescriber for an allopurinol prescription every three months. If a person stops taking allopurinol they will need to restart low and titrate again, typically taking months to get to the right level. Stopping allopurinol or being on a suboptimal dose of allopurinol is likely to result in gout flares, with considerable burden for the sufferer, absenteeism from work, negative effects on lifestyle both for the individual and those around them, damage over time and (for some) hospital admissions. Poorly managed gout results in a moderate level of physical disability and a SF-36 physical functioning score similar to people aged 75 years or over in a much younger population[4].

NSAID use rather than urate-lowering therapy (ULT) has been called *"a poor and potentially dangerous stopgap"*. Māori and Pacific patients are more likely than other ethnicities to have repeated NSAIDs for gout attacks[3], despite Māori and Pacific being at increased harm from NSAIDs than other ethnicities, including increased hospital admissions for serious adverse effects[5].

To help people to reach the optimal dose and understand the need for long-term preventative therapy, pharmacy gout programmes are in place in parts of New Zealand, e.g. in Northland, Counties Manukau (primarily South Auckland), Whanganui, Porirua and Hawkes Bay. Some pharmacy gout programmes use standing orders to enable dose titration and continuation supply by the pharmacist. Standing orders have a burden to arrange and oversee, particularly where the GP workforce is stretched, or locums are

primarily used (e.g. areas of Northland). Reclassification will enable safe and appropriate supply without the burden of standing orders and will aid access for patients.

Many people who start allopurinol discontinue them at least temporarily. While reasons for this are multi-factorial, the need to arrange a doctor's prescription, including time off to see the doctor, is an important contributor for therapy gaps. Continuation supply is important to avoid gaps in therapy and therefore avoid gout flares. Avoiding gaps in allopurinol dosing also reduces the need for anti-inflammatories or other acute gout treatments, will reduce emergency department presentations, and will potentially reduce time off work and other activities for the individual.

This application seeks to support specially trained pharmacists to titrate allopurinol as per HealthPathways and to provide continuation supply to aid people with gout to get to the correct dose for them and to reduce barriers to access and reduce the number of therapy gaps and the need to restart titration. This will benefit patients with fewer gout attacks, reduce absenteeism or presenteeism, reduce loss of wages and reduce time missing family, social, sports and church life, and reduce the need for family members to take time off to look after the person with gout. Additionally, it will reduce the burden on pharmacists, GPs and programme managers on arranging and updating standing orders, and for GPs the burden of auditing them. With gout well-managed, the patient and GP can concentrate on other health concerns/prevention of other conditions.

At the 66th Medicines Classification Committee meeting on the 11th of May 2021[6], a reclassification of allopurinol was considered. The committee "agreed that the proposal could support addressing access issues to medical practices and improve continuity of care in remote areas", and that "there are favourable equity outcomes possible from this proposal". The committee had the following concerns:

- The risk of missing and/or undertreating the associated comorbidities of gout
- Duration for pharmacist follow-up with the patient before a follow-up with their doctor
- The absence of an electronic care plan that would allow management between community pharmacies and medical practice
- Processes around training and education for pharmacists.

The meeting minutes further states: "The Committee were supportive of this submission and agreed there is an unmet clinical need however acknowledged that a change in classification alone will have limited impact on improving health outcomes and equity.

The Committee discussed their understanding that reclassification can enable a pathway for policy changes and programmatic development, however holds reservations with the current proposal until the concerns identified are addressed.

The Committee concluded there should be engagement with the Pharmacy Council process for medicines reclassification as outlined in the guidance before a recommendation can be made.

Recommendation

The Committee is deferring the decision and referring this submission to the Pharmacy Council process."

The Pharmacy Council submitted a letter to the following MCC meeting stating[7]:

"The Pharmacy Council (Council) believes that pharmacists possess the base competencies to supply allopurinol as per the proposal in the application. However, we recommend that pharmacists be required to complete a formal training programme that focuses on patient assessment and point of care testing, supply guidelines, and patient advice."

However, the applicant to the original meeting (Dr Natalie Gauld) suggested waiting for evaluation from the redesigned gout programme at Counties Manukau before reconsidering the potential reclassification (personal communication, Dr Natalie Gauld).

Since then, the redesigned Counties Manukau programme was rolled out (2022) with bespoke software from Firecrest (also has INR-Online software) and standing orders for dose titration and continuation supply by the pharmacist for people in the programme. The evaluation was conducted using qualitative interviews, a survey of pharmacists and general practice and a quantitative evaluation. This found the programme was valued and had higher rates of therapy continuation compared with the Atlas of Healthcare Variation. However, it noted: *"Challenges with seeing doctors need to be addressed for long-term continuation on therapy, e.g. pharmacist continuation supply after the programme has been completed, ability to order a repeat prescription or telehealth options."*

The points raised at the 66th MCC meeting are all addressed in this application. There is a greater need than ever before to make allopurinol accessible given the burden of gout, increasing rates of gout, pressure on our health system where gout is a preventable reason for emergency department presentation and inpatient stay, challenges of seeing a GP in NZ, and evidence of pharmacy gout services helping patients.

Part A- Regulatory Context and Proposed Classification

1. International non-proprietary (INN) name of the medicine

Allopurinol

2. Proprietary names (if applicable)

Ipca-allopurinol is the only product currently funded and available in New Zealand. Many allopurinol brands have been registered in NZ over the years, with the earliest being Zyloprim and Z-300, then Progout.

3. Name and contact details of the company/ organisation/ individual requesting a reclassification

Contact details can be removed from the form prior to publication of the Medsafe website if requested.

Arthritis New Zealand Mateponapona Aotearoa
Green Cross Health
Dr Natalie Gauld ONZM DipPharm MPharm PhD FPS
Associate Professor Peter Gow ONZM MBChB FRACP, Rheumatologist

4. Dose form(s) and strength(s) for which a change is sort (if applicable)

Tablets 100 mg and 300 mg

5. Pack size, storage conditions and other qualifications (if applicable)

There is no pack size specified as the quantity will depend on the dose for an individual, and a maximum of three months' supply will be able to be provided. Allopurinol would be dispensed and labelled by the pharmacist with no specific non-prescription pack size as such.
Storage conditions (as per Ipca allopurinol datasheet): store below 25°C. Protect from moisture. Keep container tightly closed.

6. Indications for which change is sought (if applicable)

Prophylaxis of gout.
We have used the indication as per NZ Formulary rather than as per the data sheet.

From the datasheet, this would equate to: For the management of primary gout or secondary hyperuricaemia associated with chronic gout.

7. Present classification of the medicine

Prescription medicine.

8. Classification sought

Prescription medicine except when supplied for prophylaxis of gout to people who meet the clinical and eligibility criteria of an approved training programme, when provided by pharmacists who meet the requirements of the Pharmacy Council.

9. Classification status in other countries (especially Australia, UK, USA and Canada), and any justification for harmonisation

Prescription medicine in other countries.
The 2021 application for reclassification noted there was a Scottish Patient Group Direction for allopurinol. This no longer appears to be available, probably owing to the fact that many community pharmacists can now prescribe in the UK.

10. Extent of usage in New Zealand and elsewhere (e.g. sales volume) and dates of the original consent to distribute

The Medsafe product application details show Zyloprim 100 mg tablets were approved 31 December 1969.

Sales data is not available for NZ nor is it available for other countries. However, Atlas of Healthcare readily Variation data for New Zealand identified in 2019 that 209,000 people had gout and 120,000 were prescribed urate-lowering therapy[8]. In most cases this would be allopurinol.

With allopurinol available for over 50 years in NZ, and being first-line as gout prophylaxis, the experience is clearly very extensive in NZ alone. Internationally there have been over 50 years of experience also with allopurinol "by far the most commonly prescribed ULT", e.g. 95% of US NHANES self-reports of ULT therapy being allopurinol, 96% of ULT prescriptions in South Korea in 2011 were for allopurinol[1]. This medicine is extremely well-known.

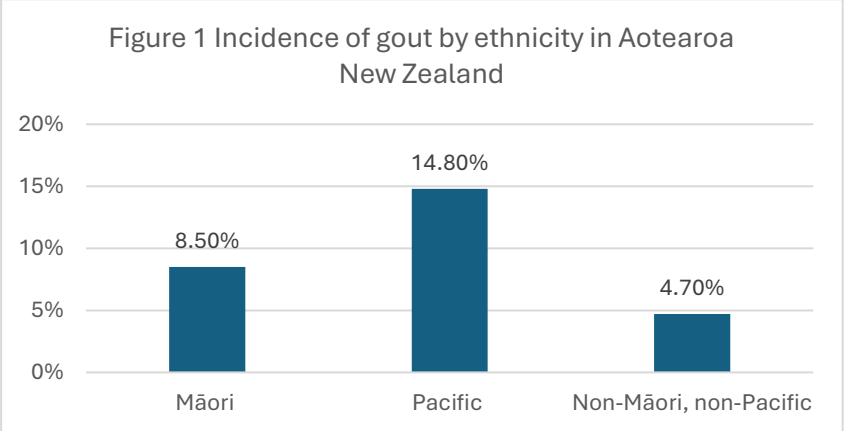
11. Local data or special considerations relating to New Zealand (if applicable)

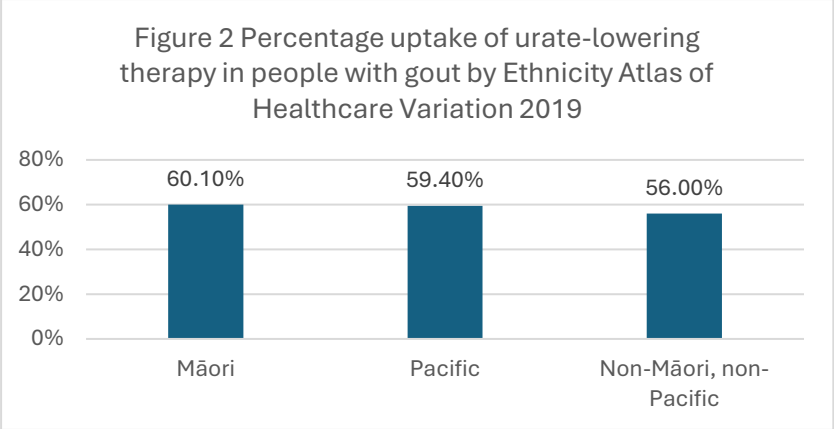
Burden of gout in Aotearoa New Zealand

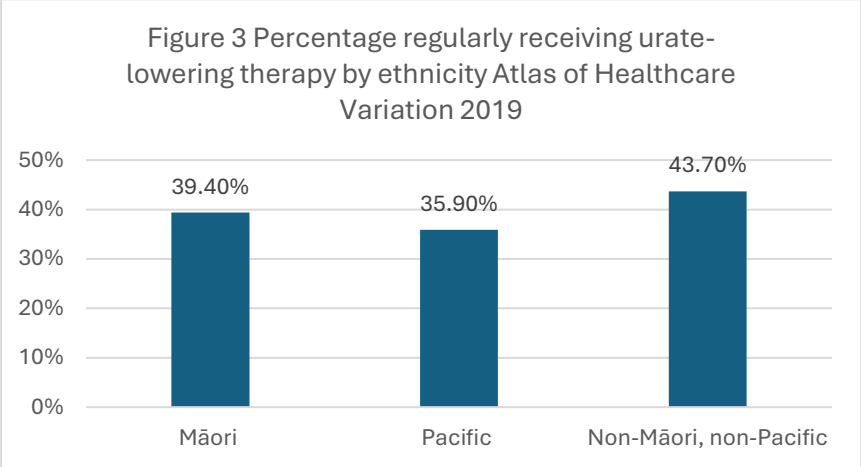
In a global burden of disease study Australasia had a prevalence of 1424 per 100,000, over twice the global prevalence[9]. However, New Zealand has particularly high rates with 5.7% of the adult population suffering from identified gout[10].

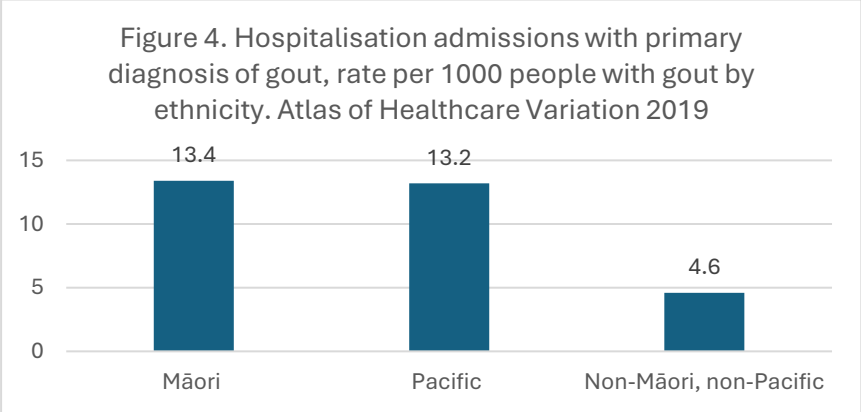
The Atlas of Healthcare Variation 2019[10] data shows that Māori and Pacific peoples are more likely to have gout than Non-Māori, non-Pacific (Figure 1). Of people with gout, Maori and Pacific people are more likely to be prescribed urate lowering therapy than non-Maori, non-Pacific (Figure 2), but less likely to be regularly receiving it (Figure 3, based on dispensing data). Of people with gout, Māori and Pacific are three times more likely to be hospitalised with it than non-Maori, non-Pacific (Figure 4). These numbers from administrative data are likely to be an undercount of perhaps 20% given some people will self-medicate for gout including borrowing others' medicines or buying medicines OTC[11] and some may not realise they have gout for some time[12].

Figure 1 Atlas of Variation Gout Incidence by Ethnicity 2019









The Atlas of Healthcare Variation shows that gout has varying prevalence around NZ, from 3.9-4.4% in Canterbury, Capital and Coast, and Nelson Marlborough to 7.7-9.1% in Counties Manukau, Northland and Tairawhiti.

In NZ, gout has higher prevalence in older age groups, but still affects an important 1.8% of people aged 20-44 years (for Māori 3.2% and Pacific peoples 7.2% in that age group). For those aged 45-64 years it affects 6.3% and for those 65 years and over it affects 13.1%. The rate of gout in males is about threefold higher than females at 9.0% versus 2.7%. In all cases the prevalence is higher in Maori and Pacific peoples than non-Maori, non-Pacific, with the highest prevalence in Pacific peoples aged 65 years or older (38.6% prevalence) and Maori 65 years or older (25.9%).

Serum urate concentrations are higher in Maori and Pacific patients[13, 14], and the impact of gout is higher in terms of pain, activity limitations, health-related quality of life and frequency of gout flares[13].

Urate-lowering therapy (ULT) in Aotearoa New Zealand

Most people using ULT in NZ are taking allopurinol. The Atlas of Healthcare Variation reports on ULT usage not allopurinol alone. While 60.7% of people 65 years and over have been prescribed ULT, this is lower in the younger age groups, 56.5% for those 45-64 years and 48.0% in those aged 20-44 years. Importantly, those regularly receiving urate-lowering therapy is far lower for those aged 20-44 years (18.7%) than the older age groups – 38.3% for those aged 45-64 years and 51.3% for those aged 65 years and over. **Many young people with gout are being started on allopurinol but not continuing on it.**

Reasons for not continuing on allopurinol are multi-factorial, including needing a good relationship, perceived stigma, lack of education, communication challenges and an expectation that they see the doctor when unwell/in pain rather than for preventative care[12]. Importantly, they include challenges accessing a doctor[14]. It is important that reasons for intentional non-adherence are addressed by prescribers and pharmacists[15], and the pharmacy gout programmes aim to do this.

BPAC states the following in their audit tool[16]:
"Allopurinol is the first-line urate-lowering medicine and initiation should be discussed with all patients with gout, as soon as a diagnosis has been established. The target for allopurinol treatment is a serum urate level < 0.36 mmol/L. The dose of allopurinol must be titrated to achieve the treatment target and serum urate testing should be performed at each dose adjustment. Once the patient has reached the treatment target, serum urate levels should ideally be checked at least once annually.
When allopurinol is initiated, "start low and go slow". A lower starting dose and lower dose increments are recommended in patients with renal impairment."

BPAC's 2021 two part guide to Managing Gout is available at:
https://bpac.org.nz/2021/docs/gout2021.pdf and is attached.

Pharmacy Gout Programmes in Aotearoa New Zealand

There are pharmacy gout programmes in NZ in Northland, Counties Manukau (South Auckland and rural), Midland, Hawkes Bay, Whanganui and Wellington. These are typically in a small number of pharmacies rather than the whole district. These have been developed to support people with gout including addressing concerns and knowledge gaps, support adherence and to aid appropriate dose titration. They are

varied. Some have standing orders to enable the pharmacists to titrate the allopurinol dose to the optimal level for the patient, and to ensure they do not run out, although this is burdensome to administer for the pharmacists, general practitioners and programme managers and delays or challenges arranging these has impacted on programme delivery. Some programmes have fingerprick point of care serum urate tests typically with the Benecheck meter. Some provide compliance packaging to all. Northland[17, 18], Whanganui[19] and Counties Manukau[14, 18] have had evaluations performed.

The continuation and expansion of these programmes show they are valued, and the evaluations show benefit. Having the reclassification will make it easier for all programmes to add dose titration and continuation supply if they do not already have these. It will reduce workload of standing orders being created for each area, being reviewed and updated locally and being signed and overseen by doctors.

The standing orders at Counties Manukau show the workability of the process and are used as a basis for this reclassification model. These were based on the Auckland HealthPathways for Gout and expert opinion (Associate Professor Peter Gow), and passed through committee review.

Software for the Pharmacy Gout Programmes

Bespoke software was developed by Firecrest (providers of INR-online) for the gout programme for Counties Manukau. It can be used in any pharmacy, at a cost, and has been used also in the Hawkes Bay pharmacy programme. It was developed to address the following needs of the gout programme: easy communication between the pharmacy and the GP, helping the patient to return for fingerprick SU tests and help them take their medicine, and to address challenges of understanding outcomes. This software has the following key features:
- Text or email a welcome to the programme email, motivational emails to back up what the pharmacist says, and reminders to come for the fingerprick SU test, including messages if the person is overdue for this test. These messages are personalised to the patient in name and greeting (e.g. Kia ora/Talofa lava), and have the pharmacy name on them.
- Email the doctor with SU results and change in allopurinol dose for each patient in real time
- A graph of the patient's SU results for them to see
- Reporting to allow evaluation of the service and of individual providers.

This software is useful but not essential, e.g. for continuation supply a pharmacist can email a doctor directly with the patient details.

12. Labelling or draft labelling for the proposed new presentation(s) (if applicable)

Not applicable, the medicine would be dispensed by the pharmacist and labelled specifically for the patient.

13. Proposed warning statements (if applicable)

There are no warning statements to be on packaging, see next section for discussion of contraindications and precautions.

Contraindications and precautions will be covered in the training and tools for supply.

14. Other products containing the same active ingredient(s) which would be affected by the proposed change

Only Ipca-allopurinol is currently funded by Pharmac. Any allopurinol brand that enters the NZ market in the future will be affected.

Part B- Clinical Context and Implications

"The management of gout is sub-optimal in New Zealand, and changes need to be made both in community awareness and in the delivery of healthcare..."[20] BPAC 2021

Gout is a painful debilitating condition with considerable impact on the patient and their whanau. It causes long-term damage and is associated with other health effects, e.g. cardiovascular diseases and stroke[21]. But gout attacks can be prevented. Allopurinol is the first-line agent but needs to start low and be titrated slowly to get to the optimal level. It also needs to be taken continuously. If stopped, it has to be restarted (with flare prophylaxis) and gradually titrated again.

Getting patients to the optimal level, adherence and continuation all need work in NZ. Widening access to allopurinol through specially trained pharmacists will support the gout pharmacy programmes to make them easier to implement and extend. Patients outside of the existing programme will have easy appropriate access to continuation supply to make it easier to keep taking the medication. This reclassification will immediately benefit the patients, their whanau, the health system and communities. It will prevent long-term damage from gout. It will be less work than standing orders for pharmacists, doctors and programme managers. Pharmacists have shown they can do this in other areas such as vaccination, COVID-19 antivirals, oseltamivir, trimethoprim for UTIs, and have recently been trusted to work collaboratively with nurses to treat patients with hepatitis C with antivirals, having shown themselves capable of testing for hepatitis C and working with the patient to help them get treated in another condition with perceived stigma.

Benefits

This reclassification has multiple benefits briefly summarised here and with further details in the sections below.

1. Making it easier for patients to be dose titrated and continued on therapy.
2. More patients will achieve the optimal dose and fewer will have gaps in therapy which will translate to very clear patient benefit – less pain (noting that gout is typically excruciating and very debilitating), less time off work and loss of income, less burden on family members (who may otherwise need to take time off work or school), less isolation, more participation in family, church, social and sporting life. Benefits are much wider than simply the individual with gout.
3. With gout managed, the general practice can concentrate on other health needs and preventative therapy.
4. Reducing the burden of standing orders which need to be developed in each location, reviewed and signed off by Health NZ, then signed and audited by either local GPs or a

person for the area. Pharmacists can use a national system and take responsibility for working within it as they do in so many other therapeutic areas.
5. Logically improved management will reduce presentations with gout to emergency departments, need for urgent appointments with the GP and hospitalisations. With a burdened primary and secondary care, this is an important benefit.
6. Good gout control will reduce long-term sequelae including tophi, joint damage and renal damage.

Risks will be managed as follows:

1. Pharmacists will undergo appropriate training which will be endorsed by the Pharmacy Council.
2. All gout patients where allopurinol is being provided or dose titrated by the pharmacist must have a consultation with their general practice at least once a year.
3. Only for gout management, no other indications.
4. Maximum 600 mg/day of allopurinol.
5. The patient will be initiated on allopurinol by a prescriber, not the community pharmacist.
6. The general practice is informed of any serum urate fingerprick test results and allopurinol dose changes.
7. The pharmacist and person with gout will share information to help understanding and motivation.
8. Pregnancy, breastfeeding and key interactions (e.g. azathioprine, mercaptopurine, didanosine, theophylline) will be excluded from pharmacist-supply. Training will cover these.

Titration

9. The patient must be on flare prophylaxis before the pharmacist titrates them, and the patient's GP/prescriber and patient in agreement that the pharmacist titrates them before they start titration – this will typically run under a pharmacy gout programme (as available in pockets around the country to provide funding for the pharmacist to perform this service). Further prophylaxis will need a doctor prescription.
10. Titration has a minimum age of 18 years and no maximum age.
11. eGFR must be at least 30 mL/min to start titration, measured no more than three months prior to dose titration starting.
12. Fingerprick serum urate point of care testing is advisable monthly if possible (noting the different programmes). Or serum urate at the lab is a less preferred option.

Continuation supply

13. Continuation supply is provided to any patient on allopurinol for gout who is on a stable dose and has not had a break of more than 5 consecutive days. If the break is

longer the person needs to be referred to the general practice as they are likely to need to start low and titrate again.

14. eGFR is required annually and needs to be at least 60 mL/min.
15. An annual Serum Urate is recommended.
16. Age 18-65 years.
17. Referral back to the GP for titration is required where the dose may be suboptimal – i.e. gout flares despite good adherence to dosing. This may be guided by serum urate. However, allopurinol can still be provided in this case.
18. Up to three months' supply is provided. This will be dispensed and labelled as usual and the information will be added to the patient's electronic record as for other dispensings.
19. Patients can get continuation supply without being in a pharmacy gout programme.
20. The same dose is provided as the dose the patient was originally on.
21. If having two or more gout flares per year despite good adherence, refer back to the doctor (can supply in the meantime).

Addressing previous MCC minuted points

In 2021 the MCC saw benefit in the reclassification but outlined several points to address[6]:

- The risk of missing and/or undertreating the associated comorbidities of gout.
- Duration for pharmacist follow-up with the patient before a follow-up with their doctor.
- The absence of an electronic care plan that would allow management between community pharmacies and medical practice.
- Processes around training and education for pharmacists.

The response to this is as follows:

1. *The risk of missing and/or undertreating the associated comorbidities of gout*

- People with gout are at risk of other medical conditions and this is well known to pharmacists. The pharmacist will ensure that they have seen their GP at least once a year when supplying the allopurinol, and the pharmacists' training will discuss risk for other health priority conditions such as diabetes and heart disease.
- Importantly, by getting the gout under control through appropriate dose titration and information sharing, and then keeping it under control through continuation supply between doctor visits, the doctor's discussion with the patient can move beyond gout to preventative health.
- If the patient uses allopurinol appropriately and gets into the habit of taking allopurinol daily long-term, they will also get confidence in the medical system and medicines for helping with other conditions.

2. *Duration for pharmacist follow-up with the patient before a follow-up with their doctor*

- In all cases the patient needs to have a consultation at their general practice at least once a year.
- When a patient starts on allopurinol through the general practice, then works with the pharmacist on titration this will be a collaborative exercise. The prescriber will be prescribing allopurinol for the patient to start on, and flare prophylaxis to cover the titration. It is likely that people will need a second prescription for flare prophylaxis at 3 months so will see the doctor then. If the pharmacist is titrating the patient's dose, the pharmacist will inform the doctor of allopurinol dose changes and finger prick serum urate tests (if done). This communication can be done through software, automated, or manually by the pharmacist sending the GP an email.

3. *The absence of an electronic care plan that would allow management between community pharmacies and medical practice*

- Pharmacists can only do the titration if the patient's prescriber of allopurinol is in agreement. Based on the experience of Dr Natalie Gauld at Counties Manukau, GPs were happy for pharmacists to help titrate given the workload and challenges for patients to reach the optimal dose. This may be done in multiple ways: the GP writes on the prescription that the pharmacist is to do the dose titration; the pharmacist checks with the general practice for permission for a specific patient, or the general practice or individual prescriber has a blanket written agreement with the pharmacy to do dose titration for anyone new starting allopurinol for gout and the pharmacy simply advises the doctor by email when a patient starts this. The pharmacist advises the doctor of any allopurinol dose changes and fingerprick SU test results (if done, not all models require this but most are using it).
- This system has worked very well at Counties Manukau as a useful collaborative exercise. At Counties Manukau and Hawkes Bay there is a software system from Firecrest which provides automation of communication to the GP. However, an email can be sent instead if desired.

4. *Processes around training and education for pharmacy*

- This is straightforward. The Pharmacy Council has confirmed that training would be needed, and this was intended in the original application.
- A pharmacy gout training is available from the Pharmaceutical Society of NZ. Gout training is also available specific to different programmes around the country. The Pharmacy Council can endorse appropriate training for the pharmacist to undertake. These would all need to include an understanding of gout, cultural competency related to gout management, perceived stigma of gout, relationship building, working with patients on gout, adherence, the usual information about the drug ie indications, dosing, contraindications, precautions, interactions and adverse effects, point of care serum urate testing, HealthPathways for gout, as well as the requirements specific to

the reclassification such as what is required to undertake titration versus continuation supply.

- It is recommended that any provider of the training has input from a rheumatologist, a rheumatology nurse, a pharmacist experienced in running the programme and providing education and Arthritis New Zealand, as happened at Counties Manukau, for example.
- The reclassification of the hepatitis C treatment is an excellent example of how training had input from a liver specialist, hepatology nurses, a programme manager and a pharmacist experienced in managing the programme and others, and was well-aligned to national HealthPathways to ensure high quality including optimising the patient experience and helping overcome perceived stigma, and using the learnings from earlier hepatitis C pharmacy and outreach test and treat programmes.

Evidence for pharmacy's role.

The Northland model published paper[17] found: "Collaboration between prescribers, community pharmacists and support workers reduced barriers to initiating prevention and long-term urate-lowering treatment and urate testing in this high-needs gout population."

The Counties Manukau gout programme redesign evaluation[14] found: *"Early data from the Gout Busters programme found high Maaori and Pasifika participation in the programme and better long-term adherence to allopurinol than in the Atlas of Variation, including for these groups, albeit limited by small numbers…. Challenges with seeing doctors need to be addressed for long-term continuation on therapy, e.g. pharmacist continuation supply after the programme has been completed, ability to order a repeat prescription or telehealth options."*

The Synergia report of the Counties Manukau earlier Own My Gout Programme and the Northland programme[18] found: *"The value chain created by the programmes enables the assumption that the programmes have contributed to the identified benefits for patients and communities. The programmes have also contributed to the broader health system by promoting integrated teamwork, contributing to health equity, reducing the burden of gout on the sector through a management focus, and providing good value for the resource required locally. Both programmes have continued to develop iteratively and have identified improvements to enhance or sustain programme benefits."* It also noted the need for easy access to medicines.

The Whanganui Stop Gout Programme[19] found: "*The early adopters of this programme demonstrated that the GSP is effective in improving the quality of life of Māori with gout. The challenge for future collaborative LTC programmes is being able to roll-out a programme with buy-in from all providers. Getting the implementation right is the key to programme reach and success. This could be supported by sustainable funding for implementation, national activities to build awareness, and integrated IT systems that better enable information sharing and collaboration."*

There is no need for further evaluations. We now need a national mechanism to enable pharmacists to support people with gout to access allopurinol appropriately – within the gout pharmacy programmes with titration and continuation supply, or outside of the programmes with continuation supply.

15. Indications and dose

- *What is the medicine indicated for, and for which indication(s) is the reclassification application for?*
- *What is the evidence that the proposed indication is an OTC indication ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?*
- *What is the treatment population for the indication (age, gender etc.)?*
- *What is the dose and dose frequency of the medicine for this indication?*

What is the medicine indicated for, and for which indication(s) is the reclassification application for?

The only indication for the reclassification is prophylaxis of gout. This is the main use of allopurinol. It has other uses which will not be treated without prescription. The data sheet lists these as:

• uric acid nephropathy.

• recurrent uric acid stone formation.

• certain enzyme disorders or blood disorders which lead to overproduction of urate (e.g. Lesch-Nyhan syndrome; haemolytic anaemia).

• hyperuricaemia associated with malignancy and cytotoxic therapy which result in a high cell turnover rate.

• The prevention and treatment of calcium oxalate/phosphate renal stones in the presence of high uric acid levels of the blood and/or urine.

What is the evidence that the proposed indication is an OTC indication, ie that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?

This reclassification is for pharmacists who have successfully completed additional training. They have already proven themselves able to manage allopurinol under standing orders, e.g. in Counties Manukau. This is not an OTC reliant on the health care consumer self-diagnosing, self-selecting and self-managing. The patient has already been diagnosed by the doctor who has assessed the patient and initiated allopurinol. The pharmacist is dose titrating effectively as per HealthPathways and will refer anyone with red flags. The pharmacist does not diagnose in this case. The pharmacist will help ensure the consumer has good understanding of gout and the treatment. Risks of inappropriate treatment are aided by clear guidelines, pharmacist

training and the collaborative general practice-pharmacist arrangement. The pharmacist will ensure flare prophylaxis has been prescribed before titrating the dose.

What is the treatment population for the indication (age, gender, etc)?
There is a minimum age of 18 years and no maximum age for titration and a maximum age of 65 years for continuation supply outside of the pharmacy gout programme.
All patients must have an eGFR > 30mL/min for dose titration and > 60 mL/min for continuation supply. The eGFR must be taken no more than three months before starting dose titration and be within 12 months for continuation supply.
About three times as many males as females will likely need this service given current prevalence of gout.
We expect dose titration will be in all ages but most commonly in those who are young who have initiated on allopurinol, or been restarted on allopurinol by the doctor or other prescriber.
We expect continuation supply to be used almost exclusively in people under 65 years, and most often in people who are not taking other long-term medication. Those who are older people and/or on multiple medicines with multiple comorbidities will be regularly seeing their doctor and regularly getting prescriptions. We do not see these people will have a need for continuation supply of allopurinol in that environment. The young working age people with allopurinol as their only long-term medication will be the ones who will find it hardest to get to the doctor every three months for a condition that is not a bother at that time. They will still need an annual visit to the doctor.
All of the population the pharmacy will help will have already been prescribed allopurinol before.

What is the dose and dose frequency of the medicine for this indication?
This dosing information is drawn from the NZ Formulary and is in line with HealthPathways:
Indication for the reclassification: Prophylaxis of gout
Dosage: Adult initially 100 mg once daily (but see Renal impairment above), increasing by 100 mg every four weeks, if tolerated, until target serum urate is reached (<0.36 mmol/L); usual maintenance dose 100–600 mg daily; maintenance dose of 700–900 mg daily may be required in severe conditions.

The datasheet has differing dosage information*:
The average daily dose is 2-10 mg/kg bodyweight, or 100mg to 200mg for mild conditions, 300mg to 600mg daily for moderately severe conditions and 700mg to 900mg for severe conditions.
Allopurinol may increase the frequency of acute attacks during the first few months of therapy; it is therefore recommended that low doses be given initially and slowly increased, and that anti-inflammatory agents or colchicine should be given

concomitantly during this period as prophylactic cover. In patients with good renal function, doses of 100mg should be given and increased by 50mg to 100mg at weekly intervals until serum urate levels of 0.6 mg per ml are achieved.

*The NZ Formulary and HealthPathways information will be used for the training and other information, NOT the datasheet. This is in line with currently used Standing Orders and appropriate for New Zealand.

16. Presentation

- *What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?*
- *What disposal considerations need to be made for the medicine?*
- *How practical and easy to use is the proposed presentation?*

Tablets 100 mg and 300 mg
The disposal considerations are no different from if the medicine was dispensed pursuant to a prescription. It is hoped that the tablets will be taken and not needing to be disposed of.
The tablets are very easy to take. They may be provided loose in bottles or in blister packs also known as compliance packs. People use these packs all the time.

17. Consumer benefits

- *What is the history of this medicine's use for the proposed indication(s) ie, number of users; number of countries used in?*
- *To what extent is this medicine used for the proposed indication(s) ie, duration of use; frequency of use?*
- *What is the evidence that improved access is beneficial for the individual?*
- *What is the evidence of improved consumer involvement in their health?*
- *What are the benefits from a consumer viewpoint?*

NZ data shows that gout causes significant disability, pain, inability to work, shame and embarrassment (or "*whakama*"), isolation from social and family activities, not playing sport or doing physical activities with their children, inability to drive, and dependence on family members who may have to miss work or school to help the person. This dependence can include toileting, washing and providing food and drink. Loss of income can be significant. In some cases people can be bedridden for some time[12, 14, 22, 23], or hospitalised[3].

Additional to this, a paper published in JAMA in 2022 found that a gout flare was associated with statistically significant increased risk of a cardiovascular event in the following 60 days (adjusted odds radio 1.93) in a nested case-control study of patients[21]. A causal link was considered *"eminently reasonable"* based on human and animal studies[24]. Similarly, venous thromboembolism incidence is significantly higher following a gout flare with a 2.31 adjusted incidence rate ratio in the first 30 days after gout flare versus the baseline period[25].

Urate lowering therapy (ULT) is recommended to prevent gout flares.
Access barriers to ULT and its continuation include: not realising they have gout, stigma of gout, communication difficulties, time off work, difficulty seeing a doctor (e.g. service opening hours, affordability, geographic location, unavailability of doctors) and insufficient knowledge about the need for ULT and gout itself[12, 14, 19, 22]. Intentional non-adherence is common with many reasons[15] which will be addressed with education by the specially trained pharmacists as per the current pharmacy programmes.

What are the benefits from a consumer viewpoint?

Reducing access barriers to ULT through continuation supply will mean more people will stay on allopurinol without a break. The benefits of this logically include:

- Reduced frequency of gout flares.
- Reduced absenteeism and presenteeism at work, and reduced loss of wages.
- Being able to continue to participate in sports, including the cardiovascular benefits of this.
- Being able to continue to participate in family events, community work, social events, church events.
- Avoiding feeling shame or embarrassment from having a gout attack.
- Less need for NSAIDs and therefore less risk of adverse effects (note: Māori and Pacific at higher risk of adverse events with NSAIDs[5]).
- Less need for urgent after hours care to address gout issues (and therefore less cost).
- Less need for long waits to treat a gout flare at urgent after hours care or the emergency department.
- With gout under control, less likelihood of needing hospitalisation for gout.
- With gout under control, less likelihood of long-term damage to joints or kidneys.
- Less need for family to care for the person with an acute gout flare, taking time off work or school to do this.
- Able to participate fully in family life, running around with Tamariki and mokopuna.
- Saving time from having to arrange an appointment with the doctor every three months.

- Convenience of getting allopurinol at a time that suits with no appointment needed.
- Getting additional education and understanding.

Supporting pharmacies to do dose titration has the following benefits for patients:
- Getting to the optimal dose of allopurinol.
- Reducing gout flares – and all the attendant concerns listed above.
- Getting gout under control means other health issues can come to the fore when seeing the doctor.
- Getting gout under control will give patients confidence in how medicine works and is likely to help them understand the importance of adherence and belief in medicine if other conditions develop.

What is the history of this medicine's use for the proposed indications ie number of users, number of countries used in?
Allopurinol will have been used by many tens of millions of people all over the world given that an estimated 55.8 million people globally had gout in 2020[9] and this medicine has been first line prophylaxis of gout for decades, and should be available in every country in the world.

To what extent is this medicine used for the proposed indication, ie duration of use; frequency of use?
The medicine is used daily long-term as prophylaxis for gout. Most people will take it until the end of their lifetime.

What is the evidence that improved access is beneficial for the individual?
We have evidence of harm from the current situation with many people in NZ not taking this medicine long-term, particularly in the younger age groups. The poorly managed gout causes many problems as listed in the first paragraph in this section. Gout programmes in NZ in pharmacies have been associated with positive outcomes in terms of achieving target serum urate in individuals[14, 17, 19] and higher than expected rates of continuation of allopurinol therapy one year on[14]. As an example of the benefit for an individual, in the Counties Manukau gout programme, one male of Pacific heritage in his 20s had never worked, having had gout since he was in his teens. After doing the gout programme with the pharmacy, he was able to get a job for the first time. These programmes vary, in some the pharmacies have been paid to do finger prick serum urate testing, provide education and help titrate doses of allopurinol and provide continuation supply.

This reclassification will support the pharmacy programmes or enable allopurinol continuation making getting allopurinol much easier. This will help overcome the barrier of having to arrange a prescription from the doctor, typically having to go in person and take half a day off work. Most pharmacies are open extended hours, they

do not need an appointment, and you do not need to be enrolled so can attend one handy to where you are at the time.

The additional education pharmacists will do to prepare for this work will ensure they are well-equipped to provide advice to people with gout collecting allopurinol about the need for long-term treatment and how it works, to encourage them to get to the right dose for them and to stay on it.

What is the evidence of improved consumer involvement in their health?
The whole point of this is to make it easier for consumers to access this medicine so they do not have therapy gaps. If they resolve their gout they may be more interested in sorting other health areas. We are not aware of evidence collected to specifically answer this question for a reclassification.

18. Contraindications and precautions

- *What are the contraindications for the medicine and how easy are they to identify and prevent?*
- *What are the precautions for this medicine and how easy are these to understand?*
- *Does the medicine have a low therapeutic index?*
- *What class effects need to be considered and what are the risks?*
- *What are the risks of the medicine being used in an OTC environment?*
- *What other drug interactions need to be considered?*
- *What food and/ or drink interactions need to be considered?*
- *Are there any other restrictions when taking the medicine ie, driving restrictions or operating machinery?*
- *Are there any special populations where exposure to the medicine needs to be restricted?*

Warning statements from the NZ formulary include:
Contraindication: not for treatment of acute gout or asymptomatic hyperuricaemia.
Cautions: initiation can precipitate gout flare—flare prophylaxis with an NSAID or colchicine should be used and continued for at least one month after hyperuricaemia has been corrected (usually for the first 3-6 months); consider testing for HLA-B*58:01 allele in individuals of Han Chinese or Thai origin (avoid unless no alternative—risk of severe and potentially life threatening cutaneous adverse reactions in presence of HLA-B*58:01 allele); ensure adequate fluid intake (2–3 litres/day) .
Renal impairment: caution in impairment, risk of accumulation and increased risk of hypersensitivity reactions.
eGFR 30–60 mL/min/1.73m^2, initially 50 mg once daily; increase dose by 50 mg every 4 weeks, if tolerated, until target serum urate is reached (<0.36 mmol/L).

eGFR less than 30 mL/min/1.73m^2, initially 50 mg every second day; increase dose by 50 mg every 4 weeks, if tolerated, until target serum urate is reached (<0.36 mmol/L).
Pregnancy – limited human data.
Breast-feeding – limited human data, potential toxicity.

These contraindications and precautions will be covered in the training and tools for supply. Pharmacists will not be initiating any patients so the doctor will already have considered contraindications and precautions. The key consideration will be renal impairment, which can change over time. An eGFR will need to be available within 3 months before a pharmacist does dose titration. An annual eGFR will be needed after this. Pharmacists have already been working with eGFR in pharmacy programmes in which they titrate the dose, e.g. the Counties Manukau Gout Busters, and with the supply of COVID antivirals. This will be available from the electronic health record the pharmacist has access to in Auckland and Northland (Testsafe) and in the South Island (HealthOne).

As with the standing orders used in Counties Manukau, the eGFR will need to be >30 mL/min for pharmacist supply to take place.

These standing orders, Auckland Health Pathway and NZ Formulary have the following dose titration: start with 100 mg/day and increase by 100 mg approximately monthly for those with an eGFR>60 mL/min; and start with 50 mg/day and increase by 50 mg approximately monthly for those with an eGFR 30-60 mL/min.
Flare prophylaxis must be prescribed by the GP during initiation and dose titration
Anyone who is pregnant or breastfeeding cannot be treated with allopurinol by the pharmacist.
Known allopurinol allergy eg anaphylaxis or previous rash with allopurinol cannot be managed with standing orders.
Maximum daily dose of 600 mg for pharmacist provision
Minimum age 18 years old
Taking febuxostat and allopurinol cannot be managed by the pharmacist but managed through the doctor.

Note: it is important that allopurinol is continued for all patients. Where continuation supply is not possible because of above criteria, emergency supply provision could be used for up to 72 hours and the person referred back to the GP. Emergency supply is not ideal because 3 days' supply does not give much time to get into the doctor and will be relatively expensive for a small number of tablets when paying for the pharmacist's time.

19. Undesirable effects

- *What are the known undesirable effects and the frequencies of these? Do these vary for special populations?*
- *What are the risks and consequences of known undesirable effects?*
- *Are there any significant safety concerns for the medicine under review?*
- *Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?*
- *Are there any withdrawal effects following cessation of use of the medicine?*

BPAC states that "Adverse effects of allopurinol are relatively uncommon"[26]
BPAC further notes as follows:
Adverse effects include gastrointestinal symptoms. Hypersensitivity reactions can occur e.g. drug rash with eosinophilia and systemic symptoms (DRESS) and Stevens-Johnson syndrome. DRESS most often occurs in the first few weeks to months of starting therapy and has a lower risk with starting at a low dose and gradually titrating as the pharmacist can support to happen. The pharmacist will be trained on adverse events and can advise to seek prompt advice if a rash is seen. Risk factors for DRESS include renal impairment, elevated starting dose relative to renal function, use of diuretics and having the HLA-B*5801 allele – often present in those of Korean, Thai or Han Chinese descent. Genetic testing for this allele is available. The doctor will be initiating therapy not the pharmacist.

The datasheet (attached) has the full list of adverse effects. There are no frequencies for this, apart from noting rash in 10% of patients, and as mentioned, this may be a significant adverse reaction.

Allopurinol has been on the market for decades, used by many people. It is well-known and generally well-tolerated.

SMARS (Suspected Medicine Adverse Reaction Search Results) data is provided from 1/1/2000 t0 31/5/2024. This included 42 cases of DRESS and 12 of Stevens Johnson syndrome.

The adverse effects section of the NZ Formulary is as follows:
Rash (see Hypersensitivity syndrome below); less commonly nausea, vomiting, abdominal pain; rarely malaise, headache, vertigo, drowsiness, visual and taste disturbances, hypertension, alopecia, hepatotoxicity, paraesthesia, neuropathy, gynaecomastia, blood disorders (including leucopenia, thrombocytopenia, haemolytic anaemia, aplastic anaemia), severe cutaneous adverse reactions (SCARs, such as Drug

Reactions with Eosinophilia and Systemic Symptoms (DRESS)), hypersensitivity reactions (including fever, arthralgia, leucopenia, and also skin reactions—see Hypersensitivity syndrome below)

Hypersensitivity syndrome

Hypersensitivity syndrome occurs rarely, but may be fatal, and includes skin reactions, exfoliation, fever, lymphadenopathy, arthralgia, eosinophilia, vasculitis, hepatitis, renal impairment, and very rarely seizures. If hypersensitivity occurs, allopurinol should be withdrawn immediately and permanently; when it is being used for gout consider consultation with a rheumatologist.

Rash is a common adverse reaction with allopurinol; it may occur at any time during treatment but risk is greatest in the first 2 months. Skin reactions (including rash) may occur as part of a generalised hypersensitivity reaction and in more severe cases can progress to Stevens-Johnson syndrome, toxic epidermal necrolysis, and DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms)—see Severe Cutaneous Adverse Reactions (SCARs).

Patients should inform their doctor if a rash occurs, and therapy should be immediately withdrawn. If the rash is mild, allopurinol may be re-introduced cautiously at a low dose and gradually increased but discontinue promptly if the rash recurs.

Higher starting doses, rapid titration, and renal impairment increase risk of hypersensitivity reactions; ACE inhibitors and thiazide diuretics may also increase risk. See Readdressing the risk of DRESS with cautious titration Prescriber Update, September 2022 and SafeRx bulletin: Allopurinol—Safe Prescribing for more information.

It is the doctor's decision to initiate therapy. The pharmacist will be informed about adverse effects during the training and will look out for any and manage as appropriate if they occur. The doctor and pharmacist need to warn the patient of rare but important effects and to advise of any rash promptly.

There are no significant safety concerns with the medicine under review. It has not been withdrawn from markets that we are aware of, and remains first-line for gout prophylaxis.

Allopurinol does not cause withdrawal effects when discontinued. The serum urate is

20. Overdose

- *Is there a potential for overdose of the medicine?*
- *What are the consequences of overdose of the medicine?*
- *Are there any reports of overdose of the medicine?*

The datasheet states the following under the heading overdose:
Symptoms: Nausea, vomiting, diarrhoea and dizziness have been reported in a patient who ingested 20g of allopurinol. Ingestion of larger doses have been reported without adverse effects. Treatment: The patient should be monitored and receive normal supportive measures and should be adequately hydrated to maintain urinary excretion of allopurinol and its metabolites. Concomitant medication may affect the effects noted. Haemodialysis may be used if necessary.

SMARS data reports 1 episode of intentional overdose since 2000.

There is no greater risk of overdose than the current risk with allopurinol prescribed.

21. Medication errors and abuse/ misuse potential

- *Would reclassification affect the risk of unnecessary use?*
- *Should the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?*
- *What are the reported medication errors post-market?*
- *What are the reported cases of abuse/misuse/accidental overdose?*
- *How would reclassification affect import considerations?*
- *What is the addiction potential of the medicine?*

Errors are no more likely than with use on prescription.

SMARS data reports 12 medication errors since 2000. This is minimal for a prescription medicine so widely used. No accidental overdose is reported in this data.

There will not be unnecessary use, the person has been diagnosed with gout and a prescriber has considered allopurinol is needed. People with gout need this medication long-term. The problem is always underuse not overuse.

The tablets are taken once a day, the directions will be clear on the label.

The medication will remain a prescription medicine for the purposes of importation so there is no risk.

This medicine is not addictive nor abused or misused.

22. Communal harm and/or benefit

- *What are the possibilities of community harm resulting from wider use of the medicine in question (e.g., the development of antibiotic resistance in bacteria or increased immunisation rates)?*
- *What are the possibilities of community benefit resulting from wider use of the medicine in question (e.g., greater herd immunity as a result of improved access to a communicable disease vaccine)?*

There is no community harm from this provision of allopurinol.

The community benefits include:

- reduced hospitalisation from gout is a benefit to all given hospitals are so often under pressure.

- having less need for urgent doctors' visits for acute gout flares is a benefit to all who may need to see the doctor given how difficult it is to get to see them.

- having more participation in sports, community life, church, social events is important to the cohesion of a community.

- not requiring time off work every three months to see the doctor for a prescription or not requiring extensive time off for repeated gout attacks is a benefit to the workplace, other workers and the family income.

- avoiding the agony of gout makes for a happier family and community.

23. Integrated benefit-risk statement

- *A summary of the reclassification benefits*
- *A summary of the reclassification risk of harm*
- *A summary of the need for the medicine at the classification proposed*
- *Precedent – how are other medicines in the same class classified?*

Benefits in short

- Making it easier for patients to be dose titrated and continued on therapy.
- More patients will achieve the optimal dose and fewer will have gaps in therapy which will translate to very clear patient benefit – less pain (noting that gout is typically excruciating and very debilitating), less time off work and loss of income, less burden on family members (who may otherwise need to take time off work or school), less isolation, more participation in family, church, social and sporting life. Benefits are much wider than simply the individual with gout.
- With gout managed, the general practice can concentrate on other health needs and preventative therapy.

- Reducing the burden of standing orders which need to be developed in each location, reviewed and signed off by Health NZ, then signed and audited by either local GPs or a person for the area. Pharmacists can use a national system and take responsibility for working within it as they do in so many other therapeutic areas.
- Logically improved management will reduce presentations with gout to emergency departments, need for urgent appointments with the GP and hospitalisations. With a burdened primary and secondary care, this is an important benefit.
- Good gout control will reduce long-term sequelae including tophi, joint damage and renal damage.

Risks of harm key points

- Patient needs to see the doctor regularly because at risk of comorbidities – the pharmacist is required to ensure annual visits
- Adverse effects listed above – these will be no more likely under this model in which the doctor starts the medicine, and sees the patient at least annually. The pharmacist has training.
- Patients with many comorbidities and polypharmacy could get allopurinol from the pharmacy and the doctor not know – these people will be regularly attending the doctor and getting prescriptions and will not need continuation supply outside of a pharmacy programme of titration (which the doctor agrees to). Almost all users of the continuation supply will be only using allopurinol long term and seeing the general practice annually.
- Interactions – no more likely than with prescribing. Pharmacists will have training.
- The general practice is not informed – this risk is managed by the requirement for the pharmacist to share allopurinol dose titration information and continuation supply. Software could enable this but communication does not need it to happen when it is a requirement as in this instance.
- Pharmacist won't know eGFR or Serum Urate results – the pharmacist needs to know this for allopurinol supply. The majority of NZ – Auckland, Northland, South Island have Testsafe or HealthOne. In other areas there can be other arrangements, e.g. Hawkes Bay where pharmacists already do this and access information through the Clinical Portal. If they don't have access, they cannot supply.
- Risk mitigation with a screening/documentation tool and mandatory training plus safeguards mentioned above, eg ages, eGFR frequency and minimum levels, ensures that this model has good safety. It has been used already with standing orders and has worked well.

Need for the medicine reclassification

This is clear – patients are having poorly managed gout when they have not got to an optimised dose or have breaks in therapy. We urgently need to solve this problem through supporting patients to get to the right dose, know what they need to about their medicine, discuss concerns about their medicine and be able to access it safely and conveniently to help them stay on it. Please do not delay.

Precedent

Patients can repeatedly use OTC NSAIDs for their gout (a very poor practice with risk) or borrow medicines, a very unsafe practice. Allopurinol reclassification in the model proposed is beneficial with mitigated risk. We also have the current precedent of management as per standing orders as in Counties Manukau Health.

24. Risk mitigating strategies

- *Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required e.g., healthcare professional education; integration of care; consumer information to be provided etc?*
- *What is the evidence that these proposed risk mitigation strategies would be effective?*
- *What post-market surveillance activities would be carried out?*
- *Is the proposed reclassification supported by professional bodies?*

Risks will be managed as follows:

1. Pharmacists will undergo appropriate training which will be endorsed by the Pharmacy Council.
2. All gout patients where allopurinol is being provided or dose titrated by the pharmacist must have a consultation with their general practice at least once a year.
3. Only for gout management, no other indications.
4. Maximum 600 mg/day of allopurinol.
5. The patient will be initiated on allopurinol by a prescriber, not the community pharmacist.
6. The general practice is informed of any serum urate fingerprick test results and allopurinol dose changes.
7. The pharmacist and person with gout will share information to help understanding and motivation.
8. Pregnancy, breastfeeding and key interactions (e.g. azathioprine, mercaptopurine, didanosine, theophylline) will be excluded from pharmacist-supply. Training will cover these.

Titration

9. The patient must be on flare prophylaxis before the pharmacist titrates them, and the patient's GP/prescriber and patient in agreement that the pharmacist titrates them before they start titration – this will typically run under a pharmacy gout programme (as available in pockets around the country to provide funding for the pharmacist to perform this service). Further prophylaxis will need a doctor prescription.
10. Titration has a minimum age of 18 years and no maximum age.

11. eGFR must be at least 30 mL/min to start titration, measured no more than three months prior to dose titration starting.
12. Fingerprick serum urate point of care testing is advisable monthly if possible (noting the different programmes). Or serum urate at the lab is a less preferred option.

Continuation supply

13. Continuation supply is provided to any patient on allopurinol for gout who is on a stable dose and has not had a break of more than 5 consecutive days. If the break is longer the person needs to be referred to the general practice as they are likely to need to start low and titrate again.
14. eGFR is required annually and needs to be at least 60 mL/min.
15. An annual Serum Urate is recommended.
16. Age 18-65 years.
17. Referral back to the GP for titration is required where the dose may be suboptimal – i.e. gout flares despite good adherence to dosing. This may be guided by serum urate. However, allopurinol can still be provided in this case.
18. Up to three months' supply is provided. This will be dispensed and labelled as usual and the information will be added to the patient's electronic record as for other dispensings.
19. Patients can get continuation supply without being in a pharmacy gout programme.
20. The same dose is provided as the dose the patient was originally on.
21. If having two or more gout flares per year despite good adherence, refer back to the doctor (can supply in the meantime).

No post-market surveillance activities will be carried out.

Professional bodies and many individuals including GPs, pharmacists, gout programme managers and rheumatologists have been consulted and are encouraged to write in themselves.

Conclusion

A brief summary of the purpose of the submission and any concluding remarks

This reclassification application has been submitted by Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld (pharmacist specialising in access to medicines) and Associate Professor Peter Gow (rheumatologist). It has been developing over several years, and has been well-informed by an understanding of the

challenges of people with gout in New Zealand, and pharmacy programmes here. The input of many people and organisations involved in gout has been greatly appreciated.

The model is for the doctor or other prescriber to initiate allopurinol and specially trained pharmacists to titrate (in collaboration with the general practice) allopurinol. It also allows for continuation supply for anyone on allopurinol that meets set criteria. This will help people get to the appropriate dose and then stay on medication. We expect this to benefit patients, their whanau, the community and the health system. There is a potential to reduce long-term harm and hospitalisations.

Allopurinol is generally well-tolerated and the model provides considerable safety. Communication with general practice is an important part of the model and so is a visit at least annually to general practice for anyone getting continuation supply.

The immediate benefit of this is to reduce the burden of standing orders, help the existing pharmacy gout programmes work as well as possible for patient benefit and help reduce people running out of tablets and stopping even temporarily then having to restart.

The Pharmacy Council would endorse training as is appropriate.

References

1. Dehlin, M., et al., *Global epidemiology of gout: prevalence, incidence, treatment patterns and risk factors*. Nature Reviews Rheumatology, 2020.**16**(7):380-390.
2. *Gout*. Auckland Region HealthPathways 2020 14 Jan 2021]; Available from: https://aucklandregion.communityhealthpathways.org/18727.htm.
3. Dalbeth, N., et al., *Gout in Aotearoa New Zealand: The equity crisis continues in plain sight*. NZ Med J, 2018.**131**(1485):8-12.
4. Kim, S.Y. and H.K. Choi, *Gout and quality of life*. J Rheumatol, 2009.**36**(5):865-8.
5. Tomlin, A., et al., *Ethnic inequality in non-steroidal anti-inflammatory drug-associated harm in New Zealand: A national population-based cohort study*. Pharmacoepidemiol Drug Saf, 2020.**29**(8):881-889.
6. Medsafe, *Minutes of the 66th meeting of the Medicines Classification Committee held in Wellington on 11 May 2021 at 9:39 am*. 2021, Medsafe:Wellington.
7. Pead, M.A. *Pharmacy Council submission on the Reclassification of Allopurinol 66th meeting on 11 May 2021*. 2021 14 Aug 2024]; Available from: https://medsafe.govt.nz/profs/class/Agendas/Agen67/Allopurinol.pdf.
8. Health Safety and Quality Commission. *Gout*. 2019 1220 Nov 2022 25 July 2024]; Available from: https://public.tableau.com/app/profile/hqi2803/viz/PHOanalysis/Gout2019.

9. Cross, M., et al., *Global, regional, and national burden of gout, 1990–2020, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021*. The Lancet Rheumatology, 2024.**6**(8):e507-e517.
10. Health Quality and Safety Commission New Zealand Kuru Taurangi Hauora o Aotearoa. *Atlas of Healthcare Variation Gout*. 2019 20 Nov 2022 25 July 2024]; Available from: https://public.tableau.com/app/profile/hqi2803/viz/Goutsinglemap/AtlasofHealthcareVariationGout/viz/Goutsinglemapdraft2021/AtlasofHealthcareVariationGout.
11. Jackson, G., et al., *Potential unmet need for gout diagnosis and treatment: Capture-recapture analysis of a national administrative dataset*. Rheumatology (United Kingdom), 2012.**51**(10):1820-1824.
12. Fatafehi-Finau, T., *Experiences and Perceptions of Tongan people diagnosed with gout living in South Auckland*. 2019, Whitireia Community Polytechnic.
13. Dalbeth, N., et al., *The experience and impact of gout in Māori and Pacific people: A prospective observational study*. Clinical Rheumatology, 2013.**32**(2):247-251.
14. Gauld, N., et al., *Gout Busters: Evaluation of the redesigned pharmacy gout management programme in Te Whatu Ora Counties Manukau* 2023, Te Whatu Ora Counties Manukau:Auckland.
15. Emad, Y., et al., *Why Do Patients With Gout Not Take Allopurinol?* J Rheumatol, 2022.**49**(6):622-626.
16. *Clinical Audit - Lowering serum urate levels in patients with gout*. 2023 July 2023 13 Aug 2024]; Available from: https://bpac.org.nz/audits/gout.aspx.
17. Lawrence, A., et al., *Facilitating equitable prevention and management of gout for Māori in Northland, New Zealand, through a collaborative primary care approach*. J Prim Health Care, 2019.**11**(2):117-127.
18. Andrews, S., et al., *Evaluation of Gout Stop and Owning My Gout management programmes*. 2020, Synergia.
19. Whanganui Regional Health Network, *Whanganui Gout Stop Programme Evaluation*. 2022, Whanganui Regional Health Network.
20. *Managing gout in primary care. Part 1 - Talking about gout: time for a re-think*. BPAC, 2021.**July**:1-8.
21. Cipolletta, E., et al., *Association between Gout Flare and Subsequent Cardiovascular Events among Patients with Gout*. JAMA, 2022.**328**(5):440-450.
22. Lindsay, K., et al., *The experience and impact of living with gout: A study of men with chronic gout using a qualitative grounded theory approach*. Journal of Clinical Rheumatology, 2011.**17**(1):1-6.
23. Stewart, S., et al., *The experience of a gout flare: a meta-synthesis of qualitative studies*. Seminars in Arthritis and Rheumatism, 2020.**50**(4):805-811.
24. Anderson, J.L. and K.U. Knowlton, *Cardiovascular Events and Gout Flares*. JAMA, 2022.**328**(5):425-426.
25. Cipolletta, E., et al., *Risk of Venous Thromboembolism With Gout Flares*. Arthritis and Rheumatology, 2023.**75**(9):1638-1647.
26. *Managing gout in prinary care. Part 2 - controlling gout with long-term urate-lowering treatment*. BPAC, 2021(July):1-6.

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Proposed model of allopurinol access

Current situation

1. Allopurinol is under-used by people in NZ with gout. Some people who would benefit from allopurinol have never taken it and many discontinue it. For example, around 50% of people with gout aged 20-44 are prescribed allopurinol at least once, but only 18% take it regularly.
2. Barriers to continuing allopurinol include delay seeing a GP, nurse or pharmacist prescriber when a script is required, e.g. waiting for an appointment and/or difficulty taking time off work.
3. Some people do not reach the optimal allopurinol dose and get flares.
4. A small number of pharmacies have contracts to assist with optimising allopurinol dosing and helping patients understand more about preventing gout. This pharmacy-general practice collaboration can benefit patients[1, 2].
5. Various pharmacy gout programmes are used. All provide patient education. Other work may include: compliance packaging, finger prick serum urate tests allopurinol dose titration, and using software to facilitate GP communication (email serum urate and allopurinol dose), text patients and provide reporting.
6. Standing orders are used for allopurinol titration and sometimes also continuation supply, but add burden on the general practice and pharmacy and are difficult to arrange where there is high locum cover.
7. An alternative collaborative model without standing orders will reduce burden and aid gout management
8. A national approach using the best strategies is preferred.
9. General practice, pharmacy and patients are busy, the proposed model is intended to best meet the needs of all to collaboratively get better gout outcomes.

The proposed models

- In both models the pharmacist has to successfully complete training endorsed by the Pharmacy Council of NZ, work within set parameters, refer if appropriate, keep appropriate records and inform the general practice of supply.
- Patients would need to fit selected criteria – based on HealthPathways, including eGFR. A flowchart/screening tool would help the pharmacist identify when referral is needed and they cannot supply allopurinol.
- Patients would be referred to their doctor if any red flags develop, if they have other health needs, with clinically important adverse events, eGFR < 30 mL/min (dose titration) or <60 mL/min (for continuation supply), or inadequate control of gout despite up-titration of doses and adherence.

1. Titration and continuation supply in a collaborative approach to gout, supporting pharmacy gout programmes
    - The proposed allopurinol supply would support pharmacy gout programmes around the country allowing both titration and continuation supply.
    - The GP, nurse practitioner or pharmacist prescriber[1] initiates allopurinol and flare prophylaxis and agrees patient can go into the pharmacist dose titration programme.
    - The pharmacist discusses gout with the patient identifying any concerns/knowledge gaps and preferably offers monthly fingerprick serum urate tests with no appointment needed (programmes vary but most would likely move to this, otherwise lab test serum urates will be needed).
    - The pharmacist titrates allopurinol dosing and provides continuation supply of allopurinol within set parameters (generally aligning with HealthPathways).
    - There is software specially developed for the gout programme in Counties Manukau and available for other pharmacies that sends an email with serum urate and allopurinol dose change to the doctor (as for INR), includes texts to the patient (motivating allopurinol continuation and reminders to get finger prick serum urate tests when due) and reports outcomes to the funder.
    - Pharmacists providing this service will discuss it in advance with their local medical centres, and this will be done as a pharmacy-general practice collaboration.
    - Patients need to see their GP at least annually.

2. Continuation supply outside of the pharmacy gout programmes
    - For continuation supply the patient does not need to be in a specific gout programme, but already on allopurinol and fitting select criteria.
    - Discussion about gout would be required.
    - The patient needs to see their GP at least annually.
    - eGFR annually, must be at least 60 mL/min.
    - Serum urate recommended annually.

Patients presenting with acute gout and not on allopurinol would be referred to their general practice for allopurinol initiation.

Benefits: this model will help patients avoid running out of tablets, will stop the need for standing orders, and will help patients get to the appropriate allopurinol dose, while

[1] Pharmacist prescriber is a specially trained pharmacist with prescribing rights usually working in general practice or elsewhere. The trained pharmacists in the community pharmacies doing allopurinol titration and continuation supply would rarely be a pharmacist prescriber.

keeping the doctor informed. Patients will learn more about gout and the importance of taking allopurinol. Doctors will be able to concentrate on other medical conditions when they see the patient rather than repeatedly managing gout flares and trying to start the patient on allopurinol.

The proposed model has received input from a variety of different stakeholders. The final documents will be reviewed by Associate Professor Peter Gow (rheumatologist) and GPs, pharmacists and programme managers involved in the current gout programmes.

References

1. Lawrence A, Scott S, Saparelli F, Greville G, Miller A, Taylor A, et al. Facilitating equitable prevention and management of gout for Māori in Northland, New Zealand, through a collaborative primary care approach. J Prim Health Care. 2019;11(2):117-27. doi: https://doi.org/10.1071/HC18082.
2. Gauld N, Gow P, Fatafehi-Finau T, Vandal A, Kaiaruna T, Fraser L, et al. Gout Busters: Evaluation of the redesigned pharmacy gout management programme in Te Whatu Ora Counties Manukau Auckland: Te Whatu Ora Counties Manukau; 2023.

Appendix 2 Consultation/Discussion

We are asking all organisations and individuals to provide their submission to MCC independently. We have greatly appreciated the feedback all organisations and individuals have had to the development of the model. Almost all feedback has been of considerable support of our proposal.

1. Input from Associate Professor Peter Gow, Arthritis NZ (including the Medical Director) and Green Cross Health throughout the process
2. Susan Reid, Director Health Literacy New Zealand
3. Gout Action Aotearoa – twice including sending model for feedback and discussions held
4. Meeting Billy Allen and Astuti Balrum, Health New Zealand-Te Whatu Ora
5. Participation in internal meeting Pharmac and phone calls with Robyn Harris
6. Ajay and Cas from Porirua, pharmacists delivering gout service
7. Programme Managers Pharmacy nationally zoom call and discussion of the model, plus two individual phone calls separately
8. Dr Sue Ward, GP involved with Northland Project, phone call and email feedback on proposed model
9. Meeting with two from the Clinical Advisory Pharmacists Association (CAPA)
10. Meeting with the College of General Practitioners after sharing the proposed model of supply
11. Meeting with the Pharmacy Council and Pharmaceutical Society
12. Meeting with the Pharmacy Guild
13. Model shared, emails and phone calls with clinical pharmacist involved in Hawkes Bay Pharmacy Gout Programme
14. Model shared and phone call with President of Maori Pharmacists Association – further discussion with the Board upcoming after the application is submitted
15. Feedback Dr Sarah Hartnall on key referral criteria after sharing the model.
16. Email model review from Professor Nicola Dalbeth, rheumatology academic
17. Meeting with General practice and Pacific team academics from the University of Auckland who are working on gout.
18. Meeting with Whanganui Stop Gout programme people

Note: This application stems particularly from the work done at Counties Manukau redesigning the gout programme which had input from pharmacists from all pharmacies involved with the Own My Gout programme at Counties Manukau, Teei Kaiaruna (Waikato-Tainui/Cook Island Maori, from the Maori Health team at Counties Manukau), Dr Lily Fraser (Ngai Tahu GP at Turuki Medical Centre, Mangere) and Arthritis New Zealand. The redesign and evaluation of this programme was led by Dr Natalie Gauld, Associate Professor Peter Gow and Thelma Fatafehi-Finau (Tongan Rheumatology Nurse). The Standing Order for this programme (a basis for the reclassification model)

was reviewed by a GP Liaison at Counties Manukau and approved by the Drug and Therapeutics Advisory Group at Middlemore Hospital.

Managing gout in primary care

Part 1 – Talking about gout: time for a re-think

Gout is a treatable form of arthritis that is associated with poor health and reduced life expectancy. Too often, gout management is focused on controlling the patient's symptoms while their risk of irreversible joint damage and negative health outcomes continues to grow. Māori and Pacific peoples are disproportionately affected by gout and often receive sub-optimal care; it is time for a re-think to address this disparity.

KEY PRACTICE POINTS:

- Gout is a serious condition that is often associated with a range of long-term negative health outcomes, e.g. co-morbid cardiovascular disease, renal failure and reduced life expectancy
- The management of gout is sub-optimal in New Zealand, and changes need to be made both in community awareness and in the delivery of healthcare; after making a diagnosis, the emphasis should be placed on providing information to patients about their condition, addressing any misconceptions or concerns and supporting appropriate medicine use
- Gout flares can be treated with a NSAID, prednisone or low dose colchicine, depending on individual clinical circumstances; all are considered to be equally effective
- Discuss urate-lowering treatment with all patients with gout at their first presentation, recommend early initiation and encourage regular and consistent use; lifestyle changes alone are insufficient to prevent future gout flares from occurring
- Allopurinol can be initiated during an acute flare of gout if it is thought that this may improve the likelihood of the patient committing to long term treatment; however, this may not be appropriate for all patients

This is a revision of a previously published article. What's new for this update:

- A general article revision
  - Update of statistics
  - Addition of genetics to the list of risk factors

For further information about initiating and titrating allopurinol, see: "Part 2: Controlling gout with long-term medicines" available from: **bpac.org.nz/2021/gout-part2.aspx**

Gout is controllable with long-term treatment

Gout is the most common form of inflammatory arthritis.[1] It is caused by monosodium urate crystals accumulating in joint fluid, cartilage, bones, tendons and other tissues.[2] Urate is produced via the metabolism of dietary and endogenous purines.[2] When urate levels in the blood reach saturation point, monosodium urate crystals can form.[2] The inflammatory response to these crystals results in gout flares which are characterised by painful, red, hot, swollen joints. Over time, the duration and frequency of these flares may increase, resulting in chronic gouty arthritis and subcutaneous deposits of crystals referred to as tophi, both of which can lead to the destruction of joints.[2]

The risk factors for gout

Long-term hyperuricaemia is the most important risk factor for the development of gout, and in most patients this will be caused by declining renal function.[2] Detecting chronic kidney disease (CKD) early and preserving renal function is therefore an important gout-prevention strategy. Additional factors that contribute to hyperuricaemia and increase the risk of developing gout include:[2–5]

- Older age
- Genetics, e.g. variants of the *SLC2A9* fructose/urate co-transporter genes have been implicated in the greater number of Māori and Pacific peoples living with gout; it is thought that these genetic variants reduce the ability to excrete urate, contributing to hyperuricaemia and therefore the risk of gout
- Male sex
- Hypertension
- Obesity
- Use of certain medicines, e.g. diuretics or low dose aspirin (for more information on the appropriate selection and use of cardiovascular medicines, see: **Part 2: controlling gout with long-term urate-lowering medicines**)
- Excessive consumption of red meat, seafood, beer, spirits, sucrose or fructose-sweetened drinks

The burden of poorly-controlled gout is often over-looked

Gout is much more than an intensely painful condition that prevents people from working, performing daily activities and participating in their communities.[1] People with gout are also more likely than those without gout to die at a younger age due to co-morbid cardiovascular disease and renal complications.[6] In New Zealand, 40% of people with gout have diabetes and/or cardiovascular disease.[7] Despite this, many people consider gout to be a condition that merely requires analgesics to control and are not aware of the potential long-term consequences.[8] Raising community awareness about gout is an important role for health professionals in primary care.

Urate-lowering treatment improves long-term health outcomes

Reducing serum urate levels in patients with gout not only means that flares are less likely, it may also reduce the risk of adverse renal and cardiovascular outcomes. For example, a meta-analysis found that compared to patients who were not taking a urate-lowering medicine (or were taking a placebo), patients with hyperuricaemia and CKD who were taking a urate-lowering medicine:[9]

- Reduced their risk of cardiovascular events or renal failure by more than half
- Had slower rates of decline in renal function
- Reduced their proteinuria

More recently, it was found that people with gout and diabetes who were taking urate-lowering treatment had significantly lower risk of coronary artery disease or stroke.[10]

Māori and Pacific peoples with gout are not receiving adequate care

Gout management in New Zealand needs to change because Māori and Pacific peoples in particular are not receiving the medicines according to their level of need. Furthermore, research suggests that inequities between how gout is managed in Māori and non-Māori is ingrained in the current model of care, with no significant reduction in disparity in recent years.[11]

Gout is more frequent and more severe in Māori and Pacific peoples

The prevalence and burden of gout in New Zealand is higher in Māori and Pacific peoples than in other groups. In 2019, gout was estimated to affect approximately 6% of people in New Zealand aged over 20 years; Māori and Pacific peoples aged 20 to 44 years have a three and seven times greater prevalence of gout than non-Māori and non-Pacific peoples, respectively.[1] The prevalence of gout increases with age; among males aged over 65 years the prevalence is 35% for Māori, 50% for Pacific peoples and 18% for non-Māori and non-Pacific groups.[1] Māori and Pacific peoples with gout are dispensed more prescriptions for NSAIDs each year (41% and 46%, respectively) than other ethnic groups (35%) and are therefore at greater risk of NSAID-related adverse effects, e.g. acute kidney injury and cardiovascular events.[1] Māori and Pacific patients with gout are also five and nine times more likely to be admitted to hospital due to gout than non-Māori, non-Pacific people.[1]

Prescribers often delay initiation of urate-lowering treatment

Numerous studies from New Zealand and overseas show that urate-lowering treatment is often delayed well beyond the point when it is indicated. For example, a small qualitative study of Māori patients with gout found that on average urate-lowering treatment was not prescribed until 18 years after the appearance of symptoms.[13] In 2019, dispensing data showed that Māori and Pacific peoples with gout were more likely to have received urate-lowering treatment (60%), i.e. dispensed medicine at least once in one year, than non-Māori and non-Pacific people with gout (56%). However, Māori and Pacific peoples were less likely to receive regular treatment (39% and 36%, respectively), i.e. dispensed medicine in three or four quarters in one year compared with non-Māori and non-Pacific people (43%).[1]

Once urate-lowering medicines are started, monitoring is also often sub-optimal, meaning that many patients will still have serum urate concentrations above recommended levels for treating gout. A systematic review predominantly of studies from the United States and United Kingdom found only 28 – 38% of patients had their serum urate levels monitored regularly and 23% of patients taking allopurinol had serum urate levels above 0.36 mmol/L.[14]

Identifying the barriers to optimal management

The barriers to the early and optimal use of urate-lowering medicines are multi-factorial. Firstly, there is a lack of clarity in guidelines as to the best time to initiate treatment, and at times there are discrepancies between guidelines. Secondly, there is sometimes a perception among health professionals that gout management is acute, rather than preventative.[8] The limited time that is available in consultations in primary care and the intermittent nature of gout flares also make it difficult for health professionals to focus on the long-term management of gout and promote patient education.[15]

Nurses and pharmacists have an important role in gout management

Most patients with gout are able to achieve serum urate targets if they are provided with effective support. This role is ideal for nurses in primary care; an essential component of gout education is overcoming misconceptions that are barriers to care (see: "Overcoming misconceptions that are barriers to managing gout"). A nurse-led programme in primary care in the United Kingdom found that with education and lifestyle advice, 92% of patients were able to achieve serum urate treatment targets.[8]

Community pharmacists can reduce delays in the diagnosis of gout and the initiation of urate-lowering treatments by asking patients who are purchasing NSAIDs about their symptoms.[8] Patients who may have gout, e.g. those with a history of gout-like flares, can be encouraged to present to general practice for an assessment, and those who know they have gout can be encouraged to discuss the possibility of starting urate-lowering treatment with a general practitioner.

Owning My Gout and Gout Stop are initiatives led by community pharmacists, practice nurses and general practitioners to improve access to medicines for gout and to build on health literacy by educating participants. Further information is available from: **https://www.arthritis.org.nz/wp-content/uploads/2020/07/Gout-programmes-evaluation-report-.FINAL_.-200228.pdf.** Another gout management improvement project was launched by the National Hauora Coalition in collaboration with Papakura Marae Health Clinic, further information is available from: **https://www.nhc.maori.nz/wp-content/uploads/2019/09/HCAnnualReport-Final.pdf**

Overcoming misconceptions that are barriers to managing gout

Perceptions and beliefs about gout can contribute to delays in initiating urate-lowering treatment.[16] Good communication helps to overcome misconceptions that are barriers to care. A structured approach to discussions is therefore recommended:

- Assess the patient's understanding about gout
- Build on their knowledge by validating information that is correct, filling in knowledge gaps and correcting misconceptions
- Check that the patient has understood the information that has been delivered

The goal is to form a loop of communication, with gaps in understanding forming the basis for further discussion.

Further information on effective discussion and communication about gout management with patients is available from: **https://bpac.org.nz/bpj/2014/april/gout.aspx**

Delivering the messages that patients and whānau need to hear

Do not blame yourself because you have gout. Lifestyle factors can trigger gout flares but are not the sole cause of the condition. Biological factors (e.g. chronic kidney disease, certain uric acid renal transporter alleles) and some medicines (e.g. diuretics) contribute significantly to the higher prevalence of gout in Māori and Pacific peoples compared with other ethnic groups.[17] Explaining to patients that they may have a genetic predisposition to gout helps to dispel the perception that the condition is self-inflicted.

Gout is serious, it's not just "a pain in the toe". Patients should understand that gout is associated with an increased risk of co-morbid cardiovascular disease and renal complications. However, by educating patients to actively manage their condition, e.g. regularly taking preventative medicines and making lifestyle changes when appropriate, they can reduce this risk.

Gout is a long-term disease caused by deposits of urate crystals. These crystals are still present in the joint after a flare has settled. The crystals will only dissolve if the urate level in the blood is kept low (< 0.36 mmol/L) by regular use of medicines such as allopurinol.[8]

In the long-term, allopurinol can stop flares from happening. If patients regularly use urate-lowering treatment and serum urate levels are treated to target, flares of gout will be virtually eliminated for many patients within two years.[18]

Allopurinol is a safe and highly effective medicine. Urate-lowering medicines such as allopurinol are associated with an increased risk of flares in the first months of treatment and this may discourage some patients to take them, even if they have collected the prescription from the pharmacist.[2] Patients can be reassured that with prophylactic medicines and appropriate dose titration, the risk of allopurinol causing a flare will be substantially reduced and ongoing use will prevent future flares.

Patient resources for gout, including Samoan and Tongan language versions, are available from: **www.goodfellowunit.org/gout-study-project/gout-study-project**

Diagnose gout, manage the flare and talk about long-term treatment

In primary care, gout is usually diagnosed clinically with supporting evidence provided by elevated serum urate levels; see "Diagnosing gout" for an example of a validated diagnosis tool and alternative diagnoses to consider.[2]

Caution is required when interpreting serum urate levels during a gout flare as up to 40% of patients are reported to have serum urate levels within the normal range;[19] repeat testing for diagnostic purposes may be required once the flare has subsided.[2] Although the gold standard for diagnosing gout is the presence of monosodium urate crystals under polarised microscopy,[2] joint aspiration is usually not necessary unless there is a high suspicion of another cause, e.g. septic arthritis.

Best practice tip: Request a renal function test at the same time as the serum urate to allow for the prompt initiation of urate-lowering treatment, should a diagnosis of gout be confirmed.

Medicines for gout flares are determined by the patient's characteristics

Patients with gout often initially present due to a flare, which will be the treatment priority. Rest and elevation of the affected joint should be encouraged during the gout flare, and some patients may find the use of an ice pack beneficial.[4] Lifestyle changes to avoid obvious triggers, limit purine and fructose/sucrose intake, and reduce weight are important, but alone are insufficient for the management of gout.[2]

Rongoā rākau does not interfere with conventional gout treatments

Rongoā rākau (traditional plant remedies with healing properties) may be used by some Māori patients to treat flares of gout.[13] This may be in the form of a poultice or plant material added to bathwater. Urate-lowering medicines can be used safely in combination with Rongoā rākau and should not be discouraged. Positive discussions about traditional medicines are helpful as they break down barriers with patients and allow prescribers to assess if any interactions with conventional medicines are likely.

Diagnosing gout

Table 1 provides an example of a scoring system to assess the likelihood of gout, which can support a clinical diagnosis. A score of eight or more is associated with a greater than 80% likelihood of gout.[2] A score of four or less rules out gout in almost 100% of patients and an alternative diagnosis should be considered.[2]

Table 1: Clinical score for the diagnosis of gout, adapted from Janssens *et al.* (2010)

Feature	Clinical score
Serum urate > 0.35 mmol/L	3.5
Metatarsophalangeal joint involvement	2.5
Male sex	2
Previous reported flare	2
Hypertension or ≥ 1 cardiovascular disease*	1.5
Joint erythema	1
Onset within one day	0.5
Score	**Maximum 13**

* Angina, myocardial infarction, heart failure, cerebrovascular event, transient ischaemic attack or peripheral vascular disease

Septic arthritis should be considered in patients with monoarticular joint pain, with erythema, warmth and joint immobility; systemic symptoms may also be present.[20] Often the patient will have an underlying condition affecting the joint, e.g. osteoarthritis, and concurrent treatment with an immunosuppressive medicine increases the likelihood of infection.[20] The knee is most often affected by septic arthritis, followed by the hip, shoulder, ankle and wrist.[20] Patients with septic arthritis will often have an elevated serum white blood cell count and C-reactive protein levels may also be raised.[20]

Acute calcium pyrophosphate crystal arthritis, also known as calcium pyrophosphate deposition (CPPD) disease, and previously known as pseudogout, is an arthritis caused by the accumulation of calcium pyrophosphate crystals.[21] Acute calcium pyrophosphate crystal arthritis has a prevalence of 4 – 7% in European populations;[21] the prevalence among Māori and Pacific peoples is unknown. Previous joint damage is a strong risk factor for calcium pyrophosphate crystal arthritis and it becomes more likely if the first onset of symptoms occurs later in life as it is rare in patients aged under 60 years.[21] Patients with calcium pyrophosphate crystal arthritis often have systemic symptoms, including fever and chills, and elevated inflammatory markers, which can make it difficult to distinguish from infection.[21] Where there is clinical uncertainty, calcium pyrophosphate crystal arthritis can be differentiated from gout and septic arthritis by requesting laboratory analysis of aspirated joint fluid.[21] Radiography can also be used to support a diagnosis of acute calcium pyrophosphate crystal arthritis in joints that are unable to be aspirated.[21] Unlike gout, calcium pyrophosphate-lowering medicines do not exist and treatment is focused on symptom relief.

Further information on diagnosing and managing calcium pyrophosphate crystal arthritis is available from: **https://bpac.org.nz/bpj/2013/october/cppd.aspx**

A NSAID, corticosteroids or colchicine may be prescribed to treat gout flares

There are several options that can be used for the acute treatment of gout flares, depending on specific patient characteristics (Table 2). There is insufficient evidence to directly compare the efficacy of medicines for the treatment of gout flares.[3] Medicine selection is therefore based on the patient's preference, renal function, the presence of co-morbidities, e.g. prednisone may be preferred over a NSAID or colchicine in a patient with reduced renal function, and the concurrent use of medicines that may interact with colchicine (see: "Particular care is required with colchicine"). If a patient is experiencing severe flares of gout, e.g. involving multiple joints, it may be appropriate to prescribe combination treatment, e.g. a NSAID with colchicine or corticosteroids with colchicine.[23]

Once treatment for the acute flare has been completed, flare prophylaxis can be started or resumed if appropriate (for further information on flare prophylaxis, see: "Part 2: Controlling gout with long-term medicines" available from: **bpac.org.nz/2021gout-part2.aspx**).

N.B. The initiation of urate-lowering treatment can also be considered during an acute flare in some patients, see: "Talk about urate-lowering treatment before the patient leaves".

Provide a "pill in the pocket" for managing future flares

Patients with gout require ready access to medicines for managing flares until they achieve long-term symptom control with urate-lowering treatment.[2] It is often necessary to prescribe an extra quantity of medicine for this purpose; emphasise to patients that they should stop taking the medicine when the flare has settled, unlike urate-lowering treatment which should be taken every day. Medicines should be stored in a secure and safe location at work and at home. Special care should be taken with colchicine as relatively small overdoses can be fatal. Patients should take medicines promptly for acute flares and those taking colchicine should do so within 12 hours of flare onset.[3]

Talk about urate-lowering treatment before the patient leaves

Urate-lowering treatment should be discussed with all patients with gout once a diagnosis has been established.[3] This includes patients who are currently experiencing a gout flare, as they should be provided with the opportunity to manage their gout immediately, and some may not return for a follow-up consultation once the pain of the flare has resolved. The discussion should also cover the importance of titrating the dose of urate-lowering treatment over time for it to be effective.

Urate lowering medicines are not indicated for the treatment of asymptomatic hyperuricaemia.[4]

Aim to initiate urate-lowering treatment early

Patients with symptomatic hyperuricaemia and any of the following should start urate-lowering treatment:[3, 4, 6]

- Two or more flares per year (this includes any flares the patient did not seek medical evaluation for)
- Tophi or erosions on X-ray
- Renal impairment (eGFR < 60 mL/min/1.73 m^2)

Table 2: Treatment options for an acute gout flare.[22]

Medicine	Dose	Additional notes
Naproxen	750 mg initially, 500 mg eight hours later, then 250 mg every eight hours until the flare has settled	Avoid if eGFR < 30 mL/min/1.73m^2
Prednisone	20 – 40 mg, once daily, for five days	Tapering the dose over 10 – 14 days can reduce the likelihood of a rebound flare, but tapering is not always necessary
Colchicine	Low dose regimen: 1 mg immediately, followed by 500 micrograms after one hour; maximum dose of 1.5 mg over a one-hour period. If eGFR 10 – 50 mL/min/1.73m^2, reduce the initial dose by half (i.e. 500 micrograms); do not exceed 1.5 mg over three days.	Do not repeat acute course within three days. Do not commence prophylaxis (very low dose colchicine) until 12 hours or more after the acute dose is taken. Colchicine should ideally be avoided, or used with caution, in frail patients, those who weigh < 50 kg, or patients with hepatic or renal impairment (eGFR 10 – 50 mL/min/1.73m^2). Colchicine is contraindicated in patients with an eGFR < 10 mL/min/1.73m^2.
Corticosteroid (triamcinolone acetonide)	Intra-articular injection, 2.5 – 40 mg	Dose determined by the size of the affected joint

- Past urolithiasis
- Serum urate level ≥ 0.54 mmol/L

A randomised controlled trial has demonstrated that urate-lowering treatment in patients with early gout (with one or two prior flares) resulted in reduced incidence of gout flares and improved MRI-determined synovitis.[24] Patients who are initiated on urate-lowering treatment are less likely to require treatment for gout flares and are therefore less likely to experience adverse effects from repeated exposure to NSAIDs.

Initiation of urate-lowering treatment can be considered during a flare for some patients, but caution is required

The optimal timing of urate-lowering treatment initiation is still debated.[25] Traditionally, initiation of urate-lowering treatment has been delayed until the pain of a flare has resolved. The rationale being that dispersion of urate crystals during the initiation phase of treatment may make the patient's pain worse. There is now some limited evidence which suggests that initiating a urate-lowering treatment during a flare may have no significant impact on the duration of the flare or on its severity for some patients.[4, 25, 26] As a result, the 2020 American College of Rheumatology (ACR) now conditionally recommend starting treatment during a flare rather than waiting for it to resolve. However, the two randomised controlled trials (RCT) used to justify this recommendation had very small cohorts, alongside strict exclusion criteria and medicine regimens that do not reflect how gout is usually managed in a New Zealand.[25] A third open-label RCT published in 2021 also found that early allopurinol treatment did not significantly worsen or prolong acute flares, however, the study population had considerably different baseline characteristics to people affected by gout in New Zealand.[26] While this strategy may be acceptable for some patients with early stage gout – particularly if they express a preference for starting long-term prevention as early as possible – further evidence is required before it can be conclusively recommended for all patient groups.

Best practice tip: If a decision is made to initiate allopurinol during a flare, start at a low dose and ensure that the patient understands that they need to continue allopurinol after the flare has resolved, even when other medicines for treating the flare are ceased. Medicines used for the treatment of gout flares can be continued at lower doses for flare prophylaxis. In patients for whom urate-lowering treatment is indicated but allopurinol is not immediately initiated, ensure that either a prescription is written for them to pick up once the flare resolves, or that a follow-up appointment is scheduled.

Regular use is the key to long-term management

Explain to patients that the use of urate-lowering medicines needs to be regular and life-long to prevent flares of gout

Particular care is required with colchicine

Colchicine has a narrow therapeutic index meaning that the range between therapeutic and toxic effects is small and can overlap. Serious adverse effects associated with colchicine include paralytic ileus, myopathy, myocardial toxicity and blood dyscrasias. Colchicine is contraindicated in patients with significant gastrointestinal or cardiac conditions or pre-existing blood dyscrasias.[22] The adverse effects of colchicine may also be exacerbated by medicine interactions.[22] Caution is advised when prescribing colchicine to patients who are taking medicines that inhibit the CYP3A4 enzyme and/or P-glycoprotein, e.g. erythromycin, clarithromycin and verapamil.[22] There have also been reports of myopathy and rhabdomyolysis in patients taking colchicine with statins.[22] Colchicine is very toxic in overdose and there is no reversal agent; deaths have occurred with accidental overdose as low as 6 – 7 mg.

Prescribe the lowest effective dose of colchicine for the patient, and provide clear instructions on how and when to take it.[4] Patients should be advised to stop taking colchicine and seek medical attention if they experience nausea, vomiting, diarrhoea or abdominal pain.[22]

If the patient is taking very low dose colchicine for flare prophylaxis, this must be stopped during low dose colchicine treatment for an acute flare.

Further information is available from: **https://bpac.org.nz/bpj/2014/september/safer-prescribing.aspx**

The NZF interactions checker provides details on medicine interactions and their clinical significance, available from: **www.nzf.org.nz**

from returning. If initiation of urate-lowering treatment has been delayed until after a flare has been resolved, ensure that patients know that they should usually continue urate-lowering treatment during any future flares (assuming they have been adherent to allopurinol in the weeks and months leading up to the event). If urate-lowering treatment is stopped, even after years of being symptom-free, most patients will eventually experience a return of flares.[3]

Keep reading: "Part 2: Controlling gout with long-term medicines" available from: **bpac.org.nz/2021gout-part2.aspx**

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References

1. Health Quality & Safety Commission New Zealand. Gout. 2021. Available from: https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/gout (Accessed Jul, 2021).
2. Dalbeth N, Choi HK, Joosten LAB, et al. Gout. Nat Rev Dis Primers 2019;5:69. doi:10.1038/s41572-019-0115-y
3. Pillinger MH, Mandell BF. Therapeutic approaches in the treatment of gout. Seminars in Arthritis and Rheumatism 2020;50:S24–30. doi:10.1016/j.semarthrit.2020.04.010
4. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Rheumatol 2020;72:879–95. doi:10.1002/art.41247
5. Butler F, Alghubayshi A, Roman Y. The Epidemiology and Genetics of Hyperuricemia and Gout across Major Racial Groups: A Literature Review and Population Genetics Secondary Database Analysis. JPM 2021;11:231. doi:10.3390/jpm11030231
6. Hui M, Carr A, Cameron S, et al. The British Society for Rheumatology Guideline for the Management of Gout. Rheumatology 2017;56:1246. doi:10.1093/rheumatology/kex250
7. Winnard D, Wright C, Jackson G, et al. Gout, diabetes and cardiovascular disease in the Aotearoa New Zealand adult population: co-prevalence and implications for clinical practice. N Z Med J 2012;126:53–64.
8. Gill I, Dalbeth N, 'Ofanoa M, et al. Interventions to improve uptake of urate-lowering therapy in patients with gout: a systematic review. BJGP Open 2020;4:bjgpopen20X101051. doi:10.3399/bjgpopen20X101051
9. Su X, Xu B, Yan B, et al. Effects of uric acid-lowering therapy in patients with chronic kidney disease: A meta-analysis. PLoS ONE 2017;12:e0187550. doi:10.1371/journal.pone.0187550
10. Yen F-S, Hsu C-C, Li H-L, et al. Urate-Lowering Therapy May Prevent the Development of Coronary Artery Disease in Patients With Gout. Front Med 2020;7:63. doi:10.3389/fmed.2020.00063
11. Dalbeth N, Dowell T, Gerard C, et al. Gout in Aotearoa New Zealand: the equity crisis continues in plain sight. New Zealand Medical Journal 2018;131:8–12.
12. Ministry of Health. Pharmaceutical Claims Collection. 2021.
13. Te Karu L, Bryant L, Elley CR. Maori experiences and perceptions of gout and its treatment: a kaupapa Maori qualitative study. J Prim Health Care 2013;5:214–22.
14. Jeyaruban A, Larkins S, Soden M. Management of gout in general practice--a systematic review. Clin Rheumatol 2015;34:9–16. doi:10.1007/s10067-014-2783-z
15. Humphrey C, Hulme R, Dalbeth N, et al. A qualitative study to explore health professionals' experience of treating gout: understanding perceived barriers to effective gout management. J Prim Health Care 2016;8:149–56. doi:10.1071/HC15017
16. Dalbeth N, Reid S, Stamp LK, et al. Making the right thing the easy thing to do: strategies to improve outcomes in gout. The Lancet Rheumatology 2019;1:e122–31. doi:10.1016/S2665-9913(19)30004-9
17. Major TJ, Topless RK, Dalbeth N, et al. Evaluation of the diet wide contribution to serum urate levels: meta-analysis of population based cohorts. BMJ 2018;:k3951. doi:10.1136/bmj.k3951
18. Perez-Ruiz F. Treating to target: a strategy to cure gout. Rheumatology 2009;48 Suppl 2:ii9–14. doi:10.1093/rheumatology/kep087
19. Dalbeth N, Winnard D, Gow PJ, et al. Urate testing in gout: why, when and how. N Z Med J 2015;128:65–8.
20. Momodu I, Savaliya V. Septic arthritis. In: StatPearls [Internet]. StatPearls Publishing 2021. Available from: https://www.ncbi.nlm.nih.gov/books/NBK538176/ (Accessed Jul, 2021).
21. Rosenthal AK, Ryan LM. Calcium Pyrophosphate Deposition Disease. N Engl J Med 2016;374:2575–84. doi:10.1056/NEJMra1511117
22. New Zealand Formulary (NZF). NZF v109. Available from: www.nzf.org.nz (Accessed Jul, 2021).
23. Golenbiewski J, Keenan RT. Moving the Needle: Improving the Care of the Gout Patient. Rheumatol Ther 2019;6:179–93. doi:10.1007/s40744-019-0147-5
24. Dalbeth N, Saag KG, Palmer WE, et al. Effects of Febuxostat in Early Gout: A Randomized, Double-Blind, Placebo-Controlled Study. Arthritis Rheumatol 2017;69:2386–95. doi:10.1002/art.40233
25. Pascart T, Lioté F. Gout: state of the art after a decade of developments. Rheumatology 2019;58:27–44. http://dx.doi.org/10.1093/rheumatology/key002
26. Satpanich P, Pongsittisak W, Manavathongchai S. Clin Rheumatol 2021; [Epub ahead of print]. doi:10.1007/s10067-021-05872-8.

This article is available online at:
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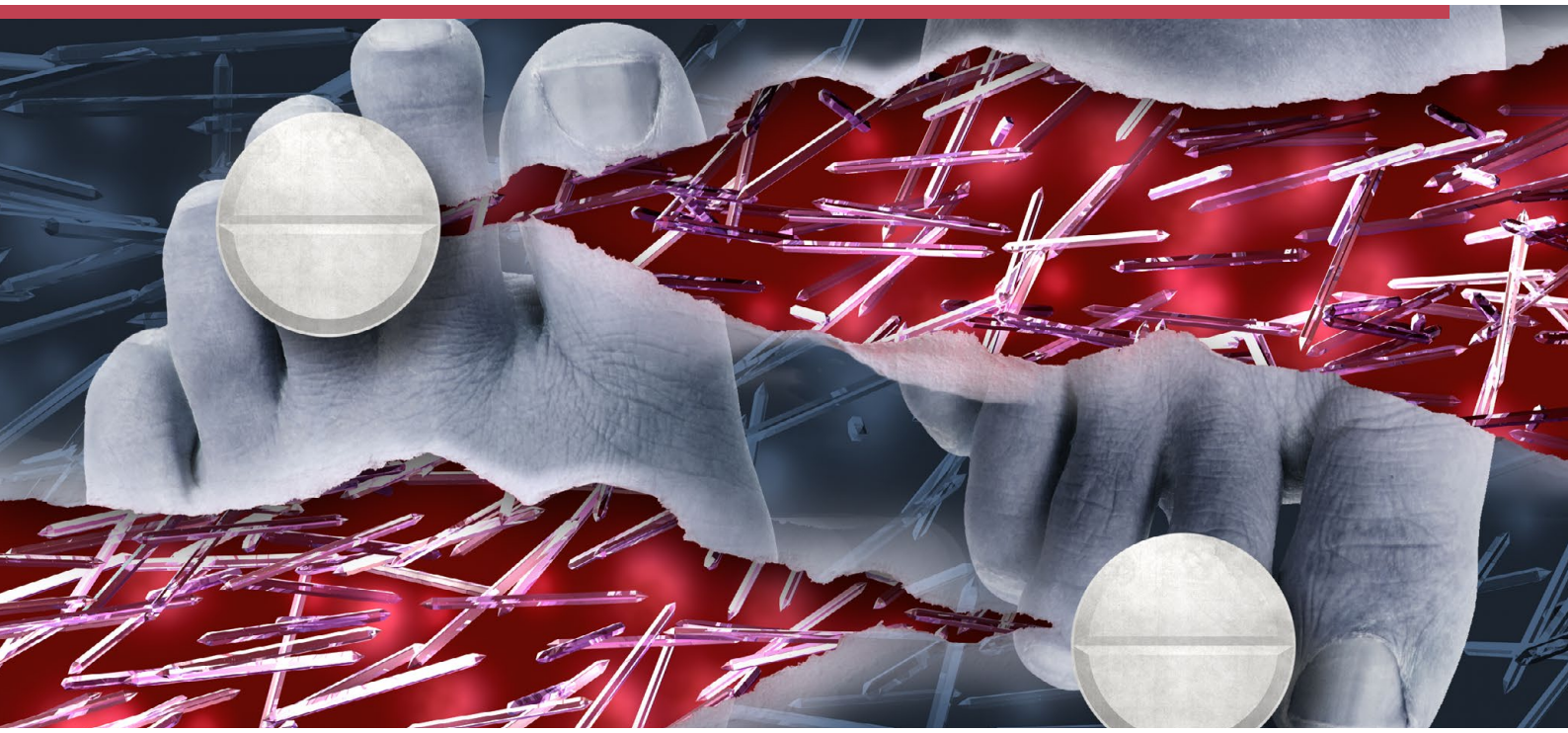

Managing gout in primary care

Part 2 – Controlling gout with long-term urate-lowering treatment

Urate-lowering medicines should be considered and discussed with patients with gout from the first presentation. Doses of urate-lowering medicines need to be titrated to effect so that patients consistently have serum urate levels that are below target. Three urate-lowering medicines are available in New Zealand and patients who are unable to achieve treatment targets with allopurinol alone should be offered an alternative regimen.

KEY PRACTICE POINTS:

- Doses of urate-lowering medicines need to be titrated so that the patient achieves a serum urate level that is below 0.36 mmol/L; a target below 0.30 mmol/L is recommended for those with features of severe disease, e.g. tophi
- Allopurinol is the recommended first-line urate lowering medicine; renal function is used to determine the starting dose
- Probenecid and febuxostat are available for patients who find allopurinol ineffective or intolerable
- Patients with gout require ongoing management of cardiovascular risk and monitoring for associated co-morbidities, e.g. chronic kidney disease and diabetes; they should also be provided with adequate support to ensure regular medicine use

For further information about managing patients with gout, including treating flares, see: "Part 1: Talking about gout: time for a rethink" available from: **bpac.org.nz/2021/gout-part1.aspx**

This is a revision of a previously published article. What's new for this update:

- Changes to urate-lowering medicines: general article revision
  - **Benzbromarone is to be discontinued.** Most people taking benzbromarone will have now switched to a different treatment and no new patients should be started on benzbromarone. Any patients remaining on benzbromarone should be changed to a different urate-lowering medicine as soon as possible.
  - Special Authority criteria has been amended for febuxostat; febuxostat is now funded for people with previous Special Authority approval for benzbromarone

Serum urate levels are treated to target

The goal of urate-lowering treatment is to reduce serum urate levels below saturation point in order to dissolve urate crystals, thereby preventing future gout flares.[1]

The recommended serum urate levels are:[2–4]

- < 0.36 mmol/L for most patients
- < 0.30 mmol/L for patients with severe gout, e.g. those with tophi, chronic gouty arthritis or frequent flares

After several years of symptom-free treatment and resolution of tophi, patients treated to < 0.30 mmol/L can be switched to the less stringent target of < 0.36 mmol/L.[1]

Testing of serum urate levels is recommended prior to dose adjustment, e.g. initially every four weeks, while urate-lowering treatment is being titrated and then every six to 12 months for monitoring.[4] During a flare, serum urate levels should not be tested for the purposes of monitoring the patient's response to treatment as their serum urate levels may be lower than normal.[5, 6]

Blister packs simplify treatment for patients and encourage adherence

Multiple medicines are often required for the initial treatment of gout, including acute flare management and prophylaxis, and increasing doses of allopurinol or another urate-lowering medicine. This requires careful instruction to ensure that the patient takes the right dose of the right medicine at the right time. A potential solution for some patients is to have medicines dispensed in a blister pack. In many cases, pharmacies will charge patients for this service, but some PHOs may fund this – check with your local PHO.

Table 1: Treatment options for flare prophylaxis.[1, 7, 8]

Medicine	Dose	Additional notes
Naproxen	250 mg, twice daily	Consider concurrent use of a proton pump inhibitor Avoid if eGFR < 30 mL/min/1.73m^2
Colchicine (unapproved indication)	Very low dose regimen: 500 micrograms, twice daily Reduce dose if required (see notes)	Reduce dose to 500 micrograms, once daily, or on alternate days, if not tolerated, e.g. diarrhoea develops, chronic kidney disease or concurrent use of CYP3A4/P-glycoprotein inhibitors (e.g. erythromycin, verapamil) Ideally avoid, or use with caution, in frail patients, those who weigh < 50 kg, or patients with hepatic or renal impairment (eGFR 10–50 mL/min/1.73m^2) Contraindicated if eGFR <10 mL/min/1.73m^2
Prednisone	5 mg, once daily	Second-line option if contraindications to NSAIDs or colchicine Taper slowly on withdrawal Monitor for corticosteroid-related adverse effects

Best practice tip: If the patient is receiving treatment for a gout flare with a NSAID or colchicine, continue the same medicine at a lower dose for prophylaxis once the flare has resolved. If a flare occurs during prophylactic treatment, stop the prophylactic dose and change to a regimen for acute treatment of a flare (for further information, see: "Medicines for gout flares are determined by the patient's characteristics" in Part 1 available from: **bpac.org.nz/2021gout-part1.aspx**).

Flare prophylaxis is recommended when initiating urate-lowering treatment

During the first months of urate-lowering treatment the rapid decline in serum urate is thought to disrupt pre-formed monosodium urate crystals making them more likely to provoke a local inflammatory response which can result in an acute flare of gout.[7]

Prophylactic treatment (Table 1) should generally be provided for at least the first six months alongside urate-lowering treatment. However, new guidance suggests that three to six months might be sufficient for some people, e.g. those who are symptom free at their three-month review after initiating urate-lowering treatment and have had a substantial drop in serum urate levels.[2] Prophylactic treatment may be required for longer than six months in people with frequent ongoing flares or tophi, e.g. 12 months or more, but the risks of ongoing treatment (i.e. adverse effects of NSAIDs or colchicine) needs to be weighed up with the potential benefits.[2] Further emphasis on optimising urate-lowering treatment and modifiable factors may be required.

Gradual dose titration also reduces the risk of flares, compared to starting full doses of urate-lowering treatment. The increased risk of flares during initiation of urate-lowering treatment should be discussed with patients and advice given to persist with urate-lowering treatment if a flare does occur.

Allopurinol is the first-line urate-lowering medicine

Allopurinol is a xanthine oxidase inhibitor that decreases the production of urate by inhibiting the metabolism of purines; it is the first-line urate-lowering medicine for patients with gout.[2, 9]

The starting dose of allopurinol is determined by the patient's renal function

Allopurinol is started at a low dose and slowly titrated upwards, to minimise the occurrence of adverse effects, until the patient reaches the target serum urate level (Table 2).[2] Allopurinol can be safely used in patients who have reduced renal function, with a lower starting dose and slower titration. Dose reductions are not routinely required in patients with declining renal function who are already established on allopurinol.

Dose titration is essential to achieve serum urate targets

Once allopurinol has been initiated, regular follow-up with serum urate testing is required while the dose of allopurinol is titrated upwards, until the serum urate target is reached. In patients without renal dysfunction, 30 – 50% will require a dose of allopurinol in excess of 300 mg per day to achieve a serum urate target.[3] Treatment with up to 600 – 800 mg per day of allopurinol can be expected to achieve a serum urate target in 75 – 80% of patients with gout.[3]

Other urate-lowering medicines (see below) are available for patients who are unable to tolerate allopurinol or achieve the serum urate target with allopurinol alone. However, some patients who continue to have serum urate levels slightly above target despite their maximum tolerated dose of allopurinol may choose to persist with allopurinol alone, rather than taking an additional medicine, if flares are controlled.

Community pharmacists may have an increasing role in the titration of allopurinol dosing with the use of standing orders provided by general practitioners, e.g. in the Owning My Gout and Gout Stop initiatives, see: **https://www.arthritis.org.nz/wp-content/uploads/2020/07/Gout-Programmes-Evaluation-Report-April-2020.pdf** for further information.

Table 2: Suggested starting doses and dose titrations for allopurinol determined by renal function.[8]

Estimated glomerular filtration (eGFR) mL/min/1.73m^2	Initial dose of allopurinol	Dose increase
> 60	100 mg, daily	Increase by 100 mg, every four weeks*, if tolerated, until the serum urate target is reached, or to a maximum of 900 mg, daily
30 – 60	50 mg, daily	50 mg, every four weeks, if tolerated, until the serum urate target is reached, or to a maximum of 900 mg, daily†
< 30	50 mg, every second day	

* Some prescribers prefer a more rapid titration, e.g. every two weeks, although this needs to be balanced against the increased risk of adverse effects

† Many people with renal dysfunction will be unable to tolerate the maximum dose of allopurinol; consider referral to or discussion with a rheumatologist if serum urate targets are unable to be achieved and an increase in dose is not tolerated, e.g. over 300 mg allopurinol daily

Adverse effects of allopurinol are relatively uncommon

Allopurinol is generally well-tolerated, although some patients will experience gastrointestinal symptoms.[1, 8] Hypersensitivity reactions caused by allopurinol can occur, e.g. drug rash with eosinophilia and systemic symptoms (DRESS) and Steven-Johnson syndrome. DRESS is a rare, but potentially fatal, condition characterised by an erythematous, desquamating rash, fever, eosinophilia, leukocytosis, hepatitis and renal failure.[4, 8, 10] DRESS is estimated to occur in 0.1% of patients taking allopurinol, most often in the first few weeks to months of initiating treatment.[4, 10] The risk of DRESS can be substantially reduced by introducing allopurinol at a low dose and slowly titrating upwards after tolerance has been established.[10] Patients should stop taking allopurinol and seek medical advice if they develop a rash or itch; an alternative urate-lowering medicine can be trialled. Risk factors for DRESS in patients taking allopurinol include renal impairment, an elevated starting dose of allopurinol relative to renal function, the use of diuretics, and having the *HLA-B*5801* allele which is often present in people of Korean, Thai or Han Chinese descent.[2, 4, 8, 10] Genetic testing for this allele is available; it is recommended to discuss testing with a local laboratory or with Genetic Health Service NZ, **www.geneticehealthservice.org.nz**

Add probenecid if serum urate targets are not achieved with allopurinol alone

Probenecid can be added to allopurinol if despite taking a relatively high dose of allopurinol, e.g. 600 mg daily, the patient is unable to achieve the serum urate target; assess for regular use of allopurinol first.[3] Probenecid can also be prescribed as monotherapy to patients who are intolerant or resistant to allopurinol.[9]

Probenecid dosing is titrated according to the patient's serum urate concentration:[8]

- Initially, 250 mg, twice daily, for one week, then 500 mg, twice daily, with the dose increased by 500 mg every four weeks, to a total of 1 g, twice daily, if required

Probenecid should be avoided in patients with an eGFR < 30 mL/min/1.73m^2.[8] Probenecid is contraindicated in patients with urolithiasis.[2, 9] Patients should be advised to drink plenty of fluids, at least two litres per day, to prevent the formation of uric acid stones and to take the medicine with, or just after, a meal.[8, 9] The most common adverse effects associated with probenecid are nausea and vomiting.[8]

Febuxostat is a further option for urate-lowering

If treatment with allopurinol and/or probenecid is ineffective or cannot be tolerated, febuxostat is a second-line xanthine oxidase inhibitor.[2, 4]

The recommended dose of febuxostat for patients with gout is:[8]

- 80 mg, once daily, increased to 120 mg*, once daily, after two to four weeks if the serum urate is > 0.36 mmol/L

* The maximum daily dose of febuxostat for patients with mild hepatic impairment is 80 mg

Special Authority for febuxostat has changed

The Special Authority criteria for febuxostat has been amended amid plans to discontinue benzbromarone (see: "Benzbromarone to be discontinued"). Febuxostat is now funded with Special Authority approval in New Zealand for patients with gout who:[8]

- Have a serum urate level > 0.36 mmol/L after having been treated with allopurinol at doses of at least 600 mg per day in addition to probenecid at doses up to 2 g per day or to a maximum tolerated dose; or
- Have intolerable adverse effects associated with allopurinol treatment requiring treatment discontinuation and have trialled probenecid at doses up to 2 g per day or to a maximum tolerated dose; or
- Have had treatment with allopurinol optimised, however, renal impairment means that probenecid cannot be added or is that it is likely to be ineffective; or
- Have had previous Special Authority approval for benzbromarone for the treatment of gout

Key prescribing points for febuxostat

Renal impairment. Febuxostat can be used in patients with renal dysfunction as this is not a significant route of elimination, however, caution is advised in patients with an eGFR < 30 mL/min/1.73m^2 due to a lack of safety data; although, as probenecid should be avoided in patients with an eGFR < 30 mL/min/1.73m^2, febuxostat is the recommended choice in this patient group (if allopurinol is not tolerated or adequate).[1, 8]

Hepatic impairment. Febuxostat should be avoided in patients with moderate or severe hepatic impairment as limited dosing information is available. Patients with mild hepatic impairment should not exceed a daily dose of 80 mg.[8] A liver function test is recommended prior to initiating febuxostat to provide a baseline as abnormal liver function tests have been observed in approximately 5% of patients taking febuxostat; liver function tests are recommended periodically thereafter based on clinical judgement.[8]

Cardiovascular disease risk. Caution is advised when considering prescribing febuxostat to patients with a history of CVD, however, this is not a contraindication.[2, 8] Some studies have suggested that febuxostat use is associated with an increased risk of CVD and all-cause mortality compared with

allopurinol.[2] The United States Food and Drug Administration (FDA) therefore updated prescribing information with a boxed warning in 2019, advising that clinicians should discuss the elevated cardiovascular risk with their patients and inform them about important symptoms to look out for, e.g. shortness of breath, chest pain.[11] More recent studies, however, have not found an increase in the risk of all-cause mortality associated with febuxostat compared with allopurinol, and one study even demonstrated a lower risk.[2, 12] Clinicians should ensure patients are aware of the evidence around CVD risk and febuxostat use as part of a shared decision making discussion.[2]

Combination treatment. Probenecid can be added to the treatment regimen if the patient is unable to achieve the target serum urate level with febuxostat alone, however, this combination is associated with a much more rapid decline in serum urate and can trigger flares in some people; prophylactic management with either a NSAID or colchicine is essential when using it for at least the first six months.[1, 7]

The adverse effects of febuxostat

Adverse effects most often associated with febuxostat are diarrhoea, nausea, elevated liver enzymes, oedema, headache and rash.[8] Rarely, hepatotoxicity or severe hypersensitivity reactions can occur in patients taking febuxostat.[8] Hypersensitivity reactions most often occur in the first weeks of treatment, including Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria and anaphylaxis.[8]

There is an increased risk of flares in patients taking febuxostat, compared to allopurinol, therefore flare prophylaxis is particularly important in the first months of treatment.[1]

Benzbromarone to be discontinued

Benzbromarone has not been included as a treatment option for long-term gout prophylaxis in this article as it is set to be delisted from the Pharmaceutical Schedule.*[13] Most people taking benzbromarone will have now switched to a different treatment and no new patients should be started on benzbromarone. Any patients remaining on benzbromarone should be changed to a different urate-lowering medicine as soon as possible.[13] The amendment of the Special Authority for febuxostat now allows patients who were taking benzbromarone to access funded febuxostat treatment.[13]

* As of July, 2021, there is no date set for delisting – for up to date information, visit the **PHARMAC website**

Supporting patients taking urate-lowering medicines[1]

- Acknowledge that taking a medicine every day for gout can be challenging. Regularly ask the patient how they are coping with this process and continue to encourage on-going use of urate-lowering medicines to prevent gout flares.
- Once the patient achieves their serum urate target, continue to measure serum urate levels at least every six to 12 months and make any necessary adjustments to the treatment regimen if the target level is not maintained. Titrating and identifying the optimal dose of a urate lowering medicine can be challenging, and patients need to be supported and reassured throughout this process.
- Re-iterate that although biological factors (e.g. chronic kidney disease, genetic variation) and some medicines (e.g. diuretics) are important causes of gout, other modifiable factors such as diet can trigger flares. By being aware of these triggers, and taking urate-lowering medicines consistently, future flares can be prevented. In some cases, patients will eventually be able to consume small portions of trigger foods, such as kaimoana (seafood), without experiencing a gout flare.
- Use motivational interviewing to encourage lifestyle changes including weight loss and regular exercise which in turn may help to reduce co-morbid cardiovascular and diabetes risk (see: "Part 1: Talking about gout: time for a rethink" available from: **bpac.org.nz/2021gout-part1.aspx**). Other medicines such as statins and antihypertensives may need to be added, if appropriate.
- Track any changes in clinically relevant biomarkers, e.g. at least an annual assessment of blood pressure, HbA_{1c} and renal function

The appropriate selection and use of cardiovascular medicines

For patients with gout and hypertension, losartan or calcium channel blockers are the antihypertensive medicines of choice as they reportedly have mild uricosuric (urate-excreting) properties.[2] Diuretics are known to reduce urate excretion and therefore contribute to the onset or exacerbation of gout. Patients who are taking diuretics for hypertension, for reasons other than heart failure, should be switched to an alternative antihypertensive, if possible.[2] Aspirin is also known to decrease excretion of uric acid, however, patients who are taking low-dose aspirin for the secondary prevention of cardiovascular disease should continue to do so.[2]

Reducing the risk of kidney stones

Kidney stones occur in one in seven patients with gout and patients taking uricosuric medicines, e.g. probenecid, are at increased risk.[1, 4] Increasing water consumption will decrease the risk of uric acid stone formation for all patients with gout (e.g. aim for ≥ 2L water daily). Treatment with a xanthine oxidase inhibitor, e.g. allopurinol, and a reduction in dietary purines (see: "Part 1: Talking about gout: time for a rethink" available from: **bpac.org.nz/2021gout-part1.aspx**) will also decrease the likelihood of uric acid stones forming.[2]

Further information on managing kidney stones and renal colic is available from: **https://bpac.org.nz/bpj/2014/april/colic.aspx**

When to consider referral to a rheumatologist

Patients should be discussed with or referred to a rheumatologist if they have:

- A serum urate level consistently ≥ 0.36 mmol/L, despite adherence to optimal urate-lowering treatment
- Persistent arthritis, despite a serum urate level that is persistently < 0.36 mmol/L
- Significant renal dysfunction and there are concerns about increasing the dose of urate-lowering treatment

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References

1. Hui M, Carr A, Cameron S, et al. The British Society for Rheumatology Guideline for the Management of Gout. Rheumatology 2017;56:1246. doi:10.1093/rheumatology/kex250
2. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Rheumatol 2020;72:879–95. doi:10.1002/art.41247
3. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. Ann Rheum Dis 2017;76:29–42. doi:10.1136/annrheumdis-2016-209707
4. Golenbiewski J, Keenan RT. Moving the Needle: Improving the Care of the Gout Patient. Rheumatol Ther 2019;6:179–93. doi:10.1007/s40744-019-0147-5
5. Dalbeth N, Winnard D, Gow PJ, et al. Urate testing in gout: why, when and how. N Z Med J 2015;128:65–8.
6. Dalbeth N, Choi HK, Joosten LAB, et al. Gout. Nat Rev Dis Primer 2019;5:69. doi:10.1038/s41572-019-0115-y
7. Burns CM, Wortmann RL. Latest evidence on gout management: what the clinician needs to know. Ther Adv Chronic Dis 2012;3:271–86. doi:10.1177/2040622312462056
8. New Zealand Formulary (NZF). NZF v109. Available from: www.nzf.org.nz (Accessed Jul, 2021).
9. Pillinger MH, Mandell BF. Therapeutic approaches in the treatment of gout. Semin Arthritis Rheum 2020;50:S24–30. doi:10.1016/j.semarthrit.2020.04.010
10. Stamp LK, Barclay ML. How to prevent allopurinol hypersensitivity reactions? Rheumatology 2018;57:i35–41. doi:10.1093/rheumatology/kex422
11. FDA Drug Safety Communication. FDA adds Boxed Warning for increased risk of death with gout medicine Uloric (febuxostat). 2019. Available from: https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-death-gout-medicine-uloric-febuxostat (Accessed Jul, 2021).
12. Choi HK, Neogi T, Stamp LK, et al. Reassessing the Cardiovascular Safety of Febuxostat: Implications of the Febuxostat versus Allopurinol Streamlined Trial. Arthritis Rheumatol 2021;:art.41638. doi:10.1002/art.41638
13. PHARMAC. Benzbromarone: Discontinuation. Available from: https://pharmac.govt.nz/medicine-funding-and-supply/medicine-notices/benzbromarone/ (Accessed Jul, 2021).

This article is available online at:
www.bpac.org.nz/2021gout-part2.aspx

Gout

Clinical editor's note

May 2023: An HRC-funded metro-Auckland clinical trial investigating optimum allopurinol titration strategies to achieve target urate in people with gout is currently underway. Both people who are starting allopurinol and those already on allopurinol with a serum urate level > 0.36 mmol/L may be eligible.

The study will recruit participants over the next 3 years.

See University of Auckland – Easy-Allo study .

Red flags

Septic arthritis suspected in a single, swollen, painful joint

Background

About gout

About gout

Gout is a form of arthritis caused by the deposition of monosodium urate crystals within and around joints, causing acute inflammation and eventual tissue damage.

- Definitive diagnosis is made by demonstration of urate crystals in synovial fluid or tophi.
- In patients with gout, the most common cause of hyperuricaemia is under-excretion of uric acid.
- Genetic variants significantly increase the risk of gout in Māori and Pacific peoples.
- Prevalence is 5.5% of all adults in New Zealand with 13.8% of Māori males and 22.5% of Pacific males. [1]
- Long-term management is based on maintaining the urate level < 0.36 mmol/L.
- Gout is an independent risk factor for cardiovascular disease.
- There is currently no evidence to support urate-lowering therapy in patients with asymptomatic hyperuricaemia.
- If gout remains untreated or incompletely managed with urate-lowering medication, the patient may develop chronic tophaceous gout i.e.:
  - development of tophi.
  - more frequent gout flares.
  - increase in the number of joints affected.
  - gradual worsening of inflammatory arthritis and erosive joint damage.

Assessment

1. History – Ask about:
   - onset – a gout flare typically presents with a single acute swollen tender joint over a 6- to 12-hour period, often associated with fever and malaise.
   - which joints are involved , and timing and severity of pain.

Joints involved

- First metatarsophalangeal (MTP) joint is involved in 50% of all gout flares, and 70% of first flares.
- Other common joints are knee, foot, wrist, ankle, hand, and elbow.

- any previous episodes and their frequency.
- systemic symptoms, including fever and malaise (common).
- treatment, including over the counter (OTC) and self-treatment, and adherence to medications.
- features and signs of chronic tophaceous gout .

> **Chronic tophaceous gout**
>
> Chronic tophaceous gout may develop if recurrent gout remains untreated or incompletely managed with urate-lowering medication. Features include:
>
> - development of tophi .
>
> > **Tophi**
> >
> > - Asymmetric
> > - Yellow-white
> > - Firm
> > - Subcutaneous lesions
> >
> > Common locations for tophi include olecranon, distal interphalangeal joints, and the ear pinnae.
>
> - more frequent gout flares.
> - increase in the number of joints affected.
> - gradual worsening of inflammatory arthritis and erosive joint damage.
> - urate nephropathy.
> - renal calculi.

2. Examination:
   - Take temperature to help exclude septic arthritis, as both can present as a single swollen painful joint over a 6- to 12-hour period:
     - A low-grade fever can occur with gout.
     - Most patients with septic arthritis are febrile, however older patients with septic arthritis may be afebrile.
   - Check joints involved and look for any signs of tophi and chronic joint disease.
3. Investigation – Arrange:
   - serum urate. During an acute gout flare, levels are often normal (in up to 50% of patients) so consider repeating during convalescent phase a few weeks later.
   - renal function if not done within previous 3 months.
   - joint aspiration if there is any doubt about the diagnosis and to rule out septic arthritis (typically a single swollen joint).

> **Septic arthritis**
>
> If septic arthritis is the most likely diagnosis, do not perform joint aspiration. Instead, request acute orthopaedic assessment.

     - Consider joint aspiration for most large joints.
     - Send fluid for cell count, crystals, and Gram stain and culture. Definitive diagnosis of gout by is made by demonstration of urate crystals in synovial fluid or tophi.

   Do not arrange plain radiology in the setting of a gout flare unless inflammation persists for more than 12 weeks.
4. Consider using the acute gout flare diagnosis rule in patients presenting with monoarthritis. It has been developed and validated in primary care.
5. Screen for any other conditions associated with gout , and assess cardiovascular risk if clinically appropriate.

> **Conditions associated with gout**
>
> - Hypertension
> - Cardiovascular disease
> - Renal impairment

- Diabetes
- Obesity
- Hyperlipidaemia

Management

Practice point

Focus on long term serum urate control

For all patients with gout, assess whether to start or optimise the dose of urate-lowering therapy. Long-term control of serum urate with regular and continuous use of urate-lowering therapy is important to suppress gout flares (target < 0.36 mmol/L). Māori and Pacific patients are less likely to receive urate-lowering therapy regularly. Consider involving a community pharmacist or a multidisciplinary team in the care and set an active recall to improve access to continuous urate-lowering therapies, especially in Māori and Pacific patients.

Gout flare treatment

1. Provide anti-inflammatory medications with choice of medications depending on age, renal function, and co-morbidities.

Anti-inflammatory medications

- Consider first-line treatment with one of the following:
  - corticosteroids e.g., prednisone:
    - Give prednisone 20 to 40 mg daily until the episode resolves.
    - Once resolved, reduce the dose over one to two weeks to prevent a rebound flare.
  - nonsteroidal anti-inflammatory drugs (NSAIDs), and consider adding a proton-pump inhibitor. Check contraindications to NSAIDS.

Contraindications to NSAIDs

- Peptic ulcer or active inflammatory disease of the gastrointestinal system
- Previous intolerance to nonsteroidal anti-inflammatory drugs (NSAIDs)
- Chronic kidney disease
- Heart failure

Use with great caution in patients aged > 75 years and the frail elderly.

Nonsteroidal anti-inflammatory drugs (NSAIDs)

Prescribe appropriate NSAIDs e.g., naproxen 500 mg twice daily.

- Use NSAIDs in the lowest effective dose for the shortest period of time.
- Avoid NSAIDs in older adults or if cardiac or renal disease.
- Avoid the "triple whammy" combination of an ACE inhibitor or ARB, diuretic, and NSAID, which may cause increased blood pressure and renal impairment.

- low-dose colchicine, although there are a number of serious contraindications and drug interactions. Overdoses from 7 mg can be fatal. [2] There is no reversal agent. Check contraindications to colchicine.

Contraindications to colchicine

- Combined hepatic and renal disease
- Severe renal impairment (creatinine clearance < 10 mL/min)
- Severe hepatic impairment

- Mild or moderate renal or hepatic impairment taking a P-glycoprotein (P-gp) or strong cytochrome P450 3A4 inhibitor e.g., ciclosporin, clarithromycin, erythromycin, ketoconazole, ritonavir, verapamil, diltiazem, statins
- Serious cardiac or gastrointestinal disorders
- Blood dyscrasias
- Hypersensitivity to colchicine
- Children
- Lactation
- Pregnancy

Colchicine

- Use low-dose regimens as high doses can be fatal. Colchicine has a narrow therapeutic margin and considerable variation in absorption between individuals.
- Use a reduced dose cautiously in older adults or patients with creatinine clearance 10 to 50 mL/min. Contraindicated if creatinine clearance is < 10 mL/min.
- Start within 24 hours of the gout or calcium pyrophosphate disease (CPPD) flare, preferably within 12 hours.
- According to local specialist recommendations:
  - give:
    - 1 mg immediately,
    - 0.5 mg one hour later.
  - if not settled after 12 hours, start colchicine 0.5 mg once to twice daily until settled.
- Advise the patient to stop if they get diarrhoea.

For adverse effects and drug interactions, see colchicine.

- If 1 or 2 joints are affected, consider intra-articular corticosteroids e.g., triamcinolone acetonide (Kenacort-A). If performing intra-articular injection, consider first taking a joint aspiration sample and send it to the laboratory for cell count, crystals, and Gram stain and culture analysis. Seek rheumatology advice if required.

Triamcinolone acetonide

triamcinolone acetonide

- 2.5 to 5 mg for small joints
- 20 to 40 mg for large joints

- If the patient has been taking allopurinol or other urate-lowering therapy regularly without interruptions, advise them to continue their current dose.
- Reconsider diagnosis if the patient is responding poorly to treatment. Consider joint aspiration to confirm diagnosis and exclude coexisting infection if not already performed.

2. If the diagnosis is still unclear after joint aspiration and/or the patient has atypical joint distribution, seek rheumatology advice or request non-acute rheumatology assessment.
3. If acute symptoms persist > 2 weeks with treatment, seek rheumatology advice.
4. Note that some local specialists suggest initiating preventive treatment during an acute gout flare in patients without tophi or renal impairment. If allopurinol is started or restarted during a gout flare, start at a low dose with appropriate ongoing prophylaxis.
5. Arrange follow-up appointment with serum urate testing at 3 weeks.

Preventive treatment

1. Consider indications for urate-lowering therapy as preventive treatment.

Indications for urate-lowering therapy

- Recurrent gout flares (2 or more flares per year)
- Gouty tophi
- Chronic gouty arthritis
- Evidence of damage on X-ray
- Early-onset gout, strong family history, and serum urate greater than 0.6 mmol/L

In patients with asymptomatic hyperuricaemia, there is no evidence to support urate-lowering therapy.

2. Determine target serum urate level i.e., < 0.36 mmol/L, or if tophi are present < 0.30 mmol/L.
3. Start urate-lowering medications using a ⌄ treat-to-target approach using the above target levels.

Treat-to-target approach

- Monitor serum urate monthly until target urate achieved.
- Review and adjust urate-lowering therapy (dose or drug) until target achieved.
- Once at target, measure serum urate every 6 to 12 months.
- Warn patients it can take more than 12 months after reaching their target for gout flares to stop, and years for tophi to dissolve.

- Prescribe ⌄ prophylactic medication to prevent gout flares for 3 to 6 months when starting urate-lowering therapy.

Medication to prevent flares

- NZF Non-steroidal anti-inflammatory drugs (NSAIDs) if appropriate, e.g. ibuprofen orally 800 mg controlled release once daily (maximum twice daily) or naproxen orally 750 mg controlled release once daily (maximum 1 g daily). NSAIDs have multiple side-effects in older people, and people with asthma, gastrointestinal, cardiac, and renal disease.
- NZF Colchicine 0.5 mg daily or twice daily.
  - This is contraindicated in the elderly and those with eGFR less than 50 ml/min/1.73 m^2.
  - Colchicine has a narrow therapeutic margin – check for interactions, and advise the patient to stop if they get diarrhoea.
- NZF Prednisone, e.g. 5 to 10 mg per day.

- Give ⌄ allopurinol as first-line urate-lowering treatment. A gout flare when starting allopurinol does not constitute intolerance or failure. Allopurinol failure is defined as failure to reach target serum urate < 0.36 mmol/L at maximum tolerated dose.

Allopurinol

NZF Allopurinol can be started during a gout flare alongside appropriate gout flare treatment. If allopurinol is started during a gout flare, start at a low dose (see below), and in combination with anti-inflammatory prophylaxis therapy.

- Avoid in combination with azathioprine, as they may interact.
- Adverse effects are uncommon, but be aware of the rare ⌄ severe allopurinol hypersensitivity reaction (DRESS) that can occur, often in the first six weeks from initiating allopurinol, and with a rash.

Severe allopurinol hypersensitivity reaction

- Allopurinol hypersensitivity syndrome, also called DRESS (drug rash with eosinophilia and systemic symptoms) is a rare (0.1% incidence) but potentially fatal adverse effect of allopurinol.
- DRESS is characterised by an erythematous, desquamating rash, fever, eosinophilia, leucocytosis, hepatitis, and renal failure, occurring most often in the first 4 to 6 weeks of treatment.
- Risk of DRESS is substantially reduced by starting allopurinol at a low dose and titrating upwards slowly.
- Warn patients that they must stop allopurinol and seek medical advice if any rash or itch develops. If this occurs, trial alternative urate-lowering medicines.
- Risk factors for DRESS include:

- renal impairment.
- high starting dose of allopurinol relative to renal function.
- diuretics.
- HLA-B*5801 allele (often in people of Korean, Thai, or Chinese descent).

See also bpacnz – Managing Gout in Primary Care: Part 2 – Controlling Gout with Long-term Urate-lowering Treatment .

- Consider ⌄ HLA–B*5801 screening before starting allopurinol in some ⌄ Asian subpopulations .

Asian subpopulations

Consider HLA–B*5801 screening as part of risk management in Asian subpopulations where there is increased frequency of the HLA–B*5801 allele. The HLA–B*5801-positive subpopulations have a very high risk for severe allopurinol hypersensitivity reaction (DRESS) e.g., Koreans (especially those with chronic kidney disease stage 3 or worse), and all those of Han Chinese and Thai descent. [3]

HLA-B*5801 screening

- Genetic testing for the HLA-B*5801 allele is available. Write "HLA-B*5801 allele" on the manual laboratory (lab) form. It is not available on electronic lab request forms yet.
- Collection for HLA-B*5801 testing is done at LabTest. The samples are processed by New Zealand Blood Services.
- Testing costs approximately $232 for non-New Zealand residents.

- Start low and go slowly.
- Warn patients to cease allopurinol if they develop a rash.
- Decide on an appropriate starting dose, based on eGFR:
  - If eGFR < 30 mL/min/1.73m^2, start 50 mg every second day, increasing by 50 mg every four weeks, if tolerated, until target serum urate is reached.
  - If eGFR 30 to 60 mL/min/1.73m^2, start 50 mg daily, increasing by 50 mg every four weeks until the target urate is achieved.
  - If eGFR > 60 mL/min/1.73m^2, start 100 mg daily, increasing by 100 mg every four weeks until the target urate is achieved.
- Aim for a target serum urate of less than 0.36 mmol/L, or, if tophi are present, less than 0.30 mmol/L. Usual maintenance dose is 100 to 600 mg daily. A maintenance dose of 700 to 900 mg daily may be required in severe conditions.
- Start patients with impaired renal function with a lower starting dose (as above). If they do not respond, gradually increase the dose and seek rheumatology advice if any concerns.
- Monitor:
  - serum urate and renal function monthly until the target serum urate is achieved.
  - creatine kinase monthly if the patient is on colchicine prophylaxis.
  - FBC and LFT every 3 months during the dose escalation period.
  - urate every 6 to 12 months once at target, to ensure the target is maintained.
- If serum urate fails to reduce, always check the patient's understanding about their allopurinol.
- If recurrent gout flares occur and the patient is at target urate, reassure the patient that it can take more than 12 months after reaching target for flares to stop.

- If allopurinol is contraindicated, not tolerated, or ineffective, consider alternative urate-lowering medications:
  - ⌄ Probenecid

Probenecid

- Used when there is:
  - a poor response to allopurinol, but is sometimes used in combination.

- allopurinol intolerance.
- normal renal function.

- Contraindicated if renal stones.
- The patient needs to have a high fluid intake (> 2 L a day).
- For full prescribing details, see the NZ Formulary – probenecid.

- Febuxostat

Febuxostat

- Consider febuxostat if allopurinol and probenecid failure, intolerance, or contraindication.
  - Allopurinol failure is defined as failure to reach target serum urate < 0.36 mmol/L or intolerable adverse effects. A flare of gout when starting allopurinol does not constitute intolerance or failure of allopurinol.
  - Febuxostat is available on Special Authority .
- Patients who get a rash or hypersensitivity on allopurinol or have renal disease may have hypersensitivity reactions with febuxostat. These can be serious. Most cases occur during the first month of treatment.
- Use with caution in patients with known coronary vascular disease, significant risk factors for vascular disease, or congestive heart failure. See MedSafe Prescriber Update .
- Avoid in combination with azathioprine, as they may interact.
- Check liver function before starting, after 2 weeks, then monthly. There is a risk of hepatotoxicity (including fatal events) with febuxostat.
- Many of the patients who can tolerate febuxostat have co-morbidities and medications which make prescribing difficult. Consider non-acute rheumatology assessment.

4. Ensure urate-lowering medications are used continuously and regularly to suppress gout flares, particularly for Māori and Pacific patients.
   - Provide patient support to improve access to medications and consider actively recalling the patient 3-monthly for prescription renewals.
   - Consider enrolling the patient in a long-term conditions programme, and involving a multidisciplinary team i.e., nurse, pharmacist, podiatrist, social worker, kaiāwhina, health coach, Arthritis New Zealand.
5. Recommend lifestyle interventions alongside urate-lowering therapy. Most people with gout cannot achieve target serum urate with lifestyle changes alone.

Lifestyle interventions

Advise the patient to:

- maintain a healthy weight.
- eat regular meals, as both fasting and overeating can trigger gout.
- drink 2 L of water per day.
- limit alcohol, if alcohol intake is hazardous.
- reduce sugar and sugar-sweetened drinks.

6. Screen for, and manage, any other conditions associated with gout .
7. Complete a Gout Management Plan .
8. Seek rheumatology advice or request non-acute rheumatology assessment if:
   - intolerance to urate-lowering medications.
   - renal impairment, co-morbidities, and medications which affect the choice of urate-lowering therapies.
9. If failure to respond to urate-lowering medications, check adherence. If good adherence, seek rheumatology advice or request non-acute rheumatology assessment.

Failure to respond

- Recurrent gout flares > 12 months after target urate achieved
- Progressive joint damage

Request

- Seek rheumatology advice or request non-acute rheumatology assessment if:
  - diagnosis is unclear.
  - atypical joint distribution.
  - acute symptoms persist > 2 weeks with treatment.
  - failure to respond to urate-lowering medications despite good adherence with treatment at maximum-tolerated dosing or target urate achieved.
  - intolerance to urate-lowering therapies.
  - renal impairment, co-morbidities, and medications which affect the choice of urate-lowering therapies
  - progressive joint damage despite therapy.
- If septic arthritis is most likely diagnosis, request acute orthopaedic assessment.
- Request non-acute rheumatology assessment if:
  - eGFR < 30 mL/min/1.73m^2.
  - considering febuxostat for patient with complicating co-morbidities or medications.

Information

For health professionals

Further information

- bpacnz:
  - Managing Gout in Primary Care: Part 1 – Talking About Gout: Time for a Re-think
  - Managing Gout in Primary Care: Part 2 – Controlling Gout with Long-term Urate-lowering Treatment
- He Ako Hiringa:
  - EPiC: Gout
  - Meeting the Needs of Māori
- MDCalc – Acute Gout Diagnosis Rule
- Suggested scripts:
  - Consultation with Patient Returning from Acute Gout Attack
  - Patient Being Prescribed Allopurinol for the First Time
  - Consultation with Patient Who is Not Taking or Has Stopped Taking Allopurinol

For patients

- Auckland Region DHBs:
  - Patient Presenting with Acute Gout at GP practice
  - Patient Presenting with Acute Gout at 24 Hour Clinic or Purchasing Anti-inflammatories at Pharmacist
- Healthify He Puna Waiora:
  - Change Your Life:
    - English
    - Samoan
    - Tongan
  - Gout
  - Medicines for Gout

SEND FEEDBACK

SOURCES

References

1. HQSC Atlas of Healthcare Variation:Gout. Wellington: Health Quality & Safety Commission New Zealand; 2020.
2. Safer Prescribing of High-risk Medicines: Colchicine – Extremely Toxic in Overdose. Best Practice Journal. 2014 Sep;63. [Abstract]
3. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care Res (Hoboken). 2020 Jun;72(6):744-60. [Abstract]

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PAGE INFORMATION

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Standing Order for Allopurinol Dose Escalation

Community Pharmacy Gout Management Service

Issued: 19/01/2016	**Updated 4 May 2022**	**Review date: 4 May 2023**
Medicine Standing Order Title	Allopurinol Dose Escalation – Community Pharmacy Gout Management Service	
Rationale	To enable the dose escalation and continuation supply of allopurinol by pharmacists, in the specific circumstances outlined in this standing order, for the optimisation of gout management.	
General Practice		
Pharmacy name		
Scope (the condition and patient group)	Trained NZ registered pharmacists who are participating in the Community Pharmacy Gout Management Service. For dose escalation or continuation supply of allopurinol in the following patients: • Diagnosed with gout • Prescribed allopurinol and a gout flare prevention medication by a Medical Practitioner or Nurse Practitioner • The patient is over 18 years of age • Serum urate level ≥ 0.36mmol/L, or ≥ 0.30mmol/L if patient has tophaceous gout • eGFR is >30 mL/min • No contraindication to allopurinol (i.e. does not meet the exclusion criteria outlined below) • Under the care of a Medical Practitioner or Nurse Practitioner who has provided written consent for their patient to be managed as part of the Community Pharmacy Gout Management Service • The Medical Practitioner or Nurse Practitioner initiating allopurinol will sign off treatment as per standing order – refer to Appendix 1 for example prescription. A new allopurinol prescription will be provided every 3 months or continuation supply for allopurinol may be used if applicable. • Patient has provided written informed consent to being managed as part of the Gout Busters Service.	
Medicine/s	Allopurinol 100 mg and 300 mg tablets	
Route of administration	Oral	
Indications for activating standing order	Patient meets inclusion criteria – refer to scope section above.	

Indication/circumstance for terminating the standing order	The patient will have their serum urate levels tested in the Pharmacy monthly and their allopurinol dose titrated accordingly until they become stable. Stable is defined as a serum urate level below 0.36 mmol/l (or 0.30 mmol/l if they have tophaceous gout) for 3 consecutive visits, with confirmation of a laboratory serum urate test. At this point, the patient is discharged from the monthly service (for continued supervision by the Medical Practitioner or Nurse Practitioner). The patient will then be followed up by the Pharmacy 12 months post-enrolment. If the Service User has an elevated serum urate at that time, the Pharmacist should liaise with the Medical Practitioner or Nurse Practitioner regarding re- enrolling the patient into the service, providing the service contract has continued.
Dosage instructions for allopurinol	**The below dosing instructions are to be used solely for the purpose of pharmacists <u>escalating</u> an allopurinol daily dose in those that have been initiated on allopurinol by a Medical Practitioner or Nurse Practitioner. These dosing instructions are <u>not to be used for the initiation</u> of allopurinol.** If serum urate level ≥ 0.36mmol/L, escalate allopurinol dose until it reaches **target of less than 0.36mmol/L** or **less than 0.30mmol/L for tophaceous gout** (to a maximum daily dose of 600 mg, at which time probenecid would be considered to add to the allopurinol). ○ If eGFR ≥ 60 mL/min - increase the total daily dose of allopurinol by 100 mg approximately monthly ○ If eGFR is 30-60 mL/min - increase the total daily dose of allopurinol by 50 mg approximately monthly • Note: When using the treat to target approach, patients with chronic kidney disease typically require much less allopurinol dose (up to 600mg) to achieve target. Discuss with the Medical or Nurse Practitioner regarding preferred maximum dose of allopurinol for patients with chronic kidney disease. **<u>Further dosing advice:</u>** • If serum urate level is at target (see above), remain on current allopurinol daily dose. • If serum urate level is at target and the patient continues to have gout flares, remain on current allopurinol daily dose and refer patient to the Medical Practitioner or Nurse Practitioner. • If the patient has had a gout flare within the last 3 weeks – remain on current allopurinol daily dose for 3 weeks after the flare has resolved before escalating. • If the patient has not been adherent (missed 7 out of 28 daily doses, or 25% of doses), remain on current allopurinol daily dose until next test. In some cases, if the patient is on a high allopurinol dose (e.g. >300 mg daily) or if they have not taken allopurinol for the last five days, you may need to restart dose escalation to avoid a flare - discuss with Medical or Nurse Practitioner. • If serum urate level remains unchanged or increases after 8 weeks of allopurinol and the patient has been adherent, remain on current allopurinol daily dose and refer to the Medical Practitioner or Nurse Practitioner. *Notes:* • An eGFR or serum creatinine (used to calculate eGFR) must be obtained within 3 months of the date of an allopurinol prescription***. If eGFR/serum creatinine is not available, do not escalate an allopurinol dose under this standing order. Pharmacist to coordinate with the practice nurse or patient's Medical Practitioner or Nurse Practitioner to obtain serum creatinine.*** • If the patient has a gout flare on presentation, manage with usual care. Refer to the Medical Practitioner or Nurse Practitioner if flare has not improved in 48hours. • Dosing based on the HealthPathways Gout Management– refer to Appendix 2.

Precautions and exclusions that apply to this standing order	**Patients are excluded in the following situations;** • Patient has not provided written informed consent to be in the Gout Busters programme • The Medical Practitioner or Nurse Practitioner has not provided written consent for the patient to be managed as part of the Gout Busters Programme • Allopurinol is not prescribed for the management of gout (e.g. haematological indication) • Patient is not suitable for gout flare prophylaxis medication (i.e. colchicine, naproxen, prednisone)-refer Appendix 2 for more details regarding prophylaxis • Serum creatinine (or eGFR levels) not obtained within 3 months of the date of the allopurinol prescription. • Patient is / has; o Less than 18 years of age o Not diagnosed with gout o Not taking allopurinol o Not taking gout flare prophylaxis medication (patients should be continuing on gout flare prophylaxis until under target level on two consecutive serum urate measurements) o eGFR < 30 mL/min o Taking azathioprine o Pregnant o Breastfeeding o Known allopurinol allergy (e.g. anaphylaxis, previous rash with allopurinol) Note: Contact the Medical Practitioner or Nurse Practitioner or Rheumatologist for advice if the patient has a known adverse drug effect to allopurinol o Chinese/Thai/Korean ethnicity, unless tested for HLA-B*5801 (higher risk of allopurinol hypersensitivity due to HLA-B*5801) o Taking allopurinol at a daily dose of more than 600mg o Taking febuxostat **Precautions** • Complex gout (patients under the care of a Rheumatologist) – contact the Medical Practitioner or Nurse Practitioner or Rheumatologist for advice • Unstable renal or liver function – contact the Medical Practitioner or Nurse Practitioner or Rheumatologist for advice • Allopurinol dose change within the previous 28 days • Gout flare within the past 3 weeks – see dosage instructions above • Non-adherence (missed 7 out of 28 daily doses, or 25%) – see dosage instructions above • Static or increasing urate level despite allopurinol dose escalation – see dosage instructions above • Drug-drug interactions • Adverse drug effects **Criteria for referral to patient's Medical Practitioner or Nurse Practitioner** • Severe medication allergy or adverse effect (e.g. rash) – stop allopurinol immediately • Serum urate level is unchanged or has increased at visit 3 (or 8 weeks on allopurinol) despite allopurinol dose escalation and adherence • If gout flare has not improved in 48 hours (may be other arthritic disease) • Other health concerns as per usual standard of care

Warnings	• Allopurinol can cause gastrointestinal disorders • *Rarely* hypersensitivity disorders and rash (can occur anytime) – seek immediate/urgent medical advice and stop allopurinol
Record keeping	When working under this standing order, the pharmacist must record the following in the patients care plan: • Visit number • Serum urate level and the date the level was measured • Serum creatinine or eGFR levels • Allopurinol dose and details of any change (e.g. dose increase to 200 mg or dose unchanged) • Details of any gout flares/allergies/side effects • Record that patient has been advised about the risk of a generalized skin rash with allopurinol, and the need to seek urgent medication if this occurs • Any other relevant information (e.g. adherence concerns, counselling points) • Date and time of next planned visit The pharmacist must use the gout buster software at each patient visit and keep a record at the pharmacy. • Pharmacist must keep records of patient referrals to the Medical Practitioner or Nurse Practitioner – refer to Appendix 3.
Persons authorised to administer the standing order	New Zealand registered Pharmacists who have completed the CMDHB provided gout training in 2022 or the PSNZ Community Pharmacy Gout Management Service Training.
Competency/training requirements for the person(s) authorised to administer	Prior to allopurinol dose escalation under this standing order, the Pharmacist is required to have completed all modules of the CMDHB provided gout training in 2022 and correctly answered the questions for CMDHB, with a certificate of completion or the PSNZ Community Pharmacy Gout Management Service training. The issuer must, at least once a year, review the competency of each person permitted to work under this standing order.
Countersigning and audit	All dose changes and continuation supplies under the standing order will be notified to the patient's nominated general practice through the Gout Busters software providing timely visibility of all work done under the standing order. The Medical Practitioner or Nurse Practitioner will provide a new prescription for allopurinol approximately every 3 months. The Doctor prescribing allopurinol will sign off treatment. Sign off will take place approximately every 3 months at the time a new allopurinol prescription is provided. The issuer will review the Standing Order every year. Adverse events related to the Community Pharmacy Gout Management Service will be reported to CARM or other relevant body by the Pharmacist working under this standing order, be reported to the general practitioner and be recorded in the patient's file in the Gout Buster software.
Definition of terms used in standing order	Gout flare – Occurs when urate crystals in the joint(s) cause acute inflammation. Characterised by pain, redness, swelling, and warmth lasting days to weeks. Tophaceous gout - A chronic form of gout. Nodular masses of uric acid crystals (tophi) are deposited in different soft tissue areas of the body. The terms urate and uric acid are interchangeable.

Additional information	• HealthPathways – refer to Appendix 2 • Allopurinol New Zealand Medsafe Data Sheet (access via www.medsafe.govt.nz/profs/datasheet/datasheet.htm) • Medical Practitioner or Nurse Practitioner Referral Log – refer to Appendix 3 This Standing Order may be signed by the practice Clinical Director on behalf of all medical practitioners in the practice, or alternately signed by each GP. All records associated with this standing order must be kept for 10 years. This standing order is not valid after the review date.

Signed by doctor:

Name: Date:

Title:

Signed by doctor:

Name: Date:

Title:

Signed by doctor:

Name: Date:

Title:

Signed by doctor:

Name: Date:

Title:

Signed by doctor:

Name: Date:

Title:

Appendix 1

Example of Allopurinol Prescription

Rx: Allopurinol tablets

Sig: (starting dose) mg PO daily, then as per Allopurinol Dose Escalation Standing Order. Please enrol in Gout Busters Programme.

Mitte: 3 months supply, monthly dispensing

Additional details required on the prescription:

Urate target (circle one) < 0.36mmol/L or < 0.30mmol/L

eGFR (circle one) ≥ 60ml/min or 30-60ml/min (circle one)

Medical Practitioner or Nurse Practitioner consent obtained YES or NO (circle one)

Patient consent obtained YES or NO (circle one)

NB: medical practitioner or nurse practitioner written agreement to the person entering the programme is a requirement of entry into the programme. This can include the GP or nurse practitioner writing on the prescription “please enrol in Gout Busters” or similar wording, or email confirmation. Patients can only be entered into the programme if they consent.

Only the selected pharmacies are funded to provide the gout busters service. Other pharmacies cannot yet provide it.

A standing order needs to be in place with the pharmacy for patients to enter into the programme.

Appendix 2

Healthpathways Medication Information

HealthPathways is available free for use by health care professionals working in community health in the Auckland metro area. It includes a number of therapeutic areas. For Gout, it is accessible at:

Link: https://aucklandregionclassic.communityhealthpathways.org/18727.htm
Login: connected
Password: healthcare

Key details of the medication recommendations from Healthpathways are included below (correct as at 4/5/22, but please go to the link above for the latest information.

Gout

Red flags

- Septic arthritis suspected in a single, swollen, painful joint

Background

About gout

Assessment

1. History – Ask about:
    - onset – a gout flare typically presents with a single acute swollen tender joint over a 6 to 12 hour period, often associated with fever and malaise.
    - which joints are involved, and timing and severity of pain.
    - any previous episodes and their frequency.
    - systemic symptoms, including fever and malaise (common).
    - treatment, including over the counter (OTC) and self-treatment, and adherence to medications.
    - features and signs of chronic tophaceous gout.
2. Examination:
    - Take temperature to help exclude septic arthritis, as both can present as a single swollen painful joint over a 6- to 12-hour period:

        - A low-grade fever can occur with gout.
        - Most patients with septic arthritis are febrile, however older patients with septic arthritis may be afebrile.
    - Check joints involved and look for any signs of tophi and chronic joint disease.
3. Investigations – Arrange:
    - serum urate. During an acute gout flare, levels are often normal (in up to 50% of patients) so consider repeating during convalescent phase a few weeks later.
    - renal function if not done within previous 3 months.
    - joint aspiration if there is any doubt about the diagnosis and to rule out septic arthritis (typically a single swollen joint).
        - Consider joint aspiration for most large joints.
        - Send fluid for cell count, crystals, and Gram stain and culture. Definitive diagnosis of gout by is made by demonstration of urate crystals in synovial fluid or tophi.

    Do not arrange plain radiology in the setting of a gout flare unless inflammation persists for more than 12 weeks.
4. Consider using the acute gout flare diagnosis rule in patients presenting with monoarthritis. It has been developed and validated in primary care.
5. Screen for any other conditions associated with gout, and assess cardiovascular risk if clinically appropriate.

Management

Practice point

Focus on serum urate control

For all patients with gout, assess whether to start or optimise the dose of urate-lowering therapy. Long-term control of serum urate is important to suppress gout flares (target < 0.36 mmol/L).

Gout flare treatment

1. Provide anti-inflammatory medications with choice of medications depending on age, renal function, and co-morbidities.

    Anti-inflammatory medications

    - Consider first-line treatment with:
        - Corticosteroids, e.g. prednisone:
            - Give prednisone 20 to 40 mg daily until the episode resolves.
            - Once resolved, reduce the dose over one to two weeks to prevent a rebound flare.
        - Nonsteroidal anti-inflammatory drugs (NSAIDs), and consider adding a proton-pump inhibitor. Check contraindications to NSAIDS.

            Nonsteroidal anti-inflammatory drugs (NSAIDs)

Prescribe appropriate NSAIDs, e.g. naproxen 500 mg twice daily.

- Use NSAIDs in the lowest effective dose for the shortest period of time.
- Avoid NSAIDs in older adults or if cardiac or renal disease.
- Avoid the "triple whammy" combination of an ACE inhibitor or ARB, diuretic, and NSAID, which may cause increased blood pressure and renal impairment.

- low-dose colchicine, although there are a number of serious contraindications and drug interactions. Overdoses from 7 mg can be fatal [2]. There is no reversal agent. Check contraindications to colchicine.

Contraindications to colchicine

- Combined hepatic and renal disease
- Severe renal impairment (creatinine clearance < 10 mL/min)
- Severe hepatic impairment
- Mild or moderate renal or hepatic impairment taking a P-glycoprotein (P-gp) or strong cytochrome P450 3A4 inhibitor e.g., ciclosporin, clarithromycin, erythromycin, ketoconazole, ritonavir, verapamil, diltiazem, statins
- Serious cardiac or gastrointestinal disorders
- Blood dyscrasias
- Hypersensitivity to colchicine
- Children
- Lactation
- Pregnancy

Colchicine

- Use low-dose regimens as high doses can be fatal. Colchicine has a narrow therapeutic margin and considerable variation in absorption between individuals.
- Use a reduced dose cautiously in older adults or patients with creatinine clearance 10 to 50 mL/min. Contraindicated if creatinine clearance is < 10 mL/min.
- Start within 24 hours of the gout or calcium pyrophosphate disease (CPPD) flare, preferably within 12 hours.
- According to local specialist recommendations:
  - give:
    - 1 mg immediately,
    - 0.5 mg one hour later.
  - if not settled after 12 hours, start colchicine 0.5 mg once to twice daily until settled.

- Advise the patient to stop if they get diarrhoea.

For adverse effects and drug interactions, see colchicine.

- If 1 or 2 joints are affected, consider intra-articular corticosteroids e.g., triamcinolone acetonide (Kenacort-A). If performing intra-articular injection, consider first taking a joint aspiration sample and send it to the laboratory for cell count, crystals, and Gram stain and culture analysis. Seek rheumatology advice if required.

- If the patient has been taking allopurinol or other urate-lowering therapy regularly without interruptions, advise them to continue their current dose.

- Reconsider diagnosis if the patient is responding poorly to treatment. Consider joint aspiration to confirm diagnosis and exclude coexisting infection if not already performed.

2. If the diagnosis is still unclear after joint aspiration and/or the patient has atypical joint distribution, seek rheumatology advice or request non-acute rheumatology assessment.
3. If acute symptoms persist > 2 weeks with treatment, seek rheumatology advice.
4. Note that some local specialists suggest initiating preventative treatment during an acute gout flare in patients without tophi or renal impairment. If allopurinol is started or restarted during a gout flare, start at a low dose with appropriate ongoing prophylaxis.
5. Arrange follow-up appointment with serum urate testing at 3 weeks.

Preventative treatment

1. Consider indications for urate-lowering therapy as preventative treatment.

   Indications for urate-lowering therapy

   - Recurrent gout flares (2 or more flares per year)
   - Gouty tophi
   - Chronic gouty arthritis
   - Evidence of damage on X-ray
   - Early-onset gout, strong family history, and serum urate greater than 0.6 mmol/L

   In patients with asymptomatic hyperuricaemia, there is no evidence to support urate-lowering therapy.

2. Determine target serum urate level i.e., < 0.36 mmol/L, or if tophi are present < 0.30 mmol/L.
3. Start urate-lowering medications using a treat-to-target approach using the above target levels.

   Treat-to-target approach

   - Monitor serum urate monthly until target urate achieved.
   - Review and adjust urate-lowering therapy (dose or drug) until target achieved.
   - Once at target, measure serum urate every 6 to 12 months.
   - Warn patients it can take more than 12 months after reaching their target for gout flares to stop, and years for tophi to dissolve.

- Prescribe prophylactic medication to prevent gout flares for 3 to 6 months when starting urate-lowering therapy.

Prophylactic medication to prevent gout flares

- Nonsteroidal anti-inflammatory drugs (NSAIDs) if appropriate e.g., naproxen 250 to 500 mg twice daily or ibuprofen 400 mg three times daily. Consider co-prescribing a proton pump inhibitor (PPI).
- Colchicine 0.5 mg twice daily (reduce to 0.5 mg once daily if renal impairment with creatinine clearance 10 to 50 mL/min). Monitor creatine kinase (CK) monthly if the patient is on colchicine prophylaxis.
- Prednisone e.g., 5 to 10 mg per day, particularly if the patient is having frequent gout flares.

- Give allopurinol as first-line urate-lowering treatment. A gout flare when starting allopurinol does not constitute intolerance or failure. Allopurinol failure is defined as failure to reach target serum urate < 0.36 mmol/L at maximum tolerated dose.

  Allopurinol

  Allopurinol can be started during a gout flare alongside appropriate gout flare treatment. If allopurinol is started during a gout flare, start at a low dose (see below), and in combination with anti-inflammatory prophylaxis therapy.

  - Avoid in combination with azathioprine, as they may interact.
  - Adverse effects are uncommon, but be aware of the rare severe allopurinol hypersensitivity reaction (DRESS) that can occur, often in the first six weeks from initiating allopurinol, and with a rash.

    Severe allopurinol hypersensitivity reaction

    - Allopurinol hypersensitivity syndrome, also called DRESS (drug rash with eosinophilia and systemic symptoms) is a rare (0.1% incidence) but potentially fatal adverse effect of allopurinol.
    - DRESS is characterised by an erythematous, desquamating rash, fever, eosinophilia, leukocytosis, hepatitis, and renal failure, occurring most often in the first 4 to 6 weeks of treatment.
    - Risk of DRESS is substantially reduced by starting allopurinol at a low dose and titrating upwards slowly.
    - Warn patients that they must stop allopurinol and seek medical advice if any rash or itch develops. If this occurs, trial alternative urate-lowering medicines.
    - Risk factors for DRESS include:
      - renal impairment.
      - high starting dose of allopurinol relative to renal function.
      - diuretics.
      - HLA-B*5801 allele (often in people of Korean, Thai or Chinese descent).

    See also bpacnz – Managing Gout in Primary Care: Part 2 – Controlling Gout with Long-term Urate-lowering Treatment.

- Consider HLA–B*5801 screening before starting allopurinol in some Asian subpopulations.

  Asian subpopulations

  Consider HLA–B*5801 screening as part of risk management in Asian subpopulations where there is increased frequency of the HLA–B*5801 allele. The HLA–B*5801-positive subpopulations have a very high risk for severe allopurinol hypersensitivity reaction (DRESS) e.g., Koreans (especially those with chronic kidney disease stage 3 or worse), and all those of Han Chinese and Thai descent. [3]

- Start low and go slowly.
- Warn patients to cease allopurinol if they develop a rash.
- Decide on an appropriate starting dose, based on eGFR:
  - If eGFR < 30 mL/min/1.73m^2, start 50 mg every second day, increasing by 50 mg every 4 weeks, if tolerated, until target serum urate is reached.
  - If eGFR 30 to 60 mL/min/1.73m^2, start 50 mg daily, increasing by 50 mg every 4 weeks until the target urate is achieved.
  - If eGFR > 60 mL/min/1.73m^2, start 100 mg daily, increasing by 100 mg every 4 weeks until the target urate is achieved.
- Aim for a target serum urate of less than 0.36 mmol/L, or, if tophi are present, less than 0.30 mmol/L. Usual maintenance dose is 100 to 600 mg daily. A maintenance dose of 700 to 900 mg daily may be required in severe conditions.
- Start patients with impaired renal function with a lower starting dose (as above). If they do not respond, gradually increase the dose and seek rheumatology advice if any concerns.
- Monitor:
  - serum urate and renal function monthly until the target serum urate is achieved.
  - creatine kinase monthly if the patient is on colchicine prophylaxis.
  - FBC and LFTs every 3 months during the dose escalation period.
  - urate every 6 to 12 months once at target, to ensure the target is maintained.
- If serum urate fails to reduce, always check the patient's understanding about their allopurinol.
- If recurrent gout flares occur and the patient is at target urate, reassure the patient that it can take more than 12 months after reaching target for flares to stop.

- If allopurinol is contraindicated, not tolerated, or ineffective, consider alternative urate-lowering medications:
  - Probenecid

    Probenecid

    - Used when there is:

- a poor response to allopurinol, but is sometimes used in combination.
- allopurinol intolerance.
- normal renal function.

- Contraindicated if:
  - creatinine clearance < 20 mL/min
  - renal stones.
- Patient needs to have a high fluid intake (> 2 litres a day).
- For full prescribing details, see the NZ Formulary – probenecid.

- Febuxostat

  Febuxostat

  - Consider febuxostat if allopurinol and probenecid failure, intolerance, or contraindication.
    - Allopurinol failure is defined as failure to reach target serum urate < 0.36 mmol/L or intolerable adverse effects. A flare of gout when starting allopurinol does not constitute intolerance or failure of allopurinol.
    - Febuxostat is available on special authority.
  - Patients who get a rash or hypersensitivity on allopurinol or have renal disease may have hypersensitivity reactions with febuxostat. These can be serious. Most cases occur during the first month of treatment.
  - Use with caution in patients with known coronary vascular disease, significant risk factors for vascular disease, or congestive heart failure. See MedSafe Prescriber Update.
  - Avoid in combination with azathioprine, as they may interact.
  - Check liver function before starting, after 2 weeks, then monthly. There is a risk of hepatotoxicity (including fatal events) with febuxostat.
  - Many of the patients who can tolerate febuxostat have co-morbidities and medications which make prescribing difficult. Consider non-acute rheumatology assessment.

- Benzbromarone – discontinued – see PHARMAC. Swap patients to an alternative medication.

4. Recommend lifestyle interventions alongside urate-lowering therapy. Most people with gout cannot achieve target serum urate with lifestyle changes alone.

   Lifestyle interventions

   Advise the patient to:

   - maintain a healthy weight.
   - eat regular meals, as both fasting and overeating can trigger gout.

- drink 2 litres of water per day.
- limit alcohol, if alcohol intake is hazardous.
- reduce sugar and sugar-sweetened drinks.

5. Screen for, and manage, any other conditions associated with gout. Consider enrolling the patient in a long-term conditions programme, and involving a multidisciplinary team i.e., nurse, pharmacist, podiatrist, social worker.
6. Complete a Gout Management Plan.
7. Seek rheumatology advice or request non-acute rheumatology assessment if:
    - intolerance to urate-lowering medications.
    - renal impairment, co-morbidities, and medications which affect the choice of urate-lowering therapies.
8. If failure to respond to urate-lowering medications, check adherence. If good adherence, seek rheumatology advice or request non-acute rheumatology assessment.

    Failure to respond

    - Recurrent gout flares > 12 months after target urate achieved
    - Progressive joint damage

Request

- Seek rheumatology advice or request non-acute rheumatology assessment if:
    - diagnosis is unclear.
    - atypical joint distribution.
    - acute symptoms persist > 2 weeks with treatment.
    - failure to respond to urate-lowering medications despite good adherence with treatment at maximum-tolerated dosing or target urate achieved.
    - intolerance to urate-lowering therapies.
    - renal impairment, co-morbidities, and medications which affect the choice of urate-lowering therapies
    - progressive joint damage despite therapy.
- If septic arthritis is most likely diagnosis, request acute orthopaedic assessment.
- Request non-acute rheumatology assessment if:
    - eGFR < 30 mL/min/1.73m^2
    - considering febuxostat for patient with complicating co-morbidities or medications.

Appendix 3

Medical Practitioner or Nurse Practitioner Referral Log

Pharmacists working under this standing order must keep a record of the following details when a patient is referred to their Medical Practitioner or Nurse Practitioner.

Date	Patient Name	Patient NHI	Pharmacist	Referral GP/nurse practitioner	Reason for referral

Appendix 6 Summary for Allopurinol between 1/1/2000 and 31/5/2024

Number of reports: 302
Number of reports where death was reported: 13
Number of serious reports: 218
Number of reactions: 644

New query

System Organ Class	MedDRA Reaction Term	Number of Reports
Blood and lymphatic system disorders	Agranulocytosis	2
	Anaemia	1
	Aplastic anaemia	1
	Eosinophilia	8
	Granulocytosis	1
	Leukopenia	2
	Lymphocytosis	2
	Lymphopenia	1
	Microcytic anaemia	1
	Myelosuppression	5
	Neutropenia	4
	Normocytic anaemia	1
	Pancytopenia	5
	Thrombocytopenia	4
	Thrombocytosis	1
Cardiac disorders	Atrial fibrillation	1

	Cardiac failure	1
	Palpitations	1
Congenital, familial and genetic disorders	Congenital anomaly	1
Ear and labyrinth disorders	Hypoacusis	1
	Vertigo	2
Endocrine disorders	Hyperthyroidism	1
Eye disorders	Eye swelling	1
	Optic atrophy	1
	Periorbital oedema	1
Gastrointestinal disorders	Abdominal distension	1
	Abdominal pain	6
	Abdominal pain upper	1
	Constipation	3
	Diarrhoea	4
	Dry mouth	1
	Duodenal ulcer	1
	Dyspepsia	1
	Gastrointestinal disorder	1
	Haematemesis	1
	Lip dry	1
	Lip swelling	1

	Lip ulceration	1
	Mouth haemorrhage	1
	Mouth ulceration	5
	Nausea	7
	Oesophagitis	1
	Pancreatitis	2
	Stomatitis	2
	Vomiting	2
General disorders and administration site conditions	Chest discomfort	1
	Chest pain	2
	Chills	5
	Disease progression	1
	Drug ineffective	2
	Drug interaction	8
	Drug withdrawal syndrome neonatal	1
	Face oedema	7
	Facial pain	1
	Fatigue	3
	Feeling abnormal	1
	Influenza like illness	3
	Malaise	3

	Mucosal inflammation	1
	Mucosal ulceration	1
	Multiple organ dysfunction syndrome	2
	Oedema	4
	Oedema peripheral	2
	Pain	1
	Pyrexia	19
	Therapeutic response decreased	16
Hepatobiliary disorders	Drug-induced liver injury	1
	Hepatic failure	2
	Hepatic function abnormal	5
	Hepatitis	2
	Hepatitis cholestatic	1
	Hepatocellular injury	1
	Hepatomegaly	1
	Liver injury	1
Immune system disorders	Anaphylactic reaction	2
	Hypersensitivity	6
	Serum sickness	1
	Type IV hypersensitivity reaction	1
Infections and infestations	Cellulitis	1

	Conjunctivitis	1
	Furuncle	1
	Helicobacter infection	1
	Hepatitis B	1
	Infection	1
	Lower respiratory tract infection	1
	Necrotising fasciitis	1
	Pharyngitis	1
	Pneumonia	4
Injury, poisoning and procedural complications	Intentional overdose	1
	Medication error	12
	Prescription drug used without a prescription	1
	Product use issue	34
	Toxicity to various agents	1
Investigations	Bleeding time prolonged	1
	Blood creatinine increased	1
	C-reactive protein increased	2
	Hepatic enzyme increased	12
	Histology	1
	Liver function test abnormal	1
	Weight decreased	1

Metabolism and nutrition disorders	Decreased appetite	1
	Fluid overload	2
	Gout	2
	Hypomagnesaemia	1
	Hyponatraemia	1
Musculoskeletal and connective tissue disorders	Arthralgia	3
	Back pain	3
	Myalgia	2
	Pain in extremity	1
Nervous system disorders	Ageusia	1
	Amnesia	1
	Ataxia	2
	Dizziness	2
	Dysaesthesia	1
	Dysgeusia	1
	Haemorrhage intracranial	1
	Headache	8
	Lethargy	3
	Migraine	1
	Neuropathy peripheral	2
	Nystagmus	1

	Paraesthesia	4
	Seizure	1
	Somnolence	3
Product issues	Product formulation issue	1
	Product quality issue	8
Psychiatric disorders	Abnormal behaviour	1
	Anger	1
	Anxiety	1
	Confusional state	2
	Depression	1
	Irritability	2
	Libido decreased	1
	Nightmare	1
Renal and urinary disorders	Acute kidney injury	7
	Chronic kidney disease	1
	Nocturia	1
	Renal failure	3
	Renal impairment	4
	Tubulointerstitial nephritis	2
	Urine odour abnormal	1
Reproductive system and breast disorders	Erectile dysfunction	2

Respiratory, thoracic and mediastinal disorders	Bronchospasm	2
	Choking	1
	Cough	4
	Dry throat	1
	Dyspnoea	2
	Epistaxis	2
	Oropharyngeal pain	2
	Pharyngeal swelling	1
	Rhinorrhoea	1
	Throat irritation	2
	Throat tightness	1
Skin and subcutaneous tissue disorders	Acute generalised exanthematous pustulosis	3
	Alopecia	1
	Angioedema	2
	Blister	1
	Dermatitis	2
	Dermatitis bullous	1
	Dermatitis exfoliative	2
	Dermatitis exfoliative generalised	2
	Dermatitis psoriasiform	1
	Drug eruption	1

	Drug reaction with eosinophilia and systemic symptoms	42
	Dry skin	1
	Eczema	2
	Erythema	2
	Erythema multiforme	2
	Erythema nodosum	1
	Exfoliative rash	1
	Lichenoid keratosis	3
	Night sweats	2
	Panniculitis	1
	Pemphigoid	1
	Petechiae	5
	Photosensitivity reaction	1
	Pruritus	13
	Purpura	4
	Rash	25
	Rash erythematous	5
	Rash macular	5
	Rash maculo-papular	34
	Rash morbilliform	5
	Rash papular	2

	Rash pruritic	26
	Rash vesicular	4
	Skin burning sensation	1
	Skin disorder	1
	Skin exfoliation	7
	Skin ulcer	1
	Stevens-Johnson syndrome	12
	Swelling face	2
	Toxic epidermal necrolysis	12
	Urticaria	9
	Vasculitic rash	1
Vascular disorders	Hypotension	2
	Vasculitis	

Te Whatu Ora
Health New Zealand

Gout Busters

Evaluation of the redesigned pharmacy gout management programme in Te Whatu Ora Counties Manukau. Summary of Findings

Research team: Dr Natalie Gauld, Associate Professor Peter Gow, Thelma Fatafehi-Finau, Associate Professor Alain Vandal, Teei Kaiaruna, Dr Lily Fraser, Melissa Bentley.

Background

- Daily allopurinol prevents gout
- Start low and titrate until SU is <0.36 mmol/L. Use flare prophylaxis. If stopped, start again low.
- Challenges include: getting people on the right dose, adherence to therapy and misconceptions
- Maaori and Pacific peoples disproportionately impacted by gout and have lower levels of continuation of allopurinol

OMG change to Gout Busters

- **Owning My Gout in Counties Manukau**
- **Feedback on challenges led to change to GB:**
  - Software for text messages to patients, comms between pharmacy and GP, graph of progress, reporting for Counties Manukau
  - Strong cultural competency in training
  - New pharmacies with high Maaori and Pacific patient populations
  - Continuation supply of allopurinol
- **Pharmacies still provide monthly visits, SU fingerprick tests, allopurinol titration, gout booklet**
- **Relaunched 1 May 2022, 13 pharmacies. People with SU >0.36 mmol/L**

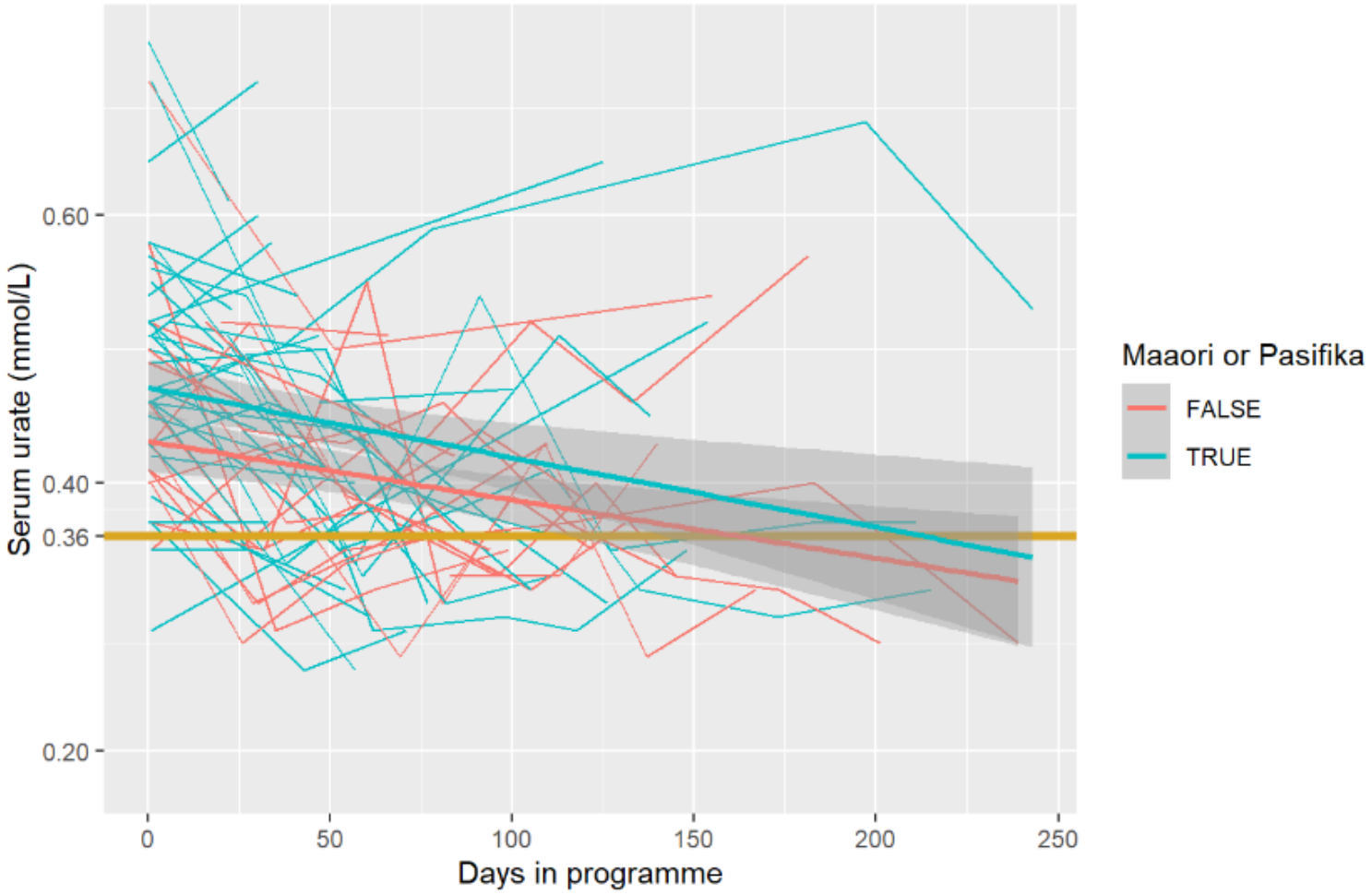
New enrolments by month

- 232 people
- 22% Maaori
- 60% Pacific peoples

Statistical analysis

- Excluded 1 pharmacy
- 1/5/22-5/5/23, 127 people
- 87% male; 17% Maaori, 59% Pacific peoples
- 47% aged 20-44 years, 46% aged 45-64 years, 6% aged 65 +
- 27% reached target SU at least once (lower for Maaori/Pacific (20%) and <45 years) n.s.
- 59% Pacific peoples were under 45 years
- NB: the proportion reaching the target SU was low because many enrolled from March 2023, so had insufficient time in GB to reach target

Serum urate changes over time

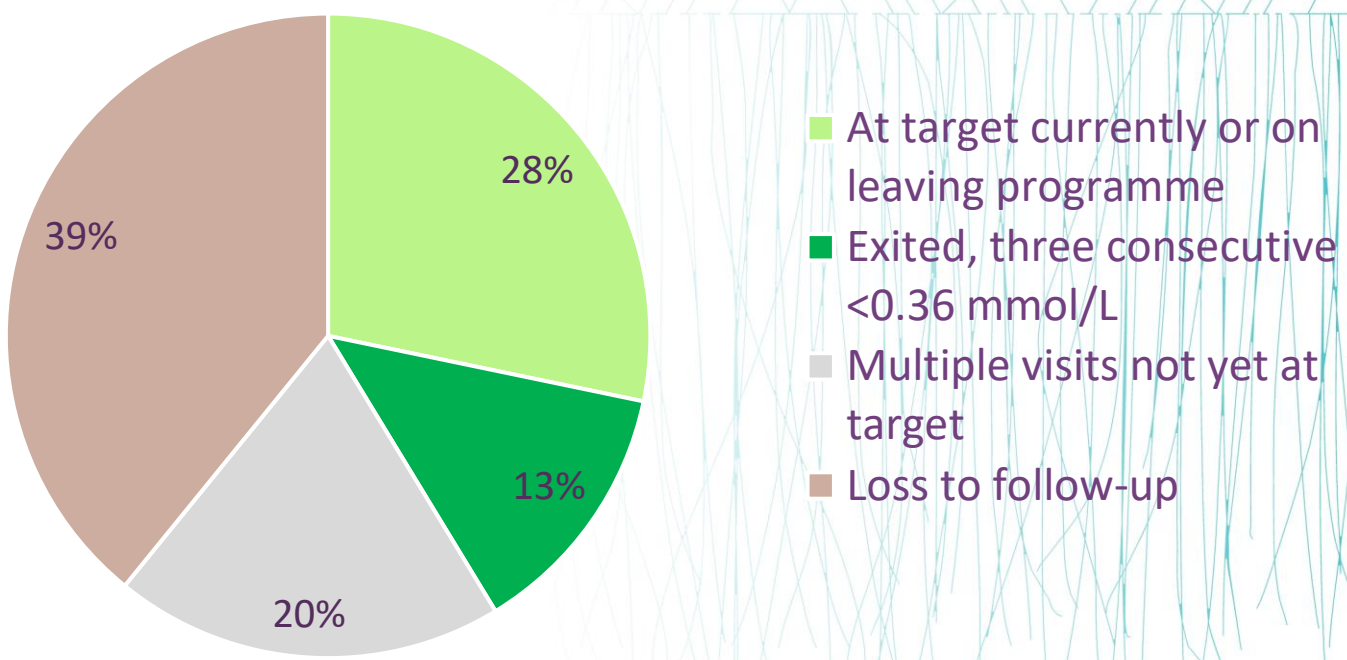


NB: Many patients were enrolled within two months of the cut-off date for data, limiting the numbers reaching the target serum urate. A downward trend is seen in both Maaori or Pacific peoples (solid blue line) and non-Maaori, non-Pacific (solid red line)

Subset with longer data

- 46 people had enrolled in 2022 so were analysed further given their longer data
- 80% attended ≥ 2 visits
  - 74% for Pacific peoples
  - 88% for Maaori
  - 86% for other
  - small numbers
- 20% left GB for ≥3 months then returned

Status at 1 July 2023 of those enrolled 2022

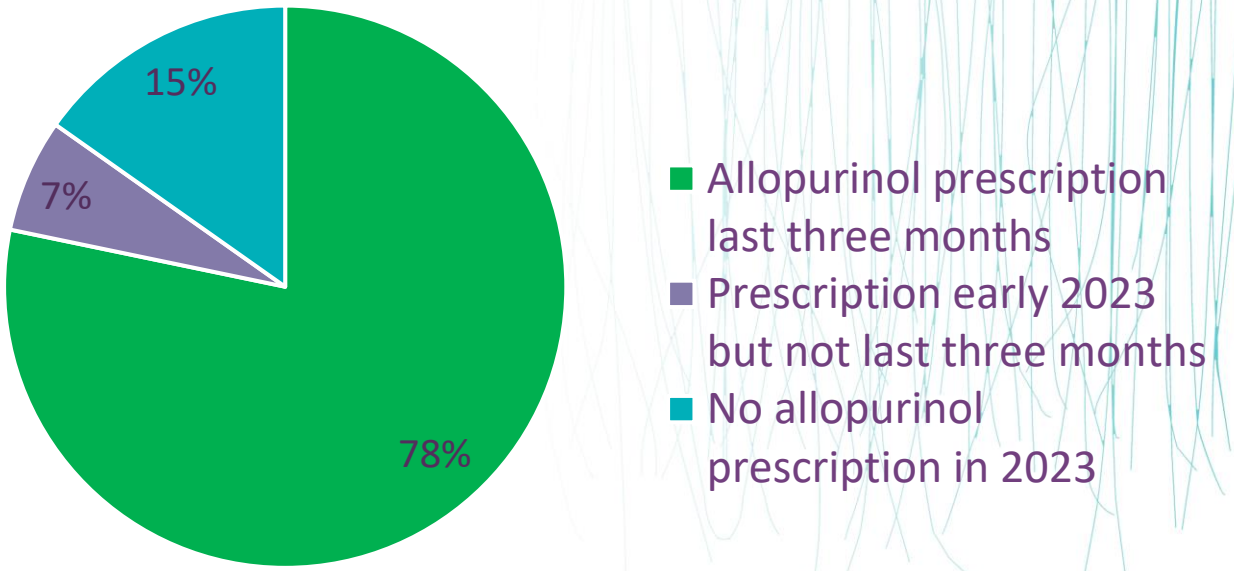


Loss to follow-up means stopped using the programme before reaching target, some of these were using allopurinol according to dispensing records

Allopurinol continuation for the 46 enrolled in 2022

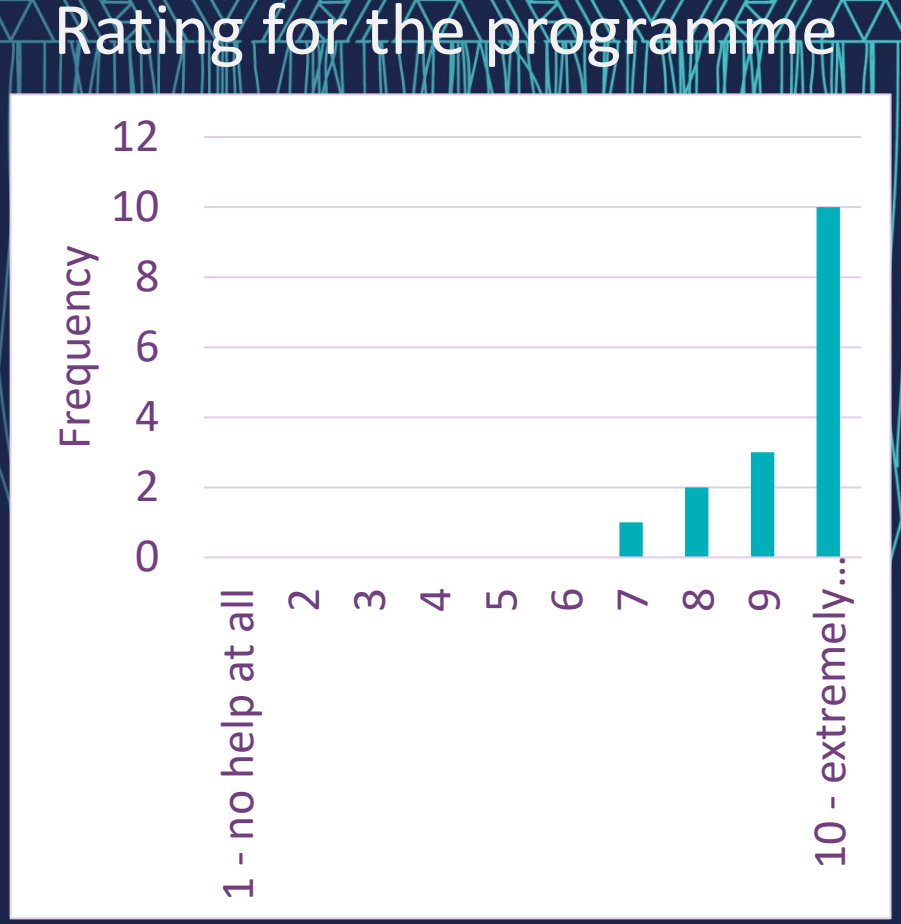
- 55% had taken allopurinol continuously since starting Gout Busters
  - 62% for Maaori
  - 45% Pacific peoples
  - 71% for others
- Low numbers – not generalisable for ethnicity
- Atlas of Healthcare Variation has regular ULT receipt in 19% of people aged 20-44 years and 38% 45-64 years

Allopurinol dispensings as at July 2023 for those enrolled in 2022



Qualitative interviews

- 16 interviews, 4 with sporadic attendance
- Age 23-65 years, five <35 years
- 7 identified as Maaori, 6 Samoan, 3 Tongan



Interviews Summary

- Liked:
  - Being informed - pharmacist, SU tests, graph, booklet
  - Free
  - Convenient
- Built positive and trusting relationships
- Helped them understand importance of allopurinol, have faith in allopurinol titration and be more likely to take allopurinol
- Taking allopurinol may show the person’s appreciation for the service, an act of reciprocity

How they were treated

Very positive comments

"…they look after me when I come in…. They don't discuss gout in front of [other customers]…. I enjoy it [the visit]…. Makes me really think serious[ly] about why I have to do it." **Interview 12**

"…as soon as I walked into the chemist … she dropped what she was doing and we moved into the side room and did all the tests and everything….. she was really good…" **Interview 3**

Two participants had privacy concerns (same pharmacy), one had to wait, one noted jargon, one said pharmacy had run out of test strips

What else they liked

- Texts – motivational and reminder to come in
- Quick visits
- Reducing stigma
- Being gout-free

"… they prick my finger … and then give me my results. First of all, nothing was happening and I thought 'am I wasting my time?' And then … I could see my results coming down… I was happy, they were happy…. They give you a high five … it's pretty uplifting" Interview 7

Challenges for patients with gout

- **Adherence to tablets**
  - Forgetting
  - No current gout/beliefs
  - Run out of allopurinol
- **Getting prescribed allopurinol – initially and ongoing**
- **Hard to get to Dr – time off, cost, long wait, attend in person for Rx**
- **Delayed pharmacy visits, esp. if no gout, busy**
- **Some will stop programme then restart after a flare**

“if you're not having any attacks, then you get into the zone …probably don’t need to go anymore …the [text] reminders that kind of helps …oh, might as well just get it…” Interview 1

Pharmacist survey

- **20 pharmacists**
- **80% rated GB 8-10/10 on getting good patient outcomes**
- **85% would recommend GB to other pharmacies**

Rated highly
Training, texts to patients, SU tests, monthly visits, continuation supply, reimbursement of co-payment, allopurinol titration

Rated medium
Working with general practice, booklet for patients, software

Lower rating
Administration work

Challenges identified by pharmacists

- Getting patients to return
- Getting renal function tests
- Patients attending a GP with no standing order
- Missing flare prophylaxis
- Patient being gout-free when trying to enrol them

Plus staff shortages, GPs busy, staff changes. Variable pharmacy uptake

Improvements pharmacists suggested

- Often no improvements suggested
- Better funding
- Faster software
- Automatic population Testsafe data in software
- Pharmacist ordering renal function tests
- Flare prophylaxis on standing order
- Better doctor engagement

GP Survey – 5 respondents

- All rated the programme 7/10 or higher

"When patients engage the pharmacy does a great job with titration. The biggest difficulty is keeping patients engaged in the process" [rating 8].

- Best part: dose titration, patient education, fingerprick test
- Liked communication from the pharmacy and being close-by/good relationship

"…takes the load off us to optimise, easy use when done well".

Other learnings

- Software very useful – reporting, graph for pts, comms with dr. Future: POC tests to Testsafe. Needs speeding up and automating reporting – to pharmacy and Te Whatu Ora
- Occasionally pharmacies have insufficient staff trained, run out of test strips, enter patients in software late
- Working with pharmacies and GPs effective – need resource
- Our pharmacies provided access for Maaori and Pacific peoples

Recommendations

- Continue GB with existing pharmacies and widen to more
- Share evaluation findings with pharmacies and GPs
- Use gout titration packs as per Northland to hasten titration
- Three-monthly dispensing not monthly
- Address challenge of ongoing prescriptions after leaving programme e.g. pharmacist continuation supply
- Consider pharmacists giving renal function test forms
- Support GPs and pharmacies
- Review funding
- Repeat quantitative research with more patients and long-term data

Acknowledgements

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- Kia ora to Firecrest for doing the software

SYNERGIA

Evaluation of Gout Stop and Owning My Gout management programmes

A final report for Arthritis New Zealand and its partners

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28 February 2020

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ACKNOWLEDGEMENTS

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We would like to thank the leads, stakeholders and providers who contributed their valuable time and insights to the evaluation, as well as the patients who provided feedback.

We also like to thank the project team, led by Sandy Bhawan of PHARMAC and Susan Reid of Gout Action Aotearoa on behalf of Arthritis New Zealand, with partners PHARMAC and the Health Quality and Safety Commission. Your ongoing engagement and support of the evaluation process has been appreciated.

We also acknowledge the contribution of Dr Sarah Appleton-Dyer, the evaluation lead at Synergia, who has supported the team with expert review of the design and reporting for this evaluation.

The expertise and experiences of all the stakeholders, through data collection and sensemaking, have enabled the evaluation to provide a detailed overview of these programmes and provide useful insights and recommendations for the ongoing response to gout and to achieve equity of access and outcomes for those it affects.

EXECUTIVE SUMMARY

Gout is a chronic long-term condition that impacts people's quality of life and is a social and economic burden. The effects of gout are preventable but access to appropriate medication is variable and only one in four people in New Zealand diagnosed with gout is on regular long-term medication to control gout's damaging effects. This is despite effective treatment being available and publicly funded/subsidised. Māori and Pacific peoples have two and three times the prevalence of diagnosed gout respectively, compared to people of other ethnicities. Maori and Pacific peoples also have poorer access to long-term medication to control gout[1].

Arthritis New Zealand, PHARMAC and the Health Quality and Safety Commission are seeking to contribute to the evidence base around what works for access to effective treatment and delivery of gout management in primary care, so that funders can understand the critical components of a successful gout management programme. Synergia has been contracted to complete a process and outcome evaluation focused on two successful gout management programmes; Gout Stop and Owning My Gout (OMG). Data collection was completed between November 2019 and January 2020 for reporting in February 2020.

This report presents the findings from the evaluation of these two programmes and the insights and considerations for future programme roll out developed from a synthesis of this evidence.

The programmes

Usual gout management care requires people to visit their GP frequently and have blood tests regularly in order for the painful symptoms of a gout flare to be controlled (by nonsteroidal anti-inflammatory drugs (NSAIDs), prednisone or colchicine) and the titration of medication (allopurinol) to lower and maintain their serum urate (SU) to a safe level (under 0.36mmol/L for most people). Usual care is highly varied in practice and isn't working well, particularly for Māori and Pacific peoples, and these two gout programmes are designed to address barriers to treatment and management of gout for their communities:

> Gout Stop is a 91-day gout management programme provided by Mahitahi Hauora PHE. The programme began as a pilot in 2015 and is now district wide across Northland District Health Board (35 pharmacies and all general practice). The programme centres around a model of collaboration between GPs (who prescribe a four-stage gout medication pack pre-loaded in MedTech), community pharmacists and kaiāwhina, working together to improve accessibility to medication and health literacy.
>
> Owning My Gout is a community pharmacist and nurse led collaborative gout management model in a pilot started in 2015 that included six community pharmacies and partner primary care practices in the Counties Manukau region. This collaborative model of care has GPs issue a standing order for community

[1] HQSC Atlas of Healthcare Variation https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/

pharmacists to prescribe gout medication. The practice nurse and pharmacist build health literacy in patients and the pharmacist titrates urate lowering medication guided by monthly point of care testing to achieve the recommended serum urate levels. This programme is in the process of expanding to 22 community pharmacies in the Counties Manukau District Health Board.

Evaluation of the gout management programmes

This mixed method evaluation design has used the following data sources

- Programme data from Gout Stop (June 2015 to June 2019, n=1421 enrolments) and OMG (October 2015 to December 2019[2], n= 158 people enrolled).
- Interviews with programme leads/stakeholders (six), providers (seven) and clients (three).

Analysis and synthesis of findings was supported by a sensemaking session with evaluation and programme stakeholders in January 2020. The small number of interviews from OMG providers and with clients from the programmes, limits the level of evidence relating to the delivery and outcomes of the education components of the programmes.

Gout programme enrolment

Both gout management programmes are achieving equity of access **for Māori and** Pacific peoples that considers both their population profile and level of need. Gout is often associated with older people but a third or more of those enrolled on both programmes are also aged under 45. Providing such access for younger people with gout is a valued feature of the programmes, as younger people can derive the greatest preventative benefits from appropriate medication and treatment. Programmes were enrolling a higher than expected proportion of males (around eight in ten people).

Gout programme participation

Both gout management programmes have around a quarter of enrolments drop out of the programme around the time the painful acute symptoms of gout have passed; 24% of Gout Stop patients do not collect their second prescription pack, and 27% of OMG patients do not have a second contact with the pharmacy recorded. Providers are aware of this and employ several responses to minimise it. Responses include timing the Gout Stop kaiāwhina input to be delivered at this time point, dispensing allopurinol early to encourage ongoing persistence and enabling reconnection or re-enrolment on the gout managing programme at any time. Additionally, programmes were less likely to retain **Māori, Pacific and younger people** than those of other ethnicities or older people, as these groups experience greater barriers to access.

Achieving clinical outcomes

The programmes have different structures and definitions of success, so are not directly comparable:

- Gout Stop measures successes as reaching SU <0.36mmol/L within 91 days. Of the 1421 enrolments that had occurred more than 91 days ago, around half (47%) completed the programme with, 253 (18%) reaching the SU target, 167 (12%) continuing with titration.

[2] The majority (114) of these people were enrolled in or after 2017

- OMG measures success as SU <0.36mmol/L for three months and is not a time limited programme. Of the 148 people on OMG for three or more months, 48 (29%) had SU <0.36mmol/L at their last three recordings and a further 5 (3%) were continuing with titration. It took around six months (median 5.3 months) for this SU to be reached.
- Programmes were more successful at maintaining engagement with Non-**Māori** Non-Pacific peoples and as a result, this group was more likely to achieve clinical success.
- The programmes do not engage with patients long enough to determine a successful transition to long term allopurinol; the ultimate programme aim and a result that could be directly compared with trends in Health Quality and Safety Commission's Atlas of Variation for Gout and PHARMAC's Medicine Access Equity Monitoring and Outcomes Framework data insights, which is under development. These results, along with the improvements in health literacy, should position patients well on that journey to long term gout management.

Improving health literacy

Education components of programmes are designed to build health literacy in providers and patients are a key difference to usual care. Though limited, the feedback we received from providers, stakeholders and the patients suggested this intent was being realised. Feedback emphasised the importance and value of an iterative, rather than transactional approach, to building health literacy of providers and patients.

Educational outcomes for providers were identified as updated gout clinical knowledge, local programme processes and knowledge to support building health literacy in patients. Educational outcomes for patients related to their understanding of gout causes and triggers, the need for medication and the personal benefits for them of managing gout with medication long term.

Building provider and patient health literacy was an important programme component to address bias, de-stigmatise gout and encourage and enable people to access care.

Programme contributions

The value chain created by the programmes enables the assumption that the programmes have contributed to the identified benefits for patients and communities. The programmes have also contributed to the broader health system by promoting integrated teamwork, contributing to health equity, reducing the burden of gout on the sector through a management focus, and providing good value for the resource required locally. Both programmes have continued to develop iteratively and have identified improvements to enhance or sustain programme benefits.

Responding to barriers

Patients experience several barriers to engaging with gout programmes. These include those generic to primary care, such as cost, travel and availability, as well as those more specific to gout, such as timely access to labs, over the counter pain relief options and the reduced incentive to complete the programme when pain fades. **Patient's** preconceptions relating to gout were identified as strongly influencing participation; this includes old beliefs about the causes of gout, whakamā or shame associated with gout and lack of acceptance that gout is a long-term condition.

Good programme design can reduce some of these access barriers and the effective building of health literacy is important to support behaviour change, and programme participation. Both gout management programmes provide standardised pathways for all patient groups; further differentiation may improve programme participation.

Collaborative healthcare service delivery in primary care

The interdisciplinary delivery of gout programmes represents a shift in the traditional roles of GPs, nurses and pharmacists and introduces opportunities for practice nurses and non-regulated roles, such as kaiāwhina.

While pharmacists we engaged with were keen to embrace this opportunity to work to top of scope there is awareness of a more mixed reaction from general practice for a variety of philosophical, clinical practice and business reasons.

The main incentive provided by the programmes has been the funding of community pharmacy activity; Gout Stop pharmacists are paid on each programme entry and (successful) completion. OMG pharmacists have only recently begun to be paid and this is per patient contact. The pharmacists we spoke with were passionate about lifting the health of their communities indicating community pharmacy funding may be an enabler, but without leadership and commitment, may not be a sufficient incentive to drive effective pharmacy delivery of gout management programmes.

The Gout Stop **kaiāwhina role** provides an informed, trusted and relatable source of information and encouragement for patients. Support provided to most patients is by a one-off phone conversation, but there is flexibility to respond to different needs and provide more support to patients and their whānau. As such, the kaiāwhina is a valued link between healthcare providers and patients. The **kaiāwhina also promotes awareness** raising about gout in the wider community, such as workplaces and marae to address outdated beliefs about gout and encourage and help people to seek support.

We were not able to interview any OMG practice nurses but others described their role as overseeing the programme for the practice and supporting patients with building their health literacy.

Feedback identified the value for patients of engaging with providers in a range of roles where they provided consistent key messages and individualised support.

Informing future roll out

The two gout management programmes are not an instant panacea to all the barriers providers and patients experience, but they have enabled real world learning to inform the future roll out of gout programmes. The programmes have enabled the evaluation to identify the following critical success factors in terms of programme components and enablers of delivery.

Essential core components of gout management programmes are:

- Easy access to medicine for patients
- Activities to build provider and patient health literacy
- Accessible gout information resources
- Awareness raising.

The key enablers of delivery have been identified as:

- Systems to provide easy access to the right medication
- Systems to share patient information
- Collaborative leadership of gout management programmes
- A common gout programme framework and measurement model
- Sound planning and ongoing improvement activity.

These components and enablers will need to be adapted to local context. It is recommended that programmes are set up not as pilots but with a view to ongoing quality improvement and long-term sustainability. Future gout programme rolls out will require resourcing, for example for community pharmacy participation, and benefit from leadership at national, district and organisational levels.

Gout is a significant health issue for New Zealand. Gout is also an equity issue and our commitment to Te Tiriti o Waitangi requires a response to the current inequitable access and outcomes for Māori. Evidence and insights from the evaluation of two gout management programmes that go beyond usual care show that gout programmes provide value not only to patients, whānau and communities, but also to the health sector through their interdisciplinary delivery.

1. INTRODUCTION

Gout is a chronic long-term condition that impacts people's quality of life and is a social and economic burden. The effects of gout are preventable but only one in four people in New Zealand with gout is on long term medication to control gout's damaging effects. Māori and Pacific peoples have two to three times the prevalence of gout than other ethnicities and have poorer access to the long-term right medication[3].

Arthritis New Zealand (Arthritis NZ), PHARMAC and Health Quality and Safety Commission are seeking to contribute to the evidence base around what works to successfully manage gout. Synergia has been contracted to complete a process and outcome evaluation focussed on two gout management programmes; Mahitahi Hauora Primary Health Enterprise's (PHE) Gout Stop programme, and Counties Manukau Health's Owning My Gout programme (OMG), now known as the Community Pharmacy Gout Management Programme. The evaluation has been funded by Arthritis NZ, PHARMAC and the Health Quality Safety Commission (HQSC). PHARMAC has supported this evaluation as it has a strategic priority to eliminate inequities in access to medicines. Gout management has been identified as one of the priority conditions for this mahi in access equity. Data collection for the evaluation was completed between November 2019 and January 2020.

This report presents the findings from the evaluation of these two programmes and the insights and considerations for future programme roll out from a synthesis of this evidence.

District Health Boards (DHBs) and Primary Health Organisations (PHOs) are the intended audience for the evaluation. There are a small number of gout management programmes based on best practice guidelines throughout New Zealand, but knowledge of their development, learning and evidence of success is not easily accessible. By contributing to the evidence base this evaluation is intended to inform DHBs and PHOs about the effective components of gout management programmes and what to consider and expect in terms of design and implementation.

1.1 Report structure

The report begins with some background context about gout in New Zealand and follows with a summary of the evaluation approach and methodology. The report then describes the two programmes before unpacking the process of programme delivery and the factors that influence it. Programme outcomes and benefits are described and summarised before recommended developments are identified. Before the final summary, the report identifies the critical design and implementation considerations for future programme roll out.

Green shaded boxed highlighting key points are inserted throughout the report.

A glossary of acronyms used in the report can be found in the appendix.

[3] HQSC Atlas of Healthcare Variation https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/

2. BACKGROUND AND CONTEXT

2.1 Gout in New Zealand context

Gout is a chronic condition caused by excess monosodium urate crystal deposition in and around joints, ligaments and tendons. Gout is caused by high levels of urate in the blood as weight, impaired kidney function and genetic factors prevent the kidneys from eliminating urate. Acute gout causes painful inflammation and swelling, limits function and has a negative impact on quality of life.

New Zealand research has shown that Māori and Pacific peoples are much more likely to have these genetic factors than other groups[4]. Māori and Pacific peoples are two and three times more likely to get gout, and, at a younger age and more severely than other population groups[5].

There is also sub-optimal and geographical variation in relation to gout in that rates of regular treatment with urate-lowering medicines are poor across all population groups[6] but especially Māori and Pacific peoples who are less likely to receive regular urate-lowering medications despite having a higher prevalence of gout. In addition, Māori and Pacific peoples are five to ten times more likely to be admitted to hospital with gout than other population groups. Poor and inequitable access to medication is a trend that the Gout Atlas of Healthcare Variation identifies as not improving. PHARMAC has highlighted the importance of supporting equity through their medicines access equity work and the theory of change informing actions to improve access to medicines. The prevalence of diagnosed gout is increasing. The contributors to this trend are multifaceted as the following quote summarises:

Barriers ... include, not adhering to best practice guidelines, delaying initiation of preventative therapy, suboptimal monitoring, long standing community, patient and beliefs that gout is caused by food and drink, patient non-adherence and health professionals biases. Furthermore, recent research has identified that the model of care for chronic arthritis management including gout in New Zealand is fragmented due to the lack of collaboration among health care providers[7].

Usual care requires people to visit their GP frequently, and have blood tests regularly, in order for the painful symptoms of a gout flare to be controlled (by NSAIDs, prednisone or colchicine) and the titration of medication (allopurinol) to lower and maintain their urate to a safe level (under 0.36mmpl/L for most people). Usual care is highly varied in practice and isn't working well, partially for Māori and Pacific peoples,

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[4] Merriman, T. R., Choi, H. K., & Dalbeth, N. (2014). The genetic basis of gout. *Rheumatic Disease Clinics*, *40*(2), 279-290.
[5] HQSC Atlas of Healthcare Variation https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/
[6] HQSC Atlas of Healthcare Variation https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/
[7] Dalbeth, N., Gow, P., Jackson, G., Shuker, C., Te Karu, L., Gerard, C., & Winnard, D. (2016). Gout in Aotearoa New Zealand: are we going to ignore this for another 3 years?. *NZ Med J*, *129*(1429), 10-3.

The two programmes included in this evaluation are programmes that have demonstrated success, have sought to address some of these barriers and are sources of learning for other regions and programmes. These are:

Gout Stop a 91-day gout management programme provided by Mahitahi Hauora PHE. The programme began as a pilot in 2015 and is now district wide across Northland District Health Board (35 pharmacies and all general practice). The programme centres around a model of collaboration between GPs (who prescribe a four-stage gout medication pack pre-loaded in MedTech), community pharmacists and kaiāwhina, working together to improve accessibility to medication and health literacy.

Owning My Gout is a community pharmacist and nurse led collaborative gout management model in a pilot started in 2015 that included six community pharmacies and partner primary care practices in the Counties Manukau region. This collaborative model of care has GPs issue a standing order for community pharmacists to prescribe gout medication. The practice nurse and pharmacist build health literacy in patients and the pharmacist titrates urate lowering medication guided by monthly point of care testing to achieve the recommended serum urate levels. This programme is in the process of expanding to 22 community pharmacies in the Counties Manukau District Health Board.

3. EVALUATION OF THE GOUT PROGRAMMES

This section describes the aim, objectives and key evaluation questions developed for the evaluation and describes the approach, methodology and data collection processes.

3.1 Evaluation aims and objectives

The aim of this evaluation is to contribute to the evidence base around what works for the effective treatment and management of gout in primary care. The evaluation will present a synthesis of what works well so that funders can understand the critical components of a successful gout management programme.

Table 1: Evaluation objectives and key evaluation questions

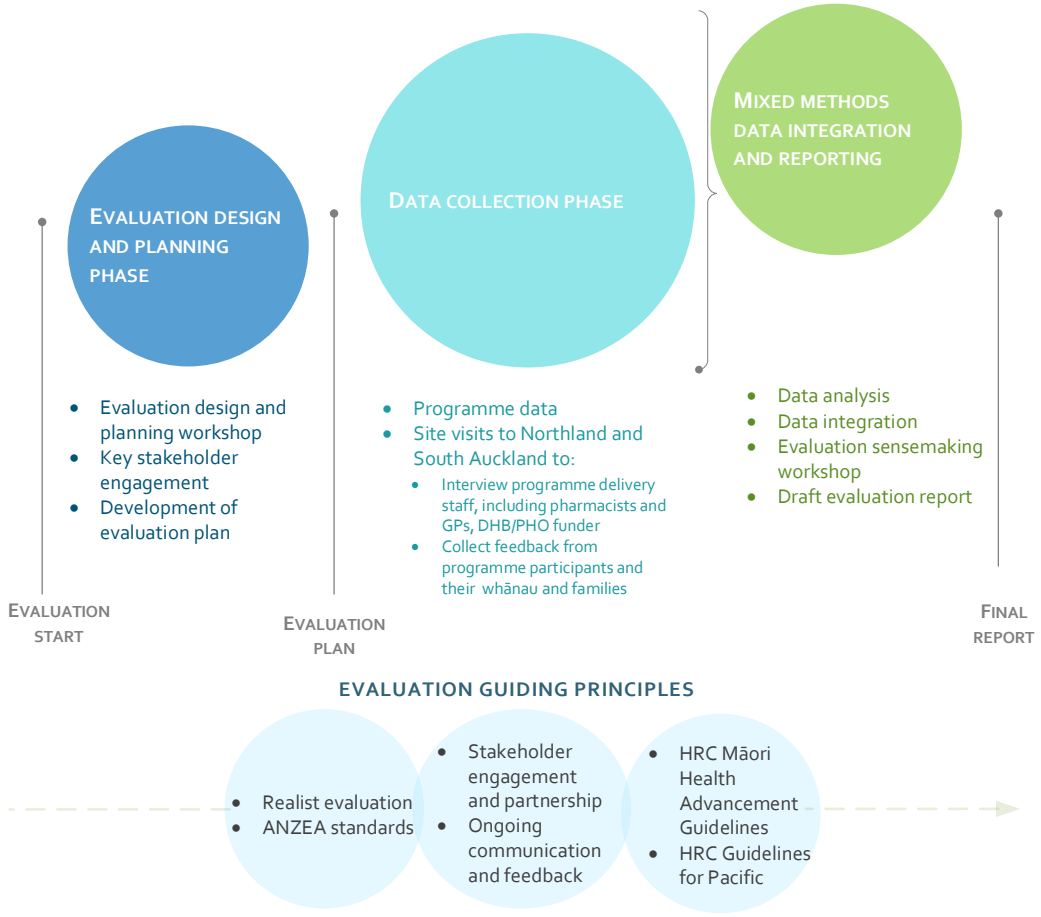
Evaluation objective	Key evaluation Questions
Documenting the programmes	How was each programme delivered? • What differed between the two? • What approaches were used for different patient groups (including at different stages of their treatment pathway)? • Are the programmes fit for purpose? Were there any unintended consequences?
Process evaluation objectives	
Determine how well the programmes have engaged and been delivered to the different clinical patient groups, including patient groups who were along various stages along the therapeutic pathway for gout.	To what extent were the programmes appropriately focussed towards patient groups who were at various stages along the therapeutic pathway for gout? • E.g. Starting allopurinol for the first time, restarting allopurinol, and titrating dosage for those who had not yet reached the target of 0.36mmol/L.
Identify patients' treatment experiences and pathways within the programmes.	Are participants being reached as intended? • How satisfied are they? • Why did participants with gout stay or not stay engaged in the programmes?
Review the appropriateness of the measures used for the programme and identify opportunities for improvements.	Were the measurements used for the programmes appropriate and how could the measurement regimes be improved?

Outcome evaluation objectives	
Determine programme success in terms of clinical and educational outcomes for patients and the contribution of each programme to this success.	Comparison of clinical and educational outcomes across both programmes. • Did either programme produce the intended outcomes in the short, medium and long term? • For whom, in what ways, and in what circumstances? • What workforce development occurred, how this came about, and how has this contributed to programme success? • What other factors have impacted on the delivery and success of programmes?
Determine programme success in terms of supporting system outcomes and alignment to government/DHB/PHO priorities.	How well do the programmes align with other government/DHB/PHO priorities? • Did either programme improve equity in terms of Māori and Pacific peoples? • How have programmes supported pharmacists and other health professionals to work to top of scope?
Determine the value of having incentives and their contribution to key outcomes.	What incentives were offered to practices, pharmacies and participants in these programmes? • Why were incentives offered and when were they used? • What effect did the incentives have and for how long? • Have the programmes provided value for money?
Summarise the key factors relevant to successful programme design and implementation.	What were the critical success factors? • Including, but not limited to, the interest, passion and drive of the respective people leading each project? • To what extent can behaviour changes (health professionals and participants e.g. prescribing behaviour, allopurinol uptake and adherence) be attributed to the programmes? • Are there any differences in outcomes for pharmacies co-located in primary care practices and community pharmacies?
Identify improvements to enhance the implementation and effectiveness of the programmes.	What improvements have been identified? • By those connected to and participating. • From a synthesis of evidence.

3.2 Evaluation approach and design

Synergia has completed a process and outcome evaluation of two gout programmes and has worked collaboratively with the project team and key stakeholders (programme leads) to deliver a mixed methods evaluation across three main phases illustrated in Figure 1. This diagram also identifies the evaluation approach, including the key methods and outputs from each phase.

Figure 1: Evaluation approach, methods and key outputs



The evaluation design and planning phase included a review of key documentation to support our understanding of the two gout programmes and their delivery. The evaluation planning and design workshop with the project team built on this early contextual understanding and resulted in a shared understanding of the evaluation in terms of its purpose, scope and key outputs.

3.3 Evaluation methods and data collection

This evaluation was carried out using a mixed methods approach designed to support insights that have both breadth and depth.

- Access to providers for interview was facilitated by programme leads. Access to patients was to be facilitated by programme providers. The evaluation had a short timeframe to complete data collection prior to Christmas 2019 and this impacted on the number of GPs, pharmacists and patients we were able to interview, particularly for the OMG programme.
- Programme data was accessed from the respective programmes and organisations (as available) to understand the demographic profile of patients, clinical profile on entry into the programmes, activities within the programmes (such as monitoring) and clinical outcomes (urate levels). This data was varied in its content and, with the Gout Stop data dating from June 2015 to June 2019; while the Owning My Gout dataset dated from October 2015 to December 2019.

- Interviews: A total of 16 interviews were used to inform the qualitative insights into this evaluation. A two-day site visit took place in Northland in late-November 2019, where programme leads, pharmacists and GPs were interviewed in both Whangarei and Kawakawa. Clients of the Gout Stop programme were interviewed over the phone in the following weeks. A total of 11 individuals were interviewed for the Gout Stop programme. Five interviews took place to support insights into the Owning My Gout programme, including the programme leads, a pharmacist and GPs. Because of the timing we were unable to be connected with patients from this programme.
- The evaluation team has interpreted and synthesised the evidence from across the different data sources to answer the key evaluation questions. Data has been analysed using descriptive statistics for the quantitative service data, and thematic analyses of the qualitative data. Evaluation questions have guided the mixed methods analysis, which was supported by a sensemaking session with stakeholders on 23 January 2020.

3.3.1 Limitations

The number of interviews complete for both programmes was fewer than anticipated within the timeframe available for the evaluation, particularly for OMG and for programme participants from both programmes. This means:

- The themes from the views and experiences expressed may miss themes identified from a broader range of provider or patient experiences.
- There is potential bias in that provider staff interviewed were those leading and/or supportive of the programmes.
- Very limited insight into the general satisfaction of patients using the programmes and the broader delivery and experiences of patients enrolled in the programmes.
- The nurse role in OMG is described only from the perspective of others.

4. THE GOUT PROGRAMMES

Stop Gout and OMG are designed to promote best practice management of people with gout, which includes short-term prophylaxis and titration of allopurinol so people can transition to a long-term dose that keeps their urate levels under <0.36. Gout Stop does this with a series of four medication packs embedded in MedTech, OMG enables pharmacies to titrate and dispense medication under a Standing Order. Patients' health literacy is built with pharmacists, nurses (OMG) and a kaiāwhina and pharmacists (Gout Stop). Gout Stop is district wide; OMG is a very small-scale pilot now expanding.

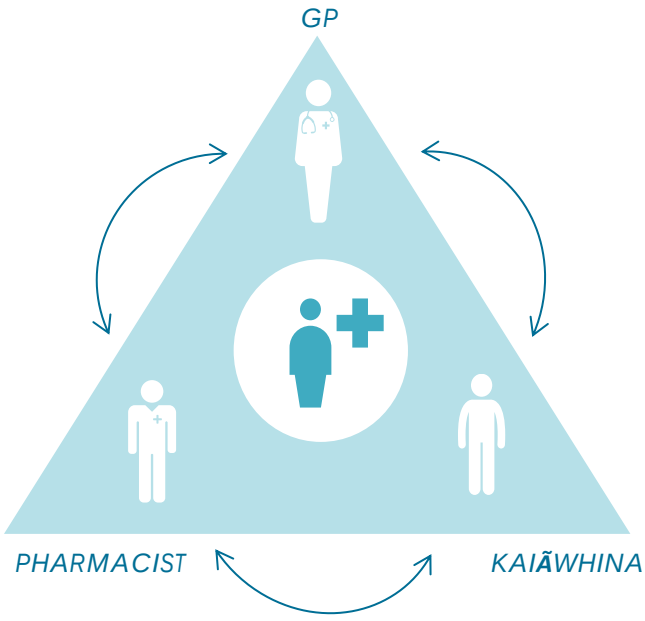
This section describes Gout Stop in Northland and Owning My Gout in Counties Manukau DHB. The components and delivery of the two programmes will be described and a pathway through each programme, using a patient lens, illustrated.

4.1 Gout Stop

According to the Ministry of Health, Northland has a population that is significantly older than the national average, and the percentage of Māori (33%) is twice as high as the rest of the country. Northland also has high levels of deprivation, with (38%) in the most deprived quintile[8]

The programme was originally intended to discover and reduce barriers to accessible gout treatment and described by programme leads as having a specific focus on Māori and Pacific peoples to support the achievement of equity in gout-related health outcomes.

Figure 2: Gout Stop model of collaboration



The Gout Stop programme began in 2015 as a pilot, funded for three years by Manaia PHO (now part of Mahitahi Hauora Primary Health Entity (PHE)). The programme continues to be led by Mahitahi Hauora PHE, in partnership with community pharmacy and general practice. Over an 18-month period, the programme grew to cover the entirety of the Northland region, with all but one of its 36 pharmacies participating in the programme. The programme became business as usual with the establishment of the PHE in July 2019. The programme is identified in the local HealthPathways (an online decision support resource for primary care).

Gout Stop aims to simplify gout management. Key features of the model include:

- The "Gout Stop Pack" prescription options, with variations of the combination of medications to be prescribed for an acute gout attack, followed by long term

[8] https://www.health.govt.nz/new-zealand-health-system/my-dhb/northland-dhb/population-northland-dhb

urate lowering medication with long term prophylaxis pain relief. The pack options include various combinations of prednisone, allopurinol and colchicine dependent on the patients' renal function and diabetes status. There are now four packs in total, of various time lengths, for a period of 13 weeks (91 days). Figure 3: Gout Stop Pack prescription options based on renal function and diabetes status.

Figure 3 describes the different options in more detail.

Figure 3: Gout Stop Pack prescription options based on renal function and diabetes status

Renal function (eGFR)	Blister Pack 1 (14 days)	Blister Pack 2 (28 days)	Blister Pack 3 (28 days)	Blister Pack 4 (21 days)
Option 1 eGFR >60	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 100 mg daily Colchicine 500 mcg twice daily	Allopurinol 200 mg daily Colchicine 500 mcg twice daily	Allopurinol 300 mg daily Colchicine 500 mcg twice daily *Laboratory form
Option 2 eGFR 31–60	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 50 mg daily Colchicine 500 mcg once daily	Allopurinol 100 mg daily Colchicine 500 mcg once daily	Allopurinol 200 mg daily Colchicine 500 mcg once daily *Laboratory form
Option 3 eGFR 10–30	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 50 mg every other day Colchicine 500 mcg every other day *Laboratory form	Allopurinol 50 mg daily Colchicine 500 mcg every other day *Laboratory form	Allopurinol 100 mg daily Colchicine 500 mcg every other day *Laboratory form
Diabetes alternative eGFR >60	Naproxen 500 mg twice daily	Allopurinol 100 mg daily Colchicine 500 mcg twice daily	Allopurinol 200 mg daily Colchicine 500 mcg twice daily	Allopurinol 300 mg daily Colchicine 500 mcg twice daily *Laboratory form

- A kaiāwhina role to work with patients and the community. The kaiāwhina role replaced the Arthritis NZ nurse educator who had been involved at the beginning of the pilot. The use of a non-regulated heath worker was intentional, to relate to clients, using non-medicalised language to communicate and build knowledge and skills with patients.
- Pharmacies ask patients for permission for the kaiāwhina to contact them and contact is usually made two weeks into the programme. Home visits or follow up calls can be arranged but most patients only received a one-off phone call so persistence in taking the medication could be supported. The kaiāwhina also visits workplaces, marae and other places where this particular group of patients tend to gather, to raise awareness through serum urate testing (with the BeneCheck© meter) and providing written patient resources on gout.
- The programme has been monitored by a strategic and operational oversight group, comprised of a clinical lead, programme coordinator, general practitioner, community pharmacist, specialist rheumatology nurse, gout kaiāwhina and the funder. The group met monthly during the pilot phase of the programme, and now, post pilot, is to meet annually going forward. The Clinical Director of Mahitahi Hauora also monitors the programme at a high level.
- Key learnings and adaptations have been the introduction of a diabetes gout pack and the employment of a local kaiāwhina. The kaiāwhina is a Māori male who brings mana to the role along with local networks. This was identified as a significant advantage for the programme.

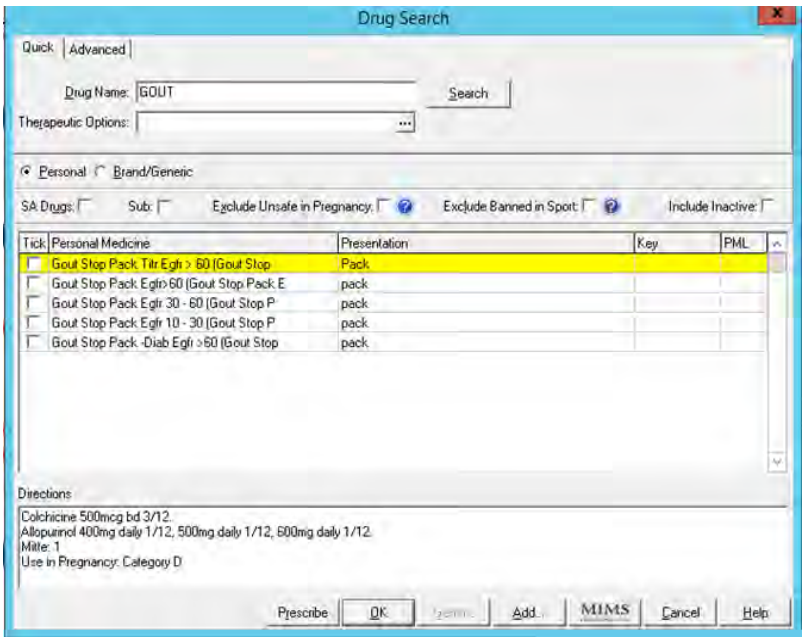
4.1.1 Patient pathway

The patient pathway through the Gout Stop programme starts with a presentation of a patient with acute gout to a general practice. Patients that are diagnosed with gout and,

have experienced two or more flares in a year, are enrolled into the programme (with consent) and prescribed one of the four medication pack options depending on their renal function (eGFR). The pack options are pre-loaded into Medtech software, for ease of use (Figure 4).

Pharmacy receives the prescription from the patient and issues a laboratory form to the patient to test their serum urate levels and other markers. The pharmacist then communicates to the patient's GP, the patient's initial serum urate levels, last dose of allopurinol and date of last prescription to finish. Following the programme, the patient revisits the GP after the 91-day course to check serum urate level and other lab results.

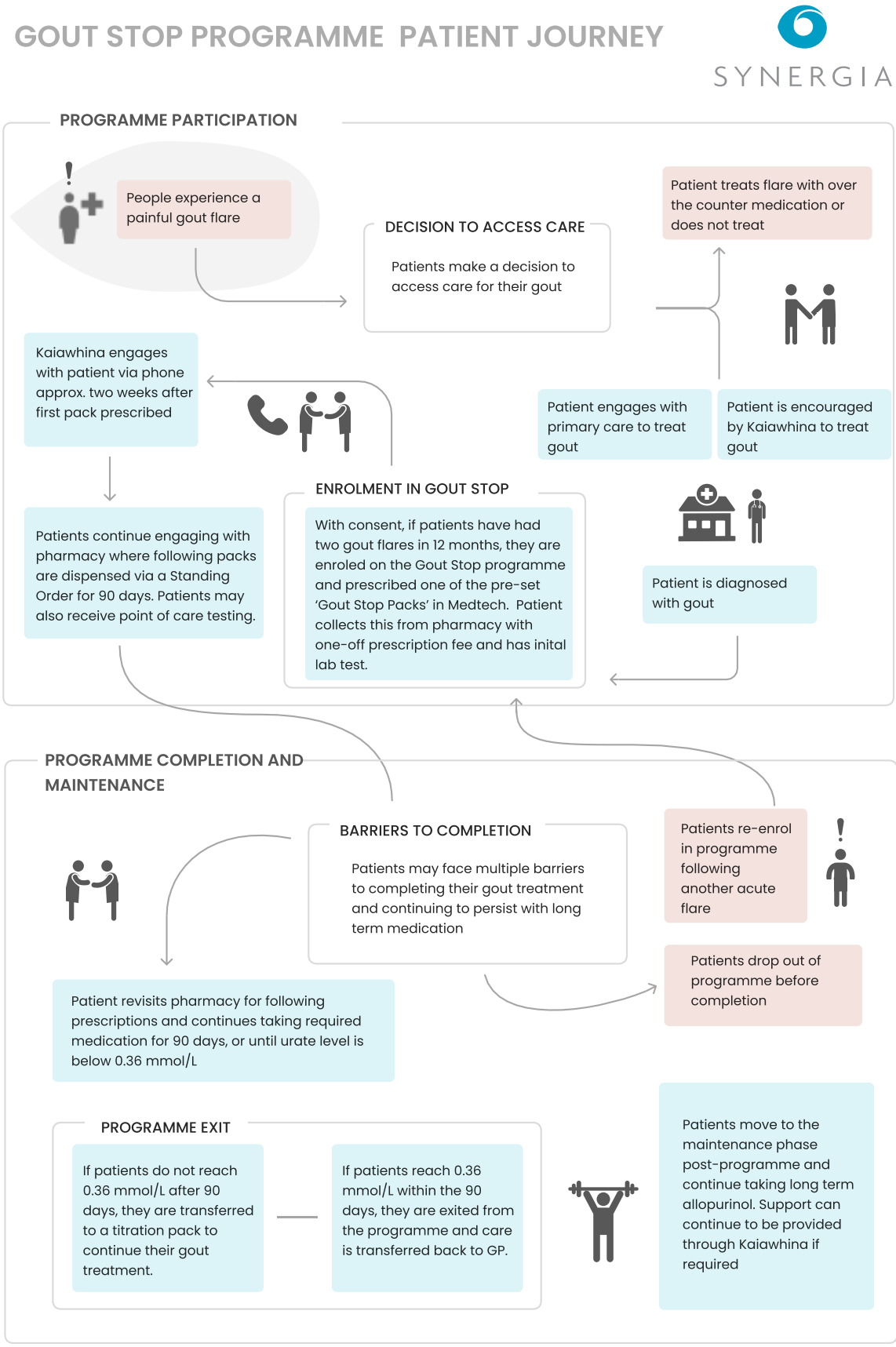
Figure 4: Gout Stop options in Medtech



If the serum urate level is below 0.36mmol/L, allopurinol maintenance therapy begins based on the last allopurinol dose. This continues as long-term medication under GP care. If the serum urate is above 0.36mmol/L, allopurinol is prescribed in a titration regime, increasing monthly with prophylaxis cover until the target is reached. Allopurinol is then continued as a long-term medication under GP care.

Figure 5 on the following page describes the programme pathway in more detail and is based on the programme descriptions and feedback on the pathways provided.

Figure 5: Gout Stop patient journey



Patient decisions to access care and the barriers to completing programmes of treatment are not programme specific and are explored and discussed in Section 6 of this report.

The Gout Stop programme published its positive results in the Journal of Primary Health Care in 2019. The research phase of the programme was from 2015-2017, during which time 160 clinicians prescribed therapy at 887 patient presentations[9]. The programme was deemed to be working well for Māori and Pacific with 71% of participants identifying as Māori or Pacific. The publication reports that the completion rate was higher for Non-Māori, Non-Pacific (84%) than it was for Māori and Pacific patients (55%). However, the research reports that following programme completion, 68% of Māori and pacific patients continued to take allopurinol, with 65% of Non-Māori, Non-Pacific doing the same. In the publication, patients were reported as having a high level of satisfaction with the programme and a reduction in prescribed non-steroidal anti-inflammatory drugs (NSAIDs) without urate-lowering treatment (ULT) across Northland was achieved. [10]

4.2 Owning My Gout

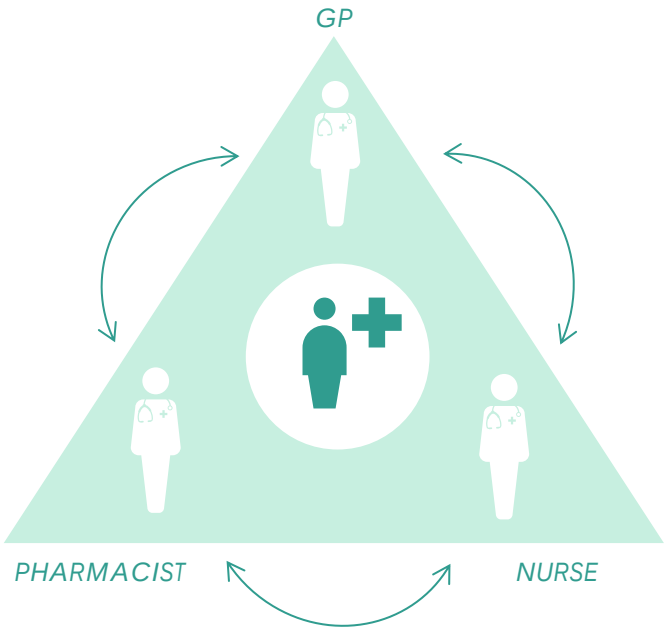
The South Auckland region served by Counties Manukau DHB has been labelled as the 'gout capital of the world'[11]. The population in this region tends to be much younger than the national average and has the highest proportion of Pacific peoples living in the region (21%) than other parts of New Zealand[12]. As in Northland, Counties Manukau DHB has high deprivation with (37%) in the most deprived quintile.

Owning My Gout is a gout management programme being piloted through Counties Manukau DHB. The model explores using community pharmacists alongside practice nurses to lead the delivery of gout management services to patients. This pilot began in July 2017 and recruited six pharmacies to participate. Originally, the intention was to recruit co-located pharmacies and general practices, however a variety of practice and pharmacy types were included in the pilot. These pharmacies and general practices were motivated by the potential health gain for their community. A payment for the community pharmacists was introduced in late 2018 when funding became available. The aim of the project has been to enable 90% of patients to self-manage their gout, with primary drivers identified to facilitate this, including; activated clinicians, activated patients and a collaborative model of care. Key features of this programme include:

[9] Lawrence, A., Scott, S., Saparelli, F., Greville, G., Miller, A., Taylor, A., & Gow, P. (2019). Facilitating equitable prevention and management of gout for Māori in Northland, New Zealand, through a collaborative primary care approach. *Journal of Primary Health Care*, *11*(2), 117-127.
[10] HQSC Atlas of Healthcare Variation https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/
[11] Phone, D. (201). Owning My Gout- A Pharmacist-led collaborative gout management model at Counties Manukau DHB. Conference presentation
[12] https://www.health.govt.nz/new-zealand-health-system/my-dhb/counties-manukau-dhb/population-counties-manukau-dhb

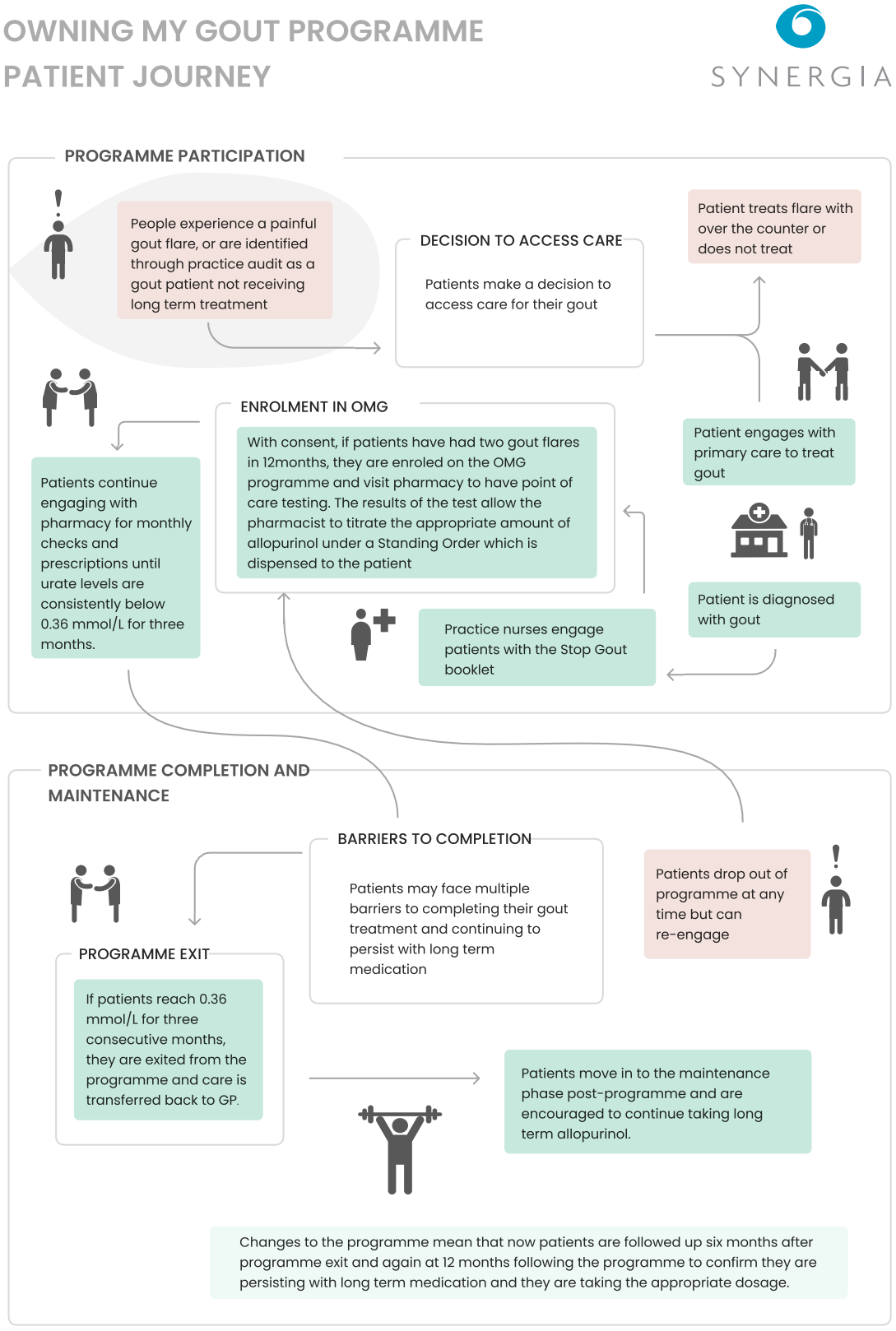
- The programme involves local community pharmacists using a Standing Order to titrate allopurinol in collaboration with GPs and practice nurses. In early phases of the pilot, a proactive approach was taken to identify programme participants. A query build identified patients who had showed symptoms of a gout attack and invite them to participate in the programme pilot. Practice nurses have a practice champion role and oversee and manage the process and interface between general practice and pharmacy. The nurses also provide gout education to patients.

Figure 6: Owning My Gout model of collaboration



- The pilot with six pharmacies and partnering practices has been led by Counties Manukau DHB, and following pilot success, a business case was put forward and accepted in 2019 for the programme to fund an expansion to include up to 22 pharmacies. This report includes data form the original pilot only.
- Pharmacists use a BeneCheck © meter to test serum urate levels. The pharmacist then titrates the allopurinol dosage based on the urate levels and dispenses a monthly prescription. The patient is required to return to the pharmacy each month for more point of care testing, and this process continues until the patient has maintained a serum urate level of below 0.36mmol/L for three consecutive months.
- Following this, care is transferred back to the patient's GP, who starts the patient on allopurinol as a long-term medication. The programme also makes use of an electronic shared-care plan to encourage communication and information sharing between health professionals, as well as the patient.
- The programme developed with a strong focus on quality improvement, using the Institute for Healthcare Innovation quality improvement framework which involves cycles of Plan, do, Study and Act (PDSAs) undertaken by the OMG project team.

4.2.1 Patient pathway



The Owning My Gout programme leads developed a business case to secure funding to support the programme to grow going forward. The business case highlighted some key successes of the programme including an average reduction of patient serum urate levels to below the targeted 0.36mmol/L.

The business case also highlights the impact of the programme on acute GP visits. A sample of 21 patients on the service were randomly selected to determine the number of acute GP visits prior to enrolment in the Owning My Gout programme and whilst they were on the programme. The results showed that the number of GP visits for acute gout had decreased from an average of 2.9 visits to 1.2 visits. Section 12 of this report considers the broader value of these programmes to the health system in more detail.

4.3 Similarities and differences between programmes

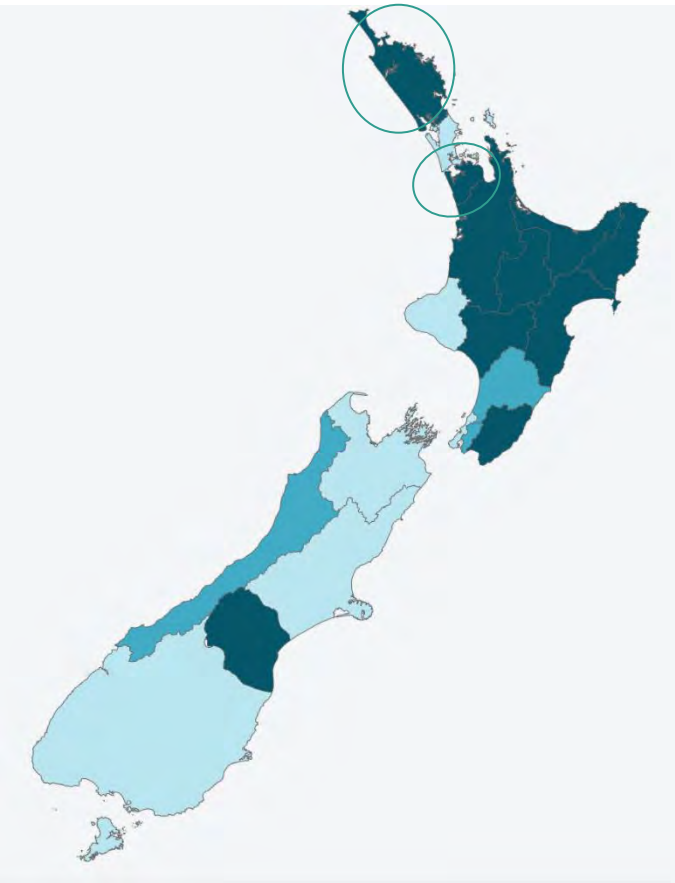
At their core, there are some considerable similarities between the two programmes. Both Gout Stop and Owning My Gout are based on best practice gout management guidelines; treating acute flares, building patients' health literacy about managing the condition and titrating to long term allopurinol usage. Both programmes are also designed to address the inequity in gout management and outcomes.

Figure 7 displays the gout prevalence by region in New Zealand[13]. The darkest shade of blue signifies the gout prevalence for that region is significantly higher than the national average, the mid-blue indicates the prevalence is in line with the national average, and the light blue signifies the prevalence for that region is significantly below the national average.

Both Northland DHB and Counties Manukau DHB regions are significantly above the national prevalence with rates of 8% and 7.6% respectively, compared with a national average of 5.3%[14].

Both regions have the need for a programme to support gout management in the community and have enough people with a

Figure 7: Map of gout prevalence in New Zealand



[13] HQSC Gout Atlas of Healthcare Variation. https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/gout/
[14] HQSC Gout Atlas of Healthcare Variation. https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/gout/

diagnosis of gout to sustain the programmes.

Both programmes have been the result of people in positions of influence who have had the passion, drive and ability to lead the collaborative activity necessary to plan and deliver the programmes.

Table 2 summarises the key programme factors that are different between programmes.

Table 2: Comparison of programme factors

Factors	Gout Stop	Owning my Gout
Implementation	Regional approach All pharmacies and general practices in the DHB.	Pilot site, 6 pharmacies and partner practices so much smaller reach.
Lead	PHE initiated and led (single PHE across the district).	DHB led.
Status of programme Dec 2019	Business as usual.	In pilot expansion phase – increasing to 22 pharmacies.
Initiation driver	Response to need.	Quality improvement and equity in primary care.
Key provider roles	GPs, Pharmacists and staff, kaiāwhina.	GPs, Pharmacists and staff, Nurses.
Contract incentive	Pharmacy payment on entry and exit. Time, overheads and consumables funded.	Pharmacy payment each contact $27.70 to fund time and consumables in expansion phase.
Prescriptions	Pre-prescribed packs 2,4,4 and 3 weeks. Free blister pack.	Pharmacists dispense monthly under a Standing Order Free blister pack.
Programme end/exit point	Measures 'success' in 91 days if SUL <0.36mmol/L achieved.	After urate levels <0.36 mmol/L for three months (monitoring up to 12 months recently introduced as part of expansion).
Information systems	Pharmacy data base. Fax referral for kaiāwhina. Pharmacy records pack option, eGFR, date packs collected, SU on exit and participation status.	Electronic shared-care plans. Pharmacy records SU against calendar month.

The following table provides more detail about key roles and responsibilities of those involved in the delivery of the gout programme.

Table 3: Comparison of key roles and functions

Key roles	Gout Stop	Owning My Gout
GP	Prescribes a Gout Stop pack. Four options depending on eGFR and diabetes status. Requests lab forms for bloods to test eGFR and serum urate levels. Refer to rheumatology specialist as required.	Prescribes prophylaxis and allopurinol under a Standing Order. Requests lab forms to test eGFR and serum urate levels. Refer to rheumatology specialist as required.
Nurse	No active role identified	Manages interface between general practice and pharmacy. Builds health literacy with patients using the Stop Gout booklet.
Kaiāwhina	Engages with patients over the phone two weeks after first prescription to build health literacy Stop Gout booklet and associated version developed by the Māori Pharmacists Association. Further contact is, as required. Engages in community activities to raise awareness about gout management in the wider district.	N/A
Pharmacist	Dispenses pack and builds health literacy with patients using the Stop Gout booklet and associated version developed by the Māori Pharmacists Association. Opportunity in some pharmacies for point of care urate testing using BeneCheck © meter.	Point of care testing of SU using BeneCheck © meter to titrate allopurinol. Dispense medication under Standing Order. Builds health literacy with patients using the Stop Gout booklet.
Patient	Sees GP for initial diagnosis and treatment. Collects four packs of medication over a 13-week period. Pays $15 for three prescribed items. Returns to GP oversight once target SU is achieved. Builds health literacy in relation to new information about gout ad persists with taking medication.	Sees GP for initial diagnosis and prescription. Attends pharmacy monthly for point of care testing and medication. Pays $15 for three prescribed items. Returns to GP oversight once target urate has been stable three months (now 12 months). Builds health literacy in relation to new information about gout ad persists with taking medication.

5. PROGRAMME DELIVERY

5.1 Programme enrolment

Gout Stop and OMG have enrolled a high proportion of Māori and Pacific peoples respectively. A third or more of those enrolled on both programmes are aged under 45 and eight in ten are male. Both programmes also experience a drop off in participation once the painful acute symptoms of gout have passed. Responses to minimise this include the timing of the kaiāwhina contact, dispensing allopurinol early to encourage maintenance and enabling reconnection or re-enrolment at any time. Further differentiation of the standard programme for key groups or needs may support continued participation.

Programme data provided by the two programmes gave an insight into the reach of the programmes. Gout Stop and Owning My Gout are at very different stages, with one programme operating district wide and considered business as usual, and the other completing its pilot phase with six participating pharmacies.

As such, programme data for the Gout Stop programme consisted of 1322 unique patients (some enrolled more than once) while the Owning My Gout programme data contained 164 unique patients. Some of these unique patients did not have all demographic information completed, so the total numbers may differ throughout this section.

5.1.1 Gout Stop demographic profile

Gout Stop programme data shows that over 60% of participants on the programme identify as **Māori**, 4.9% identify as Pacific, and 32.5% identify as Non-**Māori**/Non-Pacific. These proportions indicate effective reach into the general DHB population for enrolment there are (33% Māori, 2% Pacific, and 64% Non-Māori/Non-Pacific). Table 4 below presents the demographic programme participation statistics in more detail.

Table 4: Gout Stop demographics, age and ethnicity of unique participants with data available n=1308

Age	**Māori**	Pacific	Non-**Māori**/Non-Pacific	Total
15-29	7.4% (97)	0.9% (12)	1.1% (14)	9.4% (120)
30-44	17.1% (224)	1.8% (24)	4.9% (64)	23.8% (308)
45-64	27.2% (355)	1.5% (20)	13.0% (171)	41.7% (540)
65+	12.0% (156)	0.6% (8)	12.5% (191)	25.1% (355)
Grand Total	62.6% (817)	4.9% (64)	32.5% (440)	100.0% (1308)

Over two thirds of the programme participants (68%) were over the age of 45 across the programme. Māori are significantly over-represented in the younger age brackets, making up 72% of participants under the age of 44 (23% of total participants). Tables 7 and 8 in this report discuss the gout burden of disease in further detail with a comparison against the reach of the programmes.

5.1.2 OMG demographic profile

Owning My Gout data reflects the significant Pacific population in the Counties Manukau DHB region. The Pacific population represent 56% of the total programme participants, with

25% Māori, and the remaining 18.5% Non-Māori/Non-Pacific. These proportions indicate effective reach into the general DHB population (21% Pacific, 15% Māori, and 63% Non-Māori/Non-Pacific.) Table 5 below presents the demographic programme participation statistics in more detail.

Table 5: Owning My Gout demographics, age and ethnicity of unique participants n=158

Age	**Māori**	Pacific	Non-**Māori**, Non-Pacific	Total
15-29	2.5% (4)	8.2% (13)	5.1% (8)	15.2% (25)
30-44	7.0% (11)	16.5% (26)	8.5% (14)	32.0% (51)
45-64	13.9% (22)	26.6% (42)	6.3% (9)	43.5% (73)
65+	1.9% (3)	5.1% (8)	2.5% (4)	9.5% (15)
Grand Total	25.3% (40)	56.3% (89)	22.4% (29)	100.0% (164)

Just under half (44%) of Owning My Gout programme participants were between the ages of 15 and 44. Over half of these identified as Pacific (24% of total participants).

When exploring the breakdown of Pacific ethnicities in the Owning My Gout programme participants, majority were Samoan (36%), Tongan (29%) and Cook Island Māori (24%). This reflects reasonably well, the Pacific ethnic profile of Counties Manukau DHB. Table 6 below shows the full ethnic breakdowns for Pacific ethnicities in Owning My Gout.

Table 6: Owning My Gout breakdown of Pacific ethnicities

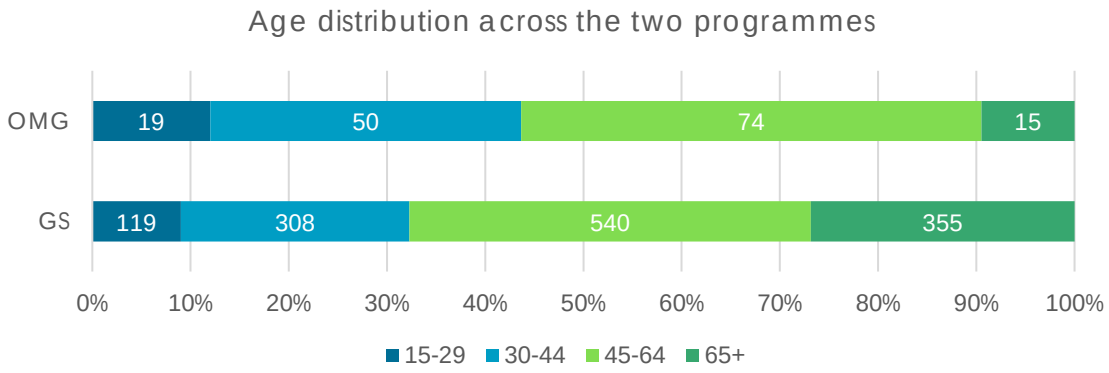
Pacific ethnicity	Percentage
Samoan	36% (32)
Tongan	29% (26)
Cook Island Māori	24% (21)
Niuean	4% (4)
Fijian	3% (3)
Tokelauan	2% (2)
Pacific Island (Other)	1% (1)
Total	100% (89)

5.1.3 Reaching younger people

Gout is perceived as a condition that affects older people and those reached by the programmes reflects this. However, it is the proportion of younger people in these programmes that is of real interest as 44% of those enrolled in OMG and 33% of those enrolled in Gout Stop are under 45 years old.

These younger populations have much to gain in terms of gout management, (continuous employment, participation in sport, whānau and community activities) however their work, contexts and community responsibilities, as well as the acceptance of the long-term nature of gout can be a barrier to persisting with long term treatment. The age profile of participants is a key consideration in the design and delivery of programmes.

Figure 8: Age distribution of both programmes



5.1.4 Reaching males

Both programmes are reaching a higher proportion of males than females with gout. Men traditionally experience higher rates of gout, as they have higher levels of uric acid than women for majority of their lives (this changes when women reach menopause)[15]. The following table presents the percentages and counts of unique programme participants by gender. These gender categories are taken from the dataset collected by both programmes. Owning My Gout had six patients where gender was not recorded.

Table 7: Gender breakdown of both programmes

	Gout Stop		Owning My Gout	
Gender	Percentage	Count	Percentage	Count
Male	82%	1078	87%	142
Female	18%	234	10%	16
Unknown	0%	0	3%	6
Total	100%	1312	100%	164

This is concordant with the HQSC Gout Atlas of variation, which identifies males being significantly more likely to have diagnosed gout. In New Zealand, gout is diagnosed in 8.4% of males, and 2.5% of females, over a three-fold difference. These programmes are reaching between four and eight-fold more males than females.

[15] Phipps-Green, A. J., Hollis-Moffatt, J. E., Dalbeth, N., Merriman, M. E., Topless, R., Gow, P. J., ... & Merriman, T. R. (2010). A strong role for the ABCG2 gene in susceptibility to gout in New Zealand Pacific Island and Caucasian, but not Māori, case and control sample sets. Human molecular genetics, 19(24), 4813-4819.

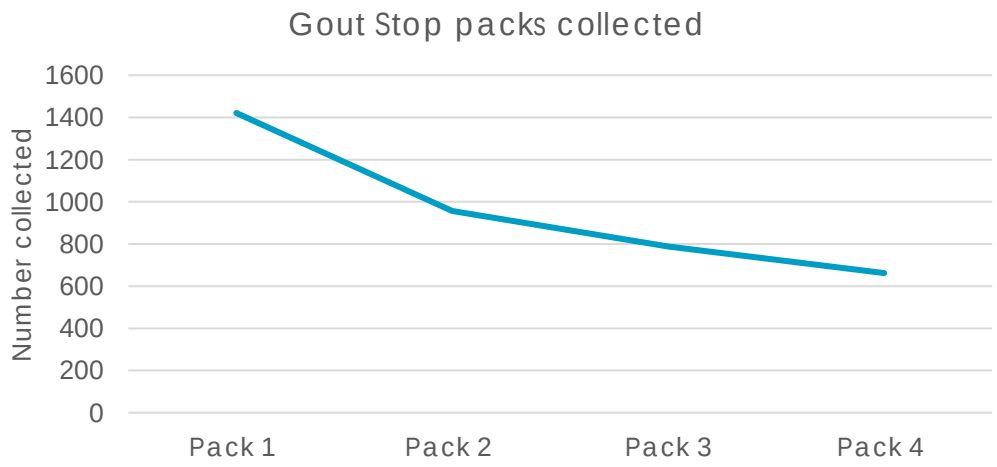
5.2 Programme participation

Best practice gout management progresses from treating the symptoms of an acute flare to titrating to a dose of long-term urate lowering medication e.g. allopurinol, that can keep urate levels at target of >0.36mmol/L long term. It is a feature of both programmes that for many patients, participation does not last beyond initial symptom relief. This is not uncommon in terms of management of gout as there are well entrenched community beliefs that gout is an acute flare which needs short term pain relief. It can take some time for people with gout to understand and accept that gout is a long-term condition that needs to be managed with long-term medication.

5.2.1 Gout Stop participation

From the programme data that was available for this evaluation, it was difficult to ascertain the extent of 'participation' in the programme. An assumption was made that if patients were collecting programme packs, they are engaging with the programme to illustrate participation. We note that people other than the patient may collect their prescription packs, and collection does not mean that any knowledge, skills or understanding has taken place. Figure 9 shows collection trend for the Gout Stop programme over the course of the programme.

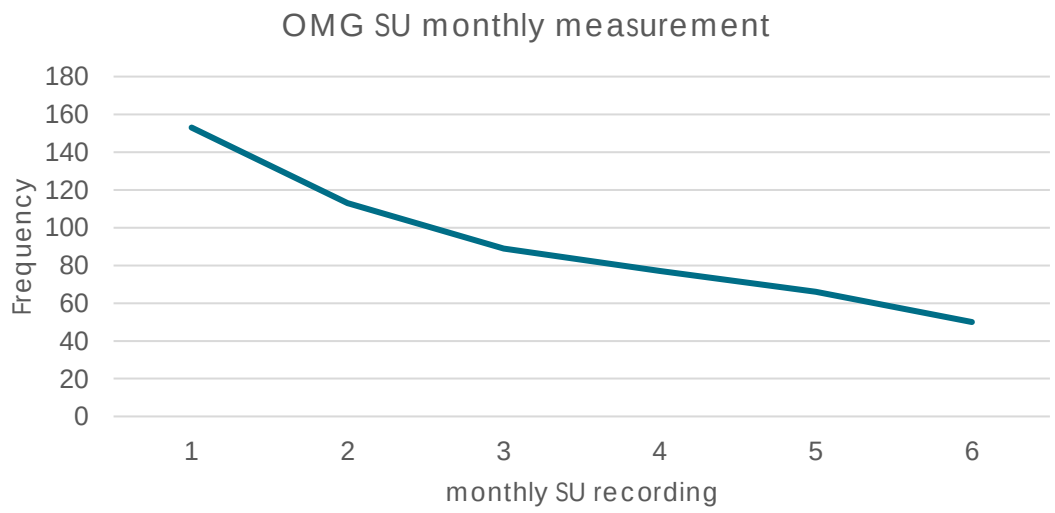
Figure 9: Gout Stop pack collection



Programme data shows that two in three (66%) participants progress to pack two. Seven in ten (70%) of those who collect pack two, go on to complete the programme, collecting all four packs. This highlights that the biggest loss in participants is between packs one and two, a trend well known to programme providers.

A similar trend is seen in the Owning My Gout programme data, where the steepest drop off point is within the first month. Programme engagement and participation is measured and recorded differently, as patients are required to re-visit the pharmacy for monthly point of care testing. The assumption here is that if the individual is visiting the pharmacy each month and picking up a prescription, then they are engaged and participating in the programme. Figure 10 below depicts a very similar trend to the Gout Stop programme data, with the highest drop off between the first and second visit once the pain has subsided. Data shows that seven in ten (73%) of those who are enrolled in the programme, and visit the pharmacy, go on to visit the second month.

Figure 10: Owning My Gout monthly participation of serum urate level testing



This point in the patient pathway is a key point for intervention and building of health literacy to encourage patients to continue taking allopurinol to reduce urate levels and minimise the risk of another acute flare. In the Gout Stop programme there are multiple opportunities to minimise the risk of drop off; the kaiāwhina attempts a first engagement with patients after two weeks, the point at which the pain has subsided, and the first course of pain-relieving medication has been completed.

"What that pack basically does is take the pain away – everyone loves that part. What they don't do is the follow ups for the next packs and so I try to get in there and explain: 'Do you know what you're taking and why you're taking it? The next pack is just as important because you're pain free now, but we need to maintain that'." (Gout Stop kaiāwhina)

This highlights not only the importance of building health literacy, but the timing of it. During an acute flare all the patient is focussed on is pain relief and at that time they are cognitively not able to take on new messages about gout. However, when the pain has diminished it is the ideal time to start talking about long term management and to start to build new health literacy knowledge of skills about the role of genes and how food and drink has not caused their gout

The kaiāwhina attempts to build rapport and relationships with patients, as there can be opportunities to support their participation via the wider whānau as well as identify others who would benefit from the programme.

"I'm very careful about how I approach them – they can hang up on me at any time. But I do mention say 'hey, is this common in the whānau? Are there other members of the whānau who are suffering from gout and don't know who to talk to?' I'm more than happy to talk to and visit people – I've had a few take it up." (GS kaiāwhina)

The Owning My Gout programme is structured in a different way from Gout Stop and does not have a time bound exit point. Patients continue in the programme until they reach their target for three consecutive months. As a continuous programme, there is little need for 're-entry' as such, as patients simply disengage, then reengage and continue on the programme. Despite this, of the sample of 153 people, 13 were identified as re-entering the programme.

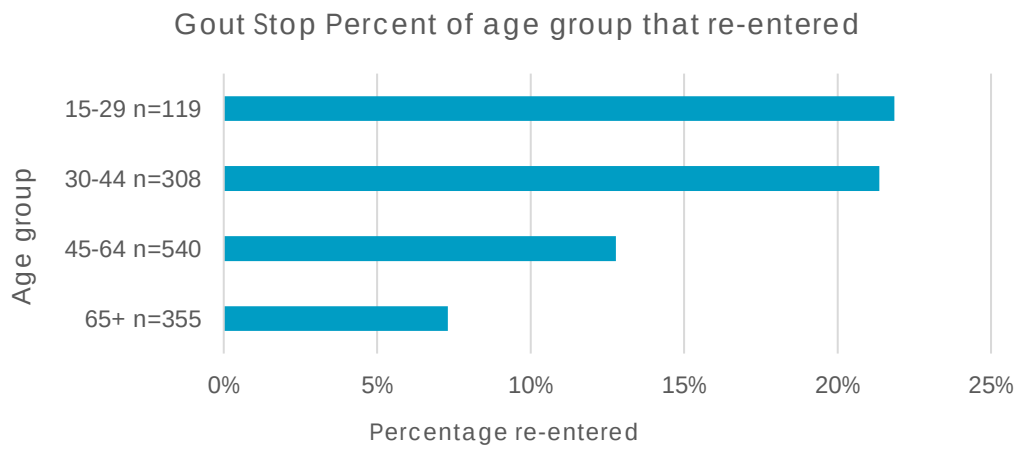
5.2.2 Drop off, re-entry and completion of the programmes

It is common for patients to drop out of the programmes and not reach urate success the first time they engage. Acknowledging and accepting that gout is a long-term condition can be challenging, particularly when outside of an acute flare, there are no symptoms. After the pain experienced during a flare is gone, there is little motivation to continue with urate lowering treatment, particularly for those where their health is a lower priority. Pharmacists often reported challenges in contacting patients for follow up prescriptions or point of care testing. Continuing engagement with patients on the programme can be challenging and time consuming, and sometimes re-engagement is only prompted by the experience of another flare.

"There are a few Missing In Actions there – sometimes cell phones disappear, sometimes we're trying to get blood tests or send them back to the doctors, and there's just no way to contact them so they fall off." (GS Pharmacist)

Clear re-entry data was available for the Gout Stop programme. This data indicates that nearly a quarter of all participants drop off and re-enter the programme more than once. Re-entry rates by ethnicity indicate that Māori (18%), Pacific (22%) and younger people (22% of 15-29s and 21% of 30-44s) are more likely to re-enter the programme. In comparison, Non-Māori, Non-Pacific patients were more likely to complete the programme and were recorded as re-entering just 6% of the time. Figure 11 displays the percentage of different age groups re-entering into the Gout Stop programme in more detail.

Figure 11: Gout Stop percentage of re-entry by age



The design of the OMG programme is such that the concept of 're-entering' is much less common; patients simply re-engage with the pharmacist or GP and continue their gout management journey. Providing comparative data is difficult, but the trends of younger people disengaging was raised in interview feedback

It is important to note that re-entry (or re-engagement) into the programme is actually a positive outcome and contributes to the individuals' journey to gout self-management. Re-entry demonstrates understanding that gout is a long-term condition as well as continued engagement with the health system. Often it takes a significant amount of time for individuals to accept the long-term nature of gout and its management.

"Re-entry really does happen, and for some people it's two or three times before they finally get it and understand that actually, yes, they do need to be on this for life." (GS Pharmacist)

5.2.3 Encouraging participation

Given the challenges patients experience in continuing to engage with the programmes, feedback from pharmacists suggest many are proactively following up with patients yet still have trouble maintaining engagement.

Evidence from interviews with pharmacists for both programmes indicate that there is enough variation in the Standing Orders that they operate under, and the packs they dispense that they can tailor dispensing to support participation and engagement.

Pharmacists have experimented with different dispensing methods, such as using blister packs, bottles with labels and sachets, to make medication adherence as easy as possible for their patients. Pharmacists are well placed in their communities to understand what works for patients and what supports continued adherence and engagement. Some pharmacists acknowledged traditional pill bottles were the most effective for patients, while other pharmacists supported using blister packs for those who are already on long term medication but could be confusing for those who had never taken long term medication before. Having the flexibility to dispense using their judgement about what best suited the patient, and autonomy, strongly supports the buy-in of pharmacists which is critical to programme success.

"My thinking is that people can only retain two or three key messages at once. This is why I stopped using blister packs, because I was using their cognitive capacity explaining how it works. Remember they are also in acute pain and they just want their tablets and get out of here." (GS Pharmacist)

Methods to support engagement and encourage participation have also included dispensing more medication at once to facilitate creating a habit of taking medication daily. Introducing allopurinol as a continuation of the initial anti-inflammatory medication can support patients to continue taking medication if it is dispensed as a whole, rather than a 'stage 2' medication. This aligns with the recommendations made by BPAC[16].

"We originally dispensed the two-week acute treatment prescription, but we found 'oh wow, that fixed me', so they wouldn't come back for the next prescription. So we do a sachet pack and make up a six-week roll, which works better than the two week start pack." (GS Pharmacist)

5.3 Pathway standardisation and adaptions: Key insights

Both programmes provide a standard pathway for all those enrolled. Often programmes have differentiated pathways for different groups based on relevant status or needs. The gout programmes have no differentiation articulated for different groups such as first-time presenters, re-enrolled or younger people for example.

We learned about adaptations in delivery through our interviews, as providers responded to the needs of individual people. This included:

- For patients who are Māori or Pacific, it was seen as important to explain the genetic link for prevalence of gout and ensure patients understand this link. Key

[16] https://bpac.org.nz/2018/gout-part1.aspx

research in New Zealand has identified specific gene variants that mean for Māori and Pacific peoples, the chance of gout is increased by more than five times[17].

- Patients who are new to regular medication may need coaching to make this part of their routine. First time blister pack users also need guidance on how to use the pack.
- There are rare but well-known side effects of taking allopurinol, including nausea and skin rashes. Pharmacists identified the delicate balance in sharing this information and the appropriate level of risk, with patients who are hesitant to take long term medication.

"It's a trade-off – how much do you tell them about that [side effects], when we're trying to get them to take it every day." (OMG pharmacist)

- Pharmacists used their discretion with the dispensing mode and frequency to encourage persistence. For example, we learned of one pharmacist who provided a patient with thee months medication at one time because they knew he would not return.

The programmes have been designed and are being delivered in the same way for all patients, however verbal messages to Māori and Pacific about genetic predisposition are provided to these people. The delivery of these messages relies heavily on the provision and quality of how health literacy is built with patients. This information is also in the gout booklets. In Northland the booklet developed by the Māori Pharmacists Association,' Gout, how to live happily without the pain' (referred to as the green book), was provided as well as the 'Stop Gout' booklet it was developed from. "Stop Gout' (referred to as the brown book) was developed by the Ministry of Health and Workbase. Owning My Gout use the 'brown book' as its main resource as it is also available in Tongan and Samoan. Both booklets present key messages and information in a simple and visual format and contrast strongly in style with some other patient resources that were also used by some pharmacies.

The potential to increase programme effectiveness through programme differentiation should be considered. Younger Māori and Pacific men may respond to a more tailored form of support. This is an ideal opportunity for co-design.

[17] Hollis-Moffatt, J. E., Xu, X., Dalbeth, N., Merriman, M. E., Topless, R., Waddell, C., ... & Stamp, L. K. (2009). Role of the urate transporter SLC2A9 gene in susceptibility to gout in New Zealand Māori, Pacific Island, and Caucasian case–control sample sets. *Arthritis & Rheumatism: Official Journal of the American College of Rheumatology*, *60*(11), 3485-3492.

6. FACTORS INFLUENCING PATIENT PARTICIPATION

Patients experience a number of barriers to engaging with gout programmes, these include those generic to primary care (such as cost, travel and availability) as well as those more specific to gout (access to labs, over the counter options and reduced incentive when pain fades). Patient's mental models relating to gout were identified as strongly influencing participation; this includes outdated beliefs about the causes of gout, whakamā or shame associated with gout and lack of understanding and acceptance that gout is a long-term condition. Programme design can reduce some of these access barriers and effective building of health literacy is important to support behaviour change.

6.1 Accessabilty of primary care for patients

The structural factors that influence patients accessing the programmes are complex and multi-faceted. Many of these reflect known common barriers to primary care engagement. Others are specific to the nature of gout and programme delivery.

- Providers we spoke with were aware that the cost of accessing primary care was a barrier for some people with gout. A recent HQSC survey[18] showed that:
    - One in five people reported not visiting a GP or nurse due to cost in the last 12 months. For those aged 15 – 44 years this was almost one in four (37%).
    - One in five Māori and Pacific peoples reported not collecting a medicine due to cost in the past year.

  These are the populations with most to gain from gout programmes, yet cost is a likely barrier.
- The providers we interviewed were aware the $15 prescription cost (three charges of $5 for three medications) was prohibitive for some. The subsidising of blister packs may benefit some patients, but this cannot be assumed as other methods, including the standard bottles and (cheaper) sachets, were preferred and used also.
- Time to access primary care was also identified during interviews with providers as a barrier. Many people with gout are working and have to prioritize time to attend GP appointments. We heard it was harder for those who live rurally or depend on others for transport to get time to see a GP, go to the laboratory, and may also have limited opportunities to go to the pharmacy. Others simply have complex lives where their health is not an immediate or high priority.
- Bias in primary care is both general and specific to gout. General, as not all organisations and providers able to engage effectively with all population groups, particularly if they are minority groups. Specific, in that variation to prescribing appropriate medication for gout occurs.
- The quality of the relationship people have with their GP and practice staff will influence their willingness to engage and trust their advice. Conflicting advice,

[18] https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/health-service-access/

hurried consultations and heavy locum use were factors identified in interview feedback from patients as contributing to negative experiences.

- The availability of over the counter (OTC) effective remedies for treating acute gout flares (for example Voltaren) can remove the painful symptoms that is usually the primary motivator for seeking medical help.
- Patients treated at emergency department and after-hours services, are provided with pain relief which removes painful symptoms. As a result, these patients have reduced motivation to follow the advice to see their usual GP for ongoing management.
- For the OMG programme, patients were required to use a pharmacy that is part of the programme. The regional reach of Gout Stop meant any pharmacy could be used.

6.2 Patients preconceptions about gout and medication

Peoples capacity to engage, accept and manage their gout varies significantly. This ability to change behaviour is influenced by people's thinking and understanding about gout. Interviews identified that this is influenced by:

- The whakamā or shame around gout that is rooted in outdated but strong beliefs that the illness is self-inflicted through laziness, alcohol and overindulgence. For Māori and Pacific peoples, the knowledge that there is a genetic predisposition for gout is important for reducing the shame around it.
- The severity of the symptoms and the impact on daily life from gout. Unbearable pain is a motivator to seek help but the determination to "staunch it out" remains for many.
- The side effects of medication may be a deterrent for some.
- The consistency, personal relevance and trustworthiness of new information about gout and its management.
- Understanding and acceptance that gout is a long-term condition that requires long-term treatment. For those already used to long-term medication one more pill may be easier to accept than lifelong medication for a 30-year-old.
- Reminders to pick up medication or to have blood tests can reinforce the seriousness of gout and can be motivating for people when they know someone is monitoring and checking up on them.

"I said I was sick of walking around with a sore foot. If you can help me get better and stay better, then I will do it" (Gout Stop patient)

"It's been really good having someone ring me every so often and see how I'm getting on." (Gout Stop patient)

"They don't understand the long-term implications; I try to anchor it in their own experiences – their relatives." (Gout Stop Pharmacist)

7. FACTORS INFLUENCING PRIMARY CARE PARTICIPATION

The interdisciplinary delivery of gout programmes represents a shift in the traditional roles of GPs, nurses and pharmacists and introduces opportunities for practice nurses and non-regulated roles, such as kaiāwhina. While pharmacists seem to embrace this opportunity to work to top of scope there is awareness of a more mixed reaction from general practice for a variety of philosophical, practice and business reasons.

7.1 Pharmacy influences

There is a shifting culture in pharmacies to work at top of scope, with pharmacists able, and willing, to move away from purely dispensing medications. These gout programmes offer a chance for pharmacists to gain contracts that support and fund time away from dispensing, developing their role to encourage health service provision.

*"Pharmacists are hugely trained, very willing, have great relationships with their regulars and dare I say it, have 'time' and are 'free'. They are willing to go beyond their traditional dispensing role and want to become health practitioners." **(Gout Stop PHE employee).***

"I'm excited; it's great to be paid to work this way with people." (Gout Stop Pharmacist)

Pharmacists are motivated to change the way they work in a landscape that is changing around them: Retail sales are falling; pharmacies are reducing staff and new operators with business models that use free prescriptions as loss leaders are emerging.

The relationships and communication between pharmacy and general practice are central to the success of the programmes. Constant and open communication supports these health professionals to work in collaboration with one another to manage the patient. These trusting relationships enable the programme to function seamlessly. Co-location of pharmacies and general practice may contribute to these relationships and communication; however, they are not essential to success.

"It's so easy because if I have a query about anything that they've done when I see the patient next, I can just zip down the hall and ask [the pharmacist]. We've always worked as a team and it's easy because we're under the same roof." (OMG GP)

Fair compensation for the time pharmacists are required to spend with patients influences how willing they are to expand their role and take part in the programmes. Ensuring that the pharmacy service specification adequately covers the resources required for pharmacists to participate in the programme is a key driver of engaging. For the most part, these two programmes appear to have struck the right balance.

Pharmacists also report enjoying some degree of autonomy when dispensing. Understanding what works for the patient population they serve, pharmacists are well-placed to judge the dispensing method (e.g. blister pack, bottles or sachets), and how long they should dispense for (e.g. dispense two weeks, or a months' worth).

Implementation insights:

- The changing business environment of pharmacy with free prescriptions and falling retail sales has created the right climate for pharmacists to want to adapt their practice.
- Having an appropriate space for patient consultation is key to enable this wider scope of practice to take place safely for patients.

- Ensuring that the pharmacy is appropriately resourced to allow pharmacists to spend private time with patients carrying out point of care testing and building health literacy.
- Key to success is making sure pharmacists are trained adequately to deliver their components of the programmes, including the use of BeneCheck © meters, and how to meaningfully build health literacy with patients.
- Their ability to engage with community beyond the pharmacy door and their ongoing follow-up of patients.

7.2 General practice influences

Both programmes support integrated and collaborative working in general practice. This encourages shifting responsibility of gout patients to nurses and pharmacists. The willingness of GPs to share delivery of patient care is variable both in, and across, practices. This is not unique to gout patients and treatment. The culture of change in general practice is not strong, with new ways of working often taking significant time and resource to implement across the system. This new way of managing gout patients was reported to be particularly challenging to accept for GP business owners, as contracts were shifted out to pharmacies to manage patients that previously came in for regular consults.

"There's GPs that just get so worked up about nurses and pharmacists doing anything that they could do…They see it as a threat." (OMG GP)

General practices that operate in different ways, outside of the traditional owner-operator model are more willing to embrace new ways of utilising other health professionals to support patient care.

"We're a trust, so we're not for profit and we want to do as much as we can for the least amount of money." (OMG GP)

Those GPs that do embrace change, often act as a source of promotion to the hesitant. A natural part of implementing a new programme is working with the willing first to establish an effect, that can then create some reassurance for those who are late adopters. It may be that health professionals who are newer to the profession have less ingrained beliefs about roles and responsibilities.

"I started doing this [programme] from the start, but there were others at my practice that wouldn't have a bar of it. Over time they saw my patients were doing really well and I had more time to work with others and slowly they've all come around. I'm younger though and don't have as much of a stake in the business. I'm just trying to do what's easy and works well for my patients." (GS GP)

"Some GPs think its bad practice not to see patients, but they weren't seeing them anyway. It's a trade-off between thoroughness and efficiency and some don't understand [this is better] - it's a very old-fashioned view" (OMG GP)

We were unable to interview practice nurses supporting delivery of Owning My Gout and have limited reflections from others on this role in practice. Nurses building health literacy and oversight the programme alongside pharmacists is likely to be more acceptable to PHOs and practices who want to retain greater involvement and control over the delivery

of education. Nurse led models for chronic diseases, including gout, are becoming more prevalent and national and international evidence can inform this.

Another challenge for general practice, is considering where gout as a condition sits on the list of priorities. There are no national or regional targets associate with gout management or health outcomes, meaning that the condition has to compete with initiatives and programmes that do support targeted, audited conditions. Unless gout is selected as an option under the equity actions in a DHB Annual Plan there is no policy incentive at a regional or national level to support innovation or changing business as usual, which can be a barrier to general practice driving the programme. There are many other competing interests which do have these levers.

Programme engagement is particularly dependent on relationships between the programme leads and general practice. Understanding the context of primary care, their particular challenges, and pressure points, can support programme leads to build relationships and networks and gain traction. PHOs are in a strong position to lead or facilitate this.

"It's not a public sector where you can just say something, and they all do it. It's all about the relationships and about motivating private owners to do what you want them to. Takes a lot of relationship building, networks and nurturing. You have to make it seem like it's their idea – bring people on the journey. It's about co-design." (Gout Stop PHE Staff)

Implementation insights:

- The leadership role of the PHO, being close to primary care and having stronger relationships and understanding is crucial to supporting buy in.
- Work with the willing first, to set up systems and demonstrate outcomes to encourage those who are more hesitant.
- Newer health professionals and other initiatives driving integrated teamwork will support uptake of new programmes.
- Practice champions – GPs who believe in the programme and can demonstrate its effectiveness can bring an entire practice on board over time.
- Clinicians may have existing skills in building health literacy and cultural competency, but this cannot be assumed.
- Nurse led delivery, or co-led delivery is a model that retains greater control for general practice and may fit well with existing roles and programme delivery.

8. PROGRAMME OUTCOMES

This section presents findings that relate to programme outcomes in terms of clinical outcomes (target serum urate achieved), equity outcomes, then in terms of broader health literacy and community benefits.

8.1 Clinical success

Gout Stop measures successes as reaching SU <0.36mmol/L within 91 days. Of the 1421 enrolments in that had occurred more than 91 days ago, around half (47%) complete the programme with, 253 (18%) reaching the SU target, 167(12%) continuing with titration. OMG is not a time limited programme but of the 148 people on OMG at least three months, 48 (29%) had SU <0.36mmol/L at their last three recordings and a further 5(3%) were in titration.
A common definition and use of success criteria across programmes would be useful and should reflect the ultimate aim of transition to long term allopurinol.

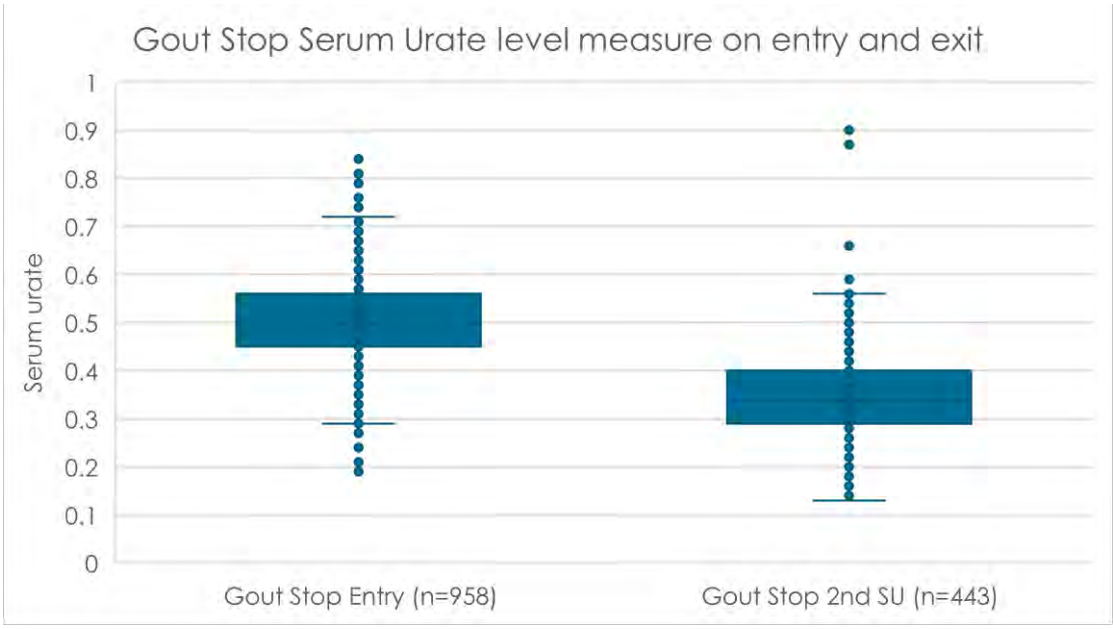
SU having reached below 0.36 mmol/L is considered clinical success as serum urate is at a safe level that won't cause long term damage. To have really achieved that safe level, 0.36 mmol/L should be maintained for three consecutive months.

8.1.1 Gout Stop clinical success

The first chart presents the distribution of entry and exit SU recorded for all enrolments. The 'box' represents this interquartile range with the lines extended above and below representing the quarter of people with the lowest and the quarter of the highest scores respectively. The median entry measure was 0.54mmol/L and the median second measure was 0.35mmol/L.

When people have a gout flare, their SU at the time of flare can be artificially low because the SU is crystallising rather than circulating in the blood stream. It is preferable for clinicians to have a recent SU measure rather than one taken during an acute flare of gout. If previous measures are available, they can be accessed online.

Figure 12: Gout Stop SU on entry and exit



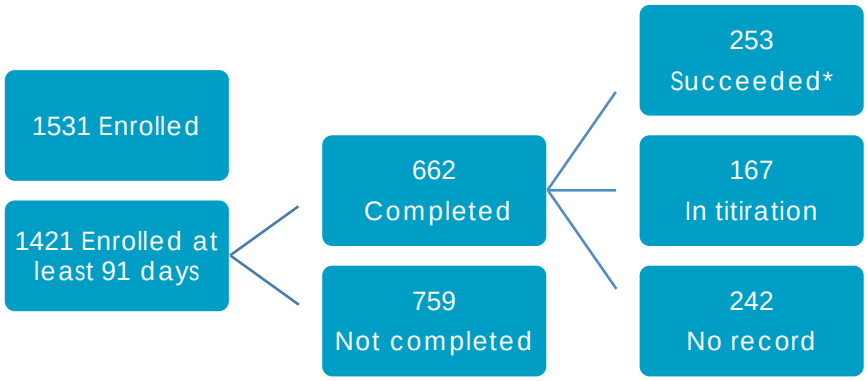
Of all enrolments, 958 had an entry SU entered. The date of the first SU measure is recorded by the pharmacist and 402 (42%) of these measures were taken in the 14 days before referral or the 7 days after referral, so these SU entry measures are likely to be on the lower side because of the acute stage of gout. For this reason, we have not taken matched pairs of data to look at individual patterns of change or calculate average change as both are potentially misleading.

The diagram in Figure 13 displays the flow of enrolments and their status. It shows that of the 662 enrolments that completed the 91-day programme, 443 had a second SU entered at the end of the programme. Of these 443 enrolments, 253 (57%) had 'succeeded' within the timeframe, i.e. had SU was <0.36mmol/L. This is a very narrow definition and measure of success as the reality is that people drop out before the end of the program or don't have a second SU recorded.

Overall programme success rate is reduced if it is considered as a percentage of all 1,421 **enrollments that had occurred more than 91 days ago as 18% (n=253) 'succeeded' within** the timeframe, i.e. had a SU of <0.36mmol/L recorded. A further 167 (12%) were in ongoing titration. Across the programme as whole this means around three in ten of all enrolments were on their way to longer term gout management.

Figure 13 illustrates the patient flow and how these numbers relate to the initial number of people enrolled.

Figure 13: Gout Stop enrolment flow



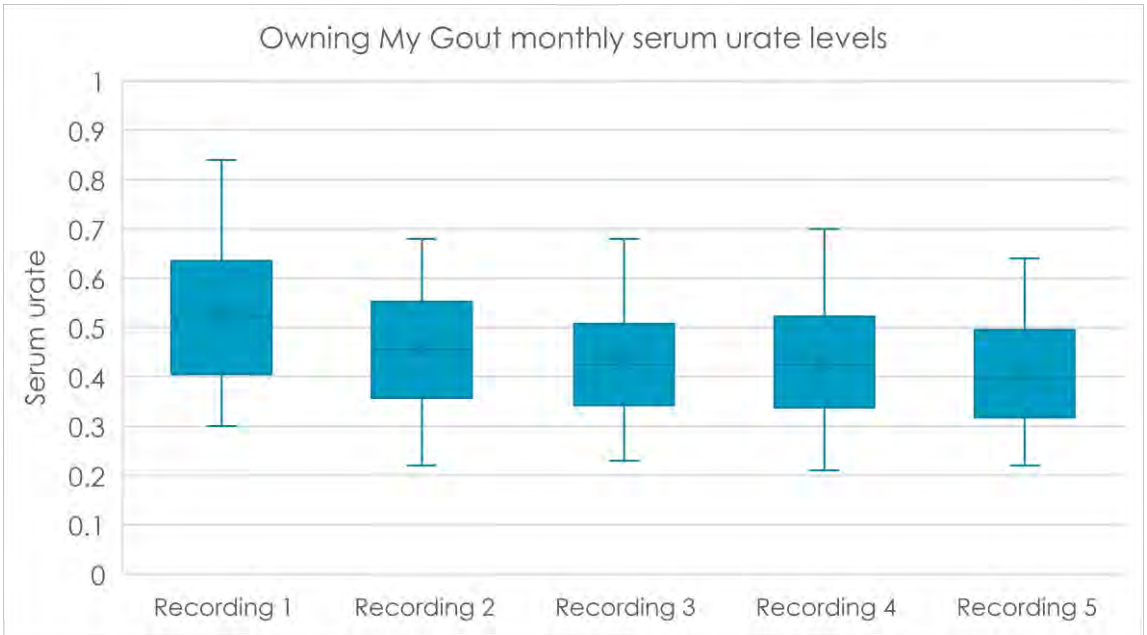
*Recorded as achieved SU<0.036mmol/L on their end of programme (second) measure.

Those 253 patients that succeed within the 91 days should have their maintenance dose of allopurinol entered in the data base. For the 196 enrolments with this entered, 300mg is the most frequent dose, but it ranges between 100mg and 600mg. Monitoring does not extend beyond this timepoint.

8.1.2 OMG clinical success

The data collected by OMG lists the month of the first and subsequent gout SU recorded and the result. The results show a gradual downward trend as SU measures reduce. This includes current enrolments so the numbers reduce because of people dropping out of the programme and because they may have only been enrolled a short time.

Figure 14: Monthly serum urate levels



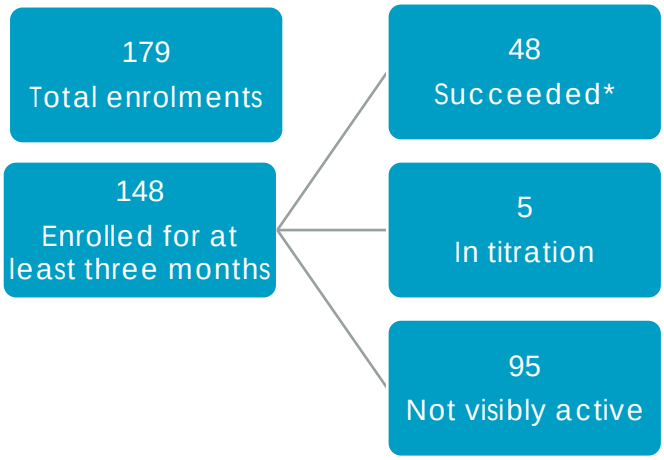
Of the 148 people on OMG at least three months:

- 71 people (43%) had achieved SU <0.36mmol/L at some point in time.
- 48 people (29%) had SU <0.36mmol/L at their last recording and had maintained this for the previous three months. This is the programme definition of success.
- For those achieving the target serum urate levels, half of them took between three and seven months[19] (median 5.3 months) to reach it for the first time.
- Of the 148 enrolments that had begun more than three months ago, 5(3%) were continuing with titration and the remaining 95(64%) were not visibly active in the programme.

These numbers are displayed on the following diagram for clarity. We have introduced the category of enrolled for at least three months for analysis only and to support some degree of comparison with Gout Stop.

[19] Not including three people who never had a reading above 0.036mmol/L

Figure 15: Owning My Gout enrolment flow



*Achieved SU<0.036mmol/L for three consecutive months

8.1.3 Clinical success summary

The different programme structures, timeframes and data recording limit the scope for comparative analysis. We have tried to present a broad picture of their achievements in terms of clinical success with the data available. These data sets identify the following:

- Three to four enrolments in ten have either achieved their serum urate or were progressing towards it (in titration) after three months on the programmes.
- There is a relatively high rate of drop out or lack of visible data for around six or seven total enrolments in ten.
- The time it may take for people to achieve the desired SU can be many months, certainly more than the three months Gout Stop measures success. Expecting success within a short window of time may disincentivise patients (who need longer to titrate to a long-term dose of allopurinol) and not highlight the real success of the programmes (which is about transitioning people onto long term allopurinol).
- Common measurement models and minimum data collection would facilitate the sharing of results and learning about what works and for whom across different programmes.
- Additionally, clinical success should be considered achieved after three months of SU <0.36mmol/L. Programme measurement models and incomplete data sets mean this is not easily evidenced. Neither programme has collected to data that evidences the transition to long term allopurinol and gout management, though OMG is currently extending its monitoring timeframe.

8.2 Promoting equity

Key points: Both programmes demonstrate they are equitably reaching Māori and Pacific peoples. Enrolment profiles show both programmes exceed the needs-based proportion of Māori and Pacific peoples in their districts. Non-Māori /Non-Pacific peoples are more likely to maintain engagement with programmes and more likely to achieve SU success.

In Aotearoa New Zealand, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes[20].

This is how the Ministry of Health defines equity. Gout is an equity issue. The HQSC Atlas of Healthcare Variation identifies the higher prevalence of gout in Māori and Pacific peoples as well as their poorer access to appropriate medication and management. As such, gout has also been identified by PHARMAC as a priority condition for improving access equity to medicines. PHARMAC defines medicine access equity as:

The absence of avoidable, unfair or remediable differences in funded medicine access among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification. Medicine access equity means that everyone should have a fair opportunity to access funded medicines to attain their full health potential, and that no one should be disadvantaged from achieving this potential. In this context, some groups may require additional support to access funded medicines than others.

Gout is a Te Tiriti issue. The principle of active protection brings a responsibility to promote and achieve equitable health outcomes for Māori and understanding gout within a Māori model of health.

This section analyses the reach, participation and outcomes of the programmes, with an equity lens.

8.2.1 Reach through enrolment

To be equitable, Māori and Pacific should be able to access services in proportion to their need. Across New Zealand Māori are twice as likely, and Pacific peoples three times as likely, as non-Māori non-Pacific peoples to have gout. Access rates that reflect this higher level of need in an equitable system, i.e. are weighted to show prevalence of need, provide a more accurate measure if equity of access.

Both programmes have demonstrated high proportions of their Māori (Gout Stop) and Pacific (OMG)communities in their enrolment profile. Equitable reach needs to consider the needs in the population rather than just the ethnic profile. Table 8 and Table 9 present data that shows a simple adjusted population burden of disease calculation. This is calculated by weighting the demographic profile of the DHB with the prevalence of diagnosed gout in those DHBs from the 2016 Gout Atlas of Healthcare variation. This compared to the ethnicity of those enrolled on the programmes.

Table 8: Northland needs-based prevalence and reach

Ethnic group	DHB % pop	DHB Gout Prevalence	Simple burden of disease weighting	Gout Stop enrolment	Difference
Māori	33.9%	12%	48%	63%	14%
Pacific	2.1%	10.4%	3%	5%	2%
NMNP*	64%	6.5%	49%	33%	-17%

*Non-Māori / Non-Pacific ethnicities

[20] https://www.health.govt.nz/about-ministry/what-we-do/work-programme-2019-20/achieving-equity

Figure 16: Equity of reach into key populations

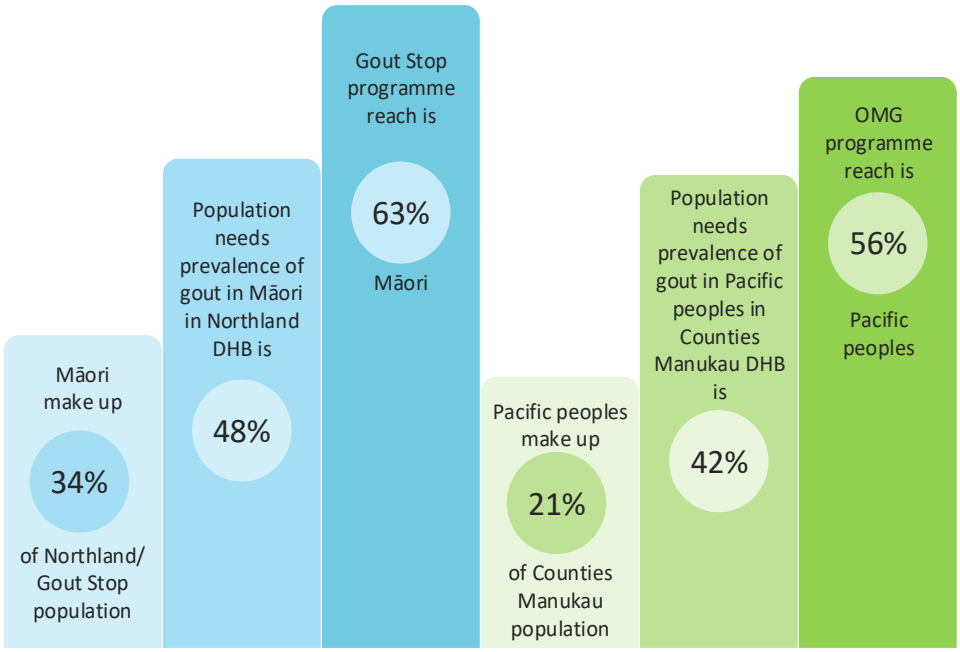


Table 9: Counties Manukau needs-based prevalence and reach

Ethnic group	DHB % pop	DHB Gout Prevalence	Simple burden of disease weighting	OMG enrolment	Difference
Māori	15.7%	10.6%	21%	25%	5%
Pacific	21.1%	16.2%	42%	56%	14%
NMNP	63.2%	4.8%	37%	19%	-19%

*Non-Māori/ Non-Pacific ethnicities

Figure 17 illustrates the scale of these differences and shows both programmes are promoting equity of reach into its prominent high needs populations. OMG also promotes equity of reach for Māori (exceeding weighted prevalence by 5%).

8.2.2 Equity of benefits

To benefit from the gout programmes (and experience the impact of those benefits), patients must participate in the programme long enough for benefits to be realised.

Gout Stop programme data showed that of the 1070 exited enrolments, the number of Pacific peoples is relatively small so should be interpreted with care.

- Non-Māori/Non-Pacific were much more likely to complete the programme (83%) than Māori (53%) or Pacific (57%).
- Non-Māori/Non-Pacific were likely to achieve target SU (50%) than Māori (39%) or Pacific (30%).
  Non-Māori/Non-Pacific were only slightly more likely to still be engaged in managing their SU (succeed or still in titration) at the end of the programme (72%) than Māori (66%) or Pacific (56%).

Table 10: Ethnic comparison of Gout Stop programme outcomes

Data	Māori	Pacific	NMNP	Total
Exited enrolments	709	47	314	1070
Number completed programme	375	27	260	662
% of exited that completed*	53%	57%	83%	62%
No completed successfully**	132	7	114	253
% of all exited that completed successfully	19%	15%	36%	24%
Titration post 90 days	102	7	58	167
% of all exited that were in titration at 90 days	27%	26%	22%	25%
Number succeed or still in titration	234	14	172	420
% of all exited succeed or still in titration	33%	30%	55%	39%

*Collect all four packs ** achieve target SU

OMG data is not as straightforward to interpret to identify equity of participation. To explore equity patterns, we have analysed the ethnicity of people who have had less than four monthly SU recorded readings with those who have had four or more.

Table 11 presents these results and shows that:

- Non-Māori/Non-Pacific were more likely to be engaged in the programme for four or more months (49%) than Māori (53%) or Pacific (49%).

Table 11: Owning My Gout data ethnicity of participation for four or more months

	Māori		Pacific		NMP	
	n	%	n	%	n	%
Less than 4 readings	83	47%	176	51%	76	35%
4 or more readings	92	53%	171	49%	144	65%

For OMG 48 people had been on the programme more than three months and had a SU <0.036mmol/L recorded on their last three recorded entries. The ethnicity of these people is identified in Table 12 and this view of programme success shows that Non-Māori/Non-Pacific people are more likely to succeed than Māori or Pacific people. We do note that this is a limited view of success and is used to illustrate differences in benefits experienced by different ethnic groups.

Table 12: Owning My Gout entry data by ethnicity

Ethnicity	Māori	Pacific	NMNP	Total
Number enrolments	40	89	35	164
% of all enrolments	24%	54%	21%	100%
No. achieved target SU	7	26	14	48
% of ethnicity entered	18%	29%	40%	29%

8.2.3 Equity summary

Usual care, as evidenced by the Gout Atlas is highly varied in practice and isn't working well, particularly for Māori and Pacific peoples. These programmes work differently to reduce barriers and improve access to care and benefits of appropriate gout management. Both programmes are strong in terms of reaching Māori and Pacific peoples in their district, even considering the higher prevalence of need, their reach is strong. Once enrolled, both programmes are benefitting other ethnic groups more than Māori and Pacific peoples.

Differences in ongoing participation is not likely to do with the cost (as the GP visit and initial prescription change has been paid on entry) but the range of factors that are stronger barriers to engagement for Māori and Pacific.

It is beyond the scope of this evaluation to interpret the higher success rate in terms of SU at programme completion for Non-Māori/Non-Pacific (five in ten) compared to Māori (four in ten) and Pacific (three in ten)[21]. The OMG programme highlighted the increased length of time it takes some people to reach this SU and it cannot be expected, even with adherence, that all would reach the desired SU in 91 days; it is not long enough. Gout Stop success at 91 days would be more accurately reflected in terms of those who have reached SU or are still engaged/in titration on the programme at 91 days. These results show that they are impacting equity in a greater way.

As these two programmes (and other programmes) review their data and adjust delivery to improve reach, participation and clinical outcomes for patients, improvements should be considered not only for the programme as a whole, but with this equity lens applied to it also so that ingoing improvements are reducing, not exacerbating, inequities that exist.

8.3 Building health literacy outcomes

Health literacy outcomes for providers (relating to gout, local processes and building health literacy) have been identified from the providers interviewed. These generate the health literacy outcomes for patients (relating to understanding gout causes, the need for medication and the personal benefits for them of managing it long-term).These outcomes are not easily captured and the lack of direct patient feedback in this evaluation limits the degree of insight into the component about how health literacy was built with patients.

In this report programme leads, and other stakeholders, talked about education being given, or provided, to patients. Education components of programmes are designed to build health literacy in providers and patients.

[21] Small numbers of Pacific peoples mean this should be interpreted with caution

Early in the evaluation we identified that outcomes about how patients' health literacy was built throughout the programmes were not quantifiable, and it was suggested participation be used as a proxy measure for this, assuming the more health literacy that was built with people, the more likely they were to persist with the programme. It has become clear that this is more complex and not a linear relationship; such assumptions are overly simplistic. The evaluation can offer insights into health literacy outcomes from the interviews completed; however, these were mostly provider interviews. The insights did concur with themes that have been evidenced in the literature around gout programmes, but it is not an extensive, nor likely complete, reflection of health literacy outcomes.

Stakeholders highlighted the aspects of messages that were critical to understanding and managing gout. These include:

- The need to replace old beliefs about gout with new information.
- That gout is not their fault and that Māori and Pacific peoples have a genetic. predisposition because of the way their bodies metabolize urate.
- That diet is a trigger of an acute gout attack, not a cause.
- Gout is a long-term chronic condition and medication is needed for life to manage it.

"I suppose [the most helpful thing is] just learning about what gout is, I mean we've all heard this myth that only people who are alcoholics get gout, or that people who eat a lot of seafood get gout or rich food. But I don't eat rich food or drink. And so, after being explained what it was…I was able to get a bit more of a clue about it." (Client)

For patients the building of health literacy - repeated and consistent messages by people they trusted - was important too. This consistency has been supported by the professional development of providers and use of the same gout education booklets.

Providers who gave feedback on their learning about delivering the programmes valued the following aspects:

- Understanding gout prevalence, the scale and of inequity of non- optimal treatment was a motivator for those keen to promote the health of their communities.
- Skills to support the building of health literacy of patients emphasized the need to acknowledge existing beliefs about gout and understand patient learning as an incremental process.

"I ask them, 'can you tell me what you know already about gout?' and most people say, 'it's because I eat the wrong things'. I say, 'yes, that's what we used to think but we now know that's not the case'." (Gout Stop Pharmacist)

More thought (and resource) is required if gout programmes are going to capture learning outcomes for providers of gout programmes and the patients participating, either as a developmental check, quality improvement measure or a more systematic process.

8.4 Community outcomes

Operating at scale has helped to increase the capacity and social capital of the Northland community to promote gout treatment. This is by creating informal gout community champions and heighted awareness and health literacy in respect of gout by pharmacists, general practice and whānau.

The benefits of gout programmes extend beyond those participating. This is because the programmes are raising awareness of gout and addressing outdated beliefs about its cause and treatment. This can be seen as an increase in the capacity and social capital of communities and was evident particularly in Northland where the gout programme is district wide.

During our site visits and interviews we identified the creation of informal gout champions who were spreading the programmes messages about gout in their communities, workplaces and whānau. These were people who had been on the programme and who were sharing and using their experiences to encourage others to learn about the condition and seek appropriate treatment. While not surprising, this is not an explicit intention of the programmes.

"I'm working in a residential home ...and I had a young man who got a swollen foot. And I said, 'oh that looks a bit like gout'. So, I got him to go to the doctors and he got the gout tablets, but he wasn't taking it regularly and the gout kept coming back. So I actually said to him 'you need to be taking this every day, cos it will stop swelling' and so on. So by the information that I've learnt, I've been able to pass it on to him. I've really been on top of him about taking his meds since." (Gout Stop Client)

The encouragement of community organisations and workplaces to include gout awareness is highly positive as this will help shift wider societal attitudes about gout and, over time, provide a more conducive setting for health seeking. This may be more achievable through national and district wide programmes, rather than small-scale programmes as broader community understanding and acceptance also has a part to play in the success of gout programmes.

"Whānau are the people who support the individual, and if they're getting the same messaging then you're able to get rid of the old wives' tales. You need to educate the whole family and they will spread their knowledge and understanding to their networks and so on." (PHE staff)

The heightened awareness of gout in pharmacies involved in the programmes is evidenced by some examples provided in interviews. These included a more proactive repose to OTC purchases of Voltaren, and the challenging of GP prescriptions to treat gout that aren't following programme protocols.

"The pharmacy I go to, if you want to buy [Voltaren], it they invariably get the chemist to come out and talk to you" (Gout Stop client)

These two examples suggest that gout programmes can support the creation of a self-monitoring primary care community that is better positioned to support people with gout.

9. HEALTH SYSTEM CONTRIBUTIONS

The value chain created by the programmes enables the logical assumption that the programmes have contributed to the benefits for patients and communities. The programmes have also contributed to the broader health system by promoting integrated teamwork, addressing health equity, reducing the burden of gout on the sector through a management focus, and providing good value for the resource required locally.

In addition to contributing to outcomes for patients and communities, programme benefits can be considered as contributions to the health sector more generally. The following themes have been identified as the key contributions of the gout programmes to the broader health system.

9.1 Promoting integrated teamwork

The gout programmes have provided a mandate for collaborative interdisciplinary teamwork in terms of day-to-day programme delivery and development. This integrated teamwork and role enrichment can be personally and professionally satisfying as well as an efficient way of using health roles. It can help maximise existing health workforce capacity and effectiveness.

The gout models of care design addresses barriers to working at top of scope identified in the literature such as hierarchical practices, siloed service delivery, conflicting or duplication of services and lack clarity of others' roles[22]. The gout programmes have well-articulated pathways that draw on multi-agency and inter-disciplinary collaboration that extends from the non-regulated workforce to rheumatology specialists. One of the strengths of these models is the clear but connected roles each plays in the gout pathway.

Strengthening this contribution: There is potential to deepen this contribution with more non-regulated roles, such as Health Coaches, being used in primary care. Ensuring gout programmes are well connected to other primary care pathways (especially those related to other metabolic syndrome conditions will also increase the benefit to patients. Where education is the responsibility of more than one provider organisation it's advisable to have a system to check this occurs and patients don't slip through.

9.2 Pro-equity clinical practice and design

Gout is an equity issue. As this report has discussed, the barriers to accessing gout treatment, especially long term ULT are multiple and include both structural and personal factors. The programmes are promoting equity by

- Demonstrating strong reach into Māori and Pacific populations with the highest prevalence of gout.
- Recognising and addressing barriers to engagement through building knowledge and skills in clinical staff that includes cultural competency and understanding biases, building health literacy and gout treatment. In Northland the prescribing rate of NSAIDs for gout reduced[23]

[22] https://www.tepou.co.nz/uploads/files/resource-assets/scope-it-right-literature-review.pdf
[23] HQSC Atlas of Healthcare Variation https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/

- Providing a pathway that reduces cost and time barriers to access (such as needing to frequently visit the GP or have blood tests) were thought to be of greater benefit to Māori, Pacific and others in in the most deprived socio-economic quintiles.

Strengthening this contribution: Gout Stop had funding available to cover GP visits and prescription costs where this was a barrier, but this funding was not well used. This suggests a systematic application of subsidies (not for all, but for those experiencing this barrier the most) would be more effective at removing the cost barriers that prevent programme participation.

Taking time off work or to travel to general practices was also a barrier identified. Off-site and virtual delivery may also improve the accessibly of general practice for initial diagnosis and prescription, as may greater availability of labs for the more comprehensive blood tests required to monitor kidney function (eGFR).

The programmes provide a standardised approach that has potential for further differentiation for different patient groups and needs, for example, targeted follow up for younger Māori or Pacific men who don't complete the programme as well as working collaboratively with Māori and Pacific organisations.

9.3 Reducing the disease burden through prevention

Gout is a form of arthritis that can impact people's health, quality of life and participation in society in the short term (through painful flares) and, more significantly, without preventative management, longer term damage and disability can be caused. The personal and societal costs of gout are high; the Deloitte Economic analysis that was completed for Arthritis New Zealand in 2018 calculated 4850 disability Adjusted Life Years (DALYs) were lost because of gout

The programmes are contributing to preventing future loss of quality of life and disability through:

- Building the health literacy of patients and professionals about the long-term chronic nature of gout and the ongoing damage of high SU in the body (with and without flares).
- Reaching people in the younger age group. More than a third of people in both these programmes were aged under 45.
- Gout Stop included raising awareness, enabling messages to reach wider communities and those not engaged with general practice.
- Reducing the shame associated with gout by acknowledging historical beliefs and providing accurate information about gout's causes and long-term effects. These messages will take time to become established in communities.

Strengthening this contribution: Investment in raising awareness on a national level would provide a foundation for localised initiatives and generate conversations within whānau and communities, further encouraging informal gout champions that can reach into communities and help drive generational change.

9.4 Providing good value

Both programmes are providing good value for money locally. This is a general statement that reflects the programmes are good enough to justify the resource used for them. These are not expensive programmes to provide and represent, in the words of a funder, "a big bang for your buck".

- Gout Stop is a permanent care pathway across Northland DHB. Pharmacies are paid for new enrolments and completions.[24]
- OMG has secured Counties Manukau DHB funding to increase from six to 22 pharmacies. Pharmacies are paid $27.70 for each contact. Pharmacy costs include pharmacy time (for building health literacy), blister pack, consumables for BeneCheck © meters and overheads for IT and blood test quality control.
- The practice nurse time for oversight and building health literacy is not funded but fits within their existing role.
- Interdisciplinary teamwork may relieve pressure from GP shortages.

Strengthening this contribution: Having strong baseline evidence about gout prescribing and management practices helps programmes to evidence their positive impact. Programmes need to monitor people into the phase when they are persisting with long-term medication to demonstrate complete effectiveness.

A value for money analysis could consider:

- Reduced primary care demand.
- Reduced hospitalisations due to gout.
- Reduced use of emergency department and after-hours services for gout.
- Reduced loss of work time.

[24] Cost/payment information was not available for the evaluation .

10. PROGRAMME LEARNINGS AND IMPROVEMENTS

The two programmes have developed iteratively and will continue to do so. The following improvements were identified by stakeholders associated with the specific programmes and they raise important considerations for all gout programmes:

Gout Stop

- Pharmacists receive two payments, one on entry and a second on successful programme completion. A pharmacist reflected on the effort that went into encouraging participation and suggested a third payment option for 'exit with effort' be considered where the programme has not been completed but ongoing effort into follow up has occurred. This would need some thought to manage in practice. We did not speak to enough pharmacists to determine if the current payment structure was a disincentive to pharmacists to persist with patients, they felt would not complete the programme.
- All stakeholders identified the value of the community reach and raising awareness function provided by the kaiāwhina. Having more time and resource to raise awareness and follow-up outside health settings was a commonly identified improvement.

Owning My Gout

- Ongoing collaborative learning sessions with programme leads and participating pharmacists. These were a feature of the programme during the pilot phase and provided an ongoing opportunity for collaborative peer to peer problem solving, additional professional development, reflection and programme development. The sessions represent the commitment to the kaupapa of the work and emphasise its purpose beyond the effective dispensing of medication.

  "*Come and understand what the core of this service is and be inspired by people who have done well and build relationships out of your siloed environment and sit with other GPs, nurses and pharmacies around the same table" (OMG Lead)*

- A suggested development related to an e-portal for patients, ideally one that could display changes in SU in a chart. While some patient groups may engage with, and benefit more from, this option than others, the e-portal would enhance the self-management tools available.

10.1 Lessons learned

Some learnings that are not reflected elsewhere in the report may be useful for others setting up or enhancing programmes to consider. These are lessons learned by these two programmes and shared for the benefit of others.

- OMG used a validated patient centred outcome measure in an effort to capture the personal impact and benefits for people. This wasn't easily or well used in practice and required lot of pharmacy time to support completion. A tool that is simple, visual and can be self-completed by those with low literacy and a range of first languages was identified as what is needed. Identification of such a tool is required and there are generic quality of life type tools available but would need some instruction, particularly for first time use.

- Gout Stop initiated a pathway from the emergency department (ED) by providing free vouchers for people who had presented with gout to see a GP for follow up. This didn't work well as the effort required to maintain a profile for the programme in the fast-paced department with high staff turnover was too great for the programme to sustain. This is not uncommon with ED based programmes. ED is a valuable setting for gout intervention, if the gout programme is well established district wide and the ED programme is sufficiently resourced, supported internally and sustained.
- Both programmes identified that medically complex patients, including those with tophi, (crystallised monosodium urate crystals within the subcutaneous tissues or joints) were more likely to be managed by a rheumatologist than on the standard gout programmes. Patients with tophi were uncommon. Tophi are a feature of chronic gout that has been untreated and can become disabling. In designing a gout programme or pathway consideration needs to be given to those patients the pathways do not serve but may not have to incorporate the complexities patients with tophi may present.
  Gout Stop initially began recruiting and educating people to become formal community champions. This was hard to sustain with available resources and local stakeholders feel the organic generation of champions (in families, workplaces and the community) that occurs through individual involvement in the programme or health awareness raising, is working well.

11. INFORMING FUTURE ROLL OUT

The gout programmes have enabled the identification of critical factors for programme success. These relate to the components of the programme that are delivered (building provider and patient health literacy, key gout resources, easy access to medicine and raising awareness), and enable the programme to be delivered (a common programme framework and measurement model, systems to provide access to the right medication, share information, collaborative leadership, and sound planning and improvement activity). These need to be amended and be sensitive to the context in which they are implemented. It is recommended that programmes are set up with a view to long term sustainability. This will require resourcing and leadership at national, district and organisational levels.

Drawing on the experience of these two programmes and the contributions of stakeholders during our sensemaking session, has enabled core components of gout programmes to be identified alongside factors to consider about implementation These are presented here to support the design and roll out of future programmes. This is represented as a guide, as programmes do need to reflect their local context and needs.

11.1 Common programme framework and measurement model

Working with two different data sets that record programme activity differently and interpret programme completion and success differently has highlighted the benefit a common measurement framework for gout programmes would provide.

Such a framework would support and monitor people not just to the achievement of SU <0.036mmol/L but beyond, so these rates are maintained and the transition to persisting with taking long-term medication has been maintained for 12 months. As people can take many months to achieve the desired SU, we propose that programme success is considered not within a fixed timeframe but as long as it takes for a person to achieve target SU for 12 months.

A measurement model that will identity key measures, common definitions and minimum data field collected will support programmes to learn from their data, share learning and track improvement with some consistency.

Implementation considerations

- Development of an agreed minimum data set. We propose this includes:
    - NHI and demographic information (prioritised ethnicity, age and gender).
    - Record of client permission to use/share their data for quality improvement.
    - Date of activity and date of SU readings.
    - The pharmacy dispensing and the general practice and GP generating the prescription.
    - SU and gout prescriptions dispensed.
    - SU measures until SU <0.36mmol/L has been stable for 12 months.
    - A record of how knowledge and skills have been shared, and where provided e.g. provided at the pharmacy (or not) for each contact.
- Ability to extract the data set as a whole (including demographic information).
- Protocols for collecting and sharing data. This could include the extraction of programme data to a secure common data vault for aggregation and reporting in

dashboard format would support dissemination and use of learning across gout programmes.

- Protocols for standard analysis to enable benchmarking for learning. This would include:
    - Consistently applied working definitions for success at different stages. For example, goal 1 achieved could be SU <0.36mmol/L for the first time, goal 2 maintaining that for three consecutive months, goal 3 and goal 4 and concordant when SU <0.36mmol/L for 12 months and allopurinol has been dispensed.
    - Consistently used numerators and denominators- for example the numbers of those achieving as a percentage of all enrolments.
    - Use age and ethnicity grouping consistent with the HQSC's Gout Atlas and analyse results to determine.

11.2 Systematise easy access to medication

The medications for gout are not new. These programmes used a Standing Order (OMG) or a preloaded pack option (Gout Stop). Systematising prescribing removes the need for patients to frequently visit their GP (saving time and costs) and makes the process easier and quicker for GPs, who only have one prescription to make. Some of these broader system barriers to accessing medicine are identified in the PHARMAC driver diagram. This is attached in Appendix 2.

Implementation considerations

- Building prescription packs into PMS systematises prescribing. In most DHBs there is likely a range of PMS in use, requiring software development that is more than a local need. MedTech has already developed and delivered this capability so could be a first choice for roll out.
- Standing Orders for prescriptions must meet the Ministry of Health guidelines 2016 (https://www.health.govt.nz/publication/standing-order-guidelines).
- Options will need to account for people with diabetes and impaired renal functioning.
- People need to be trained to use BeneCheck ©. The meters are a one-off cost (approximately $72 retail) and the consumables (test strip and latex gloves) cost approximately$2.20 per use. This provides opportunities for different funders to support initial, equipment and ongoing costs.
- Roles and responsibilities of all health workers on the gout pathway need to be understood by all, for the programme to work well and provide a cohesive experience for patients.
- Tracking the gap between those people prescribed medication and not collecting the first prescription will provide more information on accessibly to medication and if any introduced subsidies make a difference.
- BPAC guidelines recommend that prescribers provide a "pill in the pocket" for managing future flares[25] and should be considered within the broader prescription package.

[25] https://bpac.org.nz/2018/gout-part1.aspx

11.3 Building knowledge and skills in providers

Often described as workforce training or education, this component is about building awareness and skills in primary care and individual practitioners so they better able to support people with gout to self-manage. Content includes gout knowledge and best practice, the local process for gout pathway as well as cultural competency. Training also includes knowledge and skills to build health literacy in others to support self-management. Using the HQSC's Ask Build Check[26] framework that asks what people know, or want to know, builds on their knowledge incrementally and checks that new information is clear, is recommended as it emphasises the providers' role in contextualising information and building understanding and activating individuals, rather than simply providing standard education to all.

Implementation considerations

- The importance of ongoing training and learning for providers, rather than being a one-off event.
- Encourage shared learning as this fosters a common purpose and supports the professional trust and connections that are important to make local delivery work.
- An online resource has been developed, the Community Pharmacy Gout Management Service Training, and is available on demand at https://www.psnz.org.nz/Event?Action=View&Event_id=282. This resource may be used by health providers as a starting point to develop resources. This online training would need to be complemented by collaborative face to face sessions to generate the interdisciplinary working relationships to consolidate and sustain delivery.
- GP gout education is happening via Professional Education sessions and is an opportunity to introduce this broader knowledge and skill building (e.g. how to have a conversation with a young man in his 20s who has chronic gout which is impacting all aspects of his life), rather than focus on the clinical management of gout in isolation.
- Complimentary use of rongoā.
- Capturing evidence of the outcome of programmes in terms of increased knowledge and skills to self-manage.

11.4 Building knowledge and self-management skills in patients

Gout programmes are about behaviour change and are not simply a prescribing and dispensing mechanism. Patients need to understand about their gout and their persistence to take long term medication encouraged through trustworthy and relatable delivery of information. These two programmes have used pharmacists to build health literacy as well as a kaiāwhina (Gout Stop) and practice nurses (OMG). Having roles with dedicated time to spend building health literacy with patients is important to deliver this individualised support.

Implementation considerations

- Receiving consistent messages from different health workers is powerful.
- Use of non-regulated workforce roles as relatable sources of credible information.

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[26] https://www.hqsc.govt.nz/our-programmes/reducing-harm-from-falls/projects/ask-assess-act/

- Requires a shift in thinking for some professionals about building health literacy (rather than solely education) as a dynamic process rather than a single transaction.
- Different approaches may work better for different patient groups and reduce the degree of drop out.
- Including whānau in the building of health literacy process.
- Developing mechanisms to account for the delivery and quality of health literacy being built with patients and whānau.

11.5 Gout resources

There are many patient resources available about gout, included the resource developed by the New Zealand Māori Pharmacists. Feedback suggested relatable resources that were highly visual were engaging for a broad range of patients. These programmes used the Stop Gout booklet 'the brown book' and the version developed by the Māori Pharmacists' Association 'the green book'. These resources are easy to read, visual and identify the minor role of diet in the creation of high uric acid. Not all resources convey this so clearly and understanding these things enables long standing beliefs and shame associated with gout to shift. Building health literacy with resources that are accessible for Māori and Pacific was said to contribute to programme effectiveness. If health workers refer to the same gout information resource, this is simpler for the patient, makes it more likely the messages will be understood and be seen as credible.

Implementation considerations

- Local agreement about what will, and won't, be used for gout information.
- Development of resources that reflects the community and their specific circumstances e.g. in a range of Pacific languages.

11.6 Raising awareness

Raising awareness that reaches into communities can share the key messages about gout causes and treatment and begin to break down the beliefs that perpetuate whakamā (shame) that is a significant barrier to effective treatment. Well-designed awareness raising activities can effectively reach people not engaged with primary care and well as whānau who can influence health seeking behaviour.

Implementation considerations

- Synergy between any national and local activity and resources.
- Tailoring to different target groups (e.g. Pacific peoples and younger working people (under45).
- Reaching beyond health settings, into workplaces and other places where people naturally gather.
- Developing a mechanism for enrolling on the gout programme for those not engaged with primary care.
- Providing information about the gout programmes and who can help.

11.7 System to share information

Health workers need to be able to communicate securely about patients on the gout programme. This includes enrolment on the programmes and for Gout Stop, consent for contact by the kaiāwhina, SU as they are tested and titration information. Gout Stop used faxes and phone calls to transfer information and communicate about patients. OMG

developed an online secure system that has limited capability. The health workers supporting people on the gout pathway need to talk with each other and intelligent Information Technology can enable this.

Implementation considerations

- Phasing out of fax machines this year.
- Avoiding double handling of information.
- Pharmacies use a range of patient management systems which may prevent the development of a single software solution.

11.8 Collaborative leadership

Need to have funder representation, pharmacy and primary representation as well as a link to and support from tertiary rheumatology services. The group required to establish and provide strategic guidance may be different from the operation group providing oversight. Programmes take time to set up and manage. Dedicated time is required for leaders. These will be champions for the programme and will need to actively manage and drive the programme locally.

Implementation considerations

- Involving people with a passion to get the work off the ground and who have the networks and credibility to inspire action in others.
- Consider ongoing oversight of programmes and how leadership will work beyond the initial start-up phase.
- Representing key professional areas and inclusive representation of local health providers including iwi health providers.
- Presents opportunity for co-design and co-production of local services.

11.9 Plan for initial and ongoing implementation

A planned approach to roll out that allows the gout programme to be scaled up as a structured quality improvement framework

Considerations

- Capacity building in quality improvement methodology and data analytics may be required.
- Identify populations with greatest need and design an approach that is sensitive to the requirements of different populations.
- Identify and address where possible the institutional and structural barriers in the local context.
- Resourcing for planning and collaborative quality improvement.
- Aligning systems with existing structures and processes where possible.

11.10 Supporting effectiveness and sustainability of gout programmes

Identified improvements and considerations for the design and implementation of gout programmes have emphasised the need to approach delivery as a longer-term investment rather than a short-term project or pilot. Delivery of gout programmes will be supported by resourcing of action at national, district and organisational levels and consideration of the following:

National level

- Ensure the National Community Pharmacy Agreement sufficiently reflects the requirements of collaborative gout programme delivery.
- PHARMAC to review mechanisms that make access to gout medicines easier.
- Require DHBs with high prevalence of gout to develop targets relating to improved access to appropriate medication and reduced inequity of access and outcomes.
- Support the development and use of a common measurement model for gout programmes that reflect best practice and support and track patients over 12 months onto long term allopurinol.
- Support the development of infrastructure that enables safe data sharing and learning across gout programmes in New Zealand.
- Facilitate the development and dissemination of simple and standard gout resources that address inaccurate beliefs about gout.
- Health professional training provides a culturally sensitive introduction to gout.

District level

- Introduce targets in terms of people appropriately accessing medication as well as a reduction in the needs-based equity gap between Māori, Pacific people and others. This may be through the annual planning process, for example, and actions to reduce variation in equity of outcomes.
- Promote the accessibility of lab testing, especially for those living rurally, without transport and with daytime commitments.

DHBs may have a role in facilitating and endorsing the use of standing orders. This would be within the context of gout programme leadership and require collaboration across all levels of the health system.

Organisational level

- PHOs and general practices can create their own expectations and targets around people appropriately accessing medication as well as a reduction in the equity gap between Māori, Pacific people and others.
- Review use of existing funding sources and their potential contribution to gout programmes. Examples include Innovation funding, Services to Improve Access funding (SIA), Long term conditions funding streams as well as population-based funding for Pacific, Māori and high deprivation populations.
- Systematically fund GP and prescription costs for groups where this is a barrier to accessing support for gout.
- Embed gout programmes into organisational systems such as patient management systems (monitoring and decision support), e portals and long-term conditions portfolios.
- Connect pathways so those on gout programmes are connected to other relevant health programmes and vice versa.
- Succession planning for programme leadership.
- Consider the context of delivery and how this will shape the design and roll out of gout programmes. The two programmes featured in this evaluation both had a critical mass of their target populations. In other parts of New Zealand these populations are more dispersed. Providers encountering very low numbers per pharmacy or GP practice may not be viable.
- Asian populations have specific clinical management needs that need to be considered.

12. SUMMARY

Gout is treatable, its long-term damaging effects are preventable. The medication is effective and available. People can live pain free, socially and economically productive lives with ULT, yet nationally, less than half those who should, are provided with access to ULT.

The two gout programmes subject of this evaluation have demonstrated ways of implementing programmes in ways that begin to address the barriers to treatment for their communities. The programmes have strong enrolment reach into their high needs communities. Māori and Pacific are benefitting clinically from these programmes; however, non-Māori and non-Pacific people are more likely to benefit as judged by the timeframe and success measures used by these programmes.

The provider and patient health literacy components of the programmes are a key point of difference from usual care. Building knowledge and skills through health literacy is important to destigmatise gout and encourage and enable people to access care. Broader actions to increase accessibly of primary care for Māori and Pacific peoples and those economically deprived will facilitate greater access to the services and supports needed to enhance their health and wellbeing. Achieving more equitable gout outcomes will require some programme differentiation to respond to varied needs of participants and potential participants.

These programmes are low cost and deliver benefits to people and contribute positively to organisations involved and the changing landscape of the health sector. The programmes are not an instant panacea to all the barriers to initial and ongoing treatment but have provided real world learning to inform the roll out of gout programmes. This has enabled the identification of core components of programme design and insights into the implementation considerations in different contexts.

From a synthesis of the evidence collected for this evaluation it is recommended that programmes use a consistent framework that has agreed working definitions of programme success and monitors patients until their SU have been below 0.036mmol/L for 12 months. Shareable and comparable data will better enable learning and improvement across the gout community.

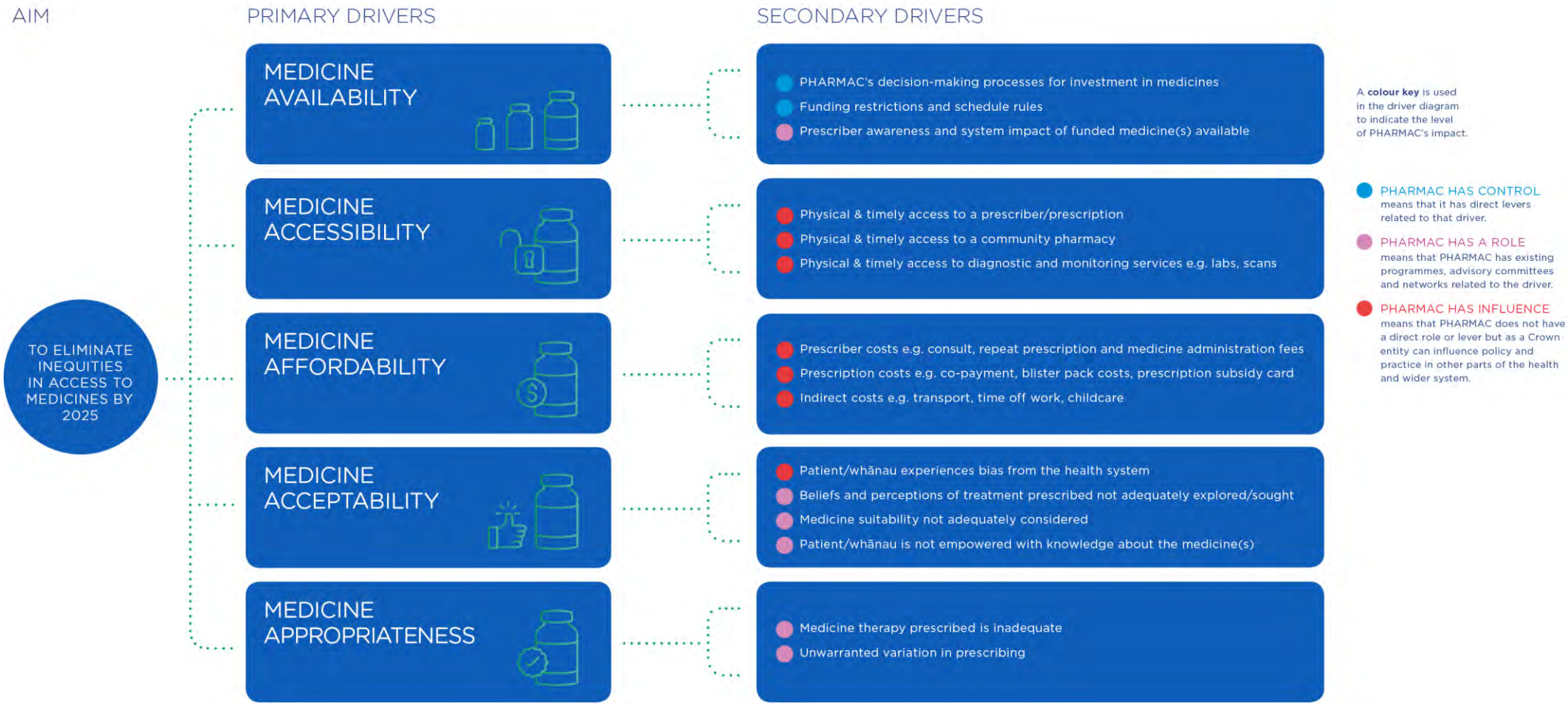
Gout is a significant health issue for New Zealand, an equity issue and a Te Tiriti issue. Delivering gout programmes provides value to the health sector as well as communities and patients. Programme implementation and outcomes can be framed through clinical management, prevention, equity of access and outcomes, workforce development and/or quality improvement lenses.

13. APPENDIX 1: ABBREVIATIONS

Table 13: List of abbreviations used in the report

Abbreviation	Meaning
DHB	District Health Board
ED	Emergency Department
eGFR	estimated glomerular filtration rate (measures creatinine, a waste product in blood to measure kidney function)
GP	General practitioner
HQSC	Health Quality and Safety Commission
NSAID	Nonsteroidal anti-inflammatory drugs
OMG	Owning My Gout
PHARMAC	Pharmaceutical Management Agency
PHE	Primary Health Entity
PMS	Practice Management System
SU	Serum urate level
ULT	Urate lowering treatment (medication such as allopurinol)

14. APPENDIX 2: PHARMAC'S DRIVER DIAGRAM



The Royal New Zealand College of General Practitioners
Te Whare Tohu Rata o Aotearoa

ORIGINAL RESEARCH PAPER

ORIGINAL RESEARCH: CLINICAL

Facilitating equitable prevention and management of gout for Māori in Northland, New Zealand, through a collaborative primary care approach

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ABSTRACT

INTRODUCTION: The Gout Stop Programme was developed for primary care in Northland, New Zealand, to address inequitable health outcomes for Māori and Pacific people with gout.

AIM: The aim of the programme was to make it easier for clinicians to prescribe urate-lowering treatment, facilitate patient adherence through education and support, and reduce barriers to gout prevention and long-term management.

METHODS: From 2015 to 2017, patients with acute gout who met inclusion criteria were prescribed treatment according to a 'Gout Stop Pack' option, based on renal function and diabetes status. Patients were monitored by community pharmacists. Gout educators and a Gout Kaiāwhina (community support worker) provided education and support to patients and whānau (families). Patient completion of the programme and outcomes, according to target serum urate level, were recorded. Patient experience was documented using a questionnaire and rating scale.

RESULTS: In total, 160 clinicians prescribed therapy at 887 patient presentations: 71% were Māori and Pacific patients. The completion rate was 55% in this group and 84% for the non-Māori and non-Pacific group. In the Māori and Pacific group, 40% reached the target serum urate level ($\leq$ 0.36 mmol L^{-1}) in 91 days, and 26% required further titration. In the non-Māori/non-Pacific group, these rates were 51% and 19% respectively. Following programme completion, 68% of Māori and Pacific patients and 65% of non-Māori and non-Pacific patients continued to take allopurinol. The 21 patients interviewed rated the programme as excellent or very good.

DISCUSSION: Culturally appropriate education and support for patients and the primary care team was essential. Collaboration between prescribers, community pharmacists and support workers reduced barriers to initiating prevention and long-term urate-lowering treatment and urate testing in this high-needs gout population.

KEYWORDS: Gout; medications; blood testing; primary health care; Māori health services; Pacific communities.

WHAT GAP THIS FILLS

What is already known: Gout prevalence is disproportionally high in Māori and Pacific people and is often undertreated in this group of people compared to non-Māori and non-Pacific people. Urate-lowering treatment is effective, yet patients with gout are often poorly managed with sub-optimal treatment.

What this study adds: The Gout Stop Programme highlights the importance of empowering patients to understand the management and prevention of gout, particularly among Māori and Pacific populations. Collaboration between general practitioners, community pharmacists, community support workers and health organisations is important in initiating prevention in high-needs populations who have the greatest gout prevalence, and in establishing patients on long-term allopurinol treatment.

Introduction

Gout, a common type of inflammatory arthritis, is a chronic disease that occurs with elevation of serum urate, causing the formation and deposition of monosodium urate crystals within joints.[1] Although a chronic condition, patients often present with recurrent flares, which are acute and extremely painful events. Metabolic syndrome, renal impairment, hereditary factors and diuretics are key risk factors for gout.[2]

In 2016, it was estimated that gout affected ~5.2% of New Zealanders.[3] In Northland, gout prevalence was 7.7%.[3] In Māori and Pacific peoples, the prevalence of gout is higher than for non-Māori/non-Pacific people. Sixty percent of the variation in urate levels between individuals can be attributed to inherited genetic variants.[4] Māori and Pacific peoples increased prevalence of gout can be partly explained by reduced renal excretion of uric acid. Key proteins for the renal excretion of uric acid are affected by the genes SLC2A9 and ABCG2, with the SLC2A9 genetic variant more prevalent in Māori and Pacific people.[5]

Oral urate-lowering therapy is effective in reducing serum urate levels to below the saturation point for monosodium urate crystals, inhibiting formation and inducing dissolution of these crystals. This effectively counteracts the cause of the acute pain symptoms of gout and reduces future joint deformities. Gout can be effectively managed with allopurinol, provided it is started at a low dose and titrated upwards monthly until the target urate level of <0.36 mmol L^{-1} is achieved. This treatment has been available for years, yet most people do not receive effective treatment and suffer from the painful symptoms of gout.[1] Inadequate treatment may be due to beliefs and stigma surrounding gout, to prescriber knowledge, variable approaches to treatment or the target urate level not being achieved or maintained. A short course of prednisone and colchicine can be used to control symptoms of acute gout and flare ups during initiation of urate-lowering therapy.

The Gout Stop programme is based on the publication entitled '*Treating acute gout and starting prevention in 7 minutes*'.[6] Goldfien *et al.*[7] in the US and Phone[8] in New Zealand have published other pharmacist-led collaborative programmes, but neither included a community support worker role. Northland's high Māori and Pacific populations,[9] the inequity of gout-related health outcomes in Māori and Pacific people[3] and the need to individualise treatment to achieve successful gout prevention and management are further driving factors promoting the development of the Gout Stop Programme. The programme aims to discover and reduce barriers to accessible gout treatment, specifically for Māori and Pacific people, and thereby achieve equity of health outcomes.

A common barrier to managing gout effectively is that patients may have a limited understanding of the condition and its treatment.[10,11] Building on patient knowledge and providing information for people at risk of, or with, gout is needed to improve health outcomes.[10] In addition, raising awareness and understanding of gout in the community is important.

Based on the positive outcomes and lessons from a pilot project involving 20 patients in 2014, the programme was modified to include an option for diabetic patients and inclusion of community support workers, and was rolled out progressively to clinicians across Northland. The treatment protocol was endorsed by rheumatologists and the renal team at Whangarei Hospital. A target of >70% Māori and Pacific patient participation

in the programme was set to address the goal of reducing health inequities. The programme has subsequently been adapted for local patient needs and is monitored by an oversight group comprised of a clinical lead, programme coordinator, general practitioner (GP), community pharmacist, specialist rheumatology nurse, Gout Kaiāwhina and the funder.

Methods

This is an open evaluation based on the collection of data from patients enrolled in the programme and prescribed the treatment protocol. Descriptive statistics were used and project approval was granted by the Northern Ethics Committee in 2015 (NDHB Locality Assessment No: 2016–5).

The population included patients from low socioeconomic communities who presented with an acute attack of gout and a history of two or more attacks per annum, according to the inclusion and exclusion criteria shown in Box 1. The treatment options included a combination of medications (prednisone, allopurinol and colchicine) prescribed for 91 days, based on the patient's renal function (eGFR in mL/min/1.73 m^2) and presence of diabetes as a comorbidity. In the diabetes option, naproxen was selected instead of prednisone. The prescription option, known as the '*Gout Stop Pack*' and specific programme laboratory form were built into Practice Management System (Medtech 32, Medtech Global Limited, Auckland, New Zealand), allowing easy selection by clinicians (Box 2). A '*GP*

Box 1. *Inclusion and exclusion criteria*

Inclusion criteria:
- Clinical diagnosis of acute gout attack.
- Vital signs within range (temperature <37C, BP systolic >100 mm Hg, HR <100 bpm).
- Patient can move joint despite pain.
- Attacks ≥2 per annum.

Exclusion criteria: (Refer to a rheumatologist)
- Doubt about diagnosis.
- Septic arthritis.
- Avoid treatment with colchicine if eGFR (estimated glomerular filtration rate) <10.

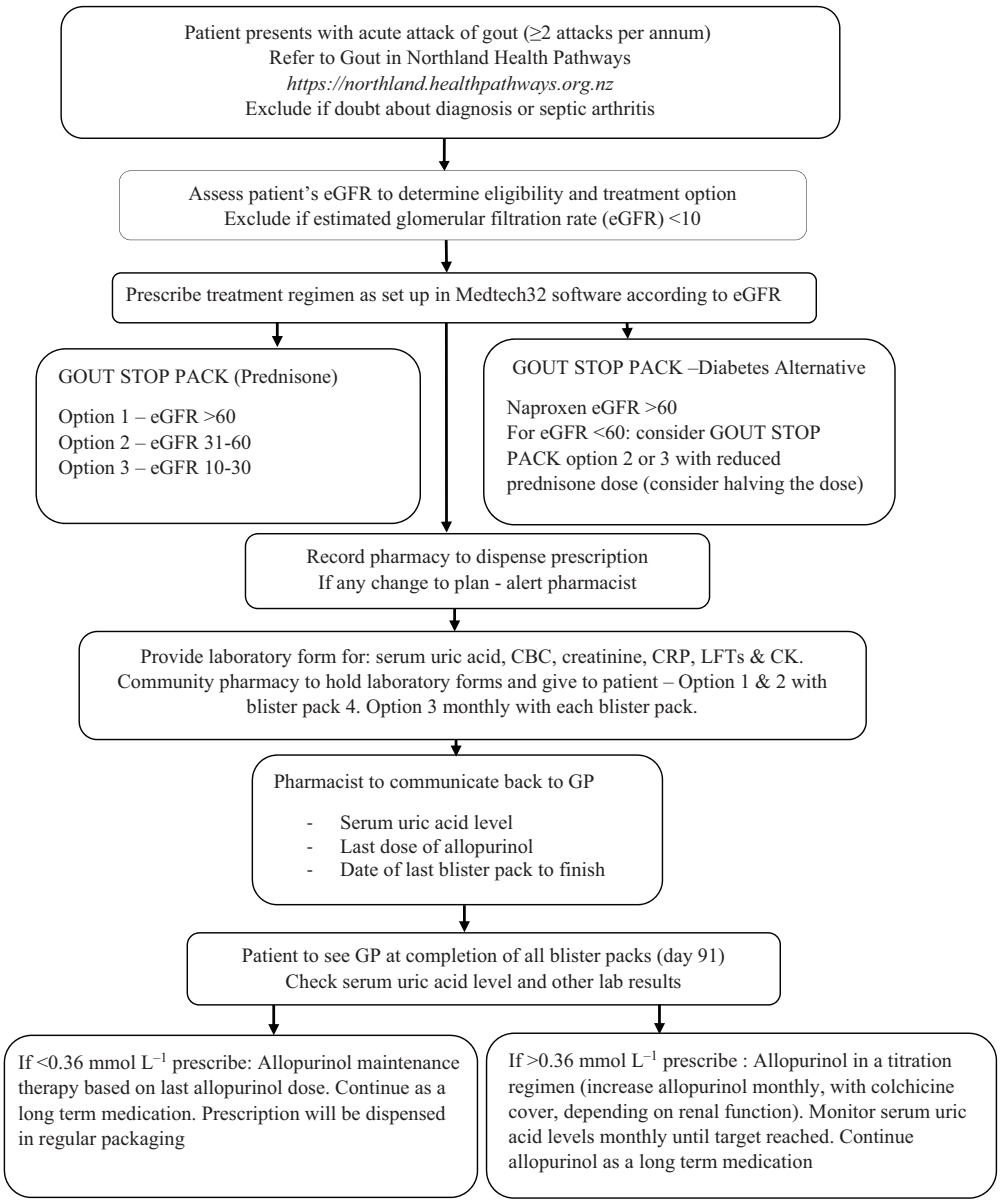
Box 2. *Treatment regimen: Gout Stop Pack*

The combination of medications to be prescribed for an acute gout attack, for a period of 13 weeks (91 days), according to the patients renal function (estimated glomerular filtration rate (eGFR)) or if there is a co-diagnosis of diabetes

Renal function (eGFR)	Blister Pack 1 (14 days)	Blister Pack 2 (28 days)	Blister Pack 3 (28 days)	Blister Pack 4 (21 days)
Option 1 eGFR >60	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 100 mg daily Colchicine 500 mcg twice daily	Allopurinol 200 mg daily Colchicine 500 mcg twice daily	Allopurinol 300 mg daily Colchicine 500 mcg twice daily *Laboratory form
Option 2 eGFR 31–60	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 50 mg daily Colchicine 500 mcg once daily	Allopurinol 100 mg daily Colchicine 500 mcg once daily	Allopurinol 200 mg daily Colchicine 500 mcg once daily *Laboratory form
Option 3 eGFR 10–30	Prednisone 40 mg for 4 days, 20 mg for 4 days, 10 mg for 3 days, 5 mg for 3 days.	Allopurinol 50 mg every other day Colchicine 500 mcg every other day *Laboratory form	Allopurinol 50 mg daily Colchicine 500 mcg every other day *Laboratory form	Allopurinol 100 mg daily Colchicine 500 mcg every other day *Laboratory form
Diabetes alternative eGFR >60	Naproxen 500 mg twice daily	Allopurinol 100 mg daily Colchicine 500 mcg twice daily	Allopurinol 200 mg daily Colchicine 500 mcg twice daily	Allopurinol 300 mg daily Colchicine 500 mcg twice daily *Laboratory form

*Laboratory form: laboratory investigations to include serum uric acid, Complete Blood Count, C-reactive protein, creatinine, Liver Function Tests, Creatinine kinase. The option for diabetic patients with an eGFR <60 is to consider the Gout Stop Pack - Option 2 or 3 with reduced prednisone dose (consider halving the dose) or consult a renal physician.

Box 3. *GP flow chart*



Flow Chart' described the process followed during the programme (Box 3).

Medication was dispensed by a community pharmacist according to the prescription for the '*Gout Stop Pack*'. The medication was provided in free-of-charge blister packaging on four occasions and regular contact was maintained to guide patients through the process. Patients were advised when to have laboratory tests, the serum urate result was checked in the clinical information sharing service, TestSafe, and the level and patient outcome was communicated to the prescriber.

Patients who completed the programme were categorised based on their serum urate levels as follows:

Success: patient completed the programme and reached the target serum urate of ≤0.36 mmol L^{-1}.

Titration: patient completed the programme but had not reached the target serum urate of ≤0.36 mmol L^{-1}.

No level: patient completed the programme but no serum urate level was available.

Patients who did not complete the programme were categorised based on the reason for non-completion as follows:

Disengaged: patient disengaged due to personal or social factors.

Withdrawn: patient was removed by the prescriber or specialist due to comorbidities or side-effects.

Lost to follow up: patient was uncontactable or had moved away.

Community pharmacists were contacted either by telephone or email between April and December 2017 to determine whether two cohorts of patients had allopurinol prescribed following completion of the programme. Pharmacists used the booklet '*To Stop Gout*'[12] as an education tool to give to patients. An informative video about the programme and its benefits was created; this includes narratives from both the health-care team and patients who participated in the programme.[13]

In consultation with Emergency Department clinicians, patients presenting to Emergency Department with acute gout were prescribed 2 weeks of prednisone and given a voucher for a free-of-charge GP visit in order to be enrolled in the programme. Patients were followed up and outcomes recorded.

Arthritis New Zealand Gout Educators provided support to patients who consented until September 2017. A Gout Kaiāwhina role was then created to support patients in the programme, link patients with clinicians and community pharmacists, and reach patients in occupations with a high percentage of Māori males in the workforce.

Patient outcome questionnaire

A cohort of 24 patients, 12 in each of the Māori and Pacific and non-Māori/non-Pacific groups and three in each outcome group (Success, Titration, No Level) were randomly selected (using www.random.org). A questionnaire based on open-ended questions, as listed in Table 1, was used to collect qualitative information from these 24 randomly selected patients. The overall rating of the programme used a scale of 0–4, where 0 = poor, 1 = fair, 2 = good, 3 = very good and 4 = excellent. Telephone interviews with patients enrolled in the programme in the previous 16 months were conducted by a medical student working on a summer internship, and responses were documented.

Results

Demographics

A total of 887 patients were enrolled in the programme. Demographic data are presented in Table 2. The mean age of Māori and Pacific males was 9 years younger than Māori and Pacific females. Māori and Pacific males and females presented with gout younger than other ethnicities (Figure 1). The percentage of Māori and Pacific patients was higher than the percentage population for Northland according to census data.[9]

Treatment outcomes

The programme was adopted by 36 general practices across Northland. A total of 160 clinicians, including GPs, specialist physician, nurse practitioners and clinicians from Māori health providers, prescribed the programme. Data for 708 patients were analysed, representing 80% of enrolled patients. The remaining 20% of patients are still in the programme or the data had not yet been obtained. Of the three treatment options shown in Box 2, 74% of patients were allocated to option 1, 18% to option 2, 1% to option 3, 3% to the diabetes alternative option and the remaining 4% had no option recorded.

The rate of completion of the programme was 55% (280/505) in the Māori and Pacific group compared to 84% (170/203) in the non-Māori/

Table 1. Illustrative quotations from patients interviewed

Questions	Selected Quotations
What did you like about the programme?	Gout triggers didn't feel as bad anymore. [#1] Made my gout way less painful. Sometimes forgot to take one some days, but it still made me better. [#3] Made my joints feel better but I had so many other things going on. [#4] The meds are easy to take. All the people I've seen were really helpful and everything explained well. [#8] Was easy. No gout, I'm able to walk, drive, and go play golf. [#11] Liked blister packs over the big bottle. Like talking to doctor and pharmacist. [#12] It makes my pain go away, so I like it. [#15] Blister packs are very useful so I don't forget to take them. [#17]
What did you not like about programme?	Still have attacks from time to time. [#6] I don't think I reached the level the doctor wanted me to. [#7] Didn't take pills anymore because he didnt need them. [#19] Oh, it didn't really work for me. Forgot to go get them. I keep meaning to. Got a text from pharmacy. [#10] I didn't finish because pain didn't come back so didn't need tablets anymore. But they made it go away in the first place so that is great. [#20]
Have you been told that medication will need to be taken long term?	No need to take as I don't get gout anymore. [#1] Yes. [#2] [#3] [#5] [#6] [#11] [#12] No only when I feel I need it. [#13] Yes my levels fluctuate so I keep taking them. [#14]
Have you had blood tests for gout? What are some of the barriers to getting the blood tests done?	Not that I can remember as I haven't had any pain. [#1] Sometimes I don't have the time. [#6] Too busy and too far. [#7] I need to find time to take one. Just really busy all the time. [#17]

Interviewed patient outcomes according to patient number (#):
Completed: success - #1, #2, #3, #11, #12, #13 Completed: titration - #4, #5, #14, #15.
Completed: no level - #6, #7, #8, #17 Not completed: disengaged - #10, #19, #20.

non-Pacific group. Outcomes by ethnicity for those who completed and those who did not complete the programme are presented in Figures 2 and 3.

Of the total number of patients who completed the programme, 66% (299/450) continued to take allopurinol following completion; 68% (189/280) of Māori and Pacific patients and 65% (110/170) of the non-Māori/non-Pacific group. Eighty-eight patients were enrolled in the programme on more than one occasion; 68 were enrolled on two occasions, 18 on three occasions and two on four occasions. Of these patients, 89% were Māori and 42% have since completed the programme.

Patients who presented in the Emergency Department (ED) with gout and were referred to the programme were followed up by telephone. Seven patients, with 14 presentations to the ED as a result of two patients presenting multiple times, were contacted. On seven occasions, patients were provided a GP voucher and three patients visited a GP and were enrolled in the programme.

Table 2. Demographic data by ethnicity

	Total	Māori	Pacific	Non-Māori / Non- Pacific
Patients *n* (%)	887 (100)	591 (67)	36 (4)	260 (29)
Age (mean)	52.2	49.8	41.9	59.8
(range)	19–98	19–95	20–67	19–98
Male *n* (%)	730 (82)	477 (81)	33 (92)	220 (85)
Age (mean)	50.6	47.8	41.2	58.2
(range)	19–94	19–90	20–67	19–94
Female *n* (%)	157 (18)	114 (19)	3 (8)	40 (15)
Age (mean)	60.8	58.3	49.7	68.6
(range)	22–98	22–95	41–67	33–98

Figure 1. Age quartiles by ethnicity.

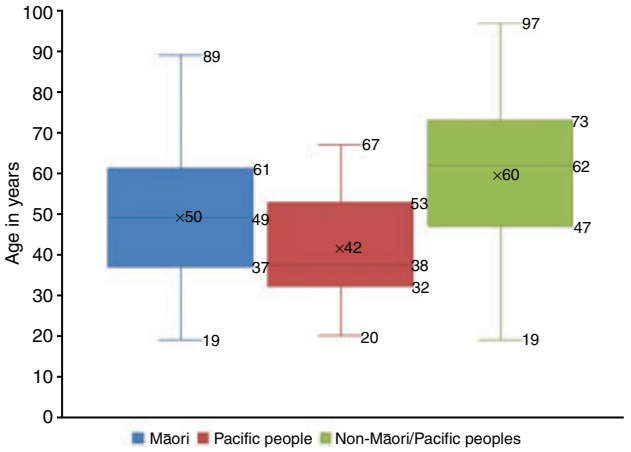
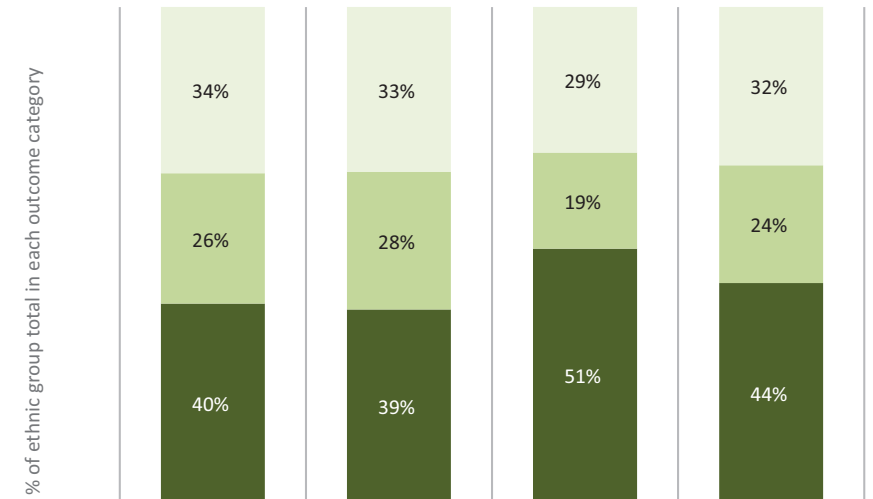


Figure 2. Completed outcome categories by ethnicity.

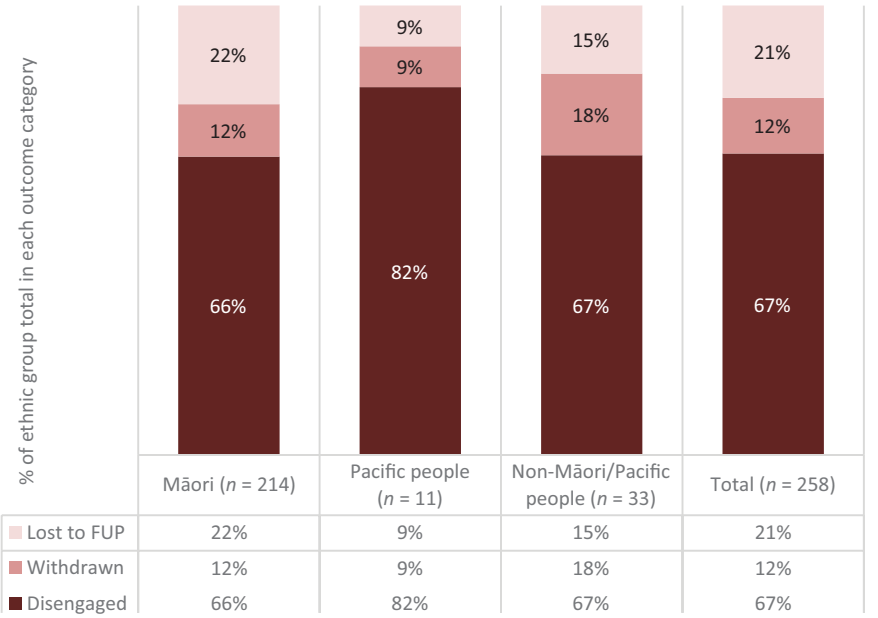


	Māori (*n* = 262)	Pacific people (*n* = 18)	Non-Māori/Pacific people (*n* = 170)	Total (*n* = 450)
No level	34%	33%	29%	32%
Titration	26%	28%	19%	24%
Success	40%	39%	51%	44%

Patient outcome questionnaire

Of the 24 patients identified for interview, 21 were contactable and were interviewed (11 Māori and 10 non-Māori patients). Of these, 16 patients had completed the programme, 13 confirmed that they were still taking the allopurinol and eight recalled having been informed that the medication was required to be taken long term. Most patients (62.5%) had a serum urate test on completion of the programme. The overall rating of the programme was recorded as excellent by 62% of patients and very good by 38%. The questions asked and patient responses are summarised in Table 1.

Figure 3. Not completed outcome categories by ethnicity.



	Māori (*n* = 214)	Pacific people (*n* = 11)	Non-Māori/Pacific people (*n* = 33)	Total (*n* = 258)
Lost to FUP	22%	9%	15%	21%
Withdrawn	12%	9%	18%	12%
Disengaged	66%	82%	67%	67%

Discussion

New Zealand research has shown that gout is undertreated and that approximately two-thirds of patients with gout dispensed urate-lowering therapy have not had serum urate levels measured in the following 6 months.[3] Consistent with other reports of gout disproportionally affecting people of Māori or Pacific decent,[14] the demographic analysis in this research demonstrated a high number of Māori and Pacific people. While the initial goal of enrolling patients in the programme being >70% Māori and Pacific people was achieved, the rate of programme completion was lower in the Māori and Pacific group (55%) compared to the non-Māori/non-Pacific group (84%). Successful completion of the programme was also lower in Māori and Pacific patients at 40% versus 51% in non-Māori/non-Pacific patients.

Factors related to the perception of gout, insufficient understanding of treatment and adherence to long-term treatment, appear to contribute to this disparity.[15] This emphasises the need for a flexible programme and the informative role of the Gout Kaiāwhina. Of the patients enrolled more than once, 42% of patients, of whom 89% are Māori, have since completed the programme, suggesting that the re-enrolment of patients is important when addressing health outcome inequities.

There appears to be a need to raise the profile of gout, emphasise the appropriate use of urate-lowering therapy, as well as the importance of a multiple therapy approach to treating acute gout attacks. Urate levels require monitoring on a regular basis, the dose of urate-lowering therapy needs to be adjusted accordingly and prescribed on a long-term basis. The Gout Stop Programme addresses these issues directly by aiding inter-provider collaboration, increasing support for health literacy and ease of prescribing.

In 2016, the Atlas of Health Care variation data for gout in Northland showed a rate of allopurinol use of 43.2% compared to the national rate of 41.6%. In Māori males, the rates were 41.5% in Northland and 39.5% nationally. The rate of non-steroidal anti-inflammatory drug (NSAID) use in patients with gout was lower in Northland at 34.6% compared to the national rate of 37.1%. Among Māori males, the rates were 40.2% and 43.6% respectively (A. Wevers, pers. comm., HQSC, February 2018). It thus appears

encouraging that within 1 year of commencing the programme, allopurinol use in Northland was higher and NSAIDs use lower than the national average, particularly for Māori patients.

A US study[7] assessed the effect of a pharmacist-staffed gout management clinic and found this more effective than usual care under a primary care physician or rheumatologist in achieving target serum urate levels in gout patients. In NZ, *Owning My Gout* is a pharmacist-led collaborative gout management project involving community pharmacists and practice nurses where an electronic shared care plan is initiated and community pharmacists titrate allopurinol doses in collaboration with the general practice team. This project demonstrated that community pharmacists can have a role in the titration of allopurinol dosing using standing orders provided by GPs.[8]

The ultimate success for patients is reaching the serum urate target of ≤0.36 mmol L^{-1} and continuing to take allopurinol as a long-term medication, to avoid acute gout flares and joint deformities. We found that 68% of Māori and Pacific patients continued taking allopurinol after completion of the programme. Patients require a comprehensive understanding of the treatment and the need for adherence. Longitudinal monitoring of the project will track the programme's effect on patient outcomes and allow for modifications to the programme in order to achieve higher rates of long-term allopurinol use.

The patient outcome questionnaire showed a disparity between the number of patients confirming they were still taking allopurinol and the number with a good understanding of the need for long-term treatment. This highlights the need for reinforcing patient education and ensuring patient understanding. Reasons for patients not accessing serum urate blood tests were captured as this is an issue documented in previous studies.[16] This, along with the fact that 32% of patients who completed the programme had no serum urate measured, supports the recent modification of the programme to include Point-of-Care testing in community pharmacies using BeneCheck meters and urate test strips as an on-site alternative to laboratory tests, and to facilitate appropriate dosing of allopurinol for individual patients at the time of medication dispensing. This approach demonstrates a collaborative and flexible programme that is geared towards meeting the goals and needs of patients and providers.

In 2017, 182 patients presented to the ED at Whangarei Hospital with the primary diagnosis of gout; 69% were Māori, of whom 79% were males (B. Johnson, pers. comm., NDHB, March 2018). A small number of patients were referred to the programme from the ED, suggesting that the process did not meet the needs of all patients or that clinicians were not aware of the programme. Referral of patients between secondary and primary care is important when initiating prevention and treatment of gout in high-needs populations. It is therefore important to understand why people access the ED for non-emergency conditions and to continuously review processes to simplify the path of accessing treatment. Similar to suggestions from other studies,[10] there should be a shift in the management of gout from a recurrent acute condition to management as a chronic disease for which there are successful long-term multidisciplinary treatment options. Primary care has a key role in coordinating the prevention and management of such conditions.

The programme was prescription driven and relied on patients being seen by clinicians who had access to the treatment protocol, the presentation and dispensing of prescriptions at community pharmacies, and referral to the Gout Kaiāwhina for support. The data collected were derived from completed patient record forms returned from community pharmacy and participation was open and uncontrolled. The number of patients interviewed was small and only 21 of 24 were contactable, but responses provided lessons for the programme.

The Gout Stop Programme is being expanded to include more structured and culturally appropriate gout education in community pharmacies, enhanced identification of potential gout patients who would benefit from the programme, as well as the identification of patients with gout who present in community

pharmacies for over-the-counter NSAIDs with the aim of referring them to a GP.

Conclusion

The Gout Stop Programme highlights the importance of empowering patients to understand the management and prevention of gout, particularly among Māori and Pacific populations. Māori and Pacific males present younger, yet have lower levels of programme completion. To achieve improved medication adherence and gout-related health outcomes, culturally appropriate education and support for patients and whānau are required.

Collaboration between GPs, community pharmacists, community support workers and health organisations is important in initiating prevention in high-needs socioeconomic populations, who have the greatest gout prevalence, and in establishing patients on long-term allopurinol treatment. Each group of health-care professionals has a key role to play in the identification of patients with gout, in successful acute and long-term treatment of gout, and in improvement of equity in health outcomes.

Removing barriers to access of appropriate treatment and serum urate testing is crucial to successful long-term gout management. The importance of treatment adherence and serum urate testing needs to be explained to patients in a comprehensible manner. Clear communication pathways between patients and members of the health-care team is essential in ensuring that all have the information needed to initiate treatment, titrate allopurinol doses and achieve successful long-term outcomes. The Northland Gout Stop programme is evidence based, flexible in approach and makes use of patient outcomes and feedback to inform on-going primary care service delivery, with encouraging results to date.

Competing interests

The authors declare no competing interests.

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References

1. Doherty M, Jansen T, Nuki G, et al. Gout: why is this curable disease so seldom cured?Ann Rheum Dis. 2012;71(11):1765–70.
2. Roddy E, Zhang W, Doherty M. The changing epidemiology of gout. Nat Clin Pract Rheumatol. 2007;3:443–9. doi:10.1038/ncprheum0556
3. Health Quality and Safety Commission. Atlas of Healthcare Variation. Gout, 2018. [cited 2018 October 01]. Available from: https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/gout/
4. Krishnan E, Lessov-Schlaggar CN, Krasnow RE, et al. Nature versus nurture in gout: twin study. Am J Med. 2012;125:499–504. doi:10.1016/j.amjmed.2011.11.010
5. Merriman TR, Dalbeth N, Johnson RJ. Sugar-sweetened beverages, urate, gout and genetic interaction. Pacific health dialog: A publication of the Pacific Basin Officers Training Program and the Fiji School of Medicine. Pacific Health Dialog. 2014;20(1):31–8.
6. Arroll B. Treating acute gout and starting prevention in 7 minutes. Goodfellow Learning Site; 2015. [cited 2015 May 05]. Available from: https://www.goodfellowunit.org
7. Goldfien R, Pressman A, Jacobson A, et al. A pharmacist-staffed, virtual gout management clinic for achieving target serum uric acid levels: a randomized clinical trial. Perm J. 2016;20(3):15–234.
8. Phone D. Owning My Gout A Pharmacist-led collaborative gout management model at Counties Manukau DHB. Int J Integrat Care. 2017;18(S1):A38.1–8.
9. Statistics New Zealand. 2013 Census QuickStats about a place: Northland Region. [cited 2019 February 03]. Available from: https://www.archive.stats.govt.nz/Census/serum urates/2013-censerum urates/profile-and-serum uratemmary-reports/quickstats-about-a-place.aspx
10. Spencer K, Carr A, Doherty M. Patient and provider barriers to effective management of gout in general practice:

a quantitative study. Ann Rheum Dis. 2012;71(9):1490–95. doi:10.1136/annrheumdis-2011-200801
11. Horsburgh S, Norris P, Becket G, et al. Allopurinol use in a New Zealand population: prevalence and adherence. Rheumatol Int. 2014;34(7):963–70. doi:10.1007/s00296-013-2935-5
12. To Stop Gout booklet. Auckland: Workbase Education Trust 2014.
13. Gout Stop 2016 - Interviews with Georgia Grant-Mackie and Dr Aniva Lawrence. Whangarei: Northland District Health Board; 2016. [cited 2018 January 12]. Available from: https://www.youtube.com/watch?v=svyrFaUHPx8
14. Dalbeth N, House ME, Horne A, et al. The experience and impact of gout in Māori and Pacific people: a prospective observational study. Clin Rheumatol. 2013;32:247–51. doi:10.1007/s10067-012-2110-5
15. Te Karu L, Bryant L, Elley CR. Maori experiences and perceptions of gout and its treatment: a kaupapa Māori qualitative study. J Prim Health Care. 2013;5(3):214–22. doi:10.1071/HC13214
16. Sarawate CA, Brewer KK, Yang W, et al. Gout medication treatment patterns and adherence to standard of care from a managed care perspective. Mayo Clin Proc. 2006;81(7):925–34. doi:10.4065/81.7.925

GOUT STOP

WHANGANUI

Whanganui Gout Stop Programme Evaluation

Final Evaluation Report

23 November 2022

Whanganui Regional Health Network

With support from Health Solutions Trust as part of the

Whanganui Regional Health Research Collaborative

Acknowledgements

We would like to acknowledge the patients who have given the time to share their experiences with us. Your insights have been extremely valuable in understanding how well the Gout Stop programme and gout-related health care works in Whanganui. In addition, the impact on multiple aspects of wellbeing described has demonstrated the significance of this mahi.

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Contents

1 Executive Summary

1.1 Introduction

Gout arthritis (gout) is a chronic, long-term, treatable condition that disproportionately affects Māori and Pacific peoples in terms of genetic causes, earlier onset, severity, and burden of disease. Gout can be effectively managed in primary care; however, the identification of gout and uptake of management services provide barriers to effectively supporting the population suffering from gout.

Whanganui Regional Health Network (WRHN) has commenced development of a local Gout Stop programme (GSP) to address the high rates and inequity of gout in the Whanganui DHB region. The Whanganui GSP builds on previous Gout programmes in Northland and Counties Manukau. The GSP is intended to be a whole of system approach and has involved activity across three main components: general practice, community pharmacy and Kaiāwhina / community engagement. The Whanganui GSP was launched in November 2020.

1.2 The delivery and achievements of the Gout Stop Programme

The delivery of the GSP is across the whole Whanganui rohe but most of the GSP engagement has come from a small group of community pharmacies, general practices and Whanganui Accident and Medical (WAM). Health providers have a large role to play in supporting patients to enter the GSP and also on the completion of the programme.

Health literacy appears to be a key component in the pathway to well managed gout. Understanding of gout was considered a contributor to people accessing the health care system for their gout and completing the GSP. Food triggers tended to be well described by patients but understanding the nature of gout as a long-term condition, the genetic causes that disproportionately affect certain ethnicities, and the role of long-term medication in prevention varied. Multiple patients described stopping their preventative medication once the gout attack had stopped. The delivery of gout initiatives, whether at the individual or community level, should focus on developing health literacy.

The GSP demonstrated equity in its reach, completion, and clinical outcomes. More than half of the patients that engaged with the Gout Stop programme were Māori, but the reach also extended beyond those recorded as being in the GSP as there was a 25% increase in the number of Māori receiving regular allopurinol from general practice across the rohe. While there was a slightly smaller proportion of Māori at the target serum uric acid (SUA) level after the programme, the average reduction in SUA was greater for Māori than non-Māori.

1.3 Conclusions and considerations for an implementation guide

The early adopters of this programme demonstrated that the GSP is effective in improving the quality of life of Māori with gout. The challenge for future collaborative LTC programmes is being able to roll-out a programme with buy-in from all providers. Getting the implementation right is the key to programme reach and success. This could be supported by sustainable funding for implementation, national activities to build awareness, and integrated IT systems that better enable information sharing and collaboration.

The Whanganui Gout Stop Programme is one example of collaborative LTC programme that is making a difference. Their experience has informed some recommendations for getting the implementation right:

- **In the initial stage of establishing a collaborative LTC programme**, start from a place of co-design with all stakeholders, including consumers. Give careful consideration to the skills, competencies and roles included when establishing the leadership and implementation team. Build equity into the programme at all stages starting from defining the programme aim.
- **When designing a collaborative LTC programme**, use planning models and tools that work for your team to ensure you can communicate how your programme activities will achieve your programme aim. Ensure that the health providers involved are able and supported to deliver the activities in the plan, and that required resources are secured. Also plan what indicators are meaningful for stakeholders to enable feedback with a learning and improvement culture.
- **When delivering a collaborative LTC programme**, use any tools and resources available to encourage provider activity. This includes establishment of champions, directing Cornerstone activities towards the topic of gout (or programme LTC in focus), including Health Improvement Practitioners (HIPs) and Health Coaches in routine pathways, and provision of regular feedback on progress.

2 Introduction

2.1 Why Gout Arthritis?

Gout arthritis (gout) is a chronic, long-term condition that causes joint pain and swelling. It is caused by too much uric acid in the blood which turns into sharp crystals in the joints. If left untreated gout can cause serious damage to joints, kidneys, and quality of life. However, gout can be effectively managed in primary care through the use of uric acid medicines and blood tests to monitor serum uric acid levels. The key to preventing gout attacks is lowering serum uric acid (SUA) levels to below 0.36 mmol/L.

Gout is an equity issue as it disproportionately affects Māori and Pacific peoples. There are genetic causes to gout that mean there is a higher prevalence, earlier onset and severity of gout for Māori and Pacific people where they experience a greater burden of disease. Despite the higher burden of disease, the identification and utilisation of management services in primary care is lower. This provides an inequitable barrier to effectively supporting the population suffering from gout. These inequities in rates of best-practice gout management result in higher rates of avoidable hospitalisations for Māori and Pacific people. Not only does this difference represent a poor health outcome that is unjust and avoidable, but it impacts on quality of life, ability to engage in mahi, with whānau, and culture.

The Whanganui rohe has a high prevalence of gout arthritis in Māori and poor management. Based on the Health Quality & Safety Commission (HQSC) Atlas of Healthcare Variation, in 2019 Whanganui District Health Board (WDHB) had 6.4% of the population with gout but this consists of 9% for Māori and 9.8% for Pacific peoples (compared to 5.6% for non-Māori, non-Pacific peoples). Note that for WDHB, Māori make 27.4% compared to 4.0% for Pacific peoples[1]. However, less than half of all gout sufferers in Whanganui were regularly receiving preventative medication and this rate was decreasing (WRHN, 2019). In 2017/18 it was estimated that 130 ED admissions were due to gout arthritis, illustrating the medical consequences from poorly managed gout arthritis (WDHB, 2019).

2.2 What do we already know about Gout Programmes?

In February 2020, Arthritis NZ, PHARMAC and HQSC funded Synergia to evaluate two gout programmes operating in New Zealand:

- Owning My Gout – A community pharmacist and nurse-led collaborative model piloted in Counties Manukau. GPs issue standing orders for community pharmacists to prescribe gout medication. Together the practice nurse and pharmacist titrate medication and build patients' health literacy.
- Gout Stop programme provided by Mahitahi Hauora PHO in Northland – The programme is based on a 91-day model of collaboration between GPs, community pharmacists and Kaiāwhina working together to improve accessibility to medication

[1] StatsNZ. Ethnic group (total grouped responses) for census usually resident population count in Whanganui district Health Board in 2018.

and health literacy. This is the programme that informed the Whanganui Gout Stop programme.

These programmes both achieved equitable levels of programme enrolment but challenges maintaining participation. The programmes were less likely to retain Māori, Pacific, and younger people which contributed to lower rates of clinical success for these priority patients.

The Synergia evaluation identified core components of gout management programmes as being easy access to medicines for patients, activities to build provider and patient health literacy, accessible gout information and awareness raising. Key enablers to delivery of such programmes were systems to provide easy access to the right medication and share patient information, collaborative leadership, a common gout programme framework and measurement model, and sound planning and ongoing improvement activity.

2.3 The path to starting a Gout Stop Programme in Whanganui

The Whanganui Gout Stop programme was launched in November 2020 but the journey started in 2018 when Arthritis NZ demonstrated the poor performance of WDHB Gout care based on the HQSC's Atlas of Healthcare Variation. At the time, management of gout was not a strategic priority for the DHB or primary care. However, it was acknowledged that it needed to be a focus area.

Primary care then did some early work to improve the management of gout. The Whanganui Regional Health Network (WRHN) provided support with a PowerBI dashboard illustrating gout data in general practice and disseminated awareness communications via their Collective Comms group and Health Matters publications. One practice implemented a continuous quality improvement (CQI) project and implemented a clinical audit. This was successful in reducing the number of patients with a gout diagnosis who did not have their serum uric acid levels tested in the last 12 months. During this CQI project, it was also identified that there needed to be a clinical update for GPs/nurses on gout. Best practice treatment and management for gout had changed over recent years and there needed to be a greater understanding of the impact of genetics on gout, especially in younger Māori and Pacific males. The process and outcome from this project were shared at a Whanganui Inter-Professional Education session and the clinical update facilitated by Arthritis NZ.

Gout was included in the WDHB 2019/20 annual plan as an equity outcome and a proposal was made to the Whanganui Alliance Leadership Team (WALT) to deliver a collaborative model of care to manage gout. It would be based on the previous Gout programme in Northland to include general practice, community pharmacy, and a community Kaiāwhina role. However, it was adapted to suit the local context and needs of the Whanganui population. The Kaiāwhina role would be jointly funded by WDHB and Arthritis NZ. From this the Whanganui Gout Stop Programme (GSP) was established.

Leadership, planning and delivery of the GSP was provided by a steering group, improvement team, consumer group, and a project lead. While the Northland programme provided a starting point, a co-design process was used to review and develop the services that would be provided as part of the GSP. The project was led by primary care with valued

contributions from Arthritis NZ, WDHB, general practices, community pharmacy, and health consumers with an experience of gout. This co-design process was supported by an equity workshop facilitated by Gabrielle Baker and Leanne Te Karu and has been embedded in the representation and activities of the implementation team.

2.4 Reason for another gout evaluation

In June 2021, the Ministry of Health (the Ministry) contracted the WRHN to undertake an evaluation of their Gout Stop programme. The objective for the Ministry was to gain insight and evidence that could support the development of implementation guidance about doing LTC programme design differently to achieve equitable health outcomes that could be utilised nationally. It would build from the evidence already gained from the Synergia evaluation which included finding a significant group of patients disengaging around 6-9 months after starting the programme. The focus was on the transferability of the programme to other contexts, the patient journey and experience of the Māori population in the Gout Stop programme, including what can be done to maintain engagement or re-engage with people in the management of their gout.

3 Evaluation aims, objectives and methods

The aim of the WRHN evaluation is to conduct a process and outcome evaluation to provide insight and evidence for the Ministry that could support the development of an implementation guide/bundle with advice about doing LTC programme design differently to achieve equitable health outcomes.

The evaluation objectives are to:

- Explore the patient journey and experience as a result of the Gout Stop programme, particularly focused on the Māori population and specifically:
    - How people become engaged and then enter?
    - When and why people exit? And what can be done to re-engage those who drop-out?
    - How to sustain changes in good management of gout?
- Explore the transferability of the programme to other contexts such as other LTCs or in other geographic locations, including consideration of:
    - Barriers and enablers to establishing the programme and delivery of the programme?
    - Opportunity for integration of Health Improvement Practitioners and Health Coach roles that are being rolled out nationally?
- Support learning and quality improvement cycles to maximise the quality and effectiveness of the Gout Stop programme.

This evaluation uses a mixed methods approach using quantitative and qualitative data sources and synthesis of this evidence to address the evaluation objectives. Specifically, this evaluation drew evidence from:

- **Programme delivery data** recorded on the TUKU referral management system. This system collected information recorded by community pharmacy, general practice, Whanganui Accident and Medical (WAM) and Kaiāwhina on new referrals to Kaiāwhina and new enrolments on the Gout Stop programme. The system also allows activity such as education consults, dispensing and SUA testing to be recorded and for patients to be discharged. As this was a new system for community pharmacy there are some limitations to the quality of data recorded on this system. This limitation was mitigated by requesting community pharmacy to review the programme data recorded for their pharmacy. Descriptive statistics were undertaken to explore the engagement with and level of delivery of the Gout Stop programme.
- **Clinical data** recorded within the practice management system (PMS) of WRHN general practices. Descriptive statistics were undertaken to identify changes in the population with regular allopurinol prescriptions (proxy for gout as there are limitations with the recording of gout diagnoses within this dataset), serum uric acid testing and SUA test results for patients involved with the Gout Stop programme.
- **Key documents** from delivery of the programme, including the equity hui feedback.

- **Key stakeholder interviews** with people involved in funding, leading and implementing the Gout Stop programme. There were six stakeholder interviews conducted from October to December 2021.
- **Patient interviews** were conducted with 13 patients, with 11 being recorded and transcribed and 2 having interviewer notes only. All patients were Māori and had a gout diagnosis recorded at a practice in Whanganui that had good delivery of the Gout Stop programme. They were conducted from February to September 2022 by an interviewer of Cook Island Māori ethnicity until data saturation was reached. Not all patients interviewed were enrolled on the Gout Stop programme as there was difficulty getting engagement and consent from Māori on the Programme. This means that interviews may not represent all the perspectives of the most hard-to-reach patients but maintains a strong focus on equity and understanding the patient experience for Māori that was important to the aims of the programme and this evaluation. Patient interviews were thematically analysed using a general inductive approach that supports a focus on the evaluation objectives while allowing flexibility for themes to arise from the data (Thomas, 2005).

4 The Whanganui Gout Stop Programme

The Gout Stop Programme is a 12-week gout management programme. It centres on a model of collaboration between general practice, community pharmacists and Kaiāwhina, working together to improve accessibility to medication and health literacy. The delivery of the programme consists of a number of different activities to reduce barriers that disproportionately affect Māori in achieving good gout management:

- **Kaiāwhina support available to all patients, with a focus on Māori and Pacific people**. This is to help address any barriers that a person is encountering on their journey; whether it is navigation, advocacy, education, or strategies to self-manage that work with their life.
- **Communication, information and education for communities**, including through employers, faith-based and other communities. This is to address the myths and stigma attached to gout which are barriers to talking about gout and accessing help.
- **Two primary care consults that are free to patients that meet eligibility criteria** (Māori, Pacific, and/or CSC card holder) to initiate their Gout Stop journey and a three-month review. This is to remove the primary care cost barrier to commencing good gout management.
- **Funded blister packaging for medications** as part of the 12-week Gout Stop programme. This is to remove the cost barrier of a solution that makes it easier to take daily medications.
- **Expanded role of community pharmacy to include gout education consults and point of care serum uric acid testing**. This is to enable the health care system to support people where they first present for care and to improve health literacy through education and engaging people in their care by seeing SUA levels.
- **Education, training and programme support for general practices, community pharmacy, and other health care providers** that encounter gout patients who may not be well managed, e.g. WAM. This is to address the barriers from myths and misunderstandings that exist around gout, and system barriers to equitable delivery such as inconsistent provision of care, and culturally appropriate engagement and messaging.
- **Localisation of gout arthritis in Community HealthPathways** to enable access to consistent clinical advice about key education points, the clinical pathway for management, and the availability of the Gout Stop programme.
- **Provision of data and feedback to general practices** for individual patients via dashboard and PowerBI report, and population level feedback with an equity focus to track their success on process and outcome measures. This is to create transparency and understanding around the issue and make it easy to act in ways that promote good gout management for Māori.

The programme logic model for the Whanganui Gout Stop Programme is illustrated in Figure 1 and Figure 2 provides a flow chart demonstrating the patient journey through the Whanganui Gout Stop Programme.

Figure 1: Gout Stop programme logic model

Programme aim: To improve quality of life of Māori living with Gout Arthritis. It will demonstrate success by achieving equitable outcomes for Māori compared to non-Māori in the district and by delivering a programme that is designed for and with Māori.

Context

- Gout arthritis is a treatable long-term condition.
- Estimated 40% of people living with Gout arthritis in Whanganui are not accessing general practice.
- High rates of OTC NSAIDS and acute presentations at pharmacy and urgent care.
- Māori experience higher prevalence of gout arthritis yet are less likely to receive best-practice gout arthritis management.
- The Whanganui region has an above average Māori population, high prevalence of gout arthritis and low capacity within general practice.
- Arthritis NZ is leading a national campaign to improve the management of gout arthritis in NZ.
- There is evidence of effective gout arthritis programmes from Northland and Counties Manukau.
- PHARMAC focus on gout
- MoH focus for LTC annual planning

Inputs

- 1.0 FTE Kaiawhina.
- Allocation of Services to Improve Access special projects funding.
- Funding to remove barriers at urgent care.
- Adaptations to contracts with community pharmacy.
- Gout Stop 3-month programme design.
- Pharmacy education programme from Midlands Health Network.
- Gout arthritis guide for general practice education and patient audit.
- Gout arthritis indicator on patient dashboard.
- Prescription packs.
- Standing orders.
- Gabrielle Baker pro-equity focus
- WRHN Programme leadership, improvement team, resources, education, comm's and evaluation
- Infrastructure development cross-system.
- General practice and WAM GOUT advanced form.

Activities

General practice:

- Support GP to undertake patient data audit and recall.
- Same day appointments for acute presentations (practice discretion).
- 2 appts SIA funded by WRHN for high needs patients.

- Provide patient education and resources.
- Three-month GOUT STOP prescriptions
- Lab forms direct to laboratory.
- Follow up appointment and prescribing at end of 3mth programme – maintenance or titration of dose.
- Commencement of group consults for gout management.
- Upskilling of clinical team and provision of tools and resources to support programme

Pharmacy:

- Pharmacists credentialing programme and team cultural education (Mauri Ora training).
- Provide patient education and resources.
- Enrol patient education and resources.
- Enrol patients on Gout Stop Programme.
- Point of care testing, monthly visits.
- Prescription charges for three months are covered.
- Refer patients to Kaiawhina.
- Re enrol if patient not met target at end of 3mths
- Data collection and referral – TUKU training.

Kaiawhina:

- Outreach visits for patient education and reduction of patient barriers to engagement and management.
- Point of care testing.
- System navigation support.
- Advocate for patients.
- Provide/facilitate opportunities for education/upskilling providers, NGO's and community as identified.
- Māori consumer engagement and programme input.

General:

- Referrals from WAM, Iwi providers and others to Kaiawhina.
- Communication campaign to destigmatise and dispel myths.
- Developing local resources to raise community awareness.
- Provide evaluation feedback loops and patient stories.
- Cross-system comms & education of clinical teams.

Outputs

- High needs patients with gout arthritis are identified by general practice, pharmacy, WAM, and Iwi providers.
- Patients with gout arthritis access the Gout Stop programme and get two appointments, three-month prescription, education and support.
- Accredited trained pharmacists.

- Practices, pharmacy, Kaiawhina and stakeholders receive evaluation feedback and patient stories.
- Pharmacy data collected systematically and can be extracted for learning.
- General practice claiming system in place.
- Iwi providers trained in medications for gout management.

Short-term outcomes

Patients

- Māori patients receive regular uric acid testing.
- Increased medication adherence of Māori.
- Increased health literacy, key messages – genetics, benefit of preventive medication.
- Māori develop personal skills to manage gout.

Workforce

- Providers have greater awareness and understanding of the inequities of gout.
- Māori patients are actively recalled and supported to manage their gout.
- Pharmacists have increased role in gout management.

System

- Increase Māori patients receiving allopurinol.
- General practice data shows increased % of Māori patients with good gout management.
- Community has good understanding of gout and where/how to seek support if needed.
- Māori consumer feedback informs programme change.
- Māori providers are resourced to support gout patients in the community.
- Learning about transferability of the approach.

Medium-term outcomes

Patients

- Māori patients have fewer acute gout attacks
- Māori have increased self-management skills with better control of their gout
- Whānau make lifestyle changes to improve gout management.

Workforce

- Māori receive timely treatment and management of their gout.
- Equitable prescribing of preventive medications for Māori patients in treatment of gout

System

- Reduced use of OTC NSAIDs for gout by Māori patients.
- Improved Māori health literacy about gout
- Facilitates national learning about programmes to address gout for Māori.

- Facilitates learning and delivery of approaches to improve quality of care for other LTCs for Māori.

Long-term outcomes

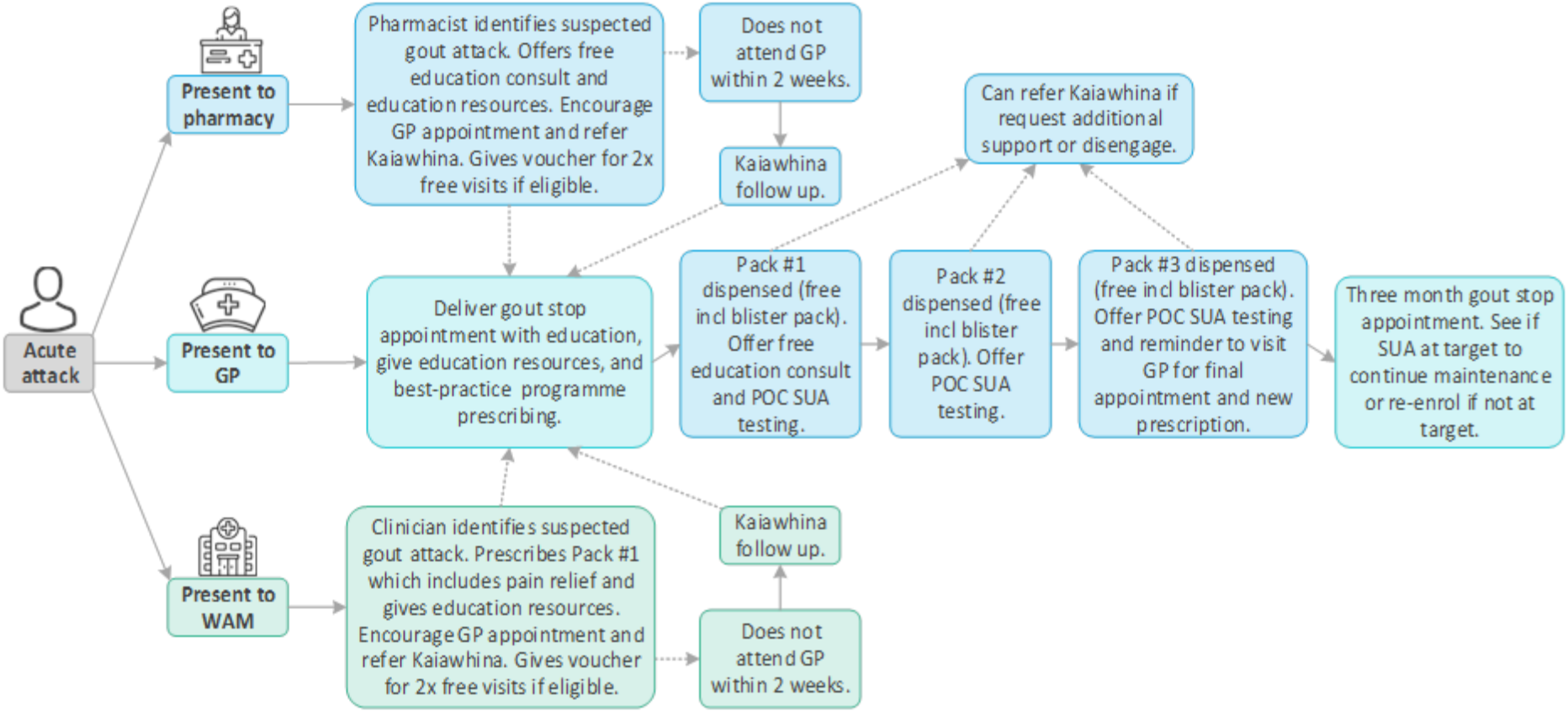
Patients

- Improved quality of life of Māori with gout.
- Improved whanau wellbeing.

System

- Cultural shift in treatment of Māori patients.
- Reduced number of Māori presenting acutely for gout in WAM and ED.
- Improved health outcomes for Māori with gout.
- Sustainable programme embedded to identify and treat Māori with uncontrolled gout early.

Figure 2: Patient journey/s through Gout Stop programme



5 The patient journey and experience of the Gout Stop programme

5.1 How do people become engaged and enter?

A total of 114 unique patients were recorded as having engaged with the Gout Stop Programme in the 17 months from commencement of the GSP in December 2020 to the start of May 2022. Over half of these patients (61%) were Māori which indicates the target group is engaging with the Programme. Table 1 illustrates the engagement with the Programme and Kaiāwhina by ethnicity.

Table 1: Engagement with Gout Stop programme and Kaiāwhina by ethnicity

	Kaiāwhina only	Both	Gout Stop only	Total engaged
Māori	30	9	30	69
Pacific	3	2	6	11
Other	7	3	24	34
Total	40	14	60	114

Interestingly, participants in general appeared to find involvement at the pharmacy level more beneficial in their gout management than attending their GP. There appeared to be a sense that the role of the GP was purely to prescribe the medication for gout, while the visits to the pharmacy provided more than that.

> *"Well my pharmacy visits are for my gout and I just go there. And all the GP does is give us pills, medication. That's it."*

GPs, however, tended to be the first port of call for a diagnosis of gout. Participants appeared to feel that GPs held a level of power over their experience of gout and what they were entitled to. Despite this, there was an expectation that GPs would provide gout sufferers with information about how best to manage their condition.

> *"I would expect the doctors to be the ones to tell me what I should be doing or shouldn't be doing. You know? It's sort of their job, isn't it?"*

5.1.1 Converting engagement to action

This engagement data also suggests that while there is a high rate of engagement with Māori, there is lower conversion to enrolment on the GSP. Table 1 shows a high number of Māori engaged with Kaiāwhina only (and not Gout Stop programme). Based on the Gout Stop Programme pathway, this suggests that Māori are more likely than those of other ethnicity to be identified outside of the GP setting (either community pharmacy or WAM) and have not yet enrolled in the Gout Stop Programme with their GP.

The GSP has been effective at reaching its target audience when they have touchpoints with the health system. The next step is to support progress through the Stages of Change (Prochaska & Velicer, 1997), from pre-contemplation to action where they enrol on the Gout Stop programme. This will take time and, while education consults are a good start, additional strategies may be required. The involvement of Health Coaches in care could support strategies that support progression through stages of change.

5.1.2 Getting active programme adoption by health practitioners

Health practitioners had a large role to play in patients' awareness of and entry into the GSP. Among the gout patients interviewed for this evaluation, a number were not aware of the presence of the programme. Awareness of the GSP appeared to be related to whether or not a health practitioner had informed them of the Programme. This demonstrates the need for health practitioners in all settings to take an active role in communicating about the programme in addition to gout education. Although GPs are a key point for providing information and enrolling people on the GSP, some patients describe being diagnosed with gout and that was all that happened.

> *"I didn't see anything about that [Gout Stop Programme]. The doctor diagnosed, he said okay, I think his words were 'well it sounds, it looks to me like you have gout'. That's how it went."*

There is variation in the GSP activity across different community pharmacies and general practices. This means patients are receiving a different level of access to best-practice care depending on where they present. Table 2 shows where the referrals have come from with a small number of sites making the biggest difference (note that some patients have multiple referrals):

- There are 15 community pharmacies in Whanganui, seven have recorded any GSP activity, but 74% of Gout Stop enrolments (55 of 74) come from just two urban pharmacies.
- These pharmacies are closely located to the two practices that have made direct referrals to Kaiāwhina. This would suggest the GSP gets best engagement and entry when both the practice and pharmacy are actively involved – it can't be carried by one health practitioner alone.
- Whanganui Accident and Medical identified a high number of people with suspected gout coming to them for acute care that could be directed to the GSP.

Table 2: Source of Gout Stop Programme enrolment and referrals

Source site	Gout Stop Programme	Kaiāwhina	Grand Total
Pharmacy A	2		**2**
Pharmacy B	19	1	**20**
Pharmacy C	2		**2**
Pharmacy D		1	**1**
Pharmacy E	36	4	**40**
Pharmacy F	4	1	**5**
Pharmacy G	11	4	**15**
Whanganui A & M		24	**24**
Kaiāwhina		3	**3**
Practice A		15	**15**
Practice B		1	**1**
Total	**74**	**54**	**128**

This variation in adoption by health providers is to be expected in the early stages of a new programme. The Diffusion of Innovation Theory (Rogers, 1962) indicates that new ideas will be trialled by a minority of early adopters before the majority. The Gout Stop programme can leverage the successes achieved by these early adopters to appeal to the majority who prefer to see evidence of success to convince them to change. It should be noted that the GSP was being rolled-out in the middle of the Covid-19 pandemic which was a challenging time to ask health providers to adopt new programmes while the Covid response made even usual business difficult to maintain.

5.1.3 Access to general practice

The accessibility of general practice has an impact on the accessibility of the GSP. This includes ensuring that care can be delivered in a way that is appropriate to the patient, taking account of preferences for kanohi-ki-te-kanohi. While the GSP was delivered in the context of the Covid-19 pandemic, the issue of telehealth was raised by an interviewee, with the view that it is not always an appropriate way of engaging with patients.

> *"Much to my distress, and I have had an appointment with her three times, each time it's been on the phone. And face to face would be... She is trying to limit me. You know, a lot of people seem to think you can do everything over the phone, but I'm one of these people who actually think that you can't do medicine over the phone. You need to be looking at the person."*

5.1.4 Patient understanding of gout

Participants varied in their understanding of what was going on for them in the early development of gout. For some participants, they were completely aware of what was happening to them. For others, gout was something that they had never heard of or considered. For those who recognised the initial symptoms of gout, there tended to be a family history of gout and exposure to whānau or others with gout had primed them to recognise the symptoms.

> *"I knew what it was 'cause my brothers have lived with it for years and yeah, just got the same thing."*

For many patients, the myths and poor understanding about gout can pose a barrier to accessing gout care. Patients described not recognising the symptoms or beliefs which led to denial that the problem could be gout. Commonly held beliefs include it being "an old man's disease" and being caused by lifestyle factors.

> *"If something did flare up, I'd be conscious about it but not quickly jump onto it, and say I had either broken a toe or broken a finger."*

> *"I just turned around and said, 'nah, I don't suffer from gout'. I meant that, you know, [at] that younger age."*

5.1.5 Influence of friends and whānau

Friends and whānau tended to have an influence over what people believed and felt about gout. Participants either described whānau influence as a positive part of their gout journey

(e.g., in helping them identify the issue or giving them insight into gout management) or stated that it played a negative role in their experience of gout. An interesting finding was that participants who had whānau with gout often held the belief that getting gout themselves would be inevitable. For these people, it was not a surprise when they started to experience symptoms of gout or were informed that that was what they were experiencing.

"Well yeah, I've heard that it is hereditary. And you can't do anything about that eh? If it's in your genes, it's in there."

Responses from friends and colleagues could reinforce unhelpful stereotypes about gout. In cases, patients described situations in which myths about gout were being perpetuated. For some, there was an element of whakama (shame) as a result of the way that friends and whānau responded to the person's gout. This appeared to be due to a feeling that their friends and whānau were making fun of them for having gout or were making light of what they were experiencing.

"It was around my 39th birthday, 'cause I remember my brother laughing at me... You get it from your friends, 'oh you're getting old' or something, I dunno. Yeah all that sorta stuff and it's like yeah it's funny and blah, blah, blah, but it's not that funny."

"I went to work with this really, really sore toe and got to work and I talked to the other guys... and they all said to me, 'what have you been doing this week?' And I said 'oh, three parties in a row', and they said 'you've got gout!' And I said 'what? What the, what, goat?' I had never even heard of it. And so the guys explained what it was."

For others, there appeared to be an element of comradery around sharing the diagnosis of gout, which had the ability to impact choices around food and alcohol use. Participants described incidents where there was a sense of sharing the consequences of choosing to eat certain foods or drink a certain amount of alcohol, whether this involved them personally, or they saw it occurring with others around them.

"Some of my cousins and some of my aunties and uncles, they go hard... Oh they just, we all go, 'ooohh man, this is going to hurt in another couple of days'. But they're prepared to go through that pain.'"

5.2 When and why do people exit?

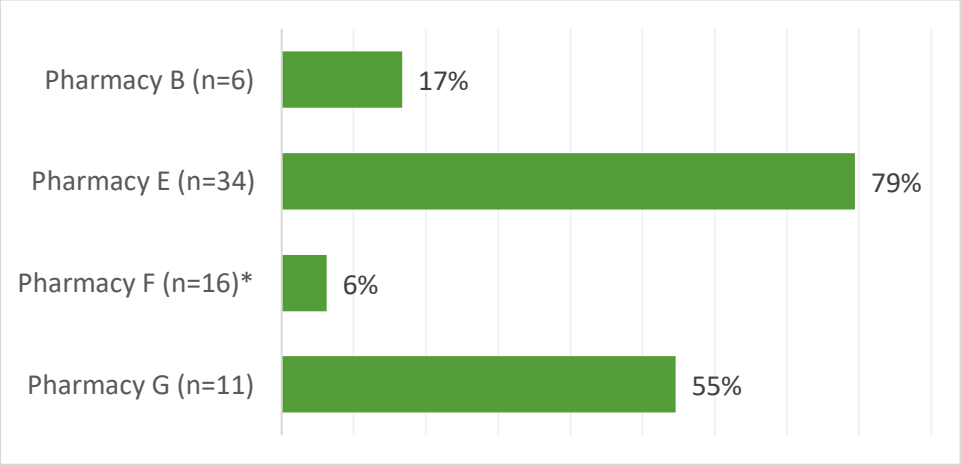
Just over half (51%) of people completed the Gout Stop programme. Data on exit status was available for 67 of the 74 patients enrolled on the GSP and is illustrated in Table 3 below. It demonstrates that completion rates for Māori reflect those of the total population but Māori who exit are more likely to exit earlier than others (but also more likely to restart).

Table 3: Completion rates and exit points along the Gout Stop Programme

Population	Completion	Exit before pack #1	Exit after pack #1	Exit after pack #2	Restarted after exit
Māori (n=37)	19 (51%)	1	13	4	2
Total (n=67)	34 (51%)	2	19	11	2

The biggest factor influencing exit rates appears to be the implementation from the health provider (Figure 3). Pharmacy E is co-located with a general practice, has good levels of implementation, and the highest completion rates (and is the provider for the two patients who restarted after exit). Pharmacy G with above average completion rates was also one of the providers with a higher level of implementation and close relationship to a nearby general practice.

Figure 3: Completion rates by pharmacy



The importance of the education consult provided by pharmacy is also suggested by the performance of Pharmacy F. This provider had 4 patients recorded as being enrolled on the GSP but when confirming their service data, there were additional patients they had not recorded. These additional patients had been supported with the GSP funded free prescription, free blister packs and SUA testing but did not receive an education consult from the pharmacy. None of these patients had completed the programme which indicates the education consult to build health literacy is a key component for successfully improving gout management.

Pharmacy E reflected on how they successfully manage delivery of the programme:

> *We are very fortunate to be next door to a GP practice who support the Gout Stop Program, plus we actively promote the GSP and get customers on board. Mostly our scripts come from this GP practice, already identified as being for Gout Stop. We do not have many requests for OTC medication.*
>
> *The patient has immediate access to a pharmacist, who runs through the program, and delivers an education package. We ask if they would like it blister packed, which we encourage if it has reducing prednisone, though*

they also have the option of bottles. Priority dispensing and/or blister packing means the patient doesn't leave without their medication and an understanding of how to take it.

When they have left, we enter them into our system to ensure they get a text reminder each month to return and collect further medication before they run out. We continue text reminders after this as well to ensure they continue getting a supply of medication. Anyone we notice falling through the cracks we can refer to the Kaiawhina to follow up with.

We really believe in this program. It's great to show the patients their decreasing uric acid levels as they increase their allopurinol. It's something visual, alongside their decreased gout attacks. One example is of Mr A, a Māori gentleman, who has slowly increased from 50mg daily over 4 months, is still increasing and still coming regularly to collect his medication with the text reminders.

The data suggests it is what providers do, rather than any patient factors that is the biggest reason for exit. The ability to develop health literacy appears to be a key causal pathway to exit. Other barriers to completion were also discussed by patient interviews. It should be noted that the people who exit the GSP are also difficult to engage in evaluation interviews and as a result, these themes are not specific to patients who exited the programme.

5.2.1 Access barriers

In the Whanganui rohe, while there are traditional access barriers with a wide geography and few transport options, it was other access issues that were most raised by patients. There was a common perspective that there is a lack of access to doctors (both for routine gout management and in a gout emergency). Patients spoke of how this lack of access for routine gout management meant that their gout needs were often superseded by other medical issues that arose, which required more urgent conversation with the GP. This was compounded by the fact that appointment times were believed to be too short.

"Just getting hold of GPs or practitioners is becoming a real mission. And everything that is not absolutely critical is getting pushed down the priority list. And unfortunately, that's got consequences. Means guys like me, I drop them off the bottom basically, where we have legitimate needs that need to be discussed, but gout?"

The consequence of being unable to see a GP for routine gout management was reported to be the inability to ask questions about the person's gout management plan.

"'Where are we at? Where are we going next?' Or such interesting things as 'are my medications correct at this time?' which is a big thing with me 'cause I'm taking about 12 different ones."

Participants also described a lack of choice in being able to access the care they prefer. There was discontent around being redirected to see a nurse. For some, this was not around

the fact that the person was a nurse; rather, there was a level of unhappiness that there was no chance to see their doctor. For others, it was insinuated that the opinion of a doctor is more trustworthy than the opinion of a nurse. Some participants were adamant that they wanted to see their GP for their gout-related care.

> *"I'm not super happy going to the doctors anymore because you never get to see your doctor. You see a nurse. They have a yak to you. They go and have a yak to the doctor and then come back with a diagnosis and give you a script and away you go."*

Discontent was also raised around the issue of telehealth, with the view that it is not always an appropriate way of engaging with patients (see section 5.1.3).

Māori patients continue to have poor experiences when accessing health professionals which influences their future engagement with the health care system. Some interviewees reported experiences leading to feelings of shame and discrimination. This appeared to be due to a sense that the doctor was blaming the patient's lifestyle for the flare up or that they were being treated as if the gout episode was their fault. In addition, these participants either personally felt that they were wasting the time of the medical staff or that the doctors felt that they were wasting their time.

> *"No the doctor, he was pretty arrogant... He goes 'just imagine what it's doing to the rest of your body, you know?'... He says 'it's your lifestyle choices.' He said, 'it's the alcohol you're drinking.' And that's first of all what he blamed."*

> *"Most probably in his mind he thought 'I'll be better treating my patients that try to take care of themselves instead of someone that doesn't take care of themselves.'"*

Participants reported that accessing medication was very difficult if you were outside of Whanganui and usually required attending the nearest Emergency Department, which was extremely time- consuming and frustrating. People discussed their frustrations around having to spend long periods of time trying to access medication that they already knew they needed, and were already being prescribed.

> *"Medical centres don't accept outside people. And especially when you're from out of town, it's pretty hard to get some healthcare."*

> *"Fortunately I have an understanding GP and they very often are happy to let me have a three month supply of the meds that I need so I've got the entire period covered. But if there's an emergency comes up, like if I get a really bad case of gout and I urgently need some prednisone, then I've really got to work hard to get that."*

It was suggested that there was a need for a national record-keeping system, which would allow doctors to have access to their records for expedience of prescribing gout-related medication.

"Well it's basically getting off their duffs and doing what they have said that they were going to do about a National IT records system that anybody can access from anywhere. And making sure that the medical assistance is truly portable."

5.2.2 Attitudes towards medication

For some participants, there was a reluctance about being on long-term medication. For some of these people, this was due to a resistance about using medication or 'drugs', while for others, this was based on preconceptions about the effects of medication, after hearing how it had affected friends or whānau.

"I didn't wanna go on the Allopurinol, because I just don't like being on medication... so I did lapse, to be honest, on the drugs. And I kinda go, 'cause I didn't wanna be on them, I didn't want to be on daily drugs."

5.2.3 Health literacy and understanding of gout

For some participants who were prescribed Allopurinol there appeared to be a lack of health literacy where they may not have understood the reasons behind taking this as a long-term gout medication. This group appeared comfortable taking their Allopurinol during flare ups but did not seem to recognise that they were supposed to be taking in between gout episodes.

"When I got gout again, I'd get more pills and they were giving me gout pills when I was getting my prescriptions, you know. Even when I didn't have gout."

"Oh no, once the gout went, that was it, I stopped the tablets."

"I wasn't even aware that you could stop gout. I'm very conscious that I laugh, I've been told that look you're going to be taking allopurinol for the rest of your life. I took that to mean I'm always going to suffer from periodic expressions of gout."

5.3 What can be done to re-engage people with their gout management?

Follow up with patients should be proactive and respectful of their right to make choices about their own care. Where they may choose not to engage with the GSP, patients need to be aware of easy and judgement-free pathways to re-entry. For the Whanganui Gout Stop Programme, this proactive follow up and re-entry contact is available through the Gout Stop Kaiāwhina. An example of how patients can self-refer to the Kaiāwhina is illustrated in the brief case study below from the Gout Stop Kaiāwhina:

Self–referral came though, he was at WAM and spoke with the receptionists who gave him the change your life booklet and Kaiāwhina contact details. The client called the 0800 number, and I gave him an education consultation and free GP voucher and referred him back to his GP. The client was happy to hear about the Gout Stop Programme as his gout has been poorly managed for years. He did take Allopurinol but

stopped taking it for 6 months and tried changing his lifestyle. But he has continued to get multiple flare ups. Now he feels it is time for him to get his gout under control. He is confident now after investing more time into learning about the condition and has a better understanding.

As health literacy is a large barrier to engagement, repetition of consistent messaging will support re-engagement. However, this will not be an immediate process and will take time for trust and understanding to develop. There are many existing beliefs about how to cure gout and patients may go on their own journey to self-manage their gout and learn from experience before they are ready to engage with the messages from their health professionals.

"I got on the phone to my brother and I got the Apple Cider Vinegar business. And he just goes, oh try that, you know, and drink heaps of water, piss it out. But I did go the chemist because that stuff wasn't necessarily, wasn't doing the job."

Educating trusted community leaders and encouraging conversations can also support re-engagement. For one patient, it was the motivation from another acute attack and the experience of talking to their kaumatua about their shared experiences with gout that helped them to engage with lifelong preventative medication.

"It's easier to stay on if you know you're going to get it again I think, so I did lapse, to be honest, on the drugs. Because I didn't want to be on them, I didn't want to be on daily drugs. But then I got gout again and so I kind of know that I'm going to be on it now, that's just it. A bit of, like I've talked to my matua, who's also got it. And, just knowing that he's got it and he's going to be on allopurinol all the time, and struggles to take it every day. But it'll keep me on it to know that, you know I can yarn to him about it."

5.4 How can we sustain changes in good management of gout?

Gout can be managed and sustained when primary care is delivered well. Good delivery of primary care works to develop health literacy and address access barriers in a way that responds to the cultural background of patients. For patients that relied on Allopurinol to keep their gout under control, it appeared to be well managed.

"I'm on medication that I take daily to get the uric acid down. And they've been awesome. Absolutely awesome... Has really stabilised my gout, to the point where I don't think I get it. I don't want to be so bold in saying that, but I haven't had an episode for quite a long time. Or since I've been taking these pills."

"So Allopurinol is just part of the daily routine. So yes, since about the year 2000 I've been on Allopurinol."

5.4.1 Building health literacy

It became evident from interviews that, where gout-related health literacy levels were low, participants were less likely to make the changes required to manage their gout well. Some participants reported that they were not always provided information about their gout at the time of initial diagnosis and, for some, it took many years to really learn about the condition. Thus, it became clear that there is a need for good gout-related education to be provided to all gout sufferers and that it should not be assumed that because they have previously already been diagnosed with gout, they have been provided with adequate levels of information.

> *"But she kinda mapped it out a little bit clearer for me, in that, you know it's, because of my genetics I'm probably going to get gout. And continue to get it if I don't get on the Allopurinol."*

> *"They put me in hospital and they filled me up with pills and stuff over 24 hours and everything came right. And then they were going to prescribe me some gout pills and I said no, I've still got some. I don't need them, I've got some. And the nurses say how come? And I said well when my gout felt better I stopped taking them. And they said that was probably the reason that I kept on getting it again. Because I wasn't finishing the medication they were giving me. And I'd stop as soon as my gout felt better. And then I ended up in hospital."*

All health professionals have a role to play in developing health literacy. Pharmacists were seen as a valuable source of gout care in the Whanganui Gout Stop Programme, and the interviews illustrate that patients look to their general practitioners as experts that should be providing them with trusted information. Participants acknowledged the benefits of being provided with adequate information about their gout. This included how to identify triggers of gout and the best options for gout management.

Beliefs around the role of food and alcohol in gout episodes were very strong and appeared to shift only when the participant had received gout-related education. A consequence of these strongly held beliefs appeared to be the belief that there was a level of irresponsibility when a person experienced a flare up, due to the fact that they had chosen to eat or drink something they knew would lead to an episode of gout.

Participants spoke of needing to learn to trust that, by following their treatment plan, their gout could be better managed. Within this, was an acknowledgement that decisions around their treatment plan (e.g., medication) needed to be based on whether or not it was working for them.

> *"Like I was very skeptical about this medication that I was taking, but look I've had 12 months of it and look, I can't, it's fantastic. It's kind of changed my life."*

5.4.2 Primary care processes

General practices can support sustainability by ensuring best-practice data recording and information set up within their practice management systems. In particular, having a diagnosis of gout recorded and recalls for ongoing testing enables best-practice care to be delivered. The GSP found a number of patients that were prescribed allopurinol but did not have a gout diagnosis recorded on their medical record or recalls for serum uric acid testing to ensure the correct dosage was being prescribed. Correct recording is beneficial for all long-term conditions managed in primary care and also enables good information about the disease burden, in addition to the access, equity and effectiveness of care provided.

There are also broader issues to improve access to care and medication when patients were out of town (e.g., if they travelled for work or were visiting friends and whānau in other areas) as in section 5.2.1.

5.4.3 Cultural considerations in the delivery of care

Providing culturally appropriate care that gives patients greater choice will help improve the relationship with health care professionals to create a safe space where management of gout can be sustained. In particular, patients talked about the recent changes (post-Covid) to being offered virtual medical appointments instead of face-to-face appointments. It was felt that virtual appointments were not always a culturally appropriate way of delivering healthcare and that being unable to see a doctor face-to-face was problematic for some. Patients described differences in the quality of their care and in their ability to understand issues around their gout management when they were able to see their GP in person.

> *"Well, I'm thinking that you are Māori, and with ethnicity and with my understanding, the whole communication thing is very, very strong. And it's greatly limiting if you can't see someone's expression. Even down to the way they hold themselves, so even just looking on a screen is not quite the same thing as being in person."*

> *"Then the second visit to the doc was in person and that was, you know, obviously much better just being in person."*

5.5 Key points to improve the Gout Stop Programme

5.5.1 Building greater awareness

There was a high level of patient support for the idea of a Gout Stop Programme. Patients learning about the GSP during interviews talked about how it would have been beneficial, and some indicated they were going to talk to their GP and whānau about the GSP. There were different motivations present for wanting to participate in the GSP; some wanted to have a safe space to talk openly about gout, to be connected to others suffering from gout for emotional support and education, for others access to free medical care was the main reason. This level of support and motivations to engage with the Programme illustrates that awareness is the main barrier to enrolment. Therefore, it is important for GPs and Pharmacists to be made aware of the importance of introducing patients who present at their services for gout.

"I'll talk to my GP next time I see her about that Gout Stop programme. I've never heard of that, so I'll talk to her about that. She didn't mention it."

"[My reason for joining the Programme was] Largely because there was two free doctor visits in it, to be blunt."

5.5.2 Support more providers to actively provide the gout stop programme

The role of health practitioners in making the programme work and achieving its goals is critical. They play a key role in communicating about the programme so that people enter. They also develop health literacy for patients and have a key role to play in whether patients complete the programme. Part of this may occur through diffusion of innovation and shared learning of what works now that there is evidence of the programme delivery in Whanganui. Gout should also be considered in the establishment of localities and how this locality approach can enable providers to work collaboratively to address LTCs.

5.5.3 Greater Programme definition

There was a sense that participants would like to take part in a gout-related programme, but that the programme as it stands is not obvious or defined well enough. Participants described it as providing a couple of additional free visits to a GP and having access to free medication. There appeared to be confusion about what the programme actually provided them, and it became clear that the programme is not well described to people during the enrolment stage. In addition, while some participants were aware that their gout-related doctor's appointment was free of charge, they did not feel that the consultation really focused on the issue at hand. There is a need for more accurate and detailed information about the programme to be provided to patients, so that they are aware of exactly what they will receive and how long the programme will last.

"'Cause literally, I've just been to the doctor and I was like, 'oh, this is just really a doctor visit'. Yeah it was about gout, but it was about other stuff as well."

"Yeah it doesn't feel, yeah I wouldn't call it a programme. It literally gives you, it's a bit of structure to give you some, to encourage you to actually treat the issue."

In addition to communication to improve definition of the programme, structural changes could be made to the delivery that set it apart from standard care. From patient interviews, there is strong support for the development of a gout group, which patients with a gout diagnosis could attend. This would provide people with additional emotional support, due to feeling that others in the group understand what they are going through, in addition to advice around how to manage different emerging issues.

6 The outcomes achieved from the Gout Stop programme

6.1 Patient level outcomes

There has been an improvement in clinical outcomes demonstrated for the patients engaged with the Gout Stop programme. For the 74 patients who were enrolled in the GSP (with Kaiāwhina or programme only), the serum uric acid test results recorded within the practice management systems were analysed[2]. At both the aggregate level (Table 4), and when narrowed to the pre-post matched pairs (Table 5), there was a substantial improvement in SUA levels. In addition, this improvement was greatest for Māori.

Table 4: Aggregate level analysis of change in serum uric acid levels for patients enrolled in the Gout Stop Programme

Population	Pre-programme SUA	Post-programme SUA	Post-programme number at target
Māori (n=39)	0.468 (n=38)	0.387 (n=32)	15 (47%)
Total (n=74)	0.455 (n=64)	0.386 (n=61)	30 (49%)

Table 5: Pre-post level analysis of change in serum uric acid levels for patients enrolled in the Gout Stop programme

Population	Mean change	Proportion of patients with reduced SUA (desirable)
Māori (n=30)	-0.107	73% (22)
Total (n=53)	-0.089	77% (41)

These patient outcomes represent substantial changes to their quality of life. Patients reported the physical impact of acute suffering, influence on whānau, and the emotional impacts of gout. For most patients, the pain was described at a level where it was difficult to manage and impacted on their ability to do everyday tasks, sleep, and work. Ability to spend time with whānau was affected. Both physically unable to participate in sports with their children because of the pain they were experiencing and less time with whānau due to having to spend long periods of time trying to get their gout under control. These impacts, and the stigma associated with the disease, contributed towards feelings of low self-worth and shame.

> *"I know a lot of older people have suffered during this whole Covid thing because they've been cut off from their mokopuna. And, you know, as an older person, that's one of your basic reasons for existence. Is the little ones, and the contact with little ones. And when you don't have that, what have you got? The temptation to just roll up and say well fuck it! And*

[2] WRHN has access to the serum uric acid levels recorded in the practice management system (PMS) of WRHN practices only. This means some patients do not have pre and post results due to; not being enrolled in a WRHN practice, not have a result in the PMS before enrolment on the programme, and/or not having a result in the PMS after starting the programme.

that's it, it's over. There's nothing left and just fade away. And I've been working in that sort of headspace for the last 30 odd years."

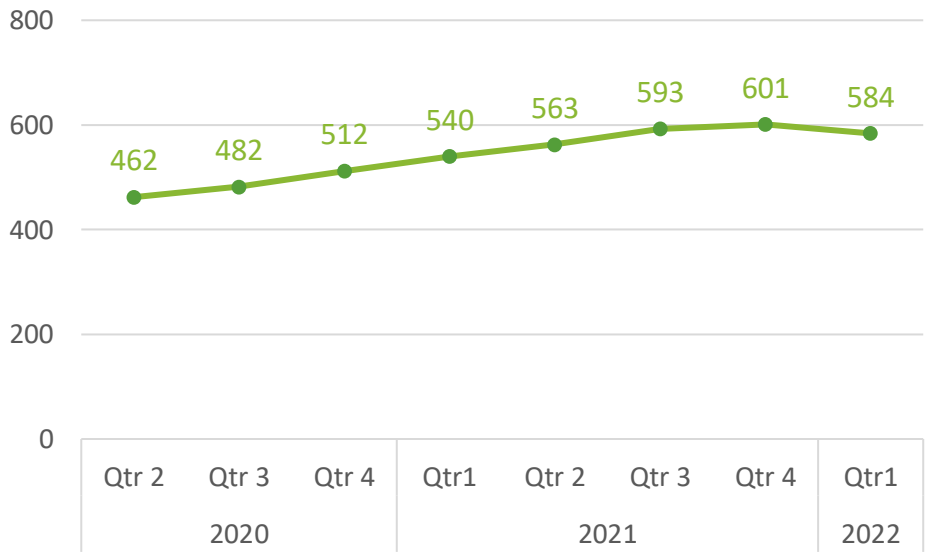
The results of the Gout Stop programme are also spreading across whānau. The Gout Stop Kaiāwhina reports a brief case study below where two sons are learning from the progress of their dad:

> Followed up the family of 3 dad is still managing his gout well. The sons are starting to follow suit. Both have been back to their GP in [rural town] and both are now on 300mg for Allopurinol. So far, no flare ups.

6.2 Improved access to gout health care

The Gout Stop Programme has successfully increased the number of Māori who are accessing preventive medication for their gout in primary care. While there were only 39 Māori enrolled on the Gout Stop programme, there were 69 with any engagement with the programme (e.g. received an education consult), and an increase of 122 Māori (25%) being prescribed regular allopurinol (Figure 4). This illustrates the work of raising awareness and educating health providers has had a greater impact on equity of gout management care than just that represented by GSP enrolments.

Figure 4: Māori receiving allopurinol at least twice within a 12-month period



There are many pathways that may have contributed to this wider improvement in access to gout care for Māori. Building of health literacy about gout is likely to be shared with wider whānau for them to seek allopurinol. Equally, education and awareness-raising activities from the gout Kaiāwhina may be leading more people to ask for preventive medication. Educating health providers may also be changing their clinical practice to improve access to preventive medication without the administrative process to formally enrol patients on the GSP.

7 Themes in exploring the transferability of the programme establishment and implementation

7.1 Co-designing not copying

The importance of taking a co-design approach was highlighted by key stakeholders. Having an equity goal and examples of previous programmes were a useful starting point to establishing the programme. The co-design process was a key enabler in ensuring the programme would meet the needs of the local context. This process included starting with an equity workshop which had representatives from funders, management / implementation, providers, and consumers. As well as ensuring the programme design and delivery was adapted to meet local needs, it also supported a shared understanding and buy-in across different groups.

Principle of co-design was also embedded in the design and functions of the GSP steering group and implementation team. This included having diverse interests represented in both groups and a core function of the implementation team was consumer engagement for the GSP. In this way, the ongoing programme adaptations, resources, etc are designed with input from funders, doers and consumers. For example, consumer engagement established principles of engagement to improve the experience of all gout patients in Whanganui when using the health system or facing health messages (Appendix 1). Ensuring the co-design approach is kept when transferring the programme to other areas (rather than direct copy of the 'product') will support their successful integration in the new landscape.

7.2 Getting the right programme implementation team and leadership

Having a multi-disciplinary team with diverse skills, experiences and relationships was perceived as a strength of the programme. It supported easy access to knowledge and feedback from different sectors. For example, having a pharmacist representative was helpful to inform new programme agreements with community pharmacy that would fit with their existing reality. Members who represented and connected to stakeholder groups enabled this diversity to be included without making the implementation group too big to be manageable. Fortnightly meetings were regular enough to keep the team moving together in the same direction.

Leadership of the programme and implementation team was non-clinical and primary care based. This leadership by a health promoter was seen as essential to ensuring the GSP took a wellbeing approach that was focused on building health literacy and reducing barriers to care and self-management. The WDHB has provided support and maintained visibility throughout the project but otherwise devolved control to primary care. The primary care control has meant the programme benefits from existing relationships with general practices. It was perceived that this approach from DHB was easier due to the smaller size, flexibility, and connections of the DHB.

7.3 Achieving practice leadership and buy-in

The Whanganui GSP has found that the changes needed in general practice are bigger than just adding programme resources and processes; building knowledge and shifting culture is also required for successful delivery of the GSP by a general practice. Providing a quality

gout consult involves sharing a different message to the lifestyle change message that many clinicians are used to sharing for gout. Another common problem identified in primary care is where patients are left on the same dose of a preventive gout medication when they don't receive a blood test and follow up.

Nurse champions have been proactive in providing practice leadership to support change where they are available. Nurse champions are also used successfully to support other projects in primary care. The challenge is to have a nurse champion who is passionate and able to take on the leadership role. This will help the wider team buy-in to adopt changes such as the new prescribing regimen, using an advanced form for PHO funded gout consults, and clinical audit of patients with gout.

Several general practices have used equitable gout care as their continuous quality improvement (CQI) project for Cornerstone. This has provided additional motivation for practices to focus on adopting the GSP and monitoring their process and outcomes. It also provides benefit to practices where they get PHO support towards their CQI project e.g. data being provided to practices.

7.4 Role of HIPs and Health Coaches in team-based care

There is potential for the Health Improvement Practitioner (HIP) and Health Coach to become valuable parts of general practice delivery of gout care. Health Coaches would have a role in supporting health literacy and self-management, which could include the provision of group consults for gout. Gout is mentioned in the training received by Health Coaches, but a stakeholder queried whether they would also benefit from completing the same Midlands training received by community pharmacists.

There are some particular contexts in which it was felt that HIP and/or Health Coach involvement would benefit patients with gout:

- Support the building of health literacy for patients who may be pre-contemplation to encourage progress through the Stages of Change. This would be particularly beneficial when patients are not yet fully engaged with the Gout Stop programme.
- Work to support behaviour change for patients where the health care process appears to be best practice, but the patient is not demonstrating the expected clinical outcomes.
- Where a patient is struggling with the psychological impacts of a new LTC diagnosis (especially at a young age) and/or the psychological impact of acute attacks impacting other aspects of their wellbeing.

The challenge with use of HIPs and Health Coaches is about how the new roles have been established within a general practice. This includes the relationship with the practice and how they are integrated as a normal part of team-based care. In Whanganui, both roles are based in the general practice (and employed by the general practice in most cases) and patients can be introduced to either role by any member of the practice team. In other regions this delivery model may differ, for example the Health Coach may be more external to a general practice or there might be an additional community support worker role.

Communication of the purpose of different roles can also be a challenge to using HIPs, Health Coaches and community Kaiāwhina effectively. In Whanganui, there has been some confusion about how the Kaiāwhina role fit with the general practice as there was very little relationship at the start of the GSP. Where the Health Coach is used as a key part of gout management, there may be less need for general practice to have a direct relationship with the Kaiāwhina – allowing for more community engagement work.

7.5 Kaiāwhina workforce

At the time of starting the GSP, WRHN was at the beginning of establishing a Kaiāwhina workforce. This has resulted in the GSP being impacted by WRHN learning about what it takes to develop, support and best utilise this workforce. One stakeholder commented that this role may have been better suited to be employed by an organisation that already had an established Kaiāwhina workforce. This would include Kaiāwhina leadership, professional support, and flexibility as part of a Kaiāwhina team. This workforce development may already be established in other regions and should be considered when deciding where a Kaiāwhina role is employed.

The GSP had a two-month vacancy for the Gout Kaiāwhina position which provided both a challenge and opportunity. The original Gout Kaiāwhina resigned to take up another opportunity and it proved difficult to recruit a replacement with multiple rounds of recruitment before the next Kaiāwhina was employed. This provided a challenge to continuity and momentum where a minimum level of activity was maintained by the WRHN implementation team. However, it meant less resource for community engagement activities. However, it did provide an opportunity for WRHN to re-think the structure of their Kaiāwhina workforce and break down silos. While there is a dedicated Gout Kaiāwhina, there is also an increased team approach with connection to the long-term conditions outreach team and other Kaiāwhina roles.

Despite these challenges, the Kaiāwhina role has been a valuable part of the team. They have different skills including a non-clinical understanding of wellbeing, some lived experience with gout, and strengths in engaging Māori.

7.6 Making a different role work for pharmacy

Overall, it was considered that the GSP was well received by pharmacy. Stakeholders considered that the WDHB is already proactive in terms of increased use of community pharmacy for health initiatives, including funded emergency contraceptive pill and rehydration services. All community pharmacies had at least one pharmacist who completed the Midland training to deliver gout education consults.

However, there has been variation in the degree to which different community pharmacies then deliver the GSP. A small group provides an excellent service with the GSP dispensing, education consults, serum uric acid level testing, and will communicate with general practice to query a prescription if they think a dosage may not be correct for a patient. Some do not appear to be delivering the GSP and many provide some aspects of the programme. The serum uric acid testing appears to be one of the activities where it has been more difficult to get pharmacy uptake. This testing is valuable in both reducing barriers

to care and building health literacy to achieve the goal of improved equity. The GSP stakeholders want to find a way to maintain access to this for their population. The benemeters used to measure serum uric acid also test for diabetes and cholesterol which would support translation of the model to other LTCs using the same testing tool.

Considerations for adaptation included smaller increments of activity and funding. One stakeholder considered that spending 15 minutes for a pharmacist education consult was too much time off the floor for a pharmacist within the way community workforce operates. This is also illustrated by some of the pharmacist feedback that they were not including all their education consults in their invoicing as they were delivering brief education and not sure it was sufficient to be invoiced as an education consult. Adaptation to involve pharmacy assistants in delivering the education consults could also be considered. The stakeholder also thought payment for specific activity rather than programme milestones would support greater GSP activity by community pharmacy. This would also provide a financial incentive to have complete recording of activities provided by community pharmacy.

7.7 Integration of information systems

Several challenges to the GSP are linked to lack of flexibility and integration between information systems. These included; MedTech prescriptions need to be pre-set for each medicine for each individual user rather than pre-set regimen in a facility, prescriptions are not marked as 'Gout Stop', making it difficult for community pharmacy to identify who should be enrolled on the GSP, community pharmacy systems are disconnected causing difficulty in automatically populating data when enrolling or sending data back to general practice e.g. sending back a serum uric acid level reading taken at community pharmacy.

The GSP implementation team have attempted to find solutions, however their experience is that these have not supported utilisation or sustainability. Writing 'Gout Stop' manually on a prescription requires the clinicians to remember an additional step, is not sustainable, and not compatible with e-prescriptions. Adding extra systems for pharmacy to complete which can send notes back to the general practice inbox were not well utilised. Investment in IT infrastructure across the system would benefit a number of programmes that aim to provide collaborative, system wide responses to health care. Different IT projects are already underway and would benefit from including community pharmacy within their scope.

7.8 Competing priorities

There were a number of competing priorities for the Whanganui health care sector that present a challenge to engagement in the GSP. One of these competing priorities was the disruption from COVID-19. The pressure on the workforce to provide both COVID-19 and influenza vaccinations, and the need to increase infection prevention measures in the way care is provided has left primary care short staffed.

The unusual origins of the programme also resulted in the GSP being added on to the WDHB priorities. It was not an original focus, but the WDHB could see the need for an equity focus

on gout, so it was added to the strategic plan and other things were changed. This resulted in a less strategic view to commissioning by the WDHB.

The foundations of the GSP needed to be pulled together from different places. There were some useful resources to pull together; the blueprint from existing gout programmes, the clinical audit that had been done. However, some bits were still being developed or pulled together including review of gout education resources and the local development of a Kaiāwhina workforce.

7.9 Monitoring progress and impact

Monitoring can support sustainability of programmes and motivate change. Recommendations from the equity workshop included independent and ongoing monitoring of the GSP. The WRHN have data monitoring and provision of feedback as a routine role of the programme team. This has focused on simple process and outcome indicators with an equity lens that are targeted towards general practice (example in Appendix 2). This has demonstrated changes in activity from practices after actively showing them their monitoring data.

It is important to integrate the narrative story around quantitative monitoring data rather than looking at indicators in isolation. For example, an increase in the identification of gout may contribute to percentage process and outcome indicators looking worse. But identification is a good first step in the provision of good gout management. The Health Quality & Safety Commission's Atlas of Healthcare Variation can also provide useful information in interpreting and understanding gout data.

8 Conclusions

8.1 Early adopters were successful in improving quality of life for Māori living with gout arthritis

The reach of the Gout Stop programme in engaging patients into the programme was focused on the health care providers which adopted the full delivery of the programme early. While some other providers delivered some activity, a smaller group of providers accounted for most of the programme engagement. However, within these early adopters, the reach of the programme appeared equitable with engagement with a high proportion of Māori patients.

For those patients engaged in the programme, the evaluation found that it was successful in improving the management of gout for Māori within Whanganui. Patients also described the impact that management of gout made across all aspects of their hauora to improve their quality of life.

8.2 Creating systemic change is more than just another programme

A key learning from the experience of implementing the Whanganui GSP is that creating change is about more than just a programme or an additional role. The wider work from the Gout Stop implementation team was successful in improving the access to gout management in primary care for more patients than those who were enrolled in the programme. A focus on providing an additional service to individual patients is useful as a 'band aid' to improve management and outcomes for patients for whom the mainstream healthcare system has not worked. And meeting the needs of these patients is important to support our equity goals. However, a team approach to educate and change the culture of the workforce and public discourse can create a sustainable system that is enabling of equitable management of gout where fewer people need a 'band aid'.

This system change includes a focus on cultural safety and a change in the relationship between Māori and the health system. Patient interviews indicated that there is still work to do in improving the cultural responsiveness of our primary care services. Some current work supports this focus, including the increased use of a more diverse workforce in primary care such as Health Coaches, Kaiāwhina and Kaiarahi (connectors). Progress towards the goal of cultural safety and participatory relationships with Māori in all aspects of the health system will support the equity outcomes for gout and more areas of health and wellbeing.

Specific to gout, the narrative and understanding around gout needs to change. When myths are busted for health care providers, patients, whānau, and communities, there can be less stigma and more open communication. It can be easier to talk about, seek support, come to terms with a diagnosis and to involve whānau in care. This includes involving Māori communities, with whānau and kaumatua involved in this conversation.

8.3 National considerations to support collaborative model of care programmes for LTCs

There is a lot that can be done regionally but these programmes will also benefit from national support. An integrated IT system would enable patients to access care wherever

they go. When developing integrated and shared care IT projects, it is important that all health system providers are included to support the collaboration in collaborative models. This includes community pharmacy.

Local efforts to build awareness can be supported by national health promotion campaigns. This requires national leadership to prioritise and plan communication campaigns that regions would be unable to implement on their own. With sufficient notice, regions can leverage this investment to maximise the value of regional programmes.

8.4 Considerations for an implementation guide for collaborative model of care programmes for LTCs

There are existing programmes that aim to improve the management of gout and other LTCs across the country, of which the Whanganui Gout Stop programme is one. This means there are numerous examples of programme delivery, but it does not mean that project planning and project set up should directly copy an existing model. In the initial stages of establishing a collaborative programme for LTCs, it is recommended that:

1. **Programmes start from a place of co-design** where funders, providers and consumers are brought together as equal stakeholders. This will enable a shared understanding of the background from different perspectives, and shared buy-in to a programme aim and objectives that are meaningful to the interests of all groups involved.
    - A consumer perspective is crucial as the intended beneficiaries of a programme. Ensuring the planning addresses their perceived needs and including them throughout the programme implementation will be a valuable resource to a successful project.
    - Providers are key to enable the implementation of the programme. As demonstrated by the Whanganui Gout Stop programme, the success of the programme was limited by the spread of the delivery by health care providers. This would suggest that the wider number of providers can be involved, the wider the programme is likely to be delivered from the start.
2. **Equity is built into the programme at all stages,** and this starts when defining the project aim. The Gout Stop Programme aim was explicitly about improving outcomes for Māori due to obligations under Te Tiriti in addition to the equity gap for Māori within Whanganui (despite the gout impact for Pacific peoples nationally, Whanganui has a very small Pacific population). Different regions or programmes may have additional equity considerations to build into their programmes.
3. **Careful consideration is given to establishing the leadership and implementation team** for the programme. An implementation team needs a mix of skills and competencies.
    - Different skills and competencies considered important for the Gout Stop programme included leadership, management, analytical, communications, consumer engagement and group facilitation, clinical knowledge and networks with general practice and primary care.

- Programme leadership delivered by a non-clinical role based within primary care was considered a strength as it ensured close relationships with primary care providers and communities, and ensured different models and perspectives were prioritised in programme delivery.
- Clinical expertise remains an important part of the implementation team to give credibility and trust to health providers that it is based on a robust clinical pathway.

When designing the LTC programme:

4. **Use planning tools** to help ensure the programme reflects your context and values and works for your region. Choose the tool/s that are most intuitive to your use, the important part is to be able to communicate how the programme activities will deliver outcomes that achieve your programme aim.
    - Fishbone diagrams were used by the Gout Stop programme in the early design stages to articulate what is currently going wrong from different perspectives and where activity can be delivered to have the most impact.
    - A logic model was used by the implementation team to communicate the intended delivery and outcomes of the programme.
    - Process mapping was used to communicate steps in the programme that needed to be delivered by different health providers – including the activities and documentation required at different stages of the patient journey.
    - Be clear on the level at which you are intervening and make the programme clear at different levels. For example, the Whanganui Gout Stop programme would have benefitted from separating the patient programme intervention and the system change interventions to enable greater definition of both complementary components.
5. **Encouraging and enabling providers to deliver the activities is a key factor for success**. The reach and completion rates require providers to be on board and this leads to achievement of outcomes. This works best when there is a collaborative relationship between different providers supporting the same patient population (often closely located general practice and community pharmacy). Other barriers to provider delivery should also be addressed in the co-design of the programme with providers.
6. **Be clear on the programme resources required** and plan to have quality, capacity and sustainability in the procurement of these resources.
    - Several gout education resources for both consumers and health providers have been developed. They have been peer-reviewed and provide the benefit of nationally consistent messaging.
    - For employment of human resources, ensure there is sufficient leadership, professional support and development for the role/s to thrive. It takes organisational capability and capacity to provide this and ensuring this is already proven reduces human resource risks to implementation.
    - Consider if scarce resources are essential to delivery as capacity and time will be a challenge to delivery. For example, when collaborative programmes

include community pharmacy, can it make use of pharmacy assistants to reduce the need for a pharmacist?
    - An ongoing commitment from funders to deliver the programme as part of business as usual will help to give confidence to providers and consumers.
7. **Plan what indicators are meaningful to stakeholder groups** and keep it simple – process and outcome with an equity lens is suggested. Plan how these will be measured and actively communicated. Feedback, learning and opportunities for adaptation should be built into the programme delivery to give funders confidence that sustainable resourcing will lead to progress against the objectives to which the funding is intended.

When delivering the LTC programme:

8. **Establish champions** in health providers, typically general practice but also other providers, to provide practice/organisation leadership and buy-in.
9. **Consider how you can leverage existing general practice requirements such as Cornerstone** to make equitable LTC management a practice priority that attracts attention and resource.
10. **Consider how new HIP, Health Coach and other roles can be included** in 'routine pathways' for LTC management, regardless of the model in which they have been established in a region. This includes introductions for new diagnoses, unmanaged gout, and psychosocial impacts from gout attacks.
11. **Provide feedback to encourage provider delivery** as provider activity is the biggest contributor to outcomes.

Appendix 1: Principles of engagement for gout consumers

Gout Consumer feedback

These principles are the core things that came from the feedback from gout patients themselves. Actively utilising these principles will improve the experience of all gout patients in the future. They can be demonstrated in small ways but make a big difference to the experience of gout patients using the health system or consuming health messages.

Principles of Engagement

Keep it whanau based. Overwhelming feedback from our consumers has been that gout is not an individual disease state. The implications of this, particularly an acute flare up are felt by the entire whanau. Therefore it is important to keep this conversation whanau based and involve more people than those with the condition only.

Be cautious about whakapapa and gout connection. Remember to keep the conversation strengths based and do not imply or explicitly state that the whanau genes/whakapapa is to blame for their condition.

One message per message. When dealing with whanau, or with health messaging remember to keep it simple and give one message per message.

Strengths based approach. Keep the conversation strengths based/solutions based. What solutions are available to support the whanau to manage acute flare ups and meet the goals of the whanau?

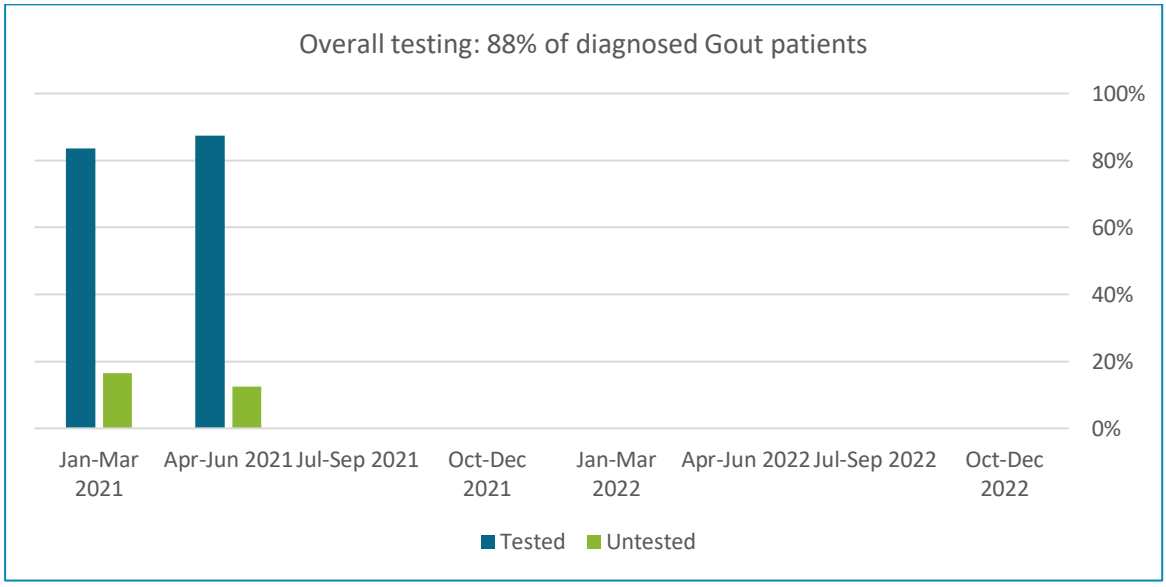
Avoid blame. It is important that when in a consultation with a gout sufferer or developing gout messages, that we avoid blaming the condition on the patient and focus on solutions and a strengths-based approach.

Appendix 2: Example of practice data feedback

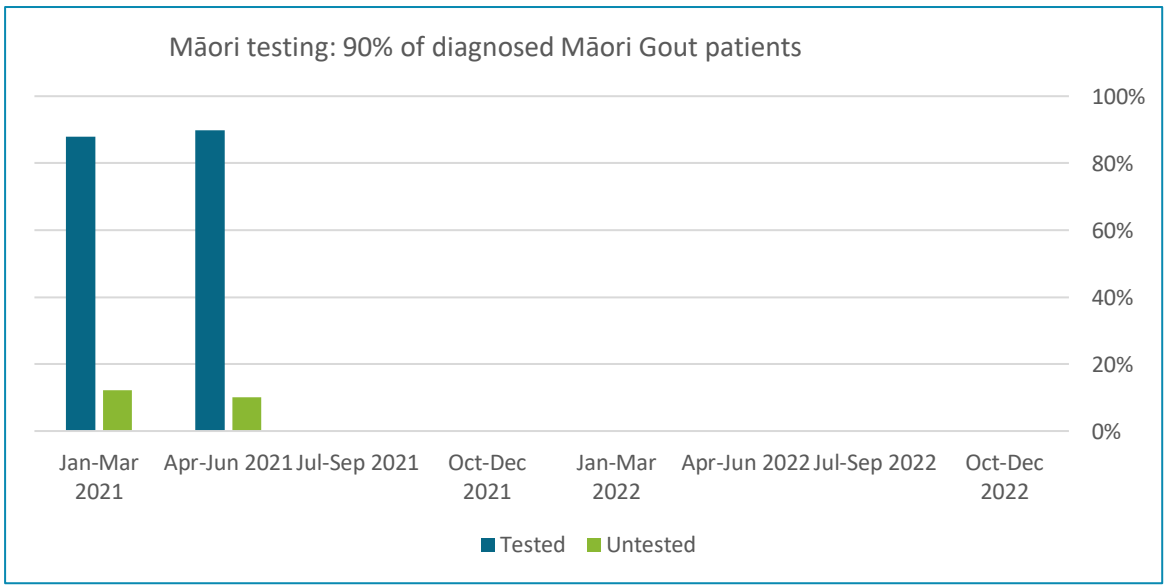
How well is Gout managed in XXX Practice?

Process – what proportion of Gout patients have had uric acid tested in the last 12 months?

Overall (all diagnosed gout patients): 88%

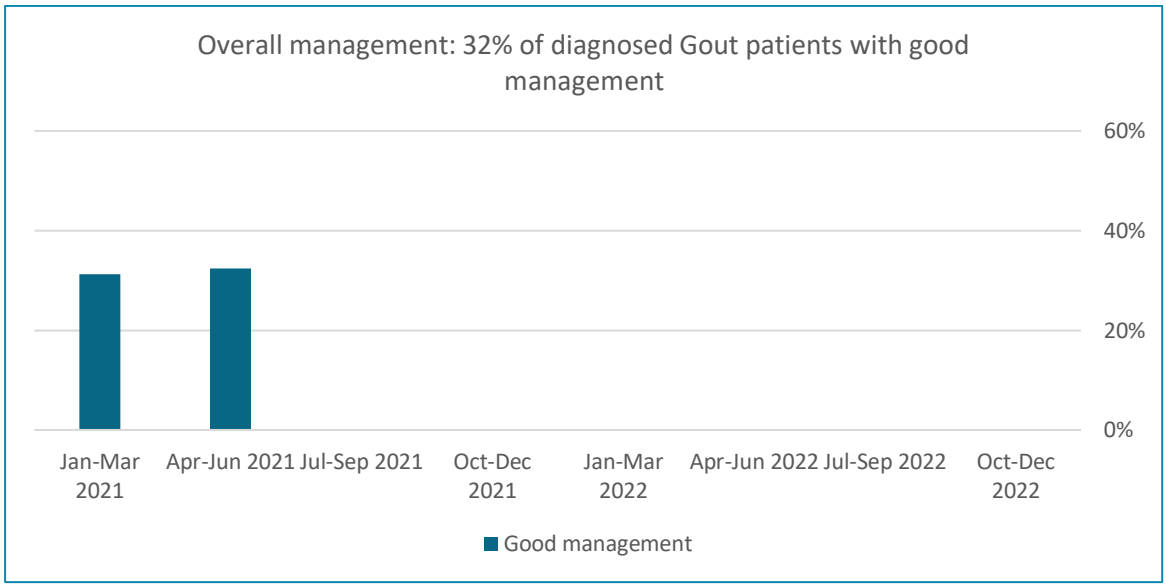


Equity: +2% difference

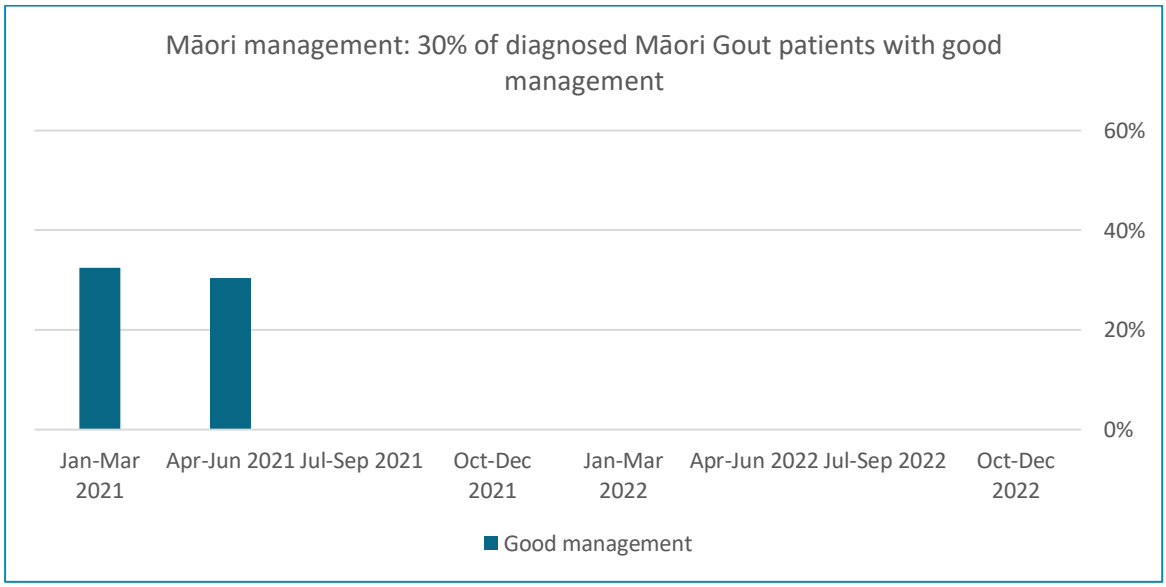


Outcome – what proportion of diagnosed Gout patients have good management (uric acid level <0.36)?

Overall (all diagnosed gout patients): 32%



Equity: -2% difference



Key points

- Audit for immediate difference
- Recalls for sustainable difference
- Classify correctly as LTC

Gout Busters
Evaluation of the redesigned pharmacy gout management programme in Te Whatu Ora Counties Manukau

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Project Sponsor: The project is run by Te Whatu Ora Te Whatu Ora Counties Manukau (formerly Counties Manukau District Health Board). Funding has been provided through the Ministry of Health Planned Care and Improvement initiative to Te Whatu Ora Counties Manukau.

Executive Summary

Background

Gout is a debilitating long-term condition disproportionately affecting Maaori and Pacific peoples, for which urate lowering medication is recommended. To be effective, urate lowering medication needs to be titrated according to serum urate (SU) levels and continued long-term. However, both are not guaranteed and Maaori and Pacific people particularly have low levels of continuation of allopurinol therapy.

Own My Gout is a gout management programme in community pharmacies that had run in the Counties Manukau area, but low enrolments in most pharmacies and many patients lost to follow-up indicated it was not working as desired. Input was sought from pharmacists and a GP involved in Own My Gout, and Arthritis New Zealand to consider barriers to entry or continuation in the programme and possible solutions. Other programmes were reviewed and a Maaori and Pasifika health focus was strengthened. The programme was redesigned as Gout Busters. This had a strong cultural focus in the training; bespoke software for reporting, communication with general practice and text messaging to patients; and used the new Gout Booklet. Thirteen pharmacies in the Counties Manukau area with high Maaori and/or Pasifika populations were contracted to provide it.

Aim

To determine whether an enhanced gout programme involving community pharmacy is effective for people with gout, pharmacists, and general practitioners.

Design and Methods

This research evaluated a redesign of a pharmacy gout programme at Te Whatu Ora Counties Manukau using outcome analysis, interviews with people with gout who are using/have used the programme and surveys of pharmacists delivering the service and general practice staff with patients in the service.

Results

Over a 13-month period (1 May 2022 to 2 July 2023), 232 patients (81% Maaori or Pacific peoples) were enrolled in Gout Busters. Uptake was slow initially, increasing after promotion to pharmacy and general practice. Enrolment numbers varied considerably between pharmacies/general practices.

Statistical analysis of 127 eligible records (1 May 2022 to 4 May 2023) found 40% of those who attended the pharmacy for at least three months reached the target SU of 0.36 mmol/L. Maaori and Pasifika enrollees had a similar SU reduction on average (0.1 mmol/L) to non-Maaori-non-Pacific but were less likely to reach the target SU level, having started at a higher SU level.

Analysis of data from 46 eligible enrollees from 2022 found a high rate of allopurinol dispensing at least eight months after they started the service (78%). Dispensing data for the 46 people enrolled in 2022 suggested uninterrupted allopurinol supply for 59% of these enrollees for this time. Maaori and Pasifika enrollees had higher uninterrupted allopurinol supply than found in the Atlas of Variation data.

Qualitative data from 16 Maaori or Pasifika service users found they valued the service (most rating it 9 or 10 out of 10). The programme aided their understanding of gout and their medication, particularly with the SU fingerprick test, motivated them to continue their allopurinol, and they liked the convenience and friendly/caring pharmacists. The texts helped motivate them to take the tablets and to attend the pharmacy. There were various reasons for suboptimal adherence, requiring different solutions. Service users were time-constrained. Cost and waiting time for doctors were barriers to getting allopurinol prescriptions and could lead to discontinuation of allopurinol. Service users often

delayed attending the pharmacy for their fingerprick tests, so relying on that for allopurinol dose titration or dispensing more allopurinol can delay titration, particularly if they temporarily discontinue allopurinol. Privacy and discretion in the pharmacy was important, and discomfort occurred when it wasn't provided. Few wanted improvements to the programme.

Pharmacists were largely positive about the service, although some struggled if sole charge in the pharmacy. Pharmacists liked doing the fingerprick tests, the training, the text messaging to patients and helping patients. Some had difficulty with getting renal function tests, delaying the ability to titrate doses. The software was slow and administration took time.

With only five general practice staff responding to the survey, results are not generalisable, but the service was valued for taking the load off them as prescribers and helping titrate the patients. They appreciated the communication via the software from the pharmacy.

Conclusion

Early data from the Gout Busters programme found high Maaori and Pasifika participation in the programme and better long-term adherence to allopurinol than in the Atlas of Variation, including for these groups, albeit limited by small numbers. Maaori and Pasifika service users found the Gout Busters programme beneficial.

Allopurinol dose titration can be slow, partly because of delayed pharmacy visits or renal function tests, and it is recommended that a fixed dose titration regimen is used, three-month supplies and pharmacists able to provide a renal function lab test form. Challenges with seeing doctors need to be addressed for long-term continuation on therapy, e.g. pharmacist continuation supply after the programme has been completed, ability to order a repeat prescription or telehealth options. Minimising patient cost is important.

Sufficient resourcing is needed to support pharmacies and general practices joining the scheme and optimise pharmacists' work, sharing best practices and encouraging those with poorer outcomes.

Repeating the statistical analysis in 9-12 months is recommended to understand patient outcomes, particularly for Maaori and Pasifika patients.

Note: throughout the report Counties Manukau area or Counties Manukau District Health Board is used for the time prior to July 2022, and after this the term used is Te Whatu Ora Counties Manukau.

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Background

Gout management

Gout is a common but treatable inflammatory arthritis caused by the deposition of monosodium urate crystals from high serum urate (SU) levels. Gout causes severe joint inflammation with extreme pain, reduced quality of life, work absences and reduced social and church participation (Dalbeth, et al, 2016; Fatafehi-Finau, 2019). Gout disproportionately affects Maaori and Pacific peoples in New Zealand with early onset, more severe disease and more frequent flares (see equity below) (Dalbeth, et al, 2013), predominantly because of genetic and socioeconomic factors. Gout management by doctors is frequently suboptimal, resulting in reduced mobility, lost wages from work absences, reduced social participation and long-term damage to joints and kidneys (Dalbeth, 2018). Poorly managed gout results in a moderate level of physical disability and a SF-36 physical functioning score similar to people aged 75 years or over in a much younger population (Young Ki and Choi, 2009).

People with gout may purchase non-prescription NSAIDs, borrow other people's gout medicines (Martini et al, 2012; Fatafehi-Finau, 2019, Te Karu et al, 2013) or present at emergency departments for gout treatment (Lawrence et al, 2019), suggesting barriers to general practice access or a need for convenience.

Preventative therapy, usually with allopurinol, can help avoid attacks of gout if the dose is correctly titrated and with good adherence (Dalbeth et al, 2016). Flare prophylaxis is co-prescribed with allopurinol initiation to reduce the risk of an acute attack. Allopurinol requires a low starting dose and escalation until the patient reaches a SU level <0.36 mmol/L. Achieving such a SU level through use of allopurinol reduces the risk of repeat acute episodes and long-term damage (Dalbeth et al, 2016). Research from 2010-2011 found only 57% of New Zealanders with gout were dispensed allopurinol, of whom only 69% received it regularly (Jackson, 2014). Many are not having sufficiently frequent SU measurements to allow optimal titration (Jackson, 2014).

Some South Auckland doctors may think of gout in terms of acute management rather than preventive care and not prescribe allopurinol, or they may perceive patients are not taking responsibility for their own health (Humphrey et al, 2016). Some GPs focus on dietary modification (which has minimal effect) and may also lack time for education (Humphrey et al, 2016). Repeat visits and blood tests to increase the dose may be difficult and expensive for the patient, and the prescriber may overlook dose adjustment. GPs report that some patients do not attend follow-up visits or forget to get their prescriptions (Humphrey et al, 2016). Acute attacks with suboptimal dosing of allopurinol may result in the patient believing it ineffective.

Long-term conditions are increasing in primary care in New Zealand with pressure on general practice. An issue identified by Humphrey et al (2016) in her qualitative practitioner study of the barriers in primary care included a focus on acute rather than long-term management. The practitioner-patient relationship is important, particularly with patients from different cultures. Time constraints and a business model which was not fit for long-term condition management was acknowledged by the primary care participants as an important systemic barrier to optimal care. These barriers are also identified from a patient perspective, with patients forced to engage in a system which is hard to access, does not always provide best practice care, and does not provide a safe environment in which understanding and messaging are encouraged (Te Karu et al, 2013). Socioeconomic disadvantage can compound the inequity (Te Karu et al, 2021).

Addressing these issues will require more effective use of a multidisciplinary team, including primary care nurses and pharmacists, with effective communication, for coordination of management, and funding which promotes this model of care.

Many gout sufferers have insufficient knowledge about gout and its management (Martini et al, 2012). Health literacy for people with gout, systematic quality improvement for condition management and reducing inconvenience and cost to patients should be prioritised (Dalbeth et al, 2019). Dose titration and/or education through the pharmacist can help (Lawrence et al, 2019; Andrews et al, 2020; Goldfein 2014; Dalbeth et al, 2019). Pharmacy has minimal waiting time, extended opening hours, no appointment needed and can use point-of-care (POC) SU for on-the-spot dose titration, and therefore pharmacists have been used in Counties Manukau and Northland areas to aid in education for people with gout (Lawrence et al, 2019; Andrews et al, 2020).

The Counties Manukau Own My Gout programme has been available in up to six pharmacies. It provides education, POC testing and dose titration of allopurinol by the pharmacist, with the patient remaining on the programme until achieving the target SU for three months. The Northland programme provides education, compliance packaging, and a standard titration scheme without POC testing. POC tests are optional and uncommonly used, and the pharmacist helps the patient to organise their next blood tests and prescription for medication from the medical practice at the end of the three-month programme.

A role for pharmacists in initiation of allopurinol has also been identified and is likely to aid access (Martini et al, 2012). Ensuring continuous supply has been recommended, reducing the risk of discontinuation (Dalbeth, et al. 2016).

Gout and equity

Gout disproportionately affects Maaori and Pacific peoples (Dalbeth et al, 2013; Dalbeth, 2018). Allopurinol prescribing in Maaori and Pacific is inequitable and many do not achieve the target SU level (Dalbeth et al, 2018). Data from 2005-2006 found Maaori had lower adherence to allopurinol than non-Maaori (Horsburgh et al, 2014). Maaori and Pacific and younger people were less likely to be dispensed allopurinol regularly (Jackson, et al, 2014). Maaori and Pacific people with gout have younger age of onset, greater pain, higher SU, more flares, more limited activities and lower health-related quality of life than people with gout who are of other ethnicities (Dalbeth et al, 2013). Hospitalisation for gout is higher in Maaori and Pacific people than other ethnicities (Jackson, et al, 2014; Dalbeth et al, 2016), and with minimal improvement over time.

For Maaori and Pacific people with gout, starting the preventative medication, allopurinol, may be delayed because doctors may have focused on symptom control rather than prevention. Or seeking help for gout may have been delayed, with many factors possibly contributing, including lack of recognition of the disease, stoicism, misconceptions and/or self-blame, cost and/or time off work (Te Karu et al, 2013; Fatafehi-Finau, 2019).

Some people may not continue on allopurinol, sometimes because of low health literacy affected by lack of communication or ineffective communication from health professionals or misunderstandings (Te Karu et al 2013; Fatafehi-Finau, 2019). There may be financial or time challenges to see a doctor (Te Karu, et al, 2013). With poorly controlled hyperuricaemia (Dalbeth, et al, 2013), many Maaori and Pacific people are being repeatedly treated with NSAIDS, described as *"a poor and potentially dangerous stopgap"* (Dalbeth et al, 2018). Some may take excessive doses of pain relievers or share pain relievers with family members or friends for gout (Fatafehi-Finau, 2019; Te Karu, et al, 2013). Indeed, Maaori and Pacific people have increased harms of NSAIDs versus other ethnicities, including increased hospital admissions for serious adverse effects (Tomlin, et al, 2020). Intensive efforts to work with Maaori and Pacific people to reduce SU and flares has been suggested (Dalbeth, et al, 2013). However, Maaori people have challenges to accessing care for gout, including cultural, financial and time barriers (Te Karu et al, 2013). Maaori in poverty found prescription costs could lead to reduced collection of medicines and consequently suboptimal dosing or interrupted treatment (Norris et al,

2016). In a qualitative study of Tongan people with gout, Fatafehi-Finau (2019) found challenges with medical care can include poor communication, rushed doctor consultations, being admonished (or embarrassment or fear of blame, e.g. about weight/alcohol use), or in the patient thinking only to solve acute pain rather than taking a preventative approach. A respectful approach and information that can be understood were appreciated.

There are over 38,000 patients with gout in the Te Whatu Ora Counties Manukau area and numbers are steadily increasing. In the first six months of 2018 there were 306 acute admissions for patients with gout, of whom 220 were Maaori or Pacific peoples. There are 320 new patients with gout seen in rheumatology clinics each year, most being Maaori or Pacific peoples. Many of these outpatient appointments and hospitalisations would be prevented by better gout management in the community (Hutton et al, 2009, Gow P, et al, 2011).

Current gout programmes in pharmacies and identified needs

Dose titration and education through the pharmacist can help as has been found in Northland and Counties Manukau areas (Lawrence et al, 2019; Andrews et al. 2020).

Counties Manukau District Health Board piloted a gout management programme in six pharmacies using POC SU tests, dose titration and education in the Owning My Gout (OMG) programme. While promising, 2019-2021 data from five of these pharmacies showed suboptimal uptake and lack of patient continuation reflecting barriers for people with gout, general practice and pharmacy. In the one pharmacy with higher enrolments, many people enrolling in the programme leave it with few tests conducted and below the target SU.

In Northland the StopGout programme involves provision of gout medicines including allopurinol which starts a set time after treating the gout attack and is followed by titration at set times with no need for fingerprick tests (Lawrence et al, 2019). The prescriber has a set up on their prescribing software to order the three months of medicines including the gout flare prophylaxis and increasing allopurinol dose. The pharmacist provides education and medicine in blister packaging. This programme has had a high uptake, showing good desire for it.

Reporting for Counties Manukau and Northland was manual with little ongoing feedback to pharmacy, GP or the districts on the outcomes of the programmes (e.g. proportion reaching the target SU) and the effect on long-term allopurinol adherence was unclear. Feedback from Northland revealed barriers to programmes access included the need to attend the doctor first, and requirement of a referral for enrolment by the doctor rather than the pharmacy. The inability by the pharmacist to titrate allopurinol or measure SU misses an opportunity to optimise medication.

Feedback from pharmacists in Counties Manukau suggested barriers to programme continuation by individual patients include requiring three-monthly prescriptions and forgetting to attend the pharmacy for POC blood tests. Pharmacists liked the suggestion of text reminders to aid attendance, similar to the text service to remind people to collect repeats, as used by many pharmacies. Text messaging has been shown to be effective in supporting behaviour change and reminding patients to engage with health providers (Willcox, 2019). In New Zealand, text messaging has been used successfully to support smoking cessation in Maaori, (Bramley, 2005), provide diabetes self-management (Dobson, et al 2018), deliver maternal health education and support to Maaori, Pacific and new migrant communities (Dobson, et al 2017 and deliver cardiac rehabilitation (Dale, 2015). Text messages aided adherence to allopurinol in a small Thai study (Bunphong and Narongroeknawin, 2018).

New Gout Busters programme

This programme involved a redesign to the existing service of gout management in pharmacy to remove barriers based on: an independent report by Synergia (Andrews et al. 2020) on the Counties Manukau and Northland programmes; feedback sought by the principal investigator from providers and DHB personnel involved in the gout programme in Counties Manukau and Northland areas; and with input from a Tongan rheumatology nurse and a pharmacist working in Maaori Health. Enrolment was encouraged by reducing the burden on the GP and primary care nurse, getting more GPs involved, allowing pharmacists to enrol with GP assent rather than requiring the GP to instigate it, allowing patients to re-enrol without needing to attend the GP and providing easily accessible reporting to general practice to aid visibility of patient progress and the programme in general. The programme was concentrated on higher priority populations, requiring at least 75% of participants to be NZ residents identifying as Maaori or Pacific Peoples.

Pharmacists could continue allopurinol therapy for enrollees under a standing order to reduce the risk of discontinuation.

Using multiple tools (i.e. POC testing, pharmacist supply of allopurinol without prescription, dose titration by pharmacists, education from pharmacists and text messages) was intended to achieve the best possible gains for gout sufferers. Written educational leaflets on gout were available in multiple languages and the text messages, although in English, were personally addressed and culturally tailored incorporating greetings in Te Reo, Samoan, Cook Island Maori and Tongan. Text messages included a welcome text to the programme, reminders to return to the pharmacy for their fingerprick test and motivational messages to encourage continuation on allopurinol.

Thirteen pharmacies in South Auckland with high Maaori and/or Pacific populations were contracted from 2022 to deliver Gout Busters. These comprise a mixture of pharmacies involved in the initial Own My Gout programme and pharmacies which have not been involved in a previous gout programme.

The redesigned Gout Busters Pharmacy Programme keeps many original features, e.g. SU POC testing, allopurinol dose titration by the pharmacist and education by the pharmacist. Additional cultural competency training, software, text messages to patients enrolled in the programme and a printout for the patient of their SU graph and current allopurinol dose are now included. Features of this programme include:

- Pharmacists receive training from Counties Manukau staff and Arthritis New Zealand staff including cultural aspects to gout and working with people with gout who are Maaori or Pacific. This involved four sessions by zoom of an hour each, available in real-time or on-demand.
- People aged 20 years or over with a doctor's diagnosis of gout and prescribed allopurinol are enrolled into the programme by the pharmacist in collaboration with the GP. The programme is only available for people eligible for healthcare in NZ, living in the Counties Manukau area, with a SU > 0.36 mmol/L (unless presenting in an acute flare when the SU is artificially lowered).
- Enrolment includes written consent to being in the programme and allowing use of their data by Te Whatu Ora Counties Manukau for programme evaluation and quality improvement purposes.
- The pharmacist accesses Testsafe information for SU, renal function and medication dispensing information relevant to their gout.
- Pharmacists can provide continuation supply of allopurinol under standing orders.
- At least 75% of people in the programme are to identify as Maaori or Pacific Peoples. Most pharmacies contracted in the programme have high Maaori and/or Pacific patient populations. Pharmacies and general practice are asked to concentrate primarily on Maaori and Pacific people

for this programme. Ethnicity of enrolments is tracked at Te Whatu Ora Counties Manukau and feedback provided to GPs and pharmacies if necessary.

- Participants receive tailored text messages to support adherence to the programme and allopurinol including reminders at appropriate times to attend the pharmacy for a test. Tailoring included language for greeting, the participant's name, and different texts if a visit is missed.
- New pharmacy software provides automated text messaging (as above), print-out graphs for individuals showing their progress, communicates SU and allopurinol dose to general practice and provides reporting to Te Whatu Ora Counties Manukau.
- Education and monthly fingerprick POC SU tests are provided while checking for adverse effects and adherence, with the intention to build knowledge. The allopurinol dose is titrated by the pharmacist as per Health Pathways under standing orders.
- After reaching the target level for three consecutive readings the person is exited from the programme. Those who stop attending can re-enrol.
- The cost of co-payments on scripts is covered.

Aim

This observational study aimed to determine whether this improved streamlined gout programme co-ordinated through community pharmacy is effective for service users (people with gout), pharmacists, and general practice.

Research question: In people with gout (including primarily Maaori and Pacific Peoples) can a re-designed programme through pharmacy, in conjunction with coordinated multidisciplinary primary care input, improve outcomes for patients by reaching the target SU of <0.36 mmol/L in at least 50% of patients enrolled (including within Maaori and Pacific people subgroups), aid adherence to allopurinol and work well for patients, pharmacists and general practice?

The interviews with service users and health care professional survey aimed to understand the patient and health care professional experience and opinions of the redesigned gout programme and how it could improve.

Research design and methods

Study design

This was a mixed methods observational study using quantitative outcomes and qualitative interviews.

Recruitment of participants

For the qualitative component, the researchers invited people within this Gout Busters Programme of who identified as Maaori or Pacific peoples and who meet a range of criteria to be interviewed (see qualitative research below). Pharmacies identified people using the programme and ascertained their interest in helping with an interview. Those who were interested were then approached by the research team. Further people were identified from the gout software report meeting the criteria of using the programme without continuous attendance or with early stopping, and these were contacted by the research team directly to invite them to be interviewed. The interview followed collection of informed consent.

Pharmacies and general practices involved in the programme were emailed an invitation for their staff to complete an on-line survey including a participant information sheet. Submitting the survey was taken as informed consent. The pharmacy and the general practice survey questions differed.

Data Sources

This study utilised the following data sources for the programme evaluation/outcomes analysis:

Gout Buster online software: Bespoke software was provided by Firecrest, the company that provides pharmacy warfarin management software in NZ. Pharmacists record patient information on this software. Relevant data to answer the research question for this project was extracted for research purposes. This included pharmacy attended, NHI, date of birth, ethnicity, gender, SU levels at each visit, renal function (eGFR), past SU levels from laboratory tests, visit dates and allopurinol dose.

Testsafe: Data were accessed from Testsafe by the pharmacist or the researchers if necessary, for SU, renal function and allopurinol dispensings.

Éclair: Data were accessed from Éclair for patients for information about hospitalisation for gout.

Quantitative Outcomes

Participant outcomes:

- number of participants joining the programme overall and by pharmacy and month
- proportion of participants reaching SU <0.36 mmol/L and period and number of visits to reach this target
- reduction in SU overall and for Maaori and Pacific peoples
- proportion who dropped out when they were not at the target SU
- number of people stopping the text messages
- re-enrolment defined as a return to the programme after a break within the programme period of three months or longer
- dose of allopurinol
- long-term use of allopurinol for those enrolled in the programme in 2022

Institutional outcomes:

- number of enrolments in each pharmacy

Statistical Analyses

Inclusion criteria

Participants enrolled in the Gout Busters programme between 1 May 2022 and 5 May 2023, who had a least one visit to the pharmacy regarding their gout, and who attended a pharmacy which enabled timely text messages.

Exclusion criteria

Participants whose enrolment in the Gout Busters Programme occurred after 5 May 2023, whose enrolment was cancelled by the pharmacy (e.g. being ineligible), or who attended a pharmacy which was not enabling the timely text messages as per protocol.

Participants from Pharmacy A who enrolled before 15 February 2023 were excluded from analyses because of delayed entry in software so text reminders to take the medication and attend pharmacy visits were not delivered as in the protocol. Their number was reported.

The analyses took place in two ways: time-to-event analyses and progression of SU over time. Because the programme was exited in only a few cases, the outcome for time-to-event analyses was time from entry into the programme until the target was reached a first time. All time-to-event analyses assume that participants lost to follow-up are right-censored immediately after they were last seen, and that

participant still in the programme ("Progressing") were right-censored on 2023-05-05. The two forms of censoring are treated in the same way in the analyses.

These analyses were themselves carried out in two ways:

• A descriptive component. This component consisted in a Kaplan-Meier curve and a quantile table for the time-to-event analysis and a mixed effects regression to estimate the rate of progression of SU overall.

The random effects consisted of intercept and slope of SU change over the number of days since starting the programme and the fixed effect consisted of this same slope. No other adjustments were carried out given that slopes were individually tailored using random effects. The estimated variance matrix of the random effects was used to compute the between-participant variance at 180 days (BPV180). The ratio of BPV180 over the sum of BPV180 and the residual variance was reported as the intraclass correlation coefficient at 180 days.

• A comparative component. This component compared participants according to age band and to ethnicity of Maaori or Pacific peoples vs the ethnicity of non-Maaori and non-Pacific peoples. Kaplan-Meier curves were produced to compare the estimated times to event in the groups. The proportional hazards assumption was assessed by plotting the log-cumulative hazard curves. If these curves were not parallel, the proportional hazards model was deemed unreliable and was not fitted. Otherwise, results from the proportional hazards model were presented.

Classical rank-based test results were also produced: p-values from the log-rank test and from the Peto-Peto-Prentice (PPP) test. The log-rank test is most powerful against proportional hazards alternatives, while the PPP test is most powerful against location alternatives from a logistic distribution (Harrington & Fleming, 1982).

The random effects model was similar to the descriptive one but included an indicator for the strata by themselves and in interaction with the number of days in the programme. A test of this interaction was carried out and the results from the selected model presented.

Qualitative component

Participants & Recruitment

Qualitative interviews of participants took place approximately 11 months after the redesigned service started using Maaori interviewers for Maaori participants and Pacific interviewers for participants of Pacific Island heritage where possible, with interviews taking place by telephone or zoom.

We aimed to recruit 16-20 people from the programme, a subset of the original quantitative research, including 6-7 people identifying as Maaori, and 10-13 people identifying as Pacific peoples.

Researchers from Te Whatu Ora Counties Manukau contacted the participant directly or through the pharmacy. The participant was provided with the information sheet and consent form and if agreeable was interviewed. People approached for the interviews comprised a mix of those successfully reaching the SU target and those who did not, including people who have stopped and restarted in the programme or missed pharmacy visits and reflect a range of ages.

Vaioleti (2016) states that during the talanoa probing questions may be asked to sustain the malie of the talanoa. The advantages of using the talanoa method is that the conversation is flexible and it 'provides opportunities to probe, challenge, clarify and realign to ensure the richness of the information gathered' (Halapua, 2000; Vaioleti, 2016). These values are closely aligned with the Pacific cultural values identified by the Health Research Council of New Zealand (2014) which include: Respect, communal relationships, reciprocity, and holism.

The intended Kaupapa Maaori approach involved Maaori input on the questionnaire design and overall design, but work pressures precluded this.

Participants received $50 in vouchers koha as reimbursement.

Interviews

Topics covered in the interviews included the workability of the model for the participant, advantages and disadvantages of the programme, how comfortable (or not) they have felt in the programme, what benefits (if any) they have received from the programme, what elements of the programme worked and what elements did not, how the programme could be improved, whether they would recommend the programme to someone else with gout (and why/why not). For those who stopped the programme without achieving the target SU, reasons for the discontinuation will be explored, and their opinions on what would be needed to keep people in the programme. Feedback would be sought on the text messages, and what impact (if any) the patient thought the messages had on them attending the pharmacy and managing their gout. Brief demographics were collected.

The Pacific and Maaori co-investigators, including the Pacific Lead, are recognised to have at least equal rights to the Principal Investigator, and their input is highly valued and sought throughout the programme – planning through to reporting and every stage in between.

With the participant's permission, interviews were audio taped and manually transcribed verbatim.

Data analysis

Transcriptions for consumer interviews were read and reread, then analysed to understand barriers and enablers to the pharmacy programme and allopurinol use, and understand which components of the programme worked or did not work.

Health care professional Survey

All health care professionals (GPs, practice nurses and pharmacists) involved in Gout Busters were invited to answer a questionnaire about the service through an email invitation with a link to an online questionnaire (Qualtrics). This included their demographics, number of their patients enrolled in Gout Busters, opinions on elements of the service and possible improvements.

Ethics

Ethical approval was granted on 9 February 2023 by the Auckland Health Research Ethics Committee (AHREC), reference AH23809 and then locality approval followed from Te Whatu Ora Counties Manukau research office.

Results

Statistical Analysis

For the statistical analysis, data were downloaded from the software for 1 May 2022 to 5 May 2023 and inclusion criteria applied, as per the flowchart (Figure 1).

Data from 127 people were available for statistical analysis. Most (87%) were male, and most (74.8%) were Maaori or Pacific peoples. The mean age at the start of the programme was 45.4 years (SD 13.47). Many enrollees were aged under 45 years (47.2%), particularly for Pacific peoples (58.7%), but not for Maaori (19.0%). Only 5 enrollees (3.9%) were recorded to have tophaceous gout. Most participants were on low doses of allopurinol at the start of the programme, suggesting they had just been initiated on allopurinol or had been initiated before but not titrated (Table 1).

Figure 1. Flowchart showing dataset for the statistical analysis

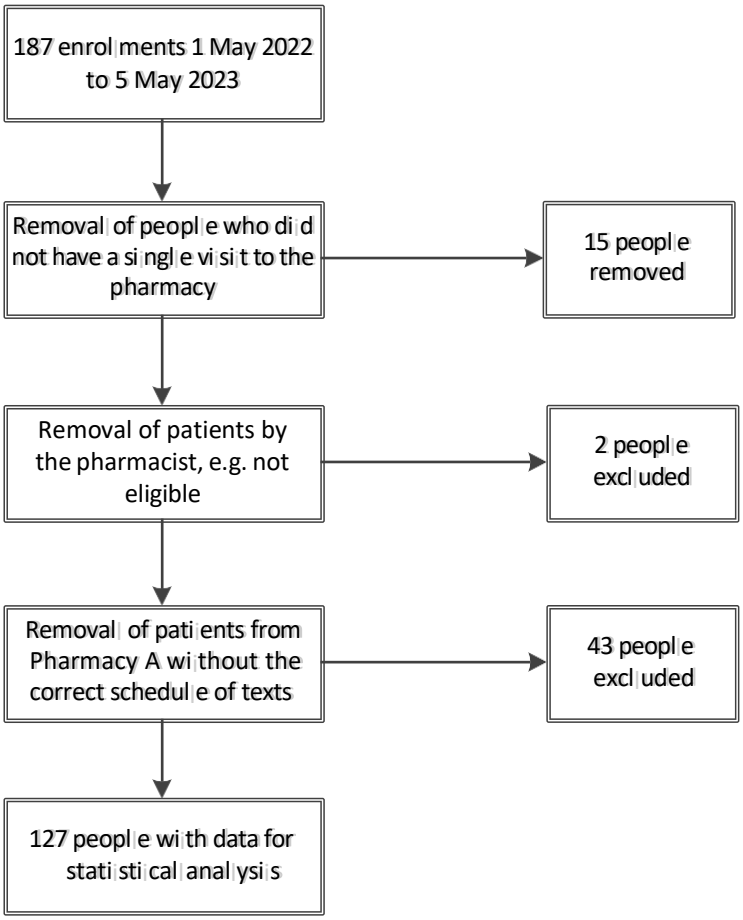


Table 1 Participant Demographics for Quantitative Data Set

Demographics	N (127 total)	%
Gender		
Male	110	86.6
Female	14	11.0
Not provided/other	3	2.4
Prioritised ethnicity		
Maaori	21	16.5
Pacific peoples	75	59.1
Neither Maaori nor Pacific peoples	31	25.2
Age band (aligned with Atlas of Variation)		
20-44 years	60	47.2
45-64 years	59	46.5
65 + years	8	6.3
Starting dose of allopurinol		
50 mg	4	3.1
100 mg	68	53.5
150 mg	1	0.8
200 mg	23	18.1
250 mg	1	0.8
300 mg	19	15.0
400 mg	7	5.5
500 mg	1	0.8
600 mg	1	0.8
Not available	2	1.6

The mean starting SU value was 0.47 mmol/L (SD 0.10) (range 0.18 to 0.73 mmol/L). Nine had a starting SU < 0.36 mmol/L. The mean SU value was similar across age groups, 0.47 mmol/L for age 20-44 years, 0.46 mmol/L for age 45-64 years and 0.48 mmol/L for age 65 years and greater. However, it was higher for Maaori and Pacific peoples versus non-Maaori/Pacific peoples (0.48 versus 0.44, respectively, p=0.092).

Reaching the target for the first time

Time-to-event descriptive analysis

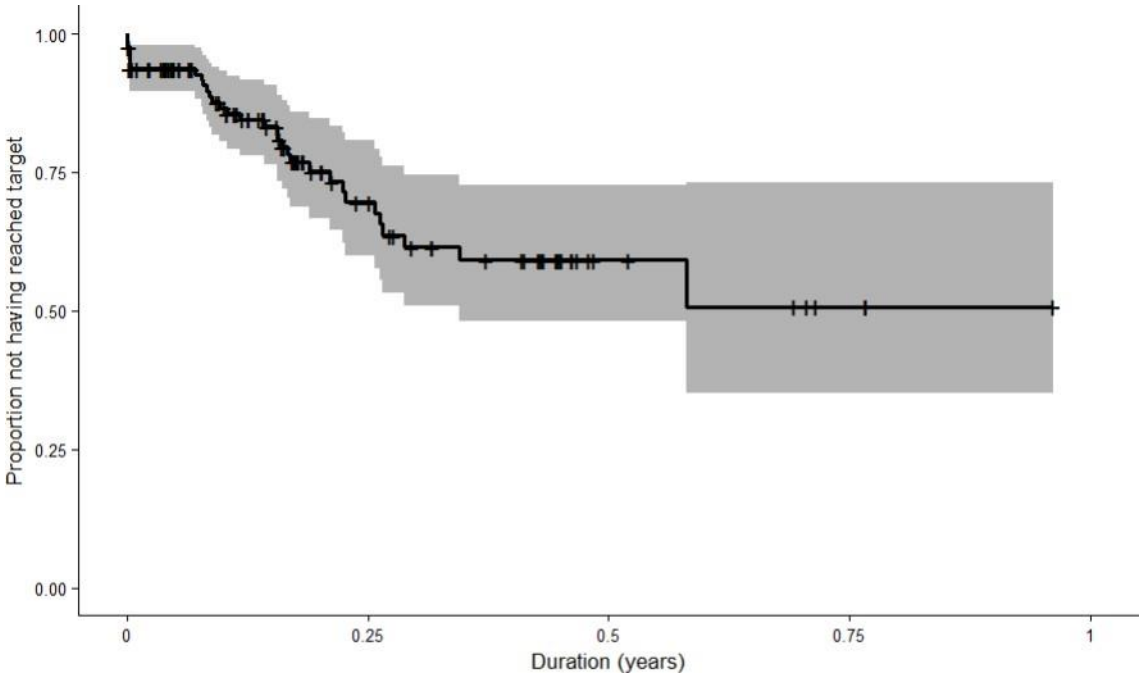
Across the whole sample, 33 people (26.8%) reached the target SU at least once. For people identified as Maaori and Pacific combined, target levels were achieved at least once by 19 participants (19.8%) while the group that was neither Maaori nor Pacific peoples had 14 people (45.2%) reach the target at least once (p=0.012). Stratified analysis by age will be confounded by ethnicity but is not able to be accounted for in the Kaplan-Myer analysis. Note that many people had a late start to the programme, starting in the last three months prior to the data cut-off that limited their ability to reach the target SU. Longer-term data is required to confirm if the disparity in achievement of target SU continues and/or can be modified.

We consider the event of reaching the target for the first time and produce graphical and descriptive statistics.

Not stratified

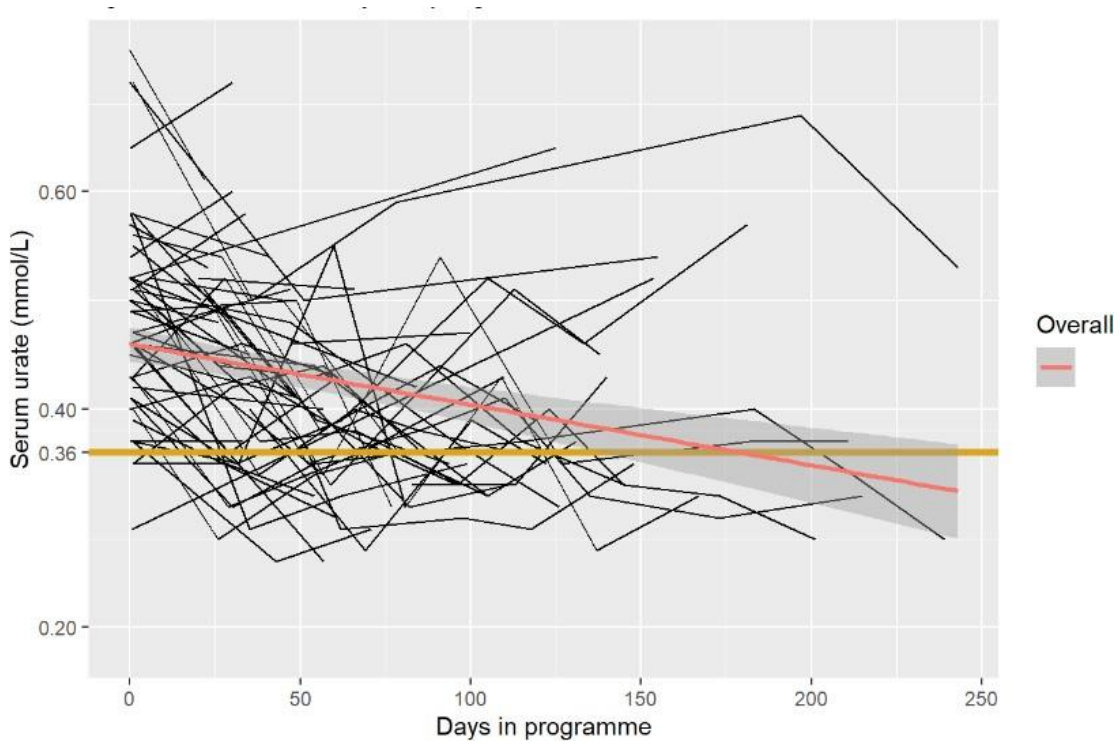
The Kaplan-Meier estimate shows the longer the person is in the programme the more likely they are to reach target, with over 40% of those in the programme for at least three months reaching target at least once (Figure 2), however, considerable differences exist between patients (Figure 3).

Figure 2. Proportion of target never reached against duration



Serum Urate Descriptive Analysis

Figure 3. Individual and average serum uricaemia trajectories



Mixed effects model

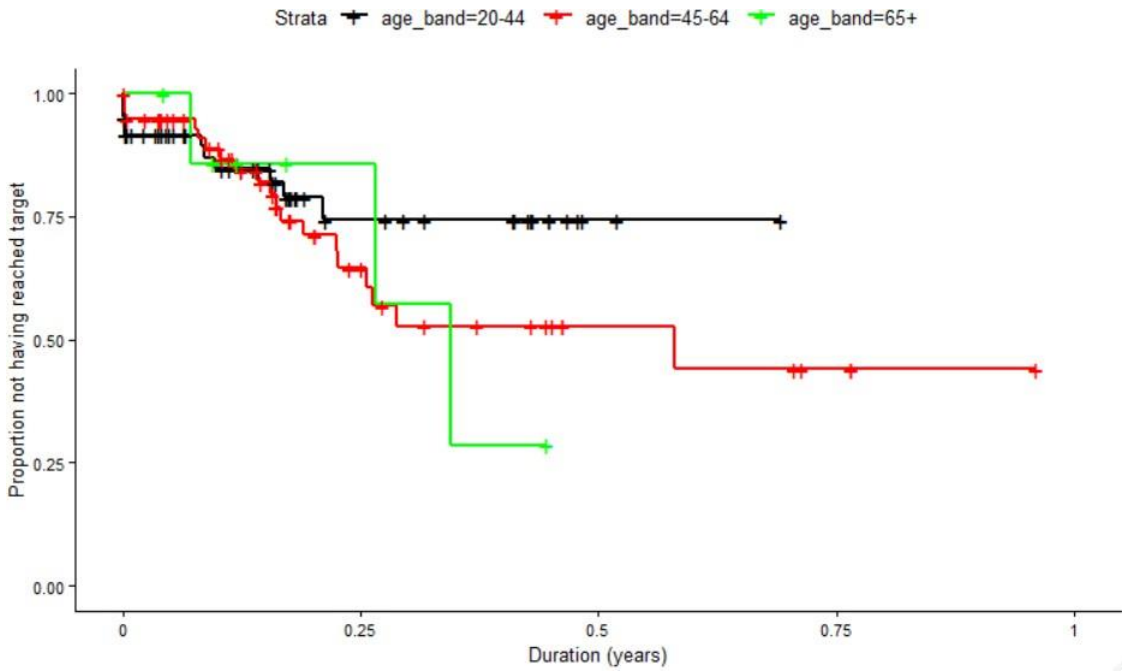
Serum urate was estimated to decrease by 0.11 mmol/L over a period of 180 days while in the programme (95%CI [0.060,0.157]). The intra-participant correlation coefficient was estimated at 0.76 at 180 days, meaning that about three-quarters of the total variability is attributable to variability between participants, compared to within-participant variability.

Effect of age band and ethnicity

We consider stratification on age band and on ethnicity of Maaori or Pacific peoples vs the ethnicity of non-Maaori, non-Pacific peoples. We compare the strata in a time-to-event analyses and SU longitudinal measurement analyses.

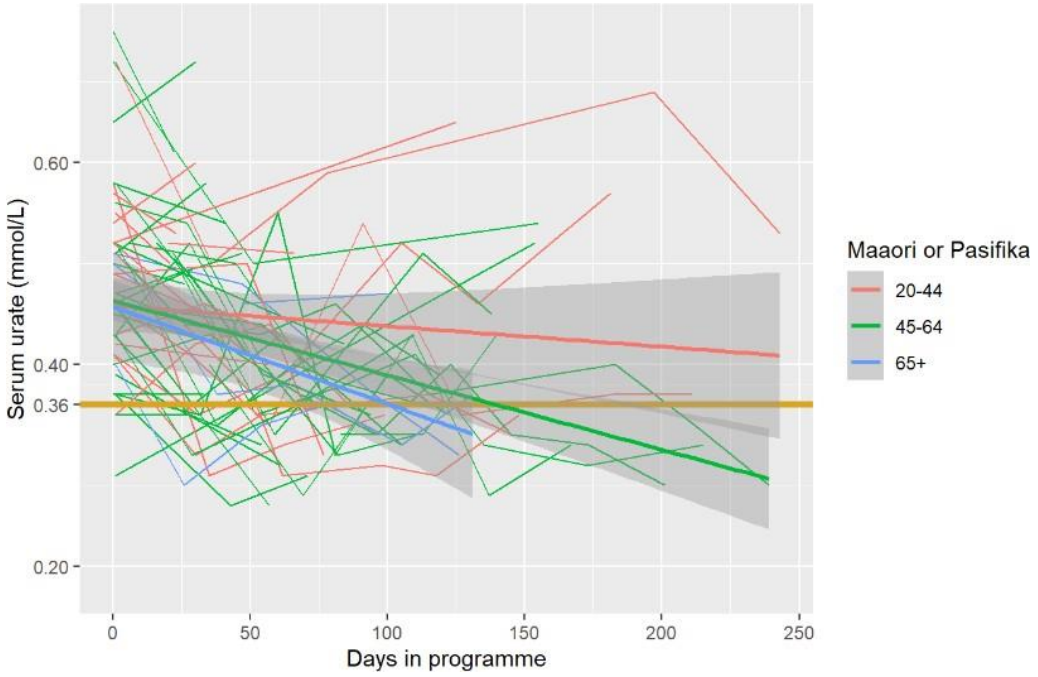
The evolution of the proportion of participants reaching the target for the first time is shown by age band in Figure 4.

Figure 4. Proportion of target never reached against time, age bands compared



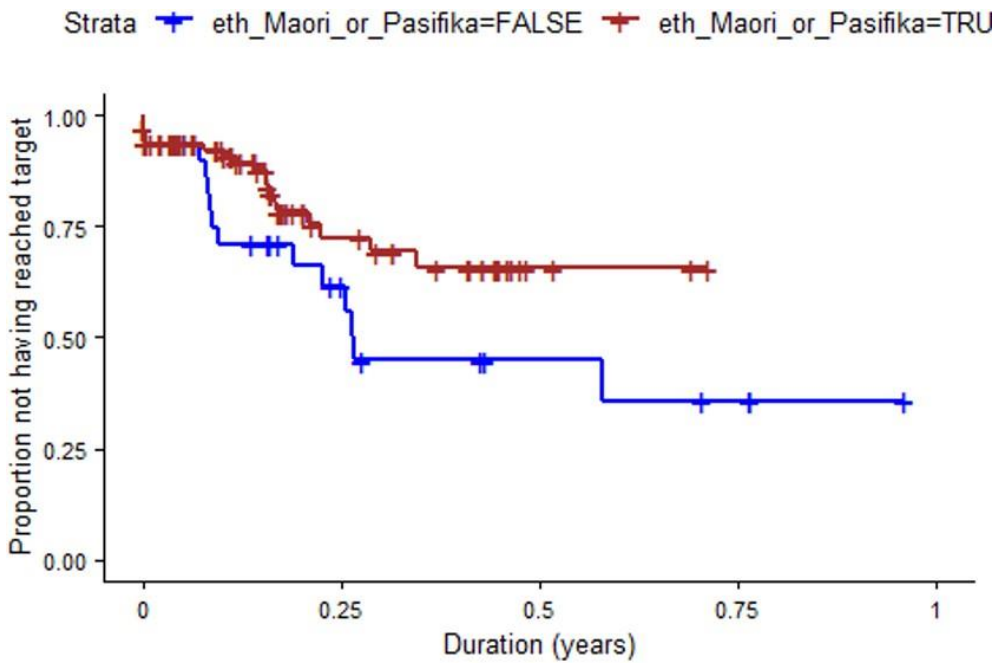
While there appears to be a difference in outcomes by age group with older groups more likely to reach target than the youngest group (age 20-44 years), as seen in Figures 4 and 5, this is not statistically significant (log-rank test yields a p-value of 0.48, the PPP test yields a p-value of 0.67).

Figure 5. Individual and average serum uricaemia trajectories and number of days since programme start, by age band



Reaching the target for the first-time using Kaplan-Meier estimate by ethnicity, Maaori or Pacific peoples versus non-Maaori non-Pacific (NMNP) is shown below in Figure 6.

Figure 6 Proportion of target never reached against time, comparison of Maaori or Pasifika ethnicity versus not Maaori or Pasifika



Maaori and Pasifika participants were less likely to reach target versus non-Maaori, non-Pasifika. The adjusted hazard ratio of reaching the target for the first time since entry in the programme between Maaori or Pasifika participants vs non-Maaori, non-Pasifika is estimated from a proportional hazards model at 0.52 (95%CI [0.26,1.05]), p=0.07.

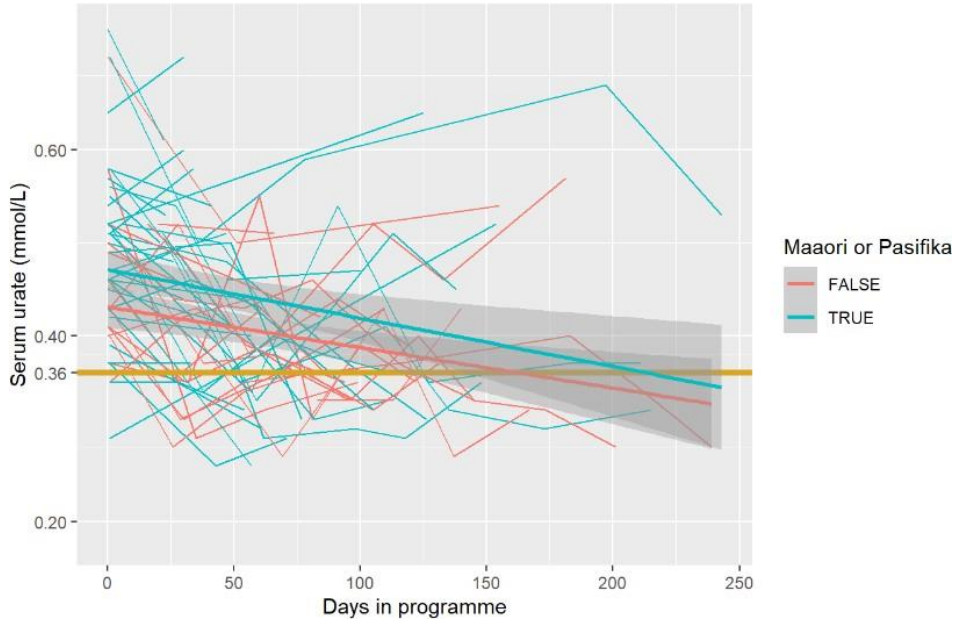
Classical test results

Testing for a difference between Maaori and Pasifika vs non-Maaori, non-Pasifika, the log-rank test yields a p-value of 0.066. Under the same setting, the PPP test yields a p-value of 0.073.

Comparing SU Trajectories

The SU figures in Figure 7 show that Maaori or Pasifika start at a higher initial SU on average than those who are neither Maaori nor Pasifika and take a longer time to reach SU. While more of the latter group reached target, the slope for both groups is similar (see below for the estimated change in SU over 180 days). A longer follow-up time may show a higher proportion of Maaori or Pasifika participants reaching the target SU.

Figure 7. Individual and average serum uricaemia trajectories and number of days since programme start, by Maaori or Pasifika



Mixed effects model

The p-value for an interaction between Maaori or Pasifika ethnicity vs non-Maaori and non-Pasifika ethnicity and the number of days in the programme was 0.43. The model without interaction was therefore retained for estimation. This model implies that the rate of change in SU is the same between the two groups, but that there may be a difference between them that is constant over time.

The estimated change in SU over a period of 180 days while in the program, for both groups, is -0.101 (95%CI [-0.151,-0.052]), p=5.7e-05, in mmol/L.

The estimated difference in the starting SU for Maaori or Pasifika participants vs non-Maaori and non-Pasifika participants, is 0.036 (95%CI [-0.001,0.073]), p=0.056, in mmol/L. Essentially, Maaori or Pasifika participants start at a higher SU (0.036 mmol/L higher) but this is not statistically significant.

The intraclass correlation coefficient (proportion of the variability attributable to between-participant variation) is 0.76, meaning that about three-quarters of the total variability is attributable to variability between participants, compared to within-participant variability.

Analysis of Pharmacy Results Data

Enrolment data were analysed from the start of the programme, 1 May 2022, to 2 July 2023. This dataset comprised all participants who were enrolled in the programme and had one or more visits to the pharmacy during the stated period. This includes people enrolled in the programme from the pharmacy excluded from the statistical analysis above, as this section did not include outcomes. There were 232 participants.

Enrolments over time

Thirteen pharmacies joined the programme. One pharmacy with no recruitments was replaced late 2022 with a pharmacy with a high Pacific population. Two pharmacies had no patient visits. The other 11 pharmacies enrolled and consulted with 232 people with gout (range per pharmacy 1-73, mean = 21.1). Overall 188 of 232 (81.0%) enrolments identified as Maaori or Pacific peoples (Table 2).

Table 2 Ethnicity of those attending the pharmacy for one or more visits 1 May 2022 to 1 July 2023.

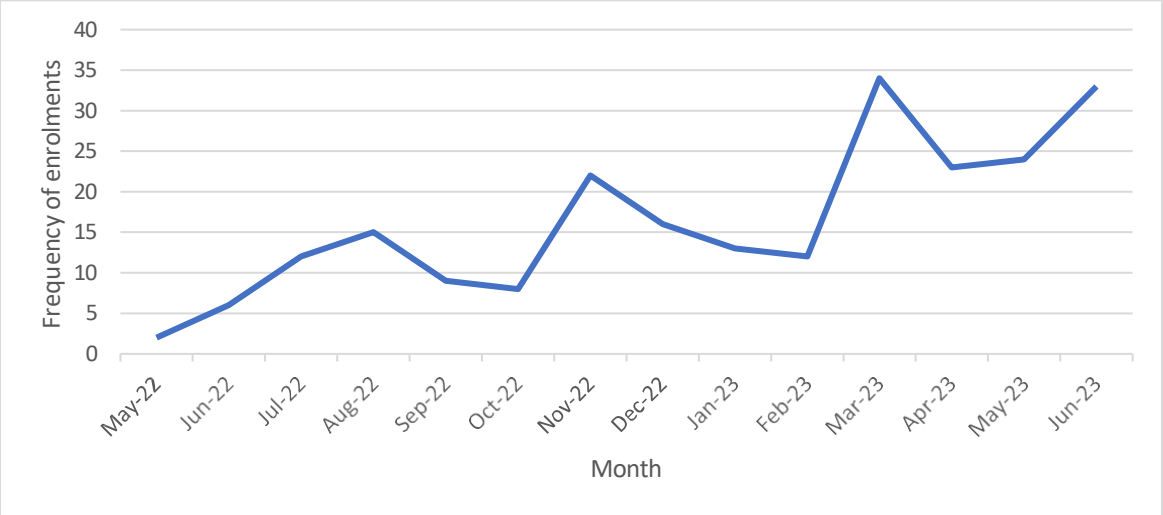
Ethnicity provided by the participant	N	%*
Maaori	51	22.0
Samoan	70	30.2
Tongan	45	19.4
Cook Island Maori	18	7.8
Niuean	9	3.9
NZ European	24	10.3
Other	17	7.3
Indian	3	1.3
Not disclosed	1	0.4

*Where Maaori and a Pacific ethnicity or two Pacific ethnicities occurred together, both were counted. The percentage is based on 232 participants and the percentage will therefore not add to 100%.

Twenty-two people discontinued attending the programme for more than three months then re-entered it. They were Maaori (n=9) Pacific peoples (n=10), combined 86.4% Maaori or Pacific peoples, and New Zealand European or other (n=3; 13.6%).

Enrolments increased over time after a slow start (Figure 8). The peak in November 2022 followed additional activity from the research team with pharmacy to encourage enrolments. In March and April 2023 the project lead visited medical centres involved in the gout service that were located the highest priority areas – Mangere, Otara and Clendon – to promote the service. This increased gout enrolments at most associated pharmacies and this increase appeared to be sustained.

Figure 8. New enrolments by month



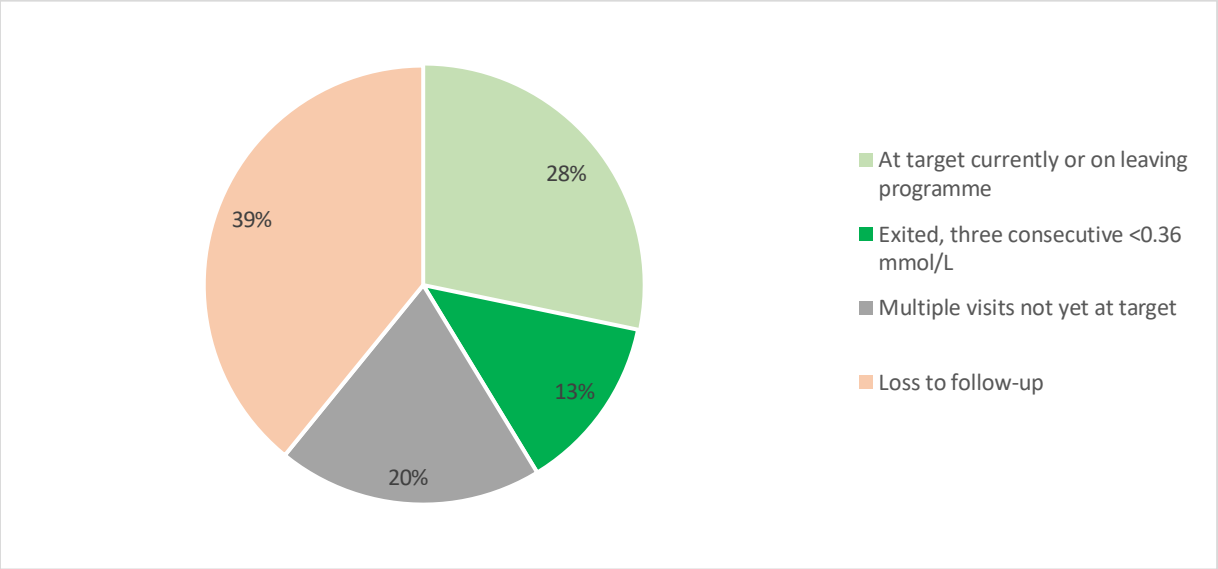
Analysis on patients enrolled in 2022

Further analysis was undertaken with data for people who enrolled from 1 May 2022 (programme start) to 31 December 2022 to allow sufficient follow-up data for visits. This information excluded one pharmacy that had delays in entering information into software delaying or missing text messaging (as per the earlier statistical analysis) and one patient where the pharmacy considered the person ineligible and discontinued their enrolment.

Forty-six enrollees fitted these criteria, comprising 23 people of Pacific Island heritage and 8 people of Maaori heritage (68.9% Pacific peoples or Maaori of 45 disclosing their ethnicity). The 46 enrolees had an average of 4.2 visits (range of 1-10 visits) from their enrolment until they left the programme or

until 1 July 2023. Nine of these 46 enrollees (19.6%), seven of whom were Maaori or Pacific peoples, had left the programme for at least three months and then returned into it.

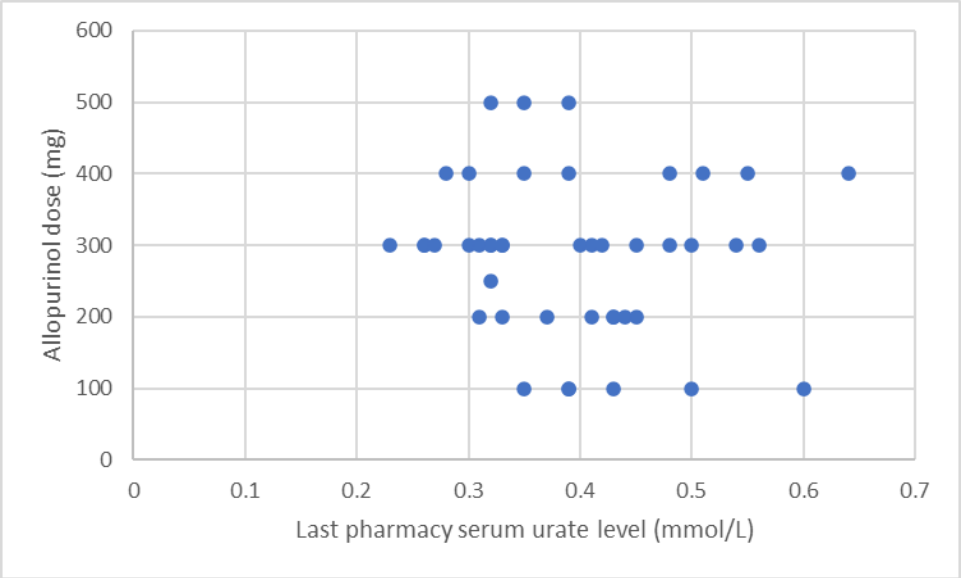
Figure 9. Breakdown of outcomes for the 46 people enrolled before 31 December 2022



SU = SU

Nine people (19.6%) left the programme after one visit among those enrolled before 31 December 2022, 80.4% attended at least two visits. Nineteen people (41.3%) had reached target on their last visit or exited after three consecutive visits at or below target (Figure 10), had an average of 5.6 visits and median of 6 visits at the pharmacy (range: 1-10). The 46 patients had a last recorded allopurinol dose in the programme of 100-600 mg, average 281 mg (Figure 10), with similar average doses across the different ethnicities (Table 3).

Figure 10. Last SU level and last allopurinol dose for the 46 people enrolling in 2022



To ascertain longer-term adherence, the pharmacy reviewed consistency of dispensing for these 46 patients since enrolment. These data were collected in late July or early August 2023. One patient was overseas so their adherence was unknown. Allopurinol dispensing data suggested that 59% of patients

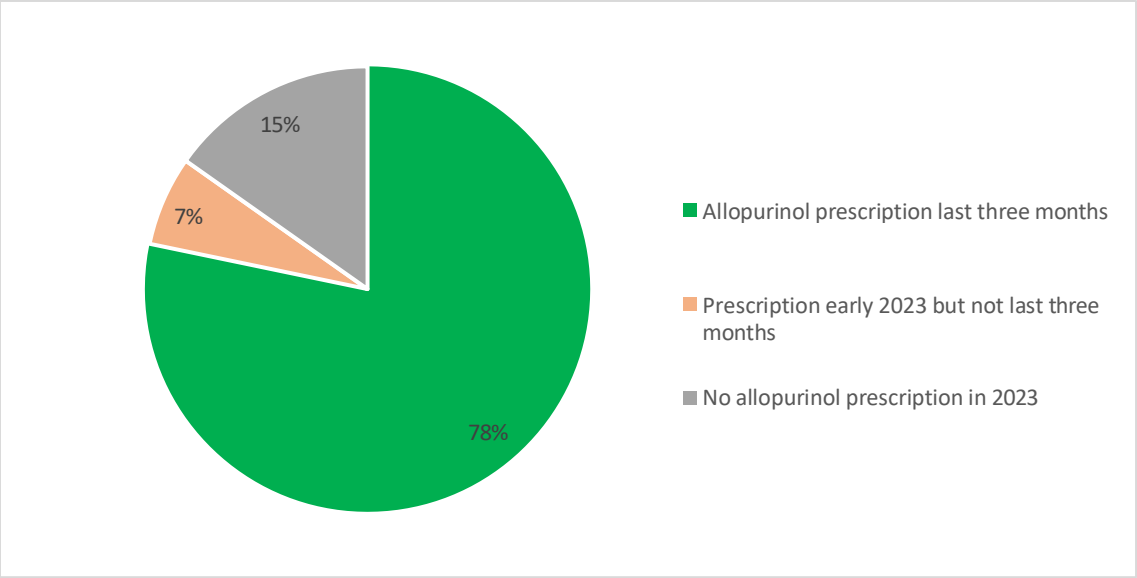
enrolled in Gout Busters were still taking allopurinol without a break, 22% had stopped and 17% were now taking it but probably had temporarily discontinued since being on the Gout Buster programme.

Most who continued allopurinol uninterrupted had reached target at their last pharmacy SU test (n=15) while 11 had not reached target but were still taking allopurinol.

Using Eclair in August 2023, the following was found:

- In total, 36 (78.3%) had a prescription for allopurinol in the last three months, one of which was a restart (Figure 11).
- Two males of Pacific Island heritage in the programme had been admitted to hospital for acute gout – one had only attended the Gout Busters programme twice in 2022 and appeared to have stopped allopurinol and was admitted to hospital in 2023. Another was admitted to hospital and immediately after started the gout programme, with five visits to the pharmacy between November 2022 and June 2023, remaining on 100 mg allopurinol per day during this time.
- Of the 19 who had a laboratory blood test in 2023 for SU, nine were less than 0.36 mmol/L and 15 less than 0.42 mmol/L which tends to corroborate the POC results. Those with SU of 0.42 mmol/L or more numbered 4.

Figure 11. Allopurinol continuation status in 2023 for those enrolled in 2022



These preliminary results show some differences between ethnicities on average number of visits, proportion reaching target SU, and proportion taking allopurinol continuously since starting Gout Busters, but their last dose of allopurinol was similar. The numbers in these groups are small so the findings will not be generalisable (Table 3).

Table 3 Data for those who enrolled in 2022 by ethnicity

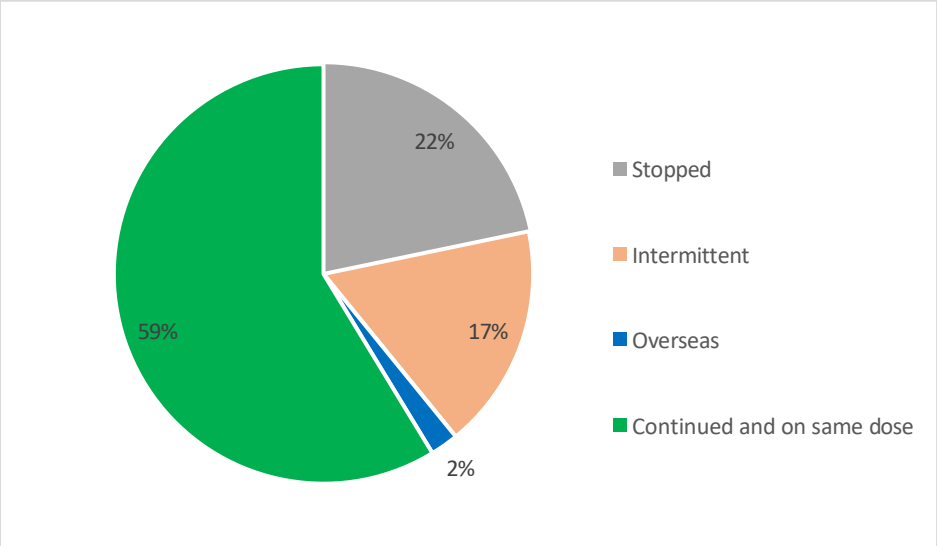
	Enrolled 2022	Average number of visits	Proportion leaving after 1 visit	Proportion at target SU at last pharmacy visit	Proportion taking allopurinol continuously since starting Gout Busters	Average last allopurinol dose at the pharmacy visit (up to 3 July 2023)
Pacific peoples	23	3.2	26.1%	34.8%	45.4%*	272 mg
Maaori	8	4.6	12.5%	62.5%	62.5%	275 mg
Non-Pacific peoples, non-Maaori**	14	5.5	14.3%	35.7%	71.4%	293 mg
Total**	45	4.2	20.0%	41.3%	55.5%	281 mg

*excludes one person who is overseas for an extended period

**excludes one person who did not disclose their ethnicity

NB: continuation of allopurinol is based on data from 2022 and 2023

Figure 12. Patient continuation on allopurinol for all 46 enrollees in 2022



Late attendance at the pharmacy for visits

Fewer people attended monthly for fingerprick tests than attended a week or more late for one or more of their visits to the pharmacy. For example, of 22 people enrolled in April 2023, three people (13.6%) attended both subsequent pharmacy visits on time, 10 attended one or more visits late (45.5%), and nine people (40.9%) had not yet attended a further visit (as at 1 July 2023). Note this is a brief snapshot, not an overall analysis.

There were also indications from the data and in discussion with doctors and pharmacists of patients being prescribed initial doses higher than that recommended in the HealthPathways guidelines, e.g. 200mg or 300 mg.

Variation between pharmacies

Pharmacies varied considerably in numbers of enrolments and their success with the programme, including some having low loss to follow-up and relatively high achievement of people reaching the target SU. Across the whole dataset, several pharmacies had reasonably high rates of achievement of exit or target SU at the last visit, with one exemplar highlighted in Panel 1.

Panel 1 Pharmacy Exemplar

Case Study Pharmacy X

The strongest performance came from a pharmacy with 18 enrolments, 78% of which were Pacific peoples or Maaori.

In this pharmacy 61% achieved target on their last test or exit following three consecutive target tests. Only 17% had been lost to follow-up. This may reflect the population being managed, but it is also likely to reflect the way they have the koorero with patients. Service users who were interviewed (discussed below) and had attended this pharmacy showed how comfortable people felt going for their gout visits, feeling very welcome, having little waiting time, liking the privacy and one noting he "*enjoyed*" these visits.

This pharmacy had previously been involved in the Own My Gout programme and was very experienced with providing add-on services.

Qualitative Interviews with Service Users

Sixteen service users from six Gout Buster Programme pharmacies were interviewed. Twelve were recruited through the pharmacy. Four who were selected for their sporadic or low attendance were cold called by the PI rather than contacted through the pharmacy. Thirteen were male and three were female. The average age was 46.6 years (range 23-65 years; five were under 35 years; one was not asked their age). Seven identified as Maaori, six as Samoan (one of whom was Samoan/Chinese), and three as Tongan. Two interviews were carried out by a male Maaori interviewer (named Interview 15 and 16), six by a female Tongan interviewer (named Interview 9-14) and eight interviews by a female New Zealand European interviewer (named Interview 1 to 8), the Principal Investigator when other interviewers were not available. Interviews took place May to July 2023 by zoom or phone call. Interviews took 12- 30 minutes, an average of 22.5 minutes.

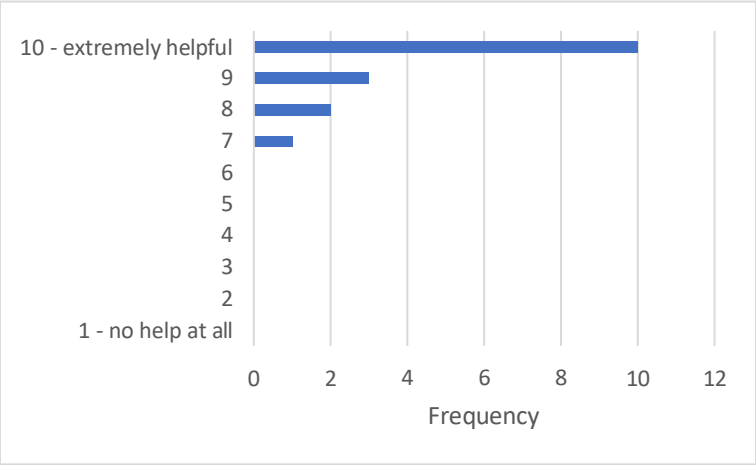
Respondents varied in the duration of their gout. The range was from 2-3 months to over 30 years, with only two people having had gout for under 12 months and three having had gout for at least 20 years; missing data for one participant. Fifteen participants were still taking allopurinol and most were taking this every day, with two reporting taking it most days and two reported having temporarily stopped their tablets recently for one to two weeks; two participants were not asked this question. Some had taken allopurinol previously before stopping it and only recently restarting it and going on the Gout Buster programme.

All respondents were linked with the Gout Buster data showing participants encompassed a range of programme attendance and outcomes. Some had successfully completed the programme and been exited, some had reached target at least once, and some had not yet reached target. Some were overdue for their test or had attended sporadically. For example, one had started the programme, attended once then stopped before restarting five months later. Three people had attended only one test at the pharmacy then not attended since, one of these had stopped taking allopurinol.

Overall, most respondents were happy with the programme as it was free, convenient and provided a rich source of gout information available to them in different modes. They were able to build positive trusting relationships so they could understand the importance of allopurinol usage, have faith in allopurinol titration and be more likely to take allopurinol. Taking the treatment may symbolise the person's way of appreciation for the service provided, as an act of reciprocity.

Most participants were overwhelmingly positive about the programme rating it 7-10 out of 10 (average 9.4; Figure 13).

Figure 13. How helpful for you was the gout service through the pharmacy? Can you rate for us how helpful it was on a scale of 1 to 10 where 1 is no help at all and 10 is extremely helpful?



Overall participants liked the Gout Buster programme, with only a couple of participants critical of aspects of the programme or the pharmacy they attended.

The pharmacist's role

Participants liked their interaction with the pharmacist. An important thread was the feeling that the pharmacist really cared about how they did. Phrases like *"[make me] feel welcome"* or *"they really care"* emerged from interviews.

"They are very helpful yeah, … and they genuinely seem concerned… about my well-being." Interview 8 who had previously stopped allopurinol.

"I quite like the way they, you know, they look after me when I come in…. They don't discuss gout in front of [other customers]…. I enjoy it [the visit to the pharmacist]. And I think the motivation is there and also… Makes me really think serious about why I have to do it." Interview 12 Pacific Island heritage.

"Look for me it actually felt like they cared ay, they like they wanted to see me wanted to see my levels come down and it kind of motivated me even more to you know towards the goal." Interview 7 Maaori who completed the programme.

One participant indicated how the pharmacist had normalised gout helping to address stigma around gout:

"Well, she explained to me that it's normal, a lot of people suffer from it, but you don't have to suffer from it was her words exactly, and they were here to help… and it's nothing to be ashamed of, which, once I told my family that I had gout, they're like oh you're, you're alcoholic,… you're unhealthy, you know, you're not fit. [There are] a few people at work that suffer from gout as well so, other people make fun of them like they unhealthy or unfit and you can't, once you get gout that's it." Interview 7, Maaori.

Some appreciated being prioritised when coming into the pharmacy:

"…as soon as I walked into the chemist she'd see me straight away and she dropped what she was doing and we moved into the side room and did all the tests and everything we are doing the fingerprick

and the gout level the acid level…. she was really good, actually." Interview 3 Maaori who successfully completed the programme

In contrast, one participant reported that, despite calling ahead, she often needed to wait at the pharmacy, sometimes for half an hour. A further participant had one occasion when the pharmacy had run out of strips when he presented for his SU test.

Although one participant reported getting too much jargon from the pharmacist and needing more simplified information and another noted the pharmacist was sometimes too busy to talk much, others received information from the pharmacist in a way they could understand. Many also indicated getting confidence from the pharmacist that they could resolve their gout, understanding the need to get the uric acid levels down, one person with long-standing gout saying:

"They explain everything clearly… and showing me the graph and… it makes me [want] to go harder and get rid of this disease." Interview 5, Pacific Island heritage.

Nearly all said they felt they could ask the pharmacist questions, although one participant said he was never good at asking any health professional questions.

Fingerprick tests

Participants generally liked the fingerprick tests which were quick, gave instant results, aided their understanding of why they experienced gout and the reason for the allopurinol, and for some were particularly motivating as they wanted to see their SU improve, or the tests held them *"accountable".*

"… they prick my finger and do it there and then and then give me my results. First of all, nothing was happening and I thought 'am I wasting my time?' And then as we got further down the line, I could see my results coming down… I was happy, they were happy…. They give you a high five when your levels come down and say well done and it's pretty uplifting, you know.." Interview 7, Maaori, who successfully completed the programme.

"It was good because you actually know that, you know there's a change of uric acid… So they tell you how much uric acid that you get 'cos … when I first started it was pretty high. So I've come right down to 33." Interview 12, Pacific Island heritage.

One participant was frustrated with long waits sometimes despite booking appointments first, but this was exceptional with others appreciating that the test was quick, and/or wait time minimal:

"I can get in easy, do what I have to do, and then I'm done, yeah in and out" Interview 15, Maaori.

Text reminders for fingerprick testing and text motivational messages

Participants liked the text reminders to attend for another visit or remind them to take their tablets every day – most saw these texts as being from their pharmacy. Some noted they would otherwise forget to return to the pharmacy, typically because life was *"busy"* or *"pretty hectic".*

"… the pharmacy kept giving me the reminders on my phone… when all the appointments were, [which helped with my] shocking memory". Interview 3, Maaori.

Some noted the encouragement to keep taking the tablets from the messages:

"I still receive texts. Yeah, just encourage to carry on. Do what I do at the moment with gout. Even if I just finished the test or the very next or the very next two days, I received a text just saying don't forget your medications." Interview 12 of Pacific Island heritage.

A woman in her 60s of Pacific Island heritage, considered adherence to be up to the person and did not need to be reminded to take her tablets as it was *"my responsibility".*

One male in his 20s of Pacific Island heritage said he is never on his phone so gets his texts late.

Gout booklet

Most received the Gout booklet and the views on this were mixed, with a minority liking it. One recorded their results in it and took it to the pharmacy visits. Only one person wanted the book to be more informative. Many indicated that written information was not their preference, two of whom suggested you tube videos instead.

"I think face-to-face is the best way. We are practical people we learn things better this way." Interview 16 Maaori.

Some received information from other sources, two had googled gout, one had attended a gout seminar and one had received all the information he needed from a rheumatology nurse when hospitalised for another reason, and had nothing new to learn from the pharmacist.

Many participants appreciated their learnings about diet and mentioned foods they were avoiding, some had a lot of focus on food, one mentioning seafood was causing his workmates to get gout, and some wanted more information about food:

"…if you know that it's high, then you're going that's enough to make you, like, change your eating behaviours … so then you'll be trying to like stick with foods that don't trigger gout. And probably do that for a while until … your uric acid levels come down." Interview 10, Pacific heritage.

Some highlighted the privacy in the pharmacy where the pharmacist avoided discussing gout in front of other patients and a private room was used. Conversely, two participants did not like that their fingerprick test was done in front of other people.

"… I wish we could go into a client space I suppose where I'm not exposed…. for me it's my personal journey and I don't want to share it with anybody else." Interview 3, Maaori.

Adherence

Many participants found it challenging to remember to take their allopurinol. This was helped by understanding the need to take it every day, getting into a routine, using a phone alarm, various motivations and having compliance packaging. One found a calendar from the pharmacy helpful.

Several participants spoke about getting into the routine of taking allopurinol.

"…the next hardest bit was remembering to take the tablet, because I had to take it one every day and then, but once I got into a routine, yeah [helped by setting an alarm on his phone], it just kind of flowed from there…. it's just natural now just every time before I have before I have lunch I'll take my tablets" Interview 7, Maaori.

One young participant noted the challenges of taking allopurinol with food:

"I find that tricky because sometimes, like when I'll eat, you know, I forget about my pills and then I'll be like 'oh now I can't take it becaus6e … my stomach's already empty again'." Interview 6, Pacific Island heritage.

Some participants found seeing the reduction of SU readings motivated continuation:

"I've seen the reductions of the uric acid so that… motivate[s] me to carry on and remember to take them." Interview 12, Pacific Island heritage.

The idea of avoiding pain was motivating, particularly for those who had a gout flare after stopping temporarily or missing some tablets. Some participants had lacked understanding that they needed to take it long-term, but had now *"learnt my lesson"* (see below for stopping the programme early or sporadic attendance).

"I [learnt] the hard way because I didn't stick to the schedule, but now I stick to the schedule it's been all good." Interview 16, Maaori.

A few participants ran out of allopurinol so stopped it for a time. One stopped taking allopurinol previously when he went overseas. Another had moved out of the area and had been unable to return to the pharmacy for more medicines, and one noted needing a new allopurinol prescription, told by the pharmacy that his prescription had finished and he needed to see the doctor, but could not get in immediately:

"I think it was about a week and a half during that time where I wasn't receiving medication." Interview 4, Maaori. [This pharmacist may have been unaware of their ability to do continuation supply]

A participant of Pacific Island heritage spoke about stopping allopurinol as an *"experiment",* then seeing the increase in SU in the pharmacy, which confirmed she needed allopurinol. She found this a good learning for her, but did not tell the pharmacist.

"I did the little experimenting myself, I didn't want to be on the tablets for life." Interview 14, Pacific Island heritage.

Access to other medical professionals or services

A common theme was difficulty accessing doctors, for example waiting one to three weeks for an appointment, the wait time to see the doctor, the cost of the doctor, and the need to take a day off to see the doctor. This had contributed to some people stopping allopurinol prior to starting the Gout Busters programme or during the programme. Many participants spoke of being busy, including working long hours and challenges getting to the doctor or, in one case, for a consultation with the rheumatology nurse.

"When I was early 30s, I [had allopurinol], but I stopped it. I didn't say stop it because I don't like it, but I stop it as I was a bit busy to go and see the doctor. It's been hard now 'cos if to be honest, if I go to the doctor, if I take a day off to go and see the doctor, I spend 4 hours sitting there. It's really annoying that's why I said it's really helpful for me to get straight to the pharmacy yeah." Interview 5, Pacific Island heritage.

The saving of time and/or cost of a GP visit when attending the pharmacy was appreciated by many, two of whom said it being free was the best part of the Gout Busters programme:

"It's a good service. Instead of you going running to the doctor and it cost you money. I'd rather go to the chemist. I was really thankful that I could go to the chemist." Interview 13, Pacific Island heritage.

Two participants were asked if they could arrange a prescription from the doctor without a consultation, and both said they had to see the doctor in person each time. This suggests that either a repeat prescription for a long-term medication was not possible without a visit, or that it was available but the participants did not know about this facility.

One participant appreciated being able to get his allopurinol from the pharmacy without needing to arrange another prescription, with the pharmacy proactive in arranging this:

"I don't need to go to the doctor for a prescription. So that's another good thing about it. I want my top up." Interview 14, Pacific Island heritage.

Only some participants were asked about whether they had been prescribed allopurinol before. One Maaori male in his 40s with gout for over 20 years had only recently started allopurinol. His previous doctor had treated him only with diclofenac for the pain, despite attending three to four times in a year, and taking two days a fortnight off with gout. It was only when he changed doctors that allopurinol was suggested and he was put on the Gout Busters programme. A few other participants with long-standing gout indicated previous allopurinol use, sometimes some years before.

Although not all participants were asked about other medicines, some mentioned being on e.g. colchichine with the allopurinol for gout flare prophylaxis on initiation but at least a couple were not on flare prophylaxis on initiation or for titration.

One participant found getting a laboratory test (for renal function) challenging with long work hours and lack of transport. This meant her allopurinol dose could not be titrated.

A further participant noted getting a SU on the spot from the pharmacy was easier than getting the form from the doctor, going for the blood test, then waiting for the result.

Involvement of whaanau/families

One young male of Pacific Island heritage attended the first pharmacy visit with his mother, but otherwise no one had whaanau attend with them. One woman in her 60s, Pacific Island heritage was offended at the idea that she might need whaanau present saying she was *"not that old"*. Others just couldn't see the need.

"[My daughter is interested, but] I'm used to doing it all by myself you know; you know what we are like." Interview 15, Maaori.

While not wanting them there for the pharmacy visit, some still involved their whaanau/families in the conversation about gout:

"Well, I don't really need the support…. every time in my appointment to the Unichem came. I, you know, I told my daughters and my wife that… today I'm gonna do my… programme." Interview 12, Pacific Island heritage

One participant had family members with gout to whom he had recommended the programme.

Some also talked about the influence of whanaau/family, for example two men whose fathers had suffered badly from gout knew how bad it could get and wanted to control theirs. Another participant had used Rongoa (Maaori traditional medicine) from his mother before but could no longer since she had passed away. Some others spoke about the effect on their family when they had gout, and/or the motivation of wanting to be well for their family, for example a Maaori woman whose gout stopped her running around with her grandchildren:

"I'm not good with needles and even if it's just a little prick it's like ohh, but I'm okay with it now I mean, it's something that I need to do for me. Do for my family, do for my grandchildren so I have to get it done..." Interview 2, Maaori.

The outcomes

"I'll get [gout] constantly before the service. But then once I started the service I hardly get the gout now. It was a good service. It really worked." – Interview 9, Pacific Island heritage who stopped attending before reaching target

"…it's so life changing aye. Yeah and my kids… they see a big difference as well, actually going out with the children now whereas when I used to have attacks stuck at home with the ice pack or whatever but

now it's that's changed a lot, 100%." His work also changed: *"[I] can walk anywhere everyone else is now, whereas before I just stand and watch. Just tell them I, I can't walk over there my knee's playing up or my foot's sore."* Interview 7 Maaori with long-standing gout not treated with allopurinol before.

The following case study provides a view of a positive outcome in a young male with gout and how the pharmacist worked with him.

Case study

This person is a male in his early 20s, Pacific Island heritage, who has had gout for years. Weekly gout attacks made employment impossible, but after entering the Gout Buster programme his gout attacks stopped, he reached the target level, and was able to work again.

This person highlighted several components helping his success: the pharmacist's information and manner; fingerprick tests; the texts; and the blister packs.

"They just really looked after me there. Properly…. it was good knowing what my uric acid level was at the start and then every month it will gradually go down so it was good to see past results…. What I learned was it was my uric acid level that was too high. And … the importance of what the foods do to my body. And ... I'm happy to see the results now…. It was easy to understand." "It's something that I look forward to every month to see what my uric acid level is."

"They made me feel like it was just temporary, and they're gonna help me get through it…. if I hadn't changed to [pharmacy name]… I could still have gout now…. they really care about their patients…"

For adherence he noted the text messages *"really encouraged me to keep taking my meds. For some nights, some days I'll forget to take the pills at night and then they remind me to take it."*

The blister packaging for medicines also helped adherence:

"I think having … my meds… prepacked. Just knowing that I have to take it daily it helped me big time, 'cos usually I would have to do it one by one in each bottle and sometimes I wouldn't even take my pills it was too much work."

Stopping the programme early or sporadic attendance

The quantitative results showed many people attended the programme sporadically or stopped early. We selected people to interview who fitted these criteria. One young man was not taking allopurinol at the time of the interview and had missed his monthly fingerprick tests. Others were taking allopurinol when interviewed, but some had stopped allopurinol previously as well as not attending the programme. Amongst those who had attended well we also sometimes learnt why they had previously stopped taking allopurinol.

Two participants stopped their tablets when moving away from the area or having gone overseas. One male in his 20s, Pacific Island heritage, with a two- or three-year history of gout but first-time taking allopurinol had stopped attending the pharmacy because he had moved to the North Shore, then stopped taking allopurinol because he kept forgetting to take them and was running out of tablets, having not recently attended the pharmacy. He said it would be helpful if the pharmacy could send him more allopurinol tablets, if he could have blister packaging (so he could break off a single tablet blister to take to work) and he could get the fingerprick test when he was in the area rather than in a monthly schedule.

Others talked about forgetting to take their tablets, and subsequently having a gout attack, which was a good lesson to restart.

One Maaori woman attended the Gout Busters programme in the pharmacy once in late 2022 when her gout started, then ran out of allopurinol *"I didn't realise… that you have to take this every day"*. She noted on her first pharmacy visit: *"that could have been said a little bit differently for me rather than for me thinking that, okay, this is going to be a one-off, I'll just take my medication like Panadol, you only need it when you have pain, but I think if it had been said a little bit… seriously … 'please take this 'cos if you don't it's gonna play up every day', it would have been, yeah, a lot better for me."* However, she restarted the programme after the gout returned, and was now attending regularly after better understanding of the role of SU elevation and need for allopurinol dose adjustment, motivated to avoid pain and be active with her mokopuna.

Sporadic attendance does not necessarily mean stopping the allopurinol. Two males in their 30s, Pacific Island heritage, who had attended the pharmacy for two or three times then stopped attending were both still taking allopurinol. One of these participants with a three year history of gout that saw him bedridden at times, was taking 100 mg allopurinol daily "most days", and he had not had a repeat attack since starting allopurinol suggesting he would likely be at risk of a further attack. When asked about not attending the pharmacy he answered:

"…busy but at the same time, I think if, if you're not having any attacks, then you get into the zone be like probably don't need to go anymore kind of thing that's I think with the [text] reminders that kind of helps to be like, oh, might as well just get it, get it done, go and when you can, there's reminders." Interview 1, Pacific Island heritage.

The other young male, Pacific Island heritage with a nine-year history of gout had one test at target then stopped attending the pharmacy. His gout had improved after heeding the pharmacist's advice to take the tablets consistently and getting into the routine of taking it daily. He could be considered a successful outcome despite not achieving three consecutive readings under 0.36 mmol/L as planned.

Improvements

When asked about possible improvements to the programme, most participants had none, being very appreciative of aspects of it as they stood. However, several improvements came through: you tube video information rather than the booklet (two suggestions); a person talking about gout at work places or sports clubs (one each); and using text messages to suggest use of a phone alarm for compliance if needed. The two participants concerned about lack of privacy with testing wanted privacy, and one who waited at the pharmacy for their fingerprick test did not want to wait.

Themes in the interviews

Key themes coming through the interviews were the participants being busy; the convenience of the pharmacy Gout Busters programme; liking understanding more about gout and their SU levels and target value; gaining confidence they could manage their gout; and the caring or friendliness of the pharmacy. These have largely been discussed above.

Being busy was such a strong theme and encompassed many aspects of the interviews that this is discussed further here. It typically arose from long work hours, although many also spoke of family. The convenience of Gout Busters in pharmacy helped them manage gout because it was quick, required no appointment and usually no waiting time. Text messages helped remind them to get to the pharmacy when they were busy. However, being busy made it difficult to get to the doctor, requiring a day off work, taking at least a week for an appointment to become available, or having to wait at the doctors to be seen, causing some people to stop allopurinol on running out before the programme or during the programme. It also stopped one person from getting their laboratory blood test which was required before the allopurinol dose could be titrated. Having the pharmacy help them manage their medicines with their busy lives was appreciated – with blister packs, provision of more

allopurinol or text reminders to get their repeat. Quotes about being busy are throughout the above analysis so not repeated here.

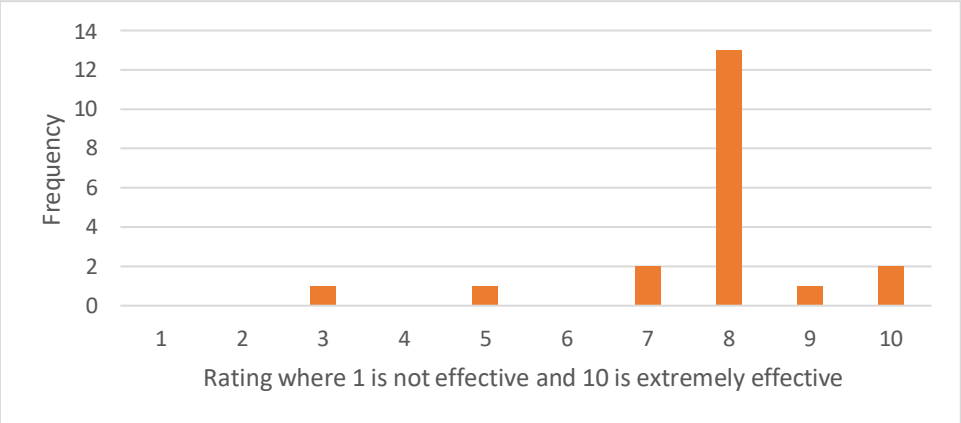
Survey of Pharmacists

Pharmacists involved in the gout programme from the 11 pharmacies which had had at least one patient enrolled were surveyed. Twenty pharmacists responded, representing an 80% response rate with 25 pharmacists trained across the 11 pharmacies surveyed.

Of these 20 respondents, 14 identified as female, six identified as male. They had practised 13.2 years on average (range: 3-38 years). Five identified as New Zealand European, four as Indian, two as Chinese, one Pacific Island heritage and 11 as other nationalities. None identified as Maaori. The respondents had personally worked with an estimated 0-43 patients on gout, with an average of 13.3 patients each. Six pharmacists had worked with fewer than seven patients. One did not state the number of patients.

When asked to rate the gout programme on getting good outcomes for patients on a scale of 1 to 10 where 1 is not effective and 10 is extremely effective, 80% rated it 8/10, the average rating was 7.75, and range 3-10 (Figure 14). There did not appear to be any link with the rating provided and number of patients they had.

Figure 14. Pharmacist rating of how effective the gout programme was on getting good outcomes



When asked why they answered this way, all responses except one had a positive tone. However, some noted loss to follow up caused them to mark it lower, and some wanted to better understand how to avoid loss to follow up. One noted time challenges if working sole charge, particularly with initiation.

"There is a lot for newly diagnosed to get their heads around. They'll often take the meds until gout-free and then stop for a couple of weeks, especially if they need to organise a new script. It is a work in progress ALWAYS with many sufferers." [rated: 7]

"The patients who have bought into the programme really like how accessible we are. We have lost some to follow-up and wonder why this is? It has got better as I have got more confident with the treatment and the computer software. It is often done on the fly. Particularly the initial contact as often the patient has been waiting at the doctors for a long time and so really don't won't to hang around for any longer." [rated: 8]

"It depends on individual patients as each patient place[s] different importance on their health. Some will take their allopurinol regularly and some will not. In terms of getting good outcomes, our pharmacy has not been able to recall patients so we won't be able to say." [rated 5]

"Easy, immediate results and advice on doses for patients so they can quickly improve control of their gout." [rated 9]

The respondent who rated the programme 3/10 for good outcomes for patients stated:

"It is not an easy task to get the patient to come in for the test as they often change their mind."

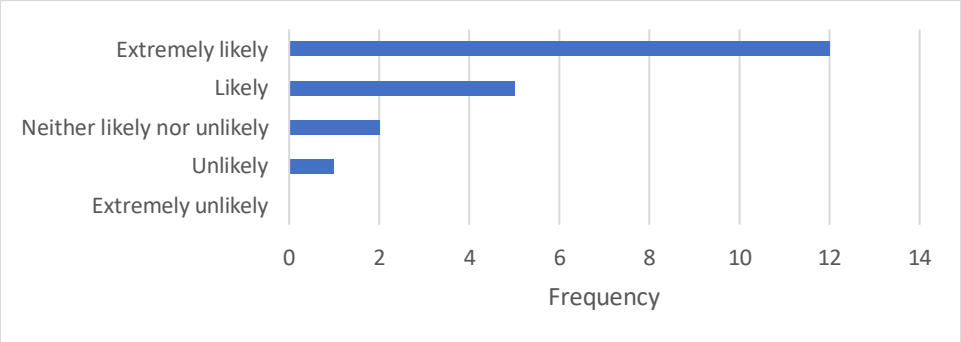
When asked: *"What was the best part of the gout programme from your perspective"*, the most common themes were: working closely with the patient/building rapport (n=7), titrating the dose/managing the patient without needing a GP appointment (n=6), getting control for patients (n=5), testing on the spot (n=4). One respondent noted minimising stigma and dispelling common misconceptions about gout. Often multiple factors were noted:

"Seeing the patients achieve target, being gout free, being engaged in their health and developing rapport with them. Also educating prescribers about gout management."

"The ability to test on the spot.....talk about the result and our desire to reach a specific number of below 0.36. Powerfully demonstrative to the patient I think."

Most (85%) were likely or extremely likely to recommend the Pharmacy Gout Busters Programme to other pharmacies (Figure 15).

Figure 15. How likely would you be to recommend the Pharmacy Gout Programme to other pharmacists?



Two of the three with the lowest recommendation scores provided reasons for their score: that it depended on the pharmacy's population; and that it was time-consuming and not cost-effective. The second pharmacist had rated the programme outcomes as an 8.

Two themes emerged strongly from the reasons for their score on recommending the programme: patient benefit (n=9) and time involved, including claiming and administration (n=5), although two others suggested it was easy to administer or set up. Three participants said it used pharmacists' skills and three had funding concerns.

"The programme uses pharmacists' skills. It allows us to help our GPs who are hard to get in to. I think it has also made the GPs think more about the need for anti-inflammatory cover during a flare and while initiating allopurinol. It is definitely beneficial for the patient and they like the ease of access."

"It can be a lot of work trying to follow up patients. Often testing is opportunistic so you need staff levels to allow this. Claiming is laborious. Funding is such that to make it worthwhile financially you need to be doing a large cohort of patients for what you invest in time and energy in the service. If doctors aren't on board or incidence of gout in your community is low, it won't stack up financially."

"Fantastic service for patients and so easy to use for pharmacists, can deliver really great results."

Rating of individual components of the programme

Pharmacists were asked to rate different components of the programme from 1 (not at all useful) to 5 (extremely useful). These are presented in the diagrams below (Figure 16-18). Training, texts to patients, fingerprick tests, monthly patient visits, titrating allopurinol, continuation supply of allopurinol under standing order, and reimbursement of patient copayments were rated highly. Software, administration work and adherence packaging provision scored lowest.

Figure 16. Pharmacists' ratings of training, software, texts to patients and administration work

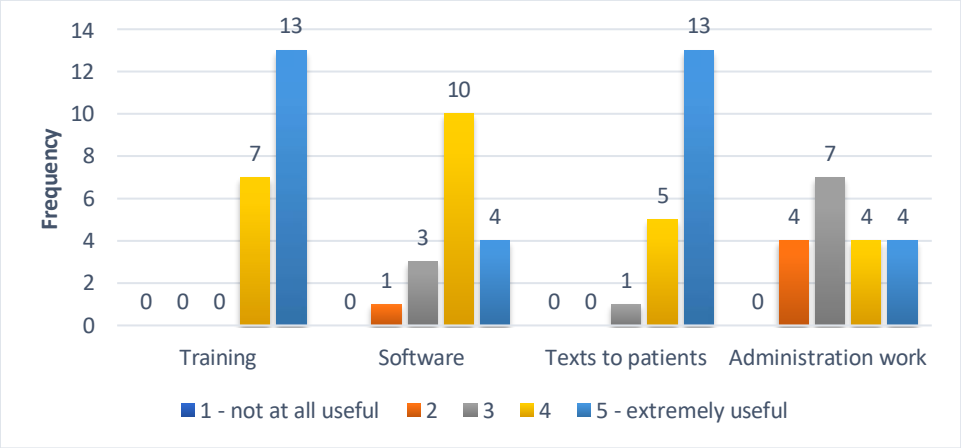


Figure 17. Pharmacists' ratings of working with general practice, fingerprick SU tests, booklet for patient and monthly patient visits

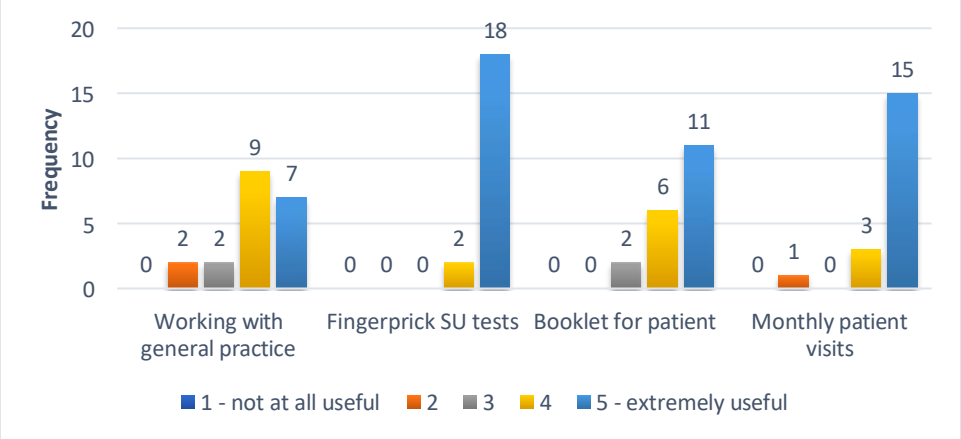
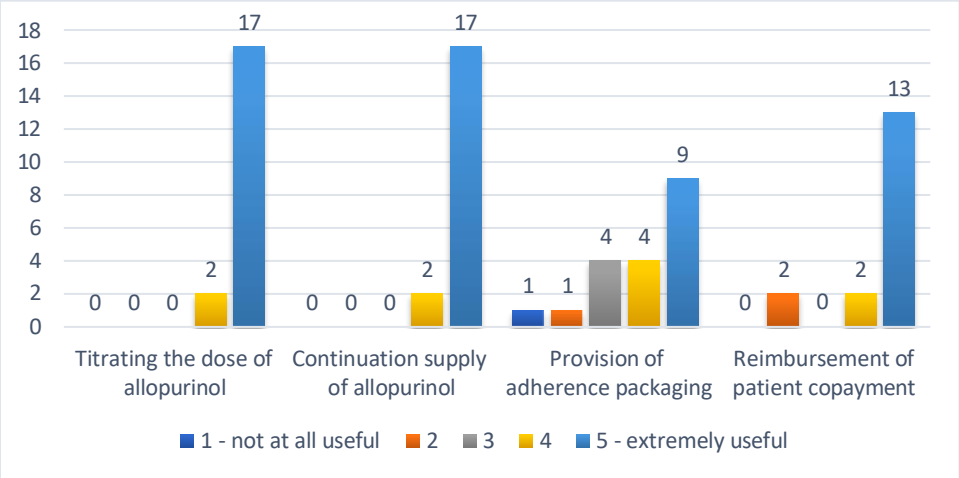


Figure 18. Pharmacists' ratings of titrating allopurinol, continuation supply of allopurinol, provision of adherence packaging and reimbursement of patient copayment



When asked about the most important elements for the success of the service, the most common elements stated were the SU tests (n=6), titration (n=5), working with the doctors/referral from the doctors (n=4) and monthly visits (n=4).

"Fingerprick SU tests as participants were interested in knowing dose and this also allows us to explain their gout therapy better. Also the gout booklet was useful."

Figures 19 and 20 rate the software. It rated highly on text messages to patients and graph for the patient SU. It had room for improvement on the other areas queried. A high non-response for the software communication with general practice likely reflects not knowing what GPs get, and the high non-response regarding invoicing probably reflects that many pharmacists will not manage invoicing.

Figure 19. Pharmacists' ratings of aspects of the software (1)

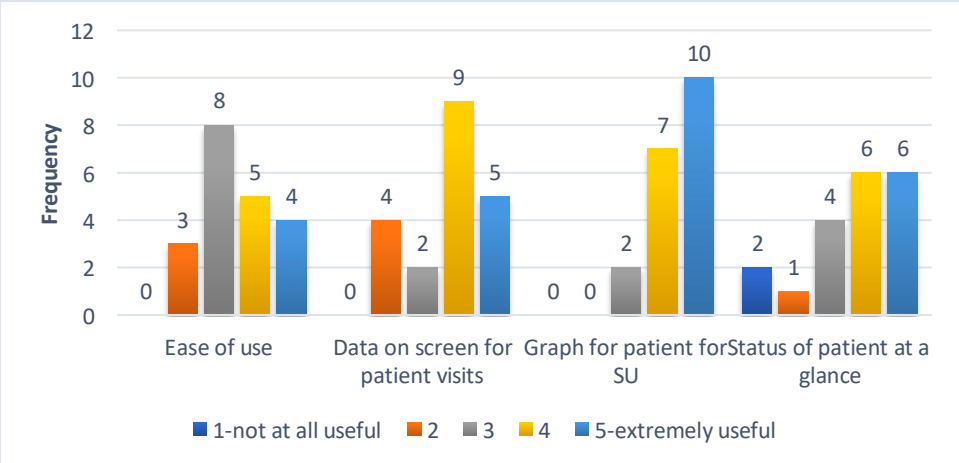
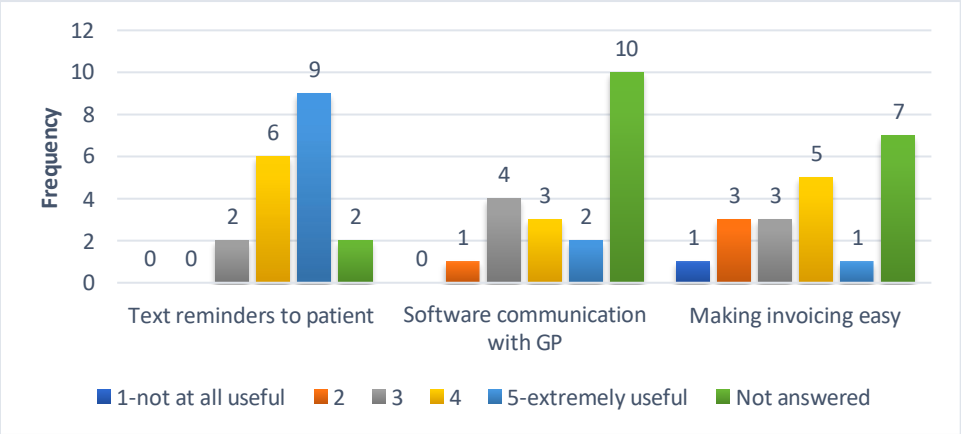


Figure 20. Pharmacists' ratings of aspects of the software (2)



The graph was the most liked part of the software (n=8). Others liked: ease of use (n=5), text reminders (n=3), and seeing the patient data on screen and patient status (n=3).

Seven pharmacists provided recommended improvements to the software. These varied and were quite specific, so will be given to the software providers rather than reported here. Examples included what is displayed on the screen.

The most common barriers to enrolling patients were: the need for a blood test for renal function (n=7); time in the pharmacy (n=3); time for the patient (n=2); patient attending a different GP with no standing order (n=2). Less common barriers (mentioned once each) included a patient not valuing the pharmacy service; the amount of information needing to enter into software; missing flare prophylaxis medication and the patient being gout-free.

Some suggested no improvements. Others suggested: better funding; faster software website; automatically populating Testsafe data into the software; the pharmacist ordering the renal function test, flare prophylaxis on standing order; and better doctor engagement. Most were raised by one person each.

Other comments yielded one negative comment about time and funding, other comments were positive:

"Time consuming, not enough funding provided for the time taken and admin work included."

"This is a really great program and will definitely achieve an improvement in health outcomes for those that continue with the service."

"It is a great programme. Stats may not show its true worth as with a lot of patients they may need to stop taking their meds a couple of times and suffer attacks for long-term commitment to long-term meds. We never see evidence of allopurinol being titrated up as result of uric acid blood tests in [general practice] so the way this programme works to do so is awesome as I hope we get to the lowest dose possible to sustain uric acid at lower than 0.36."

Survey of General Practice

The survey was sent to 11 general practices. Five people answered the online survey. Assuming an average of four staff per practice involved in gout, this would represent an 11% response rate.

Three general practice respondents were general practitioners, one a practice nurse and one "other". They had 1-31 years of experience (average 12.6 years). Three identified as female and two as male.

One was Maaori and Pacific Island heritage, one Pacific Island heritage, one NZ European, one Indian and one Other.

All rated the gout programme 7/10 or above on getting good outcomes for patients on a scale of 1-10 where one is not effective and 10 is extremely effective. Two rated it 9 or 10. The reasons for the rating reflected some challenges for those rating it 7 or 8 – keeping patients engaged, language and pharmacy cost barriers. Three acknowledged benefits, including increasing patient understanding, helping with compliance or patient engagement:

"When patients engage the pharmacy does a great job with titration. The biggest difficulty is keeping patients engaged in the process" [rating 8].

The best part of the programme was primarily titration, with patient education, fingerprick SU tests and being close-by also mentioned:

"It's right next door, we know our pharmacist very well, good relationship".

"The ease of titration with the point of care urate and the speed of titration".

Three suggested improvements: staff speaking Samoan and Tongan; free prescriptions; and resources (e.g. flyers) to share with patients and the clinical team about the pharmacy programme.

Four rated they would be extremely likely to recommend the pharmacy gout programme to other general practices. Their reasons were that it was helpful, works, and is patient focused. One GP noted:

"Because it's great takes the load off us to optimise, easy use when done well".

The person who was neither likely nor unlikely to recommend the programme to other general practices stated they were not in a position to share programmes with others.

Two stated the number of patients in the programme: 20 and 50.

Only GPs were asked the next questions. All three GPs noted the communication from the pharmacy about SU and allopurinol dose changes was good. All rated their comfort with the pharmacy doing the titration 10/10, *"They follow good guidelines and are well organised."* Two had no experience of the pharmacist referring a person to the GP to consider starting allopurinol and one had, but they liked this idea, one with a proviso: *"great if the patient turns up to the booked appointment".* One GP thought 400 of their patients could benefit from the programme, another thought 100 could.

Experience from the research team with the providers

Pharmacies approached to provide the service were keen to provide it and had quite good attendance at the initial trainings. Despite the challenges and issues mentioned in the following paragraphs, many pharmacists had a strong desire to help people with gout, and, even through the most challenging periods of interruptions to enrolment and service delivery due to COVID & staffing challenges, many pharmacists delivered the service.

The research team found variability between pharmacies in uptake of the service. Two pharmacies which had previously offered the Own My Gout service had the most enrolments initially, although one was delayed in entering data into the software. Three pharmacies did no enrolments (one of which was replaced) and two pharmacies had fewer than four enrolments.

With COVID-19 disruptions, some general practices changed their work practices, seeing few patients in person, affecting the potential to refer people into the service, or delaying the start because they had no capacity. Visits by the pharmacy lead on the programme to general practice increased uptake of the gout programme in a sustainable way in most cases, although one needed a further visit after

staff changes. Despite information being provided to some medical centres through a Primary Health Organisation (PHO), having signed an allopurinol standing order after a programme explanation, and pharmacies providing written information to individual doctors, most doctors were unaware of this service when they were visited, and appreciated understanding it and wanted patients in it. It was helpful for the pharmacist to attend these, but not always possible.

Pharmacists were sometimes slow to get trained to ensure the Gout Busters service was available during all opening hours. Some pharmacies delayed setting up the software or forgot their password delaying data entry, affecting timely texts to patients and reporting. Some pharmacies had no SU test strips after they expired or ran out, despite communication about ordering test strips. This typically reflected staffing and capacity challenges.

Feedback from pharmacists and the staff at medical centres suggested that at least some prescribers were not following Healthpathways gout management. Problems found included: doctors prescribing allopurinol but having no recent renal function test nor ordering one; doctors starting patients at 200 or 300 mg/day of allopurinol (for example considering the patient wouldn't be titrated to the correct dose otherwise), no gout flare prophylaxis with initiation or titration of allopurinol, and prescribing dose increments for titrations that differ from those recommended.

The multi-disciplinary team, with nurse, rheumatologist, pharmacy services specialist/researcher and project manager, was helpful in redesigning the gout programme and considering patient needs and education needs for pharmacists. The team had limited time, was unable to visit pharmacies before November 2022 and only able to visit some general practices February to April 2023. Visits to some pharmacies and general practices and repeat visits were not possible with the resource. This delayed problem identification and resolution and encouragement of the service.

The software made it easy to identify which pharmacies were enrolling well, which had loss to follow-up or good successes, and the effects of initiatives. However, the intention of more automated reporting for pharmacies and Te Whatu Ora Counties Manukau had not been implemented as it took time to decide what was needed in the reporting.

Discussion

Summary of results

The Gout Buster programme was evaluated with mixed methods: qualitative interviews of service users; quantitative data with statistical analysis; quantitative data with descriptive analysis; survey of pharmacists delivering the service; and survey of general practice staff referring patients for the service. This enables a wide understanding of the programme benefits and areas for improvement.

COVID-19 delayed the programme start through delays in software approval and development, and the OMICRON outbreak and influenza immunisation period affecting pharmacy capacity. The programme started 1 May 2022 with low uptake initially with COVID-19 causing staff absences overwhelming pharmacy and general practice. However, some pharmacies started enrolling patients after the November promotion to pharmacists, and enrolments accelerated after visits to some general practices from February to April 2023.

The statistical analysis of this programme included data for 127 participants. Patient outcome data were limited by the few patients with long-term data. However, the statistical analysis showed that 27% of the sample of 127 reached the target SU 0f under 0.36 mmol/L at least once – noting that some people had only joined the programme in the last two or three months, limiting their opportunity to reach the SU value. Over 40% of those in the programme for at least three months reached target at

least once, and 50% of those attending for six months reached target. Likelihood of reaching target was greater in older age groups. Maaori and Pacific peoples were less likely than other ethnicities to achieve target levels at least once with about 30% of those attending for at least four months or longer reaching target. The Maaori and Pasifika group did experience a similar reduction in SU values (-0.1 mmol/L) as the non-Maaori non-Pasifika group, but started at a higher SU value.

The pharmacy data descriptive analysis included data from all pharmacies and comprised 232 patients through until 1 July 2023. This information was analysed in addition to the statistical analysis as it allowed two more months for enrolments and pharmacy visits, allowing further data to capture the many patients who had enrolled in the programme from March to June 2023. This showed Gout Busters has been delivered mainly (81%) to people who identified as Pacific Island or Maaori heritage, as intended.

Uptake of the programme initially had low enrolments with uptake considerably increased in November 2022 following promotion to pharmacy and then further increased in March and April 2023 following promotion to participating general practices in Otara, Clendon and Mangere. Enrolments were sustained thereafter, with the quarter ending June 2023 seeing 27 enrolments per month on average, although this varied considerably by pharmacy.

The statistical analysis showed that 40% of those in the programme for three months achieve SU target levels, however, many patients drop out earlier, and some can take a long time to reach target, and it is common to see people late in attending their fingerprick visit at the pharmacy. However, analysis of the 46 enrolments from 2022 showed 78% taking allopurinol in August 2023.

Service users who participated in interviews rated the programme highly (at least 7 out of 10), even those who attended sporadically or only once. Many had improved gout (or no gout) after going on the programme, some of whom had had gout for a long-time that was not well-managed. They gained better understanding, including the value of the fingerprick SU test, often appreciated the caring or friendly nature of the pharmacist, and liked the texts which they saw as an extension of the pharmacist's work. Many received the booklet, but many preferred information delivered in person. Most liked the privacy and convenience of the pharmacy, appreciating minimal wait and no cost. This reflects their challenges getting a prescription from the doctor including considerable wait for an appointment or when attending the doctor. These challenges led to some stopping allopurinol. Patients had challenges adhering to allopurinol, but motivations included being pain-free (for themselves, work or their family), seeing the SU number drop and/or other aspects of the pharmacist visit, including increased understanding and confidence they could get prevent gout attacks. Blister packaging or a phone alarm were helpful for some. Service users were busy so needed the text reminders to help them return to the pharmacy and some struggled to get there in a timely way. A small number of service users had concerns within the programme, two mentioned a lack of privacy, one mentioned a long wait for the fingerprick test, the pharmacist being too busy to give information, and insufficient information about the long-term nature of the allopurinol use as a preventer at the first visit, leading to it being stopped. One stopped their allopurinol temporarily, reportedly instructed by the pharmacist to get a further prescription from the doctor, suggesting the pharmacist was unaware of pharmacist continuation supply. There appeared to be some instances of allopurinol being started without flare prophylaxis. Two participants suggested You Tube videos on gout rather than a booklet. Many service users discussed foods causing gout and avoiding them, sometimes this had come from the pharmacist's advice, which may have related to foods which can trigger acute gout flares.

Most pharmacists were positive about the Gout Busters Programme, 80% rating it at least 8 out of 10 and 85% would recommend to another pharmacy. They rated most highly working closely with the

patient or building rapport, titrating doses, improving patient control and testing on the spot. Some worried about loss to follow-up and how to reduce that. Texts to patients, continuation supply of allopurinol, and training were rated highly. Working with general practice was rated less well than other aspects of the programme. Administration, software (particularly the slow website) and invoicing were time-consuming, and some were concerned it was insufficiently funded.

Barriers to the programme identified by pharmacists included: the need for a blood test for renal function which is necessary to determine the safe starting dose for allopurinol, or no flare prophylaxis delaying dose titration; insufficient time in the pharmacy or for the patient and a patient attending a different GP without a standing order.

Although the sample is small, all in the general practice survey rated the programme 7/10 or higher. Improvements included staff speaking Samoan or Tongan, free prescriptions and resources such as flyers for them to give patients.

Comparison with other data

The Northland gout stop programme had a 12-week programme of titrated therapy in blister packaging with education and some pharmacies providing finger pricks. This programme evaluation with data from 708 patients analysed found 71% of patients were Maaori or Pacific peoples. The Maaori and Pacific subgroup had 55% complete the programme (versus 84% NMNP), and 40% reached the target SU level in 91 days (versus 51% NMNP). After programme completion, 68% of Maaori and Pasifika patients and 65% of non-Maaori and non-Pasifika patients continued to take allopurinol. Eighty-eight patients re-enrolled one to four times in the programme. Twenty-one patients were interviewed by telephone, and all rated the programme excellent or good. At least five appeared to have stopped allopurinol because they were no longer needed (eg gout had not returned) or they forgot to go get the tablets.

The Whanganui programme was a three-month programme, so is not comparable.

The HQSC Atlas of Variation which shows data from New Zealand Primary Health Organisations in 2019 showed that although 60.1% of Māori, 59.4% Pacific patients, and 56.0% of non-Maaori non-Pacific patients with gout were prescribed allopurinol on at least one occasion, the percentage having this urate lowering therapy dispensed regularly ie for three or four quarters of the year, fell to 39.4%, 35.9% and 43.7%, respectively. Our figures for the 2022 cohort of allopurinol dispensed without a break were 62.5%, 45.4%, and 71.4%, respectively, noting however that our numbers in each group were small. This needs to be repeated with longer-term data.

Reporting from the previous Own My Gout programme at Te Whatu Ora Counties Manukau is limited, making comparison difficult. However, of the seven pharmacies in the OMG programme, only one was regularly enrolling gout patients in the programme in early 2022, and in 2020 when first contacted about how the programme was working, most were inactive with expired test strips [personal communication Natalie Gauld]. In contrast, 11 of the 13 pharmacies in the Gout Buster's programme have enrolled patients in the last year, despite the challenges of COVID-19 and staff shortages.

Implications

Two pharmacies in Gout Busters had previously run Own My Gout in Te Whatu Ora Counties Manukau, and 10 other pharmacies involved were in in high priority urban settings and one in a rural setting. This gout programme was redesigned to help improve patient continuation and correct dosing through up-titration of urate lowering therapy with allopurinol, add text reminders and motivational messages to help the patient attend appointments and continue to take allopurinol (with continuation supply funded).

Statistical analysis of 127 patients showed people staying in the programme for a longer period had increased likelihood of reaching the target SU level. However, although Maaori and Pacific peoples had a similar reduction in SU levels, they had a 0.52 hazard ratio for reaching target SU compared with non-Maaori and non-Pacific. This was not statistically significant and having data for more patients over a longer period is needed to confirm the programme outcomes for Maaori and Pacific peoples versus others. The short-term data we used could impact more on Maaori and Pacific peoples if starting at a higher average SU value, and with more leaving and returning to the programme.

The longer-term data (from 2022 enrolments) suggested a high level of allopurinol being continued, but small patient numbers limit the generalisability. The lower rates of allopurinol continuation for Pacific peoples might reflect the challenges with ongoing access to allopurinol that we found in our qualitative interviews, and therefore might be improved with continuation supply being promoted for patients, providing three months' supply at once, and having continuation supply available long-term for these patients. It may also be that pharmacists will gain in experience with time that will enhance their work including relationship-building with patients and therefore the outcomes. The pharmacy with the lowest lost to follow-up and high achievement of target SU levels had been involved in the gout service before so had longer experience.

People who are of Maaori and Pacific Island heritage are disproportionately affected by gout, predominately because of genetic factors and the Atlas of Variation shows a disparity in treatment continuation. Our interviews found patients who are Maaori and Pacific peoples valued the Gout Busters Service, but also raised some useful areas in which we have made recommendations. Long-term data (over 12 months since enrolment) for more patients than the original statistical analysis will better show outcomes for these groups, preferably after key recommendations have been implemented to reduce barriers to access that we found.

The software allowed text messages, communicated with the GP about patient SU and allopurinol dose changes. It had a patient dashboard and SU graphs for the patients to see progress and target. The software also enabled easy monthly reporting, and this has been valuable for the funder to identify pharmacies and general practices to work with to encourage increased enrolment and the effects of communication with these providers. While software improvements were identified, reporting is easier for the contracting region, research showed the patients and pharmacy benefit from the text reminders to visit. The software sends the SU results to the GP. It would also be helpful if the POC SU results were available through Testsafe and the clinical portal, as happens for INR on-line. This functionality is possible with the software, but it needs to go through the appropriate controls to gain approval.

Gout Busters pharmacist training had a strong focus on cultural competency, relationship building, and conversations about gout including overcoming stigma. The interviews showed pharmacists were valued for their understandable information and caring, friendly, and/or welcoming approach. While many valued the privacy, discretion and fast service their pharmacy offered, two people had insufficient privacy. The need for privacy and the value placed on friendliness and prioritisation by the pharmacist of the Gout Buster visit need to be communicated to pharmacy. Using pharmacists with low loss to follow-up, and high rates achieving target SU levels and with long-term allopurinol adherence to share what works for them with all pharmacists in the programme may provide a useful learning opportunity.

Much data for the statistical analysis was for patients who had recently joined the programme with insufficient time to reach target. Repeat analysis in a further 9-12 months will more clearly show patient outcomes, overall, and in Maaori and Pacific populations.

Several qualitative interviews indicated a possible reason for stopping pharmacy visits without three consecutive tests below target is because they have not had gout flares, so they know the medicine is working. Quantitative data from those 46 enrolled in 2022 also showed some people who had not reached three consecutive tests below target continued regular allopurinol which might be consistent with lack of gout flares. Laboratory results report 0.2-0.42 mmol/L as normal SU. A longitudinal study shows that not all people with high SU measurements get gout (Robinson, et al, 2021). However, the SU targets for people with gout of < 0.36 mmol/L, or < 0.30 mmol/L if tophi are present, are widely recommended (Stamp and Dalbeth, 2022). A gout flare arises from an inflammatory response to monosodium urate crystal deposition in a joint, and in vitro testing shows supersaturation (crystal formation) at 0.36 mmol/L at the likely peripheral body temperature. Additionally, gout recurrence is lower in people who reach the target SU level. So, where possible, getting to the target of < 0.36 mmol/L remains useful and anyone who does not titrate to that level because their gout flares appear to have stopped could be advised that their dose might not be sufficient and to consider a further titration should their gout recur. More research on this population is warranted to understand what the number of gout flares over time and need for further titration.

In the Gout Busters model, delayed or stopped pharmacy visits slows or stops allopurinol dose titration. If the pharmacy provides the medication as monthly amounts with repeats to encourage them to return for the pharmacy visit and fingerprick test, some people will run out of allopurinol and therefore discontinue before returning, also delaying dose titration. The Northland and Whanganui model uses several regimens in blister packs (according to renal function and diabetes as a comorbidity) for three months selected at the click of a mouse for the prescriber. Adding this to Gout Busters and providing three months' supply at once, would provide a faster dose titration for some patients reducing their gout flares earlier. It is likely faster achievement of the target SU will see fewer pharmacy visits needed, providing convenience for the patient and reducing the funding cost for Te Whatu Ora Counties Manukau. The pharmacy visits with education, fingerprick measurement, texts, communication with the doctors via software and easier reporting than before still remain vital.

Patients not having a recent renal function test (within the last three months), commonly delays allopurinol titration. Thus, patients in the Te Whatu Ora Counties Manukau programme are likely to have slower dose titration on average than those in the other two programmes. Pharmacists could provide laboratory forms for renal function to help allow earlier dose titration. There might be Auckland factors such as bad traffic or long working hours that could make it harder to get to a laboratory for a blood test, or to the pharmacy for a visit.

The time constraints of many people with gout and the need to get a prescription every three months from the doctor is likely to see people who successfully complete the programme stopping allopurinol when they miss getting to the doctor for their next supply of allopurinol. The waiting time at the doctor and cost of the doctor also affects this. Consideration needs to be made for how this can be simplified ahead to prevent people with gout stopping allopurinol with the consequent effects on work, family life and quality of life, on need for acute treatment of gout, and on potential harms of repeated gout flare treatment rather than prevention. Examples could include:

- encouraging doctors to provide prescriptions for allopurinol without seeing the patient to avoid them running out, if this is not happening. This could be facilitated by GPs using recall systems for patients with long-term conditions with appropriate funding.
- funding pharmacy to provide continuation supply of allopurinol under standing orders (and blood test forms for renal function) for people who have completed the Gout Busters programme, or anyone on allopurinol. This would be most useful for people who are not taking

other long-term medication. A doctor's visit at least annually (or more frequently where required) would be needed.

- providing free telehealth for gout patients to make it easier to get a prescription and a blood test form.
- encouraging larger employers to provide a free gout clinic once a month with prescribing, SU fingerprick testing and phlebotomy (for renal function) provided.
- enabling longer periods for funded allopurinol supply on prescription, similar to oral contraceptives (six months' supply versus the current three months' supply).

Many gout programmes have happened over the years, but often without ongoing funding or easy reporting of outcomes. Sustainable funding for pharmacists and staff in primary care needs to be available to support patients with long-term conditions. This should not simply be a short-term programme to get control for the patient but needs to reduce barriers relating to ongoing adherence such as requiring a doctor's visit every three months for prescriptions to avoid discontinuations, gout flares and restarts and titrations of allopurinol.

The gout booklets were generally not valued by the interview participants. These booklets have recently been rewritten to maximise understanding and are available in different languages. Possibly people getting the information they need verbally means that they do not need the booklet (many preferring verbal information). Alternatively, pharmacists might be handing the booklet out without going through it with the person to maximise understanding. The booklet, for example, provides helpful information about how unimportant diet is that could have helped some participants who focused on diet and foods to avoid, not understanding that other factors are more important with gout.

We found adherence challenges had multiple reasons behind them – thinking they may no longer need to take them, forgetting, running out of tablets because they cannot get to the doctor or back to the pharmacy, or the challenge of timing with food. While text messages helped some, it is important that pharmacists explore any adherence issues and addresses these according to the individual's needs. Adherence support may include one or more of the following: blister packs; ensuring the patient (and pharmacist) knows they can have continuation supply from the pharmacy; letting them know what to do if they are running out of supply and addressing challenges taking with food. From the first visit, pharmacists need to ensure the service user understands the need to take the medication long-term to avoid gout attacks.

Strengths and limitations

The evaluation of the Gout Busters Programme provides an overview from service users, service providers and with quantitative data, helping to provide an indication of what is working and where improvements could be made.

The programme ran for only one year before data close-off, so no patients had 12 months of data for statistical analysis and very few had follow-up one year adherence data for allopurinol as intended. Additionally, the short period of follow-up meant we could not capture many who would have returned to the programme after having a further gout flare and restarting allopurinol. Approximately half of the participants had commenced the programme in the three months prior to the data collection, some of whom will only have had time for one or two visits. This limits the potential to achieve the target SU within this patient group and over-represents people attending only one or two visits. The lack of long-term data affects the ability to understand how well the programme is delivering for Maaori and Pacific peoples, particularly given they are more likely to leave the programme then return to it and can have a higher starting SU. Further long-term data are required.

Most pharmacists were new to a gout service and had no or very few patients in 2022. In time they are likely to gain confidence and capability and strengthen relationships with people using this service, so outcomes of patients they manage may improve. Staff absences from COVID-19 and influenza and low availability of pharmacists limited their ability to enrol patients early in the programme.

Allopurinol prescription collections were used for adherence data. Collection does not necessarily mean the medicine is taken, but this method is also used for the Atlas of Variation.

The patients with the longest time in the programme were often the first few enrolled by a pharmacy after their training. Experience with the service is likely to be beneficial, and therefore some outcomes may improve further as the service becomes more business as usual.

For the interviews, people to contact were purposely selected to ensure a wide range of experiences – those who had attended many sessions of the programme, including those who had exited after achieving target, those who dropped out early or dropped out then returned, people attending different pharmacies, and a variety of ages and both genders, concentrating on only the Maaori and Pacific populations. Our participants had attended one of six different pharmacies, out of the 11 pharmacies that had offered the programme.

Our Pacific peoples participants were Tongan or Samoan only. Although these are the two most common Pacific peoples in New Zealand, each Pacific ethnicity has their own unique cultural customs and traditions, and other Pacific peoples may have had different experiences.

Half of the interviews were conducted with a male Maaori interviewer (for Maaori) or a female Tongan interviewer (for Pacific peoples), but because the interviewers had time constraints, the other half of the interviews were conducted by the NZ European Principal Investigator. This could affect rapport building and information shared by participants. However, sharing that she had a long-term condition, diabetes (also with stigma), could create a commonality, and in-depth knowledge of the project helped know areas to probe according to participant answers and after reading earlier transcripts. Possibly people chosen for sporadic attendance or early stopping of the programme who were interviewed differed from those with sporadic attendance who did not respond to an invitation for an interview. Future research could concentrate more on this group, which is also under-represented in other studies.

We used text messages and phone calls to recruit people for interviews. Therefore our sample may have been those most comfortable with text messaging, affecting their answers about text messaging.

The surveys saw a strong response rate from pharmacy, at 80% response rate. It also used anonymous answers, so it is likely that this is a good representation of the views of pharmacy. For general practice, the very low response rate affects the generalisability.

Key recommendations

- Continue the Gout Busters programme with existing pharmacies and consider adding others with high priority populations
- Share the evaluation findings with pharmacies and general practices involved in Gout Busters including what is working well and areas to work on e.g. privacy, adherence, continuation supply offering, providing three months of allopurinol supply to reduce risk of running out, asking about any adherence challenges and solving them. Share case studies of pharmacies and patients doing well.

- Use the Northland gout titration packs for early allopurinol titration, add to the prescribing software for a single key stroke prescription, and educate doctors on its use, and/or ensure GPs are using best practice gout prescribing
- Address challenges of attending the doctor for prescriptions after completing the programme. For example, consider continuation supply of allopurinol through the pharmacist under standing order (or consider a reclassification for this). Use software to inform the GP of provisions. Alternatively investigate other ways to minimise cost and time for patients e.g. telehealth, programmes at workplaces.
- Enable pharmacists to provide blood test forms for renal function
- Repeat the quantitative research in 9-12 months for longer-term data including analysis of Maaori and Pacific peoples outcomes. If significant changes are made (e.g. Northland gout titration packs, ongoing continuation supply after programme completion, allowing pharmacists to provide renal function blood test forms) time the quantitative research about 15-18 months after changes are introduced.
- Ensure sufficient resource ahead to support pharmacy and general practice proactively, including with visits, to get enrolments started and problem solve. Work with pharmacies with low enrolments or high loss to follow-up in the first instance
- Software: Get reporting automated for Te Whatu Ora Counties Manukau and for pharmacies to see their performance versus average and top performance, arrange for SU fingerprick tests to go onto Testsafe. Software should aid invoicing and be faster for pharmacists to use.
- The funding for pharmacy needs to be reviewed to ensure it is appropriate for the time involved and underlying costs (e.g. test strips). Contracts need to require that pharmacies keep in-date test strips and have sufficient staff trained to provide the service at all times.
- Consider alternative ways of getting people to see a doctor about urate lowering therapy, e.g. paying for a doctor's visit if attending the pharmacy with acute gout (planned but not implemented in this project), telehealth, a prescriber visiting workplaces.

Conclusion

Early data from the Gout Busters programme found high participation in the programme for people who are Maaori or Pacific Island heritage and better long-term adherence to allopurinol than in the Atlas of Variation, including for these groups, albeit limited by small numbers. Maaori and Pacific peoples service users valued the Gout Busters programme for increasing their understanding, including through the fingerprick tests, the caring, friendly pharmacist staff, and the text messages.

Allopurinol dose titration can be slow, partly because of delayed pharmacy or renal function tests, and it is recommended that a fixed dose titration regimen is used, three-month supplies and pharmacists able to provide a renal function lab test form. Challenges with seeing doctors need to be addressed for long-term continuation on therapy, e.g. pharmacist continuation supply after the programme has been completed, ability to order a repeat prescription, telehealth options.

Pharmacists found the revamped programme worked well, although software improvements were identified. Sufficient resourcing is needed to support pharmacies and general practices joining the scheme and optimise pharmacists' work, sharing best practices and encouraging enrolments and helping minimise loss to follow-up.

Repeating the statistical analysis in 9-12 months is recommended to understand patient outcomes, particularly for people who are Maaori and Pacific Island heritage..

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References

Andrews, S., Gasparini, J, Henderson, G. (2020). “Evaluation of Gout Stop and Owning My Gout management programmes: a final report for Arthritis New Zealand and its partners.” *Synergia.* https://www.arthritis.org.nz/wp-content/uploads/2020/07/Gout-programmes-evaluation-report-.FINAL_.-200228.pdf Retrieved 20th December 2021.

Bramley, D., Riddell, T., Whittaker, R, et al. (2005). Smoking cessation using mobile phone text messaging is as effective in Maaori as non-Maaori. *New Zealand Medical Journal* 118(1216): U1494

Bunphong, K., Narongroeknawin, P. (2018). "OP0212 Mobile phone text messages for improving allopurinol adherence: a randomised controlled trial of text message reminders." *Annals of the Rheumatic Diseases* 77(Suppl 2): 155-155.

Dalbeth, N., Dowell, T, Gerard, C, Gow, P, et al (2018). "Gout in Aotearoa New Zealand: The equity crisis continues in plain sight." *New Zealand Medical Journal* 131(1485): 8-12.

Dalbeth, N.; Gerard, C.; Gow, P.; et al. Gout in Aotearoa New Zealand: are we going to ignore this for another 3 years? *The New Zealand Medical Journal* 2016, 129, 10-13,15.

Dalbeth, N.; House, M.E.; Horne, A.; et al. The experience and impact of gout in Māori and Pacific people: A prospective observational study. *Clinical Rheumatology* 2013, 32, 247-251, doi:10.1007/s10067-012-2110-5.

Dalbeth, N., Merriman, T.R., Stamp, L.K. (2016). "Gout." *Lancet* 388(10055): 2039-2052.

Dale LP, Whittaker R, Jiang Y, et al. Text message and internet support for coronary heart disease self-management: results from the Text4Heart randomized controlled trial. *Journal of Medical Internet Research*. 2015;17(10).

Dobson, R.; Whittaker, R.; Jiang, Y.; et al. Effectiveness of text message based, diabetes self-management support programme (SMS4BG): two arm, parallel randomised controlled trial. *British Medical Journal* 2018, 361, k1959, doi:10.1136/bmj.k1959.

Dobson R, Whittaker R, Bartley H, et al. Development of a Culturally Tailored Text Message Maternal Health Program: TextMATCH. *JMIR Mhealth Uhealth* 2017;5(4):e49. https://doi.org/10.2196/mhealth.7205

Fatafehi-Finau, T. Experiences and Perceptions of Tongan people diagnosed with gout living in South Auckland. Masters thesis. 2019

Goldfien, R. D., Ng, M.S., Yip, G., et al. (2014). "Effectiveness of a pharmacist-based gout care management programme in a large integrated health plan: results from a pilot study." *BMJ Open* 4(1): e003627

Gow P, Gow V, Waldon J Societal and cultural attitudes to gout : an important consideration in the successful management of gout among Maaori in Aotearoa New Zealand *Current Rheumatology Reviews*. 2011;7:170-180

Gow P, He J. How healthy are our patients with gout? A study of health status and management of patients with gout at two primary care practices. *Annals of Rheumatic Disease*, 2014.73:784.

Halapua S. (2000). "Talanoa process: The case of Fiji." *East West Centre,* Hawaii.

Health Research Council. Pacific Health Research Guidelines. 2014. Available at https://gateway.hrc.govt.nz/funding/downloads/Pacific_health_research_guidelines.pdf Retrieved 24 Oct 2021

Health Safety and Quality Commission. (2020, 12 May 2020). "Gout." Retrieved 14 Oct 2020, from http://www.hqsc.govt.nz/atlas/gout.

Horsburgh, S., Norris, P, Becket, G., et al (2014). Allopurinol use in a New Zealand population: Prevalence and adherence. *Rheumatology International* 34(7): 963-970.

Humphrey, C., Hulme, R., Dalbeth, N., et al. (2016). "A qualitative study to explore health professionals' experience of treating gout: Understanding perceived barriers to effective gout management." *Journal of Primary Health Care* 8(2): 149-156.

Hutton I, Gamble G, Gow P, et al Factors associated with recurrent hospital admissions for gout: A case control study *Journal of Clinical Rheumatolofy* 2009;15:(6) 271-274

Jackson G, Dalbeth N, Te Karu L, et al. Variation in gout care in Aotearoa New Zealand: A national analysis of quality markers. *New Zealand Medical Journal* **2014**, *127*, 37-47.

Martini N, Bryant L, Te Karu L, et al (2012). Living with gout in New Zealand: An exploratory study into People's knowledge about the disease and its treatment. *Journal of Clinical Rheumatology* 18(3): 125-129.

Norris P, Tordoff J, McIntosh B, et al. Impact of prescription charges on people living in poverty: A qualitative study. *Research in Social and Administrative Pharmacy* 2016, 12, 893-902, doi:10.1016/j.sapharm.2015.11.001.

Robinson PC, Frampton C, Phipps-Green A, et al. Longitudinal development of incident gout from low-normal baseline serum urate concentrations: individual participant data analysis. BMC Rheumatology 2021, 5, 33, doi:10.1186/s41927-021-00204-4.

Stamp LK, Dalbeth N. Critical appraisal of serum urate targets in the management of gout. Nature Reviews Rheumatology 2022, 18, 603-609, doi:10.1038/s41584-022-00816-1.

Te Karu L, Bryant L, Elley C. Maori Experience and perceptions of gout and its treatment: a kaupapa Maori qualitative study *Journal of Primary Health Care* 2013;5(3): 214-222.

Te Karu L, Harwood M, Bryant L, et al. Compounding inequity: a qualitative study of gout management in an urban marae clinic in Auckland. *Journal of Primary Health Care* 2021; 13(1): 27-35.

Tomlin, A. Woods, D.J., Lambie, A., et al. (2020). Ethnic inequality in non-steroidal anti-inflammatory drug-associated harm in New Zealand: A national population-based cohort study. *Pharmacoepidemiology and Drug Safety* 29(8): 881-889.

Vaioleti, T. (2016). Talanoa research methodology: A developing position on Pacific research. *Waikato Journal of Education*, 12(1).

Whittaker, R. (2018) The potential of mobile health – reaching those in need. *BMJ Opinion*. Available at: https://blogs.bmj.com/bmj/2018/05/17/robyn-whittaker-the-potential-of-mobile-health-reaching-those-in-need/

Willcox, J., Dobson, R., Whittaker, R. (2019). "Old fashioned tech in the time of bling: Is there a future for text messaging in health? (Preprint)." *Journal of Medical Internet Research* 21 (12): e16630.

Gout in Aotearoa New Zealand: the equity crisis continues in plain sight

Nicola Dalbeth, Tony Dowell, Catherine Gerard, Peter Gow, Gary Jackson, Carl Shuker, Leanne Te Karu

In January 2016 we reported growing prevalence of identified gout in the general population, while the numbers of those regularly receiving appropriate long-term preventive treatment (urate-lowering therapy such as allopurinol) had remained low and static for three years.[1]

Data to 2014 from the New Zealand Atlas of Healthcare Variation by the Health Quality & Safety Commission (the Commission) showed not only were Māori and Pacific populations with greater gout prevalence being treated least appropriately compared to other ethnicities, but large numbers were being treated with repeated prescriptions of non-steroidal anti-inflammatory drugs (NSAIDs), a poor and potentially dangerous stopgap.

Gout in Aotearoa New Zealand was growing and being mismanaged with differential prevalence and treatment by ethnicity.

We asked the question: "Gout in Aotearoa New Zealand: are we going to ignore this for another three years?"[1]

New data for 2018—and the answer is "yes"

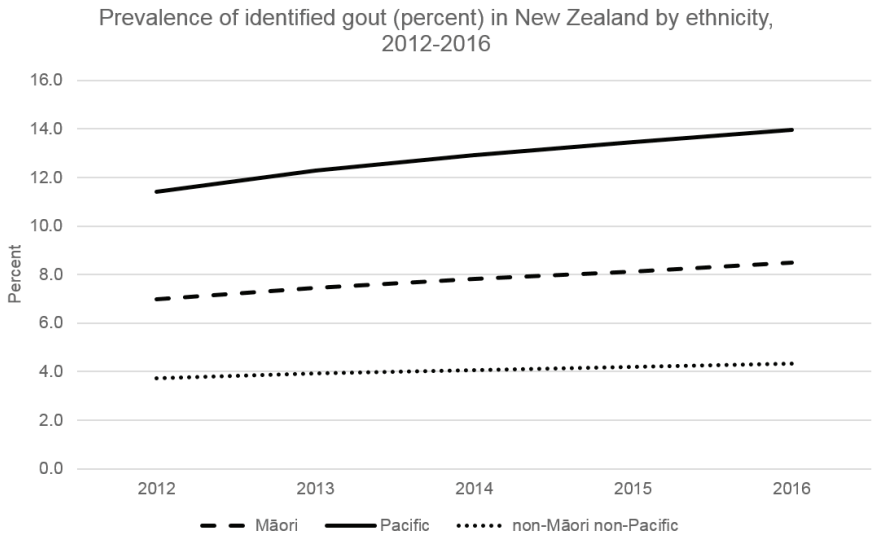
Gout is the most common form of inflammatory arthritis affecting adults. It is a chronic disease of monosodium urate (MSU) crystal deposition, typically presenting as recurrent attacks of severe joint inflammation. Gout causes severe joint pain, work disability and reduced social participation. Untreated, tophi can develop, leading to joint damage. Gout is independently associated with cardiovascular disease, diabetes, kidney disease and overall mortality.[2,3] Gout can be effectively managed with long-term urate-lowering therapy such as allopurinol. Colchicine, often used to treat gout flares, still has a role, particularly to prevent gout flares during initiation of long-term urate lowering therapy. Oral steroids are increasingly used to manage acute flares, to limit use of NSAIDs. Rheumatology guidelines recommend that urate-lowering therapy be continued long-term to reduce serum urate levels to <0.36mmol/L, at which point MSU crystals dissolve.

The gout domain of the Atlas of Healthcare Variation publishes data by district health board (DHB) on six indicators of gout prevalence and treatment. Data including 2016 just published show an escalating crisis in inequity: there is more gout nationwide, and worse and less treatment for Māori.[4] A similar picture exists in terms of inequity for Pacific peoples. As partners under the Treaty of Waitangi, there is a governmental obligation to ensure Māori have at least the same level of health as non-Māori.[5] Under Article 24 of the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP),[6] to which New Zealand became a signatory in 2010, Māori, as the indigenous people of Aotearoa New Zealand, "have an equal right to the enjoyment of the highest attainable standard of physical and mental health".

New data from the atlas: increasing prevalence, worse treatment, more hospitalisations

Prevalence of identified gout in Pacific peoples across New Zealand continues to climb more steeply than other ethnicities and remains more than three times higher than European/other ethnicities. Prevalence of gout in Māori is twice as high as European/other, and still climbing. Administrative health data suggest at least 182,000 people across the country now struggle with the condition, up from 145,443 in 2012, from 4.5% to 5.35% of the population (Figure 1).

Figure 1: Prevalence of identified gout in New Zealand, by ethnicity, 2012–2016.



Gout treatment is inequitable. Though Māori and Pacific peoples were more affected by gout, the new Atlas data show Māori and Pacific peoples continue to be less likely to receive regular urate-lowering therapy such as allopurinol. While by count the number of people with gout regularly receiving allopurinol has increased by 16,435 people since 2012, more people have been identified with gout. Rates of this best treatment have effectively remained static over time, and by ethnicity are inversely proportional for those most affected (Figure 2).

NSAIDs can improve the symptoms of the gout flare, but repeated courses of NSAIDs without urate-lowering therapy represent poor care, due to the risk of kidney disease and other complications. It is thus striking to see 37% of people identified as having gout were dispensed an NSAID compared with 23% for the resident adult population in 2016. Māori and Pacific people aged 20–44 with gout were dispensed NSAIDs more than other ethnic groups. Forty-seven percent of Pacific peoples and 41% of Māori with gout were dispensed an NSAID in 2016, compared with 34% of those identifying as European/Other ethnicities.

The cumulative effect of increased prevalence and differential poor treatment appears as presentation to acute services—in 2016, Māori and Pacific peoples had four to nine times as many hospital admissions due to gout than those of European/other ethnicities. Furthermore, the rate of hospitalisation of Pacific people for gout continues to climb in the new data, while the rate of European/other admissions remains low and static (Figure 3).

Figure 2: Regularly receiving urate-lowering therapy in New Zealand, by ethnicity, 2012–2016.

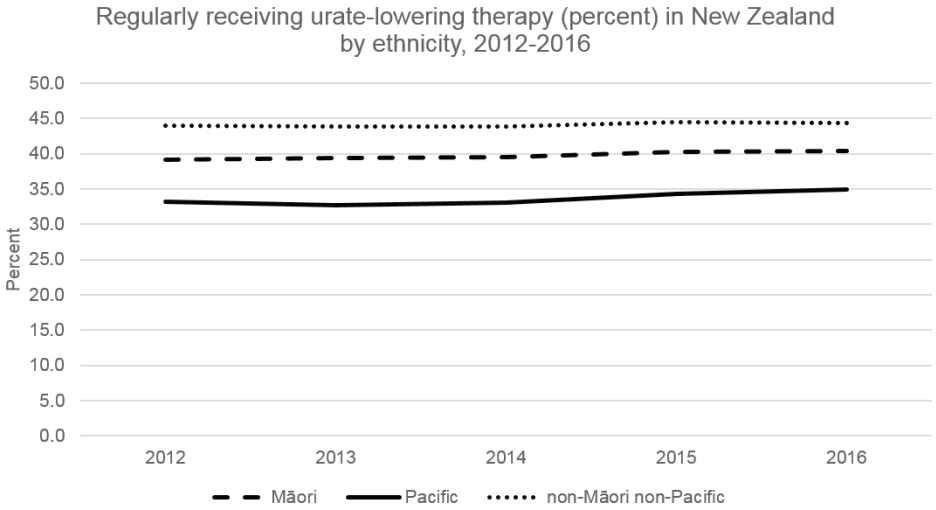
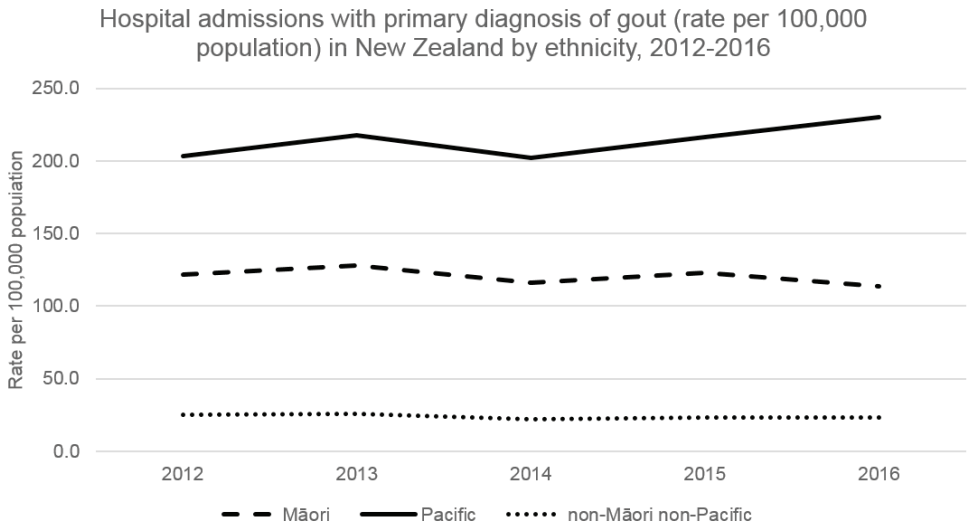


Figure 3: Hospital admissions with primary diagnosis of gout, by ethnicity, per 100,000 population.



Estimates using PHARMAC methodology costing ($730 for a day stay or emergency department admission and $1,000 for a medical ward bed night) suggest avoidable gout admissions and hospital length of stay cost the health system more than $3.8m in 2016.[7,8]

What's driving these poor results?

Gout prevalence, inequity and failures in treatment that further differentiate and exacerbate inequitable outcomes appear to be the product of barriers to access to primary care and health literacy dynamics, including professional failure to build comprehension and awareness of the condition and its treatment in people with gout.[9,10]

Structural barriers to proper diagnosis, treatment and adherence appear in part to be financial. Allopurinol requires a three-monthly co-payment from the patient of $5. Each quarter, the patient must incur further costs including GP or prescriber appointment fees, transport and time off work.

New Zealand Health Survey data have long shown cost barriers to primary care and prescription medicines vary by ethnicity.[11] The 2016/17 survey found 22.2% of Māori adults and 17.8% of Pacific adults did not visit a GP because of cost. Further, 13.8% of Māori adults and 15.5% of Pacific adults failed to pick up prescriptions due to cost. These latter proportions dropped in the latest year after increasing three years in a row.

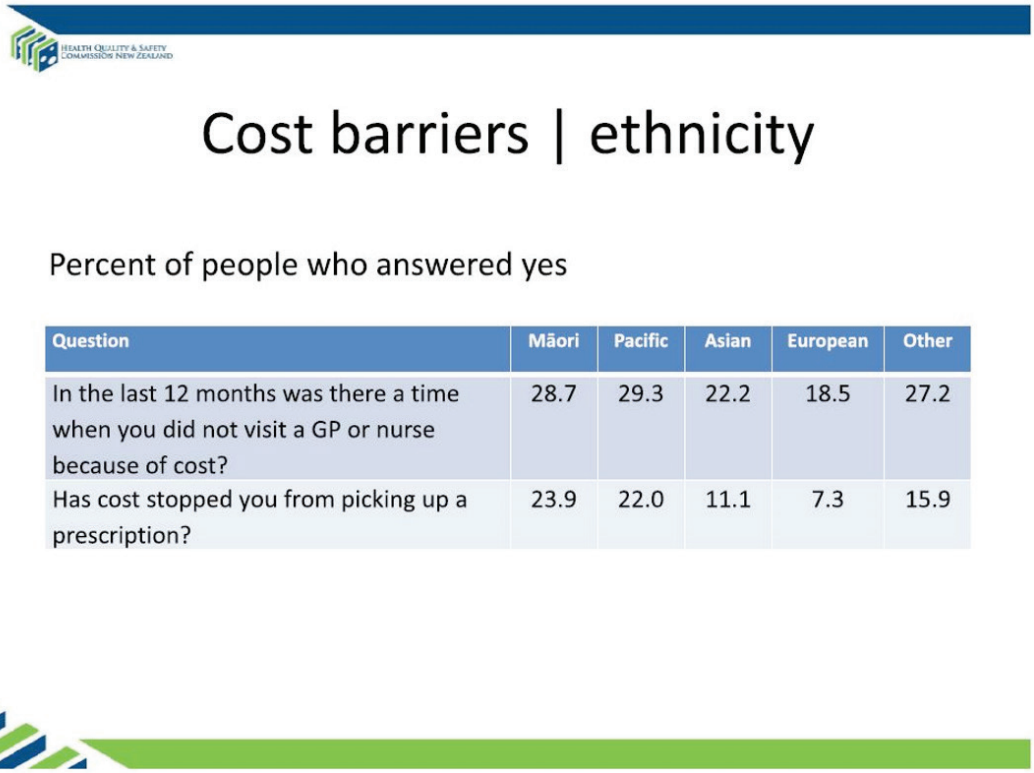
However, recent patient experience data from the Ministry of Health and the Commission's Primary Care Patient Experience Survey seem to suggest greater inequities than previously identified in the Health Survey data. The Patient Experience Survey found nearly a quarter of Māori and 22% of Pacific patients identified cost as a barrier to picking up a prescription, compared with only 7% of Europeans and 15% of other ethnicities. 28.7% of Māori patients and 29.3% of Pacific patients identified that cost was a barrier to visiting a GP or nurse, compared with 18.5% in European patients.[12] Māori adults were, furthermore, less likely than Europeans to answer yes to the question "Was the purpose of the medication properly explained to you?"

Effective treatment of gout requires continuous allopurinol prescription, regular laboratory monitoring of urate levels, and allopurinol dose titration and treatment to serum urate targets. This in turn requires long-term medication adherence, patient understanding of the condition and of the different roles of their medications, and under current conditions, a co-pay and repeated presentations to a GP or prescriber for new prescriptions and monitoring.

What can be done about it? Culturally competent primary care, pharmacy and whānau empowerment programmes

Successful primary care approaches are available. A recent UK randomised controlled trial of nurse-led care using a treat-to-serum urate target approach showed major benefits in gout flare frequency, tophi and health-related quality of life compared to standard GP care.[13] In the US, a community-based personalised pharmacist

Figure 4: Primary Care Patient Experience Survey: cost barriers to primary care by ethnicity.



Question	Māori	Pacific	Asian	European	Other
In the last 12 months was there a time when you did not visit a GP or nurse because of cost?	28.7	29.3	22.2	18.5	27.2
Has cost stopped you from picking up a prescription?	23.9	22.0	11.1	7.3	15.9

programme, which included pharmacists contacting patients by phone and use of a protocol-based structured approach to urate-lowering therapy dosing, led to maintenance of low serum urate levels in most participants in the programme.[14]

In Aotearoa New Zealand projects with a specific equity focus, with pharmacy and nursing input, that pursue direct engagement and empowerment of communities, have had positive effects. These include the 'Gout Stop' programme in Northland, a collaborative, equity-focused primary care initiative across 36 practices designed to break down barriers to primary care in Northland. 'Oranga Rongoā', initiated at Papakura Marae Health Clinic, is a multi-dimensional care approach to gout management. It is premised on a culturally competent and culturally safe interaction for whānau utilising a multidisciplinary team approach of GPs, nurses, prescribing pharmacist, community health workers and community champions. A decision support tool has been developed for prompting and guiding prescribers with the opportunity for direct rheumatology specialist review. Whānau empowerment-weighted approaches seem promising and acceptable to local iwi. In Opotiki direct iwi involvement was solicited to design multiple hui with pharmacists in attendance to build local champions and upskill local GPs simultaneously. Funding for such approaches, despite available and forthcoming evidence of positive effects, remains fragmented and inconsistent.

Conclusion

The new data from the gout domain of the Atlas of Healthcare Variation show a problem that is far from stabilising, let alone waning. Biased prescribing exists throughout Aotearoa New Zealand, creating inequities in health, defined as "differences which are unnecessary and avoidable, but in addition are considered unfair and unjust".[15]

Our current healthcare system contains financial and other structural barriers that restrict the number of those on effective urate-lowering therapy, diminishing the productivity and quality of life of people with gout, while increasing the costs to patients and the system through the burden on acute care services. Despite the established benefits of long-term urate lowering therapy such as allopurinol, the situation is worsening, and the health system is falling short of its obligations under the Treaty principles and the United Nations Declaration. Successful gout management takes time and effort. Barriers to effective care for patients must be addressed, including the cost of accessing long-term medications, and the necessary funding, support and training provided to clinicians in both primary and secondary care. It is long past time for effective programmes to be implemented before the next atlas update arrives.

Competing interests:
Dr Dalbeth has received speaking fees from Pfizer, Horizon, Janssen and AbbVie, consulting fees from Horizon and Kowa, and research funding from Amgen and AstraZeneca, and is currently principal investigator on a clinical trial of intensive urate-lowering therapy (funded by the Health Research Council of New Zealand). Within the last five years, she has been principal investigator on a clinical trial of febuxostat in early gout, and received consulting or speaking fees from Takeda, Menarini, and Teijin.

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REFERENCES:

1. Dalbeth N, Gow P, Jackson G, Shuker C, Te Karu L, Gerard C, Winnard D. Gout in Aotearoa New Zealand: are we going to ignore this for another 3 years? N Z Med J. 2016 Jan 29; 129(1429):10–3.
2. Bardin T, Richette P. Impact of comorbidities on gout and hyperuricaemia: an update on prevalence and treatment options. BMC Med. 2017 Jul 3; 15(1):123.
3. Perez-Ruiz F, Martínez-Indart L, Carmona L, Herrero-Beites AM, Pijoan JI, Krishnan E. Tophaceous gout and high level of hyperuricaemia are both associated with increased risk of mortality in patients with gout. Ann Rheum Dis. 2014 Jan; 73(1):177–82.
4. Health Quality & Safety Commission. Atlas of Healthcare Variation. Gout. http://www.hqsc.govt.nz/atlas/gout
5. Ministry of Health. He Korowai Oranga. New Zealand's Māori Health Strategy. http://www.health.govt.nz/our-work/populations/maori-health/he-korowai-oranga/strengthening-he-korowai-oranga/treaty-waitangi-principles
6. United Nations Declaration on the Rights of Indigenous Peoples. http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf
7. PHARMAC. Cost Resource Manual Version 2.2 October 2015. http://www.pharmac.govt.nz/assets/pfpa-v2-2-cost-resource-manual.pdf
8. Health Quality & Safety Commission. Routine analysis. Day stays (ie length of stay (LOS) = 0) count coded M10 in ICD-10 was 609. Length of stay up to 20 days was total 3392 days. LOS longer than 20 days was excluded.
9. Spencer K, Carr A, Doherty M. Patient and provider barriers to effective management of gout in general practice: a qualitative study. Ann Rheum Dis 2012 Sep; 71(9):1490–5.
10. Horsburgh S, Norris P, Becket G, Arroll B, Crampton P, Cumming J, Keown S, Herbison P. Allopurinol use in a New Zealand population: prevalence and adherence. Rheumatol Int. 2014 Jul; 34(7):963–70.
11. Ministry of Health. New Zealand Health Survey Annual Data Explorer December 2017. http://minhealthnz.shinyapps.io/nz-health-survey-2016-17-annual-data-explorer/_w_aba46903/#!/explore-indicators
12. Health Quality & Safety Commission. Primary care patient experience survey routine data collection. http://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/patient-experience/primary-care-patient-experience/
13. Doherty M, Jenkins W, Richardson H, et al. Efficacy and cost-effectiveness of nurse-led care involving education and engagement of patients and a treat-to-target urate-lowering strategy versus usual care for gout: a randomised controlled trial. Lancet. 2018 Oct 20; 392(10156):1403–1412.
14. Goldfien RD, Ng MS, Yip G, Hwe A, Jacobson A, Pressman A, Avins AL. Effectiveness of a pharmacist-based gout care management programme in a large integrated health plan: results from a pilot study. BMJ Open. 2014 Jan 10; 4(1):e003627.
15. Whitehead M. The concepts and principles of equity and health. Int J Health Serv. 1992; 22(3):429–45.