

# PROTOCOL

## **Pasifika intervention for rheumatic fever prevention in South Auckland Pasifika communities**

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**Project sponsor**

The Royal Society Te Apārangi MBIE Te Whitinga Fellowship

**Ownership of Data**

The study will be carried out under the Pacific Health Section of the University of Auckland. The University of Auckland will thereby own the study results.

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## 1. Overview

**Title:** Pasifika intervention for rheumatic fever prevention in South Auckland Pasifika communities

**Study period:** 3 years

## 2. Rationale

Rheumatic fever is an autoimmune condition that occurs in response to a Group A infection, most often in children between 5-15 years. This can manifest via a sore throat, sore and swollen joints, ongoing fevers and small lumps under the skin. While rheumatic fever is rare amongst developed countries, Pasifika youth in New Zealand experience some of the highest rates globally. Between 2017-2018, the rate of initial acute rheumatic fever hospitalisations in New Zealand among Pasifika children was 81 cases per 100,000 for Pasifika children (1). Data from 2020 shows that Counties Manukau District Health Board had the highest rate of first episode rheumatic fever hospitalisations nationally. Although there have been interventions in the past, the burden of acute rheumatic fever for Pasifika people in South Auckland continues. Through a co-designed process led by community engagement, this research project aims to develop a novel health promotion intervention to facilitate the prevention of rheumatic fever. The goal of this study is to use a co-design approach with Pasifika people to develop a possible intervention to improve the situation.

The Pacific People's Health Advisory Group (PPHAG) comprises community members from a number of Pacific ethnicities and backgrounds, ranging from young people to the retired. The group was developed after Dr Tana Fishman (then a South Auckland general practitioner) and Ms Rose Lamont (Samoan teacher) received Patient and Clinician Engagement (PaCE) training in North America (2,3). PaCE is based on the premise that community engagement in generating research questions is necessary for evidence to be translated into best practice to improve health and well-being (the principle of co-design). A Pacific Practice-Based Research Network (PPBRN) was set up through the Alliance Health Plus (AH+) Primary Health Organisation (PHO), with designated research officers for each member practice. A research officer may be a GP, nurse, practice manager or clinical administrator. Dr Ofanoa and Prof Goodyear-Smith have provided workshop training for both groups in Pasifika methodologies, and how to identify and ask relevant and important questions which might inform and change practice to benefit Pacific people. The partnership group comprising members of PPHAG, PPBRN, AH+, other PHOs and University of Auckland researchers is known as the Collective.

In previous workshops, PPHAG and PPBRN groups identified key questions that were important including improving Pacific urate lowering therapy for Pasifika people with gout, a research project which is currently underway. This protocol presents the second key research question based on addressing the rheumatic fever rates amongst the Pasifika community. This research proposal, based on participatory action research and co-design, involves a partnership of researchers and end-users (community members, patients, clinicians) collectively involved in the design, conduct and dissemination of the findings of research. Research that is "carried out with and by local people rather than on them" is an effective means of reducing health disparities (4). The collaboration extends beyond this specific project, for a long-term synergistic relationship, continuing to build on what has been learnt.

The core principles of primary care are a patient-centred equitable approach, providing services that are available, accessible, and affordable (5). Services need to be comprehensive (caring for the whole person, not just a specific disease), continuous (maintained over time), and coordinated with other services (6). We add to this that the central tenet of primary care is effective relationships. Quality care depends on good communication between providers and patients, on acknowledging connections, and on engaging in collective decision-making. An effective intervention to improve Pasifika rates of rheumatic fever and maintain use of appropriate medication needs to address all these primary care components.

### **3 Aims and Objectives**

**Aim:** Building on this knowledge, this study aims to develop a novel innovative intervention to address the rheumatic fever burden among Pasifika people in South Auckland.

**Objectives:**

1. To determine ‘how big is the problem’ by measuring the incidence of acute rheumatic fever and the prevalence of rheumatic heart disease in Pacific people compared with Māori and non-Pacific non-Māori, and how has this changed over the past five years
2. To use a co-design approach to assess ‘what Pasifika think’ (Collective members including community members, clinical staff, PHO workers and other key stakeholders such as people with rheumatic fever and their whānau) about possible approaches to addressing rheumatic fever leading to design of a novel innovative and feasible intervention for South Auckland Pasifika communities and a plan for its implementation (Phase 2). The intervention will be informed by a stocktake of current New Zealand initiatives and international systematic review of interventions addressing rheumatic fever.
3. To evaluate the implementation of the plan to see how well this intervention performs in the real world in a South Auckland context, including its feasibility and acceptability to relevant end-users (especially patients and health care providers), using an implementation science approach (Note: Phase 3 is not intended to be covered under the current ethics application).
4. To prepare an implementation framework to guide future implementation roll-out in other New Zealand settings (Phase 3)

### **4. Study design and methodology**

This is a mixed methods study using the Samoan research framework Fa’afaletui as a culturally appropriate framework for research with Pasifika participants. This approach focuses on the importance of considering different perspectives in research, including ‘people at the top of the mountain’ (for example, a national overview) ‘at the top of the tree’ (a regional perspective), who bring long- and middle-distance lenses to the issue, and the ‘man in a canoe fishing’, who is closest to the ‘school of fish’, and most affected by the problem (community members, patients, primary care clinicians).

## 5. Methods

There are three components this study. Initial ethical approval will be sought from the Auckland Health Research Ethics Committee (AHREC) for Phase 1 and 2 in 2022. Once the intervention has been designed, ethical approval will then be sought for Phase 3.

### Phase 1: Quantitative assessment of burden

Observational times series study will use routinely collected data to determine the incidence of rheumatic fever and the prevalence of rheumatic heart disease. We also wish to assess the proportion who get their prescribed penicillin injection and who receive these on a regular 28 day basis.

### *Data sources*

The secondary anonymised datasets used will be:

1. Clinical data of the de-identified enrolled patient population in Alliance Health Plus (AH+), ProCare, Tamaki Health and National Hauora Coalition.
2. National and regional DHB (Waitematā, Auckland, Counties Manukau) data from the National Minimum Dataset.

### *Primary Health Organisation data*

Routinely collected data stored by electronic health records and provided by AH, ProCare, Tamaki Health and National Hauora Coalition. AH+, for example, has a network of 40 general practices with a total of approximately 117,000 enrolled patients of all ages. The study denominator will be all people enrolled with AH+ at 1 March 2022 and the numerator is the number of people with rheumatic fever.

The following variables will be obtained for individual visit data from the PHO:

- Patient identifier - the PHO will de-identify data and apply codes to replace NHI.
- Sex
- Date of birth
- Ethnicity - prioritised
  - Total Pacific (as a binary variable – any Pacific ethnicity reported Y/N)
  - Total Tokelauan (ethnicity group Level 2; binary)
  - Total Niuean (ethnicity group Level 2; binary)
  - Total Tongan (ethnicity group Level 2; binary)
  - Total Cook Island Māori (ethnicity group Level 2; binary)
  - Total Samoan (ethnicity group Level 2; binary)
  - Total Other Pacific Peoples (ethnicity group Level 2; binary)
  - Total Pacific Peoples not further defined (ethnicity group Level 2; binary)
  - Total Fijian (ethnicity group Level 4; binary)
  - Māori (ethnicity group Level 1; binary)
  - European (ethnicity group Level 1; binary)
  - Asian (ethnicity group Level 1; binary)

- MELAA (ethnicity group Level 1; binary)
- NZ Deprivation (NZDep) index decile
- Numbers of throat and skin swabs taken
- Numbers of throat or skin swabs positive for Group A strep
- Within cases of positive Group A strep, what was the management (i.e. amoxicillin)
- All cases of acute rheumatic fever
- Date of rheumatic fever diagnoses
- Numbers and dates of prescriptions for penicillin in the period 31 March 2017 to 1 April 2022
- Numbers and dates of penicillin injections done in the period 31 March 2017 to 1 April 2022
- Hospital admission(s) with the primary diagnosis of rheumatic fever and/or rheumatic heart disease.

### *Analyses*

Data will be analysed in R. We will use descriptive epidemiology to determine the prevalence of patients with throat/skin swabs positive for Group A strep and the proportion who have a diagnosis of rheumatic fever by ethnicity (Pacific, Māori, and non-Pacific non-Māori) and gender over the past five years. We will measure the percentage of the adult population diagnosed with rheumatic fever by ethnicity (Pacific, Māori, non-Pacific non-Māori), and the proportion who have had penicillin injections, and hospitalisation for rheumatic fever or rheumatic heart disease. We will conduct sub-group analyses by age, gender and New Zealand Deprivation Index quintile (NZDep) and time series to determine trends.

The study population will be described according to gender, age, ethnicity, NZDep decile and whether they have a primary care-coded diagnosis of rheumatic fever. Continuous variables (age) will be summarised as means with standard deviations and medians with interquartile ranges, and categorical data (sex, ethnicity, NZDep decile and rheumatic fever) as frequencies and percentages.

The proportion of participants with rheumatic fever diagnoses will be compared by ethnicity, for sex and 10-year age groups. Among participants with rheumatic fever, the proportion who were prescribed and who received penicillin injections will be compared by ethnicity, for sex and 10-year age groups. Differences in proportions between ethnic groups will be assessed using a generalised mixed methods model with binomial or Poisson distribution.

### *Data transfer and storage*

Deidentified data from AH+ and other participating PHOs will be transferred using the University's secure, electronic, web drop where possible, or via an encrypted USB memory stick as a backup. All data will be stored on a password-protected University of Auckland drive.



## *Phase 2: Designing the intervention and developing the implementation plan*

### *Summary of the existing initiatives*

A stocktake of Aotearoa New Zealand rheumatic programmes and interventions, including those not published in the peer reviewed published literature, will be conducted. These will include the Rheumatic Fever Prevention Programme conducted by the Ministry of Health, Mana Kidz lead by Counties Manukau District Health Board and rheumatic fever awareness promotion undertaken by AH+. A concise, user-friendly summary of the types of complex interventions identified by the systematic review and the national stocktake will be produced to inform key stakeholders on what has already been tried, and what has been shown to be effective in different contexts. This will include visual representations, for example in PowerPoint presentations, posters, videos and/or storyboards.

### *Qualitative enquiry*

The intervention will be designed through qualitative enquiry using nominal group technique where possible to ensure all voices are heard. At the beginning of the first workshop, the participants will be informed about existing interventions and their degree of success, using the summary materials outlined above. A series of workshops will be conducted with Collective members and other key Pacific stakeholders and community representatives to explore their views on interventions currently available, their perceived barriers to Pacific people receiving appropriate treatment, and to brainstorm innovative alternatives. The final intervention will be designed through workshopping with the Collective.

### *Sampling*

Participants will be the current partners in the Collective (PPHAG, PPBRN and AH+) plus other identified key stakeholders attending the design workshops.

- *Pacific People's Health Advisory Group (PPHAG)*: This group comprises male and female community members aged in their 20s to their 70s, of mixed Pacific ethnicities (Samoan, Tongan, Niuean) with a range of occupations including nursing student, teacher, social worker, broadcaster and retiree. All PPHAG members will be invited to participate in the workshops and the project is open to their inviting others they judge can add value to the workshops.
- *Pacific Practice-Based Research Network (PPBRN)*: All PBRN research officers (who include general practitioners, nurses, and receptionists depending on the practice) from South Auckland practices in the Network will be invited to participate in the workshop/s. The research officers will be asked to extend the invitation to other practice staff members to participate, should they wish to do so.
- *Alliance Health Plus (AH+)* The clinical director, the nurse lead and any other AH+ relevant staff will participate in the workshops.

- *Other relevant stakeholders:* Invitations to participate will be extended to other relevant stakeholders such as community pharmacists, community members and/or others identified during the course of the design phase.

All participants will receive the Participant Information Sheet and sign written consent forms prior to the onset of the workshop. Demographic details of participants (age, ethnicity, gender, and membership of co-design groups) will be collected. Workshops will take place either in-person or via virtual means such as zoom, depending on availability, preferences, and COVID-19 restrictions. Results may be collected on paper and through photographs of whiteboard workings etc. No individual contributors to the collective decision-making will be identified.

### *Conducting the workshops*

The workshops will take place in-person if at all possible, at Alliance Health Plus or another suitable South Auckland venue. Workshops will be held on Saturdays or at other agreed times to best accommodate working people. Lunch and other refreshments will be provided. Pacific participants will be engaged using appropriate cultural processes and protocols. Talanga (interactive talk with a purpose) will be used to ensure two-way dialogue takes place when communicating with Pacific people. The large group will separate into smaller working groups each facilitated by a Pacific member of the research team, and then report back to the whole group. PPHAG members will receive koha (\$100 supermarket voucher) in recognition of their time.

### *Theoretical frameworks and analyses*

The luva approach (presentation to others), as exemplified in the Kakala research framework will be used to feedback the synthesised material to the collective group at a subsequent workshop. The novel intervention will be informed based on the Pasifika peoples' holistic view of health as in the Fonofale model. This model addresses social, physical, mental and spiritual well-being, grounded by family, and overlaid by the Pacific cultural values of connectedness and collaboration, to create an innovative approach feasible to implement within South Auckland Pacific communities.

The data collected from the workshops s will be collated and synthesised. Key themes may be identified and analysed in NVivo software using a general inductive approach. Suggested interventions and intervention components may be discussed with advisors and other key experts.

### *Design of the intervention*

Once an intervention has been drafted, the Collective will collectively refine it through workshopping and other digital communications with key stakeholders into a strategy that can be implemented in South Auckland. Factors to be addressed in the intervention include what components it entails (e.g., health promotion, education, prescribing, access to healthcare, patient reminders, family/whanau involvement), who leads it (e.g., doctor, nurse, pharmacist, team, community-led), and where it takes place (e.g., health premises, community location) and any possible digital modes of delivery (e.g., app, txt messages). See Appendix A for a list of the questions to be asked at the workshop.

### *Implementation plan*

A framework to map the intervention implementation will be developed. A logic model of change (a graphic representation of the relationship between the intervention, the mechanisms of change, and behavioural and health outcomes – see Figure 1), will be created using an intervention mapping framework (7). The logic model will define the inputs (resources, investment needed to implement intervention); key activities (tasks needed to successfully implement the intervention); outputs (measures to be made to demonstrate that the activities have been undertaken), and short-term outcomes (changes which are expected to result).

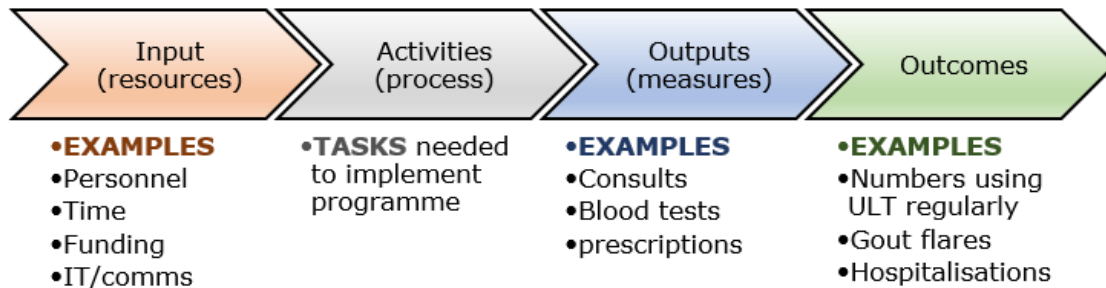


Figure 1: Logic Model of Change

### *Phase 3: Evaluation of the intervention implementation*

Precise details of the evaluation will depend on the nature of the novel intervention and its characteristics.

#### *Study approach*

This phase will use an implementation science approach, which is a systematic study of the activities that facilitate the successful uptake of an evidence-based health intervention, in this case a strategy and programme to improve rheumatic fever rates amongst Pasifika in South Auckland. The design of the evaluation of the intervention implementation will be underpinned by a theoretical framework and informed by behavioural change theory, whereby a person's attitudes, personal or subjective norms, and their perceived behaviour controls (not doing what they think is wrong) shape an individual's behavioural intentions, and hence their actual behaviours (Figure 2) (8).

Evaluation will focus on:

1. *Process*: How components of the strategy are delivered or adapted, and how much they conform to the intended intervention components and principles. This includes acceptability and feasibility of intervention delivery.
2. *Mediators of change*: Whether these components reduce perceived barriers, or enhance perceived enablers.
3. *Outcomes*: How well the intervention assists Pasifika people towards preventing rheumatic fever.

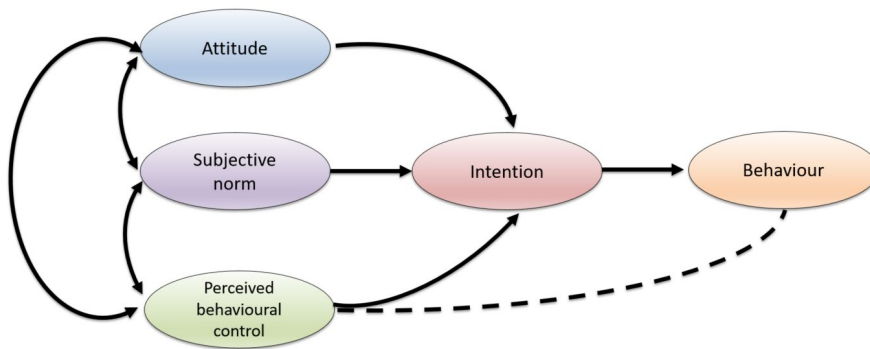


Figure 2: Theory of planned behaviour

### Data collection

1. Process data: Measures will assess the feasibility of the implementation of the intervention including mechanisms to promote its use to Pasifika families affected by rheumatic fever, its acceptability, and any enablers and barriers to its use. Patients will be invited to undertake in-depth interviews on their experience of rheumatic fever and its management; whether they used the intervention and the enablers and barriers they identify. Family members will may also undergo interviewing. The Fonofale model will be used, exploring how well the intervention met patients' physical, mental, spiritual, social, family and cultural needs. Acceptability and feasibility data will be sought from personnel involved in providing the intervention. This may be in the form of survey responses (e.g., Likert scale, free text, or both); individual interviewing by phone or zoom, or through focus groups, depending on circumstances and participant preferences.
2. Mediators of change: Potential data collected include numbers and frequency of intervention delivery, its duration, costings, events that facilitated or impeded its delivery, and other factors dependent on the nature of the intervention. Adaption to real-world circumstances requires a cyclical rather than a liner approach. Iterative changes to the programme delivery may be made in response to feedback and process data analyses during the evaluation period, to improve systematic uptake of the intervention.
3. Outcomes: Both qualitative and quantitative data, including experiences of the intervention and how it potentially impacts rheumatic fever rates will be utilised.

### Analyses

Analyses will be guided by an evaluation framework such as RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance – Figure 3) (9). Translation of knowledge into practice requires engagement of all relevant stakeholders, behavioural change, and a flexibility of approach to adapt to real-world contexts. We will evaluate the influences on patient, healthcare professional, and organisational behaviours in the intervention setting to assess whether it can successfully reverse the evidence-practice gap. While the logic model and plan are presented as step-wise and linear, in reality implementation of a

complex intervention requires an iterative co-design process, with audits of various components leading to cyclical changes and then being reassessed in a series of feedback loops, and end-users (patients and providers) engaged throughout the process.

### Implementation framework

Finally a framework will be produced based on the Consolidated Framework for Implementation Research model (Figure 4), which may serve as a guide to extend the implementation to other settings, tailoring the processes and outputs to different contexts (10). This Framework provides a menu of constructs arranged across five domains (intervention characteristics, outer setting, inner setting, individual characteristics and process) that can provide a practical guide for systematically assessing potential barriers and facilitators, in preparation for implementing an innovation in a particular setting. This will serve as a guide for adaption and implementation of the intervention in other settings.

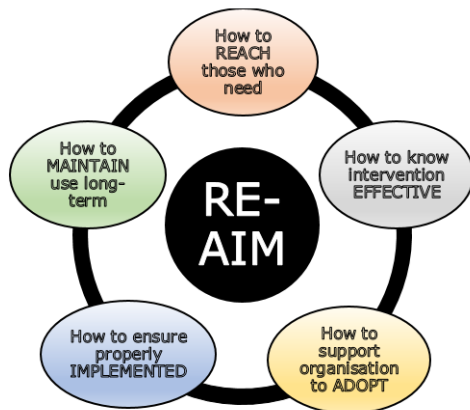


Figure 3 RE-AIM

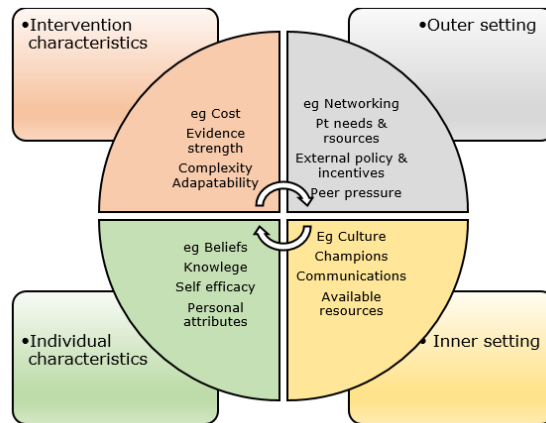


Figure 4 Consolidated Framework for Implementation Research

## 7 Dissemination of Results

The results of this study will be disseminated via many platforms. Firstly, study participants may wish to receive the findings. Hence, a brief summary will be sent to them via email or other relevant methods. Second, the findings will be presented at national and international conferences and will be published in academic journals.

## 9 Research impact - benefits of this research

This study aims to enhance health and wellbeing for Pasifika in New Zealand, contribute to the creation of Pacific health knowledge and the translation of research findings into Pacific health gains. The aim is to design a novel, innovative and feasible health promotion intervention for Pacific patients in South Auckland to facilitate prevention of Streptococcus A infection progression to rheumatic heart disease, and hence reduce morbidity and mortality in Pasifika. An intervention tailored and targeted for Pacific people will help to reduce health disparities. Potential longer-term impacts could include the use of this

initiative throughout Aotearoa. Although the study focuses on Pasifika, Māori face similar challenges, and innovative interventions may translate to Māori health care.

The project will contribute to Pacific capacity and capability research gains in NZ, with an early career Pasifika researcher as the principal investigator and supported by Pasifika co-investigators and clinical experts. This project will also enable the general upskilling of the community, practice and PHO members involved in the co-design process. Overall, this project aims to improve health outcomes using a ‘by Pacific, for Pacific’ approach.

*Approved by the Auckland Health Research Ethics Committee on 21/03/2022 for three years. Reference number 23838.*

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## Appendix A workshop questions / topics for discussion

Background information and existing interventions to address rheumatic fever will be presented and discussed in a summarised, easy-to-understand format e.g., PowerPoint, videos, storyboard.

Following this presentation workshop participants will discuss the following prompts in a collaborative, focus group setting:

1. Considering what we have just discussed, at what point of the disease progression do you think our intervention should be targeted for our Pasifika community?
  - a. Prompts: Prevention (via detection and treatment of sore throats), management of rheumatic fever (e.g. receiving regular penicillin), treatment of rheumatic heart disease.
2. Regarding Pasifika families understanding the signs and symptoms of rheumatic fever:
  - a. What do you see as the barriers to this?
  - b. What might help with this?
3. Regarding Pasifika families accessing appropriate health care for rheumatic fever cases:
  - a. What do you see as the barriers to this?
  - b. What might help with this?
4. Regarding Pasifika people getting their prescription for antibiotics dispensed (getting their medications) and taking this medication when required on an ongoing basis:
  - a. What do you see as the barriers to this?
  - b. What might help with this?
5. Considering the barriers and opportunities we have discussed, what can you think of that might work that has not yet been tried?
6. Where might this take place? Prompts: hospital, health centre, pharmacy, workplace, church, home, etc
7. Who might lead this intervention? Prompts: nurse, pharmacist, community worker, lay person, GP etc
8. Who else might be part of the team?
9. Who is this intervention for?
10. How will we know if it is working?

Responses will be synthesised and refined by the research team and fed back to participants over several workshop cycles.