

Development of a parental information pamphlet for rheumatic heart disease echocardiography screening

Focus group testing - key findings

CBG Health Research - August 2016



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EXECUTIVE SUMMARY

A focus group workshop was completed to qualitatively assess the Rheumatic Heart Disease screening material.

Overall, the group were happy with the question style approach and section layout.

The group advised less literate people would struggle to read the material. A literacy assessment (Appendix 1) supports the finding. To bring the material within the recommended skill levels, we suggest revising it to:

- Increase the use of plain and simple language
- Remove acronyms and technical terms
- Replace with layman words
- Increase the use of personal language; “you” and “your”

Overall participants suggested the material requires mitigation of the doubts raised and increased assurance about the necessity for, and outcomes from, the screening.

Tables of participant suggestions are provided throughout the report.

METHOD

Introduction

This report provides the findings from the qualitative assessment of the ECHO RHD screening information pamphlet. The research comprised a focus group workshop. The assessment is detailed in the attached discussions guide (Appendix 2).

Sample

The group comprised of eight parents of children likely to be targeted by RHD screening. Parents identified as Māori (4), Samoan (1), Tongan (1), Fijian (1) and European New Zealander (1). They had children aged 2-17, the majority in the range of 2-10 years' range.

Recruitment

Participants were personally recruited via CBG surveying networks. They were provided with the participant's information sheet and consent form (Appendix 3). Participants signed and returned the form before taking part in the workshop.

The day before the workshop, recruiters confirmed the participant's availability and commitment to attend. A reminder call was made on the day. Participants received a koha to reimburse for their time, as well as travel and childcare costs.

The Workshop

The workshop took place on Saturday 20 August in a private location, accessible to all the participants. It lasted 2 hours with a 10-minute refreshment break.

The facilitator used the discussion guide to direct the group in assessing the material. To begin, participants were asked to indicate willingness to take part in the screening without having seen the pamphlet (Appendix 4). Participants were then invited to read the material and share first impressions. The group then worked to review and discuss each section. Finally, participants were invited to indicate their willingness to take part in light of the material.

FINDINGS

Pre-pamphlet

Participants indicated they would be happy for their child to undergo the proposed test because it is non-invasive, painless and free. One participant expected the scan would not always be accurate. Accordingly, they considered it might misdiagnose a few children. Parents of younger children were concerned to understand the nature of the test and where it would be completed. They expected some might be unwilling to participate if scans are completed at school, rather than in a medical environment.

“Yes to a painless, not invasive free check of her heart.”

First Impressions: Layout, Readability & Cultural Appropriateness

The ‘question posed’ style was admired. Equally participants found the section layout helpful as a comprehension aid. The participants deemed the material readable but they felt it would not be readable by everyone. It was assumed that it will be made available in different languages.

Participants did not identify anything culturally inappropriate. However, they judged some Pacific and/or less literate people would struggle with the number of words and sentence structure. A lack of pictures and the literacy level demanded by the material underpinned the judgement. With this finding in mind, we asked one of our researchers to evaluate the literacy level required to understand the material. The results are provided in Appendix 1.

Layout liked

“The answering question style is good. Nice way to approach it. Sections split it down so it’s more readable”

“My husband and his siblings (Tongan) would struggle to read this. English is their second language. They can read but not stuff like this. Pictures would be helpful”

Literacy may be of issue

“Literacy is not great for some of us and I think you need to be able to read at a good level to read this.”
(Māori)

On first reading, participants were left with questions about the test:

“How does this link with sore throat – this is how children get rheumatic fever or that’s what we are being told but it does not say that?”

“Only 1% have the disease. Is this trying to look for a needle in a haystack? I am confused, sorry”

“Mixed vibes. Let’s do this. Ah let’s not. I am not sure. What do you think? They are kind of saying this scan is not going to work anyway and is it actually needed; the disease is difficult to detect. Or have I got it wrong?”

"I am left thinking they are saying it is kind of not worth it. What is an ECHO. It does not say?"

"The child could be misdiagnosed but then so what. It really hit me. How many times would this test fail? When would you find out? What happens if they are treated with antibiotics?"

"It tells us the scan probably will not work and even if it does, it is not really required because the detection is low. 1% and they might miss them if it's not accurate?"

What are the Benefits, Harms and Uncertainties?

Participants identified the title question comprises two negatives to one positive word. For some, this set a negative tone. The group shared that overall the tone of the material seems to be one of doubt about the value of the screen.

Doubt results from a combination of the following impressions:

Forty percent with the rheumatic fever are missed

Only 1% actually get rheumatic heart disease

Rheumatic fever is a problem of the past (45% drop in rates)

Diagnosis is difficult (Only 1% found, coupled with the statement that diagnosis is not straightforward)

This scan is likely to misdiagnose (the absence of misdiagnosis rate informed ideas of 'likely' because if it is low, it would be stated)

If the diagnosis is borderline, there is no available treatment

Respondent Suggestions to Improve First Impressions

To lower doubt and increase certainty about the value of the screen, consider:

Screening for rheumatic heart disease (RHD): What are the benefits, harms and uncertainties?

What is RHD?

- Rheumatic heart disease (RHD) is a potentially serious heart problem affecting your heart valves.
- The seriousness of this problem ranges from mild symptoms that do not cause problems during your lifetime, through to very severe disease that requires heart surgery and sometimes causes heart failure and death.

Why screen for RHD?

- RHD only occurs if someone has had rheumatic fever in the past. The problem is many with undiagnosed RHD don't know they have had rheumatic fever.
- People who have had rheumatic fever in the past are more likely to have it again, and each episode can cause more damage to the heart.
- Screening aims to detect early damage to the heart so that people can be given antibiotic treatment to reduce their risk of future attacks of rheumatic fever.
- This sounds like a good idea – but it's important to understand that every screening test has benefits, harms, and uncertainties.

What are the potential benefits?

The main benefit of RHD screening is that it may help to prevent RHD from getting worse.

If someone with definite RHD gets rheumatic fever again, it can make their RHD worse. The main reason for RHD screening is to reduce the chance that these people will get rheumatic fever again – mainly by finding undiagnosed disease and prescribing monthly antibiotic injections.

Everyone who has RHD must have had rheumatic fever at some point in their life. However, 40% of those admitted to hospital with RHD do not have a medical history of rheumatic fever.

This means that these people did not receive the usual clinical care given to those who are diagnosed with rheumatic fever, which may have helped stop their condition from becoming worse. Screening may help find these patients.

40% of patients hospitalised for RHD were never diagnosed with rheumatic fever.

You will be provided with more information about the test itself and what may happen afterwards by those who are running the screening test.

- Stating that the screen is a necessary heart check for children to find any signs of RHD.
- If it is advisable to convey that RHD is rare then explain this in the context of why the screen is required.
- Removing the advice that diagnosis is not straightforward. Rather provide treatment paths associated with different outcomes.
- If possible, provide the expected rate of misdiagnosis. If this is not possible, explain why and detail how the rate will be monitored.
- Advise this is a new but worthwhile trial, but provide assurance that the scan is tried and tested. Detail that it offers a non-invasive, quick and painless means of detecting heart problems.
- Removing the 'No treatment' advice for borderline cases to allow the monitoring to be seen as treatment.

To improve look and readability of the material, consider:

Adding pictures that provide real life connections to the messages, ideas included:

- RHD boy from the HPA advertisements
- ECHO machine
- Children being scanned or treated

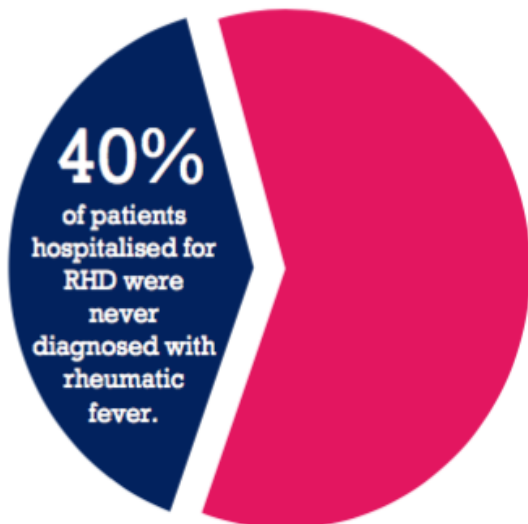
Reducing the number of words and simplify the sentences.

Using a fold out pamphlet to:

- Help the sections be more discrete
- Allow the reader to concentrate on one part of the information without the distraction of other sections
- Aid navigation and flow of the material
- Encourage retention of the material on the fridge or in a bag



Screening Benefits



Participants understood the main benefit to be identifying rheumatic heart disease in its early stages.

The 40% undiagnosed was taken to mean that a lot of rheumatic fever cases are missed, so RHD can result. This was cited as the key reason for the screen. Adding the words 'a lot' to the message was recommended, as below:

"It would be good to say, a lot of people who have rheumatic heart disease did not know they had ever had rheumatic fever. Some struggle with statistics"

The Pacific representatives associated the icon opposite with cutting cake which they deemed distracting from the message

Participants' suggestions to improve the 'What is RHD' panel:

What is RHD?

- Rheumatic heart disease (RHD) is a potentially serious heart problem affecting your heart valves.
- The seriousness of this problem ranges from mild symptoms that do not cause problems during your lifetime, through to very severe disease that requires heart surgery and sometime causes heart failure and death.

Opening with the advice that:

"Rheumatic Heart Disease is caused by Rheumatic Fever"

Continuing with points that position the screen as an address for a serious problem:

- In some cases, RHD is serious
- It can result in surgery or be fatal
- The scan will find early signs of the disease
- We can then try to stop further heart damage

Participants suggestions to improve the "Why Screen" panel:

Why 'screen' for RHD?

- RHD only occurs if someone has had rheumatic fever in the past. The problem is many with undiagnosed RHD don't know they have had rheumatic fever.
- People who have had rheumatic fever in the past are more likely to have it again, and each episode can cause more damage to the heart.
- Screening aims to detect early damage to the heart so that people can be given antibiotic treatment to reduce their risk of future attacks of rheumatic fever.
- This sounds like a good idea – but it's important to understand that every screening test has benefits, harms, and uncertainties.

Participants worked together to compile a layman story that links rheumatic fever with RHD with prevention of further heart problems.

- Rheumatic heart disease only happens in people who have had rheumatic fever
- Many people do not know they have had the fever because it was just a 'sore throat'
- So heart damage can happen without a person ever knowing
- Those who have had rheumatic fever can get it again
- Each attack can cause more heart damage
- The scan checks for any signs of RHD damage
- If there are signs, antibiotics can prevent rheumatic fever happening again
- This will help prevent any further heart damage.

“Sounds like a good idea but...”

Participants agreed that having engaged the reader in the notion of the scan as a means of detecting heart damage, this bullet point then undermines the engagement. The group were united in recommending it is removed.

“It takes away what has just been said. Sort of having said all that, well we are not really sure.”

“Sounds good in theory but... now let’s discuss. A muddy let’s do it, ah maybe not uncertainty plant.”

“I found it confusing in you are making an offer and now your deciding it is not certain about it.”

Screening Harm

The group identified the main harm is misdiagnosis leading to unnecessary antibiotic treatment. Some felt this would deter people from taking part. The group requested more information on rates of misdiagnosis and details of:

- How diagnosis will be checked
- Frequency of repeat scans or follow up
- The stage at which a wrong diagnosis will be apparent
- Risks associated with long-term use of antibiotics

Respondents questioned the necessity to state that the diagnosis will cause worry as it is a given. They were also united in the view that the impact will be different for everyone. It will not always comprise the imposition of physical limitations. Accordingly, they advised it is better to say wrongly labelling a child may affect how they choose to live.

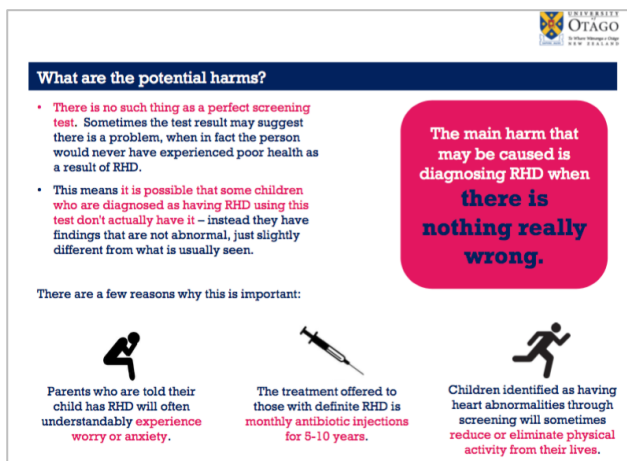
“At what stage would they find out it is wrong. What is the harm from the 5-10 years of antibiotics and how many children are we talking about?”

“No one knows how it will affect. What about the kid that does nothing and the parents decide they need to walk to strengthen? Or change their diet, or sleep more or take more vitamins or see the doctor more”

Most participants felt it unnecessary to state there is no perfect screening because it is known. Some disagreed as it may not be known to everyone. However, the group concluded it is not necessary to state because it is evident in the advice that wrong diagnosis may happen.

“We all know there is no perfect screening”

“We do but some parents might not. It is enough to say there will be wrong labelling without saying there is no perfect screening.”



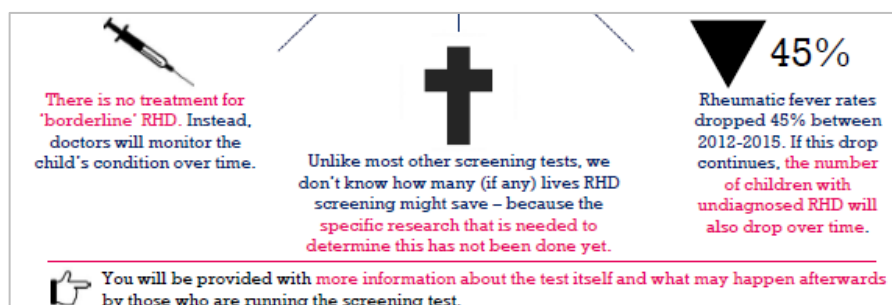
The icons were disliked for one or more of the following reasons:

- Needles align with pain and parents do not want to expose a child to pain
- The 'worry' icon looks like a person on the toilet
- The running man is heading off the page signalling 'get out of here'
- They lack visual appeal
- Perceived as comical distraction from otherwise serious considerations.

Uncertainties

Participants advised the section should precede the harm of misdiagnosis. The icons were disliked. In particular, Pacific representatives advised the cross signals death. As previously discussed respondents questioned the value of providing:

- Prevalence of RHD with respect to the necessity for this screen
- Picture of RHD as a diminishing problem
- Advice there is no treatment for borderline cases



The advice about 'more information' was missed and participants requested detail about the test and follow up. They deemed this necessary to help mitigate fears about the necessity for the test, misdiagnosis and unnecessary treatment.

"What this is and what happens is vital when you are faced with a scan that may not work and unnecessary treatment. To be honest with the 1%, the 45% drop, what are you exposing your child too?"

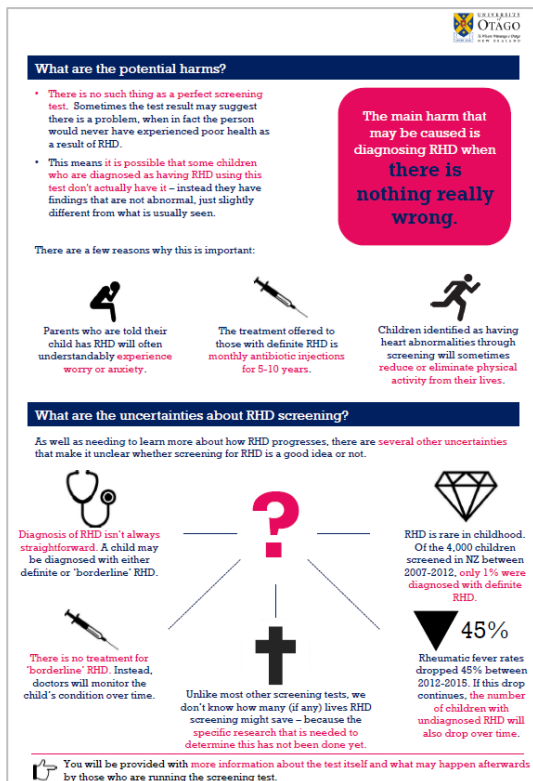
Overall the harms and uncertainty, coupled with the “sounds like a good idea but...” notion; left participants questioning the value of the test:

“The negative reasons not to, we don’t know messages. Overall there is more doubt than certainty. More reasons to not do this, than to do it.”

“It has to use more positives, install confidence, especially for something new.”

“I no longer think this is worthwhile because of that 1% and my child may be misdiagnosed anyhow. It fails to mention that it’s painless, non-invasive or free.”

Participants suggestions to improve the ‘Harm’ and ‘Uncertainty’ panels, consider:



Removing the ‘There is no perfect screening’ advice
And limit the advice of potential harm to:

- There is a risk the test may wrongly diagnose some children
- This could affect how they choose to live

As previously discussed if possible:

- Provide the expected rate of misdiagnosis and/or advice on how it will be monitored and mitigated
- Remove the icons and replace with pictures of children being scanned or treated
- Remove the prevalence and incidence advice or explain of how it fits with the proposed test

Compiling the statistical information into one table.

Post-pamphlet

The participants found it useful to learn that:

- Rheumatic heart disease is exclusively associated with rheumatic fever
- Many children have rheumatic fever and do not receive a diagnosis
- Antibiotics can prevent heart disease

The main screening benefit was understood to be checking the heart state of children who have had rheumatic fever but were not diagnosed. The group understood treatment would then follow to reduce the potential of future heart problems. Screening costs were identified as:

Cost of 'finding a needle in a haystack' in light of prevalence and reduced incident information.	Treatment costs associated with misdiagnosis, in terms of tax payer dollars and the health and well-being of the children concerned
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Having read the material, half of the participants (Tongan, Samoan and Māori) would take part in the screening. These participants indicated family history of heart issues and one participant had a child who had tested positive for strep throat. The remainder (Māori, Fijian, European) stated they would no longer take part for one or more of the reasons:

Potential of misdiagnosis occurring at an unknown rate.	Test seems unnecessary because low occurrence and detection rates of the disease coupled with the potential for misdiagnosis.
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The pamphlet itself seems uncertain about the value of the test	Absence of information about: <ul style="list-style-type: none">• The screen – 'What is an ECHO?'• Screening follow up – 'How often would the screen be repeated?'• What happens if a child receives antibiotics that are not necessary?• When, if at all, would misdiagnosis be evident?• The rate of false positives?
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The group who declined to take part sought more assurance about:

- Reliability of the test
- Nature of the screen and the frequency of follow-up scans
- Expected detection rates/correct capture versus incorrect capture
- Impact of receiving unnecessary antibiotics
- Detail of when (if ever) it would be become apparent that misdiagnosis had occurred

It is important to note the participants scrutinised the material in more depth than the average reader. However, the first impressions are aligned to a typical reader and many of the initial views are apparent in the section feedback.

APPENDIX

Appendix 1 – Literacy Assessment

Tests and Outcome

The tests employed to assess the literacy skills required to read the material are provided in the table below. They measure the number of words in each sentence and the number of syllables in each word, to identify the reading age and education level. The RHD findings are provided in the last column of the table.

Test name	The scale/measurement	RHD score and meaning
Flesch Reading Ease	1-100 (100 is easiest) Recommended 60-70	55.1 (<i>Fairly difficult to read</i>)
Flesch-Kincaid Grade Level	School level /reading age Recommended 7-8	9.6 (<i>Comprehension is secondary school level</i>)
SMOG ¹	Number of education years required to read the material	9.3 (<i>As above</i>)
Conclusion	The reading age and skill level required is secondary education level. The results are above the recommended levels for each test.	

Flesch Reading Ease score table

Score	School Level	Notes
90.0–100.0	5th grade	Very easy to read. Easily understood by an average 11-year-old student.
80.0–90.0	6th grade	Easy to read. Conversational English for consumers.
70.0–80.0	7th grade	Fairly easy to read.
60.0–70.0	8th & 9th grade	Plain English. Easily understood by 13- to 15-year-old students.
50.0–60.0	10th to 12th grade	Fairly difficult to read.
30.0–50.0	college	Difficult to read.
0.0–30.0	college graduate	Very difficult to read. Best understood by university graduates.

¹ Simple Measure of Gobbledygook (SMOG) estimates the years of education required to understand the material.

New Zealand Health Literacy

Health literacy includes the ability to read health information in order to make informed decisions. It can be measured using a scale from 1 to 500, where 1 is the lowest literacy and 500 is the highest.

In 2010, the Ministry of Health, relying on 2006 New Zealand literacy data, identified 56% of New Zealand adults have literacy at a 1-2 level, scoring less than 275². Māori and Pacific people were overrepresented in this category.

The complexity of the RHD material, identified as secondary school level and fairly difficult, correlates with a health literacy level of 3-4. With the Ministry of Health findings in 2010 and notwithstanding Māori and Pacific will be over represented in the RHD target audience, we expect more than 56% of readers could struggle with the material.

Health Literacy Table

Level	Description
Level 1: score 0–225	Very poor literacy skills People at this level may, for example, be unable to determine from a package label the correct amount of medicine to give a child.
Level 2: score 226–275	A capacity to deal only with simple, clear material involving uncomplicated tasks People at this level may develop everyday coping skills, but their poor literacy makes it hard to conquer challenges such as learning new job skills.
Level 3: score 276–325	Adequate to cope with the demands of everyday life and work in an advanced society This roughly denotes the skill level required for successful secondary school completion and into tertiary education entry.
Level 4: score 326–375 and level 5: score 376–500	Strong skills An individual at these levels can process information of a complex and demanding nature.

Conclusion

To bring the material within the recommended skill levels, consider revising it to:

- Increase the use of plain and simple language
- Remove acronyms and technical terms (replacing them with layman words)
- Increase the use of personal language, e.g. 'you' and 'your'

² Ministry of Health report, Kōrero Mārama (February 2010)

Appendix 2 – Focus Group Discussion Guide

Thanks & Introductions	We are here to provide feedback on this information pamphlet.
Pre-pamphlet understanding of RHD screening	<p>Questions to be asked BEFORE pamphlet is given:</p> <p>Your (healthy) child has brought a letter home from school, asking for your consent to allow them to undergo a painless chest scan to look for underlying heart problems. The test is free.</p> <ul style="list-style-type: none"> • Would you be happy for your child to undergo this test? • Can you foresee any problems with having this test done?

Hand Out Pamphlets & Invite Participants to read it.	
First Impressions	Probes (if not covered)
	Look/Appeal
	Ease of reading
	Understandable
	Concise
	Other comments
	Layout
	Level of detail
	Factual
	Culturally appropriate
	Suggestions

What is the pamphlet talking about?	
The benefits of screening?	Probes (if not covered)
	What will readers understand the benefits to be?
	Does the information provide understanding of the possibility of improved health outcomes via early diagnosis?
	How (if at all) could this information attract people to screening?
	Any improvements?
The harms of screening	What will readers understand the harm to be?
	Does the information provide understanding of:
	<ul style="list-style-type: none"> • unnecessary diagnosis? • likelihood of anxiety? • possible changes in physical activity? • the fact that the screening will not just test for RHD?
	How (if at all) could this information deter people from screening?
	Any improvements?
Uncertainties around screening	What will readers understand about uncertainties?
	Does the information provide understanding of:
	<ul style="list-style-type: none"> • uncertainty around diagnosis? • the lack of treatment for borderline RHD? • that RHD is a rare disease, and that rates of RF appear to be reducing?
	How will people receive this information?
	How (if at all) could this information deter people from screening?
Post-pamphlet	Questions to be asked AFTER pamphlet is given:

understanding of RHD screening	<p>What are some of the benefits of RHD screening?</p> <p>What are some of the 'costs' of RHD screening?</p> <p>Knowing what you know now, would you still be happy for your child to undergo echo screening for RHD?</p> <p>What extra information would you want to receive before allowing your child to undergo RHD screening?</p> <p>Did you find the learning material useful?</p> <p>What did you find most useful?</p>
Last Impressions	Other comments/suggestions
Thank & Close	

Appendix 3 – Participant Information Sheet and Consent Form

Participant Information Sheet

Study title: ***Development of a parental information pamphlet for rheumatic heart disease echocardiography screening***

Locality: **University of Otago, Wellington** Ethics committee: **University of Otago Human Ethics Committee**

Lead investigator: **Dr Jason Gurney** Contact phone number: **(021) 279 3597**

You are invited to take part in a study to help develop an information pamphlet for parents of children having heart screening. Whether or not you take part in the study is your choice. Please read this information sheet carefully before deciding to take part.

If you agree to take part, you will be asked to sign the Consent Form on the last page of this document and attend a Focus Group discussion. You will be given a copy of both this Participant Information Sheet and the Consent Form to keep. On pages 2 and 3, there is a list of people you can get in touch with if you have any questions, concerns or complaints about the study.

WHAT IS THE PURPOSE OF THE STUDY?

What is the aim of the study?

The study aims to design a one-page pamphlet for parents of children undergoing heart screening for rheumatic heart disease. The pamphlet aims to inform parents about the benefits, harms and uncertainties around rheumatic heart disease screening.

Who is running this study?

This study is part of a wider study called 'Safety of Screening for Rheumatic Heart Disease' and is being jointly led by Professor Diana Sarfati and Dr Jason Gurney at the University of Otago, Wellington. This study has received Otago University Level B ethical approval from the Department of Public Health, Wellington.

Who is funding this study?

This project is part of a wider Health Research Council (HRC) project (reference # HRC 13/965), jointly funded by the Heart Foundation, Cure Kids, the HRC, Te Puni Kokiri and the Ministry of Health.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Why have I been asked?

We are asking parents or caregivers of children from a mixture of Māori, Pacific Island and New Zealand European families to join our study, since it is these populations that have been the target of RHD screening in the past.

What does the study involve?

Taking part in this study involves joining in a **focus group discussion**, which will be run by trained researchers from a company called CBG Health Research Limited. The focus group will include around **7 other parents** and should last about **1-2 hours**. We will ask you questions

about heart screening, as well as questions about our draft pamphlet which we will give to you during the focus group discussion. When the focus group is over, you will not be asked to do anything else for this study.

What happens if I agree to be in the study?

The research team from CBG Health Research will organise the focus group discussion, including the time and place where it will take part. We will offer you a koha to cover your costs of travel and/or childcare. Before the focus group discussion begins, you will be able to ask any questions you (or your family) may have about the study before you sign the consent form. The researchers from CBG Health Research will **take notes** of the focus group discussion. The researchers will ensure everybody in the group gets time to talk. We will use the results of the focus group discussion to revise the pamphlet.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We would like to improve the knowledge of parents of children taking part in heart screening in the future. We hope to ensure that parents are able to make an informed choice regarding their child's participation in screening and understand the risks and benefits involved. We do not believe that there are any risks for you in taking part.

WHAT ARE MY RIGHTS? WHAT IF I CHANGE MY MIND?

Whether or not you take part in this study is your choice. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out at any time during the data collection phase. If you would like to pull out, please contact the Study Manager.

Your privacy will be respected both during and after the study. Given the nature of focus groups, confidentiality of discussion within the focus group cannot be guaranteed but your name and contact details will be kept private within the study team, and we will never share any information which could be used to identify you with anyone outside the study team.

WHAT HAPPENS AFTER THE STUDY?

At the end of the study (November 2016), all information which could be used to identify you will be permanently deleted. The data collected during the study will be stored in a secure password-protected University of Otago computer.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

This study has been approved by the Department of Public Health, University of Otago, Wellington, as stated above. If you have any concerns about the ethical conduct of the research, you may contact the University of Otago Human Ethics Committee through the Human Ethics Committee Administrator (ph +64-3-479-8256 or gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.

If you have any other **questions, concerns or complaints** about the study at any stage, you can contact either:

Dr Jason Gurney (Study Manager)

Ph: (021) 279 3597

Email: jason.gurney@otago.ac.nz

Professor Diana Sarfati

Ph: (04) 918 6042

Email: diana.sarfati@otago.ac.nz

If you want to talk to **someone who isn't involved with the study**, you can contact an independent health and disability advocate on:

Ph: 0800 555 050 Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

For **Maori health support**, please contact the Study Manager who will direct you further.

Consent Form

Please tick to show that you consent to the following:

I have read the Participant Information Sheet, or have had it read to me in my first language, and I understand it.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I have been given enough time to think about whether I want to take part in this study, and also to discuss the study with whomever I needed to (e.g. whānau, legal representative).	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I understand that taking part in this study is my choice, and that I can withdraw at any time up until the end of the data collection phase. If I want to withdraw from the study after this time, I agree that my focus group data can still be used – as long as anything that could identify me has been deleted.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I consent to the research staff collecting and processing focus group data for the purposes of this study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I understand that my participation in this study is private and that nothing that could identify me will ever be published.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I know who to contact if I have any questions about the study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I understand that taking part in this study will involve participation in one focus group only.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I would like to receive a summary of the study results.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Declaration by participant:

I consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____



Screening for rheumatic heart disease (RHD): What are the benefits, harms and uncertainties?

What is RHD?

- Rheumatic heart disease (RHD) is a potentially serious heart problem affecting your heart valves.
- The seriousness of this problem ranges from mild symptoms that do not cause problems during your lifetime, through to very severe disease that requires heart surgery and sometime causes heart failure and death.

Why 'screen' for RHD?

- RHD only occurs **if someone has had rheumatic fever in the past**. The problem is many with undiagnosed RHD don't know they have had rheumatic fever.
- People who have had rheumatic fever in the past are **more likely to have it again**, and each episode can cause more damage to the heart.
- Screening aims to detect **early damage to the heart** so that people can be given antibiotic treatment to reduce their risk of future attacks of rheumatic fever.
- This sounds like a good idea – but it's important to understand that **every** screening test has **benefits, harms, and uncertainties**.

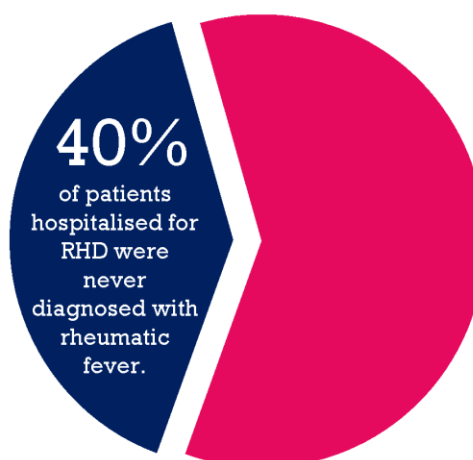
What are the potential benefits?

The main benefit of RHD screening is that it may help to **prevent RHD from getting worse**.

If someone with definite RHD gets rheumatic fever again, **it can make their RHD worse**. The main reason for RHD screening is to reduce the chance that these people will get rheumatic fever again – mainly by finding undiagnosed disease and prescribing **monthly antibiotic injections**.

Everyone who has RHD **must have had rheumatic fever** at some point in their life. However, 40% of those admitted to hospital with RHD **do not have a medical history of rheumatic fever**.

This means that these people did not receive the usual clinical care given to those who are diagnosed with rheumatic fever, which may have helped stop their condition from becoming worse. **Screening may help find these patients**.



You will be provided with **more information about the test itself and what may happen afterwards** by those who are running the screening test.

What are the potential harms?

- There is no such thing as a perfect screening test. Sometimes the test result may suggest there is a problem, when in fact the person would never have experienced poor health as a result of RHD.
- This means it is possible that some children who are diagnosed as having RHD using this test don't actually have it – instead they have findings that are not abnormal, just slightly different from what is usually seen.

The main harm that may be caused is diagnosing RHD when **there is nothing really wrong.**

There are a few reasons why this is important:



Parents who are told their child has RHD will often understandably **experience worry or anxiety.**



The treatment offered to those with definite RHD is **monthly antibiotic injections for 5-10 years.**



Children identified as having heart abnormalities through screening will sometimes **reduce or eliminate physical activity from their lives.**

What are the uncertainties about RHD screening?

As well as needing to learn more about how RHD progresses, there are **several other uncertainties** that make it unclear whether screening for RHD is a good idea or not.



Diagnosis of RHD isn't always straightforward. A child may be diagnosed with either definite or 'borderline' RHD.



RHD is rare in childhood. Of the 4,000 children screened in NZ between 2007-2012, **only 1% were diagnosed with definite RHD.**



There is no treatment for 'borderline' RHD. Instead, doctors will monitor the child's condition over time.



Unlike most other screening tests, we don't know how many (if any) lives RHD screening might save – because the **specific research that is needed to determine this has not been done yet.**



Rheumatic fever rates dropped **45%** between 2012-2015. If this drop continues, **the number of children with undiagnosed RHD will also drop over time.**



You will be provided with **more information about the test itself and what may happen afterwards** by those who are running the screening test.