

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

*Brief Study Summary and Discussion of Focus Group Recommendations*

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*This document is intended to compliment the focus group report produced by CBG Health Research Ltd., which provides the key findings from the focus group workshop. This report can be viewed at <http://www.otago.ac.nz/wellington/departments/publichealth/research/cancercontrol/projects>.*

*The current document provides a brief background and summary of the study, and then details changes made (or reasons why changes were not made) following the recommendations of the focus group.*

## **Acknowledgements**

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## **Ethical Approval and Consultation**

This study received ethical approval from the University of Otago Human Ethics Committee (reference # D16/168). Consultation was also undertaken with the Ngai Tahu Research Consultation Committee.

## Introduction

Each year, more than 150 New Zealanders die of rheumatic heart disease (RHD).<sup>1</sup> New Zealanders of Māori and Pacific ethnicity are up to ten times more likely to die of RHD than non-Māori/Pacific New Zealanders.<sup>1,2</sup> The prevalence of RHD peaks in the 20-59 year age group,<sup>3</sup> while mortality from this disease is most likely to occur in middle age (mortality rate for 50-59 age group: Māori 28 per 100,000; Pacific 18 per 100,000, non-Māori/Pacific 1 per 100,000).<sup>1</sup>

RHD is the cardiac consequence of acute rheumatic fever (ARF). At the root of ARF is an immune response to streptococcal infection (typically Group-A streptococcus, or GAS), the results of which may include joint pain, rashes, abnormal movements (chorea) and endocarditis. It is the last of these consequences which may permanently damage heart valves, and it is this manifestation which is the primary characteristic of RHD.<sup>3,4</sup> This valvular damage can lead to debilitating chronic heart disease, heart failure and consequent increased risk of mortality.<sup>3</sup>

### *Screening to reduce the burden of RHD*

Beyond the primary prevention of ARF, a reduction in the burden of RHD may be possible by identifying the condition while the patient is still asymptomatic and then intervening with secondary antibiotic prophylaxis, or with cardiac surgery if severe disease is observed. It is estimated that 40% of patients who present with symptomatic RHD do not have a known history of ARF,<sup>5</sup> and it is these patients who should be the target of population screening. Screening aims to identify these patients before they become symptomatic, and therefore preventing ARF reoccurrence via secondary prophylaxis. The goal is to reduce the likelihood that these patients progress to a severe, symptomatic stage of RHD and thus be less likely to require costly and risk-filled intervention.<sup>6</sup> There are obvious benefits of early-detection among those who would have progressed to severe, symptomatic RHD – including the possible prevention of substantive morbidity and early mortality.

It has been suggested that “*all screening programmes do harm; some do good as well*”.<sup>7</sup> There is ongoing debate about whether it is socially and ethically appropriate to screen for rheumatic heart disease (RHD) in a symptomless population. There are several reasons why this controversy exists, relating primarily to uncertainty around the natural history of RHD, issues around who should receive secondary prophylaxis, and diagnostic definitions of sub-clinical or ‘borderline’ RHD.<sup>8</sup> Over-diagnosis of questionable abnormalities (or ‘false-positive’) is of particular concern.

### *Informing choice through increased health literacy*

Ensuring that screening participants and their families understand the risks and benefits of rheumatic heart disease (RHD) screening to better make an informed choice regarding participation is crucial in ensuring the safety of the screened population. The aim of the current study was to **develop an educational tool to inform the screened population** and their families about the likely balance of benefits, potential harms and uncertainty around RHD screening.

## Summary of Methods

### *Information pamphlet*

We designed a **one-page learning material** (i.e. pamphlet) for circulation among present and future screened populations and their families. This learning material was intended to have a mixture of clinical- and screening-related content, and was constructed with experts from both these fields as well as other relevant parties.

The learning material aimed to cover the following areas: a) description of the potential benefits of screening, including improved health outcomes via early diagnosis of RHD; b) description of the potential harms of screening, including over-diagnosis; and c) description of the uncertainty around RHD screening, including the unknown natural history of symptomless RHD.

The pamphlet was not designed to address operational issues relating to the screening test itself. It is envisaged that such information would be provided separately to prospective screening participants and their family/ whanau.

We sought and gained feedback from clinicians, public health workers and researchers with expertise in rheumatic fever, rheumatic heart disease and/or screening (JC, MB, NW, CS) regarding the factuality and relevance of the material content. We then amended content based on this feedback.

Once the content of the information pamphlet was finalised, we designed and illustrated the learning materials in Microsoft Powerpoint. We used exemplars from highly-effective materials published in similar contexts, particularly material from the New Zealand Government's Social Policy Evaluation and Research Unit ('Superu').<sup>9</sup>

### *Ethical approval and iwi consultation*

We sought and gained approval for the focus group component of the study from the University of Otago's Human Ethics Committee (reference # D16/168). We also undertook consultation with the Ngai Tahu Research Consultation Committee, who provided a letter of consultation.

### *Focus group*

The usefulness of the pamphlet was qualitatively assessed using a **focus group of parents**. CBG Health Research Ltd. ('CBG'), an independent provider of public sector surveying with skills in convening focus groups, assisted with identifying and recruiting focus group members from a sample of the target population. We recruited 8 participants; 4 Māori, 3 Pacific and 1 NZ European, to (loosely) reflect the incidence of Acute Rheumatic Fever (ARF) in New Zealand.<sup>10 11</sup>

Prior to the focus group, the study investigators collaborated with CBG to develop a pro-forma (or discussion guide) to guide the focus group workshop, including a) questions pertaining to what participants understand about ARF and RHD screening pre- and post-focus group, and b) questions/discussion points relevant to the learning material itself. The final discussion guide is included in the appendices of this brief report (Appendix 1).

CBG convened the focus group for a 2 hour workshop, and focus group participants were offered a koha to cover costs of travel, time and/or childcare. Following the focus group, CBG prepared a full report, highlighting the key findings and recommendations of the focus group.<sup>12</sup>

## Key Findings from the Focus Group Workshop

Findings from the focus group workshop are presented in detail in the CBG report.<sup>12</sup> The key recommendations made by the focus group were:

- The group liked the question style approach and section layout.
- The group advised that less-literate people would struggle to read the material, and recommended revising the material to
  - a) increase the use of plain and simple language,
  - b) remove acronyms and technical terms,
  - c) replace with layman words, and
  - d) increase the use of personal language.
- The group observed that the learning material left doubt regarding whether the parent/guardian should agree to have their child screened, and recommended removal of this doubt and assurance of the need for this screening test.

When participants were told about the screening test before the focus group began (using the description outlined at the beginning of the pro-forma/discussion guide), all eight were happy to have their child undergo the test – because it was non-invasive, painless and free of cost. At the conclusion of the focus group – after going through the pamphlet – half (4 out of 8) said they would still be happy for their child to undergo the test.

## Response to Focus Group Recommendations

Based on the report produced by CBG,<sup>12</sup> we have identified a series of recommendations made by the focus group. These recommendations were taken into consideration by the study investigators, and the information pamphlet was substantially revised as a result. A side-by-side comparison of the pre-focus group and post-focus group pamphlets can be viewed in Figure 1.

Each of the recommendations is detailed below, followed by our response and details of relevant changes made to the material.

**Recommendation 1:** *The focus group made several recommendations with respect to making to the material easier to understand, including increasing the use of plain and simple language, removing technical terms and replacing these with ‘lay’ words, and increasing the use of ‘personal’ language.*

- **Response:** We have made extensive changes to the wording of the pamphlet, including using more plain language, removal of technical terms (and replacement with lay-terms where possible) and attempted to increase the use of personal language. All of these changes have both reduced the word-count and made the material easier to read and understand.
- For example, we have taken the recommendation of the focus group to simplify the explanation of the text beneath the headings ‘What is RHD?’ and ‘Why screen for RHD?’, and changed these to a more pointed bullet-point list involving more lay-language.
- However, there is also risk associated with simplifying a complex issue – and we have attempted to strike a balance between accurate reporting of best-evidence and simplicity of the language used in the material.

**Recommendation 2:** *One of the main points raised by the focus group was as follows: “Overall participants suggested the material requires mitigation of the doubts raised and increased assurance about the necessity for, and outcomes from, the screening.”*

*The focus group makes recommendations “to lower doubt and increase certainty about the value of the screen.”*

- **Response:** Before the focus group occurred, the facilitators (CBG Health Research Ltd) were informed that the objective of the pamphlet was not to convince people to undertake RHD



screening (i.e. ‘sell’ the screening), but rather to inform them about the benefits, harms and uncertainties around screening. They were also told that the pamphlet was supposed to be a balanced (lay) representation of the current state of evidence around RHD screening.

- Despite this, based on the key recommendation above (and many other recommendations made in the report), it appears that the focus group were of the opinion that we should make the pamphlet more unequivocal, by removing doubt and providing assurance regarding whether someone should undertake screening. For example, one focus group member commented: *“It has to use more positives, install confidence, especially for something new.”* This reflects the commonly observed, and very powerful, intuitive appeal of screening that assumes screening must be good.
- The objective of the learning material was to present the best evidence available regarding the possible benefits, harms and uncertainties associated with RHD screening, so that parents/guardians can make a relatively informed choice regarding whether their child should take part. There is insufficient evidence to assure parents/guardians that screening is a good idea (or not) – and this is reflected in the level of uncertainty presented in the learning material.

**Recommendation 3:** *“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.”*

- **Response:** As mentioned above, we have made extensive changes to the wording of the pamphlet, which has both reduced the word-count and made the material easier to understand.

**Recommendation 4:** *A number of participants made comments regarding their confusion about what they were supposed to take away from the pamphlet. Was screening a good idea, or was it a bad idea? They were unsure.*

*“The group shared that overall the tone of the material seems to be one of doubt about the value of the screen.”*

- **Response:** These comments reflect the high degree of uncertainty around RHD screening – since those researching this topic are uncertain about the efficacy of this screening, it isn't surprising that a lay audience – when presented with the best knowledge that we have on the subject – would also feel uncertain after reading this material.
- There are uncertainties about both the benefits and harms of RHD screening, so the fact that participants identified this uncertainty after encountering the material may indicate a better understanding of the issues than they had before encountering the material.

**Recommendation 5:** *“This scan is likely to misdiagnose (the absence of misdiagnosis rate informed ideas of ‘likely’ because if it is low, it would be stated).”*

- **Response:** In the absence of a RCT of RHD screening, it is very difficult to estimate the extent to which over-diagnosis might be occurring in the context of a population-based screening programme. Thus, it is not possible to adequately address this recommendation.
- We have added an additional point to the pamphlet which states: *“We need to learn more about the benefits and harms of screening. For example, we are still uncertain how many children might be wrongly labelled as having a problem when, in fact, there is not one.”*

**Recommendation 6:** *The focus group made recommendations to add “pictures that provide real life connections to the messages, ideas included: RHD boy from the HPA advertisements, ECHO machine, children being scanned or treated.*

- **Response:** We have chosen not to include these pictures, but rather stay with neutral symbols. Such pictures will be provided by the purveyors of the screening test, and as such do not need to be part of the current material.

**Recommendation 7:** *The focus group recommended changing the structure of the pamphlet to 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; (and) encourage retention of the material on the fridge or in a bag.”*

- **Response:** While there is certainly merit to having a fold-out version of this pamphlet, in the first instance we would like to keep the current format – since it is conducive to online viewing, which is where the pamphlet will first be made available. We may develop a fold-out version of this pamphlet in the future.

**Recommendation 8:** *The focus group recommended adding the words ‘a lot’ to the data presented regarding the proportion of RHD patients who do not have a documented history of rheumatic fever. “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.”*

- **Response:** Rather than adding the words ‘a lot’ to the relevant section, we have replaced the percentage (40%) with a phrase that is possibly more intuitive to understand: “Four out of ten people who are admitted to hospital...”.

**Recommendation 9:** *The focus group wanted more information about what is involved with the screening test.*

- **Response:** This is outside the objective of the current pamphlet. This material is supposed to sit alongside other material that fully-explains what is involved in the test.

**Recommendation 10:** *“The Pacific representatives associated the icon opposite with cutting cake which they deemed distracting from the message.”*

- **Response:** We have removed the pie chart from the pamphlet, and replaced with a simple word-bubble that summarises the primary justification for screening (“Many people who have RHD do not know that they have had rheumatic fever.”) While this statement is actually ambiguous – since we do not actually know whether these patients knew that they had had rheumatic fever – we have included it here because it explains the primary justification for screening in an intuitive manner.

**Recommendation 11:** *The focus group members universally disliked the ‘icons’ that were used, and made several comments to this effect.*

- **Response:** In the ‘uncertainties’ section, we have replaced the majority of the icons with large text. We have also changed other icons where relevant, but contrary to a recommendation from the focus group we have retained the icon which shows a syringe. We believe this icon quickly conveys the fact that treatment for definite RHD involves injections (rather than pills), without needing to convey this information at length.

**Recommendation 12:** *The focus group recommended removing the term “This sounds like a good idea but...” from the pamphlet.*

- **Response:** We have replaced this phrase with ‘However’.

**Recommendation 13:** *The focus group recommended changing the title of the pamphlet, since it involves two ‘negative’ words to one ‘positive’ word.*

- **Response:** Since these are three key components that underpin this pamphlet, we disagree with the focus group and have decided not to change the title.

**Recommendation 14:** *With respect to the harms of screening, the focus group respondents “questioned the necessity to state that the diagnosis will cause worry as it is a given.”*

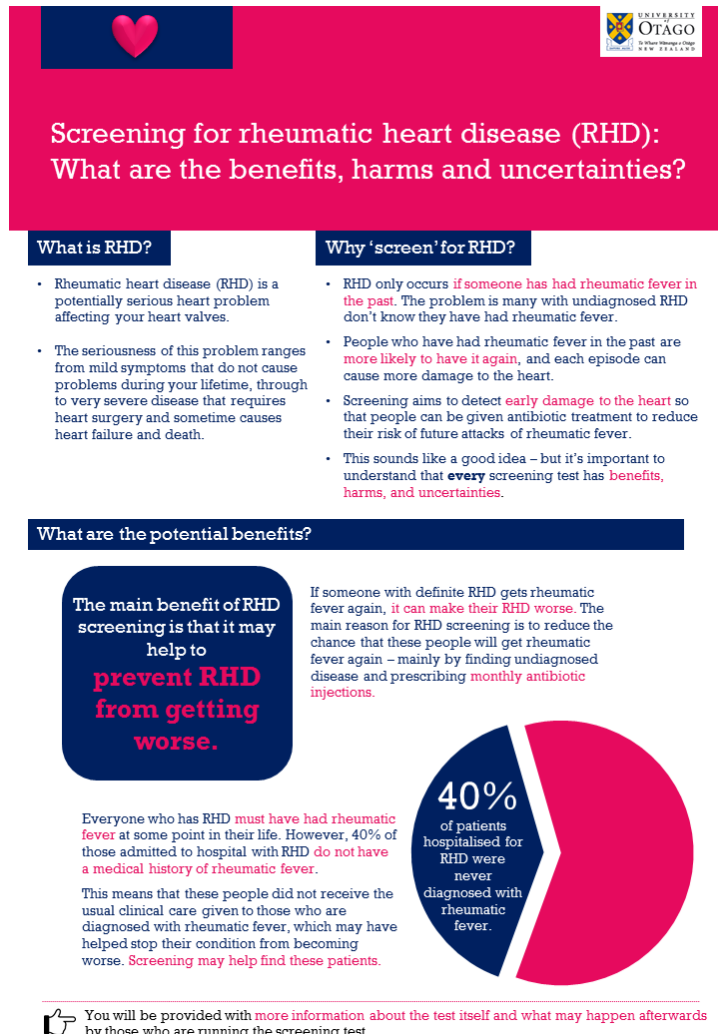
- **Response:** While worry surrounding an accurate diagnosis is indeed a given, the primary harm associated with RHD screening is that not all children diagnosed will actually have the disease. The worry experienced by parents who are (wrongly) told that their children have RHD is a screening-related harm – and thus is important to include in the current material.

Finally, one of the comments from the focus group regarding the information provided about the recent drop in rheumatic fever rates was quite concerning. One focus group member stated that *“Rheumatic fever is a problem of the past (45% drop in rates).”* The pamphlet should not leave the reader with the impression that rheumatic fever is a problem of the past – particularly since recent

notification data from the Institute of Environmental Science and Research (ESR) shows a marginal increase in first-episodes of RF between 2015 and 2016.<sup>13</sup> Another reason for dropping this point is that the issue of whether rates of RF are reducing or not at a population level is unlikely to significantly affect a parent's decision to allow their child to be screened for RHD.

Figure 1: Side-by-side comparison of pre-focus group and post-focus group versions of the information pamphlet.

Front page – Pre-focus group:



**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.

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.

Post-focus group:



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

**What is RHD?**

- Rheumatic heart disease (RHD) is caused by rheumatic fever.
- RHD is a problem involving your heart valves.
- The seriousness of RHD ranges from mild through to very severe symptoms.
- Severe RHD may require heart surgery, and can sometimes cause heart failure and death.

**Why 'screen' for RHD?**

- Many people with RHD do not know they have had rheumatic fever.
- Those who have had rheumatic fever can get it again, and each attack can cause more heart damage.
- 'Screening' checks for signs of heart damage.
- If there are signs, antibiotics can help prevent rheumatic fever from happening again.
- This will help to prevent further heart damage.
- However, 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 might help to **stop RHD from getting worse.**

If someone with RHD gets rheumatic fever again, it can make their RHD worse.

Screening helps to find people with RHD who don't know they have it, so that they can be treated. Antibiotics can prevent rheumatic fever happening again. This might prevent any further heart damage.

Four out of ten people who are admitted to hospital with RHD have no record of ever having rheumatic fever.

This means that they probably didn't get the medical care that rheumatic fever patients usually get – like antibiotic injections – which might have stopped their heart damage from getting worse.

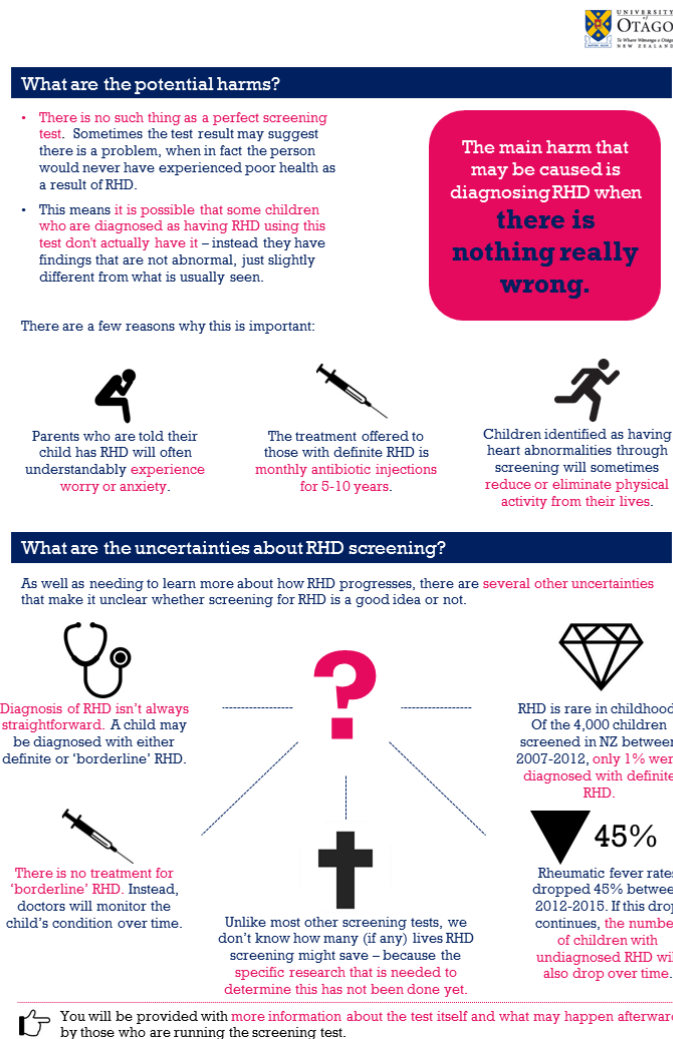
Screening might help find these patients.

Many people with RHD do not know that they have had rheumatic fever.

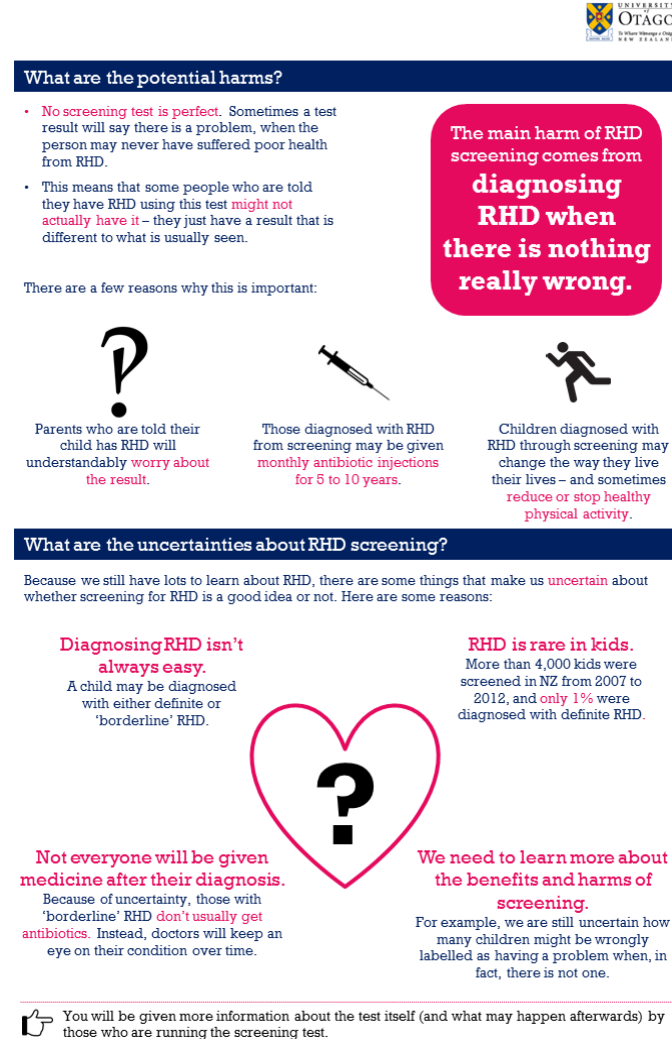
You will be given more information about the test itself (and what may happen afterwards) by those who are running the screening test.

(Figure 1, cont.)

Back page – Pre-focus group:



Post-focus group:



## Conclusions

The information pamphlet that we have developed is unique, in that it is the first (to our knowledge) attempt to present the current evidence regarding the benefits, harms and uncertainties of RHD screening to a lay-audience. It has been amended based on critique from experts in the field of rheumatic fever, rheumatic heart disease and population screening, and also a focus group of Māori, Pacific and European parents.

We believe that we have presented the best-quality pamphlet possible, and that the information presented adequately reflects the current state of evidence in this context. As can be noted from both the focus group report and our responses to the focus group recommendations, there is difficulty in balancing accuracy with simplicity in what is an inherently complex area. As more evidence comes to hand, it may be possible to reduce the amount of uncertainty expressed in the pamphlet. However, we believe that the current pamphlet will at least increase the probability that the parents of children approached to undergo RHD screening will make a choice that is consistent with their own values.



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## Appendix 1: Focus group discussion guide

The document below was developed by the study investigators, in conjunction with CBG Health Research Ltd. It was used to guide discussion during the focus group.

<b>Thanks &amp; Introductions</b>	We are here to provide feedback on this information pamphlet.
<b>Pre-pamphlet understanding of RHD screening</b>	<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"> <li>• Would you be happy for your child to undergo this test?</li> <li>• Can you foresee any problems with having this test done?</li> </ul>

### Hand Out Pamphlets & Invite Participants to read it.

#### Probes (if not covered)

<b>First Impressions</b>	<p>Look/Appeal</p> <p>Ease of reading</p> <p>Understandable</p> <p>Concise</p> <p>Other comments</p> <p>Layout</p> <p>Level of detail</p> <p>Factual</p> <p>Culturally appropriate</p> <p>Suggestions</p>
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### What is the pamphlet talking about?

#### Probes (if not covered)

<b>The benefits of screening?</b>	<p>What will readers understand the benefits to be?</p> <p>Does the information provide understanding of the possibility of improved health outcomes via early diagnosis?</p> <p>How (if at all) could this information attract people to screening?</p> <p>Any improvements?</p>
<b>The harms of screening</b>	<p>What will readers understand the harm to be?</p> <p>Does the information provide understanding of:</p> <ul style="list-style-type: none"> <li>• unnecessary diagnosis?</li> <li>• likelihood of anxiety?</li> <li>• possible changes in physical activity?</li> <li>• the fact that the screening will not just test for RHD?</li> </ul> <p>How (if at all) could this information deter people from screening?</p> <p>Any improvements?</p>

**Uncertainties around screening**

What will readers understand about uncertainties?  
Does the information provide understanding of:

- 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?  
Any improvements?

**Post-pamphlet understanding of RHD screening**

Questions to be asked AFTER pamphlet is given:  
What are some of the benefits of RHD screening?

What are some of the 'costs' of RHD screening?

Knowing what you know now, would you still be happy for your child to undergo echo screening for RHD?

What extra information would you want to receive before allowing your child to undergo RHD screening?

Did you find the learning material useful?

What did you find most useful?

**Last Impressions**

Other comments/suggestions

**Thank & Close**