

Evidence Review, Co-Production and Prototyping A Process of Creating a Consumer Research Contact List in a Paediatric Health Setting: The PARTICIPATE Project

Fenella Jane Gill (✉ f.gill@curtin.edu.au)

Curtin University Faculty of Health Sciences <https://orcid.org/0000-0003-4697-9640>

Catherine Pienaar

Perth Children's Hospital

Tanya Jones

Consumer and Community Involvement Program

Research Article

Keywords: Paediatric, child health research, parents, research participation, consumer and community involvement

Posted Date: February 22nd, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-218047/v1>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Version of Record: A version of this preprint was published at Research Involvement and Engagement on August 7th, 2021. See the published version at <https://doi.org/10.1186/s40900-021-00300-2>.

Abstract

The impact of child health research can be far reaching; affecting children's immediate health, their adult health, the health of future generations and the economic wellbeing of countries. Consumer and community involvement is increasingly recognised as key to successful research recruitment. Systematic approaches to research recruitment include research registries or research contact lists.

Objective: Develop a process of creating a consumer research contact list for participating in future research opportunities at a children's health service.

Methods: A healthcare improvement approach used a 3 stage framework; 1) evidence review and consultation 2) co-production of a research communications plan with stakeholders and consumers, including a draft research information brochure 3) prototyping involved iteratively testing the brochure, surveying parents or carers who attended outpatient clinics or the hospital Emergency Department, and conducting follow up telephone calls.

Results: There was overall support for the creation of a research contact list, but some unknowns remain. 367 parents or carers completed the survey and 36 participated in a follow up telephone call. Over half were willing to join a research contact list and more than 90% of the children of parents or carers surveyed were not currently participating in research. Several potential barriers identified by stakeholders were dispelled. Research communications and a future contact list should be available in electronic form.

Conclusions: There was strong support for creating a research contact list. The co-production approach will inform our future directions including creation of an electronic research contact list easily accessible by consumers of the children's health service

Plain Language Summary:

Recruiting enough children to participate in research studies can be challenging. Establishing a registry or list of young people willing to be contacted to participate in research is one way of addressing this problem. At our children's health service, we wanted to explore the idea of developing a research contact list and we were particularly keen to involve consumers and community members in this process, which involved: 1. Reviewing other examples of research contact lists and consulting with a range of people, including consumers and community members, 2. Co-producing a research communications plan with parents, young people, health service and research staff, including a draft research information brochure for families, and 3. Testing the acceptability of the brochure by surveying parents or carers who attended outpatient clinics or the hospital Emergency Department, and conducting follow up telephone calls with them. 367 parents or carers completed a survey and 36 participated in a follow up telephone call. Over half were willing to join a research contact list and more than 90% of the children of parents or carers surveyed were not currently participating in research. Several potential barriers raised by consumers and health professionals in the first stage of the project were not found to be an issue for the parents or carers surveyed. Responses showed research communications and a future contact list should be available in

electronic form. These findings will inform the future creation of an electronic research contact list, easily accessible by consumers of the children's health service.

1. Introduction

The impact of child health research can be far-reaching; affecting children's immediate health, their adult health, the health of future generations and the economic wellbeing of countries [1]. Despite this, children are underrepresented in clinical research [2]. Opportunities to involve children in research today are much greater [1], yet recruiting paediatric research participants remains challenging. Specific challenges include ethical and practical concerns about overburdening parents in acute and emergency healthcare contexts where families may be experiencing intense emotional or psychological stress [3]. Recruiting insufficient research participants can be a barrier to conducting research and result in waste of research resources [4-6].

Research registries are an emerging strategy to optimise participant recruitment [5, 7]. A registry is an organised system to collect uniform data to evaluate specified outcomes for a population[8]. Clinical or hospital-based registries, are used to collect patient information, improve quality of care [9] and to study specific conditions [10]. Population-based patient registries can be interlinked with other databases and include entire nations. For example, although not primarily designed to enable access to research participants [5], the Danish National Patient Registry has been used to collect administrative and clinical data from all hospitals since 1978 [11]. Data are used extensively for research and can be linked at the patient level with other registries, other trials, and population surveys. In Australia, national population-based registries also exist [12, 13].

1.1 Consumer and Community Involvement in Health Research

The involvement of 'consumers and the community' or 'patients and the public' is increasingly recognised as important in healthcare decision making [14], as well as design and conduct of research [15-17] and setting of research priorities [18]. Consumer and community involvement ensures that research focuses on issues relevant to the public [19] and has been shown to have an impact at all stages of research [20]. Nonetheless, debate remains about best-practice and how to evaluate the impact of involving consumers in research [21]. A systematic review mapping the impact of patient and public involvement (PPI), found there was evidence of PPI at all stages of the research process, from setting research objectives, to consumer-focused interpretation of data and dissemination of results, but overall evidence of PPI impact was weak [22]. PPI or consumer and community involvement (CCI) in research needs to be genuine and more than a box-ticking exercise. Whilst patient engagement has become integrated into organisations and is often a pre-requisite for funding, tokenism or superficial involvement can occur when consumer input is not reflected in decisions made about the research [23].

In Australia there is also recognition of the importance of CCI in determining what is researched and how it is undertaken [24], and the National Health and Medical Research Council provides guidance on [25] and promotes active involvement of consumers and community members in health and medical

research. In the Western Australian (WA) context, CCI in research is facilitated by the Western Australian Health Translation Network [26] enabling the community voice in research through the Consumer and Community Involvement (CCI) Program (formerly the Consumer and Community Health Research Network) by partnering with consumers, community members and researchers to make decisions about health research priorities, policy and practice to embed CCI as standard practice in health research [27]. The CCI Program explored CCI from the perspectives of WA researchers, reporting that consumers provide unique perspectives on research and can identify issues that may not be obvious to researchers. They also highlighted that consumer endorsement of research is vital to achieve community support [28].

1.2 The PARTICIPATE Project

At the West Australian Child and Adolescent Health Service, there was no mechanism for families to express their wishes to be contacted about research opportunities. There was a need to address this gap and improve the health service's research capacity in a manner that was feasible and acceptable to all stakeholders. The purpose of the PARTICIPATE project was to develop and test a process of creating a contact list for future research opportunities at the health service. The healthcare improvement project approach involved using a three-stage framework, adapted from Hawkins et al. [29], consisting of 1) evidence review and stakeholder consultation, 2) co-production and 3) prototyping (See Figure). The methods used at each stage facilitated the integration of evidence from the literature with stakeholders' knowledge, expertise and preferences. Health service governance approval was obtained for Stage 3 of the project only, as the purpose of consultation undertaken in the first two stages of the project was to actively involve consumers, community members and other stakeholders in the planning and development of the research, which does not require Ethics Committee approval [30, 31] The SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence) publication guidelines were followed [32].

2. Methods

2.1 Stage 1: Evidence review and stakeholder consultation

The overall aim of Stage 1 was to both learn from what had been reported in the literature and to gather the perspectives of multiple stakeholders about the issues related to establishing a research registry.

2.1.1 Evidence review

A non-systematic literature search was conducted to address the following two research questions; In healthcare settings, what initiatives have been used for research participant recruitment? and; In healthcare settings, how have research registries been implemented and evaluated? Proquest and PubMed databases were searched. Key terms were as follows: Registr*, System*, Opt-in, Research consent system, Patient* consent, clinical registr* and paed*. Included were full text, peer-reviewed publications in English between 2013-2018. Additional strategies included searching end-text reference lists of identified articles and searching of key websites. Results of the search identified 256 articles from Canada, United States (US), Europe, United Kingdom (UK) and Australia. Articles included descriptive

reports, qualitative and quantitative studies, and systematic reviews. Subsequent searches followed an iterative process and included the identification of relevant CCI literature.

2.1.2 Review findings

There are many challenges to recruiting research participants, some unique to the acute paediatric healthcare setting [33, 34]. Difficulty recruiting participants is a common reason for discontinuation of trials. For example, of 559 paediatric randomised control trials, recruitment difficulties were cited in 37% of the 104 discontinued trials [33]. Further, of 3428 United States (US) closed studies, 152 were terminated before completion, with 83 of these reporting termination was due to insufficient recruitment [35]. A UK review of child health research found less than 5% of registered studies involved children, and less than 2.5% of two million National Health Service paediatric patients were recruited into research studies [1]. A plethora of strategies have been used to improve research recruitment. A systematic review identified 72 strategies, with three that demonstrated good levels of evidence [36]. Only two strategies effectively improved recruitment: conducting open trials rather than blinded placebo-controlled trials and following up postal invitations with telephone reminders [36]. In an attempt to further understand recruitment challenges, interviews with researchers identified four factors that were positive influences; an infrastructure supporting researchers' access to potential participants, study design, if the treating doctor mentioned the study to potential participants, and participants being motivated by altruism [4]. Recruiting research participants is complex, even more so in the paediatric setting, and successful recruitment requires a systematic approach to be taken.

A consumer research register is one systematic approach [33, 5]. The feasibility of an Australian 'consumer registry' to facilitate direct patient recruitment from hospital populations was assessed in New South Wales hospitals [5]. A survey was used in an outpatient population to measure consent rates, preferred methods and frequency of contact, and the feasibility of establishing the register. The concept of a register was found to be feasible, with most participants willing to be contacted multiple times utilising methods such as email [5].

We explored Australian paediatric hospitals' websites for research registry personnel contact details. At the Children's Hospital in Victoria, a component of the Electronic Medical Record includes a patient portal for families to register interest for research contact [37]. We were unable to verify how well utilised this capability is, or to find information about other paediatric hospital research registries. We did not identify any existing registries to model for our context.

2.1.3 Consultation

We used a variety of methods for stakeholder consultation ranging from regular meetings with stakeholders to one-off unstructured consultations. A steering group of key stakeholders was established with a smaller working party to progress initiatives and provide representation from key areas of the health service. Stakeholders included health professionals, researchers, information technology

professionals, legal services professionals, the health service communications team, and health service clerical staff.

Initially a targeted approach was used to identify stakeholders, and engage with other relevant professionals, individuals and groups. In collaboration with the steering group, we created an initial list of people and departments who would be impacted by or would likely wish to provide input about creating a research registry. We contacted them by email or telephone to arrange to meet in person or consult by telephone. As further stakeholders were identified and recommended by others we expanded the number and range of consultations. The aim was to gather multiple perspectives about possible solutions and identify barriers for a feasible process to create a registry. These unstructured consultations were undertaken as individual interviews or small group meetings where the topic of creating a research registry was broadly introduced and stakeholders had the opportunity to provide their input. For some consultations eg. with information technology professionals, questions were more targeted to understand the capacity to integrate a research registry into the health service's existing systems. The consultations were verbal with field notes taken. A written record of key points from each consultation was returned to stakeholders to confirm. Some stakeholders provided written input by email. The key points were collated to identify similarities and differences across stakeholder perspectives and to inform subsequent consultations.

We consulted a range of researchers at local private and public hospitals, including research directors who shared their insights, experiences, views and ideas. We found one private hospital had an existing research registry using an opt-out process, administered by clerical staff during admission of patients, however, the completion of the consent field in the database was not a mandatory field and consequently sub-optimally captured. We also sought input from researchers at one public hospital who had previously held a consultation with consumers and community members to explore their perspectives on an opt-out approach to using routinely collected health information for low risk research [38].

Given the recognised benefits and value of consumer and community involvement in the development of research, consumer and community consultation was also undertaken from the outset of the project. A range of strategies were employed, including engaging with Nursing Research Consumer Advisory Panels (consisting of parents and young people who had utilised the health service), the health service Consumer Advisory Committee and holding "a Community Conversation"; a consumer and community event involving young people and parent users of the health service. See Table 1 further detailing consultation.

Table 1 Consultation

Groups	n
Health professionals	
Steering group	25
Working party	6
Other Divisions of Child Health Service including Community and Mental Health groups	40
Health Service Research and Research Governance	12
Allied Health professionals	3
Other professions	
Patient management systems	35
Health Information management system	3
Information and Communication Technology	2
Legal services team	2
Communications team	5
Business Intelligence professional	1
Consumer and Family Engagement team	3
Consumers	
Community Conversation	26
Youth Advisory Panel	7
Consumer Advisory Panel	6
Individuals	
Researchers and healthcare professionals within health service	14
Health and relevant professionals from other organisations	13

We worked together with the CCI Program team [27] to host the 'Community Conversation' using a World Café format [39]. The Nursing Research Consumer Advisory Panels also advised on the planning and promotion of the event, and the wording of the discussion questions. Attendees were accessed through social media platforms and the CCI Program consumer database. Seated in small groups in a welcoming "café"-style environment, 16 parents/carers and 10 young people discussed the following three questions: what are your thoughts about a research registry?; how and when would you prefer to be approached to join a registry, and who should approach you to join the registry?; and what information should be collected and how should it be managed? To avoid impeding the flow of conversation, consumers did not move tables in between questions, as is the standard process for the World Café

methodology, and most of the young people were seated at one table. After the three rounds of questions, a spokesperson from each table shared insights and summarised the conversations. Facilitators and note-takers were situated at each of the tables and later compared notes, synthesised and agreed on the key findings.

2.1.4 Consultation findings

In total, more than 80 meetings were held with individuals and groups, of which over a quarter were representative of the patient and carer population. We found strong consumer and health service support for establishing a systematic process to contact families about research and learnt that families are generally motivated to participate in research by altruism, and a desire to improve future health outcomes. The feedback indicated that families would want to manage their own registry preferences using online technology. Importantly, we found we had incorrectly assumed that consumers already understand research and what research participation involves. In addition, consumers identified that the term 'registry' was unclear and that this may be a barrier for some. Following the Community Conversation, the Nursing Research Consumer Advisory Panels recommended using the term 'contact list' instead. It was clear there was a gap in communicating with consumers and the community about the research conducted by the health service and about research participation. Barriers to creating a research registry were mostly raised by health service staff. These included views that consumers would be too concerned about their privacy to wish to join a contact list, would be overburdened, were unlikely to join a contact list if their own doctor did not suggest it, or would be concerned about how to update changes. Other health service staff concerns were about using existing service-based information technology systems, uncertainty about governance and legal requirements for patient privacy, using families' contact details for secondary purposes other than clinical care, and the need for a research registry to be sustainable (not dependent on specific project funding or individuals).

The Community Conversation identified seven key issues relevant to establishing a research registry. These were; foreseen concerns, benefits, consent methods, raising awareness, approaching participants, information collection and information management. Logistical issues foreseen by consumers included how participant updates would be managed, such as 'unsubscribe' if a person no longer wanted to be part of the registry, managing data once a child turns 18 years, and knowing who would have access to their data. Registry benefits included facilitating research to increase knowledge to benefit others in the future, despite no direct benefits for participants. Most consumers supported an opt-in approach to consent. Importantly the group highlighted that adequate information was key to raise consumer awareness about research and a research registry at the health service. Consumer input regarding how best and, who would be the most appropriate person to approach families to join the registry, revealed a range of potentially acceptable options requiring further consideration. Last but not least, consumers emphasised the need for consistent transparency about the collection and management of personal information. Although there was broad agreement supporting the use of health information for research, consumers felt that the general public may be reluctant to adopt an opt-out approach, unless this was preceded by a concerted consumer engagement and public awareness campaign.

2.2 Stage 2: Co-production

The outcomes of the Stage 1 consultation led us to first address the need for communication of research information to health service consumers. The aim of Stage 2 was to co-produce these solutions with the health service communications team, a project working party (members of the working party were purposively selected to represent key stakeholder areas), and consumers (members of the Nursing Research Youth and Consumer Advisory Panels). A research communications plan was developed which included three key strategies, namely, a social media campaign, messaging throughout the health service and developing a prototype research information brochure.

The Co-production process involved an action research cycle of a series of meetings to develop an information brochure, that was titled 'What is child health research?', and a survey. There were iterative rounds of discussion, rewording and redrafting using multiple mediums (in-person meetings, email communication, and voting) until agreement was reached. Careful consideration was given to balancing the need for clear messaging to a mixed audience of varying levels of health literacy and providing sufficient detail in the brochure to achieve the health service duty of care regarding full disclosure of information. The brochure contained information to address issues raised at the Community Conversation such as explaining child health research, the goal and planned process of creating a research contact list, the information to be collected and how patient privacy would be managed. It was agreed that the term 'research contact list' be used to reflect the collection of consumer contact details only at this point (not linked to health information). The initial survey items were created and further developed in Stage 3. The brochure content and survey item refinements were made, presented and discussed with the different groups until agreement was reached about the content and presentation. This stage resulted in the development of a prototype colour brochure [40] and a draft survey presented in English language.

2.3 Stage 3: Prototyping

Using the survey developed in Stage 2, the aim of Stage 3 was to assess health service users' views about:

- The prototype brochure
- Being contacted about research and being part of a possible future research contact list
- A number of uncertainties regarding potential consumer participation in the research contact list, as identified in stage 1 of the project

The quality improvement activity involved requesting consumers to complete an online survey and agree to receiving a telephone call. Health service governance approval was obtained (Reg No 29335). Participation was voluntary, and the survey did not collect any identifying information unless participants agreed to be contacted for telephone follow-up and provided their name and telephone number.

The objectives for Stage 3 (and the intervention) were to:

- Assess appropriateness of approaching families to discuss research in the hospital settings of outpatient clinics and Emergency Department
- Assess content, clarity and presentation of the prototype brochure via a survey
- Measure families' recall and satisfaction with their responses and obtain feedback and suggestions to refine the brochure.

2.3.1 Setting

The setting of the quality improvement activity was a 250 bed specialist children's hospital serving a population of 500 000 children and young people. During 2018/19 there were 227 337 outpatient clinic attendances and 67 592 Emergency Department attendances [41]. Participants were recruited while attending a wide range of outpatient clinics including medical, surgical, and dental clinics. Emergency Department participants were recruited from areas in the triage waiting room catering for low-acuity patients. Participants who could speak, read and understand English were included. Data collectors were experienced in communicating with families in healthcare settings. Parents or carers with acutely ill children or who appeared to be anxious or distressed were not approached. Data collection was coordinated with clinical and clerical staff to minimise disruption to workflow.

2.3.2 Planning the intervention

A 20 item survey was initially tested with 40 families who attended the children's hospital and a community health clinic during an annual week-long patient engagement event. The testing resulted in minor wording changes to improve item clarity. The iterative testing process resulted in an additional question to understand families' preferences about being contacted about research by health service researchers only, or by researchers from other organisations. This was to answer another uncertainty about whether families' preference may differ depending on the research affiliation. The first 11 survey items captured participant characteristics. There were six items addressing key issues raised during consultations including willingness of families to be part of a contact list for future research studies, preferences for how to be contacted, preferred frequency of contact, the preferred person to inform families about the contact list and feasibility of the proposed process. The final four items requested participants to rate (using 5-point Likert type scale from strongly agree to strongly disagree) their level of agreement about the brochure and the online survey content and presentation.

The telephone follow up consisted of four closed questions capturing participants' recall about receiving the brochure, whether they would have liked additional information, whether they remained satisfied with the response given to being contacted about research, and their knowledge of how to update a change of preference about being contacted for research. The final question was open ended and invited suggestions to improve the delivery of information in future.

2.3.3 The intervention

One of two data collectors approached families as they waited for their outpatient clinic appointment or in the Emergency Department triage waiting room. Participants who agreed to complete the survey were invited to participate in a follow up phone call. These two settings were selected to access a large volume of families who may not have previously been exposed to research and to assess the appropriateness of approaching families in these settings.

2.3.4 Methods of evaluation

Data collection was completed in 2 parts between July and August 2019.

Part 1. Each participant was provided the brochure to read and invited to complete an online survey. The brochure was available to be taken away and some families did take a brochure. Survey responses were entered by participants on a tablet using Survey Monkey© software, There was no time limit to complete the survey.

Part 2. Two to three weeks later a telephone call was made to evaluate the experience of participants in Part 1. A maximum of three attempts to contact participants were made over a seven-day period. The purpose of the phone call was to capture participant recall of receiving the brochure, completing the survey, and to obtain feedback to improve the brochure.

2.3.5 Analysis

For the survey and telephone call responses, descriptive data analyses were undertaken using frequencies and examined for distribution and percentages. Categorical data are presented using proportions and frequencies.

3. Results

Five hundred and fifty five parents or carers were approached and 367 (70.3%) agreed to participate, read the brochure and completed the survey. Three hundred and twenty six (88.8%) participants had attended outpatient clinics and 41 (11.2%) had attended the Emergency Department. In the Emergency Department there were several parents or carers who appeared anxious and the data collectors did not approach them, for example, potential participants who did not make eye contact or appeared to turn away. One participant stated that he did not feel the Emergency Department setting was conducive to being asked to read a brochure and complete an online survey. No parents in the outpatient clinic setting appeared overtly anxious.

3.1 Part 1 Survey

Most participants (342, 93.4%) were parents of a child attending the clinic or Emergency Department. The majority were female (299, 81.5%) and in the 36-49 years age group (202, 55%). Ten (2.7%) parents or carers and 22 children (6.1%) identified as Aboriginal or Torres Strait Islander. Most (287, 79.1%) were also primary carers of other children under 16 years. English was the primary language spoken at home

for most (329, 89.7%) families. The remaining 38 (10.4%) identified 20 other languages as the primary language at home. Most frequently reported were Arabic, Mandarin and Mayalam (4 each). There were 25 (6.9%) children currently enrolled in research studies.

Four items received responses from all participants. Item response rates decreased progressively, with the final five items skipped by up to 25 participants. The item most commonly skipped (25, 6.8%) was the question 'what is the best way we can provide you with information about being contacted for future research?' Survey responses are presented in Table 2.

Table 2. Survey responses

Survey items	Responses n (%)
Please indicate your willingness to be part of a future research contact list	(n= 359)
Yes	196 (54.6)
Undecided	57 (15.9)
I need more information before I decide	27 (7.5)
No	79 (22)
The Health Service	
The Health Service or the co-located Research Institute	
Any collaborating organisation	183 (97.3)
	171 (91.9)
	154 (82.4)
Preferred information delivery methods about future research studies (more than one response was allowed)	(n=342)
Email	212
Social Media (PCH Facebook=57 Instagram= 40 YouTube =14)	111
Text message or phone call	78
Information screens in hospitals	51
Self check-in kiosks in hospitals	27
Brochures (not specified as paper or electronic)	130
Letters	91
Outpatient visits	63
During hospital admission or discharge	54
Advertising e.g. TV, billboards, buses	25
Banners in the hospital	24
Newspapers	15
	479
Maximum number of studies to be contacted about in 1 year period	(n=353)

1	86 (24.4)
2	71 (20.1)
3	32 (9.1)
4	4 (1.1)
5	4 (1.1)
>5	21 (6)
Unsure	83 (23.5)
Does not want to be contacted	52 (14.7)
Preferred person with whom to have research conversation (more than one response allowed) (n=352)	
Any of the listed Health Service staff	164
Doctor	112
Researcher	67
Nurse	66
Allied health professional	42
Someone I have seen before at the clinic	25
Administrative staff such as clinic receptionist	13
I do not want to be asked	43
Other specified - Unsure	1

*Total for all electronic methods of communication

The key survey item assessed participant willingness to be part of a future research contact list. More than half (196, 54.6%) were willing to join a contact list, 57 (15.9%) were undecided, 27 (7.5%) wanted more information, 79 (22%) indicated they did not want to be part of a contact list and eight skipped this question. For those willing to be part of a future research contact list, most (154, 82.4%) did not have a preference whether researchers from the Health Service, the co-located research institute, or any of the Health Service's collaborating partners contacted them about future research studies. Participants preferred to receive information about research electronically. Email information delivery was most popular (212, 62%). Eighty six (24%) participants indicated a preference for a maximum of one annual contact, 71 (20%) selected two, and 61(17%) were willing to be contacted more than three times in a one-year period. There were 83 (24%) participants who were uncertain. Almost half of the participants (164,

47%) did not indicate a preference for a specific health service professional to contact them about research, and approximately one third (112, 32%) preferred contact to be by a doctor.

Responses to the acceptability items indicated that the brochure and survey were both appropriate for the purpose with the right amount of information and content. Table 3 shows the responses.

Table 3. Feasibility and acceptability of brochure and survey

Feasibility and Acceptability	Rating scale n (%)				
	Strongly agree	Agree	Unsure	Disagree	Strongly disagree
Information in brochure was easy to understand	151 (43.8)	185 (53.6)	5 (1.5)	1 (0.3)	3 (0.9)
Amount of information in brochure was just right	116 (33.7)	215 (62.5)	8 (2.3)	3 (0.9)	2 (0.6)
Survey questions were easy to answer	177 (51.3)	161 (46.7)	5 (1.5)	1 (0.3)	1 (0.3)
I am glad I took part in the survey	117 (34.0)	200 (58.1)	24 (7.0)	2 (0.6)	1 (0.3)

3.2 Part 2 Telephone follow up

Telephone calls were placed a mean of 19 days following completion of the Part 1 Survey. Thirty six parents provided telephone feedback. Over 80% (29) were successfully contacted at the first attempt. All remembered receiving the brochure. Almost all (35, 97%) were satisfied with their response to the survey question about being part of a research contact list. Almost all (35, 97%) said that there was no other information they would have liked to receive at the time. Twenty spontaneously provided positive feedback about the brochure, indicating that it was informative, comprehensive and easy to understand. A few parents suggested shortening and refining the brochure. They indicated that more concise information would be more appropriate for families with lower health literacy. It was also suggested that we should provide links for electronic access to information.

4. Discussion

We adapted a three-stage framework [29] approach consisting of 1) evidence review and stakeholder consultation, 2) co-production and 3) prototyping to test a process of creating a contact list for future

research opportunities at a children's health service. The evidence review reinforced the value of taking the co-production approach. The stakeholder consultation stage indicated overall support for establishing a paediatric research contact list, as well as a considerable number of unknowns and potential barriers. The iterative prototyping process involved developing and testing a research information brochure. The survey and follow up telephone call findings enabled us to answer a number of unknowns and address potential barriers.

During consultation, most barriers were presented by staff working within the health service who expressed their own views about consumers' preferences. A number of these issues had been reported by others [42] and reflected the need for an organisational cultural shift to be open to change and responsive to consumer demand. The consumer consultation revealed that before establishing any registry there was a need to better inform health service consumers about research. At the consultation stage the consumer involvement steered the project to include a research communications plan and informed change of terminology from research registry to research contact list.

The prototype stage revealed there was overall consumer support to create a research contact list with more than 50% of survey participants indicating they would be willing to join a list and an additional 23% who were undecided or wanted more information before deciding. Without the knowledge gained from reading the brochure information, there may have been fewer parents or carers who indicated they would be willing to join a research contact list. The research information brochure was deemed to be appropriate and useful by parents and carers. We also found that most parents or carers were willing to be contacted by researchers from the health service or any collaborating organisation. Furthermore, although many parents preferred a doctor to talk to them about research participation, recruitment was perceived as a 'team effort' where parents did not have specific preferences about which team member talked to them about research [4]. Joining a research contact list will potentially enable greater access to research participation for families beyond the research affiliations of the treating medical team [42]. We found the outpatient clinic setting was a more appropriate environment than the Emergency Department to talk to families about research. This is likely because families experience stress and anxiety waiting in Emergency Departments and are therefore less willing to engage in dialogue with researchers [3, 43].

Our consumer population preferred research communication to be electronic rather than paper based, and for individuals to be able to manage their choices if they changed their mind about being contacted. These findings were similar to other Australian settings [5] and will inform our future directions to move to electronic systems that can be accessed by consumers. Our findings indicated that being contacted once or twice per year was acceptable to most participants. We found a smaller proportion of families willing to be contacted about research three or more times in a 12 month period which is more than previously reported in the adult context [5]. This may be because time commitments to future research studies are unknown. The survey showed that more than 90% of the children of survey participants were not currently participating in research and provided an indication of the potential benefit of establishing a research contact list. This finding is similar to other research participation reports [1].

Limitations of the quality improvement activity include that the focus was on the co-production approach for the development of the research brochure in a paediatric healthcare setting where most consumers are parents of children under 16 years. Electronic communication about research may not suit an older population of health consumers. We did not examine all concerns raised during consultation or test other aspects of the communications plan such as the social media campaign and health service messaging. It may be that other communication strategies could be more effective for awareness raising than an information brochure [36]. However, we did seek consumer feedback on information delivery methods. We obtained feedback only from participants who attended the outpatient clinics or Emergency Department. We did not assess the views of families who use the rest of the health service and their views may be different.

It was beyond the scope of the project to further examine reasons why a quarter of survey participants did not want to be part of a contact list. It may be because they felt their concerns about management of their child's health information were not adequately addressed by the brochure content, or because they were time poor. The project involved participation by English speaking participants only. The survey revealed a linguistically and culturally diverse population using the health service, with 38 (over 10%) participants whose primary language at home was not English. There may have been families who declined participation because they could not speak sufficient English. Future work needs to consider this diversity and find ways to cater for the needs of all families when a research contact list is created. The survey was tested for content validity but appeared to contain too many items (the final five items were skipped more frequently than the first 16). Findings will inform future work.

5. Conclusion

We used an adapted three-stage framework [29] approach to develop and test a process of creating a consumer contact list for future research opportunities at a children's health service. Stage 1 indicated overall stakeholder and consumer support as well as a considerable number of unknowns and potential barriers. Consumer and community input uncovered there was a need to better inform consumers about research and that terminology should be changed from research registry to research contact list. These insights steered the direction of the quality improvement activity, that is, the development and testing of a research information brochure for users of the health service, which was not initially planned. This demonstrates the value of consumer and community involvement from the outset of a research activity or process to ensure the outcome is of relevance and benefit to the public.

Stages 2 and 3 enabled us to address a number of unknowns and potential barriers. There was overall support to create a research contact list and most parents or carers were willing to be contacted by Health Service researchers or researchers from any collaborating organisation. Parents or carers did not have specific preferences about which research team member talked to them about research participation. Our consumer population preferred research communication to be electronic rather than paper based, and for individuals to be able to manage their participation choices. More than 90% of children of parents or carers surveyed were not currently participating in research, confirming the potential benefits of

establishing a research contact list. The consumer population included people from culturally and linguistically diverse backgrounds. The quality improvement activity findings will inform our future directions towards establishing electronic systems that can be easily accessed by consumers of the children's Health Service.

Abbreviations

patient and public involvement (PPI)

consumer and community involvement (CCI) in research

United States (US)

United Kingdom (UK)

Declarations

Ethics approval and consent to participate: Health service governance approval was obtained for Stage 3 of the project only, as the purpose of consultation undertaken in the first two stages of the project was to actively involve consumers, community members and other stakeholders in the planning and development of the research, which does not require Ethics Committee approval.

Consent for publication: Institutional governance approval was received for publication. Participant informed consent was verbally obtained for Stage 3 data collection.

Availability of data and material: Institutional governance approval does not permit sharing data

Acknowledgments

Funded by Telethon Channel 7 Trust

Perth Children's Hospital Nursing Research Consumer Advisory Group

Perth Children's Hospital Nursing Research Youth Advisory Group

Consumer and Community Involvement Program www.cciprogram.org.au

PARTICIPATE steering group and working party members

Conflict of Interest statement for all authors:

There are no conflicts of interest for any author

Funding details: The project was funded by Telethon Channel 7

Author Contributions

All authors

1. Have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2. Been involved in drafting the manuscript or revising it critically for important intellectual content;
3. Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; and
4. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

FG made substantial contributions to the conception and design of the work; the acquisition, analysis, interpretation of data; drafted the work, substantively revised it, approved the submitted version

CP made substantial contributions to the conception and design of the work; the acquisition, analysis, interpretation of data; drafted the work, substantively revised it, approved the submitted version

TJ made substantial contributions to the design of the work; interpretation of data, substantively revised the work, approved the submitted version

References

1. Modi N, Clark H, Wolfe I, Costello A, Budge H. A healthy nation: strengthening child health research in the UK. *The Lancet*. 2013;381(9860):73-87. doi:10.1016/S0140-6736(12)61818-2.
2. Bourgeois FT, Avillach P, Kong SW, Heinz MM, Tran TA, Chakrabarty R et al. Development of the Precision Link Biobank at Boston Children's Hospital: Challenges and Opportunities. *Journal of Personalized Medicine*. 2017;7(4). doi:10.3390/jpm7040021.
3. Brierley RC, Pufulete M, Harris J, Bucciarelli-Ducci C, Greenwood JP, Dorman S et al. Developing a UK registry to investigate the role of cardiovascular magnetic resonance (CMR) in patients who activate the primary percutaneous coronary intervention (PPCI) pathway: a multicentre, feasibility study linking routinely collected electronic patient data. *BMJ Open*. 2018;8(3):e018987. doi:10.1136/bmjopen-2017-018987.
4. Newington L, Metcalfe, A. Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams. *BMC Medical Research Methodology*. 2014;14. doi:10.1186/1471-2288-14-10.
5. Bryant J, Sanson-Fisher R, Fradgley E, Hobden B, Zucca A, Henskens F et al. A consumer register: an acceptable and cost-effective alternative for accessing patient populations. *BMC Medical Research Methodology*. 2016;16(134):1-11. doi:10.1186/s12874-016-0238-8.

6. Lai YS, Afseth, J.D. A review of the impact of utilizing electronic medical records for clinical research recruitment. *Clinical Trials*. 2019;16(2):194-203. doi:10.1177/1740774519829709.
7. Bellgard MI, Beroud C, Parkinson K, Harris T, Ayme A, Baynam G et al. Dispelling myths about rare disease registry system development. *Source Code for Biology and Medicine*. 2013;8(21):1-7.
8. Gliklich RE, Dreyer NA, Leavy M. *Registries for evaluating patient outcomes: a user's guide*. 3rd ed. Rockville MD: AHRQ Publication 2014.
9. Evans S, M, Bohensky PA, Cameron PA, McNeil J. A survey of Australian Clinical registries: can quality of care be measured? *Internal Medicine Journal*. 2011;42-9. doi:10.1111/j.1445-5994.2009.02068.x.
10. Hebal F, Hu, Y., Raval, M.V. Research using clinical registries in children's surgical care. *Seminars in Pediatric Surgery*. 2018;27:345-52.
11. Schmidt MK, Schmidt SAJ, Sandegaard JL, Ehrenstein V, Pedersen L, Sorensen HT. The Danish National Patient Registry: a review of content, data quality, and research potential. *Clinical Epidemiology*. 2015;7:449-91.
12. Cystic Fibrosis. 2020. <https://www.cysticfibrosis.org.au/>. Accessed 15 June 2020.
13. Australian Institute for Health and Welfare. Australian cancer database. 2020. <https://www.aihw.gov.au/about-our-data/our-data-collections/australian-cancer-database>. Accessed 15 June 2020.
14. Mc Carron TL, Noseworthy T, Moffat K, Wilkinson G, Zelinsky S, White D et al. Understanding the motivations of patients: A co-designed project to understand the factors behind patient engagement. *Health Expectations*. 2019;22:709-20. doi:10.1111/hex.12942.
15. Boivin A, L'Esperance A, Gauvin F-P, Dumez V, Macaulay A, Lehoux P et al. Patient and public engagement in research and health system decision making: A systematic review of evaluation tools. *Health Expectations*. 2018;21:1075-84. doi:10.1111/hex.12804.
16. Marjanovic S, Harshfield A, Carpenter A, Bertscher A, Punch D, Ball S. Involving patients and the public in research. Rapid Literature review: The Healthcare Improvement Studies Institute 2019. Report No.: 978-19996539-4-1.
17. Biggane AM, Olsen, M., Williamson, P. R. PPI in research: a reflection from early stage researchers. *Research Involvement and Engagement*. 2019;5(35):1-9. doi:10.1186/s40900-019-0170-2.
18. Manafo E, Peterman L, Vandall-Walker V, Mason-Lai P. Patient and public engagement in priority setting: a systematic rapid review of the literature. *PLoS ONE*. 2018;13(3):1-18.
19. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *Research Involvement and Engagement*. 2017;358:1-7. doi:10.1136/bmj.j3453.
20. Wilson P, Mathie E, Keenan J, McNeilly E, Goodman C, Howe A. ReseArch with Patient and Public InvOvement: a RealisT evaluation - the RAPPORT study. *Health Services Delivery Research*. 2015;3(38):1-208. doi:10.3310/hsdr03380.

21. Snape D, Kirkham J, Britten N, Froggatt K, Gradinger F, Lobban F et al. Exploring perceived barriers, drivers, impacts and the need for evaluation of public involvement in health and social care research: a modified Delphi study. *BMJ Open Access*. 2014;4:1-11. doi:10.1136/bmjopen-2014-004943.
22. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysal C et al. Mapping the impact of patient and public involvement on health and social care research: a systematic review. *Health Expectations*. 2012;17:637-50. doi:10.1111/j.1369-7625.2012.00795.x.
23. Bombak AE, Hanson HM. A critical discussion of patient engagement in research. *Journal of Patient Centred Research and Reviews*. 2017;4(1):39-41. doi:10.17294/2330-0698.1273.
24. Miller CL, Mott K, Cousins M, Miller S, Lawson T, Wesselingh S. Integrating consumer engagement in health and medical research -an Australian framework. *Health Research Policy and Systems*. 2017;15(9):1-6. doi:10.1186/s12961-017-0171-2.
25. National Statement on Ethical Conduct in Human Research 2007 (updated 2018). Canberra: The National Health and Medical Research Council.
26. West Australian Health Translation Network. 2020. <https://cciprogram.org/>.
27. West Australian Health Translation Network. Consumer and Community Health Research Network. 2020. <https://www.involvingpeopleinresearch.org.au/>.
28. McKenzie A, Bulsara C, Haines H, Hanley B, Alpers K. Barriers to community involvement in health and medical research: researcher perspectives on consumer and community involvement in research: a qualitative study. Perth, Western Australia: UWA; 2016. p. 1-34.
29. Hawkins J, Madden K, Fletcher A, Midgley L, Grant A, Cox G et al. Developing a framework for the co-production and prototyping of public health interventions. *BMC Public Health*. 2017;17(689):1-11. doi:10.1186/s12889-017-4695-8.
30. Freysteinson W. The ethical community consultation model as preparation for nursing research: A case study. *Nurs Ethics*. 2010;17(6):749-58. doi:10.1177/0969733010379176.
31. INVOLVE. Promoting public involvement in NHS public health and social care research. Patient and public involvement in research and research ethics committee review. Eastleigh, Hants: INVOLVE2009.
32. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (*Standards for Quality Improvement Reporting Excellence*): revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety*. 2016;25:986-92. doi:10.1136/bmjqs-2015-004411.
33. Pica N, Bourgeois, F.T. Discontinuation and nonpublication of randomized clinical trials conducted in children. *Paediatrics*. 2016;138(3):e20160223. doi:10.1542/peds.2016-0223.
34. Brierley RC, Pufulete, M., Harris, J., Bucciarelli-Ducci, C., Greenwood, J.P., Dorman, S., Anderson, R., Rogers, C.A., Reeves, B.C., Developing a UK registry to investigate the role of cardiovascular magnetic resonance (CMR) in patients who activate the primary percutaneous coronary intervention (PPCI) pathway: a multicentre, feasibility study linking routinely collected electronic patient data. *BMJ Open*. 2018;8(3). doi:10.1136/bmjopen-2017-018987.

35. Shamliyan T, Kane, R. Clinical research involving children: Registration, completeness, and publication. *Pediatrics*. 2012;129(5). doi:10.1542/peds.2010-2847.
36. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F et al. Strategies to improve recruitment to randomised trials (review). *Cochrane Database of Systematic Reviews*. 2018:1-185. doi:10.1002/14651858.MR000013.pub6.
37. My RCH Portal. Royal Children's Hospital. <https://myrchportal.rch.org.au/>. Accessed 2020.
38. Chakera A, Slatyer, S., Read, C. Opt-out approach for low risk clinical research: Community responses. 2017.
39. The World Cafe. <http://www.theworldcafe.com/>. Accessed 22 April 2020.
40. Child and Adolescent Health Service Government of Western Australia. What is child health research? Information for families. 2019. <https://pch.health.wa.gov.au/-/media/Files/Hospitals/PCH/General-documents/Research/What-is-research-A5-booklet-final-for-web.pdf>.
41. Child and Adolescent Health Service. CAHS Annual Report 2018/19. Perth, Western Australia. 2019. <https://www.cahs.health.wa.gov.au/-/media/HSPs/CAHS/Documents/About-us/Annual-Reports/2018-19AnnualReport.pdf>. Accessed 16 June.
42. Sacristán JA, Aguarón A, Avendaño-Solá C, Garrido P, Carrión J, Gutiérrez A et al. Patient involvement in clinical research: why, when, and how. *Patient Preference and Adherence*. 2016;10:631-40. doi:10.2147/ppa.S104259.
43. Rittenmeyer L, D H, C G. The experience of patients, families and/or significant others of waiting when engaging with the healthcare system: a qualitative systematic review. *JBI Database of Systematic Reviews & Implementation Reports*. 2014;12(8):193-258.

Figures

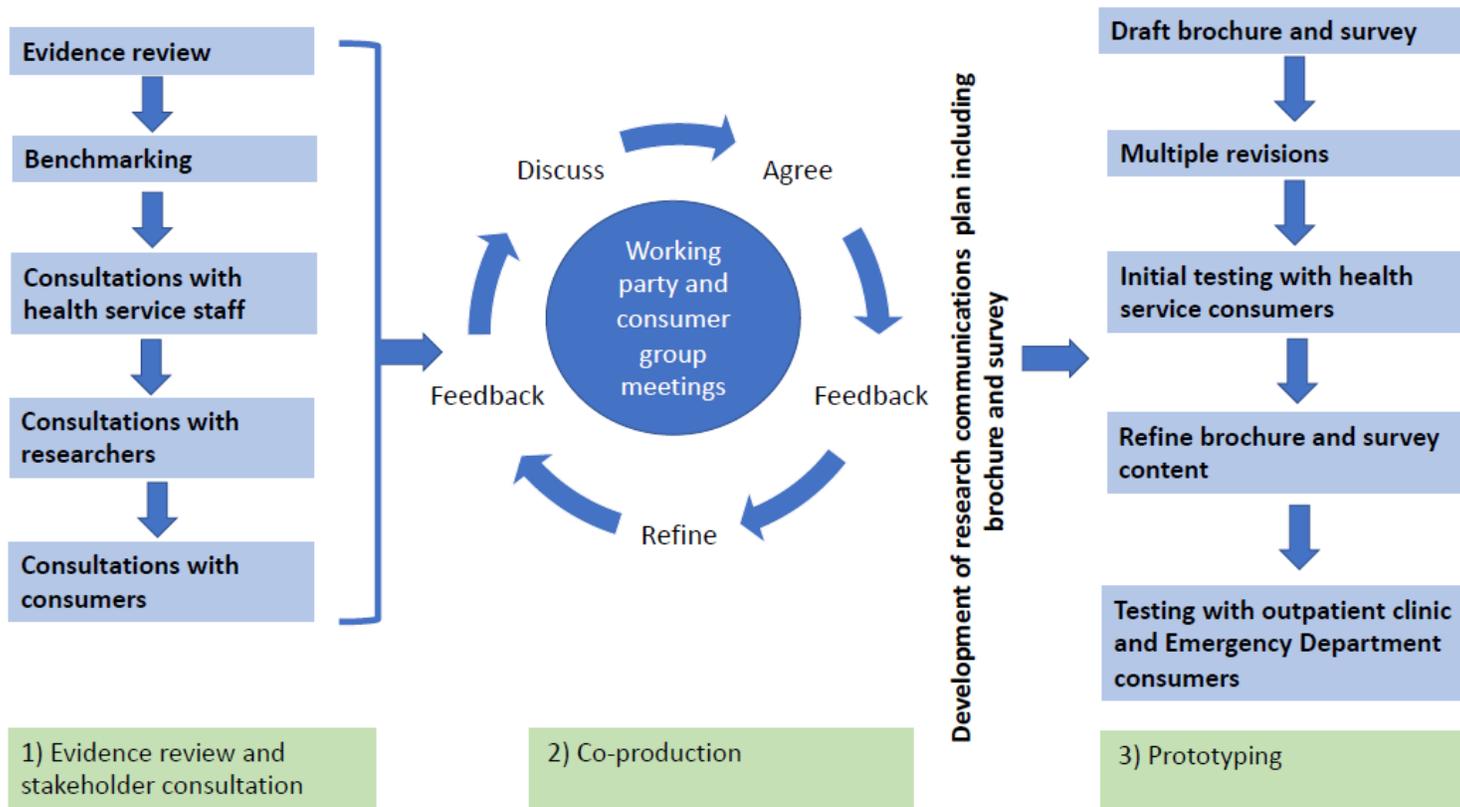


Figure 1

The PARTICIPATE Project