Facilitators and barriers to implementation of a pragmatic clinical trial in Aboriginal health services

Trials that address a priority health issue, have had strong health service engagement and adequate local support seem more likely to succeed

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Abstract

Objective: To identify facilitators and barriers to clinical trial implementation in Aboriginal health services.

Design: Indepth interview study with thematic analysis.

Setting: Six Aboriginal community-controlled health services and one government-run service involved in the Kanyini Guidelines Adherence with the Polypill (KGAP) study, a pragmatic randomised controlled trial that aimed to improve adherence to indicated drug treatments for people at high risk of cardiovascular disease.

Participants: 32 health care providers and 21 Aboriginal and Torres Strait Islander patients.

Results: A fundamental enabler was that participants considered the research to be governed and endorsed by the local health service. That the research was perceived to address a health priority for communities was also highly motivating for both providers and patients. Enlisting the support of Aboriginal and Torres Strait Islander staff champions who were visible to the community as the main source of information about the trial was particularly important. The major implementation barrier for staff was balancing their service delivery roles with adherence to often highly demanding trial-related procedures. This was partially alleviated by the research team's provision of onsite support and attempts to make trial processes more streamlined. Although more intensive support was highly desired, there were usually insufficient resources to provide this.

Conclusion: Despite strong community and health service support, major investments in time and resources are needed to ensure successful implementation and minimal disruption to already overstretched, routine services. Trial budgets will necessarily be inflated as a result. Funding agencies need to consider these additional resource demands when supporting trials of a similar nature.

The principles of conducting ethically sound health research involving Aboriginal and Torres Strait Islander peoples have been well documented.[1-3] There are, however, many challenges to implementation of these principles and negative experiences have been reported.[4-11] A key element to the National Health and Medical Research Council (NHMRC) guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research is the notion of reciprocity — that the benefits of the research be clearly articulated, negotiated and implemented in such a way that it will build community capacity.[1] In the context of clinical trials, this includes ensuring that studies test interventions in the settings in which they will eventually be delivered, rather than contrived environments that are conducive to easier trial implementation. Such trials are often referred to as pragmatic randomised controlled trials (PRCTs).[12]

The Kanyini Guidelines with the Adherence Polypill (KGAP) study was a PRCT that tested whether a polypill-based strategy would improve prescriber and patient adherence to recommended treatments for cardiovascular disease (CVD).[13-15] The trial was conducted between 2008 and 2012 across five Australian states in 20 general practices, 11 urban, rural and remote Aboriginal community-controlled health services (ACCHSs) and one government-run Indigenous health service. Participating services were each supported by one to three nominated community pharmacies. Design features that mimicked real-life practice included the prescribing of medicines by treating general practitioners, patient copayment charges for all study and other medicines at standard Pharmaceutical Benefits Scheme rates and the dispensing through community pharmacies. A major challenge to trial implementation was attaining target recruitment rates; only 623 of the target 1000 participants were randomised.[16] This led to a longer study duration than anticipated, with concomitant budget pressures.

In this qualitative study, we aimed to identify facilitators and barriers to trial implementation in the ACCHSs and government health service from the perspective of providers and trial participants. The study forms part of a broader trial process evaluation.[15]

Methods

Fifty-three interviews were conducted with 32 health care providers and 21 Aboriginal and Torres Strait Islander patients at six ACCHSs and the government health service from April to December 2012. (Appendix 1 and Appendix 2). Five ACCHSs that were involved in the trial were unable to participate due to limited capacity at the time when interviews were being conducted. Participants were recruited purposively to yield a maximum variation sample based on location, age, sex, ethnicity, presence of CVD, and medication for patients, and location and profession for providers.

Interviews were conducted at the conclusion of the trial as part of the overall process evaluation and included exploration of experiences regarding trial implementation. Interview guides were developed and iteratively revised to explore themes and issues emerging from earlier interviews. A team of

seven researchers, including three Aboriginal researchers, from a range of disciplinary backgrounds (health economics, pharmacy, nursing and public health) who were not involved in the implementation of the trial conducted the interviews. Most interviews were conducted face-to-face, with a small number conducted by telephone for logistic reasons.

Interviews were professionally transcribed and coded by two researchers (HL and LM) using NVivo 9 (QSR International). Twelve transcripts were selected (six patients and six health care providers — pharmacists, GPs, nurses and Aboriginal health workers [AHWs]) and were coded independently by the two researchers. These researchers identified the major themes arising from these 12 interviews and developed an initial coding framework. Insights gained by the research team about the context of the interviews and the local setting were documented and used to aid interpretation. The coding framework was then discussed and refined by a multidisciplinary group comprising the study investigators and the interview team. This included two ACCHS clinicians who were site principal investigators on the trial. The two researchers then coded the remaining interviews and made minor, iterative changes to code definitions.

For this study, we analysed codes specifically relating to issues relating to trial implementation. The randomised controlled trial, including its process evaluation, was approved by seven regional human research ethics committees, including one Aboriginal-specific committee. All participants who contributed data were provided a description of the study by the interviewer and given the opportunity to discuss any concerns before obtaining written consent.

Results

Four principal themes relating to barriers and facilitators for trial implementation were derived. Appendix 3 contains additional quotes that further illustrate the findings.

Health service governance of research

Ensuring community representation in governance of the research was a dominant issue. ACCHSs were invited to participate through initial discussions with senior management and governing boards. Formal memoranda of understanding (MOUs) with the coordinating research institutes were established. Amendments were made to the standard Medicines Australia clinical trial agreement to include intellectual property rights of ACCHSs and the roles and responsibilities associated with data custodianship. The discussions associated with setting up these agreements were critical in establishing mutual roles and responsibilities, data governance, capacity building plans and establishment of funding arrangements. One participant referred to the MOU as being a "landmark document" (GP 23, urban service).

In some instances, these agreements were facilitated by local governance processes. An AHW at an urban ACCHS described how previous negative experiences with external researchers prompted the establishment of a local research committee that would scrutinise external organisations' research proposals:

> In the past, the research that's been conducted has left some scars … what has helped has been being more organised about having our own research agenda … so if you want to do research [with us then] this is what's important to us. (AHW 47, urban service)

Motivation to participate

An expectation that the intervention could tangibly address an important health issue was extremely important for both patients and providers:

> When you see people that are dying around you that are the same age as you and even younger, it's all to do with health that they died not taking medication. Maybe if they were given the one pill instead of taking half a dozen they might be still here today. (Patient 4, urban service)

Several participating services had been involved in the Kanyini Vascular Collaboration before the trial and many staff were aware of the treatment gaps documented in the collaboration's audit of patient records.[14] Consequently, there was strong support from health care providers for strategies to address these gaps.

Effectively communicating the need to address these gaps to the community was particularly important. At one urban ACCHS this was done through a community forum and launch of the trial.

A related facilitator of participation was the role played by Aboriginal staff champions. These staff were often the initial point of contact for participants seeking information and were also referred to by other staff. One AHW discussed her role:

> At first it was hard to communicate with them. But once it got mentioned once, twice, maybe three times what was in the tablet, what the benefits would be it started sinking into their brains then. (AHW 32, urban service)

Balancing service delivery and research requirements

An important aspect of the research was to incorporate the intervention into usual service delivery. Efforts to streamline the intervention included the prescribing and dispensing of the polypill within existing software platforms, timing pathology tests to coincide with scheduled visits and recruiting community pharmacies that were accessible to the participating sites. Despite these efforts to integrate the intervention into routine care processes, some GPs felt it created "confusion in their management" and "confusion about what they were on when they went into hospital".

Some providers indicated challenges balancing trial operations with existing workloads. This manifested differently in urban and remote settings. For example, in urban settings, transport services were enlisted to facilitate study visits and access to medicines, potentially leading to

limited transport availability for non-trial patients. In remote settings, fly-in fly-out doctors provided services to highly mobile populations. This created substantial challenges for clinic staff to coordinate follow-up study visits. One GP felt that the trial was more suited to urban ACCHSs:

> You cannot compare it to an AMS [Aboriginal Medical Service] in Sydney … because we are serving about 200 000 square kilometres at this AMS. … our patients might come into town but they could be based 500 kilometres away … and it's a very transient place for many of our patients. (GP 40, remote service)

Such logistic challenges inevitably resulted in delays in recruitment and follow-up. To alleviate these challenges the study team committed additional unbudgeted resources to support trial sites.

Research capacity-building challenges

A core study objective was to build health service research capacity through involvement of staff in the clinical trial. Most of those interviewed considered trial participation to be a positive experience, with many staff members describing enhancement of clinical skills, increased awareness of clinical trial processes, and deeper collaborations between the health service and pharmacies.

A key capacity-building initiative was the creation of local Indigenous research fellow (IRF) positions to perform trial coordinator duties. In practice, however, recruitment of suitably trained individuals was challenging and only four positions were filled.

> The idea was that we were going to have an [IRF] is a great idea, but it just turned that we didn't really have anyone that took it on with a passion … [The role] is quite complicated … (GP 3, urban service)

Moreover, like all clinical staff, IRFs frequently had competing responsibilities, and found it difficult to balance their research role with service delivery. This led to staff turnover in the early part of the study, which affected the trial conduct. Overall, most trial sites commented that additional on-site support from research institute staff would have been beneficial. This was easier to provide at those sites located closer to the coordinating research institutes, and those sites tended to manage the trial with fewer challenges.

Discussion

This study examined the often-overlooked views and experiences of patients and health care providers from Aboriginal health services participating in a clinical trial. The key facilitators of participation were the interrelated factors of research governance, patient and provider perception of the need for this research, deployment of effective strategies for communication to the community at large, and enlisting the support of Aboriginal staff champions. These facilitators were tempered by several challenges related to adequate integration of the intervention strategy into routine care processes, large competing demands with routine service delivery, and only partially successful attempts at building local research capacity. These challenges manifested differently due to the highly diverse settings in which the participating services operated.

In Australia, several Indigenous health RCTs have been successfully conducted through established health service–researcher partnerships, particularly in the area of child health.[17-19] Many have experienced challenges in meeting recruitment targets and implementing the trials as originally conceived. Occasionally, trials have had to be abandoned altogether due to insurmountable constraints.[20] Our findings help determine the factors that both hinder and promote successful conduct of such trials. The integration of complex trial protocols that are not supported by senior management into underresourced health service settings is a recipe for implementation failure. Conversely, trials that address a priority health issue, have had strong health service engagement and adequate local support seem more likely to succeed.

The study was an indepth exploration of issues from a sample that was not necessarily representative of all participants and providers in the trial. Fewer interviews were done in remote sites, and staff who had left the service or participants who had withdrawn by the end of the study were not interviewed.

Although this study was based on a PRCT, such a design will not always be feasible nor acceptable. Alternative designs, such as stepped wedge trials and cluster RCTs of health service interventions, have been successfully implemented in collaboration with ACCHSs.[21,22] Other designs, such as crossover studies, interrupted time series analyses and propensity score matching, are also practical and often cheaper to implement. Use of automated de-identified data extraction and opt-out consent processes can considerably reduce data collection burden and reduce demands on Aboriginal health services.[22] There is also much to be gained from observational studies, in which routinely collected clinical audits can inform the evidence base about effective health service strategies.[14,22-27]

Although community participation in prioritising the research question is of fundamental importance, substantial research infrastructure investment in health services is of equal importance. Aboriginal governance and leadership of the research agenda must be in place, and there are now good examples of how large-scale research can incorporate this from the outset.[28,29] Associated with this is clear articulation of the resource implications associated with participation and ensuring there is adequate recognition of this within study budgets. The model for capacity building had mixed success, mainly due to the excessive and competing demands on individuals and limited existing research capacity; novel models to increase research capacity are needed.

There is clearly a need for more interventional studies to build the evidence base of what works in Aboriginal health service settings.[23,30] It is important that research funding bodies recognise the factors

highlighted in this study in their grant schemes. The overall $5 million (around $8000 per randomised patient) spent on the Kanyini GAP trial was several times higher than the amount originally granted and multiple additional funding applications were required. Although guiding statements on appropriate ethical conduct of research involving Aboriginal and Torres Strait Islander peoples acknowledge these issues, project-specific funding schemes tend not to recognise the importance of long-term investments in research capacity building, beyond what is immediately required to complete the project.[1,2] In addition to non-project specific schemes, such as the NHMRC Centres for Research Excellence, project-specific loadings for research conducted in collaboration with already overstretched Aboriginal and Torres Strait Islander health services ought to be considered to support local research capacity building and establishing the governance arrangements needed to ensure community support. Such investments would build the evidence base on models associated with success and strengthen the application of reciprocity in the conduct of Aboriginal and Torres Strait Islander research.

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