Beyond the Form: Engaging with Participants Throughout Clinical Research

Interviews with people working in clinical research

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BACKGROUND

The connection between someone in a clinical research study and their study team is important, and can change how safe, supported, and informed the person may feel throughout their experience. This project seeks to explore ongoing communication strategies in Australian clinical research and associated barriers and opportunities. The 'Beyond the Form' project has been established by CT:IQ and the VCCC Alliance. The project team includes sponsor, CRO, ethics, and consumer representatives. The project will include:

1. Identifying communication strategies adopted by people working in research (surveys and interviews), consumers (survey) and reviewing published evaluations of strategies (white paper)
2. Workshops with past research participants to explore their reactions to identified strategies
3. A stakeholder workshop to refine suggestions

The final output will be a toolkit to help researchers incorporate effective communication into study design, and suggestions for site staff in carrying out these strategies. [fig 1: timeline]

This poster presents the findings from the interviews with people working in research.

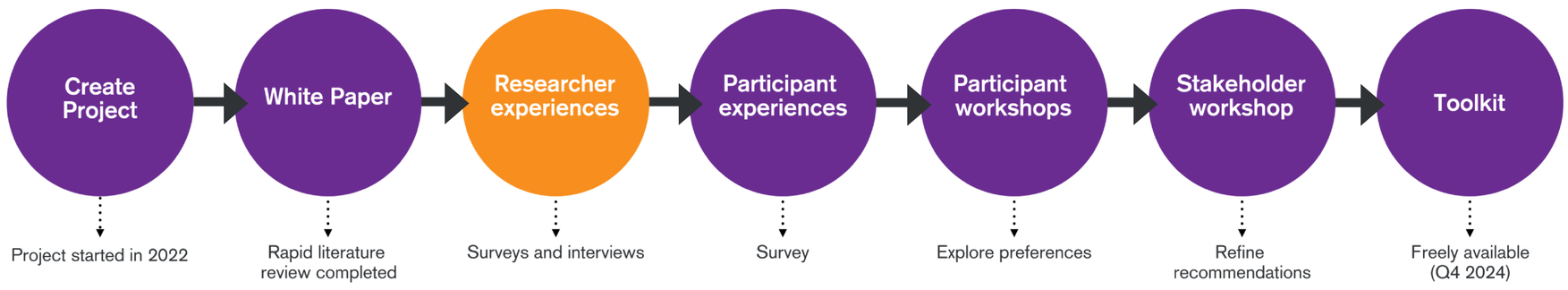
METHODS

Twenty interviews were conducted with persons working in research between August and October 2023. Interviews covered interviewees':

1. Professional background, current role, and research activities
2. Participant characteristics, including age, disease status, and motivations to participate
3. Thoughts on the effectiveness of communication strategies they have used or seen employed
4. Ideas for improving communication with participants, and what barriers there might be to implementation

Most (15) interviewees had worked in clinical research for > 5 years. Interviewees included persons in public and private hospitals (14), industry (1), government organisations (2) and academic research institutions (3). Seven (7) worked in regional or rural areas. Most worked exclusively with adults (14), but some worked specifically with children or adolescents (6).

A context analysis on the interview transcripts was performed by investigators Wells and Eckstein using a positivist approach.



"A feeling of alienation can be particularly difficult for long trials where the participant is also sick. My blood cancer clinical trial was 2.5 years, but the last 2 years was oral chemotherapy where I had minimal hospitalisation and felt very isolated at home, trying to look after my young daughters like 'normal'."

- Health consumer

CATEGORIES AND THEMES

A. Knowing your participants

How participant characteristics and motivations impact effectiveness of different communication strategies, and barriers that participants may face to engaging with communication strategies (such as timing of phone calls, familiarity with technology used, language).

B. Designing for success

Things that sponsors should consider, and sites should review in the design of protocols and budgets. How ethical and governance approvals and site policies can shape what is possible.

C. Care-research interface

The impact of the clinical research coordinator in the delivery of effective communication, and how clinical research interacts with clinical care.

D. Effective communication

Different modes of communication, and why different choices might be made depending on the reason for communicating. The long-term benefits of effective communication include improved data quality, recruitment, retention and repeat participation in future trials.

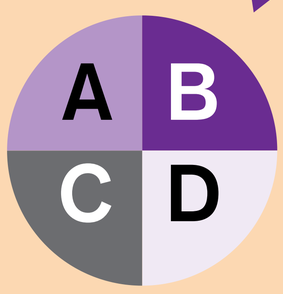
"With healthy volunteers, I don't even know how you'd keep that engagement going. Ours is very simple because they want to be here for the free therapy that's potentially going to save their life."

"Providing information about study progress for participants is not something I've ever raised with the sponsor because I think it would need to be an industry wide thing: it's just not done."

"I have not yet come across a trial where a particular communication method has been incorporated into the protocol."

"We're quite ethically bound about what we can do. Anything that comes from us needs to be approved to be a formal communication. We can initiate it, but the sponsor would need to approve it, ethics would need to approve it, and governance would need to approve it."

"Honestly the feedback that I get from parents is if there's a password and a log in, that's a barrier. Parents are like, give me a hard copy piece of paper I can write on."



"An excellent study coordinator has both the skill set that you can do the work, but you can also get that rapport with the patients that they trust you. You do become part of their world, but without overstepping. That is a really difficult skillset to put into place because sometimes these patients are quite sick as well, so you're very involved in their lives."

"I feel like text is the key ingredient to teeing up a time and making this happen when you try and call them. Some are schoolteachers, some work on building sites and won't have access to their phone all the time, so dropping them a message a couple of days early saying, "We're due for our six monthly catch up on Thursday, what time works best for you?"

"For follow-up calls we usually check their medical record first before we even contact the patient, because it's really important for us to know if they are going through something quite rough. If they've just progressed or they end of life, we sometimes will go and chat to the doctor before we call them being like, is it appropriate for us to actually call them?"

"I see consent is as a continual discussion. It's not just at the beginning, it's not just when you have an update but all the way through. We actively encourage our participants all the way through to tell us if they're not happy, if something's happened, or if they have any complaints or concerns."

DISCUSSION

Thoughtful consideration of participant characteristics and flexible communication strategies have been identified as leading to tangible benefits. These include increased data quality and completeness, retaining participants (which is particularly difficult for healthy volunteers), and improving future recruitment efforts through repeat participation or word-of-mouth encouragement to others.

The next step for this project will be to take strategies discussed in these interviews, the white paper and surveys, and workshop them with participant groups to explore their preferences. This will facilitate Australian research that shows respect for participants throughout their clinical research journey.

Read more about Beyond the Form

White Paper

CT:IQ acknowledges Aboriginal and Torres Strait Islander peoples as the traditional custodians of the land on which we meet, work and learn. We pay our respects to Elders past and present.

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