Participation in Clinical Trials at Cabrini

Report: Consumer Experience and Insights on the National Clinical Trials Governance Framework
July 2023

Background

The Australian Commission on Safety and Quality in Health Care developed the National Clinical Trials Governance Framework (NCTGF) to support a nationally consistent approach to the accreditation of health services for the conduct of clinical trials.

Clinical Trials are now part of the Hospital Accreditation Standards, with particular focus on clinical governance standards and partnering with consumers.

The Cabrini Board and Executive Group are committed to embedding the NCTGF in all aspects of service provision, knowing that high quality research will provide better outcomes for patients and the broader community.

Cabrini Research is privileged to partner with the Cabrini Research Consumer and Community Involvement Committee (CRCCIC). At its 7 June 2023 meeting it was proposed that a focus group workshop would be held to discuss the implementation of the NCTGF, and to provide feedback on a proposal for developing a Cabrini Research Virtual Patient Tour.

The invite was extended beyond the CRCCIC to Cabrini clinical trials participants given their valuable perspective of the lived experience. Understanding patients' and families' experiences, perceptions and preferences is vital to Cabrini Research's quality improvement initiatives.

Method

A focus group workshop was held on Wednesday 26 July 2023 between 1.00-3.00pm, in the Boardroom of Cabrini Institute, Malvern.

Although face-to-face participation was preferred, remote on-line access via Zoom was also provided.

The focus group was planned consistent with Cabrini policy Consumer Focus Groups and as such records of focus groups involving consumers will be maintained by the Cabrini Patient Experience team. The focus group was approved by the Cabrini Research Governance Office, and Cabrini Research NCTGF Working Group. It was a stand-alone quality improvement exercise rather than a research project.

Pre-reading material was provided to the participants covering the different elements of the NCTGF which require consumer engagement.

The focus group workshop was recorded with verbal permission. A photo opportunity was also taken with verbal permission

The purpose of the focus group workshop was to seek opinion on:

1. The NCTGF, which has been mandated to ensure that hospitals conducting clinical trials are working at best practice. The standard of partnering with consumers was the particular focus as one of the five components of the framework

2. Developing a Cabrini Virtual Patient Tour, to prepare, inform and guide expectations of patients about to be recruited onto a clinical trial

The focus group was facilitated by a Cabrini staff member (Project Lead for the NCTGF) who had previous experience conducting consumer consultations. The discussion took around 90 minutes, including a brief power point presentation by the Project Lead for the NCTGF covering clinical trials and the framework elements.

Results: Key themes

There were 8 participants in the focus group workshop. 7 consumers participated face to face. 1 participant utilised online remote access.

The composition of the group included 3 males and 5 females.
6 participants were current or past clinical trials participants, one participant was a spouse of a clinical trials participant and 1 was a CRCCIC member.
2 participants were from regional Victoria.

1 participant provided additional written feedback after the focus group, and this information is included in the thematic analysis.

Thematic analysis is described below. Included quotes have identifying information removed.
The Virtual Patient Tour discussion will not be included in this report.

Benefits of clinical trials participation: Attention and opportunity

The participants were complimentary of their clinical trials experience at Cabrini and felt participation provided another level of support and opportunity. Research participation allows people to feel hopeful:

I felt very confident in my care. The support team was wonderful. I did not feel rushed – things were explained *along the way and I felt very comfortable with the procedures. I am really keen to be involved as I know how much this helps people.*

For me it made sense to say 'yes' to a clinical trial as it meant I was receiving another level of attention… if you are getting good care and it can go to another level by entering a clinical trial, I think that is an advantage that can also be promoted, particularly when you have an overarching specialist who is working alongside your physician to say 'This is how we are doing the research'.

I decided there wasn't another alternative – I could have gone for chemo or radiotherapy. So far it has been amazing. I am very very fortunate. I have signed again for another year.

I know of patients (when I was working) who would love to have had the opportunity to be on a trial for their conditions. I remember seeing a woman who was very upset as she just wished there was some other opportunity / option to help her husband – the clinical trial is that hope.

Communication and consent

Research participant consent forms can be lengthy and complicated. Best practice supports timely and ongoing verbal communication to supplement the written explanation:

The Principal Investigator took time to explain and there was a lot of details. No issue with PICFs. Took the PICF home to read through a couple of times and understand. Had no problems the whole way through with communication. My coordinator (name removed) is very good and has taken me through each step. The way staff have explained things is quite good and everything has gone smoothly. A small introductory video for new patients would be helpful*.

As a former trial coordinator, complicated consent forms were an issue. Patients seemed to feel too scared to ask (for clarification). Do patients really understand what they are consenting to, especially those with language barriers? Doctors are often rushed when they really need to be taking time – this responsibility is often pushed onto the study coordinator

Getting to understand the meaning of the consent. People can be very passive and accommodating, and they won't say that they don't quite understand for whatever reason – fear of feeling stupid. But if you have someone that can reinforce the follow-up, that might be the role of an extra person on the team that can be efficient, not only providing better care, but limit the time from the physicians.

There is so much complex language. This 'interpreter' could put this into language participants can understand.

Clear communication around the time commitment is an important aspect when discussing a study with a potential participant. This includes the time commitment for carers who may be assisting their family member to attend appointments.

You need to very carefully explain the time commitment and the impact it will have on carers – it's not like standard clinical care. Patients can come for a standard clinical care appointment and be interested in a clinical trial but not realise the difference in time commitment.

Yes. I had to be. I am with (name removed) all the time for his visits and am learning all the time

Consent is an ongoing process throughout the life of a study:
The consent forms have needed to be re-signed. It was all explained well. I was given a copy and the changes were highlighted so I understood. I definitely had an opportunity to ask questions. It was one-on-one with the PI who went through all the procedures – it was well explained*

There was unanimous support to proactively seek the reasons for patient withdrawal from a clinical trial.

Promoting access to research

Barriers to research participation, and the opportunity that technology provides, was discussed. The response to perceived barriers were varied:

Cabrini is a captive hospital in that you have a number of physicians that practice here, have rooms here, Cabrini is their hospital of choice to practice. Once the patient has been identified as being suitable for a clinical trial, that physician would pass that responsibility onto a specialist physician. Some people opt out or just don't turn up. There is the tyranny of distance which can be overcome by Zoom but if you are doing it with drugs and other procedures, you need to be here. For me it wasn't a problem but it might be for others for whom it is a barrier to do the procedures on the ground here.

Distance is not a barrier. I'm used to driving. My family live in Melbourne and live locally if I need to stay overnight.

Use of technology as an available option was seen as beneficial to access and quality of life:

Opportunities to use technology like Zoom helps with participation, meaning people don't have to travel into the city. People don't feel so isolated, especially when she doesn't have someone to drive her in for appointments.

Promoting awareness of research

Participants felt that research awareness raising is important not only for patients, but also within the organisation:

How do clinicians know what trials are going on in their relevant area to refer patients, even if they are not directly involved on the trial?

Promoting Cabrini as a specialist research hospital was encouraged:

You've got a 500 bed hospital – a big hospital. You run certain specialities and I believe they should be promoted 'we specialise in this and we have the following consultants' – you do that already. The next step is promote that there is clinical research and it is different to going into the hospital for clinical care. The hospital has a lot of clinical associate professors doing teaching and research. Is it an educational hospital? Is it a teaching hospital? The next stage is 'Is it a clinical trial hospital'? And what do we do with that? You have some pretty good minds here.

Provide trial information at the point of admission on a flyer 'Do you qualify for research?' 'Where to go for your questions about research'

Letting people know about the wonderful work being done is so important. It's like all the evidence-based fine top quality research that is going on – they are hiding their light under a bushel. You are competing with influencers and social media.

A suggested communication strategy was to promote the lived experience and outcomes of research:

Promote the stories of the people that have participated. Can you collaborate with other health services? Provide some feedback after the event to participants to know if the trial worked or not.

Support elements – peer and staff

Themes of 'continuity of care' and 'support' staff were elicited as part of the discussion:

It's also about consistency. There is nothing better than the familiarity and sense of comfort in continuity, knowing you are going to see the same person who is more at a level where people can be open and vulnerable 'I'm not sure about… issues with travel, about side effects – worrying about if it is another metastases etc.'. If you have someone that can just be there on a really human level – a consistent conduit.

When I was on the previous trial (21 years ago), I had a person ring me regularly to check how I was going and if I had any questions. I found that to be very inclusive and informative at a very personal level so I thought that was an excellent idea. The trouble with that is that it costs money for the person to be there all the time. I'm not sure how you get over that money (i.e. funding the role) issue.

My specialist has a far better idea of what is happening with my eyes and my disease through consistent care.

Is there an opportunity for a dedicated patient advocate within the team? So that you have someone that liaises with the patient and sets a gold standard for the approach we take? You know the physicians have limited time. To have someone that works with the trial coordinators and closely with the team to address the concerns of the consumer

A suggestion for peer support was of interest. Mechanisms for connecting with other Australian participants of the trial are not usually integrated into clinical trial provision and could be examined further for opportunity, including online:

I would have liked to have met other people with the same symptoms or side effects – I know this is not possible for my current trial. Do other people on trials have meetings with other people on the same or similar trials?

Communication with general practice, and between specialties, was strongly encouraged:

I say 'I'm the patient – that is what I want… I insist that my GP gets the same results as all the specialists. I have trained my people. If I have a kidney / heart / prostate problem, I don't want any of you saying you practice silo medicine. I don't mind having a physician that has overall responsibility with my tests going to everybody, or being a guinea pig, but my physicians have to be in the loop.

Diversity and inclusion

There were questions from consumers around how sponsors could support recruitment of participants from different cultural background through the provision of study material in other languages:

I don't know what support is given from Sponsors for providing this information but increasing trial patient diversity is important. Is there a particular CALD group that Cabrini could target and seek support from Sponsors for? Is there money available to do this for any IITs*? Would this also require interpreter services to be available for the trial participant visits?*

When a question was posed around the framework suggestion for reports on interpreter use in clinical trials to be provided to consumers this elicited an expectation that interpreters are available the same as for general clinical care. It also highlighted previous themes around desire for continuity of care.

We just assume the services are there. Are clinical trials participants just at Cabrini or is it a wider group?

It reflects diversity – cultural and linguistic – within the clinical trials and hospital populations. Agree this is an important area we need to report on. Patients are on a long trial journey but there can be turnover in interpreters which can pose challenges. Does Cabrini experience this?

Have you had a lot of people that have ended the trial? And have you noticed you have needed that service after? How do we ensure then interpreters have clinical knowledge?

Feedback on clinical trials - a two way street

When asking participants how they see consumers providing feedback on research it was very evident that communication works both ways. Whilst the health service organisation is interested and engaged in hearing feedback, consumers are also interested in the progress of research:

*I think most participants want this [*standard 2.2: Feedback of clinical trial data to consumers*]. As final results can take many years to be obtained I think it is important a participant understands this. But information on the trial status and any interim data would be valued by patients*.

Methods of seeking feedback from clinical trial participants elicited varied responses:

Apart from information on the website are there feedback forms in the clinical trial area?

Getting the group together is a good idea. Discussion amongst a group makes people think about topics or issues they hadn't previously considered.

Interview / direct / verbal is preferred to a survey which can contain confusing / off-putting language. For surveys that have answers like average or better than average – what is that going to tell me? A short survey could be good as an 'early warning system' before things go off the rails. A short survey is fine if it is really well thought out.

Could this be as basic as a poster/document letting patients know that reporting of any risk or potential risk is welcome and how to do this?

Security around identity, anonymity and data security was also expressed:

Patient feedback/review on the overall process of Cabrini's risk management system? As a patient I would want to be sure that no reports or data analysis could be identifying. Is this a risk given some trials have small number of recruits? I'm thinking here not general incidents like trips and falls but where an incident is related to a specific test or

procedure that is unique to a trial.

I can see this (Charter of Rights) *on the Cabrini website. Does it need to be provided physically to the participant?*

Feedback on the Framework: empowerment or consumer fatigue?

Whilst there is support for consumer engagement in research there were some reservations expressed about the scope of consumer input required as described in the Commission's framework:

Increasing consumer involvement is a great thing to do so long as there is sufficient interest from participants and a large enough number of them to share the work. I can see an issue with consumer fatigue occurring if the same group of people are called upon repeatedly to assist.

*…There is a risk of survey fatigue also, there seem to be a lot of time points and areas where feedback is asked for [*in the framework user guide*]…*

There was a sense that sections of the framework were asking for feedback on very similar matters. Elements of standard 2.3, 2.8, 2.9 and 2.10 appeared to consumers to be seeking very similar information, or could be captured in a consolidated way:

Is some or all of this covered by the Survey and the Cabrini feedback form?....
Is this information available through other Cabrini surveys or are we needing to capture just research participants? Applies to sections 2.8 also…

This feels like it's wrapped up in questions that are asked in previous sections about consent

Is this asking for feedback from the patient or to show that Cabrini has a policy regarding communicating AEs and incidents to patients?* (ref: standard 2.10 incidents and adverse events communication)

Discussion and recommendations

In 2021 Cabrini celebrated 25 years of research. Cabrini Research leads with a vision to be the leading private research institute for cancer, cardiac, and musculoskeletal research in Australia.

Cabrini has a proud history of being a community of care, reaching out with compassion, integrity, courage and respect. Partnering with consumers is embedded in the culture of care at Cabrini.

Consumers bring a broad range of valuable perspectives and experiences that can improve the quality and impact of research. Whilst the focus group consultation was with a small number of clinical trials participants it is interesting to note the themes were similar in nature to those described by the Commission in its 2022 *Community Perspectives Survey Report Addendum 3 – National One Stop Shop and National Clinical Trials Front Door Consultation Report*[1]. These included the barriers and enablers to recruitment, motivations to participate in a clinical trial, respectful relationships with members of the research team, ongoing communication and updates throughout the trial, and sharing results at the end of the project.

Similarly in 2022 the *Good Clinical Trials Collaborative* promoted how members of the public can play a key role in refining and prioritizing research questions. Potential participants and/or members of the relevant community provide valuable contributions to the design, execution and interpretation of randomised control trials. Best practice is to provide clinical trial participants with relevant, easily understandable information while carefully balancing the duty to inform within the clinical context against the risk of information saturation.[2]

A summary of the Cabrini consultation observations and recommendations include:

1. Aspects of care in research are no different to those of general clinical care in so far as there is a desire for 'continuity of care', individualised care, departments working in an integrated way (no silo's), good communication, and a point of contact/support staff person.

2. There is an expectation from the community that Cabrini understand their patient demographic profile and endeavours to also understand the clinical trials participant profile and make accommodations to support their needs. Interpreter access is a key aspect of this delivery.

3. Engage with sponsors to support the partnering with consumers standard. These include: consideration of support groups access, patient materials in languages other than English, consent forms using simple language, updates on the progress and results of the study communicated to participants in a timely and ongoing manner.

4. In seeking feedback from participants utilise a variety of formal and informal methods. A short survey supports quantitative data collection and anonymity. Face to face informal chats and check-ins are encouraged. Focus groups and feedback sheets/mechanisms are also to be encouraged. Endeavours to document reasons for withdrawal also require collation and examination for quality improvement opportunities.

5. Acknowledge and respect that each individual clinical trial participant and their family have different desires and expectations in their engagement and feedback provision. The nature of participation can lead to information overload and consumer fatigue.

6. In demonstrating that Cabrini is meeting the S2 standard of partnering with consumers care must be taken to not overburden individuals or groups.

7. Engage with marketing in order to increase the research profile for internal and external promotion. Utilise and share stories of clinical trial participants. Promote Cabrini's key research specialties as well as growth targets. Promote between departments as well as to the broader community.

8. Utilise knowledge around the enablers and benefits of research to promote access and participation. Educate patients about research as part of routine clinical care.

9. Reiterate that communication underpins all clinical trials work. Training and policy updates on research consent, GCP (Good Clinical Practice) and research integrity/code of conduct warrants attention.

10. Foster a culture of consumer engagement through the life of a study, from research feasibility and funding through to post study follow up and reporting of results.

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*Glossary

PICF – participant information and consent form
PI – Principal Investigator
CALD- Cultural and linguistically diverse
AE- adverse event
IIT – Investigator Initiated Trial

Reference

[1] Australian Commission on Safety and Quality in Health Care. *Community Perspectives Survey Report Addendum 3 – National One Stop Shop and National Clinical Trials Front Door Consultation Report,* May 2022

[2] Good Clinical Trials Collaborative, *Guidance for Good Randomized Clinical Trials*, May 2022. goodtrials.org

Focus group participants. Printed with permission.