

Development of the Consumer Involvement & Engagement Toolkit: a digital resource to build capacity for undertaking patient-centred clinical trials in Australia

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Abstract

Objective: This manuscript describes the novel approach to developing a toolkit to support meaningful consumer involvement in clinical trials in Australia to help guide others in considering the development of similar resources. The toolkit aims to support greater consumer involvement in shaping how clinical research is prioritised, designed and conducted.

Type of program or service: A working group of researchers, research organisations and consumers was established to co-develop the Consumer Involvement and Engagement Toolkit (the 'Toolkit'), a digital resource to guide researchers and organisations regarding consumer involvement in clinical trials.

Findings: A literature review and international scan of best practice revealed numerous resources outlining best practice for consumer involvement in clinical research and clear evidence of its impact and value. Through a novel content-sharing process, we were able to utilise these resources to develop a comprehensive Toolkit for researchers and research organisations that provides world-class guidance.

Key points

- There is a growing movement to promote consumer involvement in all aspects of healthcare, with new standards in Australia raising the bar on consumer involvement in all aspects of clinical research, including clinical trials
- A working group of researchers, research organisations, clinicians and consumers was established to co-develop the Consumer Involvement & Engagement Toolkit (the 'Toolkit'), a digital resource to guide researchers and organisations regarding consumer involvement in clinical trials
- A content sharing agreement enabled the inclusion of international resources that could be ratified and adapted to suit the Australian research environment, enabling the rapid development and launch of the Toolkit

Lessons learnt: There is a growing movement to ensure consumer involvement in healthcare, including in clinical research. We discovered its proponents were willing to share their tools and resources to promote international consumer involvement. Although these international tools and resources needed adaptation to suit the Australian research environment, this was achievable with far less effort than developing them from scratch.

Introduction

Consumer involvement in health system operations is a common theme across many international initiatives to improve clinical research conduct.¹⁻³ The Australian Government Department of Health is implementing the National Clinical Trials Governance Framework, which extends the National Safety and Quality Health Service 'Partnering with Consumers' accreditation standard to clinical trials.⁴ This requires healthcare organisations to develop, implement, and maintain systems to ensure consumers and their communities guide all aspects of clinical research strategy. However, many commentators caution that for effective and meaningful consumer involvement, organisations and their researchers must see the value of this activity, be skilled and funded to undertake it, and ensure the consumers they involve have the confidence and support to contribute fully and effectively.⁵⁻⁷

In 2018, two government-funded organisations, the Australian Clinical Trials Alliance (ACTA) and Clinical Trials: Impact & Quality (CT:IQ), surveyed clinical trial networks, coordinating centres and industry to determine the extent and impact of consumer involvement in their trials.⁸ The surveys confirmed that additional support for researchers, research organisations and consumers would strengthen consumer involvement practices across the sector, both at an organisational and trial level.⁸ In response, ACTA and CT:IQ began work in October 2018 to develop a comprehensive online resource, which was launched in October 2019.

This paper describes the rapid development of the Consumer Involvement & Engagement Toolkit (the 'Toolkit') and the novel approach to content sharing that

has enabled the developers to produce a comprehensive national resource within a tight project timeframe.

Methods

A working group of researchers, research organisations and consumers was established to codevelop the Toolkit. Individuals were identified through an open call to ACTA member organisations. Their first task was to develop the Toolkit's project plan and its core design and development parameters. The key requirements identified are summarised in Table 1.

The Working Group favoured a digital resource (website) that could be readily updated as consumer involvement best practices evolve. To ensure the Toolkit was populated with evidence-informed practice, a synthesis of international guidance and published literature was undertaken to identify best practices for consumer involvement. This review included:

- A Medline database search using key words including 'patient', 'public', 'consumer', 'involvement', 'engagement', 'health', 'research' and 'value' among others, identified 1344 articles (published from 2005 to 2021) of which 103 were relevant. A snowball search of the 6 systematic reviews from this search and a Google Scholar search identified a further 48 articles. A total of 157 publications qualified for review.
- An appraisal of guidance provided by key international bodies responsible for consumer and community involvement, including National Institute for Health Care Research (NIHR) Involve (UK)⁹, the Strategy for Patient-Oriented Research (Canada)³, the Clinical

Table 1. Stakeholder advice to guide the Toolkit's design and development

Requirements	Rationale
Conduct a literature search of international best practice and partner with international organisations to enable sharing of resources and ideas.	To build on existing resources and enrich the Toolkit's content, accelerate its development and minimise its development cost.
Use the literature to support Toolkit content so that researchers/organisations can access the evidence underpinning its content.	To ensure the Toolkit content is informed by current thinking and evidence of best practice.
Include sections on equity and diversity and provide translations for any consumer-facing content that reflects the Australian population's diversity.	To support ethical research and to make research more generalisable to the Australian population. To ensure the Toolkit's content is accessible.
Include practical tools, forms, and templates suitable for use in all health disciplines, that can be downloaded for use (and amended to reflect local processes and the specifics of the involvement activity).	To ensure researchers and organisations do not have to duplicate efforts by defining and developing these tools themselves.

Trials Transformation Initiative (US)¹⁰, and the Patient-Centered Outcomes Research Institute (US).¹¹

The review also informed the choice of topic headings for the Toolkit's 'Routemap', a series of 19 nodes positioned in a sequence that prepares researchers to conduct consumer involvement, before illustrating how it can be operationalised across the life cycle of a clinical trial (Figure 1).¹²

Since consumer involvement consists of discrete activities along the clinical trial life cycle (involvement activities can take place at any stage during a trial), the Toolkit's design was modelled on the UK's Clinical Trials Toolkit¹³ offering 'a dip in and dip out' approach to information access (Figure 1). Each node hyperlinks to a landing page that provides a detailed description of the topic, signposts to external resources including publications from the review to support best-practice, and downloadable tools to help researchers operationalise their consumer and community involvement activities.

Upon establishment of the core design, a priority-setting workshop was held with a wider group of stakeholders utilising a 'dotmocracy' voting approach (in which participants vote on their chosen options using a limited number of dot stickers) to ratify further and inform content development to meet user needs. Content writing progressed in parallel with the website build to meet international standards for web-content accessibility.¹⁴ Following an iterative review and revision process, the Toolkit was finalised in September 2019.

This project was conducted in fulfilment of ACTA's project plan as agreed by the Department of Health rather than as a research study, therefore ethics approval was not sought.

Results

The Toolkit guides researchers and organisations (both not-for-profit and commercial), covering four

key consumer involvement stages: 1) understanding, 2) planning, 3) undertaking and 4) evaluating activities (Figure 1). As described above, the content displayed within each node opens a landing page that describes a key area of activity and provides tools to help operationalise consumer involvement. Examples include:

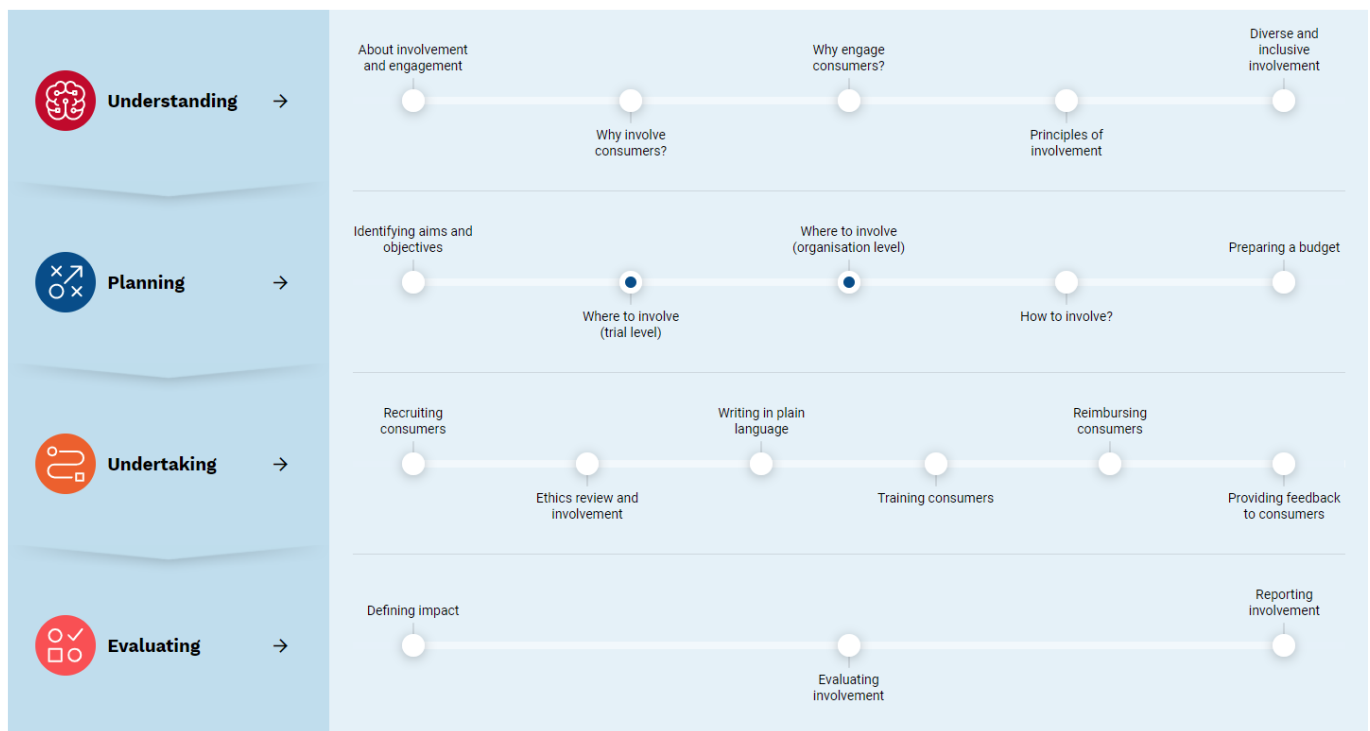
- A template to develop a local consumer involvement strategy
- A confidentiality agreement and Terms of Reference document for advisory groups
- Recruitment tips
- Consumer involvement agreements
- A costing tool so researchers can budget for their involvement activities
- Templates for researchers to evaluate their involvement activities.

Users can adapt these tools to add organisation logos and amend them to align with local processes or the specifics of their involvement activity. A small but growing section of the Toolkit is dedicated to supporting consumers seeking to get involved in clinical trials. We have developed videos to enhance awareness of clinical research in several languages to ensure they are accessible to Australia's multicultural population. We illustrate consumer involvement with a series of case studies. We include a 'Consumer Involvement Pack' to improve consumers' understanding of the trial process and introduce new consumer representatives to their role in clinical trials.

Discussion

While the Toolkit now serves as a consolidated resource to support consumer involvement in research, its development had its challenges. Firstly, there was a lack of standardisation in the terminology used to describe the activity. The terms 'involvement' and 'engagement' and 'participation' are used interchangeably in Australia and internationally. The Working Group recommended

Figure 1. Consumer involvement & engagement route map concept



Source: Australian Clinical Trials Alliance. Consumer Involvement & Engagement Toolkit.¹²

alignment with prominent national guidance on involving consumers in research¹⁵, and so the following definitions were adopted:

- **Involvement:** Where consumers and community representatives actively work with researchers and research organisations to help shape decisions about health research priorities, policy, and practice.
- **Engagement:** Where information and knowledge about research are shared with consumers and the community so that they are better informed on why, how, where and by whom research is conducted.
- **Participation:** Where patients or healthy volunteers take part in clinical trials.

The original plan for the Toolkit was to signpost users to existing national and international resources. However, very few could be adopted without alteration due to the local or regional initiatives, infrastructure, and terminology embedded within them. We generated a simple reciprocal content sharing arrangement to overcome this issue that enabled parties to adapt resources with appropriate acknowledgement. Each time an exemplar document or tool was identified, the authors and corresponding organisations were contacted, and without exception those approached agreed to the sharing arrangement to further the consumer involvement movement internationally.

As local research groups were also encouraged to share their tools during the Toolkit's development, the project's leadership team quickly recognised that a transparent method for triaging new content was needed. This was managed by appointing the Working

Group (with no vested interests) as the final arbiter. When multiple versions of similar tools were received, the Group was free to select a single tool for adaptation and acknowledgement or to suggest the content from several tools be combined to create a new resource, with contributors acknowledged.

Considering the scale of this project, the timeframe for its delivery was ambitious (12 months from concept to launch). Success in delivering the project on time was due in no small part to the codesign approach taken and the commitment of all involved. The funders' initial concern that involving consumers in every decision would cause delays proved unfounded, as consumers unambiguous articulation of 'end-user needs' served to reduce indecision on the part of other team members.

Further work

Future plans for the Toolkit include an evaluation of its use and value to stakeholders and enhancements that were not addressed in the first phase of development, such as:

- Plain-language training and resources for both researchers and consumers
- A mechanism for more diverse involvement of consumers and communities
- A platform to connect researchers and consumers
- Resources to promote consumer-driven research including opportunities for patients and their communities to generate research ideas and proposals.

As some stakeholders are yet to be convinced that consumer involvement justifies the resources used and the costs incurred, work to build the value proposition for consumer involvement is needed. International guidelines for reporting the context, process, and impact of consumer involvement are now available.¹⁶ As the reporting of consumer involvement in research manuscripts increases, the Toolkit will continue to highlight its value.

Conclusion

Consumer involvement is a critical component of good research practice and Australian Government plans to improve the quality and safety of clinical trials. But the broader uptake of consumer involvement in research is likely to depend on efforts to debunk the common misconception that consumer involvement is simply when researchers communicate with consumers to enrol them in their trials. It is not.

By delineating common terms such as involvement, engagement, and participation, equipping researchers with knowledge of why, where, and how to involve consumers, and the tools to do so, the Toolkit now supports the embedding of meaningful consumer involvement in Australian clinical research.

Many valuable resources for consumer involvement exist internationally, and to avoid reinventing the wheel, the project used a novel content sharing agreement to enable the inclusion of international resources (e.g., tools and templates) to support consumer involvement in Australia. Drawing on the experience and expertise of international advocates of consumer involvement has enriched the Toolkit and enabled the development of a national asset. This would not have been feasible within the project's timeframe and budget without this approach. We promote the Toolkit to facilitate broader sector engagement in the practice of consumer involvement here in Australia and as a resource to be shared and adapted for use further afield.

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Peer review and provenance

Externally peer reviewed, not commissioned.

Competing interests

None declared.

Author contributions

TS, JB, NS, and AMcK were responsible for the design, drafting, analysis of data, and editing of the manuscript. TS and NS were responsible for reviewing and editing the manuscript and overseeing the data analysis. JFF, LW, JA, RM, SJ and MS were responsible for reviewing and editing the manuscript. All authors read and approved the final manuscript.

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