



**Australian  
Clinical  
Trials  
Alliance**

# Consumers' role in clinical trials research. *Where to from here?*

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*‘No matter how complicated the research, or how brilliant the researcher, patients and the public always offer unique, invaluable insights. Their advice when **designing, implementing** and evaluating research invariably makes studies more effective, more credible and often **more cost efficient** as well’*

Professor Dame Sally Davies, Chief Medical  
Officer UK DH



**Today...**

What?

Why?

ACTA's  
Activity

Who?

International  
Scan

Consultations

**What's Next?**

# Who...

## **Consumer:**

Patients and potential patients, carers, and people who use health services

## **Consumer representative**

Someone who voices consumer perspectives and takes part in the decision-making process on behalf of consumers.

*- Statement on Consumer and Community involvement in Health and Medical Research, NHMRC 2016*

## What...

**Public involvement in research is**  
research that is carried out  
'with' or 'by' patients and/or members of the public  
*rather than* 'to', 'about' or 'for' them.

Involve, UK, FAQs. <http://www.invo.org.uk/frequently-asked-questions/>



**Engagement**

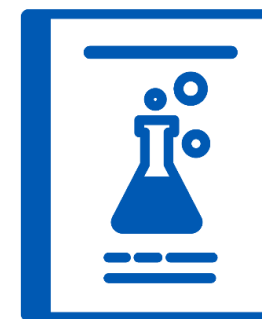
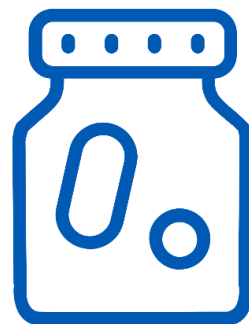


**Participation**



**Involvement**

## Why is this becoming 'a thing'?



# Impact

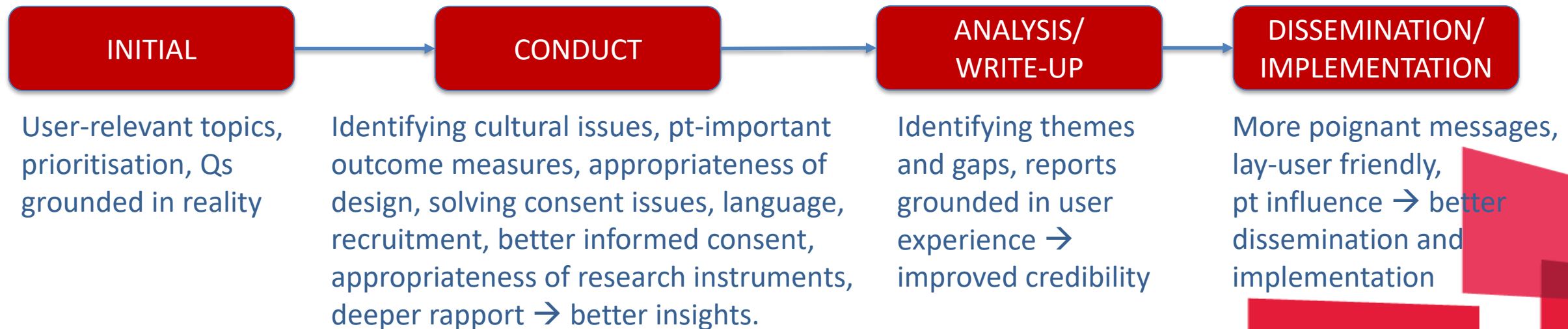


## Mapping the impact of patient and public involvement on health and social care research: a systematic review

Review Article |  Open Access |

First published: 19 July 2012 | <https://doi.org/10.1111/j.1369-7625.2012.00795.x>

- Studies from 1995-2009: n= 66 (incl 2 RCT, 1 cohort, 46 qual)
- Benefits across research lifecycle:



# Reference Group E

## ‘Strengthening Consumer Engagement in Developing, Conducting and Reporting Clinical Trials’

### Members ...

- › >20 Members: Consumers, Consumer Advocates, Clinicians, Researchers, NHMRC, Co-ordinating Centres, AHRTCs, etc
- ... ***everybody with a stake in research***

### Aims include:

- › Strengthen capacity and ability to involve consumers in research.
- › Messages for the general community

### Approach:

- › Inspiration from others internationally
- › Understand what’s happening in CTNs and CCs now, and what’s needed



# International Scan: Consumer Involvement in Research/CTs



## Purpose:

- Learn from countries with more established national strategies
- Collate 'involvement' materials
- Inform the terminology ACTA will use

→ Definitions aligned with NHMRC

# International Resources

Examples internationally:

INVOLVE (UK), CTTI (US), EUPATI (EU), SPOR (Canada), Cochrane (Intl), BMJ, Therapeutic area-aligned research groups, etc

→ Compliment initiatives in Australia

Found...

- Training material: consumers and researchers
- 'How to' guides (identification of consumers)
- Involvement cost calculator
- Financial model to calculate

*Return on Investment*



# Sector Consultation Approach

## Aim:

To *understand how consumers are currently involved with the sector* at an

- organisational level (e.g. clinical trial network, co-ordinating centre)
- at an individual trial level
- from the sector consumer perspective

## Method:

*Conduct two surveys; 1) sector and 2) sector-specific consumers,* attempting to identify and explore the levels of consumer-involvement across different research networks, engagement methods, consumer activities, support and training, impact and value amongst others.

## Sector Consultation Results (*Prelim*)

- Conducted Apr 2018
  - **65% completed** (n=22/34 clinical trial networks)
  - **70% involve consumers** (n=14) within network clinical trial activities
    - *Common Network Activities* include; board member, vision development, setting research priorities, communication etc
    - *Common Trial Activities* include; gap analysis, participant information, informed consent etc
    - *Diverse Range of Trials*; perinatal, brain cancer, intravenous therapy, prostate cancer, paediatric food allergy, epilepsy, mental health, haematological malignancy
- **Consumers involved in full spectrum of clinical trial activities**

## Sector Consultation Results (*Prelim*)

- **50-60% of networks provide training** for researchers and consumers
- **Around 80% did not report impact of involving consumers** within activities of networks and individual trials
- **100% of clinical trial networks and individual clinical trials could describe the value of involving consumers** in various activities
  - e.g. identify priorities important to the community
  - e.g. a forum for mutual information and support for participants to exchange views and experience of the trial and related issues.
  - e.g. direct impact on the study design

**100% stated they would involve consumers in future studies based on the experience from this clinical trial**



## Consumer Consultation Results (*Prelim*)

- **27 sector consumers completed survey**  
(e.g. involved in clinical trial network and trial activities)
- **>80% had never participated** in a clinical trial before
- commonly **motivated by personal experience or potential to help others** in the future
- **average involvement 3-4 years**, across full range of clinical trial activities
  - *Common Activities include*; board member, priority setting, funding applications, patient information, development of consumer materials
- **68% of consumers received support** to facilitate their involvement
  - most useful support: travel expenses, multiple options to be involved (e.g. in-person, telecon, email/web, paper) and suitably timed meetings

## Consumer Consultation Results (*Prelim*)

- **Suggestions to researchers to identify consumers;**
  - *communicate with consumer organisations, ask patients and carers directly (e.g. doctors and nurses), raise awareness of research and opportunities, outline support offered*
- **Consumers described the value of involvement in research activities;**
  - *researchers can sometimes lose sight of patients, families and the impact of their work to them*
  - *suggest how to embed trial activities into real-world care settings*
  - *consumers are the end-users of healthcare research*
  - *effective sharing of clinical trial results to broader community; including funders and policy-makers*

# Consumer Consultation Results (*Prelim*)

## What does being a consumer mean to you?

- *It meant I had a voice,*
- *I feel my role contributes to enhanced family-centered access to health services, therapies and drugs for the Australian community,*
- *It helped keep me engaged in life, and offered me a chance to make a difference to others,*
- *I feel it's been a valuable experience to further knowledge and information, not only for myself but in conversation with other patients,*
- *Patient/Carer perspective differs from researchers and healthcare providers; we need to work together to advance healthcare*

**100% participants would recommend a consumer role within a CTN or trial**



# What's Next?

- **Good Practice Guidance & Toolkit:**

Support the sector to undertake meaningful consumer involvement

- **Community Awareness**

Assist in identifying messages and mechanisms to improve public awareness and understanding of research

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