



**Australian
Clinical
Trials
Alliance**

Consumer Involvement in Clinical Trials: Consultation Report

May 2019

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1. BACKGROUND

ACTA is the peak body for the clinician-led, investigator-initiated clinical trials sector nationally. Our aim is to promote effective and cost-efficient healthcare in Australia through investigator-initiated clinical trials and clinical quality registries that generate evidence to support decisions made by health practitioners, policy-makers, and consumers.

To gather this information ACTA formed a reference group to understand more about 'strengthening consumer engagement in developing, conducting and reporting clinical trials'. The group is composed of a diverse range of stakeholders including consumers, consumer advocates, researchers, clinical trial networks, co-ordinating centres and policy-makers amongst others. The overarching aim of this group is to undertake a program of work seeking to understand how the research sector undertaking clinical trials can work in partnership with consumers and the community, to build the capacity and ability of the sector to involve consumers in all activities across the research continuum.

PROJECT RATIONALE

In 2018, led by the ACTA Consumer reference group, we undertook national consultations with clinical trial networks, co-ordinating centres, triallists and consumers to understand more about current practices, including barriers and enablers to consumer involvement.

The aim was to comprehend how research organisations and triallists involve consumers in operational activities and more specifically at an individual clinical trial level. Involvement does not mean participating in a clinical trial but actually working in an active partnership with researchers e.g. to identify healthcare needs, design research projects and understand how this could change healthcare services to suit patients better. The intention of the sector consultations was to help clarify and inform best practice and demonstrate the importance of ongoing consumer involvement within research activities.

To ensure we approached the consultations comprehensively, we decided to also directly consult consumers working with research organisations or on particular trials. Once more the aim of this consultation was to understand exactly how consumers become involved with clinical trial networks or research organisations, and how consumers work with researchers across a wide range of research activities. We also wanted to understand what helps support the role of a consumer and identify specifically how consumer involvement can help shape healthcare research.

2. APPROACH

CONSULTATION DEVELOPMENT

Using work completed earlier by the reference group to generate an environmental scan mapping consumer local and international initiatives consumer involvement activity and initiatives, we developed brief survey instruments. The aim of these surveys was to capture activity level, types of activity, training and education, support for researchers and consumers, and the impact and value of consumer involvement within the investigator-led research sector.

The intention of the consultations was to identify current practice and inform development of guidance for the research sector and all relevant stakeholders, around opportunities to improve the capacity and ability to involve consumers more effectively and across all research activities, particularly clinical trials.

DEFINITIONS

Consumer	Patients and potential patients, carers, and people who use healthcare services.
Community	A group of people sharing a common interest (e.g. cultural, social, political, health, economic interests) but not necessarily a particular geographic association.
Consumer Representative	Someone who voices consumer perspectives and takes part in the decision-making process on behalf of consumers. This person may be nominated by, and may be accountable to, an organisation of consumers.
Clinical Trial Network (CTN)	National or state/territory-based networks or groups of clinician-researchers based in Australia.
Co-ordinating Centre (CC)	Dedicated Australian-based centres for conducting state/territory-wide, national or international investigator-led clinical trials.
'Sector' response	Responses from network, trial and co-ordinating centres to the consumer involvement survey, including organisational responses, and from both active and complete clinical trials.
'Consumer' response	Responses from consumers who have been involved in clinical trials in some capacity to the consumer involvement survey.
Research Organisation	Both clinical trial networks and co-ordinating centres.

SURVEY DISSEMINATION

We developed three surveys: A) for clinical trial networks & co-ordinating centres (research organisations), B) for individual trials and C) for consumers directly involved with clinical trial networks or co-ordinating centres.

Surveys A and B were sent directly to clinical trial networks and co-ordinating centres using contact details of ACTA members and additional organisations identified by the Reference Group members. In total, Surveys A and B were sent to 49 investigator-led research organisations (e.g. 34 different clinical trial networks across a diverse range of clinical disciplines and 15 co-ordinating centres). Survey C was sent to the same mailing list (e.g. CTNs, CCs and additional identified organisations), for direct completion by consumers involved with those organisations. The Reference Group decided on this approach to ensure confidentiality and privacy for respondents.

The surveys were piloted in early 2018, then revised and distributed to participants between April and September, and finally closed in October 2018.

3. FINDINGS

A total of 80 respondents completed the surveys in full. A profile of survey respondents is shown in Table 1.

Table 1. Characteristics of Respondents

Respondent Type	Number Surveyed	Number of Respondents	Involving Consumers	Planning to Involve Consumers
Clinical Trial Network (CTN)	34	25	76% (19)	8% (2)
Co-ordinating Centre (CC)	15	5	60% (3)	40% (2)
Trial (Active)	-	13	13	-
Trial (Complete)	-	10	10	-
Sector Consumers	-	27	-	-

We found 76% (n=19) of responding CTNs and 60% (n=3) of responding CCs were currently involving consumers in their research activities at an organisational level. Most of the remaining research organisations planned to involve consumers in the future.

Within the trial specific survey (B), it was encouraging to see respondents highlighting consumers were involved to almost similar levels across active (commenced 2015 onwards) and completed (from 2010 to 2018) clinical trials.

Twenty-seven consumers completed the survey. Data received was anonymous, however given the number of respondents and the approach that was used, it was thought these consumers represented a diverse sample across a range of clinical disciplines.

A number of key themes were generated from both the 'Sector' and 'Consumer' responses. For the purpose of this report, the results are separated into three sections. The first two sections follow a brief, report style separated by 'Sector' and 'Consumer' responses. A third section, 'Analysis', discusses and analyses responses across the data, with expansion on the themes relating to barriers and enablers of consumer involvement.

SECTOR (NETWORK, CO-ORDINATING CENTRE & TRIAL) RESPONSES

Clinical trial networks and co-ordinating centres (organisations) were asked survey questions in relation to activity level and type of consumer involvement, training and impact. The richest responses from the qualitative survey related to the perceived 'value of consumer involvement' and 'barriers' to involving consumers and are discussed in detail in the Analysis section of this report.

Activity Level and Type (network, co-ordinating centre and trial)

Networks, co-ordinating centres and active and complete clinical trials involve consumers at all stages of the research cycle. Consumer activities in the early stages of the research cycle include research priority setting, study design and protocol development, research proposal reviews and grant application reviews. This also included document development, such as review of consent forms, patient information sheets, and lay summaries of the research. One active trial had a consumer implementing one arm of the study intervention. Dissemination of results was supported by consumers providing lay summaries of study findings in several instances. The most common activity type was consumers reviewing new research proposals, specifically reviewing relevance of a clinical trial.

Consumers are and have been involved with research teams in the development and design of clinical trials (early and late phase) across numerous disease areas, predominately oncology but respondents highlighted activity in perinatal, mental health and hematological studies. Involvement of consumers as investigators was limited; several clinical trials respondents had listed a consumer as an Associate Investigator in their trial, with the consumer holding an advisory role throughout the trial. Some respondents expressed interest in involving consumers as investigators.

Reasons for involving consumers in individual trials varied and respondents in some instances stated more than one reason (see below).

Table 2. Rationale for involving consumers in clinical trials

Status of trial	Main reason for involving consumers in clinical trial (respondents were able to select more than one reason)			
	Funding requirement	Specific matter/issue that consumer involvement could address	Consumer involvement has been useful in previous studies	Other
Active (recruiting or in follow-up) (n=13)	23% (3)	31% (4)	39% (5)	7% (1)
Complete (recruitment and follow-up finished) (n=10)	17% (4)	35% (8)	39% (9)	9% (2)

Results outlined in Table 2 highlighted that all three of the pre-set reasons for involving consumers were important considerations for research teams developing clinical trials. Overall, the main reason was the usefulness and value of previous consumer involvement in such activities. Other reasons stated by respondents included consumer-driven research approach taken and two respondents noted it was a directive of the organisation to involve consumers in research activities.

Consumers are also involved at an organisational level, with six organisations having an established consumer advisory panel or group. Consumers sit on scientific committees, trial management committees, trial steering committees, management advisory boards, and within a third of organisations (CTN and CC) as a member of the Board.

Consumers are recruited through three major strategies: informal word of mouth, formal ‘call-outs’ via social media or e-mail lists, or through connecting with external stakeholders. External stakeholders that support organisations in finding consumers include consumer health networks, disease-specific organisations and other professional organisations.

We found that most organisations do not have a specific policy relating to consumer involvement, however if one does exist, it is most commonly a Terms of Reference. One organisation embedded consumer involvement in all Standard Operating Procedures, while another embedded involvement in its five-year strategic plan.

Lastly respondents reported that the main barriers to involving consumers at an organisational level were ‘unsure of how to undertake meaningful involvement (i.e. avoid tokenism)’ and the ‘lack of funding’. To a lesser extent, other barriers included ‘difficulty accessing suitable consumers (e.g. lack of tools for identifying and engaging)’, ‘lack of time to involve consumers’ and least of all ‘consumer involvement deemed not necessary’. Further details are included within the Analysis section.

Training (network, co-ordinating centre and trial)

At an organisational level, less than a third (27%) indicated that specific consumer involvement training was provided to their employees/members. However, at a trial level training in consumer involvement is currently being provided to consumers in the majority of active trials and has been in previously completed trials, to a lesser extent.

Training for researchers and consumers could be formal, informal, delivered face to face, web-based, internal or external. Common formal training was often delivered by dedicated consumer organisations, and in one instance via online training modules. Some consumers are being trained at organisational scientific committee meetings, and some through Consumer Advisory Panels. Informal training includes mentorship whereby consumers ‘train’ one another, indirect training through consumer networks, and support through the research team.

Materials and resources most useful to enable consumer involvement included formal training (web-based and in-person workshops), any information that supports consumers in understanding clinical trials, the structure of the research network, governance processes, ethics, analysis and publications, as well as their role as a consumer. Developing this knowledge, however, may take time, as evidenced by the following quote: “A lot of our [consumer] members have taken a couple of meetings to work out what they are going to contribute”. One respondent suggested “A flyer or information pack that clearly outlines what consumer involvement means and what benefits it might have for the person would be useful”, highlighting the need for consumers to have a clear understanding of their value and role.

Impact (network, co-ordinating centre and trial)

Survey responses indicated that reporting on the impact of consumer involvement in research activities is not routine (see Table 3). Many respondents stated that the impact of consumer involvement was ‘difficult to measure’. Some respondents wished for ACTA to provide guidance on how to report and measure impact. However, one organisation responded that it was mandatory to report impact of consumer involvement.

Table 3. Reporting on the Impact of Consumer Involvement

Respondent type	Reported on the impact of consumer involvement (n)		
	Yes	No	No Response
CTN	16% (3)	74% (14)	10% (2)
CC	33% (1)	67% (2)	0% (0)
Completed Trial	10% (1)	50% (5)	40% (4)

Novel approaches to consumer involvement were identified, one organisation measuring the impact through the uptake of social media posts, while another considered inviting consumers to presentations as impact, however it was not elaborated on as to how these activities were related to impact. One research organisation respondent expressed that measuring impact is important, however a tool to do so is not currently available; perhaps if guidance were provided, impact would be measured.

Many respondents from active trials did not respond to the question of impact of consumer involvement on the trial, with some respondents stating it was too soon to see impact. Only one respondent answering the completed trial survey reported impact was measured, the lack of response may indicate a lack of 'know-how' and potentially the lack of 'suitable measurement tools' available and fit for different purposes.

CONSUMERS

Consumers were posed survey questions in relation to consumer roles and level of involvement, training provision and effectiveness, time of involvement, impact and value, as well as barriers and enablers to involving consumers.

The majority of consumers became involved (with organisations or clinical trials) mainly through a desire to potentially help others in the future, from having personal experience of the condition being studied or were involved in a charity or foundation concerned with the disease under study. Involvement often resulted from a direct invitation, or in response to an expression of interest. Some became involved on referral from their treating clinician. Prior to the consumer involvement role, less than 20% (n=5) had participated in a clinical trial.

Consumers confirmed they were involved in clinical trials in a number of roles, with responses mirroring those of the Sector; they are involved at every stage of the research cycle and in a variety of operational and organisational level roles. Consumers surveyed had been involved for a minimum of a few months to a maximum of 28 years, with most consumers having provided input for the last 3 to 6 years. Time spent on consumer activities was extremely variable.

Activities and Training

Respondents were involved across the whole research continuum, with most common activities (> 15 respondents) including the role of a board or committee member, setting research priorities, preparation of grant and funding applications, development of participant-facing materials (e.g. information sheets and consent forms) and encouragingly consumer involvement support or education material.

Training was often provided to consumers in a formal (training course) or informal capacity (information session or meeting), with positive responses related to the content and usefulness in relation to ability to support contribution. However, the survey indicated that, training is provided, it is often variable across the range of activities. Also, that it was clearly lacking in some key activities consumers are involved in such as setting research priorities, working with researchers to understand the best ways to share study results with the wider community, and how to develop future consumer involvement support or educational material.

We explored the common involvement activities versus contribution element further, to understand any potential enablers to strengthen consumer involvement related to training and education needs, as below.

Table 4. Involvement vs Contribution

Consumer involvement activity	Number of consumers undertaking activity	Capacity to contribute to activity (n = number of consumers)		
		High	Medium	Low
Role of a Board or Committee Member	20	13	6	1
Setting research priorities	17	8	7	2
Helping with the preparation of grant / funding applications	17	6	7	3
Developing patient information materials (e.g. study posters, information sheets, consent forms)	16	11	4	1
Helping develop consumer involvement support or educational material	18	13	3	2

The results outlined in Table 4 indicate most consumers expressed a high capacity to contribute but that opportunity exists to improve and provide education and training to enhance consumer knowledge and skills required for such diverse roles.

Consumers were asked to suggest any recommendations to improve training. Responses included making sessions shorter, improving cultural appropriateness, and primarily ensuring training is accessible. Some consumers did not feel they required training at all. Many consumers brought relevant experience in health and research to the consumer experience, which supported their role.

Involvement experience

The majority of consumers found their experience of involvement positive and expressed being adequately supported by research teams. Virtually all respondents (92%) would recommend the consumer role to other potential consumers, stating it was a meaningful experience that led to knowledge exchange and learning about the research process. One consumer in particular said that it supported them in feeling engaged in their life and they enjoyed making a difference to others. Others enjoyed it as it provided them with a voice and an opportunity to give back to the community. One consumer did not feel it was satisfying as they did not have a dedicated role, showing the need for roles to be established, especially as it is commonplace to have more than one consumer involved with an organisation or on a specific clinical trial.

Consumer recommendations

More than half (56%) of respondents said they received support that helped facilitate their involvement within research organisations. When asked to rank different types of consumer support that had been, or would be, useful to support these involvement activities, they responded:

Table 5. Useful Consumer Involvement Support

Type of support	Rank Order (1= most useful to least 7 = least useful)
Suitably timed meetings (e.g. less busy time of the day)	1
Travel expenses	2
Multiple options to be involved (e.g. in-person meetings, teleconferences, central on-line document library, paper copy documents)	3
Payment for consumer time (reimbursement)	4
Singular point of contact (e.g. dedicated personnel or researcher)	5
Cost-free communication (e.g. toll-free telephone numbers, postage paid mail, internet cost coverage)	6
Carer Costs	7

Most respondents stated that the research organisations they were involved with tried to include consumers from different cultural, language and literacy backgrounds, in their consumer involvement activities. Also, within their role as consumers working with research teams on a specific clinical trial, some had helped develop approaches and materials to facilitate people from minority backgrounds to consider participation.

Consumers also provided recommendations on how to recruit study participants from culturally and linguistically diverse (CALD) backgrounds, suggesting having local community leaders involved, dissemination of tailored media in the community, provision of a translator or interpreter, and translation of materials.

4. ANALYSIS

This section is categorised into two parts: the Value of Consumer Involvement, and Barriers and Enablers to Involvement, with data drawn from all three surveys. These two broad themes were generated as a result of the particularly rich survey responses relating to value, barriers and enabling factors of involvement.

VALUE OF CONSUMER INVOLVEMENT

It is evident in the data that consumer involvement is highly valued by research organisations, researchers and consumers. The responses in the survey provided insight into the way's consumer involvement is valued and why it is valued, as well as the meanings attributed to consumer involvement. Value was expressed differently, with 'Sector' respondents focusing on the practical value that consumer involvement, while 'Consumer' respondents expressed wider principles of, and rationale for, consumer involvement.

One respondent stated that "It is difficult to measure objective value with no formal review of consumer impact conducted", overwhelmingly consumer involvement is considered valuable. The following responses provided evidence:

"Consumer perspective has been very enlightening." (Network Member)

"It has been key to have a community perspective on the value and importance of the trial, and input into design / grant / ethics / oversight." (Triallist)

Consumers add value as they influence specific aspects of trial design and assist in identifying research gaps and priorities:

"Consumers provided feedback to researchers on participant recruitment methods, data collection and dissemination of outcomes. This was valued by the researchers at the Annual Scientific Meeting where researchers acknowledged the feedback from consumers and made appropriate changes to their study protocol. Consumers also provided their perspective on dissemination of study findings to the consumer audience using user-friendly approaches." (Network Member)

They also provide valuable input into the language used in research participant materials and support in communicating the value of research to patients:

"They can raise issues or concerns from a different perspective than a clinician, research nurse, trial coordinator at site and co-ordinating centre staff. Explaining medical terms and procedures to patients is often difficult so it is great to get consumer engagement." (Triallist)

Consumer involvement was also said to allow rapid and effective engagement of the community when developing trials and promoting trials, potentially improving recruitment and translatability.

However not all 'Sector' respondents believed there was value in consumer involvement, one respondent stated:

"Value was definitely limited. Consumer involvement was not a high priority." (Triallist)

This response indicates that consumer involvement may have been valuable if it has been a prioritised activity. Another respondent could not see the value in consumer involvement as consumer representative expertise was not utilised effectively or regularly enough to inform research activities, showing a need for more training.

Consumers at times are seen by researchers as valuable in bridging the gap between research and the wider community:

"Researchers can sometimes lose sight of the people, families and carers who are impacted by their work. Not just data." (Consumer)

However, being involved as a consumer can be reassuring to consumers that researchers have not lost sight of the people they are working with:

"Involvement has reassured me that trials and researchers have the best intentions at heart, they are passionate about their work." (Consumer)

"Consumers provide a feedback mechanism to other consumers on research dispelling myths and are advocates for researchers and the work undertaken." (Consumer)

These two quotes highlight the value of consumer involvement as consumers reminding researchers of the people, they are doing research with and for, as well as increasing awareness of the importance of research in the wider community.

The 'Consumer' responses to value of consumer involvement were generally different to 'Sector' responses, as they specifically honed in on the principles and philosophy behind involvement as giving a rightful voice to the end-user, an aspect that was largely missing from 'Sector' responses. Such as:

"Clinical trials exist for the benefit of patients. We represent their interests therefore our contributions are inestimable. Any investigator-led trial requires impartial feedback that it is well designed, maintains equipoise, that public funding is being used effectively and that recruitment targets are achievable. We have a vested interest to ensure good quality trials will produce results that will ultimately improve standards of care and therefore improved patient outcomes." (Consumer)

"Important because they ensure that trials create value to consumers at the end of the day." (Consumer)

Very few consumers expressed the value of consumer involvement as a practical aspect of a trial, one respondent mentioned:

“...It [consumer involvement] will cause an increase in the number of patients volunteering for trials.” (Consumer)

Another consumer stated the importance of communicating with consumers effectively, showing that consumer involvement in itself may not be enough to make it a valuable exercise, and that communication must be effective:

“Extremely valuable as long as it is a transparent process and information pre and post-trial is forthcoming. No one likes to contribute and then hears nothing about the trial activities thereafter.” (Consumer)

These responses from both ‘Sector’ and ‘Consumer’ respondents highlight that consumer involvement in clinical trials is valued, and that value is measured in different ways. Neither form of valuing consumer involvement is incorrect, rather, it is interesting to note that ‘Sector’ respondents focus on the value to the research itself, while the ‘Consumer’ respondents focus on the value to the patient community. There is currently a ‘gap’ in how organisations and consumers attribute meaning to consumer involvement.

BARRIERS AND ENABLERS TO INVOLVEMENT

Multiple barriers and enablers were noted by respondents across the data set. These include lack of resources in the form of training or funding, lack of understanding on how to involve consumers at an organisational and operational level, and lack of evidence that consumer involvement adds value to clinical trials. Enablers included provision of resources and training, early involvement of consumers and engaging more than one consumer representative. The following analysis focuses on some key barriers and enablers.

Resources: Barrier and enabler

A lack of resources was one of the major barriers to engagement at an organisational level, with many in the sector expressing that they would involve consumers if funding was available. Of those Sector respondents who did not involve consumers in any network or organisational activity, resources were the key reason behind a lack of consumer involvement:

“Shortage of resources is a barrier to effective CI and needs to be addressed systematically to improve CI in research across the board.” (Network Member)

“Inadequate funds and person power to do this.” (Co-ordinating Centre Member)

An enabler, therefore, is increased funding, as evidenced by the following response to a question on what would increase the likelihood of consumer involvement at an organisational level:

“Increased funding dedicated to consumer involvement in health research.” (Network Member)

One respondent expressed the expectation, perhaps from an organisational level, of consumer time not being valued, and the need for reimbursement:

“Consumers are often asked to participate voluntarily, and this is not adequate in my mind. If we’re asking for expertise, we should be able to pay for it.” (Network Member)

One consumer expressed that their involvement could have been better supported with more resources:

“A small contribution towards the internet and phone bills.” (Consumer)

One respondent expressed the influence of government and NHMRC funding requirements on increasing support for resources dedicated to consumer involvement:

“Only recently have external drivers emerged such as government, NHMRC & other funder requirements. This provides increased motivation to direct scant resources to CI initiatives.” (Network Member)

This response is particularly interesting as it shows the how consciousness may be beginning to shift positively in relation to consumer involvement as a result of the NHMRC grant funding requirement changes. Beyond the organisational level, other resources deemed necessary but lacking in order to involve consumers included funding for training:

“...[Training] is in planning but not developed – funding is required.” (Network Member)

Resources specific to training are important in order to meaningfully involve consumers in clinical trials.

Training: Enabler

Across the data, respondents from both ‘Sector’ and ‘Consumer’ surveys valued education and training as a substantial way to improve the consumer involvement experience for both researchers and consumers. While most responses did not detail the type of training provided, the value of training was evident. Several respondents believed training to be one of the main facilitators of consumer involvement generally:

“Training for researchers. We all know we should be engaging consumers but how to do it effectively and not as tokenism.” (Network Member)

“Providing training and support to consumers will improve [consumers’] ability to be involved in clinical trial activities. By educating consumers, they can in turn educate other consumers and improve overall awareness.” (Network Member)

These responses highlight the need for training to be provided as standard practice for both researchers and consumers. The last quote above shows that training is considered a form of professional development for consumers, and that consumers should be offered learning opportunities.

An interesting response elicited about training was that it could give consumers skills beyond providing the consumer perspective:

“Having consumers sufficiently trained to value add is important to differentiate between 'my experience' and the wider research agenda.” (Network Member)

“It is important the consumer representative understands their role is broader than their own personal experience.” (Consumer)

This provides insight into how the role of a consumer is perceived. Consumer involvement is believed to be enhanced when consumers offer more than their unique perspective and understand the research itself. There is a need for research-related training for consumers, as shown in the following quote:

“More training is needed as well as specific topics such as recruitment, stats.” (Consumer)

Training that was accessible was considered important, as well as a need for researchers to know about the training available to consumers:

“Important that sources of training are easy for consumers to find and also that researchers are also aware of what consumer training is available.” (Consumer)

The value of training is found in leading consumers to better represent their views:

“Training courses are particularly useful. All should be offered this as it leads to a better-informed consumer who then is able to collectively represent the views of many not just their own experience.”

Several active clinical trial respondents provided online training through a national consumer learning website. However, two respondents suggested the need for face-to-face training rather than online training alone.

People with low computer literacy may need further support. Furthermore, ensuring diversity of the consumer voice is important and people of culturally and linguistically diverse backgrounds may need to have tailored training:

“Help the training be culturally appropriate if working with different ethnic groups.” (Network Member)

“Keep training simple and easy to understand.” (Consumer)

Provision of training is clearly an important and valued facilitator of meaningful consumer involvement in health research. Furthermore, these responses highlight the need for training to be tailored to the needs of consumers in terms of literacy and diverse cultural and linguistic backgrounds.

Lack of know-how: Barrier

Training is particularly important as there is a clear need for both researchers and consumers to understand how to be involved in clinical trials as consumers. Some sector respondents lacked involvement of consumers in any network or organisational activity because of lack of knowing how to involve them at that level:

“Not sure how, not sure of role or appropriateness at organisational level.” (Network Member)

“There remains scant evidence around effective consumer involvement models, including at the organisational level.” (Network Member)

These responses show that there is poor knowledge and understanding of consumer involvement at an organisational level, especially around appropriateness. Enablers for organisational-level consumer involvement include an improved level of information, resources and training:

“Availability of more information and resources including practical tools.” (Network Member)

“Understanding more from the sector and role of consumers at different levels.” (Network Member)

Support and training in the importance of consumer involvement, as well as senior management encouragement and understanding, may overcome this barrier.

The need for evidence: Barrier and enabler

Several respondents discussed the need for researchers to be provided with evidence that consumer involvement is important, as evidenced by this quote:

“Building evidence for the impact and value of consumers will help to address the issue of researchers not understanding or appreciating the impact consumers can have.” (Network Member)

Responses from the ‘Sector’ in relation to questions around facilitators of consumer involvement and highlight that the sector in particular may need to build a pool of evidence on consumer involvement impact at different stages.

Organisational and work culture barriers: Barrier

Another barrier to involving consumers at an organisational or network level was a lack of senior level awareness or interest:

“No real awareness or appetite from board of directors.” (Network Member)

A ‘work culture’ that did not include consumer involvement as usual practice was another barrier to involvement:

“We think historically consumer input has been seen as an afterthought.” (Network Member)

This barrier could be overcome with support from senior staff, and for consumer involvement to become a regular part of the research process. An enabling factor could be to have a visible champion in the organisation who supports consumers, as evidenced by one consumer involved in clinical trials:

“Having a champion within the organisation to support consumers has been invaluable.” (Consumer)

5. SURVEY LIMITATIONS

The survey was developed via extensive consultation amongst the ACTA Reference Group (range of diverse stakeholders – including consumers), however it is possible we may not have captured all viewpoints and considerations prior to conduct.

The overall sample size for research organisations (CTN & CC) was small – particularly when considering engagement of co-ordinating centres, which may reflect limited consumer involvement in this space. However, representation by clinical trial networks was effective to demonstrate current levels of consumer involvement activity and the provision of more granular information at an individual clinical trial level was suitable.

Respondents were not mandated to answer all questions as the intent was to capture as much information as possible, acknowledging respondents were often very time poor. Yet due to this approach not all respondents answered all questions, therefore in some instances we may not have captured a complete response to the question being asked. Lastly whilst research organisations (e.g. networks and co-ordinating centres) were approached to complete this survey, clinical quality registries were not. Therefore, going forward reviewing and potentially redesigning the survey will be important to understand the challenges and opportunities in relation to consumer involvement activity within national registries.

6. CONCLUSION

Consumer involvement in research, and particularly clinical trials, is rapidly growing across Australia, with noteworthy engagement both at an organisation and individual study level. Research organisations existing in the investigator-led environment vary in the consumer involvement levels, range of activities and provision of support for both researchers and consumers. However, at all levels (organisation, trial, consumer) it is evident consumer involvement is valued in the development, design and dissemination of clinical trial results to the broader community.

Opportunities exist to continue to foster and strengthen active ongoing partnerships between organisations, researchers, policy-makers and consumers will need to focus on providing practical education and training, adequate funding and increasing awareness and support for consumers in the future.

The next step for the reference group is to collaboratively work with key national and international organisations, to draw on best practice resources and guidance (practical advice for researchers and research-organisations wishing to conduct patient-centred research) to strengthen consumer involvement and engagement in clinical trials across Australia. With the aim to develop an online, centralised repository of resources to facilitate consumer involvement and engagement along the lifecycle of a clinical trial, and across the whole research continuum.

ACKNOWLEDGEMENTS

All clinical trial networks, co-ordinating centres, researchers and consumers, we thank you for your time and contribution.

WORKING PARTY

ACTA Group Expert Reference Group: strengthening consumer engagement in developing, conducting and reporting clinical trials, chaired by Ms Anne McKenzie.