Statement on Consumer And Community Involvement In Health and Medical Research

A Dementia Australia Submission

June 11, 2024

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About Dementia Australia

Dementia Australia is the national peak body for people impacted by dementia in Australia. We exist to support and empower the more than 421,000 Australians living with dementia and the more than 1.6 million people involved in their care.[i] Dementia is the second leading cause of death in Australia yet remains one of the most challenging and misunderstood conditions.[ii] We involve people impacted by dementia and their experiences in our activities and decision making, ensuring we are representative of the diverse range of dementia experiences across Australia. We amplify the voices of people impacted by dementia through advocating and sharing stories to help inform and inspire others. Dementia Australia is the source of trusted information, education and support services. We support people impacted by dementia, and to enable them to live as well as possible. As part of our advocacy for positive change for people living with dementia, their families and carers, we support vital research initiatives.

Dementia in Australia

Dementia is one of the largest health and social challenges facing Australia and the world. It is estimated that in 2024, there are 421,000 Australians living with dementia and more than 1.6 million people involved in their care.[iii] Without a medical breakthrough, the number of people living with dementia in Australia is expected to increase to more than 812,500 by 2054. Dementia is now the leading cause of disease burden among Australians aged 65 and over and is the second leading cause of death for Australians and the leading cause of death of women. In 2024, it is estimated there are almost 29,000 people with younger onset dementia, and this is expected to rise to more than 41,000 people by 2054. This can include people in their 30s, 40s and 50s.[iv]

Dementia as an ‘invisible’ disability

The 2008 United Nations Convention on the Rights of People with a Disability (UN-CRPD) recognised dementia as a cognitive disability but unlike physical disability, community understanding of dementia as a disability remains limited. This is at least in part because, unlike a physical disability, the cognitive and other changes that are associated with the condition are often under recognised or rendered ‘hidden’ or ‘invisible.’ People living with dementia relate the common experience of being told that they ‘can’t possibly have dementia’ because they don’t appear, speak or act in a way that corresponds with community expectations or understanding of the disabling nature of dementia.[v]

“If you just saw them and didn’t know them, how would you even know if they had dementia?” (Australian resident with no lived experience of dementia) [vi]

The invisible nature of a cognitive disability and the attitudinal and other societally imposed barriers mean people living with dementia can experience additional stigma or challenges when undertaking daily activities, engaging with the health care sector or interacting with people in the broader community.

The lack of awareness and understanding about dementia, particularly in relation to assumptions about decision-making abilities, has also had a significant impact on whether people living with dementia have been included in research. Ethics committees, researchers and institutions have historically often excluded people living with dementia based on erroneous perceptions about their inability to understand information, provide informed consent and fully participate in research activities.

The Dementia Australia Advocate Program

Dementia Australia’s Dementia Advocate Program provides opportunities for people living with dementia, carers and former carers to share their stories, identify current issues and positively effect change. Advocates are involved in all aspects of our operations including research and policy work, learning and education products and systemic advocacy activities focussed on raising awareness of dementia, tackling stigma and discrimination and influencing change.

Improving the lives of people living with dementia, and their family members and carers, through participation in research initiatives, is a key focus for many Dementia Advocates. The key objectives in revising the Statement - to increase awareness and promote the importance of consumer and community involvement across the research cycle - are critical priorities for Dementia Australia stakeholders.

Dementia Australia embraces the consultation call for ‘stakeholder insights on areas where implementation of better practice consumer and community involvement in research could be enhanced and supported.’ Our submission applies a dementia-enabling lens to the values embedded in the Statement and roles and responsibilities of all parties, from participants and ethics committees to researchers, institutions and funders, with a specific focus on the issues, concerns, and priorities related to the participation of people living with dementia in research initiatives.

Dementia Advocates and members of the Dementia Australia Policy and Consumer Engagement teams attended workshops offered to support this consultation and we also conducted a focus group discussion with Advocates with a specific interest in systemic advocacy in research and related issues. Our submission is fundamentally informed by the observations and experiences of Dementia Advocates and structured in line with the headings and discussion questions in the Position Paper. Unless otherwise indicated, all quotations included in this submission are verbatim observations from Advocates.

Dementia Australia, Dementia Advocates and research

Dementia Australia Research Foundation is the research arm of Dementia Australia and awards more than $1 million to support innovative, dementia research every year. As a neutral, national champion for the involvement of consumers in dementia in research, the voices of people with a living experience of dementia are firmly embedded in the Foundation's annual grant process.

The Foundation's Scientific Panel comprises both academic and living experience experts (Advocates) in dementia. The Advocates on the Panel are responsible for assessing applications, to determine whether researchers have included the voice of people living with dementia, their families and carers in the project in a meaningful way. To support this process and to build the capacity of both researchers and Advocates, the Foundation funds a research-specific consumer engagement role, with a focus on connecting researchers with Advocates and providing support to foster meaningful and effective collaborations.

Definitions of Consumer and Consumer Representative

The position paper states that perspectives differ on what defines a consumer and consumer representative and that " … the terms 'community', 'community member', 'consumer', 'stakeholder', 'patient' are as diverse as the Australian population in terms of gender, sexual orientation, age, socio economic status, physical abilities and religious beliefs.' Acknowledging that diversity of perspectives, some Advocates felt that these definitions were nevertheless, too limiting:

> 'The consumer representative definition doesn't do the job.'

As one Advocate noted, a person caring for someone with a disability could theoretically conform to both categories, as a consumer and as a person representing an individual, rather than an organisation.

Values

Dementia Australia believes the existing Statement's values of 'shared understanding, respect and commitment' are worthy but broad and should be strengthened. The proposal to include 'accountability, transparency, collaboration and partnership, equity, diversity and inclusiveness' was supported in principle by Dementia Advocates but it was also felt that these could also be developed further. Empathy was identified as a value that was key to a genuinely informed and inclusive approach to research that seeks to involve people living with a disability, including people living with dementia. Empathy underpins the values of collaboration and partnership, equity, diversity and inclusiveness that should inform all

Advocates also noted that in relation to values such as respect, diversity and inclusiveness, the wording associated with these values could be expanded to reinforce the importance of guarding against stigmatising or discriminating (unconsciously or otherwise) in relation to people living with a disability in terms of the language used, and the way in which all forms of engagement are conducted.

Better Practice Principles for Consumer and Community Involvement in Research

Dementia Australia strongly supports all of the proposed principles in the position paper, noting that these were fundamental in conducting research involving consumers and the community, particularly those living with a disability. Advocates identified ‘Respect for lived experience’ as the most significant principle underpinning research endeavours that involved people living with dementia.

Advocates endorsed an approach that positioned consumers and researchers in partnership, as with the imperative to embrace diversity and equity. There was a range of opinions in terms of the need to involve consumers and the community at all stages of a research project. Some Advocates believed that this was an important part of the process in order for study participants to be fully informed about the project and its potential benefits and outcomes. Others noted that there is a spectrum of consumer involvement in health and medical research. It may not be necessary or appropriate to involve consumers at all stages but at the very least, it should be considered when developing a research proposal.

> ‘If you are doing research, but don’t involve consumers from the outset, it is not always beneficial for them i.e. you need people to be involved and informed from the start so they are aware of the benefits and potential outcomes…it should not be compulsory but should always be considered.’

Regardless of the stage at which consumers were involved, there was strong agreement that to ensure safe, ethical and informed involvement, it was vital that consumers with a disability, including dementia, were provided with accurate information in an appropriate and accessible format that took into account the specific communication needs of each individual. This could include Plain English, audio, video or other formats of the relevant research documents and resources.

Advocates therefore strongly supported ‘Honesty in the development, undertaking and reporting of research, including presenting information truthfully and accurately in proposing, conducting and reporting research’ as a key principle in the Statement.

Roles, expectations and responsibilities of consumers and community members

Advocates agreed that consumers and community members have a responsibility, as with all other parties, 'to consider the best person(s) for a particular role or task, taking into consideration issues such as age, gender, disability, cultural background and experience, health system experience and availability.' Advocates felt that minority groups and populations should be included in the description of the approach for selecting the 'best person (s)' for a specific role or task.

Advocates strongly endorsed the emphasis on ensuring that consumers and community members are provided with the skills, information and support in order to contribute to the development, conduct and communication of research, reinforcing the point made above in relation to the importance of effective communication throughout the research process. Consumers living with a disability, including dementia, will require different kinds of support and information to ensure their equitable involvement in research.

Given the potentially lengthy trajectory of some research projects, and the physical and cognitive changes people living with dementia can experience, the type of support and information required might also vary over the course of a research project. Advocates noted that consumers have a responsibility to indicate their specific needs and inform researchers how best to support their involvement, and researchers have an equal responsibility to acknowledge and accommodate these needs.

> 'Consumers might need support to participate equitably, for example in the presentation of information. Consumers need to let researchers know what might be needed including different formats and ways of participating.'

If consumers and community members are advising research institutions and researchers on their consumer and community perspectives and lived experiences, the issue of appropriate remuneration must be addressed. Advocates involved in research projects over many years reported variable experiences of remuneration, from assumptions by researchers that none was required through to receiving appropriate recompense for their participation.

As one Advocate noted:

> 'Being an Associate Investigator can involve a lot of time, and that often isn't recognised or remunerated.'

There was consensus that being given the choice of being paid for involvement in research acknowledges and respects the importance of community and consumer involvement in research and makes a significant contribution to empowering and encouraging consumers to participate in future research endeavours. The Health Consumers NSW **Remuneration and reimbursement guidelines for consumer involvement in health and medical research** was cited as a useful resource in this context.

Roles and responsibilities of researchers

Any research project involving dementia or dementia-related issues must involve a consumer and/or community representative. Advocates felt this was a clear ethical requirement and should be a non-negotiable condition of conducting dementia-related research that all researchers involved in the field must be aware of.

> ‘It should be a fundamental expectation of being involved in any research on dementia that you need consumer involvement in projects in the dementia field.’

Educating students about consumer consultation and participation in research at undergraduate level in tertiary institutions is critical in this context, so when they commence research careers, they have a comprehensive understanding and awareness of respectful and ethical engagement and other considerations.

Advocates believed that in relation to dementia-related research projects, researchers must be responsible for educating themselves about dementia, and be confident and competent to engage with and support consumer representatives living with the condition. This must necessarily include being aware of how to effectively communicate with people living with dementia, and the potential sensitivities and issues around obtaining informed consent for research participation for a person living with dementia. Protecting privacy and confidentiality, and the right to withdraw from a project at any time without prejudice underpin all research endeavours but Advocates felt that these issues were particularly important to reinforce in the Statement in relation to researchers’ responsibilities in relation to people living with dementia.

> ‘Researchers must educate themselves on consent in relation to a person living with dementia and how to obtain it, and be aware of the ethics of involvement.’

Advocates recommended that if a consumer is providing a lived or living experience perspective of a disability or disease on a particular research project, the relevant peak body should be consulted for specific information and guidance to ensure researchers are fully informed and able to appropriately support their consumer participants.

Acknowledging that it might not always be easy for researchers to identify the best person for a research role or task, Advocates felt that what was most important was that researchers considered all potential study participants without discrimination, including people living with dementia.

Advocates who had been involved in dementia-related research as the sole consumer representative reported variable experiences. These experiences included consumer representation being a ‘tick box exercise’ that satisfied the research grant criteria but did not involve consumer contributions being taken seriously or being formally recognised in the project findings and associated documents. Consumer representatives also reported being marginalised in Advisory Committees or Reference Groups. If a research project involves a particular disease or disability such as dementia, Advocates strongly recommend that at least two consumer representatives are appointed to the Steering Group or Advisory Committee and/or that a Consumer Reference Group is part of the project plan.

As a corollary of this, Advocates emphasised the importance of acknowledging the participation of consumers and the community in research papers and other documents relating to the research project. Advocates noted that if the consumer was involved to a significant degree, this should be acknowledged by listing the person (s) name as a co-researcher. This form of tangible recognition would assist in encouraging and promoting future consumer and community involvement in research.

If researchers are genuinely collaborative in relation to consumer and community participation, and as part of an inclusive approach to dementia-related research, consumers should also be encouraged and supported to suggest research topics.

Roles and responsibilities of research institutions

Advocates supported all the responsibilities listed in the position paper as key to the appropriate conduct of institutions involved in research. As Advocates noted in relation to the roles and responsibilities of the researcher, education and training is fundamental to well-informed institutional approaches to research involving consumers and the community, and to their inclusive and supportive engagement with people living with disabilities, including dementia.

Expanding on the issue of remuneration raised in relation to the responsibilities of researchers, Advocates recommended that institutions could consider allocating seed funding that would actively encourage and support consumer and community involvement in the early stages of the development of a research proposal, accompanied by clear guidelines requiring transparency on how the money will be used to support consumer consultation and participation. Advocates felt that even a modest form of remuneration (for example, a gift card or similar) would indicate respect for the contribution of time and expertise.

Institutions could further promote and support consumer and community involvement in research by specifying that there must be an allocation of funds to support consumer involvement as a standard requirement in all grant funding applications. If remuneration is considered, outlining a clear time frame for potential payments over the course of the project would be valuable from a consumer perspective.

Roles and responsibilities of funders

Advocates expressed different opinions on mandating consumer and community involvement with some feeling strongly that it should be a requirement for funding. In contrast others believed that mandating consumer involvement from the outset or at various stages, might limit what funders were prepared to support and if consumer and community involvement was not appropriate or relevant, might potentially restrict the scope and ambition of research proposals. Funders should instead be strongly encouraged to consider consumer involvement as a condition for the allocation of funding, and if consumer involvement was not part of the project proposal, should be required to provide a clear rationale for this

As with issues raised earlier in relation to remuneration at various stages of a research project, Advocates felt it was important to distinguish between potential consumer involvement at a pre-funding stage and subsequently, when funding was confirmed. It was important that the funding rationale for each, and the way in which consumer and community involvement were supported in these different phases, was clearly outlined.

There was a broad consensus on the need for rigorous governance and reporting guidelines, and clear policies and processes for how consumers were involved at all stages of the project, including how they were being consulted and engaged.

> ‘Funders must be kept abreast of the involvement of consumers and any other key element in the research activity they were funding. In fact, if this was not a “pre-condition” of funding support, I would have some concerns as to the credibility of the funders themselves.’

It was noted that there is currently no uniform or universally adopted process for reporting on how consumers are involved in research and that this was a significant issue in terms of encouraging and promoting future consumer and community engagement in research. Advocates believed funders had a responsibility to ensure they were fully informed by requiring researchers and institutions to regularly report on how consumers are being engaged at all stages of a research project, including involvement in Reference and Advisory Groups. These issues were seen as particularly pertinent in ensuring that appropriate safeguards and supports were in place for the safe and ethical involvement of people living with dementia in research initiatives.

Conclusion

Dementia Australia appreciates the opportunity to make a submission to this consultation on the revision of the existing Statement on Consumer and Community Involvement in Health and Medical Research. We believe that the revised Statement will be an important document that promotes and encourages consumer and community involvement in future health and medical research initiatives. People living with dementia, as with other disabilities, must be appropriately supported as part of the broad endeavour to encourage consumer and community participation. Dementia Advocates identified respectful and inclusive engagement and consultation with people living with dementia, dementia-aware and informed approaches by researchers, institutions, ethics committees and funders, the provision of information in appropriate and accessible formats, consideration of remuneration for participation, and the formal recognition of consumer involvement as fundamental to supporting the future participation of people living with dementia in research.

Dementia Australia welcomes the opportunity for further consultation to explore any of the issues raised in this submission to ensure that the concerns of people living with dementia, their families and carers, are represented in the Statement.

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[i] Dementia Australia (2023) Dementia Prevalence Data 2024-2054, commissioned research undertaken by the Australian Institute of Health and Welfare

[ii] Dementia Australia (2023) Dementia Prevalence Data 2024-2054, commissioned research undertaken by the Australian Institute of Health and Welfare

[iii] Dementia Australia (2023) Dementia Prevalence Data 2024-2054, commissioned research undertaken by the Australian Institute of Health and Welfare

[iv] Dementia Australia (2023) Dementia Prevalence Data 2024-2054, commissioned research undertaken by the Australian Institute of Health and Welfare

[v] Former CEO of Alzheimer's Switzerland Birgitta Martensen's account of her recent diagnosis includes the most recent and compelling example of this. https://www.alzint.org/news-events/news/my-life-with-alzheimers-disease-living-better-with-a-diagnosis/

[vi] Dementia Friends & Dementia Friendly Communities Program. Exploratory report, Kantar Consultants, 2019