

Strategic Review of Health and Medical Research

Submission from Anne McKenzie (Consumer Advocate)

on behalf of the community members of the Consumer and Community Advisory Councils

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Summary of submission

Consumer and community participation is integral to the ethical conduct of research. The Declaration of Alma Ata¹ and the Ottawa Charter² reinforces this is a democratic and ethical right. The Consumers Health Forum made recommendations outlining these rights to the Wills Review³ (1998) which were integrated into the review report. There is a plethora of peer reviewed evidence to support the notion that active involvement of consumers and the community, working in partnership with researchers, improves the quality of research.

Benefits of active consumer and community participation may include:

- research being valued and supported because of its relevance to community priorities;
- improved health outcomes for health consumers;
- improved recruitment rates; and
- community support for the translation of research.

Internationally countries such as the US, UK and Canada have developed clear processes and policies that articulate the value of the contribution that consumers and community members make to research. Australia has an ad-hoc approach to integrating the community 'voice' into its research programs. This has resulted in a range of up-take with only some research demonstrating best practice involvement with meaningful partnerships between researchers and the community. Unfortunately this is not standard practice and many research projects are conducted with little or no community input and in turn the results and findings have limited uptake or importance in the wider community.

It is vital that policies, guidelines and a co-ordinated approach are developed and implemented to raise the status of consumer and community input to be equal in value to that of other stakeholders. This will result in consumer and community participation becoming standard practice in research. The community is an 'untapped' resource in health and medical research and given the opportunity, will make a vital contribution in supporting governments to address increased demands on health services and budgets.

¹ Declaration of Alma-Ata International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978

² Ottawa Charter for Health Promotion First International Conference on Health Promotion Ottawa, 21 November 1986.

³ The Virtuous Cycle, Working together for health and medical research. Health and Medical Research Strategic Review Discussion Document. December 1998. Commonwealth of Australia

Recommendations:

1. Active consumer and community participation must be integrated into all aspects and all levels of research in Australia. This should be done by utilising a similar good practice model that has been developed for research that is conducted with Aboriginal people⁴.
2. Research funding bodies must facilitate consumer and community participation in research by mandating that researchers applying for funding are required, in the funding application, to describe their plans for involving consumers and the community in their research.
3. Processes must be developed to support the mandated requirement in recommendation 2. These processes will include the development of criteria to assess the plans described in grant applications for involving consumers and the community. This can be done by using similar processes to those which are already established to assess community involvement in research that is conducted with Aboriginal people⁵. Alternatively international models for assessing involvement of consumers and the community can be used and adapted to the Australian context^{6 7 8}.
4. Systems must be developed to ensure consumer and community participation is fully integrated into the peer review processes of funding bodies and into the National Statement on Ethical Conduct in Research⁹. These will include establishing processes to recognise and reward researchers and research organisations that currently integrate consumer and community participation into their research activities. The track record process could reflect any involvement initiatives and their outcomes.
5. Develop a mechanism to increase the status of, and value for, the contribution consumers and community members can make to research. Stakeholder consultations for research activities traditionally include researchers, health professionals, policy makers, administrators, industry partners and non-government organisations. Consumers and community members are often not included in these stakeholder consultations.
6. Establish a national consumer and community support unit. This will enable a co-ordinated national approach to be developed and ensure researchers and research organisations can meet the requirements of recommendations 1-5. INVOLVE¹⁰ which is a UK unit, is funded by the National Institute of Health Research to support the implementation of patient and public involvement in health and social care research. This unit provides a good practice model that can be easily adapted to the Australian context. A

⁴ Throughout this document the term Aboriginal is used to also include Torres Strait Islander people

⁵ NHMRC. The NHMRC Road Map II: A strategic framework for improving the health of Aboriginal and Torres Strait Islander people through research. 2010

⁶ <http://www.cihr-irsc.gc.ca/e/193.html>

⁷ <http://www.nihr.ac.uk/awareness/Pages/default.aspx>

⁸ <http://publictrust.nih.gov/introduction.cfm>

⁹ National Statement on Ethical Conduct in Research Involving Humans, Commonwealth of Australia, 1999

¹⁰ www.invo.org.uk

fully funded national support unit will build on already established good practices as well as have responsibility for providing the following services and support:

- a. Development of systems and processes to ensure that consumer and community participation is assessed and reported on in the prioritising, reviewing, funding, conducting and reporting of research. This will be done using good practice models and the lessons learned from research organisations in both the national and international arena;
- b. Facilitation of training and resource development to support and guide researchers, consumers and community members;
- c. Establish and maintain a national database of consumer and community participation activities to promote knowledge transfer and shared learning; and
- d. Establish mechanisms to ensure the wider community has increased knowledge about Australian research programs through the effective dissemination of research findings and results.

Recommendation 6 is based on the *Involving People in Research Symposium 2008 Communiqué*¹¹ developed with input from 240 consumers, community members, researchers and students who attended the Symposium.

¹¹ The University of Western Australia School of Population Health and the Telethon Institute for Child Health Research. *Involving People in Research Conference Communiqué*. Perth 2008

Overview of consumer and community participation in health and medical research in Australia

In 1998, the Health and Medical Research Strategic Review¹² recommended that consumers should be able to participate in prioritising health related research; that those who take part in that research are told about the outcomes; and that researchers involve the community. The Report discusses lifting community engagement by “a more productive approach to further inform, engage, and involve the community”. As a consequence of these recommendations, the National Health and Medical Research Council (NHMRC) and Consumers Health Forum of Australia (CHF) developed a “Statement on Consumer and Community Participation in Health and Medical Research”¹³ (the Statement). The Statement was followed by “A Model Framework for Consumer and Community Participation in Health and Medical Research”¹⁴ (the Framework).

The Statement’s vision was for ‘Consumers and researchers working in partnerships based on understanding, respect and shared commitment to research that will improve the health of humankind’. At the time of their development, the Statement and Framework were considered good practice internationally to facilitate consumer and community participation in health and medical research.

There are examples of where the Statement and Framework have underpinned programs of good practice consumer and community involvement in Australian research. Unfortunately there remains limited uptake of the philosophies espoused in the NHMRC & CHF joint Statement and Framework across the nation. This has resulted in a sporadic approach to the widespread implementation of consumer and community participation in research organisations throughout Australia. This has a limiting effect for the benefits that can be gained from active involvement of consumers and the community in research.

Saunders and Girgis¹⁵ conclude:

‘The part played by science in society is becoming more influential. A national model framework for consumer involvement in health research exists, on paper, in Australia. However its usefulness is diluted by a number of structural and strategic factors including a lack of resourcing; a failure to properly embed consumer involvement into strategic research objectives and funding and review processes; an absence of mechanisms to fully support involvement; failure to link consumer involvement to other strategic goals and unclear responsibility for implementing consumer involvement among key stakeholders’.

The Strategic Review of Health and Medical Research will provide a unique opportunity to:

¹² The Virtuous Cycle, Working together for health and medical research. Health and Medical Research Strategic Review Discussion Document. Commonwealth of Australia. December 1998

¹³ National Health and Medical Research Council & Consumers Health Forum of Australia, Statement on Consumer and Community Participation in Health and Medical Research. 2002

¹⁴ National Health and Medical Research Council & Consumers Health Forum of Australia. A Model Framework for Consumer and Community Participation in Research. 2002

¹⁵ Saunders C, Girgis A. Status, challenges and facilitators of consumer involvement in Australian health and medical research. *Health Research Policy and Systems* 2010, 8:34

- fully evaluate the implementation of the recommendations relating to consumer and community participation as outlined in the Wills Review;
- build on the early work done by the NHMRC and CHF; and
- expand on the good practice examples and principles of community involvement for research that is conducted with Aboriginal people across all areas of research in Australia.

International models for consumer and community participation

Consideration has been given to three countries whose national research organisations have adopted strategies that encourage consumer and community participation in health and medical research, these are:

- Canada: Canadian Institutes of Health Research (CIHR);
- UK: National Institute for Health Research (NIHR);
- US: National Institutes of Research (NIR).

Canada, the UK and the US all have a commitment to actively involve consumers in health research. This is not only publicised in written documentation of the relevant organisations but is evident in their structures, processes and governance. Each organisation has established a national body to support consumer and community participation. The NIHR have established INVOLVE who support active patient and public involvement in NHS, public health and social care research¹⁶. The NIH has the Council of Public Representatives to provide advice to the Director of the NIH on issues relating to public participation in NIH activities¹⁷. The CIHR has consumers and community members on all of its Institute Advisory Boards, each of which act in an advisory capacity to the Scientific Director and the Governing Council¹⁸.

These bodies produce guidance and advice that is easily accessible, for consumers and researchers on various aspects of consumer and community participation about: including: setting research priorities; commissioning research; peer reviewing research proposals; reporting results back to the community; providing training; and networking events for researchers and the public.

¹⁶ <http://www.nihr.ac.uk/awareness/Pages/default.aspx>

¹⁷ <http://publictrust.nih.gov/introduction.cfm?renderForPrint=1>

¹⁸ <http://www.cihr-irsc.gc.ca/e/18156.html>

An effective model for consumer and community participation in Western Australia

The Consumer and Community Participation Program is a joint initiative of The University of Western Australia's School of Population Health (the School) and the Telethon Institute for Child Health Research (the Institute), and was first established in 1998. The purpose of this program is to enhance the quality of research through increased consumer and community participation. Support for researchers, consumers and community members to work together in partnership to make decisions about research conduct and priorities are enabled by:

- Senior level support and commitment
- Funded consumer advocate staff positions
- Governance and policy framework
- Consumer and community advisory councils
- Bespoke training workshops for researchers, consumers and community members
- Range of participation models for individual research projects
- Resources, publications and a dedicated website
- Links to community through a facilitated network and national alliance
- Hosting inaugural 'Involving People in Research Symposium'

There has been an increasing level of up-take of the engagement strategies by Western Australian researchers, consumers and the community since 2004 as evidenced in the figures below. Figure 1 demonstrates a 350% increase in attendance at consumer participation forums and events from 2004 – 2011, while Figure 2 depicts a steady increase in the number of research-related committees involving consumers and community members from 2004-2011. Both of these figures demonstrate a marked change in culture.

Figure 1

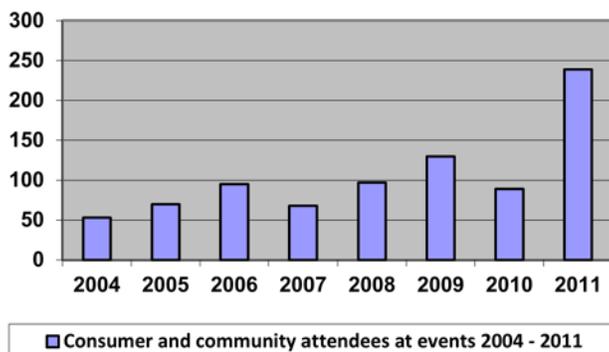
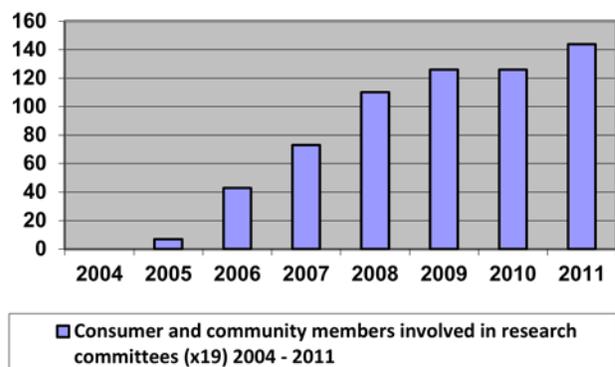


Figure 2



The aim of the joint Participation Program is to increase participation by building capacity of the School and Institute staff to: acknowledge the various levels of participation; understand and respect the contributions of each party; and willingly share knowledge and power. By adopting a planned long-term approach that was

inclusive and sought to address issues as they arose, risks were minimised of implementing a policy that was tokenistic and had little added value to the staff, the community and the quality of research.

The Participation Program is supported by the Health Consumers Council WA and is based on good practice principles of consumer and community engagement that are driven by community values. The program is now recognised nationally and internationally¹⁹.

The dedicated website for the joint Participation Program has been established to house resources and to provide information to researchers, consumers and the community. Since its launch in May 2011 the website has experienced 2000 hits from 49 countries of which 1266 are unique views. Of the 1266 unique views, 724 visitors from 12 countries including Australia, UK, US and Canada have viewed the Fact Sheet Series, demonstrating interest from the global community in these resources. Whilst it is difficult to know who these visitors are, those that can be identified from their internet service providers include 62 different universities, 16 government agencies, and 18 institutes and hospitals²⁰.

The uniqueness of this joint Participation Program is highlighted by its establishment being grounded in a collaborative partnership between the School, the Health Consumers' Council of WA and the Institute rather than a 'top-down' approach from government or funding bodies. The Participation Program has been jointly funded by competitive research grants and more recently, by general and infrastructure funding sources. This is a testament to the intrinsic value the School and the Institute place on the Participation Program and the benefits of consumer and community participation.

This effective and successful program is readily transferable as a model for the establishment of a national support unit.

¹⁹ The University of Western Australia School of Population Health and the Telethon Institute for Child Health Research. Achievements in Consumer and Community Participation. Perth 2011. Available from:
<http://www.involvingpeopleinresearch.org/images/pdf/achievements1.pdf>

²⁰ www.involvingpeopleinresearch.org.au

Response to Review Questions

Why is it in Australia's interest to have a viable, internationally competitive health and medical research sector? (Terms of Reference 1 and 6)

Having a viable, internationally competitive health and medical research sector will provide opportunities for all Australians to benefit from discoveries at the forefront of research. This will lead to the quicker uptake of discoveries and their translation into changes in policy and practice. Consumers and community members can play a key role in providing input into priorities for health and medical research. Community priorities must align with the need to continue scientific discoveries i.e. through investigator driven 'blue sky' research. The lived experience of consumers and community members is pivotal to identifying gaps in research that will ultimately translate into improved health outcomes for all.

Consumers and the community expect that Australia will have an internationally competitive health and medical research sector which must be funded appropriately. An example of this is the community support for the *Discoveries Need Dollars Campaign* held in 2011. At the School and the Institute our consumer and community networks were activated to lobby government via letters, e-mails and taking part in the Perth rally about maintaining research funding.

How might health and medical research be best managed and funded in Australia? (Terms of Reference 2, 3 and 7)

Consumers and community members can provide links between the research sector and other sectors i.e. industry, non-government organisations and philanthropic organisations. Giving equal status to consumers and community members in stakeholder consultations will ensure these links are fully exploited. The NIH provides a model for this where each research institute has an advisory council made up of researchers and members of the general public including leaders in public policy, law, health policy, economics and management¹⁷.

The lack of a co-ordinated approach to prioritising and funding research leads to: duplication in research and administration; missed opportunities for collaboration, knowledge transfer and shared learning; and a lack of accountability for the use of public money. When funding is finite it is imperative to involve the community in making decisions about how research is prioritised, funded and conducted to ensure research is relevant to community needs.

Processes must be developed to support a mandated requirement for researchers to describe their plans for involving consumers and the community. These processes should include the development of criteria to assess the plans described in grant applications for involving consumers and the community. There are untapped opportunities to develop better systems and mechanisms for reporting back to the community about research and sharing scientific knowledge. This will provide higher levels of accountability and transparency for the administration and monitoring of the expenditure on research.

By involving the community in these systems, community trust and support for research will increase as evidenced in the NIH Public Trust Initiative "Partners in Research" program²¹.

Active consumer and community participation needs to be integrated into all aspects and all levels of research. Providing a coordinated approach which is mandated, funded and supported will lead to opportunities for consumers and community members to work in collaboration with researchers. This will enable effective partnerships where the consumer 'voice' is valued and listened to.

The National Health and Medical Research Council has already developed internationally recognised good practice philosophies in their Statement¹³ and Framework¹⁴, and Roadmap II⁵ for conducting research with Aboriginal people. The lack of a national co-ordinated implementation strategy for embedding consumer and community participation in all research has resulted in Australia lagging behind other countries such as Canada, the UK and the US, all of whom have developed national initiatives and mandated processes.

Consumers and community members must be involved in all aspects of decision making about how research is prioritised, funded and conducted. Australia currently has models for consumer and community involvement that are limited to one sector of the community i.e. Aboriginal people and some specific areas of health and medical research e.g. breast cancer research. Consumer and community participation is not integrated throughout research and as such is a missed opportunity for collaboration. The UK example of integrated community involvement into all aspects of the NIHR is a model that can be adapted to address these gaps. Active consumer and community participation is greater than having a single consumer representative on committees. Developing systems to integrate consumer and community participation across all aspects of research including processes relating to human research ethics and peer review, will provide real opportunities for the consumer and community 'voice' to be heard and have an impact on decisions about research.

At the individual research project level, the integration of consumer and community participation must be planned, funded, evaluated and reported on. Systems need to be developed to support researchers to fully integrate consumer and community participation into their projects.

This will also include establishing processes to recognise and reward researchers and research organisations that currently integrate consumer and community participation into their research activities. The track record process could reflect any involvement initiatives and their outcomes. "What gets measured gets done"²².

It is very difficult for consumers and community members to access information in plain language and other appropriate formats about research that is being conducted. Internationally there are good practice examples of national research bodies reporting back to the community²³, providing information about opportunities to

²¹ <http://www.nih.gov/news/pr/oct2007/od-23.htm>

²² Osborne & Gaebler, Addison-Wesley Publications Co. 1992

²³ <http://www.cihr-irsc.gc.ca/e/20452.html>

become involved in the decision making processes relating to research²⁴ and how consumers can take part in research as participants²⁵.

Researchers must have support to integrate consumer and community participation. Lack of training on consumer and community participation was cited as a key barrier by 240 researchers, students, health professionals, consumers and community members who attended the inaugural national 'Involving People in Research Symposium' in Perth 2008²⁶. The joint Participation Program at the School and the Institute responded to this request by developing and facilitating nationally recognised training workshops. These workshops are unique in Australia and have been developed in collaboration with a leading UK Consumer Advocate. Over 400 attendees from WA, SA, NSW, VIC and ACT have attended 16 workshops since 2009. Over 85% of attendees stated they intend to change their practice following the workshops. Increases in requests for support, coupled with the increase in the number of events and committees, validate these intentions.

The joint Participation Program at the School and the Institute demonstrates that funded, integrated and valued support for consumer and community participation leads to increased levels of 'up-take' by researchers and the community, see Figure 2 (page 4).

²⁴ <http://www.peopleinresearch.org/>

²⁵ <http://www.crncc.nihr.ac.uk/ppi/>

²⁶ <http://www.sph.uwa.edu.au/community/involving-people>

3 What are the health and medical research strategic directions and priorities and how might we meet them? (Terms of Reference 5, 12 and 13)

There is a real need to engage consumers and the wider community in addressing the 'Big Issues' for health in 2012 and beyond. Without this engagement any strategic directions and priorities may miss meeting the needs of the community and therefore not have a real impact on improving health outcomes. Consumers and community members can contribute their lived experiences to addressing current and future issues relating to the social determinants of health through active involvement processes.

The current system of funding research encourages the states, research organisations and researchers to compete rather than collaborate. Having the states compete for limited funding, without the benefits of collaboration, means research funds which should be spent on prevention and improving patient experiences of living with disease are sometimes wasted on duplication of research and associated administration costs.

There is little evidence available to consumers and the community that research programs and their findings are co-ordinated, aligned and implemented to address the nation's health priorities. This is reflected in a comment from a community member of the Consumer and Community Advisory Council at the School:

'Aboriginal people and people with mental illness who have been researched for years – all we have is the same life expectancy first identified by the research with no practical or implementable ideas to address this'.

Saunders and Girgis¹⁵ state: *'As a considerable proportion of new scientific knowledge can only be applied in and emerge from processes that are underpinned by human values and societal contexts, and given the heightened political importance of reducing health care costs, it may be timely to give an increasing focus and commitment to consumer involvement in health and medical research in Australia.'*

The community is already involved in setting research priorities in Canada, the UK and the US. This trend is likely to continue to increase along with the involvement of the community in all stages of the research cycle due to the accountability and transparency of all public spending and governance of public bodies demanded by taxpayers globally.

Australia has a unique system where we have national and state consumer organisations which are aligned and linked to patient support groups and non-government organisations. These established consumer peak bodies already have developed systems and processes to effectively integrate the consumer 'voice' in health service delivery. The research sector can adopt the health service delivery model. This will require appropriate funding and resources.

4. How can we optimise translation of health and medical research into better health and wellbeing? (Terms of Reference 4, 8, 9, 10 and 11)

Strategies to improve health and wellbeing of the community must be developed in collaboration with consumers, community members and researchers. By engaging the community throughout the research process it is more likely they will advocate for, lobby for and support the implementation of research findings that are relevant to them.

Collaboration between consumers and researchers will facilitate translation of research findings to make a difference to people's lives and their health outcomes. There is an opportunity to 'tap' into existing consumer support groups and organisations and the peak consumer bodies to support and drive translation into policy and practice. Researchers and research organisations should be required by funding bodies to publish results and findings of research more widely to make this information readily available to the community. Again this will facilitate consumers and community members driving the translation of research.

There are limited opportunities for consumer driven research to be funded due to the current funding and track record process. In other countries, such as the UK's NIHR Public Health Research Program²⁷ there are dedicated funding streams that enable community driven research. Research funding bodies need to develop processes to facilitate community driven research in Australia.

Facilitating consumer and community input into Health Technologies Assessment and the pharmaceutical and medical services assessment processes will ensure people's experiences of living with disease and/or accessing health services are embedded into the decision making processes. The Pharmaceutical Benefits Advisory Committee has established good practice processes for including the consumer 'voice' through consumer impact statements²⁸. The National Institute of Health and Clinical Excellence²⁹ have also developed processes, systems and guidelines for patient and public involvement in all aspects of their decision making.

There is evidence that research using anonymous linked data protects and increases people's privacy³⁰. By involving and informing consumers and community members of the benefits of this process, privacy issues become secondary to the benefits and potential impact of research findings. Processes and systems must be implemented to ensure the community can also easily access information about this type of research and its results and findings, given that the information used in this type of research is often collected without consent and knowledge. By providing mechanisms to ensure this happens, there must be decreased fear and concern and increased trust and support from the community for data linkage research.

²⁷ <http://www.phr.nihr.ac.uk/fundingopportunities/>

²⁸ <http://www.health.gov.au/internet/main/publishing.nsf/Content/amwg-interim-report-attachmentb>

²⁹ <http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/ppipinvolvementprogramme.jsp>

³⁰ Holman CD, Bass AJ, Rosman DL, Smith MB, Semmens JB, Glasson EJ, Brook EL, Trutwein B, Rouse IL, Watson CR, de Klerk NH, Stanley FJ. A decade of data linkage in Western Australia: strategic design, applications and benefits of the WA data linkage system. Australian Health Review. 2008 Nov; 32(4):766-77

An example of how consumer and community participation can effectively be implemented into research using the data linkage process is the Developmental Pathways Project at the Institute. This project is a large research project that links data from a number of state government agencies to understand the health and wellbeing of children and youth in Western Australia. Following a series of consultations, which included two forums that were attended by over 40 people, a Community Reference Group has been established. The Community Reference Group has 16 community members who have an interest and association with either the Institute or the partner agencies. The Community Reference Group has an oversight role for governance, standards and practices relating to consumer and community participation by:

- Providing a community perspective on activities associated with the project;
- Building an understanding of community perspectives that the linked data may be about private and sensitive issues that represent people's stories and lives;
- Providing advice regarding the interpretation of findings and results;
- Providing input into the development of information and dissemination strategies;
- Providing input into the development of ideas and priorities for future research projects.

One of the aims of establishing this group was to bring the community on-board with a large data linkage project. The findings of this project will have an influence on, and implications for, future policy and practices that effect the community.