



Victoria's Health Consumer Organisation

**SUBMISSION TO
STRATEGIC REVIEW OF HEALTH and MEDICAL RESEARCH
IN AUSTRALIA – The 'McKEON REVIEW'**

**Achieving 'Best Practice' in engaging Consumers and the Community
to participate in the Governance, Design, Management and Conduct
of Health and Medical Research in Australia – The Way Forward?**

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of Health and Medical Research in Australia – the Way Forward?**

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1. Introduction

The Health Issues Centre welcomes the opportunity to make a submission to the Strategic Review of Health and Medical Research in Australia – ‘The McKeon Review’ – on behalf of health consumers. The Review is timely as it has been some years since the last major review.

As the leading health consumer body in Victoria, the Health Issues Centre provides independent consumer focussed research and policy development, advocacy for improvements to health care, and training and resources to consumers, service providers and government officers on implementing consumer involvement in health.

Our submission will focus on the opportunity that this review offers for the Australia government and the health research community to finally make good on a decade or more of commitments to and developments in engaging health consumers and the community in health research. The community are the ultimate beneficiaries of medical and health research and therefore have a major interest in its strategic direction, funding and management. In that context consumer involvement in all aspects of governance, organization, design, and conduct of research is both equitable and efficient. Equitable in that, as it is their tax dollars which fund much of the research it is appropriate that they should be involved in decisions about what to fund and how to conduct research; and efficient in that the value of their contribution has been demonstrated to enhance many aspects of research outcomes.

We argue that, although there have been numerous policy statements and commitments to consumer participation, Australia has not, as yet, (with some specific notable exceptions) progressed as far as comparable countries in establishing the national planned and resourced approach and infrastructure necessary to enable effective implementation of its policies on consumer participation within the research community. As a result, compared to other similar countries with significant profiles in health research such as United Kingdom, United States, Canada; or countries in the European Union like the Netherlands and

Germany we are further from 'Best Practice' in implementation. Australia now has an opportunity through this review to redress this and progress strategies to make the most of the benefits and opportunities to the research enterprise that follow from effective engagement and involvement of consumers in all aspects of that endeavour.

The terms of reference for the McKeon Review focus specifically (TOR 7) on '*the institutional arrangements and governance of the health and medical research sector, including strategies to enhance community and consumer participation*'. Our submission will focus primarily on this term of reference; however we note that consumer involvement is relevant generally to most of the TOR = in particular those focused on international competitiveness and future developments, given the growing recognition of the value and importance of consumer participation internationally and the resulting development of planned and resourced programs to support this in research elsewhere.

A brief comment on terminology. There are a wide variety of words and language used as descriptors of a common core theme – the idea that consumers and the community should be involved and participating in the research enterpriseⁱ. To better reflect an emphasis on *partnership* in the consumer/health service interaction, we have chosen to use the terms 'Consumer and community engagement' (CCE) rather than 'participation' (used in the NHMRC standards – see below – and in this review's TOR) because we consider it more accurately reflects the need for the research community to be as dynamic and proactive in engaging consumers as partners in the research enterprise, as are consumers in participating.

The submission briefly covers the following areas:

- The case for involving health consumers and the community in health and medical research
- Context – the current situation in Australia and gaps.
- Framework for CCE – what does 'best practice' look like
- Examples from overseas and Australia of 'doing it well'
- What is needed – recommendations.

2. The Case for CCE – why engage consumers or the community and why do we need to improve?

The case for improving our performance of CCE within research in Australia is threefold:

a. The Evidence of benefit?

Does CCE improve the quality of research? Does it work? What is the evidence base for its value? How does it impact on health research either positively or negatively? There is an increasing amount of evaluative literature, largely from UK, presenting assessments and analyses of the impact of CCE on the research endeavourⁱⁱ. Results are generally positive (although they also identify challenges and difficulties). There are many examples within the literature of consumers 'adding value' to all aspects of a research project, as well as at the governance level. For example, in UK, in 2009 the Clinical Research Collaboration published a series of critical assessments of its 'PPI' (Patient and Public Participationⁱⁱⁱ) program^{iv}.

The benefits of CCE are identified as enhancing 'relevance, credibility, dissemination and transferability'^v. Consumer input has been found to be particularly helpful in:

- Research governance (e.g. funding decision making; priority setting; ethics approval etc.)
- identification of research questions,

- recruitment of participants,
- survey design,
- improving response rates,
- conducting interviews,
- analysis and dissemination of results,
- evaluation.

b. Matching International developments

Relative to comparable English speaking countries, Australia, despite its 'on paper' national policies on CCE, generally has not progressed as far in the *execution* of its stated commitments (with some notable specific exceptions). If Australia is to remain internationally competitive in health and medical research and also meet consumer and community expectations, it needs to 'lift its game' both in terms of implementation of its commitments and in ensuring that the benefits and structures necessary to actually 'do' CCE properly are resourced, required and in place throughout the research enterprise.

c. Community Expectations.

In recent times there has been a strong growth nationally in government support for enhanced consumer involvement in health care generally, combined with a increasing understanding of its 'value-add'. For example the latest iterations of accreditation standards for hospitals now set numerous standards relating to the mechanisms and demonstrations of effectiveness for consumer participation in the management of health care. Quality and safety standards envisage consumer engagement in all aspects of providing 'safe patient centred' care. Victoria has played a leading role nationally by establishing consumer participation policies for public sector health care. In Victoria all public sector health services are required to have consumer advisory committees at the highest Board level as a condition of funding. West Australia has had a well resourced and active Health Consumer Council supported by the State Government for the last 19 years.

As well, strong disease specific groups with well organised and articulate consumers (for example Cancer councils; Arthritis Australia) are demanding more of a say in research into their specific health issues.

As a result, consumer expectations of involvement and participation in decisions about what is researched, how it is approached and the use made of results has never been stronger.

3. Context – the current situation in Australia.

In 2002 the NHMRC issued the "*Statement on Consumer and Community Participation in Health and Medical Research.*" which set the standard for CCE in Australia. This followed recommendations by the Wills Report on consumer participation in priority setting and also dissemination of the benefits of research results to the community^{vi}. The NHMRC Statement conceives of 'Consumers and researchers working in partnerships based on understanding, respect and shared commitment to research that will improve the health of humankind'^{vii}; and "a collaboration between consumers and researchers drawing on each other's knowledge to the benefit of (all) health research in Australia". This was to be achieved through *partnerships* between consumers and researchers which shape decisions about research priorities, specific research questions and design of research projects. Following release of the Statement 10 years ago, the Council instituted various compliance requirements for researchers.

However, advancement in follow up by NHMRC in the years since has been slow.. There are consumer members on major committees and a Consumer Consultative Committee has been established (consisting of consumer members of principal committees) which sits alongside NHMRC governance structures, but a planned resourced approach to implementation – with encouragement and support for

researchers (through provision of training, additional resourcing), compliance monitoring etc. – has not really occurred to any great degree. However, there are encouraging signs. The NHMRC has recently initiated a process to review the 2002 National Statement – this will provide an up to date platform from which to nationally develop more strategic approach to implementation.

Other national research leadership and funding organisations are in a similar position. For example, a recent 'stock-take' by the Australian Primary Health Care Research Institute (APHRI) of primary health care research it funded, found 'users' of primary health care were infrequently engaged by researchers. APHRI is only now, in the last year, undertaking initiatives to improve its consumer engagement performance in its own governance structures and in terms of its requirements of funded research projects and centres.

The most developed contribution in Australia by lay community members to health research, at least in governance, is to be found in ethics approval processes. Under the auspices of the NHMRC Australian Health Ethics Council (AHEC) Guidelines, all research in Australia involving humans as subjects must have ethics approval from an appropriate ethics committee (Human Research Ethics Committees - HREC), on which there *must* be community membership (at least 2) drawn from outside the institution. There is a network of HREC's around the country attached to various health and research institutions. The endeavour is resourced and supported by research institutions and nationally by NHMRC. This network is seen as part of the requirements under Australia's international obligations as part of the world wide research community to ensure ethical research and the involvement of community members in this. It provides an excellent model of leadership and implementation which could be expanded to improve generally the engagement of consumers in research in this country.

In summary, at national level, apart from monitoring the conduct of ethical research, recent moves to update the 2002 NHMRC National Statement, plus some consumer representation on major committees, few resources or strategies have been committed by government or the research community at a national level to actively encourage or require 'on the ground' participation by the community or consumers in health research, or to support researchers in engaging with consumers or the community.

What does exist in terms of implementation could not be regarded as part of a national strategic approach – it does so in very specific areas under localised initiatives – within particular disease areas, in specific institutions, or in research about the health of specific population groups identifiable by, for example, ethnicity, socio economic status, age, or disability.

Possibly the best example of a successful local initiative is the Community and Consumer Involvement Unit in WA, a collaboration by the University of Western Australia School of Population Health and the Telethon Institute for Child Health Research. It has developed comprehensive policies and systems to support and carry out consumer and community participation in all aspects of their research activities – governance, priority setting, funding decision-making, design and conduct of research. It runs regular training workshops for consumers to empower them with the skills and confidence to be effective partners in the research enterprise, and for researchers to support them in engaging with consumers successfully. As well, it has recently commenced a 'Participation Network' to identify consumers interested and suitable to participate in research and a capacity to link them to researchers. This program is probably the most developed general initiative for engaging consumers in research within the Australian health research community. In the absence of leadership in this area from the national research organisations, it has built up a national profile – but operates on a shoe string budget, with one officer, provided by a combination of sponsorship from the W.A.

Health Consumers Council and the two State based research institutes, plus fees from the training seminars.

Other examples in particular areas of research include cancer, arthritis and mental health consumer groups in Australia (which have developed programs of CCE in research relevant to their areas of research), and Aboriginal health research. For example training support is offered to consumers and researchers by Cancer Councils in NSW and Victoria (through the Health Issues Centre^{viii}), and by Arthritis Victoria (through the WA Community and Consumer Involvement Unit). The ANU Centre for Mental Health Research provides a consumer perspective on research content and practice and a focus on the engagement of consumers. Aboriginal Health research has a history of involving local Aboriginal communities in public health research about them – a notable example is the Cooperative Research Centre for Aboriginal and Torres Strait Islander Health funded by the Commonwealth Government which brings together the Aboriginal and Torres Strait Islander health sector, government health agencies and research institutions to ensure that research conducted into Aboriginal health is controlled by and benefits Aboriginal people.

Therefore, while there are significant initiatives in this country, and some progress has been made, it is our submission that, despite policy commitments at the highest levels, there is still much to be done. 'On the ground' action has been slow, particularly at the level of national leadership. Australia is not alone in this. Ward et al (2010)^{ix} comments that, despite policy directives to involve consumers in research in Australia and UK, there is evidence of significant gap between policy and practice. He wonders why. The article presents the report on a UK qualitative study of researchers about their perceptions and experiences of consumer involvement in research. There was a consensus on the value of consumer involvement in research, but a disparity between this and the 'grass roots' extent and impact of actual engagement.

However, in Australia, unlike these other countries, , a comprehensive general approach at the level of national leadership to execution of policies and guidelines which provides resourcing and a strategic 'whole of sector approach' has not really happened yet. Therefore, compared to other similar research countries, Australia needs to develop even the basic infrastructure and support at a national level which 'best practice' indicates is necessary to so much as get to the starting blocks in fostering genuine consumer researcher partnership within the research community as a whole. The next section examines what these 'best practice' ingredients are.

4. How to 'do' CCE – what does 'Best Practice' look like?

It is not difficult from available literature and guidelines to identify models and guidelines, as well as components, for 'best practice' and 'what not to do'. There is a large range of material on CCE, on a great number of aspects and relevant sub-topics. There are a number of comprehensive recent bibliographies and reference lists already available which thoroughly index the published literature.

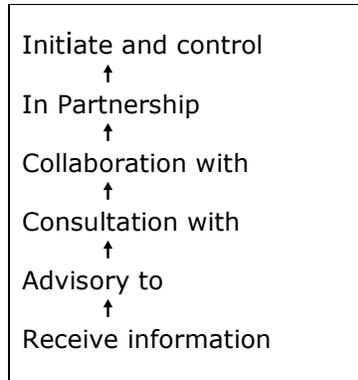
a. Statements, Policies and Guidelines

Policy Statements and guidelines on consumer engagement in research published in Australia and elsewhere have several common themes. They contain key values and principles which guide CCE policy and processes, plus the various components of research processes in which consumers should be engaged. Principles include an appreciation that consumer engagement will add value to the research program or project; commitment to openness and mutual trust and respect; active and engaged involvement by consumers and researchers alike; recognition of the need for support to consumers and researchers to effectively engage; plus an understanding that policies and processes must be sufficiently flexible to accommodate particular organisational situations as well as those of consumers.

b. Levels and Types of CCE – A 'hierarchy' of engagement

The different 'levels' of CCE that can occur within an organisation or research has been characterised in the literature as a continuum from low to high.^x This is expressed as a 'ladder', or 'hierarchy', of participation. The 'ladder' provides a useful summary of different points at which consumers can become engaged in the research process, as well as providing 'signposts' to organisations in determining their CCE policy objectives as to selecting the degrees to which they might wish to involve consumers. It should also be noted that organisations may choose to engage with consumers at different levels in different research projects, or at different stages of the research process. Diagrammatically the 'hierarchy of engagement' can be represented as follows^{xi}.

Consumers



Progression up this 'ladder' can be interpreted as one of increasing empowerment of consumers within the research process. The NHMRC Statement characterises the desirable working relationship between consumers and researchers as one of 'partnership'^{xii}.

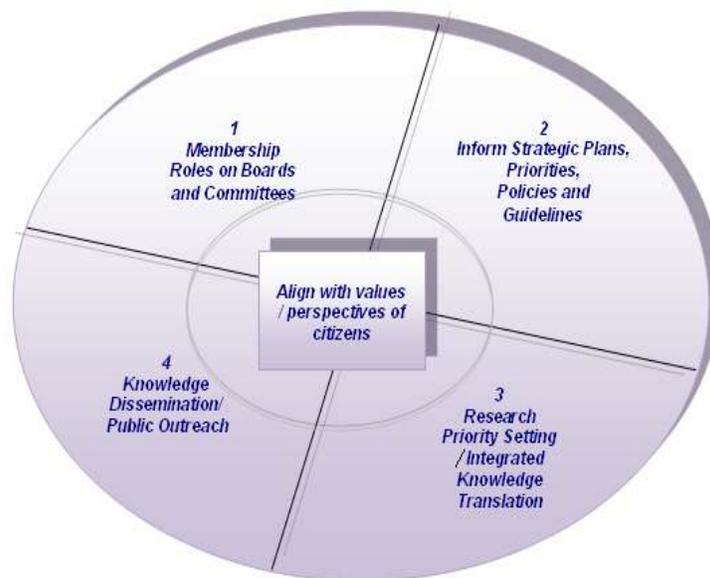
c. Components of Research Process where CCE applies

Processes in which consumers can be involved encompass the full scope of the research enterprise. A comprehensive CCE strategy will include all of them. They include:

- a) *Governance within a funding organisation:*
 - Membership of governance bodies, advisory bodies and the like.
 - Selection and prioritising of research agenda
 - Development of grant application policies and guidelines
 - Grant application assessment.

- b) *Within the research activity:*
 - research design (selection of research questions etc.);
 - engagement of participants;
 - field work (interviews; survey design etc.);
 - analysis of results and
 - dissemination of results.

The Canadian Institute of Health Research (CIHR) has a useful diagrammatic representation:



d. Elements of Best Practice – what is necessary to generate effective CCE:

There are a number of resources and articles which identify and evaluate the elements of good consumer engagement, and what makes the difference between success and failure. They involve a number of principles. Critical factors in 'best practice' and the keys to a successful implementation of CCE policy are enumerated below. They include:

- Commitment from senior levels of the organisation/research team;
- CCE as a coherent and stated policy priority;
- An overall strategic planned approach and objectives with key milestones (even though only a small portion of it may be actually implemented at a time – it is important for everyone to have a shared vision of where they are going);
- Transparency and open communication – taking the time to develop a shared understanding (recognizing that organisational adoption of CCE in research usually requires a culture change within the organisation, and this takes time);
- Detailed guidelines as to what is expected of all participants
- Sufficient and dedicated resources – effective CCE takes time and commitment – this is difficult for already bare bones funded research organisations. (UK Clinical Research Centre (CRC) in fact had a 'ring fenced' budget for its pilot program);
- Development of a network of consumers engaged with the organisation (without a network to draw from the few consumers involved get overstretched and there is a risk of tokenism)
- Dedicated training and support for both consumers and researchers.

Traps to avoid ('what not to do!') in order not to fail / stall include, for example:

- Merely producing a policy statement without any follow up;
- Limiting CCE to token consumer membership of an advisory group;
- Bringing consumers in too late into a process (priority setting, grant assessment etc) or project;
- Undertaking isolated one-off initiatives without the context of a comprehensive, practical, strategic overview or action plan.
- Inadequately resourcing the activity particularly in relation to recruiting and supporting consumer participants; and
- Not recognizing or allowing for the 'culture change' aspect of CCE within the research community.

5. International Models and Examples of 'doing it well'

Internationally, Policy Statements similar to those of the NHMRC on CCE have been published by the Medical Research Council, the National Health Services (NHS) and the National Institute of Health Research (NIHR) in UK; the Canadian Institute of Health Research (CIHR), and the National Institute of Health Research (NIH) in US.

The best supported and developed initiatives in CCE in the English speaking health research community are probably found in the United Kingdom, where the NHS has committed significant resources to supporting 'PPI' ('Patient and Public Involvement') within British health and medical research. The major organisation supporting consumers and researchers is "InVolve". It is a UK national advisory group which promotes and supports greater public involvement in NHS, public health and social care research. InVolve works with others towards creating 'the research community of the future which will be broader, more inclusive and more representative of the population as a whole'. It is funded/sponsored by the NHS through the National Institute for Health Research and contains a wealth of resources and materials, including a data base of relevant research and periodically updated bibliographies and literature reviews. As well it conducts seminars, workshops and training sessions for researchers and consumers and maintains a networked data base of consumers for researchers to access through a website which aims to connect members of the public wanting to get actively involved in research with organisations that want to involve them.

Within clinically focused medical research, the Clinical Research Collaboration (CRC) promotes patient and public participation (PPI) clinical research, as part of facilitation and support for excellence in clinical research within the UK through partnerships with major research organisations. It works strategically and focuses on engaging the public to participate in establishing PPI in CRC research advisory groups and in governance (the Board etc.) as well as evaluating and building the evidence base to demonstrate the value of PPI.

The James Lind Alliance aims to identify the most important gaps in knowledge about the effects of treatments, and has been established to bring patients and clinicians together in 'Priority Setting Partnerships' to identify and prioritize the unanswered questions that they agree are most important within their area. It facilitates partnerships between patient and clinician groups around specific topics. Examples of past and current partnership areas include diabetes, stroke, pressure ulcers, urinary incontinence, prostate cancer and asthma. This information is then used to make those who fund health research aware of what matters to patients and clinicians. It is a non-profit making initiative, funded by the [Medical Research Council](#) and the [Department of Health](#).

The Wellcome Trust is a health and medical research funding foundation established privately in the earlier part of the 20th century to promote biomedical research and its integration into health care with the objective of improving human and animal health through supporting health research and medical humanities. It has a major general public engagement policy and strategy, working with researchers and the creative industries to help societies to explore and become involved in biomedical science, its future directions, its impacts on society and the ethical questions that it brings.

Two initiatives in North America are also worth noting: The Canadian Institute for Health Research (the main health research funding organisation in that country) has developed a Citizen Engagement Framework and Strategy. Project LEAD is the US National Breast Cancer Coalition's (NBCC) science training program for 'activists'. It works within breast cancer research and public policy. The courses prepare graduates to engage in the wide range of local and national forums where breast cancer decisions are made. Project LEAD graduates bring an educated consumer perspective and critical thinking skills to the important issues and

controversies in breast cancer. As a result of NBCC's work, scientists, government agencies and private industry have changed the way they design and implement breast cancer research and programs. Through the research work of NBCC and the training of Project LEAD advocates, a model for consumer influence in research has been created which involves a nationwide peer relationship among scientists, researchers, policymakers and consumers.

In these examples of leadership in developing effective strategies for CCE, all of the major ingredients of 'best practice' are present. Particular elements of their success are:

- Leadership;
- a planned strategic approach;
- recognition that concrete practical support mechanisms and strategies (through training, development of data bases, etc.) are necessary to bring about the changes necessary within the culture of the research community which enable consumers to participate effectively and researchers to successfully engage with them;
- dedicated resources to bring this about.

6. What is needed – recommendations

In the light of the above, in this submission Health Issues Centre makes three recommendations to the McKeon Strategic Review of Health and Medical Research. These are directed at taking the policies already in place (e.g. The updated 2002 NHMRC National Statement) to the next stage of practical implementation so that they can have a real impact. A planned resourced approach over the next five years, with basic support infrastructure and programs for CCE established through and alongside the major national research funding and governance organizations would achieve a great deal.

Recommendation One

Health Issues Centre encourages the McKeon Review Panel to recommend that a national process be instituted to develop a *five year Strategic Plan for CCE: to assess progress and further support implementation of the updated 2002 NHMRC National Statement on Consumer and Community Participation in Health and Medical Research in all publicly funded health and medical research within Australia*

As discussed, following the release of the 2002 NHMRC National Statement on CCP in health and medical research, the comprehensive general approach in Australia for CCE at the level of national leadership needed to execute these policies and guidelines with the support of appropriate resourcing, infrastructure and a strategic 'whole of sector approach' has been slow. Therefore, the first step, in conjunction with Recommendations Two and Three (see below) would be to develop, at a national level, a strategic five year plan to do this. Such a project would involve extensive consultation with the research community and with consumer organisations. Additionally it would anticipate ongoing infrastructure and resources to support the research community and consumers (through training etc.) to make the necessary changes to facilitate effective CCE in all levels of health and medical research, as well as provide compliance monitoring mechanisms.

Recommendation Two

Health Issues Centre encourages the McKeon Review Panel to recommend that a national *audit* of health and medical research currently funded in Australia be carried out to determine the present position in terms of compliance with the 2002 NHMRC Statement by publicly funded health and medical research.

Little is known as to what is actually the position in terms of CCE within health and medical research in Australia. One suspects that, across the board consumers are conspicuous by their absence in most research activities except for isolated pockets and areas – generally in more qualitative community based research. Such an audit is necessary ten years after the NHMRC Statement on CCP to provide a base line from which to both assess its impact in the last ten years, and to enable future assessments of progress, particularly in light of recent action by NHMRC to initiate review of the 2002 Statement. There has never been a national audit, even of publicly funded, research activities in this country. There are examples in the literature of CCE research audits overseas conducted by various research organisations. They provide useful models of audit processes. Examples include the audit of research funders done by the James Lind Alliance for the Medical Research Council in the UK; and the annual log of activities done by the UK Clinical Research Collaboration as part of its PPI program^{xiii}.

Recommendation Three

Health Issues Centre encourages the McKeon Review Panel to recommend the establishment of mechanisms to support increased active consumer participation in research – in particular the establishment of a *National Consumer Health Research Engagement Centre* modelled on the NHS organisation InVolve in UK, and drawing on the experience and expertise in 'doing' CCE already existing within Australia – for example in West Australia and Victoria.

In their submission Consumers Health Forum proposes the establishment and funding of an organisation in Australia similar to "Involve" from the UK, to support consumers and researchers in active participation by consumers in research through training, resources, consumer networks to link consumers with researchers, evaluation capacity, and so on. Health Issues Centre supports that recommendation. However we would advocate that such an initiative build on that which already exists in Australia rather than invest in a completely new enterprise. For example the Centre established in West Australia by the School of Population Health (UWA) and the Institute for Child Health Research already has a developed training program for researchers and consumers attended by researchers and consumers from all over Australia, consumer networks, and resources. It also has strong links with 'Involve'. The founder CEO of InVolve – Bec Hanley – regularly teaches at the training sessions and is co-author of their 'How to' resource book – The Green Book^{xiv}.

ⁱ Herxheimer A, Goodare H.' Who are you, and who are we? Looking through some key words'. Health Expectations 1999;2:36

ⁱⁱ Note however that the methodology for the CCE evaluations found in a brief literature search were based mostly on anecdotal accounts drawn from participants (researchers and consumers) in interviews or surveys rather than rigorous comparative or outcome based methods.

ⁱⁱⁱ For example, in UK CCE is known as 'PPI' – 'Patient and public involvement'.

^{iv} UK Clinical Research Collaborative with TwoCan Assoc. (2005) "A critical assessment of the development of patient and public involvement in the UK Clinical Research Collaboration: Lessons learned – Executive Summary" at p 7.

^v Ward, PR; Thompson, J. Barber; R. Armitage; CJ. Boote, JD; Cooper, CL. Jones, GL. "Critical Perspectives on 'consumer involvement' in health research – Epistemological dissonance and the know-do gap". 2010, J. Soc. 46, 1: pp. 63-82 at p64

^{vi} 'The Virtuous Cycle - Working together for health and medical research – The Wills Report' 1999; Australian Government Dep. of Health and Aging / Publications.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/hmrsr.htm>

^{vii} NHMRC 'Statement on Consumer and Community Participation in Health and Medical Research' (2002) at p. v.

^{viii} In 2009, Health Issues Centre was funded by the Victorian Cancer Agency to develop and deliver a program of training for consumers in consumer participation in research. The project also developed resources for consumers and researchers.

^{ix} See note v

^x See Boote, J, Telford, R. and Cooper, C. – “Consumer involvement in health research: a review and research agenda” 2002 Health Policy 61 213–236, at p.224; also the ‘Ladder of Consumer Involvement’ in ‘The Green Book’ (Mackenzie and Hanley 2007 UWA Press) at p.17.

^{xi} Adapted from Boote et al 2002 and Mackenzie and Hanley 2007.

^{xii} NHMRC Statement on Consumer and Community Participation in Health and Medical Research’ 2002 Summary p.1; see also par.2.2

^{xiii} UK Clinical Research Collaborative Log of Activities (2007 and 2008) – ‘Developing an evidence base for patient and public involvement in research.

^{xiv} ‘The Green Book – Consumer and Community Participation in Health and Medical Research, a Practical Guide’ 2007 UWA Press.