A RESOURCE NOTEBOOK

for

Consumers in Research – Systematic reviews from a consumer perspective

The purpose of this notebook is to alert you to some of the issues involved in being a consumer interested in healthcare research, the evidence base for interventions used in health care and how information from clinical studies is assessed and collated. The materials presented have been prepared with consumers in mind who wish to be involved in the development and implementation of evidence prepared by The Cochrane Collaboration.

As such, it provides a pathway to participating in providing a consumer perspective to systematic reviews of best evidence.

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MEDICAL RESEARCH

What is medical research?

You can think of *research* as any organised activity undertaken to increase knowledge, that is, determine facts or 'truth' about a subject. In health care, research involves setting a question or hypothesis that may enable the systematic investigation of how the body functions normally, in an altered or disease state or that addresses possible ways of approaching treatment and determining its effectiveness. The ultimate outcome is increased knowledge, an improved understanding of health and the provision of good health care.

How does medical research affect you?

This will very much depend on:

- your own health or that of others close to you;
- life experiences and what you consider to be important in life;
- what you believe about health and expectations you may have;
- how self sufficient you are;
- the levels of support you have around you;
- how much 'control' you have over your life;
- costs and commitments or burdens you live with;
- the culture around you;
- where and how you live (setting and social influences);
- the level of knowledge and understanding you have gained.

The terminology used - what we call ourselves as receivers or users of health care

This is often influenced by the agenda of the person or organization using the term. For example, the term *patient* can carry overtones of sickness and dependency – a person who is being treated by a doctor or healthcare provider and needs some action.
Others use the term *consumer*, which implies economic rights such as user satisfaction, quality service and value for money.
Disease is an abnormal, unhealthy condition or sickness whereas illness may be considered as the subjective experience of the individual when unwell. This is where the consumer can give an expert witness view, their own perspective.

Ethics – are about individual rights, a sense of community responsibility, social justice and accountability

Ethics entail formal or professional rules of right and wrong, moral conduct, duty and judgments that guide our behaviour. They are not static and actually change as societies build on knowledge and understanding, individuals take greater or differing responsibilities and societal values change. It can be considered both prudent and ethical for a consumer to understand the possible benefits and harms of healthcare systems, a healthcare research project or an intervention that involves them working toward lifestyles that promote health and shared responsibilities in health care.

For governments, the growing demand and escalating costs for health care are of concern – demand management is largely focused on controlling access to services by either limiting availability of services (eg number of magnetic resonance imaging [MRI] scanners, a system of surgical waiting lists), cost disincentives (including co-payments) and limiting access to payment subsidies through clinical rules (in the case of Bone Mineral Densitometry, radiographs for sprained ankles, drugs such as etanercept [disease-modifying antirheumatic drugs] in rheumatoid arthritis).

Is all medical research useful - how can we tell?

Medical research is expensive and needs to be well planned to give meaningful results. The way a healthcare study is done can affect or determine the results of that study.

Key points – for studies determining the effectiveness of healthcare interventions

- The main thing is to look at research critically – AND to be as critical of the things you believe in as those you do not
- Everyone has expectations or prejudices (biases) that affect what we see, do and believe
- Even well-intentioned, logical interventions may not always work – treatments do not work effectively in everyone! Some people may experience unwelcome or dangerous side effects (harms) from particular treatments; an example is allergies to some antibiotics

What do you personally understand about 'bias'?

By bias we mean any factor, recognized or not, that distorts the findings of a study.

- If you genuinely want to know the effects of an intervention you need to study it in a way that minimizes biases from everyone concerned and the effects of chance. Because two things happen at the same time it does not necessarily mean that one causes the other or that they will always occur together.
- Bias is a systematic 'error' or mistake in the judgments and decisions made that influence the results of a study or a review Bias differs from a 'placebo effect', which is where participants of a study (or assessors of the outcomes) perceive a beneficial effect, or harm, with an inactive treatment.

This means dividing people into groups that are similar in every way possible and giving different interventions to the different groups while in every other way treating them the same, and following everyone who started the study. The influences of expectations are minimized by making sure people do not know which group a person is to be allocated to (by randomization) and for assessing outcomes (blinding).

Integrity of research is important

The highest quality clinical studies are termed randomized controlled trials (RCTs) as they minimize bias. Such studies consider outcome measures that can be expressed numerically (quantified).

Study results can still be influenced by:

- doses or levels of intervention and comparative treatment chosen;

- criteria set for being a participant of a study and in what environmental setting;
- the time course of the study and outcomes measured;
- how well controlled and carefully carried out the studies are;
- how the data is collected and analysed;
- sources of funding.

Descriptive or qualitative information is potentially valuable in supporting the results of well-controlled quantitative studies. Qualitative measures include 'quality of life' and lifestyle changes, obtained from detailed questionnaires. Qualitative studies may also use narrative interviews where participants are asked to talk about their experiences. The interviews centre around sets of semi-structured questions and prompts that explore particular issues that information is needed about.

What are our own expectations about research?

What does the consumer (patient or receiver of health care, carer and parent) want from research – and what are you ready to hear? The media is very ready to announce 'breakthroughs' in research but more often than not these statements do not hold up over time and further investigation.

Are we really prepared to hear that a treatment works in only a proportion of people?

It may be effective in only a limited percentage of those given the treatment (expressed often as 'number needed to treat' for one to benefit). The hope is that we will be the lucky one, and anyway it is worth trying, even if adverse effects (harms or side effects) can be quite marked and long term consequences (of benefits and harms) unknown.

People, more and more, are asking for screening for one disease or another – yet screening is only effective if we can provide effective treatment of the condition that has been identified. There may be actual risks attached to screening – of false positive or negative results, and treatment of conditions that were not dangerous where the treatments themselves carry risks.

Why do receivers of health care need information on research?

Information and understanding

Consumers of health care are exposed to varied sources of information. Patient support groups and the pharmaceutical and other industries (eg dairy foods) provide educational materials often in the form of brochures made available at chemists and health provider premises. The internet has revolutionalised the availability of information and the ability for people with similar diseases to communicate with each other. This information varies greatly in quality, in the evidence for statements made and in the source of funding used to make the information available; sometimes a corporate logo is not clearly visible. Some organisations attempt to assess the quality of various health web sites, for example, the Health on the Net Foundation (http://www.hon.ch/home.html).

Increased awareness by health consumers to identify and select information that meets their needs, which is evidence based and relevant, is important. This has been described as knowledge translation in Canada, getting research into practice (GRIP) in the UK and translating research into practice (TRIP) in the US. Terms used to describe such a person are: the effective consumer, the expert or resourceful patient (in UK), and the smart patient (Australia). Being well informed

can be demonstrated to be associated with improved health outcomes (Street, 2001). With good information we can also be more effective in seeking health care, participating in shared decision making with our service providers, working toward treatment plans and continuity of care (particularly important for chronic conditions) and in the prevention of serious illness.

In the UK, The National Health Service (NHS) sets out to ensure that medical research and development focuses on what is important for patients and users. Indeed, consumer involvement has improved the way that research is prioritized, commissioned, undertaken, disseminated and used. The policy of the Australian Government Department of Health and Ageing is also to foster active involvement of consumers at all levels of development, implementation and evaluation of health strategies and programs integral to their success.

Consumers and researchers are encouraged to think about who is affected by healthcare research, others who may have an interest, and how to ensure effective participation. Better communication is also the key to more effectively recruiting patients to clinical studies. By involving consumers in the design (helping to define research questions) and conduct of controlled trials, the quality of patient information is improved and trials are made more relevant to the needs of patients. Both patients and carers (caregivers) are involved in discussing issues of informed consent and ethics to give clarity in the process of clinical studies, expected and reported outcomes.

New drugs or interventions may not offer any real improvement over existing treatments. Less is known about possible adverse effects because the interventions are new and do not have a history of use. There are also potential issues introduced as a result of recruiting to clinical trials, promising greater benefits and exposing patients to new drugs before they are finally approved by the appropriate government authorities. The attention received and free treatment as a result of participating in a clinical trial may effectively 'win people over' to the new treatments before the interventions are freely available and covered by government subsidy schemes.

CONSUMERS

Why consumer involvement in research?

As the users of healthcare and medical services we can provide valuable input into discussion about research, in terms of insights into a condition and its treatment, and life experiences. Involvement helps ensure the integrity of research and accountability to the community for its quality and relevance. Consumer presence also introduces a responsibility to be respectful of each others' knowledge, to share information, declare conflicts of interests (on any level) and in the application of pertinent ethical considerations. Conflicts of interest are important and can influence outcomes, for example in the findings of clinical studies (Lexchin 2003).

The potential benefits are that issues which are important to consumers, and therefore hopefully to health services as a whole, are identified and prioritized; money and resources are well used; and there is a push for outcomes that have greater relevance to receivers of health care (rather than only what is most easily measured). Morally it is ethically right for consumers to have a voice in research and health care which can impact on our community and health status; the receivers of healthcare are important.

Such exposure also creates a balance, a sense of 'reality', to sensational descriptions of new technologies and research developments as given in the media.

Which consumers?

A consumer in this context is a person who uses healthcare products and services. This term is used in place of others such as patient, citizen, user or receiver of health care. It is used to portray the sense of a more democratic and open provision of service delivery than has existed in the past. With it comes a request for user satisfaction and quality of care as well as protection from misleading information and promotional practices. Some healthcare professionals, therefore, may encourage consumer involvement in understanding their health care.

The traditional paternalistic medical model was of the passive patient and active, treating doctor. The philosophy that 'the doctor knows best' is, however, no longer accepted by many. People want more of a say in decision making and what is most important to the individual, the family and the community. The image of a 'compliant, trusting and uncomplaining' patient is fading as litigation becomes more of an every day practice. Good can come out of this practice in terms of improved documentation of health care, better informed decision-making processes with both benefits and harms discussed, legitimate informed consent for treatment and the measurement of performance outcomes in healthcare organisations.

The concept of consumer (lay, public or community) participation in healthcare research is difficult to implement. Positively influencing confidence in making contributions to a shared responsibility for healthcare research (and indeed one's own health care) is very much a policy issue related to control and accountability. The latter factors may involve yourself, those immediately around you, your healthcare providers, the culture and society you live in and your confidence in your level of knowledge and understanding to undertake an active role.

Consumers sometimes want to gain knowledge and understanding about a health condition that directly affects the individual or where there is cause to access health care on a regular, intensive basis. Breast cancer activists have been exemplary in educating and informing themselves and others about research methodologies, statistics and what it is like to be a person – or carer or family of someone – with breast cancer.

*Consumerism involves….new concepts of corporate responsibility, including protection of the safety and health of citizens and a meaningful choice for consumers in the products they buy (*Ralph Nader)
Consumerism…. is leading to…. excessive concentration on saleable products, rather than on healthy and happy living (Julian Huxley).

How can consumers participate?

Types of participation include consumers describing their experiences (qualitative information and research), being involved in focus groups and consultations, having representation in priority setting and decision-making processes, commenting on medical research and clinical study design, and having input into the development of systematic reviews of evidence for healthcare interventions.

Consumers are encouraged to think about who will be affected by the research, others who may have an interest in order to give a blended view, and how to ensure effective participation in a way that constantly improves the value of healthcare research.

In this way, contributions can be made to the research questions posed; priorities for research; design of studies; the availability and language of information provided; and availability and language of reports and results of the studies.

Consumer participation is about moving beyond informed consent to informing researchers and research participants about outcomes; access to research results (the wider community too); and in influencing consumer/community support for research. Consumers think of different issues than those raised by researchers - such as being fully informed before consenting to participate in a study; who else should be consulted at any stage during a project; reporting on the progress of the study and any results or outcomes; providing accessible lay information about research. Disadvantaged groups are a particular concern - in deciding what research is needed; consumers to identify issues and concerns, how possible benefits can be optimised; who else should be consulted, and how; and encouraging the use of flexible collaborative processes.

What are some of the barriers?

Possible barriers that have been identified include a lack of encouragement to participate by family and peers; or by healthcare providers – an individual relies on an ongoing relationship with healthcare provider and does not want to undermine that relationship.

Difficulties are faced by consumers who: are already struggling with the challenges of a chronic condition, often with limited funds and energy; may come from less-advantaged parts of society and who are reluctant to speak up; live in less-developed countries and have no easy access to support groups or the internet.

Even in Western countries, contributing to research as a consumer can be hard work, time-consuming and involve substantial voluntary work without payment. Consumers may have little say in the planning of their required time commitments. Healthcare research is often complex and technically difficult with its own unique concepts and language (jargon).

Consumers are a varied lot of people coming from all walks of life. Recognised differences exist in attitudes to risks and benefits associated with healthcare and treatments offered, with different areas of concern for different consumers (as is also the case for researchers and healthcare providers). Often confidentiality is involved in a research project so that it becomes more difficult to consult a wide group of consumers. Consumer views are sometimes not well accepted and there is a lack of acknowledgment that we are expert in what we presenting, the consumer perspective.

Healthcare providers often consider that, as they too are consumers of health care, they can represent the patient viewpoint. They, however, come from a different level of knowledge and understanding, have connections in health care, and may have different value judgments about healthcare choices because of their professional experience and knowledge base.

What is the key objective of consumers in research?

The key objective can be seen as political – within a context of citizenship, contributing as taxpayers and staking a claim for rights to the best health care possible. A view too often expressed is that consumers drive the demand for health care, providing ‘the loudest voice’. If this is so, it is driven by media stories, industry advertising (direct and indirect) and funding

of patient support groups and healthcare research, and the lack of balanced comprehensive and open information, particularly by government departments and healthcare organisations. Our wellbeing reflects us as individual consumers or carers, our culture, the healthcare system and the society in which we live. As consumers we have rights that we must exercise as well as responsibilities toward ourselves, the healthcare system and society. The healthcare system must, in turn, exercise its responsibility towards the consumer and society to provide useful and accessible information and services, and to empower consumers through their own self management.

SYSTEMATIC REVIEWS and THE COCHRANE COLLABORATION

Why systematic reviews of healthcare research?

The role of systematic reviews in medical research, policy and health care

Systematic reviews are a way of capturing the volumes of information obtained from healthcare studies that are carried out, many of which are published in journals all over the world. All relevant studies in relation to a set question about the effectiveness of a healthcare intervention in a particular health condition are identified. The results, or data, from the studies are combined (generally termed pooling) wherever possible (meta-analysed) to give the best single estimate of effect (meta-analysis). Information on harms is also obtained, where applicable. They are a solid basis for clinical practice guidelines.

A well-defined process and research methodology are followed as a way of minimizing bias, or influence by the reviewers, on the outcomes of the review. Such reviews provide the highest quality evidence on the efficacy of a healthcare intervention. They also identify where there are gaps in our knowledge and highlight areas that require more research.

The availability of such systematic reviews is important for steady improvements in the quality and safety of health care – by monitoring the effectiveness of healthcare interventions, identifying gaps in our knowledge, and reviewing the outcomes of such healthcare interventions, ideally from both a service provider and consumer perspectives. This information can be matched to performance within healthcare settings.

What does The Cochrane Collaboration do?

The Cochrane Collaboration is an international not-for-profit organization that develops systematic reviews of best evidence on the efficacy and safety of healthcare interventions.
The purpose of developing systematic reviews is to make good healthcare information more accessible. The Cochrane Collaboration achieves this by publishing its reviews on an electronic library, *The Cochrane Library*. The Library is an important tool in evidence-based health care.
A bonus is that by collating information from a number of trials it is possible to determine the effectiveness of an intervention (or harm) before any one trial is put together with enough participants to give the same information. People will not, therefore, be unnecessarily exposed to inactive treatment (or a potentially harmful intervention) when the required information is available. This has happened with giving blood thinners for the prevention of stroke (and routinely treating with a particular drug to settle the rhythm of the heart after a heart attack).

How do consumers fit into producing systematic reviews?

To achieve its goals and objectives, The Cochrane Collaboration is made up of groups that are based on a particular health condition. These groups are termed collaborative review groups as they liaise with reviewers from anywhere in the world, and with consumers who comment on reviews as they are being researched and developed.

Consumers contribute in a number of ways. These include commenting on priorities for the development of reviews, the development of a review question, how the reviewer is going to approach the review question, and to provide a consumer perspective of the final review before it is published on *The Cochrane Library*. Balancing accuracy of the statistical results of a review, readability of the review and its relevance to end users can be challenging. Consumers also have the opportunity to contribute to how the information from a review can be presented in a short summary aimed at a general audience.

Why consumers in The Cochrane Collaboration?

Consumers know what it is like to be the patient, the receiver or user of health care, or the carer of someone who is. Consumers have a unique perspective of health care and research which is based on their own experiences and the experiences of their family, friends and people in the community. We may not have the specialist knowledge of a healthcare professional but often we become very expert in the management of our own ongoing health challenges and care.

We know how we want to be talked about and treated, what we want out of health care and whether a service or system is 'working' from our ethical viewpoint. We do this in a broad, representative way.

We are aware of what outcomes, benefits and harms we are looking for from a healthcare intervention; and the price we are prepared to pay. This may be financially, physically, mentally and emotionally, in the short-term and in the long-term. Our views may well differ from that of our service providers. A principle of shared responsibility in health care is that it enables such perspectives to be considered.

What can The Cochrane Collaboration do for me?

The Cochrane Collaboration is a way of being involved in health research, making consumers participants rather than the 'subjects' of healthcare research. It provides us with the opportunity to increase our knowledge base and understanding of the research behind whether or not a healthcare intervention works; we have a better concept of the likely benefits and harms.

In being involved in the preparation of healthcare information, we are better able to assess the quality of healthcare research for ourselves and articles or brochures that are presented to us as a result of, or about, that research.

In this way we are contributing to potential improvements in the quality of health care.

What do I do and how - how much do I need to know?

Patients with medical conditions become the experts on living with those conditions, even if they aren't necessarily the experts on the science of their treatment. "Long term patients as repeated users of the healthcare system are an incredibly underused resource in how that system works for, or sometimes against, them." (Forbes 2003)

You provide your own personal experiences blended with representative consumer views in the areas that they are applicable. There is no real reason why you should understand every aspect of a review and how it is researched and written. Sometimes systematic reviews are very technical but always the information, or data, involves a person who is receiving health care.

In The Cochrane Collaboration you are one link in a chain – and one of a number of 'peer-reviewers' who look at the review in its final stage of development. This means that the review is looked at from a number of points of view, for its content, methodology, relevance to consumers, and use of language. The review groups are distributed in various countries so you need access to the internet. English is the common language of The Cochrane Collaboration.

You can prioritise review topics from your perspective, contribute to discussion on the important outcomes to be considered when assessing if an intervention is effective or not, consider the types of people and settings in which studies take place, the relevance of findings about an intervention from a consumer perspective and how the information is expressed and disseminated.

The Cochrane Consumer Network

The support I can expect

The Cochrane Consumer Network (CCNet) is an integral part of The Cochrane Collaboration. It works toward enabling and supporting consumers in contributing to the functions of The Cochrane Collaboration and the development of high quality systematic reviews that inform evidence-based practice in health care. It encourages the concept of evidence-based practice and a forward thinking approach to improvements in health care.

The Network works to ensure that consumers have the required knowledge, skills and support to contribute effectively. It does this be developing and maintaining a web site, organizing workshops and presentations, enabling pathways for consumers to communicate with each other, providing representation in The Cochrane Collaboration and materials such as the present document.

"If I lived in a society where being in a wheelchair was no more remarkable than wearing glasses and if the community was completely accepting and accessible, my disability would be an inconvenience and not much more than that. It is society which handicaps me, far more seriously and completely than the fact I have spina bifida." A Davis: From where I sit, Triangle, 1989.