Involving patients in clinical research

Improves the quality of research

Education and debate p 774

Traditionally, patients have been involved in research as "subjects," or even "objects," but definitely not as colleagues. In 1995 the *BMJ* argued that "patients should help to decide which research is conducted, help to plan the research and interpret the data, and hear the results before anybody else."[1] How far have we come in the past four years in realising these hopes?

We need to recognise that patients (participants, users, consumers, what you will)[2 3] have the experience and skills that complement those of researchers. They know what it feels like to suffer a particular disease and to undergo the treatments with their various side effects. They will have a good idea of which research questions are worth asking, and when a question should be framed differently.[4] For instance, researchers at Mount Vernon Hospital hypothesised that moving follow up breast cancer clinics to primary care might relieve the burden on hospital outpatient clinics. After consulting women with experience of the problem, however, the protocol was redesigned to address the issue of easier access to specialists.[5]

Some progress has certainly been made in the United Kingdom in the past few years. Several conferences and projects have explored the possibilities for involving consumers in NHS research.[6] This makes sense for both the health service and the pharmaceutical industry[7]—for if outcome measures are not relevant to patients why should they bother to take part in clinical trials?

So how does the partnership work in practice? The international Cochrane Collaboration has made a great effort to involve consumers from the beginning. The NHS Health Technology Assessment Programme too has made strides in involving consumers in its work.[8] However, practical problems abound. Funding for consumer attendance at conferences is now easier to obtain, but so far there is none for the sometimes onerous task of assessing protocols. For academics this is regarded as all in the day's work, but consumers have to take time off from other commitments and perhaps learn new skills before feeling competent to comment. In Australia consumers are attending training courses on science and advocacy to help them develop the necessary skills and are seeking funding to attend the project LEAD (leadership, education, and advocacy development) course in the United States, which is now seen as a prerequisite for women participating in breast cancer research activities funded by the US Department of Defense and the National Cancer Institute.

There are also major cultural differences still to be overcome. Yet with some imagination these differences can be dealt with. In this issue, for example, Macaulay et al review participatory research with communities and illustrate successful research partnerships with communities as diverse as a Mohawk community in Canada and a township community in South Africa.[9] In the United States the Department of Defense funds about $150m worth of breast cancer research annually. This appropriation was initiated by consumers as a means of increasing breast cancer research while not affecting levels of research in other health areas. The US army already had a breast cancer research programme because of the impact of the disease on women in the army. Since congressional funding programmes are ring fenced, it was necessary to build on an already existing programme rather than divert funds from one area to another. In return consumers have made a major, although initially controversial, impact on the research process. In the first year the inclusion of consumers on both peer review and programme review panels was questioned, so an evaluation was undertaken. Preliminary findings from the quantitative data indicate an increase in scientists' positive views of consumer reviewers and an increase in positive views among consumers, who felt that the concerns of patients were extremely influential in the review process.[10] This model has now been incorporated into other American research organisations such as the National Cancer Institute.

In Australia consumers are being included on the management committees and scientific advisory committees of large research groups such as the Victorian breast cancer research consortium and are being consulted on specific issues such as informed consent by groups organising clinical trials in breast cancer. This latter involvement led to many suggestions by consumers for new research questions—such as, what is the prevalence of lymphoedema after surgery for breast cancer? For such activities to be successful, consumers must be well organised, skilled in advocacy, thoughtful about their approach and accountable to, and representative of, a range of people.

At a recent workshop in the United Kingdom, it was recommended that researchers requesting funding should show evidence that they have consulted consumers in drafting their proposals and should budget for the expenses of doing so. It was even recommended that there should be a majority of consumers on research committees: "Instead of being asked about their research priorities, they would be asked about what problems they see or experience, and supported to translate these into research questions."[11] Other recommendations included acknowledging the importance of qualitative research methods for exploring many of the issues that matter to patients and providing lay summaries of research protocols and research findings.

The implications for medical journals are clear. Besides insisting on informed consent from trial participants,[12 13] they should set new standards for consumer consultation at all stages of clinical research submitted for publication. Wherever possible, consumer peer review should be sought. Where there has been no consumer input into the original design (and obviously it will take some time for this recommendation to be implemented), journals should seek consumers' commentaries on published papers. These

BMJ 1999;319:724–5

are tough requirements, but they are likely to ensure greater rigour and relevance for future research.

Heather Goodare *consumer representative, BMJ editorial board*

Horsham, West Sussex RH13 6DF

Sue Lockwood *chair*

Breast Cancer Action Group, PO Box 281, Fairfield, Victoria 3078, Australia

HG chairs BREAST UK (Breast Cancer Research Ethics and Advocacy Strategy).

1 Goodare H, Smith R. The rights of patients in research. *BMJ* 1995;310:1277-8.
2 Herxheimer A, Goodare H. Who are you, and who are we? Looking through some key words. *Health Expectations* 1999;2:3-6.
3 Neuberger J. Let's do away with "patients." *BMJ* 1999;318:1756-7.
4 Chalmers I. What do I want from health research and researchers when I am a patient? *BMJ* 1995;310:1315-8.
5 Bradburn J, Maher J, Adewuyi-Dalton R, Grunfeld E, Lancaster T, Mant D. Developing clinical trial protocols; the use of patient focus groups. *Psycho-Oncology* 1995;4:107-12.
6 Hanley B on behalf of the Standing Group on Consumers in NHS Research. *Involvement works: the second report of the Standing Group on Consumers in NHS Research*. London: Department of Health, 1999.
7 Liberati A. Consumer participation in research and health care. *BMJ* 1997;315:499.
8 National Coordinating Centre for Health Technology Assessment. *Annual report of the NHS Health Technology Assessment Programme 1998*. London: Department of Health, 1999.
9 Macaulay AC, Commanda LE, Freeman WL, Gibson N, McCabe ML, Robbins CM, et al. Participatory research with communities and lay involvement. *BMJ* 1999;319:774-8.
10 US Department of the Army. *Congressionally directed medical research programs, fiscal year 1998. Status report*. Fort Detrick, MD: US Army Medical Research and Materiel Command, 1998:25.
11 Standing Group on Consumers in NHS Research. *Strategic Alliances workshop 27 January 1999: workshop report*. Winchester: Help for Health Trust, 1999.
12 Herxheimer A. The rights of the patient in clinical research. *Lancet* 1988;ii:1128-30.
13 General Medical Council. *Seeking patients' consent: the ethical considerations*. London: GMC, 1999.

Shared decision making in a publicly funded health care system

Policies exist to reduce the risk of conflict between individual and society

Imagine you are a general practitioner. A middle aged male patient of yours has taken a cholesterol test at a pharmacy which showed raised concentrations and wants to discuss his treatment options. Following sound evidence[1] and national guidelines,[2] you tell him that, because he has no other risk factors, medical intervention is not warranted. However, the patient knows that recent trial evidence shows that statins can reduce cardiac events even in populations with mildly raised total cholesterol concentrations.[3] You know that such use could greatly increase the cost of such drugs—to as much as £3.5bn in England,[4] from £113m in 1997.[1]

You support shared decision making with patients,[5 6] but you recognise the dilemma here: should you see yourself as the agent of the patient, focusing on the effectiveness of treatments, or of the healthcare system and the population it serves, focusing on affordability?

If you choose the system perspective there is more scope for conflict between you and the patient about the treatment of choice. In some cases conflict can arise because the patient's choice is likely to affect negatively the health of others. For example, the efficacy of some forms of immunisation requires high utilisation to ensure herd immunity, but individuals focusing on its costs and benefits to them may decide not to have immunisation. Similarly, a patient requesting antibiotics for a simple viral infection may be reluctant to recognise the dangers to population health of inappropriate antibiotic use.

In most cases the treatment chosen by the individual patient does not so directly impact on the health of others, yet it will still have an opportunity cost. Resources used to treat one individual will be unavailable for other patients covered by the same health system. This situation applies to all collectively funded systems, including those based on private insurance.[7] Moreover, when patients do not personally bear the costs of treatment there is little incentive for them to constrain their pursuit of maximum health gain. If, together with the patient, you decide to prescribe statins because it will slightly reduce his risk of a cardiac event, regardless of the cost of this form of management, the patient's extra benefit will be at the expense of others in the system who are unable to have their preferred—and possibly more effective—treatment. If the objective of the system is to maximise total health benefits from available resources then, within a collectively funded system, the individual doctor-patient partnership may not be able to make an unconstrained choice.

If shared decision making is an important policy objective how can the risk of conflict be reduced? One approach is to augment the clinical evidence with information about costs of treatment.[8] You and your patient would then be expected to weigh up all the attributes of treatment, including costs. To be consistent with the system's goal, the final decision needs to strike a balance between the likely benefits to your patient and the benefits forgone to other patients. Healthy individuals may behave altruistically in health care—blood donation is one example. Nevertheless, it is an important research question whether, when the implications of limited resources are explained to them, ill patients are willing to agree to decisions which result in less chance of health gain for themselves but improved aggregate outcomes.

An alternative to relying on the individual patient's altruism is for the doctor to filter the information and tell patients only about treatments the health system is willing to fund. However, as more sources of information become available to the patient, for doctors to discuss only cost effective treatment options would threaten the trust that has to underlie a successful partnership.

BMJ 1999;319:725–6