The Contribution of Consumers and Patients to Clinical Research

Andrew HERXHEIMER

Most research projects undertaken by clinical investigators are designed to answer questions that interest them or their sponsors for scientific, medical or commercial reasons. Unfortunately they rarely address the issues, questions and problems that particularly matter to patients. The reason is that the healthy people or patients who volunteer to take part in research have until now rarely had a share in deciding what questions it should answer, or by what methods: their contribution has mostly been limited to one of passive subservience to the researchers. This undervalues their participation. They should be regarded as members of the research team and treated accordingly. Patients should have a voice in the formulation of the research questions, to try to ensure that the study will answer questions that they consider important as well as those that the investigators and sponsors want to ask.

Representatives of consumers and of patients

To make this a reality requires commitment and effort by groups of consumers and of patients to gain the necessary background knowledge and skills to become effective partners in research. In Britain such work has been pioneered by the Association for the Improvement in Maternity services and then the National Childbirth Trust (NCT). The NCT decided in 1987 that "to press for randomised controlled trials without openly acknowledging the need for participation in those trials is not a tenable position." It has since supported numerous controlled trials. Before giving its support the NCT scrutinises published reports and the protocol to decide whether the investigation is likely to address questions important to women, and whether it has any reservations about the ethics of the study, including its source of funding. Questions that have arisen include the implications of relying on scarce resources and the efforts of lay volunteers to support trials, and the legal responsibilities of lay members of advisory groups or steering committees. A UK patients' organisation that has pressed for and supported clinical trials to investigate important neglected questions is the National Eczema Society. One such trial studied the effect of avoiding house dust-mite allergen on atopic dermatitis.

Another vital task for consumers has emerged with the development of the international Cochrane Collaboration, begun in 1993 to organise the creation and maintenance of systematic reviews of the effectiveness of all interventions in health care. The reviews are produced by Cochrane Review Groups (CRG) within this Collaboration, each taking responsibility for reviewing the evidence in one area of medicine, eg stroke or skin disease. It has become a cardinal principle of the Cochrane Collaboration that each CRG must include consumer representatives as well as scientists, to ensure that the reviews incorporate the perspectives of patients as well as of all the relevant professions. This will eventually result in more widespread understanding of the need for good evidence on the effects of treatments and for its correct and balanced interpretation by lay people as well as health professionals.

Informed consent

Investigators, ethics committees and lay representatives of consumers and patients must ensure that participants in research can understand the essential points of the protocol, what is expected of them, to what risks and inconveniences they will be exposed, and what the expected benefits to themselves and to future patients may be. If they are to understand these points, the information given to prospective participants in a study should be drafted and tested with the active help of consumers/patients. Participants should be entitled to receive a report of the completed study in a form that they and other patients can understand, and to insist that the results will be published or at least be publicly accessible. They can then contribute to their dissemination and use.

A major unsolved problem concerns the effect of patients' preferences on recruitment to randomised trials and so on the generalisability
of the trials. A trial compares two or more treatments to find out which is more favourable, usually when this is not known. But one treatment may promise or seem to promise more than the other, or it may be more troublesome or safer than the other. Patients therefore often prefer one or other of them, and do not wish to be randomised. There is so far no clear view of how best to proceed when randomisation is either impossible or unacceptable to most patients.

**Conclusion**

Every organisation connected with health research should include consumers who can represent the interests of patients and the community. Their participation should be funded from the research budgets. Participation by consumers/patients should be audited independently and publicly.

**REFERENCES**

5. See: The Cochrane Library 1996, Issue 3 (Database on disk and CD ROM). Oxford: Update Software [PO Box 696, Oxford OX2 7YX, UK. Fax +44 1865 513918. E-mail <update@cochrane.co.uk>]