The cost of questionnaire based research

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The emotional cost to patients and researchers of questionnaire based research has recently been assessed in a study on the implementation of guidelines for women presenting with breast disorders in primary care.¹ The possible distress experienced by patients was considered and contrasted with the need of researchers to remain objective and resist any pressure to respond to patient questions and anxieties. However, the impact of the Bristol and Alder Hey Inquiries will mean that future studies must tackle these issues at an early stage in the planning process. Effective communication will become mandatory not just in the clinical setting but in any situation where health workers and patients interact. The term “health worker” is wide and includes non-clinical researchers. Clearly the need to ensure patients are satisfied with the quality of information and care that they receive is critical to the future of questionnaire based studies. A failure to meet this standard may lead to further limitations on clinically based research.

The traditional relationship between a doctor and a patient has been paternalistic.² The doctor has identified what is best for patients and then protected them from unpleasant experiences. The Hippocratic view of health care rejected any open partnership with patients in favour of an approach comparable to a father caring for his vulnerable child.³ The end of the 20th century may have witnessed the demise of such attitudes. The Bristol Inquiry⁴ and the Department of Health⁵ have called for a more open approach in which patients make choices and these are based on clear understanding of the issues and associated risks. Although these developments have been in clinical care the principles should also apply in the field of research. Subjects need to be:

- Fully informed about the purpose of the research
- Fully informed about potential benefits as well as risks
- Aware of the significance of the research for their own care
- Informed of the results at the completion of the research

Under new guidelines issued by the Department of Health⁶ clinicians are expected to confirm that elderly patients have the capacity to give consent and to test this by checking their ability to:

- Paraphrase the information they have received about the procedure
- Ask questions about the procedure
- Confirm its relevance to their own care

During any research project patients should expect to receive high quality care and advice, as well as retain the right to withdraw from the study. They need to understand the reasons for the research and the principles that lie behind the methodology chosen. Such an approach should apply to all forms of investigation and not simply to therapeutic or surgical interventions. Those who conduct sociological studies,

opinion surveys and patient audits; indeed any form of patient contact; should expect to practice by these standards.

Ethical research on people cannot take place in a vacuum. The patient is a participant in the project and should expect:

- To receive answers to questions he or she asks about their disease or about their care

The exclusion of vulnerable people from studies on attitudes to information and care protocols defeats the purpose of the study. The client base includes vulnerable people and their views are as important as those of robust individuals. Indeed to some extent their views may be more important—because they are the people most likely to be failed by the current system. Rather than exclude the vulnerable, research protocols need to be designed to be inclusive and so to provide support for vulnerable patients. Minority groups include the illiterate, the blind, deaf, ethnic minorities—you and me. The whole purpose of randomised controlled trials is to achieve an equal distribution of the whole range of humanity in both intervention and control groups. Because questions may be disturbing, it does not mean we can exclude certain vulnerable groups and then believe that the answers we obtain also apply to those who were excluded.

What are the consequences of a study that raises questions about the quality of clinical care? The study should lead to an improved approach to clinical care in that field. What are the consequences of a study that raises questions about the quality of care a person has received? It should lead to improved care for that individual patient. Clinicians are under an ethical obligation to identify and respond to bad clinical practice. Nurses are expected to act as patients advocates by the Nursing and Midwifery Council.⁷ For some other researchers there is no professional body to impose such ethical standards. In their case regulation depends upon ethics committees, employing universities, the editors of academic journals, and their own consciences. However, by involving themselves in clinical studies it is not unreasonable for such researchers to adopt similar standards of practice to those recommended by professional bodies. Indeed if they do not should doctors and ethics committees make the names of patients available to researchers? The consent process needs to be clear and follow the principles laid down in new clinical consent forms. It should include a statement to the effect:

“Do you agree to information about you being seen by research workers who are neither doctors nor nurses?”

“Yes”

“No”

The purpose of research should be to improve patient care. This ethic needs to characterise the conduct as well as the outcome of the research. The use of independent monitors to ensure that the research is conducted appropriately and is reviewed regularly has gained currency during the past decade. A similar mechanism should be available for patients with issues raised by questionnaire studies. Patients should not be ignored and it is unreasonable to expect them to dissociate their personal care from participation in a study. Why should patients be expected to understand the roles and

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responsibilities of researchers, as defined by researchers? Patients did not ask for the intervention and so the responsibility must lie with researchers and they need to consider their role in a much wider context. The solution to these difficulties lies in the planning of the research project; the inclusion of patients should be mandatory. Self help groups abound and most have local branches with members who are keen to promote a better understanding of their disease and improved patient care. Patient involvement would be a much more effective learning experience for researchers rather than role play. A role for patients in planning and developing research will help identify possible areas of concern and also ensure that consent processes allow patients to make a choice based on information that is understood. Failure in communications between professionals and patients has led to significant problems in the clinical setting. These range from those identified in the Bristol Inquiry through to the failure of screening programmes to detect early cases or to adequately explain the limitations of this form of disease prevention.⁸

Robust procedures need to be developed for questionnaire studies. Researchers have an ethical and legal responsibility to ensure that participants in a study are able to ask questions, comment on the quality of their care, and to receive answers. It is essential that all participants are fully aware of the mechanisms by which they can express any concerns and also of any limitations on these processes. Clearly these should be discussed with patients at the planning stage and be incorporated in any ethical submission.

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