Guest editorial

Ethical problems of futile research

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In the field of health care, futile research may be defined as research which does not produce results that are useful. A major source of futile research is the need for members of some health care professions to undertake research as part of their career development. In the past this requirement fell particularly on doctors seeking a research-based higher degree, PhD or MD, who usually had access to sufficient time, resources and scientific supervision to produce worthwhile work. There is now a growing epidemic of research arising from health care professionals undertaking MSc and BSc courses which require a piece of research to generate material for a dissertation. In contrast with PhD or MD studies, these courses may not provide the time, resources or quality of supervision necessary for research that can produce results of scientific value. The agendas of research ethics committees, particularly those concerned with applications from non-medical health professions, are becoming laden with proposals for research which will not lead to useful results, is unlikely to be published, and has not been adequately scrutinised for scientific validity. The challenge from such applications probes aspects both of the working of ethics committees and of the principles upon which they make their decisions.

It is generally regarded as unethical to expose human or other animal subjects to risk of ill-effects from research which will predictably produce results of no value. Ethics committees do not necessarily include people qualified to judge the scientific quality of particular research proposals - nor is this necessary for research applications that have been approved by the peer review procedures of bodies such as the research councils. Most research proposals of the kind under discussion have not been assessed by anyone other than the students' supervisors or course leaders, the quality of whose own research records is often not available to the scrutiny of assessing ethics committees.

A common problem with research projects devised in the context of MSc and similar courses is that researchers have insufficient time to study samples large enough to produce results that are statistically reliable. It is no defence that small and inconclusive studies might later be incorporated by

somebody into a meta-analysis. Unless pre-planned in a coordinated process involving standard protocols, meta-analysis may be misleading; the GIGO (garbage in, garbage out) principle applies with particular force to meta-analyses.

Much of the research under consideration is qualitative rather than quantitative, but this may compound rather than avoid the problem. The validity and utility of quantitative research can be predicted by such criteria as sample size and provenance, power, and confidence limits. The issues of sampling in qualitative research are more subtle. One sometimes hears it asserted that because qualitative research is not based upon probabilistic concepts, sample size need not be considered in its design. If this were true qualitative researchers would presumably never need a sample size greater than one. The relevance of sample size and provenance for qualitative studies lies not so much with the epistemology of the research methods as with the utility of the results. When one reads, say, a research report extolling the benefits of a particular form of pre-bereavement counselling on the relatives of six terminally ill patients, one will certainly be interested in epistemological issues such as how the researcher avoided bias in the methods of interview. One will be equally interested, however, in the extent to which the findings from the families of the six patients studied can be extrapolated to the families of the sort of patients that one has to deal with oneself. It is at that stage that one worries about uncertainties in the provenance of the researcher's sample and unassessable inter-individual variance.

We may accept that it is desirable for young health professionals to have training in research but we need to consider the propriety of other people being subjected to inconvenience in order to serve such training. There is a long tradition of patients in hospital being troubled by the attentions of medical and nursing students in training. Many patients are glad to take part in this process as a gift they can offer in return for the care they receive from the trained members of those professions. Hospital patients will know that they are taking part in a training exercise rather than an interchange which may be of direct value to them. The gift relationship is also relevant in

research. Medical and social scientists find that many members of the public, particularly older people, welcome what they see as an opportunity to contribute to society by taking part in health care research. In contrast with the teaching situation, however, the subjects of futile research will rarely appreciate that the exercise will lead to no advancement in human knowledge, is unlikely to be published, and is merely aimed at advancing the career of the researcher.

Informed consent to futile research could be made more valid if ethics committees required research applications to be formally categorised, by scientific review, into those with scientific utility and those which are only training exercises. Ethics committees could then require that specifically informed consent should be obtained from subjects recruited for the latter. Since research ethics committees are not constituted to ensure capability for assessing the scientific value of what comes before them, they would need to institute independent scientific review committees to decide which category particular research applications fall into. This would still, however, be insufficient to protect the public. Patients solicited by a trainee health professional to take part in research to further his or her career may feel under an obligation to participate. As in most research, a relevant issue is the balance between the inconvenience or danger to which individuals are exposed and the value of the research to others. In some instances it is possible for the subjects of research to make their own informed judgment on this. For example, much nursing research is still concerned with research on nurses rather than on nursing and it is reasonable that members of a profession should be willing to help each other in their career development. It is doubtful whether inconvenience, potential distress or risk to patients can be justified in the pursuit of research where value lies only in the training of the researcher. Much futile research involves interviews and questionnaires rather than more invasive procedures, and research ethics committees may be tempted to assume that the principle of minimal risk will necessarily apply to such studies. This underestimates the potential impact of interviews and questionnaires. Recent examples that have caused personal concern include bereaved relatives being required to discuss (retrospectively!) their experience of anticipatory grieving, and a middle-aged man precipitated into depression

by a mailed questionnaire about friendship networks. The questionnaire made him realise that he had lost all his friends and was unlikely ever to acquire new ones, reflections he would have been happier to have been spared.

The problems of futile research could be solved at their source by changing the research training required in middle-grade degree courses. It has not been proven that carrying out futile research is actually a good way of training people. Many students, one suspects, do not realise and are not told how futile their projects have been, and may continue their professional career with unrealistic ideas of what constitutes high quality research. There are at least two other ways of providing research training. One is a rigorously directed and interactive course in research methods and evaluation not involving direct participation in research. Another would be to engage paid or volunteer panels to "role-play" as research subjects so that students could gain direct experience of the practicalities of carrying out research. Indeed such subjects could be artfully briefed to illustrate the range of difficulties and frustrations that a researcher might expect to encounter and to have to overcome in real life. These forms of training would be more relevant than futile research to the career needs of most students of middle-grade degrees. Few will be contemplating a career in research, and they would anyway need to proceed to a doctoral level degree. The important requirement for the generality of health care personnel is to be literate and, preferably, numerate in research, so as to be able to appraise the scientific evidence on which their practice is based and to recognise the need and practical opportunities for research in their working lives. A requirement to undertake the futile research that currently clutters the agendas of research ethics committees is unlikely to be a good preparation for this responsibility. Universities would be stimulated into devising more suitable research training programmes if their local research ethics committees gave notice that research involving members of the public, and categorised as scientifically futile by an appropriately constituted review process, would no longer be regarded as ethically acceptable.

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