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Ethical review of qualitative studies and health services research in Medicine

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Introduction

The 1964 *Declaration of Helsinki* (World Medical Association 2000) has recently been described as «the ethical cornerstone of biomedical research» (Woodman 1999). Since 1964, ethics committees have become so well established that an editorial in the *British Medical Journal* felt able to state that «it should be obvious to all participating in human research that ethical principles should be followed and that approval of a study by an ethics committee should always be sought» (Alberti 1995). This sweeping statement was not followed by a consideration of the different types of human research, although sociological studies were recognised to be a difficult area. In fact, although human research may be conducted using a wide variety of different methodologies, the constitution of ethics committees does not take account of this variation. Most ethics committees are primarily oriented towards the assessment of randomised controlled clinical trials (RCTs), and they normally use the same review procedures and criteria for all types of human research.

The academic discipline of medical ethics is dominated by what Guillon calls «the four *prima facie* principles of health care ethics»; namely, respect for autonomy; beneficence; non-maleficence; and justice (Guillon 1994), (Armstrong and Humphrey 1994), (Beauchamp and Childress 1994). These are universal principles and therefore may be supposed to underlie the work of all ethics committees in medical research. However problems of variability have been reported (Garfield 1995) (While 1995).

In this paper we draw upon our experiences of a qualitative research project about children with asthma and their parents (ASPRO2). The project was designed by a multidisciplinary group of scientists from several European

countries who gave particular attention to the inclusion of ethical guidelines in the protocol. The co-ordination of the project was funded by BIOMED, through the European Commission Directorate General XII. Co-ordinators of studies from six European research sites (UK, Spain-Tenerife, Spain-Madrid, Germany, Greece and Finland) sought the approval and participation of clinics. The proposed methodology of using focus groups with children (and separately with their parents) is a non-invasive technique of data collection. Adult facilitators who moderate the focus group discussions collect the data. Although focus group methodology does not constitute an intervention, it has its own ethical issues.

Gaining ethical approval for the identical protocol presented in different locations was so varied that all project co-ordinators discussed this process at several ASPRO co-ordination meetings. This has led us to reflect on the remit and constitution of ethics committees for human research. In particular, we consider the appropriateness of current arrangements for evaluating health services research, the application of the four principles to different types of methodology, and we make some suggestions for improvement.

Some of the variations we identified in relation to ethics committees appear to characterise the workings of ethics committees generally, and have been discussed in the medical press. Questions have been raised about the criteria that should be used, the functions of ethics committees, their composition, and the difference between audit and research. The issues raised in this paper are part of this general uncertainty, but our experiences of interdisciplinary multinational research have given us some particular insights into these problems.

Given the possibilities of terminological confusion in this paper, we will clarify our usage at this point. The term "medical research" will be used as a generic term to include clinical and health services research. The term "respondent" will be used to refer to people participating in research who are not the researchers or clinicians. For the purposes of this paper, the term "ethical principles" will be used to include health care ethics and principles of bioethics.

A. Differences in ethical evaluation in different countries

The international committee of ASPRO and the EU approved the ASPRO study. Guidelines about ethical issues were included in the original protocol. These guidelines covered informed consent and confidentiality. They

confirmed that pharmaceutical products would be neither tested nor promoted, that researchers would not provide information about treating asthma, and that children found to be in need of medical care that was not being provided would be assisted in obtaining appropriate care.

Researchers in each site had to seek local funding and ethical approval, on the basis of the same research protocol. It might be expected that, in countries which had all endorsed the Helsinki Declaration and which have similar legal requirements for medical research, ethics committees might behave in similar ways. However, we experienced a wide variation in ethics committee requirements.

In the *UK*, the study has to be submitted to two ethics committees. On various occasions, concerns were raised about the "seriousness" of the study according with RCTs methodology. Several copies of the protocol and supporting documentation had to be provided, and approval was only given after a period of several months. Before it could be granted, the UK researchers had to provide information about how the participating GP practices would select children; about the facilitators; about the indemnity arrangements for the facilitators; and about the letters to parents and consent forms.

In *Greece*, the approval by the head physician of the department of paediatrics where the study was carried out was the only requisite, without any formal application to any ethics committee. Similarly, in *Finland*, the study took place in a health centre and in a hospital, and the head nurse and the head doctor gave permission. No formal application was made. However, the ethics committee for an earlier study had given ethical approval to the same team with a similar methodology (open interviews but not focus group discussions with children).

In *Spain*, the heads of the departments involved (including the hospital paediatric board) approved the protocol after careful evaluation. The researchers wanted to submit the study to the local ethics committee for clinical research, but were not allowed to, as the regulations governing ethics committees only deal with drug trials (according to the "*Real Decreto*" 561, April 1993).

It seems that the question of whether a study is considered by an ethics committee or not depends on local and subjective factors. This variation raises a number of questions.

Do these differences reflect different standards of research and ethical assessment? Do they reflect cultural differences? Should ethics committees be entirely concerned with local issues or should they reflect universal val-

ues? Are the current systems appropriate for health services research? Alberti (Alberti 1995) noted that what he termed "social" protocols seemed to create the biggest uncertainty for ethics committees. It is possible that some of the variation we experienced was due to the fact that the study used a focus group methodology to explore parents' and children's experiences of asthma.

B. Should medical ethics committees evaluate health services research and qualitative studies?

The origin of contemporary ethics committees lies in the Nuremberg code of 1947. This code was a response to the medical crimes committed by Nazis during the holocaust. The enormity of these crimes was a product of the particular characteristics of clinical research; namely, the great potential for harm combined with the powerlessness of the patient. This situation thus represents the violation of at least two of the four ethical principles: non-maleficence and respect for autonomy. The power imbalance in most doctor-patient relationships may compromise the patient's autonomy even in situations where the doctor has the patient's best interests at heart. In clinical research, the uncertainty of the outcome may also compromise the principles of beneficence and justice. Thus, clinical research has the potential to violate all four ethical principles. However, this raises the question of whether health services research (HSR) and qualitative research (QR) in general fall into the same category. We believe not, for the following reasons.

The potential for harm in HSR and QR is much lower than in clinical research because the nature of the intervention is very different. HSR and QR do not usually involve direct physical intervention. Instead, the potential harm of these approaches includes the taking up of people's time, the invasion of privacy, and the asking of questions which may be upsetting or conflict-evoking. The imbalance of power is not the same as in clinical research, as most people would probably find it easier to ask an interviewer to leave their house than to refuse medical treatment. Respondents are not likely to have any previous relationship with the researcher and have nothing to lose if the relationship is terminated. Clinical and health services research are probably less divergent in relation to beneficence and justice, as all medical research must have the potential to benefit at least some sections of society if it is to be considered in the first place.

The particular characteristics of clinical research, and especially the randomised clinical trials (RCT) referred to above, mean that

it is usually underpinned by legal requirements. Other kinds of medical and health services research are free of such well-defined legal requirements, but subject to general regulations regarding privacy and confidentiality as well as to procedural requirements from funding bodies or research agencies. Although this is standard practice, it also means that this kind of research is susceptible to more subjective assessments from researchers.

In social science research, ethical issues such as confidentiality, privacy, respect for autonomy and consent is dealt with through the use of professional guidelines [6].They are all concerned with articulating guidelines, responsibilities or obligations for their members, who are exhorted to conduct their research in an ethical manner and not bring their discipline into disrepute. Thus, for example, the British Sociological Association's Statement of Ethical Practice (British Sociological Association 1994) includes a detailed specification of informed consent. It states that research participants should be made aware of their right to refuse participation whenever and for whatever reason they wish; research participants should understand how far they will be afforded anonymity and confidentiality, and should be able to reject the use of data-gathering devices such as tape recorders and video cameras; where there is a likelihood that data may be shared with other researchers, the potential uses to which the data might be put may need to be discussed with research participants. It goes on to state that when making notes, filming or recording for research purposes, sociologists should make clear to research participants the purpose of the notes, filming or recording, and, as precisely as possible, to whom it will be communicated. They should also point out that it may be necessary for the obtaining of consent to be regarded, not as a once-and-for-all prior event, but as a process, subject to renegotiation over time. Finally, guidance is given for those situations in which access to a research setting is gained via a "gatekeeper". There is a similarly detailed explanation of sociologists' obligations in relation to anonymity, privacy and confidentiality.

Thus the question remains: should non-RCT medical research be evaluated by the same ethics committees as RCTs, or is it sufficient that researchers follow the guidelines produced by their own professional organisations, which do not necessarily refer to respondents who are also patients? This raises the question of how HSR and QR differ from other forms of social science research. In many cases, perhaps the only difference is that health services researchers may access respondents' medical details either directly or indirectly.

C. How the four principles relate to different methodologies in medical research

Medical research embraces a range of methodologies from invasive and experimental clinical trials to observational studies. Each one has its own theoretical background, its own scope and objectives, and its own technical procedures. Each one addresses a different type of question. Some want to test well-defined accountable hypotheses in an experimental design, some want to explore different organisational procedures, some describe different approaches in health care delivery, and others try to elicit, discover and generate hypotheses. These different approaches can be divided into three main categories:

1) Experimental studies, including randomised controlled trials and meta-analyses, are very powerful but usually answer very limited questions; the same applies to HSR which adopts the same type of experimental and randomised approach.

2) A second category is quantitative population based studies. These include epidemiological research seeking to establish the distribution of a risk factor or disease in the population, through analysis and observations of a limited number of previously defined variables. It also includes quantitative non-experimental studies, which are the only way to get sufficient information about health settings that cannot be exposed to experimental designs, as well as survey research. In some cases, medical research is based on the formation of large banks of biological specimens or data (for example DNA samples) that could be further linked with other medical data from patients.

3) Finally qualitative studies aim to elicit the perceptions, attitudes, knowledge or approaches to health and health care delivery of patients and users. This type of research is based on individuals. Qualitative studies are based on methods and theoretical approaches deriving from sociology and anthropology, which are often very different from those of biological medical research. Health service research's includes both quantitative and qualitative approaches.

These various research methodologies, if they are assessed at all, are normally assessed by ethical committees with expertise in one particular type of research; mainly the experimental design of the RCT. Although knowledgeable about trial design, members of ethical committees may lack the necessary expertise in all other fields and types of research. The scientific merit and the ethical issues concerning such a variety of designs can only be adequately assessed by a multidisciplinary and open approach.

The methodological requisites of qualitative studies are different from those of RCTs in a number of ways. Firstly, qualitative research is more likely to generate and discover new hypotheses or lines of work than to test pre-established and well-defined hypotheses. For these reasons qualitative research relies on a more intensive analysis of a relatively small number of respondents. The methods of data collection are also different and often

use open questionnaires or interviews in which no predetermined answers are given. Statistical analysis is often inappropriate, and new interpretations of behaviour and its causes and effects, or new views of reality are more important than quantifying numbers of occurrences or similar variables. It must also be taken into account that analysis is often performed at the same time as the collection of data, and may modify the same data collection. In a qualitative study it is not usual or advisable to wait until the whole data collection is finished before the analysis is undertaken. These differences have nothing to do with the quality of research but with different methodologies. It would be as inadvisable to carry out a RCT with qualitative methodologies, as it would be to use the RCT methodology to perform a qualitative analysis.

Are there common grounds for the evaluation of such different types of approach? Which ethical requirements do they have in common, and which ethical requirements are different for RCTs and qualitative studies, to take two extreme examples? Are the four principles equally applicable to all these types of research?

We argue that even if theoretical backgrounds, goals and purposes and methodologies are different, the four ethical principles can be applied to both RCTs and qualitative research.

Non-maleficence

Non-maleficence is the injunction to do no harm. One of the main reasons for ethical assessment of clinical research is to ensure that the risk of causing patients harm with new treatments is minimised and correctly balanced with their expected benefits. Much of the design of clinical trials goes to ensuring the protection of respondents.

In qualitative research, interventions are much less intrusive. Possible harm is mostly related to issues like the invasion of privacy; upsetting or inappropriate (according to the respondent) questions; conflict evoking or reappraisals of personal difficulties; even the use of the "patient's" personal time for research. Ethical assessment of qualitative research must ensure that the researchers have no hidden agendas which they impose on respondents, especially if this is done in a subtle or manipulative manner, and that no "brain-washing" methods are used. The ideal, not only for ethical reasons, but also for methodological purity, is to minimise interference with respondents' private lives. Nevertheless, ethics committees and especially their lay members must be clearly aware that respondents' views and expectations do not always correspond with doctors' biomedical views.

Social scientists are not supposed to "impose" the "correct" knowledge, as they are not trying to be health educators but are trying to learn the points of view of the "other side".

Autonomy

The other main rationale for the ethical assessment of medical research is to protect the autonomy of respondents who are patients. This is especially important because patients, as sick people, are disadvantaged in terms of the balance of power with health professionals. An important part of the job of an ethics committee is to protect people from doctors. They have to ensure that the weaker partners in the relationship are supported in their right to refuse a treatment, a research protocol or a new intervention, without jeopardising their clinical care. The most visible part of this is informed consent. Ethics committees dedicate a considerable amount of time to ensuring that patients are given correct and sufficient information about the trial, and that they are free to accept or refuse the intervention. Lay members of the committees have a special role in this issue.

The same considerations apply to social science research. Social research usually requires the active participation and continuous consent of the "informant" for any data to be collected. It may sometimes be easier for a respondent to opt out of an RCT, by just "forgetting" to take a drug, or calling up to say that he or she does not want to continue in the trial. In qualitative research it may be harder for the respondent to say directly to the researcher that she/he doesn't want to continue. On the other hand, patients' dependence on the health system, and sometimes on the same doctor, may prevent them from opting out of a particular study, whereas it may be easier to refuse participation in a study that has nothing to do directly with their lives and health care. In the ASPRO study, high non-attendance rates for focus groups in all the participating countries indicated that no coercion was involved and that potential respondents indeed felt free to refuse.

In an RCT, the main concern is likely to be about causing (physical) harm. In social sciences the main concern is often protecting the privacy and confidentiality of the individual, and the very private and personal information that may be gathered through interviews, observations, and so on. For this reason a primary concern in the ethical assessment of social science research must be patients' anonymity and the security of data collection and analysis.

Beneficence

An RCT should only be undertaken if there is a potential benefit of the new treatment or procedure to be tested, which is not clearly known or quantified. All participating respondents should have a potential benefit from the intervention and the knowledge should be made available to the scientific community. In social science research applied to health, the benefits for the individual respondent may be minimal (even if sometimes talking and discussing the research questions may benefit and relieve the respondent). The knowledge gathered may be used, later on, to identify and test new hypotheses and to develop educational or intervention programmes for the benefit of future patients.

Justice

Justice has been regarded as one of the main ethical principles. In the particular field of health research it is mainly related to the adequate allocation of health care (and research) resources, and the extent to which the results of the research can be generally applied to society. It is mainly a societal concern. In this regard, RCTs may give a very precise and concrete benefit, in terms of knowledge and subsequent behaviour (dosage forms, drugs, and so on) but very often they offer a marginal benefit to society. On many occasions the applications of the trial go beyond its original scope, which can be misleading and even dangerous.

Social science research has little potential benefit for the individual respondent, but the information obtained may be used in a broader context for the improvement of health care. In this sense, even if the knowledge provided is less precise and immediately applicable it may make a big change in health care procedures or educational strategies.

D. Possible strategies for ethical assessment of health services research and qualitative research.

How should HSR and QR be ethically evaluated? We wish to outline four different approaches to this question, without making any final recommendations at this point.

Some scientists support the idea that social studies do not fall within the framework of medical ethics committees, even if they study patients, because the subjects of the studies are individuals or citizens who just happen

to be sick. They also maintain that their studies have nothing to do with clinical interventions and could not possibly cause "health harms" to the "informants". In those cases, the ethical "gold standards" must be the research guidelines drawn by the different professional bodies, such as the British Sociological Association guidelines. The studies must follow these ethical guidelines, but ethics committees should not be involved in this evaluation because they lack both the right and the knowledge. This is a model of professional accountability within the different disciplines involved. While this may seem extreme, it is what actually happened in most of the countries involved in the ASPRO study.

At the other extreme, research funding agencies, university bodies and even editorial boards of health journals now require approval by an ethics committee of any research done with anybody labelled as a "patient" or in any way related to health. This model is clearly reinforced by strict laws for a particular type of medical research, namely RCTs. The rest of health research, including HSR and qualitative studies, are not encompassed by legal regulations, but are assessed by the same ethics committees. If these committees do not have the necessary expertise to evaluate the scientific merit and the ethical requirements of other types of research, the results of their evaluations can be misleading or, even worse, random. This model does not work for any kind of research that does not fit the narrow description and the requirements of RCT, and should be improved in one way or another.

One way of improving this situation could be to create separate multidisciplinary and more broadly-defined ethics committees for non-experimental research. These new committees should take into account the methodological particularities and the ethical characteristics of qualitative project designs, as well as those of the population-based type of studies (epidemiological, quantitative non-experimental, sampling studies, and so on). In order to do this, the composition of the committees should reflect the types of study being evaluated, and health professionals should be represented but not be the majority. These committees may cover wide geographical areas [7]. This kind of Ethics Committees should be an alternative to, and not in addition to, the existing committees. They should also aim to diminish bureaucracy instead of increasing it.

If this suggestion cannot be put into practice, in the meantime, ethics committees evaluating other types of health research (HSR, qualitative studies and the like) have the duty to look for internal or external expertise in the appropriate methodologies. Instead of the "Good Clinical Trial practices" they should use the BSA and existing professional guidelines for social science research before coming to any judgement. A good start could be

the HSR evaluation published by the HTA (Murphy *et al*. 1998).

This whole issue requires further discussion. Health services research is improving, as is the quality and level of clinical research. All of them are necessary and must be promoted. The rights of the patients and doctors (in fact, individual citizens) should be protected by safe and independent assessment but each methodology should be evaluated with the appropriate instrument.

Notes

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(6) For example, the *British Sociological Association* (British Sociological Association 1994), the American Sociological Association (American Sociological Association 1997), the British Psychological Society (British Psychological Society 2000), the American Anthropological Association (American Anthropological Society 1998) or the National Association for the Practice of Anthropology (National Association for the practice of Anthropology 1988) all have their own sets of guidelines, none of which recommend evaluation by external ethics committees. The American Anthropological Association has even published a handbook on this field, which is available online (Cassell & Jacobs 2001).

(7) For example, the recently constituted "Ethics Committee" of the University of La Laguna, in Tenerife, Spain, is composed of five members with different backgrounds (a Professor of Ethics in the Philosophy school, a Professor in Penal Law, a Professor in Psychology, a Professor in Biochemistry and Molecular Biology, and, finally, a Professor in Medicine, clinical Pharmacologist and president of one of the "RCTs Ethics Committees" of the region).

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