
 FROM THE COLLEGE OF MEDICINE

Ethics and epidemiological research

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Introduction

In 1982 the Council for International Organisations of the Medical Sciences (CIOMS) published proposed International Guidelines for Biomedical Research Involving Human Subjects¹. The guidelines dealt mainly with the ethical issues surrounding clinical trials and other types of research involving individual human volunteers. Since 1990 the CIOMS has been working on a similar set of guidelines more directly related to research on groups and communities². The working group, under the able chairmanship of Professor John Last, has reached its fifth draft revision which, if approved by the Advisory Committee on Medical Research, will be circulated to national research granting agencies and similar bodies. It is premature at this stage to comment on the content and wording of the guidelines, but there are certain ethical considerations, already published elsewhere¹, which are of particular relevance to research in countries such as Malawi.

Objectives

The objectives of the guidelines are to "inform lay members of ethical review committees, investigators, students and others" and to "assist the development of national standards for ethical review of epidemiological studies"². They are not, as Last says "carved in stone, but written in sand that shifts with the tides of human values, advancing medical science and changing health problem." Whether the guidelines achieve their objectives depends, of course, on their acceptability and utility, and this will only emerge with time. That they are needed at all is beyond argument, when so much research is developed and funded outside the set of cultural values and expectations in which it is carried out. Any honest attempt to make explicit the ethical principles on which research proposals and acti-

vities should be judged, and to stimulate the mechanism for doing so is surely commendable - even if, in the way of many international guidelines, the wording ends up a little clumsy, and falls short of satisfying the moralists in any culture.

Principles

The guidelines derive (inevitably?) from a loosely conceived Greek-Judeo-Christian-Liberal tradition of thought, with too little input from the cultures of the developing world. It is much easier, of course, to interpret conceptual meanings from a long history of written philosophical debate than from cultures with equally valued beliefs held in oral tradition. It might be argued, for instance, that cultural differences in the perception of individual autonomy jeopardize a universal understanding of "informed consent"; or that differing concepts of the importance of past and future vitiate shared ideas of 'risk'. There is no way the guidelines can deal adequately with such issues, so they take their starting point far to the right of philosophical debate, in the three commonly accepted, utilitarian principles of medical ethic. If, to some, this seems to be dodging the main issue, it does at least avoid the arguments of the utilitarians and deontologists⁴ among ethicists, as well as steering reasonably clear of situational ethics. The three principles are respect for persons, beneficence and justice; and it is some of the issues surrounding these that it is worth looking at in the Malawian context.

Respect For Persons

The concept embraces 'autonomy' - the right of individuals and communities capable of setting up their own value systems to have their goals and decisions respected; and 'protection' - the right of individuals and communities not fully autonomous to be protected from exploitation. An autonomous individual or community has an absolute right to adequate information and to the whole truth about a study; this is the only legitimate framework for informed consent. Groups or individuals without full autonomy - children, prisoners etc. - are protected from being used in studies which would, scientifically, be equally suitable using autonomous individuals or groups. For all with diminished autonomy, proxy consent by a parent or guardian may be allowed, so long as the consent is freely given, the proxy has no conflict of interest and the protec-

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tion of the dependant individual or group is of first concern.

Individual informed consent remains paramount, but where group agreement is culturally important, as often in Malawi, this too must be sought. In this case, researchers must consider carefully whether leaders appointed by agencies, such as governments, outside the group express the collective will, and to seek if necessary a more 'credible representative'. "In all cases where it is proposed not to seek consent from subjects whose identities will be known, or discernible, an epidemiologist must be prepared to defend his proposal to an appropriate ethical review committee, or more than one"¹.

Beneficence (And Non-maleficence)

Beneficence - to strive for the greatest good, and non-maleficence - to do no harm, have connotations for communities as well as for individuals. Thus, a study does harm when it violates community expectations, when it diverts the energies of scarce local health service workers, or when health care priorities are changed without a community's agreement. Harm is done when groups within a community are stigmatized, lose their self-esteem, or their faith in others by raising discomfiting suspicions. If, for instance, a study found a high level of gonorrhoea among secondary schoolboys in an unidentified school, a community might easily come to believe that all school boys were so infected.

The principle of beneficence is usually served if a study has a sound scientific design and is conducted by competent researchers able to assure the well-being of their subjects and to demonstrate to an *independent* review panel that expected benefits *far outweigh* anticipated risks.

Justice

Justice, apart from reinforcing the rights of the individual and community to informed decision making and protection from harm, also has an important distributive element. New knowledge must benefit the same sort of people who took part in the research, and those who benefit must bear a due share of the risks and burdens of the study. Weaker members of a community should not be the subjects of a study if all members are intended to benefit. It would be wrong for instance to do drug trials with their attendant risks, using groups who could never benefit from them because of cost or government policy.

Principles of justice also penetrate the realms of publication and dissemination of results. Communities must be told in advance of the uses to which findings will be put, and how their privacy will be safeguarded; and, if there are benefits in the

results, the way these benefits will reach them in health education, policy changes or improved services. In this way, too, individual anxieties raised by the study about personal health status can partially be overcome; a well-planned, well accepted message about steps to be taken in the event of certain signs and symptoms etc. may discharge the duty.

Justice demands, too, that a community take an active part in planning and implementing the study and that individuals within the community are not initially approached by strangers but by local health providers, or others, familiar with their situations and anxieties. And lastly it demands that if epidemiologists argue the public benefit to justify privileged access to information, they should make their findings public. This applies equally to those employed by government, international, institutional and private sector agencies, who should all anticipate and plan to prevent or reduce partial, distorted or misconstrued releases of information.

Discussion

That is enough to give some pointers to what are, or will be, a very comprehensive and very useful set of guidelines. Almost every point they make is locally arguable, but it is as much in stimulating debate as in achieving blanket agreement that their importance lies. There are however three ideas that are much stressed and that are not covered by the three principles outlined above.

The first is the *independence* of ethical review committees, on which the guidelines lay continual emphasis. The second is the material and other benefits that a society can reasonably expect to accrue as a result of any study, be they an improvement in some aspect of health care, some diagnostic facility, or the training of personnel in clinical technique or data analysis. And the third is the hope that the guidelines will be applicable to all who look at, or collect data, in an 'epidemiological' way, and not merely to those designated 'epidemiologists'.

For any single commentator, least alone non-Malawian, to draw out the implications any further at this stage would be both impertinent and premature. Suffice to say that when the guidelines are generally available they will be more than enough for debate; and the interests of the people of Malawi will be best served if that debate is wide, open and free.

References

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4. Sprigge TLS. In: The Rational Foundation Of Ethics. Routledge London & New York 1988.