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Ethical aspects of epidemiological studies

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SUMMARY This article aims to stimulate discussion about the ethical problems which can arise in an epidemiological study. It is suggested that in such studies there are new ethical problems which require a widening of the present codes.

It has been recognized for some time that there must be a well-defined ethical code which limits medical experiments on human beings. The Medical Research Council (1964) and the World Medical Association (1964) have laid down guidelines for clinical investigations which emphasize the following points. In an experiment carried out to obtain information which is not of direct benefit to the subject, true consent must always be obtained. In a controlled trial, where the aim is to find out how to improve the patient's own condition, such consent must also be obtained, except where it might not be in the patient's best interest to seek it. Such trials can be carried out only if there is genuine doubt within the profession as to which treatment or preventive regime is best.

Ethical problems also exist in epidemiological studies, but general guidelines are not available. In some respects the ethical problems of such studies are similar to those found in clinical trials and analogies can be drawn. However, when a study of a population in its natural environment is carried out, two new problems arise. First, whereas a clinical trial is usually carried out in the context of a pre-existing patient care programme, subjects are often chosen for an epidemiological study just because they are not participating in existing medical or social programmes. Furthermore, although a clinical trial is usually carried out where there is a continuing commitment to the subject's total health, an epidemiological study usually has no such commitment.

Secondly, there is the problem of consent. In a clinical trial this involves an explanation of all possible outcomes of the experiment in so far as it affects the individual. However in an epidemiological study such consultation with each subject is often impracticable.

POOR COMMUNITIES

Because the ethical problems are usually obvious, some attention has been given to the difficulties of studies in poor communities. In considering nutritional studies, Birch (1969) has written '. . . *it is an immoral scientific and political experiment to intervene by modifying a food supply without guaranteeing that there can be a perpetuation of this modification in the future*'. In the course of such a study, the usual ecology of food gathering, food cultivation and economics may have been disturbed, and the community may be left with new and more serious difficulties once a study has ended. Furthermore, for the sake of scientific validity, it is often necessary that the environment of the groups being studied should not be changed (other than by design) during the course of the study, in any way that might affect the factors being measured. A sudden improvement in public health services, for example, could be as important a factor in improving the health of a community as the 'treatment' being supplied in a nutritional programme. Thus there might be a built-in desire for such studies to maintain the environmental status quo. The ethical implications of this, especially in a long-term study, are clear.

What is often not so clear, however, is whether the same considerations apply to other kinds of epidemiological studies which do not ostensibly involve the same kind of intervention in the environment and are not so obviously concerned with maintaining the status quo; for example, the so-called 'observational' study where the aim is to measure various characteristics of the population, possibly over a long period of time, repeatedly on the same individuals.

GENERAL LEVEL OF HEALTH

A basic ethical requirement of an epidemiological study, as in a clinical trial, is that nobody is thought likely to suffer because of the study. There is little doubt that this requirement is satisfied in most studies where the facilities used to carry out the study are additional to those usually available. In some instances, however, where use is made of personnel such as doctors to carry out special examinations, there is the possibility that other groups in the population may suffer some reduction of attention. That the subjects to be studied may be selected at random does not avoid the ethical problem.

In some studies sufficient extra resources may be provided to ensure that no group receives less attention than they otherwise would have had and in many epidemiological studies the effect of diminished resources on the general community will in any case be slight. Also this problem will not be important in populations where the level of resources is already high. However, it does deserve close attention in populations with low resources, few trained personnel, etc., where diverting scarce resources could seriously affect the overall health of the population.

INCREASING DEMAND

It is clear that any reasonably large study which provides additional resources in order to observe but not to treat individuals, is likely to identify additional individuals requiring further attention. This may well be an advantageous side-effect of the study, being of direct benefit for these individuals. However, this will put an extra burden on resources already available for such work, and it may be that this extra demand will result in a general deterioration of the service. In such circumstances the disadvantages may outweigh the advantages. A further problem is that it is often very difficult to predict, even approximately, the number of additional individuals who will be identified. This is likely to be a more important problem in a 'low resource' area than in a 'high resource' area. In planning a study therefore, these considerations may imply that the study can only be carried out in a 'high resource' area. This raises the general methodological problem that some studies may be carried out almost exclusively in 'high resource' areas with consequent lack of information about 'low resource' areas.

When an observational study ends the resources may revert to the pre-existing level, but the expectations of the community may be increased. The example of poor communities taking part in nutritional experiments is an obvious one, but the same may be true of an affluent community. Such a community could become dependent on a large amount of attention and may change its behaviour patterns. For example, individuals may no longer take the initiative for clinic attendance when the previous incentives are removed. The consequent frustration may lead to a worse situation than if the study had not taken place. There is therefore an ethical responsibility to take such factors into account and to be prepared to meet situations of this kind with

adequate resources. At the very least there is a responsibility to monitor the situation after the end of the study.

SUBJECT CONSENT

The Medical Research Council (1964) statement warns '*Owing to the special relationship of trust that exists between a patient and his doctor, most patients will consent to any proposal that is made. Further, the considerations that are involved in a novel procedure are nearly always so technical as to prevent their being understood by one who is not himself an expert. It must therefore be frankly recognized that, for practical purposes, an inescapable moral responsibility rests with the doctor concerned for determining what investigations are, or are not, proposed to a particular patient or volunteer.*'

In an epidemiological study the consent of subjects is normally obtained after they have been selected by a sampling procedure. The problem then arises of how far an investigator is justified in going in his attempts to persuade a subject to participate, and when such attempts at persuasion become an invasion of privacy. There is also an additional responsibility which rests both with the research workers and with those legally concerned for the health of the whole community to determine whether and how such studies may affect the community. In a society where power is given to elected representatives who are then responsible for the protection of the public health, it would seem that consent has to be obtained from these representatives. It is not often that a whole community is asked directly to give consent to a particular programme, although a most effective, albeit somewhat negative, method by which the individuals in the sample can make their views felt is by refusing to cooperate.

CLINICAL ENCOUNTER

Confronted by an individual, a doctor always has a duty to respond to his needs. To make a correct diagnosis he needs all the relevant available information, and it would be considered unethical to suppress any of this. However, information about which treatment has been applied is not usually available in the standard double blind clinical trial, because it might introduce bias. Such information is not considered relevant unless important side-effects appear, in which case attention to these side-effects is required and the patient might have to be removed from the trial.

In an epidemiological study a similar situation may exist, where for example a dietary supplement is subjected to a trial. Also, however, it may sometimes be scientifically undesirable in an observational study for an examiner to have knowledge of a subject's clinical history. In a longitudinal study, for example, such knowledge could lead to biased results. This varies from the usual clinical situation where all relevant patient information is available, so that whereas scientific considerations may demand ignorance of past events, ethical considerations may demand knowledge of them.

ENVIRONMENTAL STATUS QUO

Acts of policy or accidents may change the environment in which a study is carried out, in such a way that the study becomes scientifically invalid. Accidents cannot be helped, but research workers may be able to influence external policy decisions. Where such decisions would improve the public health of a poor community, it becomes necessary to sacrifice scientific validity to ethical obligations. The same considerations may also apply in affluent communities. An external decision to fluoridize a water supply, for example, could have a scientifically disastrous effect on a dental study comparing two populations, one from a fluoridized area and one from the previously unfluoridized area. Scientific considerations will therefore favour the maintainance of the status quo, while ethical considerations may demand change.

CONCLUSION Some observers have noticed an increasing reluctance on the part of health workers and the public to participate in epidemiological surveys. This reluctance has also been noted in other fields and it has been suggested that surveys are receiving an increasingly poor response from the community. One of the reasons for this may be that there may sometimes be a lack of genuine concern for the welfare of the population in favour of the scientific results of the study. If workers have communicated this feeling to their subjects, then these subjects, who are not participating in any other aspect of the research and who may not be informed of the results, may feel that they are merely being used as 'guinea-pigs'. This may contribute to a general unwillingness to cooperate. In the case of health personnel they may feel not only this, but also that their own time is being wasted and this may have deleterious effects on their interest and on the quality of the data they collect.

We have attempted to describe some of the ethical problems which may arise in the course of epidemiological studies. Although we have only dis-

cussed medical studies many of these considerations may also apply to other kinds of survey, whether social, educational, economic, etc. Our remarks are intended to be preliminary to a general discussion of these problems, and we would hope that out of such a discussion a generally acceptable ethical code for epidemiological studies could be formulated. Just as clinical trials have to satisfy ethical criteria for those conducting and financing them, so epidemiological studies should have to do the same.

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