Ethical aspects of epidemiological studies

PAMELA ZINKIN
Wellson Centre, Institute of Child Health,
30 Guilford Street, London WC1 AND

HARVEY GOLSTEIN
National Children's Bureau,
5 Walden Street, London WC1V 7QE

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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 regimen 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 context. In a clinical trial that involves an individual, the situation is simple. However, an epidemiological study with considerable overlap is often unanswerable.

Because the ethical problems are usually obvious, some attention has been given to details of the study, including selection of the population and the controls. In considering the adequacy of the study design, the larger the number of cases involved, the more serious the question of whether the design is adequate. While it is true that the ethical and social problems of an epidemiological study are often difficult to answer, it is not true that they are not important in the design of the study. The study should be of adequate size and duration to answer the questions adequately. In some studies, insufficient extra resources may not be available to ensure that the study is of adequate size and duration. The goal of the study is to design the study so that the questions can be answered adequately. If one were to design a study to address all of the ethical and social problems of an epidemiological study, it would probably be too difficult and too expensive to be feasible. However, it does not mean that one should avoid the ethical and social problems of an epidemiological study. It does mean that one should be aware of these problems and make every effort to design a study that is of adequate size and duration to answer the questions adequately.

INCREASES DEMAND

It is clear that any reasonably large study which provides additional resources for the study of the problem may be considered in order to observe, but not to treat individuals. It is also clear that the individuals requiring further attention are those who, in any event, are already available for study, and that the study should be directed towards those who are already available for study. To show that this extra demand would result in a general derogation of the advantage of the study is a false step. In such a case, the study might show the disadvantages of the study, but it would not be possible to show that the extra demand would result in a general derogation of the advantage of the study.

A further problem is the question of whether the individuals who will be studied are considered to be at risk. If the study is directed towards those who are already available for study, the question of whether the individuals who will be studied are considered to be at risk is not relevant. The question of whether the individuals who will be studied are considered to be at risk is relevant if the study is directed towards those who are not already available for study. In such a case, the study might show the disadvantages of the study, but it would not be possible to show that the extra demand would result in a general derogation of the advantage of the study.

When an observational study is carried out, the resources may be used only if the subjects are selected randomly. The selection of the individuals who will be studied is important in an observational study. Such a study could become dependent on a hypothesis of an individual who has not observed the study. This is likely to be a more important problem in a low-resource area, where it is more difficult to obtain data and information about the individuals who will be studied. However, it is also possible to show that the extra demand would result in a general derogation of the advantage of the study.

The criticism of the study is that it is difficult to select a representative sample of the population, possibly over a long period of time, especially on the same individuals. A critical point of such an epidemiological study is that a clinical trial is a study that can be conducted in a low-resource area, where the facilities do not take into account. The facilities used to carry out the study are additional to those usually available in some instances, however, where one is not in a position to carry out the study.
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 'Going 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 too technical 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 those 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 fluoridate 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 maintenance 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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