ETHICS IN OCCUPATIONAL HEALTH RESEARCH

David Coggon

Ethical aspects of medical research have had a high public profile in the UK lately. There has been concern, for example, about the level of information provided to participants when consenting to clinical trials; regarding the retention of organs removed at necropsy without the knowledge or permission of next of kin; and about the rights and wrongs of cloning human tissues. In general, occupational health research is less controversial. Most studies involving human subjects are observational rather than experimental, and do not entail hazardous clinical procedures. Nevertheless, difficult ethical questions do sometimes arise, both in the design of occupational studies and in the communication and application of their findings. Moreover, the acceptability of some epidemiological methods that have been widely used in occupational health research is now being questioned. It is important that the potential consequences of abandoning or restricting such techniques are properly considered before limitations are imposed.

RANGE OF ETHICAL ISSUES IN OCCUPATIONAL HEALTH RESEARCH

The ethics of medical research come into question most obviously where investigations entail risks or disadvantages to individual participants that are not clearly outweighed by concomitant personal benefits. However, the range of ethical issues in occupational health research extends wider than just the design and conduct of studies (box 1).

Study question
There may be doubts about the acceptability even of posing some research questions, if there is a possibility that doing so could in itself cause harm. For example, some people nowadays suffer severely disabling symptoms, which they (and sometimes their medical advisers) attribute to low levels of synthetic chemicals in their environment. It is hypothesised that they are unusually sensitive to a wide range of substances, although the evidence for underlying toxic or immune mechanisms that might explain the phenomenon is currently unconvincing. An alternative explanation might be that the symptoms represent a conditioned response to exposures perceived, for example, because of an odour or mild irritant effects. A conditioned response of this sort could be susceptible to cultural influences and prior beliefs, and if this is correct, it is possible that research into “multiple chemical sensitivity”, by increasing public awareness of the problem and giving it scientific legitimacy, would promote its development where it would not otherwise occur. In deciding whether to commission research on the disorder, this concern would need to be weighed against the potential benefits from a better scientific understanding of the condition.

Study design and conduct
The ethical principles that govern the design and conduct of occupational health research involving human subjects are the same as apply in other branches of medical science, and are set out, at least in part, in the Declaration of Helsinki (box 2). Among other things, the declaration covers the need for independent ethical review of studies; for sound scientific design; for scientific competence of researchers; to ensure that the importance of the objective is in proportion to the inherent risk to the subject; to protect the privacy of subjects and minimise the impact that the study has on them; to inform subjects adequately about the aims, methods, anticipated benefits and potential hazards of the study; and to obtain freely given informed consent to participation. These principles provide a valuable frame of reference, but they must be interpreted in the context of each specific study design, and some types of research that are applied in the field of occupational health require special consideration.

For example, in some occupational studies, experimental interventions are carried out at a group rather than individual level (for example, the introduction of ergonomic modifications to an industrial process), and it may not be practical to obtain individual consent from all who will be affected by the change. In these circumstances it is especially important that neither those
exposed to the intervention nor any control group with which they are compared should be importantly disadvantaged by the study.

Even when individual consent is feasible, it is still important that any risks that a participant might incur are acceptably small and properly understood. One area of controversy is the deliberate experimental exposure of healthy volunteers to toxic substances. This has been done, for example, to assess the impact of low doses of organophosphates on cholinesterase levels and the potential of some pesticide products to cause skin sensitisation. Such experiments are accepted in the development of new pharmaceutical products, where before a drug reaches the stage of clinical trials in patients it is first tested in healthy subjects. However, some commentators have argued that the benefits to mankind from pesticides are not su...
Implications of changing ethical standards

The changes in ethical standards that occur in a society over time can reflect various influences. Perhaps one of the most important factors in the UK over the last century has been a trend to emphasise more strongly the rights and freedom of the individual, sometimes at the expense of obligations owed to the wider community. Thus, for example, conscientious objection to military service is today considered morally legitimate and perhaps to be admired, whereas at the time of the first world war it was widely viewed as an improper dereliction of duty. In medical research, this change in values has shifted the balance that is drawn between the rights of individual participants and the public benefits that may accrue from a study.

Another factor which has pushed thinking in the same direction has been the revolution in information technology, especially over the past two decades. This has generated concerns about the potential for breaches of privacy when large quantities of personal information are held in electronic form that is much more accessible and transmissible than paper records. In response, the European Union has promulgated two directives on data protection, and these have been translated into national law in the UK through the Data Protection Acts of 1984 and 1998 (box 3). The main target of the legislation is information used commercially, and it makes some exceptions for data handled in medical research. However, the exact scope of these exceptions in the UK is as yet undefined, and an important impact of the laws has been to raise doubts about the legality of certain established research methods. This in turn has caused some people to question the ethics of the methods.

Paradoxically, the problem lies not in research that involves invasive or hazardous procedures, where individual informed consent has long been the norm. Rather it is in the use of personal information in the course of epidemiological research. Consider, for example, the selection of random samples from the general population for cross sectional surveys, or of community based controls in case–control studies. Both these techniques are frequently applied in occupational health research, and in the UK general practice...
patient lists have often been used as the sampling frame. This has the advantage that subjects can be selected according to their age and sex, and that the general practitioner can advise against contact with individuals who might find an approach upsetting—for example, because they are seriously ill or have recently been bereaved. The approach is made by the research team with a covering letter from the general practitioner, and subjects then decide for themselves whether to take part.

Our group and others have used this method to contact many thousands of subjects, and only a tiny minority (fewer than one in a thousand) have queried the practice. Moreover, response rates have generally been high, exceeding 80% in some rural locations. However, some authorities now argue that even where safeguards on confidentiality are in place, doctors should not release the names and addresses of their patients to researchers without explicit individual consent. As an alternative, they suggest that the research team should prepare letters for the general practice to mail on their behalf to patients selected according to criteria that they have prescribed. Some practices with an interest in research may be equipped for this, but for many it would not be possible on the scale required. Thus, there is a danger that a useful form of research will be lost, even though the indications are that the large majority of the public find it acceptable.

Also threatened are hospital based case–control studies. Our group has recently completed data collection in a case–control investigation of infectious pneumonia and occupational exposure to metal fumes centred on 10 hospitals in the West Midlands. Cases were identified by the study team from hospital records and approached, either in person while still in hospital, or by post after they had been discharged, with an invitation to undergo interview about their work and lifestyle. This method was approved by all the local ethics committees concerned, but some people are now suggesting that researchers should not have access to any clinical information about patients (including diagnoses) without their express consent. They suggest that cases should be identified and approached by a member of the team providing their clinical care. However, where, as in this example, each clinical team will only encounter cases infrequently, such a method of recruitment is likely to be far from complete, with a consequent reduction in statistical power and potential for bias.

In the UK various bodies contribute to the definition of which research designs are ethically acceptable, including the General Medical Council,7 Medical Royal Colleges,8 Medical Research Council,9 and British Medical Association,10 as well as research ethics committees. Once a momentum for change builds up, it can be difficult to halt, each group wishing to be seen to protect patients’ interests as much as the others. However, if the current trend continues unchecked there is a serious danger that valuable research methods will be lost to the disadvantage of the community as a whole. It is important, therefore, that the topic is properly debated and that the research community contributes actively, pointing out the value of the methods that are threatened.

This paper is based on the Alexander Howard Memorial Lecture which was delivered on 3 October 2000 to the Royal College of Physicians Faculty of Occupational Medicine.

References
