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...
Box 1: Aspects of occupational health research in which ethical issues may arise

- Study question: posing some questions for research might be harmful
- Study design and conduct: the same principles apply as in other branches of medical science
- Communication of results: both to individual participants and to others with an interest in the findings
- Application of research: is it acceptable to use the results from research that is ethically dubious?

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 sufficient to justify even very low risks from their experimental administration to humans. Particular difficulties may arise when the subjects are employees of the organisation carrying out the research, because of the possibility of indirect coercion (for example, if participants believe that volunteering may enhance their career prospects).

Many epidemiological studies do not entail hazardous exposures or investigations, but require the collation and analysis of information about identifiable individuals. Here the ethical issues centre on the rights of potential subjects to privacy. Difficulties may arise where information is collected by questionnaire (self administered or at interview) on topics that participants might find intrusive or embarrassing (for example, related to their sexual function). Also controversial are the circumstances in which personal data can be used for research without individual consent. Opinion on this is currently evolving (see below—Implications of changing ethical standards).

As in other clinical fields, a distinction must be drawn between research and audit. It can be argued that unlike research for the wider benefit of mankind, the analysis of personal information to check on, and if possible improve, the quality of care provided by a clinical service is intrinsic to the management of its patients. This does not mean that it is exempt from ethical constraints, but they differ somewhat from those which apply in research.

Difficulty may sometimes occur in distinguishing research from audit, and also from other aspects of routine clinical care. In the UK employers have a statutory obligation to carry out routine health surveillance where workers are exposed to an occupational hazard and there is a significant chance that detectable health effects will result from the exposure. Guidance has been issued, for example, on the monitoring of employees working with respiratory sensitisers, the recommended level of surveillance varying according to the potency of the sensitiser. Over the past decade, latex allergy has emerged as a growing problem among health care workers in many countries, probably because of changes in the use of rubber gloves in response to concerns about HIV and other blood-borne infections. To establish what level of surveillance, if any, would be appropriate for this hazard in different groups of health professionals, our department undertook a survey of the prevalence of allergic symptoms in relation to glove use. It could be argued that this survey fulfilled a statutory duty, and therefore did not require ethical review. However, we felt there was doubt about this, and sought approval from our local research ethics committee in the normal way.

As well as drawing on human studies, occupational health practice is informed by research in animals. For example, much of our understanding of chemical toxicity is derived from experiments in laboratory animals. In almost all cultures the sacrifice of animals for the benefit of humans is accepted, particularly as a source of food. However, many people have reservations about the use of animals for scientific research. In deciding on the acceptability of studies using animals, factors that must be taken into account include the species that will be employed, the nature of the procedures that will be performed (for example, whether they are painful), and the potential benefits from the research. In the UK all medical research using vertebrates is strictly regulated.

Box 2: The Declaration of Helsinki

Adopted by the 18th World Medical Assembly in Helsinki in 1964 and subsequently amended on several occasions, this sets out guidance for physicians on biomedical research involving human subjects. Among other things it covers the need for:

- independent ethical review
- sound scientific design
- competence of researchers
- objectives that justify any risk to subjects
- careful assessment of risks and benefits
- respect for the privacy and integrity of all subjects
- avoidance of research in which potential hazards cannot be predicted
- accurate publication of results
- informed consent from participants
- avoidance of pressure on individuals to take part
- provisions when participants are incompetent to give informed consent
- a statement of ethical considerations in the research protocol

Communication of findings

The ethical obligations of researchers do not end with the collection and analysis of their data. Questions also arise in relation to the communication of results, particularly in a society where the media are hungry for new stories and may be more concerned to sell their own product than to provide the public with a reliable and balanced account of new discoveries. Researchers must decide to whom results are made known, in what order, and in what form. Parties with a potential interest in occupational health research include the participants in studies, their fellow workers who are exposed to the same hazards, their employers, regulatory authorities, funding agencies, the wider scientific community, and the public at large.

In general, the first obligation of the researcher should be to those who participate in the research, but there is usually a strong argument for some form of confidential peer review before findings are communicated. Problems may occur if
results reach the lay press before they have been adequately reported in the scientific literature, with dissemination of scare stories to which regulators, employers, and health and safety professionals cannot adequately respond. For this reason, when a study has addressed a controversial question, careful coordination may be needed to ensure that publication in the scientific literature rapidly follows the communication of results to participants.

Another difficult area is the handling of adverse findings on individual subjects that emerge in the course of research. For example, our group is currently collaborating in a study of DNA and protein adducts in workers exposed occupationally to diesel exhaust. If an individual were found to have unusually high adduct levels, we would have to decide whether to communicate this to him, and if so, in what terms. Such decisions are best thought through before the study begins, and in this case we decided that the implications of high adduct levels would be too uncertain to warrant passing on the information and perhaps causing unnecessary worry. However, if a study revealed that a participant might benefit from medical intervention (for example, showing previously undiagnosed hypertension or diabetes), the position would probably be different.

Application of research

When a completed study is ethically contentious, questions arise as to whether or not its findings should be used. For example, part of our knowledge about the toxicity of organophosphates comes from US experiments carried out in prisoners 30 or more years ago, and it is not always clear from the available reports whether consent was properly informed and voluntary. We must now ask whether it is justifiable to use the results of such research in pesticide regulation, either as reassurance of safety to support the continued use of a product, or as a basis for withdrawing or restricting use if it indicated that the exposures of operators might be unacceptably high. A further complication might occur if the research had initially been commissioned or supported by a company that stood to benefit commercially from continued use of the pesticide product.

Most people would probably agree that the ethics of a study's design should be taken into account when deciding whether or not and how to use its results. However, there is no universal consensus on what is ethically acceptable, and values differ between societies and in the same society over time. Is it enough that a study was judged to be ethical at the time and in the place where the results will be used? If the latter, who should decide whether it is acceptable? These are difficult questions that merit more public debate than they have received to date.

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

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**Box 3: The Data Protection Act 1998**

- Covers only information about living people who can be identified directly or indirectly from the data
- Individuals should normally have the opportunity to know what organisations hold information about them and why
- When people give information, they should be told what it will be used for and to whom it will be passed
- Allows information to be used for research in ways that were not foreseen when it was first collected if the research will not be used as a basis for decisions affecting the individuals involved and is unlikely to lead to substantial damage or distress
- Medical data should only be processed by health professionals or persons with an equivalent duty of confidentiality
- If doctors know, at the time it is collected, that patient information will probably be used for specific research projects, they must tell patients this
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.

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