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Ethical Aspects of Health Research

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Abstract

Research that involves human subjects or participants raises unique and complex ethical, legal, social and political issues. Research ethics is specifically interested in the analysis of ethical issues that are raised when people are involved as participants in research. Many of the norms of research promote a variety of other important moral and social values, such as social responsibility, human rights, animal welfare, compliance with the law, and the public health and safety. Ethical lapses in research can significantly harm human and animal subjects, students, and the public. In this article, we will see the various Ethical aspects of Health research.

Introduction

The application of experimental methods to biomedical research is a product of the 20th century. Many fundamental discoveries were made before this time, but progress was subsequently achieved through the application of scientific principles to medical and public health practices.

During almost the whole of human history, the only drugs used were naturally-occurring substances of animal, vegetable or mineral origin, and long experience had shown that, in the doses used, they did no serious harm (and, in most cases, not much good either). However, a century ago, the chemical industry started to develop, for medical use, synthetic compounds that had never existed in nature. The first of these to have an important impact on the treatment of human disease was Salvarsan (arsphenamine), introduced primarily as a remedy for syphilis.

An experiment is an attempt to discover something unknown, or to test a supposition or principle, but we cannot be sure of the outcome. By definition, an experiment involves chance. It is because of this chance or element of the unknown that ethics become a paramount issue in those experiments which involve human subjects. Much basic and

developmental biomedical research could be undertaken successfully on animal models; however, absolute reliance cannot at present be vested in these models as indicators of physiological, pharmacological or toxicological response in man. All innovative scientific interventions, whether diagnostic, prophylactic or therapeutic, should ultimately be evaluated in human subjects. The need for safeguards in human experimentation cannot be overemphasized, and several important codes have been developed for the protection of human subjects.

The three underlying principles are:

1. beneficence, which requires that good should result, harm should be avoided, or that benefits should justify the expected risk or harm;
2. respect for rights, including the free choice of the subject and protection for those of diminished autonomy; and
3. justice, which requires an equal distribution of burden and benefit.

International declarations

The first important code of ethics was the Nurenberg Code of 1947: no research could proceed on human subjects without 'voluntary consent', and this has remained unchanged in subsequent codes.

The World Medical Association, assisted by WHO, developed an expanded and revised code of ethics to guide doctors in research involving human subjects, called the Declaration of Helsinki. This was followed by a revised Declaration in 1975 (Helsinki II), which changed the emphasis from 'clinical research' to 'biomedical research involving human subjects'. This was adopted at the 29th World Medical Assembly in Tokyo in 1975.

The demands for new and better treatment, and its greater distribution, have vastly multiplied the demands for biomedical research involving human subjects – especially clinical trials. In the regulation of trials and other biomedical research involving human subjects, processes of review have been developed by governmental and institutional boards and committees, which draw heavily upon the guidelines of the Helsinki codes, including, particularly, the following:

- Biomedical research should follow scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
- The design of each experimental procedure involving humansubjects should be clearly formulated in an experimental protocol, to be reviewed by an independent committee.
- The experiment should be conducted by scientifically qualified person(s) and under the supervision of clinically competent medical experts.
- Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objectives can justify the inherent risk to the subject.
- Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or

others. Concern for the interests of the subject must always prevail over the interests of science and society.

- The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on his or her personality.
- The accuracy of research results must be preserved.
- In any research on human beings, each potential subject must be adequately informed of the aim, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.
- When obtaining informed consent for a research project, a doctor should be particularly cautious if the subject is in a dependent relationship to him or her. No pressure or threat should be exercised.
- In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation.
- Subjects should be informed that they are free to abstain or to withdraw from participation at any time.

Of itself, however, informed consent offers an imperfect safeguard to the subject, and it should always be complemented by independent ethical review of research proposals. Moreover, many individuals, including children and adults who are mentally ill or defective, or who are totally unfamiliar with modern medical concepts, are therefore incapable of giving adequate consent. For such groups, in particular, independent ethical review is imperative.

Consent of subjects

1. Children

It is axiomatic that children should never be the subjects of research that might equally be well carried out on adults. However, their participation is indispensable for research on diseases of childhood and conditions to which children are particularly susceptible. The consent of a parent or other legal guardian, after a full explanation of the aims of the experiment and of possible hazards, discomfort or inconvenience, is always necessary.

2. Pregnant and nursing women

Pregnant and nursing mothers should, under no circumstance, be the subjects of non-therapeutic research that carries any possibility of risk to the fetus or neonate, unless this is intended to elucidate problems of pregnancy or lactation. Therapeutic research is permissible only with a view to improving the health of the mother without prejudice to that of the fetus, to enhancing its viability or to aiding the nursling's healthy development, or the ability of the mother to nourish it adequately.

Research directed to induced termination of pregnancy, or undertaken in anticipation of termination, is an issue that is dependent upon national legislation and religious and cultural precepts, and therefore does not lend itself to an international recommendation.

3. Mentally ill and mentally defective persons

   Substantially similar ethical considerations apply to the mentally ill and the mentally defective. They should never be the subjects of research that might equally well be carried out on adults who are in full possession of their mental faculties. They are, however, the only subjects available for research on the origin and treatment of mental disease or disability.
   The agreement of the immediate family -- whether spouse, parent, adult offspring or sibling -- should be sought, but it is sometimes of doubtful value, especially as mentally deranged or defective patients are sometimes regarded by their families as an unwelcome burden.

4. Other vulnerable social groups

   The quality of the consent of subjects who are junior or subordinate members of a hierarchically structured group requires careful consideration, as willingness to volunteer may be unduly influenced by the expectation of adventitious benefits. Examples of such groups are medical and nursing students, subordinate laboratory and hospital personnel, employees of the pharmaceutical industry, and members of the armed forces. More seriously objectionable is experimentation on exclusively selected national or cultural groups.

5. Community-based research

   When research is undertaken on a community basis --for example by experimental treatment of water supplies, health systems research, large-scale trials of new insecticides, and nutritional fortification or substitutes -- individual consent on a person-to-person basis may not be feasible, and the ultimate decision to undertake the research rests with the responsible public health authority.
   Nevertheless, all possible means should be used to inform the community concerned of the aims of the research, the advantages expected from it, and any possible hazards or inconveniences.

Review procedures

In highly centralized administration, a national review committee may be constituted to review research protocols from both scientific and ethical standpoints. In countries where medical research is not centrally directed, protocols are more effectively and conveniently reviewed from the ethical standpoint at local or regional level. The basic responsibilities of locally operative ethical review committees are twofold:

- to verify that all proposed interventions and, particularly, the administration of drugs under development have been assessed by a competent expert body as acceptably safe to be undertaken in human subjects; and
- to ensure that all other ethical considerations arising from a protocol are satisfactorily resolved, both in principle and in practice.

Whatever the pattern of the procedure adopted for ethical review, it should be based on a detailed protocol comprising the steps outlined in this manual. Care should be taken to ascertain the criteria for determining admission and withdrawal of individual subjects, including full details of the informed consent procedure.

Information should also be included to establish:

- the safety of each proposed intervention and of any drug or device to be tested, including the results of relevant laboratory and animal research;
- the presumed benefits and potential risk of participation;
- the means proposed to elicit informed consent, or, when this is not possible, satisfactory assurance that the guardian or family will be appropriately consulted and the rights and welfare of each subject will be adequately protected;
- that the investigator is appropriately qualified and experienced, and commands adequate facilities for the safe and efficient conduct of the research;
- that provisions will be made to protect the confidentiality of the data; and
- the nature of any other ethical considerations involved, together with an indication that the principles enunciated in the Declaration of Helsinki will be implemented.

References and further reading

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