Ethical issues in health research

While planning a health research, ethical issues that might arise during implementation should be identified and their handling should be considered in the research protocol. Failure to do this could lead to problems in approval and ethical and legal implications. Therefore an understanding of basic ethical principles and their application in health research is essential for researchers.

Ethics

Ethics is derived from Greek *ethos* meaning custom. Ethics is the study of principles that guide human conduct. In this sense ethics covers general beliefs, attitudes and standards that guide customary (normal) behavior.

Biomedical ethics

Biomedical ethics (ethics in health care) was developed as a separate field of study in the 1960s in USA. The most popular theory of biomedical ethics (Principalism) was put forward by American philosophers Beaauchamp and Childress. Principalism is a theory that analyses biomedical ethics under 4 principles of respect for autonomy, non-maleficence, beneficence and justice.

1) Respect for autonomy

Autonomy of the individual means the person has enough understanding to take an informed decision and is free from interference by others that try to control him/her. When an individual has no access to sufficient understanding about the subject or when there is controlling interferences from others, the autonomy has been diminished. So, autonomy simply means understanding and freedom to act.

An autonomous choice is a choice that is made intentionally (the person knows that he is making a choice deliberately), with understanding (understands what the choice means) and without controlling influences by others (not forced in any what to make that choice).

In relation to health research autonomy means

1. The research participant is provided with enough information to help him/her understand what is going on, and what are the risks and inconveniences that he/she may encounter as a result of his participation in the study; and
2. He/ she is free to or not to participate in the study without any coercion of any form and that withdrawal form the study is possible at any time without these affecting the level of care that the person is entitled to.

There are some issues which have to be kept in mind in this regard. Firstly providing information is not equal to understanding and understanding is not a yes or no issue. The bottom-line is that the person has to have sufficient understanding about the issue to enable him make an informed decision. Therefore the focus is on sufficient understanding rather than providing

information. Respect to autonomy means acting to respect the person and this necessitates taking into consideration his capacities and potentials.

Secondly, coercion does not simply mean directly forcing the person to participate. Any attitude or behavior that could indicate coercion is not acceptable. For example if you imply in some way that the person would be better cared for if he participates in the study is coercion. Therefore, the person should clearly be informed that he is free to participate and that failure to participate will not deprive him from any privileges he might be entitled to.

2) Non-maleficence and 3)beneficence

Non-maleficence means "not inflicting or doing harm" on others. This is a moral obligation that we are all expected to follow. A lesser obligation is beneficence which is a positive action and means "doing good" which could cover a range of actions from "preventing harm" through "removing harm" to "doing good".

These two principles are usually considered together and the underpinning theme is harm or injury. Harm here includes any kind of injury (such as physical, mental, disability, and death) and any kind of injustice or wrong-doing against the interests of an individual.

In relation to health research, non-maleficence means that the participants are not subjected to any actual harms (injury, disability, death,) or any potential risks that may cause them harm in the future. However, while health care is a beneficent act as it benefits individuals; beneficence is less evident in health research because the benefit may not be visible for individuals participating in the study. However, here, beneficence could be though of in relation to the wider community and advancement of knowledge.

4) Justice

Justice is usually thought of in terms of fairness, entitlement to what one deserves. In health care justice usually means fairness in distribution of benefits and burdens of the society in relation to health i.e. distributive justice. Distributive justice is concerned with fairness in allocating resources and therefore is specifically relevant while setting health priorities and planning actions to improve the health of the society. In health research the principle of distributive justice in also relevant in the sense of benefits and burden meaning that people who take the burden of a research by being participants should get more benefits from the results of the research. For example it would be unethical to undertake a field trial of a new vaccine in a community while knowing that the vaccine would not be available to them afterwards. In the same way it would be unethical to undertake the field trial of an expensive antiretroviral drug in a poor African community without a realistic hope that the drug would be accessible to that community when marketed.

Approaches to ethical analysis of health research

Ethical analysis is not merely a matter of individual judgment; it is rather based on certain principles of rationality and logic because different individuals in the society might have different standards of morals. Ethical analysis of any action or proposal in health research to decide whether or not it is morally acceptable, could be based on three approaches: goal-based, duty-based and rights-based.

Goal-based approach basically means that if the outcome of an action is good, then the action is morally acceptable. In other words "the end justifies the means" but only if the end (the outcome) is good. In context of health research, this approach means that the research is morally acceptable if the outcome of the research is of moral value i.e. if it benefits individuals and communities. Researchers should always ask themselves before planning a study "is this study i.e. its outcome, of moral value? Does it benefit individuals and the community". This is usually one of the first questions considered by donors and ethical committees. However, it is not an easy question to answer as it may seem because there might be a lot of unresolved issues in health while resources are not sufficient to address all of them. The researcher has usually to be able not only to justify that the study question is important but also that the study can answer the question and therefore it deserves to be allocated a portion of the limited resources available for research.

Duty-based approach focuses another aspect of morality of research which is the duty of the researcher and his obligations towards safety of research participants. This approach aims to answer questions such as "how are the study participants treated?"; "What risks will they be exposed to?"; and " Are these risks acceptable in study circumstances?" To be morally acceptable based on this approach, participants of a study should be treated according to moral principles mentioned earlier and they should not be exposed to unacceptable risks.

Rights-based approach focuses on the rights of research participants to freedom of choice and respect to human dignity. In context of health research, freedom means that participants will be free to participate or not and to withdraw at any time and therefore informed consent should be sought in advance. Respect to human dignity reflects on how the informed consent is obtained, how the participants are treated throughout the study and how their privacy and confidentiality are respected.

A framework for ethical assessment of health research

The Department of Health in the UK advocates the following framework for ethical assessment of health research by research ethics committees. A research ethics committee is a body responsible to assess the ethical aspects of a study and certify whether or not study is ethically acceptable by looking into how the study is justified and how it has taken into consideration the ethical principles discussed earlier.

The framework covers ethical principles and approaches described earlier and aims to set the reviewer's mind to assess ethical acceptability of the study by raising various questions about validity of the study; welfare of study participants; and dignity of study participants.

1. ***Is the study valid?***
   Decision on validity of the study is made after considering the following questions in order to make sure that the study is properly thought of, appropriately designed and well-placed to answer the research question.
   - How important is the research question?
   - For whom is the research question important?
   - Is it important for future patients?
   - Has the question been answered by someone else? Is it ethical to repeat? How different is the approach in the current study to the previous one?
   - Is the study design appropriate to answer the question?
   - Is this the best way to address the question?
   - Are the researchers properly qualified to do the study?
   - Can the study be monitored and progress reviewed?

2. ***Welfare of study participants***
   The study has to safeguard the interests of people participating in the study; they are not subjected to undue risks; and their dignity and human rights are protected. Answering the following questions makes a decision on this aspect possible.
   - What are the costs on participants in terms of inconvenience, time and effort?
   - Are there any known or potential risks to the subjects? Are they acceptable?
   - If the study involves new medications/ devices, are they subject to any legal restrictions?
   - If the study is sponsored by a pharmaceutical company, is a special certificate needed and provided?

3. ***Dignity of study participants***
   The study has to make sure that dignity and rights of participants are protected. Answer to the following questions help reach in a decision in this regard.

   - How confidentiality is respected? Is data kept confidentially? Are patients anonymized by not collecting/keeping data that could identify the patient?
   - Is informed consent obtained and how?
   - Are patient information sheets provided? Are they clear enough?
   - How are people invited to participate?
   - Is participation free of coercion?
   - Are participants paid for participation? Is such payment justified?

Further reading

- World Medical Association. 2000. Declaration of Helsinki: Ethical principles for medical research involving human subjects. From www.wma.net
- The Council for International Organizations of Medical Sciences (CIOMS)/WHO. 1993. International Ethical Guidelines for Biomedical Research involving Human Subjects.
- The Council for International Organizations of Medical Sciences (CIOMS). 1991. International Guidelines for Ethical Review of Epidemiological Studies.