

Ethical Codes in Medical Research and the Role of Ethics Committees in the Protection of Human Subjects

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Eubios Journal of Asian and International Bioethics 11 (2001), 8-10.

Technological developments, especially in medical fields, have brought about new hopes for the prevention of some diseases and treatment of some others. Undoubtedly, the foundations of, or introductions to, these progresses and achievements are the research made in this field. Although experiments are initially conducted on animals before performing any research on human subjects in order to survey the unknown hazards derived from theoretical and experimental outcomes, this measure, still, does not make experiments performed on human subjects free from risks. This research have brought hope of a better life for people, especially patients, on the one hand. On the other hand, in view of bitter historical experiences such as abuse of prisoners in the Second World War in medical research (1), studies such as the Tuskegee Syphilis Study (2), and the like, have caused a concern that some people might be abused in experiments as research subjects, especially in non-therapeutic research, or measures could be taken that contradict respectable ethical principles simply justified by pretexts such as the keeping of the benefits of the majority or the expansion of the frontiers of human knowledge and the like.

Therefore, to establish a proper ethical reflection in research is considered an integral part of the strategies of technological developments in the biomedical field. Thus, in order to prevent these problems and concerns, it is essential that controls be put on research made on human subjects in such a way that scientific and technological progress is not obstructed, and that research is conducted in such a way that ethical principles are also followed. The issuance of international codes such as Nuremberg (1947), Helsinki I and II (1975), and CIOMS (1995), and the steps different countries have taken in this regard based on the culture and religion current in their societies have been made in line with this goal.

This paper intends to survey cultural and religious considerations in compiling ethical codes in medical research and the role that the ethics committees can play in protecting human subjects.

Cultural and Religious Considerations in Formulating Ethical Codes in Medical Research If we look at present statements on the application of ethics in research, we realize that the dominant factor in these statements and in the necessity of their formulation is protection of ethical and cultural values in research, and their focus of attention is on human subjects participating in research.

Humane values share common dimensions in different societies; however, according to social, historical and even geographical differences, some dimensions seem to some extent to be more vigorously emphasized and distinguished in different societies. For example, in religious societies, religious ethics play a more prominent role, and there is a close relationship between ethical, cultural and religious principles of the society. The mutual impact of these elements on each other is in such a way that it creates a special harmony and co-ordination in the society's cultural, ethical and religious identity.

In the second part of the Belmont Report, it has been asserted that in view of the cultural acceptance of the society (that is, American society), three principles of; 'respect for person's', 'beneficence', and 'justice' have been chosen as ethical criteria to judge research performed on human beings. It means that the ethical principles that contradict the society's culture cannot be adopted as criteria. Of course, this applies to principles that contradict the religion of the society since in the religious society (i.e., Islam) one cannot choose a foundation for judgement that contradicts Islamic principles.

For example, it is forbidden to drink alcoholic drinks in Islam, and Muslims are prohibited to drink (3). For this reason, the researcher is not permitted to propose a research project in which the subjects are asked to drink some alcoholic drinks. Hence, in item 21 of the Iranian ethical codes whose compilation was fortunately completed last year, it has been stated, 'Research methods that contradict religious and cultural principles of the society must not be sought (4).'

Cultural norms of different societies differ so much so that when each of us become aware of a cultural feature or habit in a different society, we get amazed and ask ourselves why there is such a social belief in that society. Whereas, this belief is part of that society's culture even if it is considered odd, surprising or even scornful for another society. Therefore, we should respect religious, ethical, and cultural heritage of different societies and recognise the right of that society to practice it. On this basis, in some international codes on doing research in host countries, special emphasis has been made on the necessity of observing the cultural and ethical standards of those countries. Such codes are taken as criteria for practice (5).

In the 'autonomy' section of Belmont Report, respect for autonomy has been elaborated as follows: "To respect autonomy is to give weight to autonomous persons' considered opinions and choices, while refraining from obstructing their actions, unless they are clearly detrimental to others."

As it can be noticed from the above quotation, there is no mention of negative effect on one's own self, but just on others. Perhaps, with the same view, the item 5 of Nuremberg codes points to the autonomy of human beings as follows: "No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur: except, perhaps, in those experiments where the experimental physicians also serve as subjects " (6).

This means that a physician has the right to take himself or herself as a subject of his or her own research where there is a high risk of death or disability. However, according to Islamic principles, just as an individual has no right to inflict injury on others, nor is he or she allowed to expose himself or herself to irrational risks like death (7). Therefore, the definition of autonomy will be different in a religious perspective. Such differences will obviously influence the formulation of ethical codes in research (8). During the compilation of ethical codes in Iran, a question that raised frequent discussions was that: How would it be for a member of a married couple (a husband or wife) to take part in a non-therapeutic research? How is the informed consent obtained? Does it require two signatures: one by the research subject, the other by the spouse; or just the research subject's consent alone would be sufficient? Eventually, in light of religious and cultural considerations, the research team came to the conclusion that: if participation of a spouse (a partner) in non-therapeutic research and its consequences might affect their joint marriage life (and duties), then it is necessary to obtain consent from both partners. It is noteworthy that this issue is not raised in therapeutic research; therapeutic research is considered as exceptions.

Also, in regard to obtaining children's consent for participating in a research: in some international codes such as CIOMS, it is considered necessary that consent is obtained from the child based on his or her capabilities in addition to the consent obtained from their parents or legal protectors. In some societies like Iran, there is a difference between the age of religious maturity after which an individual is bound to perform religious duties and that of legal maturity (i.e., 16) after which an individual is allowed to vote in elections. Even the age of religious maturity is different between girls and boys. Therefore, these religious and cultural differences should be taken into consideration in delineating ethical codes in medical research.

At the final part of this section, I would like to mention a point that poses some questions for me: the fact that there are research that have an international scope and whose results will not only overrun geographical borders, but also violate ideological and cultural frontiers. Perhaps, it can be said they have impacts on mankind. For instance, one can point to human genome project and the results derived from it. Such a state will certainly cause special ethical problems.

The Role of Ethics Committees in Protecting Human Subjects Since ethics is nowadays considered as an integral part in the strategies of scientific and technological progresses (9), the establishment of ethics committees has been anticipated as a suitable strategy to implement ethical codes in medical research and finally creating an ethical reflection in this regard.

The members of these committees are chosen in such a way that the representatives of multidisciplinary sections of the society, specialised or non-specialised, can take part in it so that their views can reflect specialised scientific perspectives as well as public opinion. In brief, the role of these committees can be surveyed in a few aspects:

the supervisory and consultative role,
the training role, and
the role in quality upgrading.

In this section, the role of these committees in upgrading and improving the quality of research in regard to 'protecting human subjects' will be discussed. Although in ethical codes in research, the observance of autonomy has been stressed under the issue of the necessity to obtain informed consent, even with complete implementation of these codes, the principle of 'respect for person' can be trampled. For instance, in a research conducted in a research institute, if the researcher is superior to the personnel of the centre ('an employee advantage'), the staff are considered as 'preferred subjects' for the research (especially in non-therapeutic research)—as they are always accessible and most practical problems of the research will be resolved by choosing them as subjects. In such conditions, even if the consent is signed by the personnel (research subjects), due to the presence of 'a hidden coercion' that overshadows this state of affairs, it is obvious that such a consent cannot regard the principle of 'respect for person', even though it appears to be appropriate. The same thing (i.e., coercion) may be true in using pupils of a school (children) as preferred subjects in a research. It is the responsibility of ethics committees among other things to determine such a state of affairs and to direct research in an ethically proper course. Undoubtedly, this role of ethics committees will become more prominent in checking the quality of obtaining consent from individuals in special groups such as mentally handicapped patients, prisoners, and fostered children, and also in determining the necessity of their participation in a research.

On the assessment of risks and benefits, as mentioned in international codes, the necessity of this assessment is based on the principle of beneficence (10). Since the aim of a research is to find out the unknown, to achieve such an aim involves some hazards. Therefore, research is not free from risks. However, the significant point here is that if the ethics committees give more weight to 'more benefits' in this assessment (of benefits and risks), in other words, if they take 'more benefits' as the standard of their assessment, then it will be readily justifiable to expose the subjects to a high-risk situation under the pretext of more benefits for the society and even for the subjects themselves. This condition may gain significance especially in such research as vaccine trials. However, if the committees give more weight to the degree of risks inflicted on the subjects in this assessment, that is, if they take the amount of risks inflicted on the subjects as their standard, then they will do their best to protect the subjects against impending risks and search for strategies to lessen the degree of risks or even survey alternative methods of research.

Obviously, in the process of research, the researcher believes that the existing information and theoretical and laboratory studies already carried out on the research topic are sufficient to let the research be performed on human subjects. Even based on his or her personal opinion, it may be justifiable to expose the research subjects to high risk under such pretexts as more benefits for the society and science. However, it is the duty of ethics committees to match the present information in proposals with existing scientific realities so as to prevent subjects from taking part in research that involve a high risk. In other words, in order to be able to create a balance between the researcher's excessive optimism and protection of the subject. An efficient committee with its multidimensional nature should have the capability of making such a comprehensive assessment even though it is compelled to consult with professional specialists of the field study of the research out of the

committee.

For this reason, in the codes compiled in Iran, it has been anticipated that the counselling opinion of professional experts in the related field of the research will be evaluated and taken into consideration as a superior criterion in assessing benefits and risks. Furthermore, the subjects' view will be taken as a criterion to evaluate the intensity of harm and risk (11).

Among other very important issues that should be taken into consideration by the committees is the provision of preventive, diagnostic, and therapeutic equipment at the time of experiment by the conductor of the research (i.e., the researcher). The quality of these provisions can help lessen the research risks for the subject to a large extent. This can also create a good relationship with trust between the researcher and the subject. A major problem facing the ethics committees in performing their duties will be to match a research proposal with the codes that point to distributive justice in research and to find answers to questions such as: Are the concluding results used by the subjects who take part in the research and tolerate its burdens, as well? Or is it the case that just a special group has the duty to take part in a research as subjects whereas another group who, of course, belongs to a different class of the society would benefit from the results of the research? Perhaps, it can be said that the qualitative differences between ethics committees lie in their ability to take into consideration the ethical principles related to justice. This is one of the delicate tasks of these committees.

Of course, in regard to the issue of justice, it should be noted that in the distribution of health resources, the ethics committees should respond to the question: Is the topic of research appropriate for the health priorities of the country where the research is carried out or not? For example, in a country where children die of simple infectious diseases, is it necessary to carry out research which require complicated technologies by spending enormous expenses? This is one of the important points that must be considered carefully by the committees.

Conclusion

Taking heed of the society's religious and cultural considerations in delineating ethical codes in medical research is an important factor in the protection of humane values, that is, the very aim that has made human community to formulate these codes. Therefore, the more the contents of these criteria match with ethical and cultural principles prevalent in the society, the more successful they will be in practice. It seems that the main problem facing the formulation of global ethical codes in research comes from this cultural and religious variety in different societies, though the human community agrees on general principles of ethics. Thus, any attempt made in this regard should take special heed of these cultural varieties in human societies.

However, what distinguishes the ethics committees from each other are their qualitative differences. Two approaches can be mentioned in this respect:
a committee whose aim is to implement ethical codes in the form of a checklist;
a committee that seeks to protect the subject.

In a quantitative approach, the committee members feel obliged to observe the ethical principles mentioned in codes just like a checklist. However, in a qualitative approach, the committee members deal with the chief aim of these codes, that is, the real protection of subjects, and the codes are there as a means to achieve this aim. They know it is possible that these ethical codes might be ticked, while their aim, to protect the subject, is not achieved.

Note

As Beauchamp and Childress, discussing the concept of autonomy, stress the 'need to refine the concept in light of the particular analytical objectives of a theory of autonomy' under a task

sometimes called reconstruction of the concept, the scope of the value and concept of an ethical principle seem to differ in different cultures.

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