

COST-BENEFIT ASSESSMENT IN MEDICAL RESEARCHES

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ABSTRACT

One of the fundamental issues in the ethics of medical researches is cost-benefit assessment which consists a main part of related codes. This article is aimed to propose a model for ethical assessment of researches with judgment about their costs and benefits.

After reviewing related materials and our experiences and discussions with experts, we proposed a model for ethical assessment of costs and benefits of medical researches.

It seems that there can be a complex table that shows the potential influenced groups such as patients, researchers, their families, society, and ... , and in the other side of the table, we can see the aspects of such influences, including physical, economical, psychological, social, spiritual, political, and so on. So, the authors designed a table showing the above mentioned types of influences, for using in ethical assessments of the costs and benefits of medical researches.

Because of the complexity that exists in various aspects of the costs and benefits of a research, the researcher can not accomplish this analysis alone. It reveals the philosophy of the composition of the research ethics committees. The proposed table of this article will help the researchers and ethical committees for implementation of the above mentioned principles in research activities.

Key Words: Cost, Benefit, Medical Research, Ethical Assessment

INTRODUCTION

One of the fundamental issues in the ethics of medical researches is cost-benefit assessment which consists a main part of related codes.

Based on his or her own reasoning, each person does this assessment when he or she makes a decision. This is true in medical interventions, too, and is of even more importance in research activities.

There is a great differences regarding ethical concerns, between suggesting a new treatment for a patient and proposing the same treatment to a research subject, in the second one, it should be approved by related ethical committees (1). This is because of the great difference that exists between clinical practice and research in nature. According to the Belmont report: "The term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term "research" represents an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)" (2).

In the clinical practice it is the patient's interests that takes the highest priority, however, the benefits of a research belongs to the society (3).

Thus, in research, the main ethical concern is preventing from sacrificing the subject's interests to that of society and future patients (1).

Also, in our divine instructions, using unethical tools for achieving even excellent goals is forbidden (4).

Therefore, in ethical evaluation of a research, having an exact and holistic point of view regarding the costs and the benefits of the research, is of great importance.

This article is aimed to propose a model for ethical assessment of researches with judgment about their costs and benefits.

MATERIALS AND METHODS

For collecting related articles, a search was made available search engines and databases in the web site of Tehran university of medical sciences, including: Pubmed, Proquest, Springer, Elsevier, Blackwell, John Wiely, EBSCO, Ovid, Oxford and Iran Medex, using these terms as key words: Cost, Utility, Benefit, Research, and Effectiveness. Furthermore, related guidelines and books were found in internet and the library of the medical ethics and history of medicine research center.

Finally, after reviewing these materials and our experiences and discussions with experts, we proposed a model for ethical assessment of costs and benefits of medical researches.

RESULTS AND DISCUSSION

The costs and benefits of a research, affect not only the researcher and research subjects, but also family members, related groups, research societies, and even the whole society(1).

The researcher should assess the effects of his or her own activities on others, including the patients, their families, and the society (6). This assessment should be made in all aspects. Including physical, societal, economical, and ... (1). This fact reveals the complexity of such assessments. Numerous researches and articles were engaged in various aspects of costs and benefits (7-14), even in animals (15). So, it seems that there can be a complex table that shows the potential influenced groups such as patients, researchers, their families, society, and ... , and in the other side of the table, we can see the aspects of such influences, including physical, economical, psychological, social, spiritual, political, and so on. So, the authors designed a table showing the above mentioned types of influences, for using in ethical assessments of the costs and benefits of medical researches (table 1).

As an example, imagine a research in which the researcher wants to measure the prevalence of the Acquired Immunodeficiency Syndrome (AIDS) in an urban area and assess its transmission factors. For each research subject, such diagnostic test may lead to some degrees of anxiety, and a positive result may lead to deep psychologic impacts, in addition to significant influences on his or her social and financial status, since he or she may lose his or her job. On the other hand, timely diagnosis of such important disease may help to better management and better physical outcomes for the patient. The researcher is exposed to possibly infected blood samples, that is a greater risk; furthermore, interactions with the patients may have psychological burden for him or her. On the other hand, this research activity may help him or her to promote his or her own scientific and academic position. The families, especially those of the patients', may involve in significant problems resulted by such diagnosis including psychological, financial, social difficulties. The health system of the area or even the country may be influenced by the results of this study, since it may allocate more resources to infective disease control programs.

CONCLUSION

Although it seems that the ethical cost-benefit analysis of a research, following the above mentioned pattern, is a comprehensive ethical

assessment, because of the complexity that exists in various aspects of the costs and benefits of a research, the researcher can not accomplish this analysis alone. Using the opinions of the research subjects may be helpful but can not complete the assessment. It reveals the philosophy of the composition of the research ethics committees, which remains controversial (16). Presence of the president of the university, a clergy, a lawyer, the deputy of research, and even a representative of the public sector in such committees can help to comprehensive assessment of the costs and benefits of each proposed or ongoing research.

Of course, independent to the judgments of the above mentioned committee, the research subject has her or his own right to accept or reject his or her participation in the research, at each stage.

In Islamic Republic of Iran, the charter of ethical principles in medical researches, containing 26 articles, is the basis of ethical assessment of research projects. Twelve articles of this charter are related to cost- benefit assessments (17).

The above mentioned articles reveal these incumbencies:

- 1- Imposing any unnecessary risk to the research subject is forbidden (2nd, 14th and 13th articles)
- 2- The potential benefits of a research should not be used for justification of imposing harms or risks to the research subjects(9th article)
- 3- It is necessary to reduce the potential risks to minimum (6th, 18th, 18th, and 21st articles).
- 4- Research using human subjects are justifiable only if its potential benefits make its potential risks justifiable, for such assessment, the judgments of the researchers or even the research subjects are not sufficient, but also the research ethics committees should assess and approve the research proposals and supervise them(4th, 13th, and 16th articles).

The proposed table of this article will help the researchers and ethical committees for implementation of the above mentioned principles in research activities.

Of course, our proposed table has some shortcomings. It is possible to add some new rows or columns to this table. On the other hand, some cells of the table are useless, for example the health system does not have any physical aspect. Furthermore, without a reliable system for weighting the cells of the table, it can not be used for quantitative analyses. However, resolving such shortcomings should be proposed as the subject of the related future researches.

Table 1: Table of cost- benefit assessment in medical researches:

Vulnerable groups	Patient	Researcher	Family	Research System	Society of Patients	Health System	Society	Others
Aspects of Influences								
Physical								
Psychological								
Spiritual								
Social								
Economical								
Political								
Others								

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