

Ethical Principles of Biomedical Research on Human Subjects: Their Application and Limitations in Latin America and the Caribbean

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Biomedical research on human subjects involves certain ethical principles, several of which are described in this article. It is also true, however, that application of these principles in real life poses problems, especially in the case of international research conducted under culturally diverse conditions. This presentation examines certain cultural and institutional circumstances prevailing in much of Latin America and the Caribbean that show a predilection to pose problems of this kind. This is not done to encourage research without ethical principles, but rather to familiarize investigators with cultural differences, so that these differences can be considered when studies on human subjects are being conducted, thereby improving the prospects for beneficial research that respects ethical principles within different cultural contexts.

Interest in biomedical research on human subjects is based on the legitimate desire to cure or effectively combat disease. And while it is true that most medical advances depend on existing knowledge of physiopathologic processes, it is also important for some of these advances to be tested on human subjects—who will be the ultimate beneficiaries (1).

In the past, most medical research on human subjects was conducted in developed countries, since they were the ones with the necessary economic and technological resources. Over time, however, this situation has been changing, to a point where this type of work is becoming increasingly common in developing countries—much of it being carried out by specialists from developed nations.

There are several explanations for this trend. First, some health problems are peculiar to certain regions; in order for researchers to understand them, the conditions prevailing where they occur must be analyzed. Second, conducting biomedical research in developing countries makes it possible to reduce costs. And third, it sometimes permits avoidance of rules and requirements that are overly complex in the researchers' countries of origin. In many Third World countries, legal provisions providing for ethical surveillance of biomedical research on human subjects have not yet been prepared, while in others these rules exist, but the individuals who, because of their professions, should assume a vigilant role have not been properly identified or are inadequately trained.

From a multicultural perspective, the increasing volume of biomedical research on human subjects conducted in developing countries by investigators from developed nations gives rise to sensitive ethical problems. In principle, ethical

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considerations applying to human subjects are the same anywhere in the world. One must admit that uniform application of these considerations in different areas is extremely difficult. Nevertheless, is it justifiable for an investigator from a developed country to apply different ethical standards when conducting research in a developing country? And conversely, if one recognizes that in principle he should respect the same ethical principles that he would respect in his own country, what obstacles would he face in conducting research in countries with different levels of economic, industrial, and social development? This article seeks answers to these questions.

BASIC ETHICAL PRINCIPLES

Many efforts have been made to draw up guidelines for medical research on human subjects. In the international arena, concrete examples can be found in the Nuremberg Code dating back to 1947, the Declaration of Helsinki issued in 1964 and amended in 1975, and the International Guidelines for Biomedical Research Involving Human Subjects proposed in 1982 by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO). These documents have assisted in charting the ethical principles that are most relevant to biomedical research on human subjects.

Among the more widely discussed ethical principles in the West, three are especially relevant to the subject of research on human subjects, these being (a) the principle of respect for persons, (b) the principle of beneficence, and (c) the principle of justice. However, neither these nor any other principles discussed on these pages offer specific rules for resolving concrete problems relating to research on human subjects. Rather, they

provide a frame of reference for obtaining coherent and well-reasoned solutions to specific ethical problems (2).

The Principle of Respect for Persons

The modern basis for this principle lies in the Western concept of the individual as an autonomous being capable of giving shape and meaning to his life. (An autonomous person is someone who follows a specific course of action, in accordance with his own plans and objectives—3.) Excluding the exceptions set forth in law, in principle there is no ethical justification for denying an individual the option of choosing what he will do with his own self.

As it relates to biomedical research on human subjects, this principle has two main aspects: on the one hand, respect for the rights of the person submitting to the research as well as for the actual person; and, on the other, respect for the general well-being of those participating in the research. The first implies a need to provide potential research subjects with the information they need in order to decide if they are willing to participate in the project (4). The second relates to the principle of beneficence, which is discussed later.

Beauchamp and Childress³ have grouped the elements involved in this principle into two categories: (a) elements pertaining to information, and (b) elements pertaining to consent. The first category relates to communication and understanding of the relevant information. The second focuses on voluntary consent and the ability to provide consent. Overall, the principle of respect seeks to ensure that each individual participating as a research subject does so

³T. Beauchamp and J. Childress (3), p. 70.

with full knowledge and understanding of what is to be done, of the possible consequences, and of his right to choose not to participate in the research or even to withdraw from it after it has started.

However, it is clear that being autonomous as a person and having that autonomy respected are two different things. Indeed, many of the ethical problems that arise in practice stem from lack of respect for this autonomy—as illustrated by instances of failure to obtain voluntary informed consent, undue interference in the subject's life, and violation of the confidentiality of medical information pertaining to the subject.

Respect for an individual's autonomy implies recognition of his capabilities and views, including his right to have specific ideas and make specific decisions. Furthermore, it implies that his actions and decisions must not be stymied, except when it is clear that they would adversely affect other people.

In medical research involving human subjects, as CIOMS and WHO assert (1), the ideal would be for every person asked to participate as a research subject to have sufficient intellectual capacity, give sufficient thought to the matter, and know enough about the risks, benefits, and options available to provide effective consent. At the same time, this individual must be sufficiently independent to decide whether or not to participate in the research without fear of later reprisals.

The Principle of Beneficence

Ethical treatment of people not only implies respect for their decisions but also promotion of their well-being. The principle of beneficence is held sacred by the Hippocratic Oath, in the part that states: "I will apply dietetic measures for

the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice."⁴

Following the categories of Beauchamp and Childress,⁵ on the one hand this implies beneficial action (a) preventing pain or injury, (b) counteracting injury, or (c) otherwise doing or promoting good. On the other, it implies avoiding acts that could be harmful or prejudicial.

This duality of the principle of beneficence can lead to conflict in complex situations where, for example, a beneficial action conflicts with noncommission of an act that could prove prejudicial. In such cases, the doctor must decide between avoiding harm and providing assistance to the patient. In situations like this, as Albert Jonsen says, the doctor gravitates towards the maxim "of doing no harm, unless such harm is intrinsically related to the benefit to be derived" (5).

Among the possible benefits that the doctor tries to obtain for his patient is the curing of a wound or illness. Among the injuries that he wants to avoid are pain, suffering, incapacitation, and illness. In therapeutic research projects, the possible gains and losses—benefits and injuries—are similar to those just mentioned. However, in nontherapeutic research projects the researcher places the focus upon acquisition of scientific knowledge. Therefore, therapeutic research tends to differ from nontherapeutic research in terms of the desired objectives. Nevertheless, the imperative of not harming the research subject is still very important and should be applied effectively in both cases. Within this context, it might be said that therapeutic research can have a wider margin of risk, provided this risk is

⁴T. Beauchamp and J. Childress (3), p. 106.

⁵T. Beauchamp and J. Childress (3), p. 108.

compensated by potential benefits received by the subject (6).

The difficulty of establishing a clear criterion or procedure to weigh possible risks and potential benefits is evident. Furthermore, in biomedical research it is recognized that in order to prevent injury, it must first be known what actions have the potential to cause harm. In the process of determining this, some people may be exposed to the risk of harm or even suffer harm.

To guide us in how and where to draw the line between what is justifiable despite the risks involved and what is not because of the magnitude of the risks that must be taken, different international instruments have attempted to establish concrete guidelines. The Nuremberg Code, for example, states that "the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment" (7). The Declaration of Helsinki clearly states that in biomedical research involving humans, "concern for the interests of the subject must always prevail over the interests of science and society" (8). Similarly, it is generally understood that as a rule the doctor must help the patient, and if he cannot help him must at least be careful not to harm him: "*Primum non nocere*," as the Latin sentence ascribed to hippocratic writings states.⁶

The Principle of Justice

This principle, which is hard to define, deals chiefly with the question of who should receive the benefits of research and suffer its damages. The principle of justice has been applied to a person if he is offered treatment that is fair, due, or deserved. Any refusal to offer some

benefit, service, or body of information to a person entitled to receive it would be unjust. Similarly, it would be unjust to impose an undue burden or obligation on a person or to demand more of him than is required by law.⁷

Underlying this principle is the idea that irrespective of the criterion adopted, equal people should receive equal treatment. However, this does not tell us how to determine the level of equality among people. In this sense, the principle leaves the field open to different interpretations of its content. Given the fact that in every group of people there will be many features that stand out as similar and many others that seem different, equality should be understood as "equality in terms of specific features."⁸

Many theories have been put forward to help answer the question of who should bear the burden of research and who should enjoy its benefits. The criteria for measuring fair distribution in either sense can range from the merits of each person to the needs of each. The first part of the question relates to the selection or recruitment of research subjects and the second part deals with distribution of research-derived benefits, or distributive justice.

The process of selecting human subjects for research necessarily entails classifying people. For example: Is it a research requirement to choose a specific type of person? If so, can such people be included in the study without violating ethical principles or the laws of the country in question? And if they can, should the selection process employ some pattern or criterion based on the prospective subjects' personal characteristics?

These distinctions are important insofar as they can encourage the establish-

⁶A. Jonsen (5), p. 200.

⁷T. Beauchamp and L. Walters (6), p. 32.

⁸T. Beauchamp and L. Walters (6), p. 33.

ment of national policies that deal with the topic more consistently.⁹ In many developing countries, the answer to the foregoing questions is fundamental (even though it is often not provided in formal terms), because it provides a means of ensuring adherence to the principles of respect and beneficence and establishes guidelines for local and foreign investigators. In the final analysis, the objective should be to determine whether the real reason for selecting one group of people over another is linked to the type of research itself or to elements that are purely arbitrary or convenient for the investigators.

With regard to the enjoyment of research benefits, although it seems obvious that people paying the costs of research should receive its benefits, the reality is sometimes different. To begin with, it is generally difficult to come up with an exact estimate of the potential research benefits.¹⁰ It is possible that positive results may not be obtained, or that they may take years to materialize. Beyond that, the benefits of international research conducted in developing countries are not always available to the people of those countries or may not reach them quickly, perhaps on account of those benefits' high cost.

LIMITATIONS

Up to this point, we have looked at the theoretical dimension of ethical principles that have critical implications for biomedical research on human subjects. It should be noted, however, that application of these principles in real life poses problems, particularly in the case of international research conducted under diverse conditions.

In the case of Latin America and the Caribbean, each country can be said to have its own characteristics. However, there are certain common features that distinguish the subregion as a unit, among the most notable being marginality, poverty, and inequity. It thus comes as no surprise to observe that what constitutes a basic unmet need in our countries is often a concrete achievement in developed countries.

To cite just one example, most of a developed country's population takes access to basic health services for granted. In contrast, most people in Latin America do not have access to these services. Therefore, the stark contrast between conditions prevailing in a Rio de Janeiro slum and in any U.S. suburb underscores a need to reconsider whether ethical principles really should be applied uniformly in the manner discussed in the first part of this article.

We have used the term "limitations" to describe the features analyzed on these pages, since failure to heed them can turn them into obstacles for those wishing to conduct research on human subjects in Latin America and the Caribbean. It should also be noted that the particular features covered are only some of the most striking found in this subregion, where extremes of wealth and poverty exist side by side. Our purpose in examining them here is to help foreign investigators understand the context within which they will be working, and, insofar as possible, to facilitate their application of the ethical principles that should guide their work.

Conceptual Limitations

Based on the foregoing, it would be appropriate to ask if the three ethical principles discussed are universally known, and whether they are recognized in Latin America and the Caribbean as the best

⁹T. Beauchamp and J. Childress (3), p. 196.

¹⁰A. M. Capron (4), p. 143.

source for solutions to ethical problems encountered in the course of biomedical research on human subjects.

To help answer this question, we will consider applying the principle of respect for persons. As we have seen, this principle calls for obtaining the voluntary informed consent of anyone asked to be a research subject.

The concept of voluntary informed consent is based on the idea that a conflict of interests exists between society and the individual. In view of the desire to protect all individuals, steps must be taken to ensure that the interests and well-being of each person take priority over those of the society (9). In some parts of Latin America and the Caribbean, however, the relationship of the subject with society is not viewed the same way. Rather, some communities in this area think of each person as a participant in the common efforts of a collective whole. Hence, the life of each person assumes meaning in relation to his role in the community. Accordingly, he is expected to participate in projects that are of interest to the community, putting forward his best effort.

In this type of society it is difficult to imagine how the interests of the subject can conflict with those of his community. Since the needs of this community are generally pressing and affect all its members, the rights of the research subject and the ethics of the project must be viewed in the context of the goals that this society has set for itself.¹¹ In particular, it is important to note that in many instances the most successful projects are those supported by the official or traditional authorities, who obtain the collaboration of almost everyone. It should be stressed that this is especially apt to be true in remote or isolated places where

national authorities have little or no involvement—places such as many of the indigenous communities in various countries of Latin America and the Caribbean, where people tend to live under very difficult conditions, particularly with regard to health.

Insofar as the second aspect of the principle of respect for persons is concerned, it is worth examining the validity of the right to refuse to participate in research. International guidelines call for someone who is a research subject to be aware that he is free to refrain from participating or to withdraw whenever he so desires. But in the small social groups characteristic of rural communities, very strong social pressure is brought to bear on each community member. This has a powerful influence on the decisions that he makes with regard to his personal life. In such a case, the investigator can inform the potential subject that he has the right to withdraw whenever he wishes. However, if the community views his participation as important, the individual's freedom to decide will at the very least be reduced.

Another aspect of the principle of respect for persons that is useful to examine here is the relationship between the investigator and the research subject. If a doctor or investigator is to adhere to the principle of respect for persons and their autonomy, he must be especially careful about the doctor-patient relationship that will inevitably be established. Often, despite the efforts of the doctor or investigator, relationships based on power are established between him and possible research subjects, ones expressed in terms of dependency and submission (10). This is practically inevitable in places where anything foreign is considered "the best" or "the solution." Such a bias is sometimes reinforced by the authorities, without consideration for the well-being of the people where the study is being

¹¹R. J. Levine (9), p. 20.

conducted. It should also be remembered that in places with many needs, the doctor usually plays a key role, to the extent that after the local authorities, he may be the most prominent figure in the community.

Given these special dynamics of the doctor-patient relationship, it typically becomes extremely difficult for the doctor to explain the requirements of the principle of respect for persons and, in addition, for members of the communities involved to even consider the possibility of not participating in research suggested or recommended by the health authorities or local doctor.

Another relevant aspect of the principle of respect for persons relates to the method generally used for obtaining voluntary informed consent, a method that tends to encounter numerous obstacles in isolated rural communities.

Robert Levine¹² makes a distinction between the purpose served by informed consent and the document used to obtain it. The purpose of this consent is to protect the person participating as a research subject. On the other hand, the document seeks to protect the investigator and the institution sponsoring him. Based on this, we can consider the concrete expression of this consent contained in a signed document as almost completely valid among populations with a very low level of illiteracy. Under these circumstances, it can be assumed that the potential research subject will not only be able to read the document he is asked to sign, but will also be able to understand its content and, on the basis of this, make a decision.

However, in many parts of Latin America and the Caribbean this assumption would be totally erroneous. It should be pointed out that although the illiteracy

rate has fallen in recent years, the situation has not improved in many sectors, particularly among women. Added to this illiteracy problem is the feeling of mistrust that exists in many communities toward anyone who asks for the signature of a person as a commitment. In countries like those of Latin America, where great importance is attached to legal formalities, and where the person who signs a document may end up with all kinds of unexpected obligations, the fact that an investigator asks for a signature on a document drawn up in language that is hard to understand can give rise to reactions of rejection and mistrust.

It seems evident, therefore, that in certain circumstances rigid application of the informed consent requirement may not be suitable. This is so, for example, when the people who are potential research subjects are part of a culture where the concepts of individuality and freedom to choose do not correspond to typically Western concepts. As WHO and CIOMS have recognized (1), such a situation would call for intervention by the community leader for the purpose of obtaining informed consent. A similar situation arises when individuals do not have the minimum level of scientific knowledge necessary to understand the explanations of the doctor or investigator.

Just as we have discussed some of the aspects of the principle of respect for persons, we could equally well discuss some of the aspects relating to the principles of beneficence and justice that would create problems for any simplistic application of these principles in Latin America and the Caribbean. In sum, it is reasonable to assert that these three ethical principles are not universally known and therefore cannot be rigidly applied to a wide range of diverse situations.¹³

¹²R. J. Levine (9), p. 26.

¹³R. J. Levine (9), pp. 16, 26.

As William Curran (11) points out, the principles called for in the Nuremberg Code and declarations of the World Health Assembly were essentially directed toward implementation in developed countries or very urbanized areas of developing countries. They are principles that reflect a specific concept of the nature of people and their relationship with society. Therefore, cold and merely explanatory imposition of the ethical principles we have described will not satisfy the purpose of guiding doctors or investigators in research projects, since these principles do not properly reflect the specific views of the culture involved or the specific relationships between the individual and society.¹⁴

Undoubtedly, it would be more appropriate to apply these principles in a way that recognizes the validity of prevailing cultural patterns. There is thus a clear need to understand ethical principles within a framework of cultural relevance, so as to be able to apply them in accordance with local reality. Without renouncing the idea that basic ethical principles are universally valid, one needs to recognize that different contexts require different applications. This does not mean that the principles themselves should be called into question, but rather that the best method of applying them to the specific situation should be sought in order to achieve the best results.

Institutional Limitations

Given the developmental characteristics of most Latin American and Caribbean countries, countless serious problems are caused by an institutional structure that is multiple, crude, overly bureaucratic, and chronically short of technological, human, material, and legal

resources. In light of this reality, it is important to underscore the fact that laws, rules, or ordinances regarding the ethical aspects of research on human subjects may not exist. It is clear that in countries where all or almost all basic social needs merit priority, it is impossible to work effectively on all fronts at once.

With regard to the health sector, its role in the economic, industrial, and social development of each country is clear. Most Latin American and Caribbean governments are preoccupied with trying to provide their entire populations with basic health services. Coverage in this area is still incomplete. Despite this, there is a growing awareness among people in these countries of the possible benefits to be derived from research projects conducted on their territory.

However, the preparation of rules regulating biomedical research on human subjects is a long and painful process. And even in countries where the first steps have been taken, another major problem is emerging—the problem of how to establish coercive mechanisms to ensure observance of the rules. In many cases such mechanisms do not exist, or else they are too weak, or worse still are not respected. This is a serious general problem for many Latin American and Caribbean justice systems—one that tends to deprive them of both institutional credibility and the opportunity to truly protect their people.

Nor do ministries of health escape widespread difficulties associated with poor resource allocation, a weak political position within the national institutional structure, serious administrative and management problems, and problems relating to excessive bureaucracy. It is undeniable that the health sector receives high priority in every country, but it must also compete with other sectors that may have even more pressing demands. For example, armed conflicts in several coun-

¹⁴R. J. Levine (9), p. 26.

tries have forced governments to devote tremendous resources to military matters and relegate other needs to second place.

Then there is the perpetual problem of bureaucracy arising from the government's excessive size. The employees of public entities have responsibilities that cover a host of different areas. This makes it particularly difficult to find those who effectively intervene in the process of studying the matters of interest to us. So decision-making proceeds from desk to desk in a process that is slow and not always based on careful study. In general, the problems of bureaucracy are found with little variation in all of the countries. With regard to our specific field of interest, the worst problems are the typical slowness and resulting loss of time, since a proposed piece of research must often be done in a specific place and at a specific time.

Furthermore, the ministries of health have not demonstrated the capacity to provide linkages with other social entities—such as social security institutes, universities, and various nongovernmental institutions—that are in a position to contribute to specific research projects. The resulting need to find an entity capable of coordinating the activities of the different health sectors involved in research is thus extremely important, if one wishes to find viable and effective solutions to basic problems confronting both the health field and research within that field.

Also, the Latin American and Caribbean countries have been slow to form ethics committees for monitoring health research projects. Here an important role is being played by research projects sponsored by developed countries. Given the fact that most developed countries require approval of these projects by a local ethics body, committees of this sort have started to emerge for the sole purpose of overseeing such projects. This

is a positive development; for once created, regardless of the initial motive, these committees seem destined to continue working and fulfilling the task of monitoring the ethical development of research.

Unfortunately, the institutional problems that plague the Latin American and Caribbean countries are not limited to those specific problems described here. To enumerate all of them would be tedious and out of place. What should be considered, however, is that such problems may be found elsewhere, and that they exist to one degree or another in virtually all countries, irrespective of levels of economic, industrial, or social development.

CONCLUSION

The current upsurge in international biomedical research projects being conducted in Latin America and the Caribbean has great potential for both the sponsoring and host countries. If the research is carried out properly, the results can be of immense benefit to the host countries—in terms of possible transfer of appropriate technology, access to advances of medical science, and possible discovery of cures or treatments for some of the endemic diseases affecting the subregion.

Even so, the growth of research conducted by foreign investigators in developing countries has understandably roused growing controversy. The foregoing discussion has centered on efforts to apply ethical principles when conducting research on human subjects. Even in this limited area, myriad difficulties can arise when one attempts to put theoretical principles into practice, since those principles reflect a particular view of the world that is not necessarily shared by other peoples.

We have stressed two essential ele-

ments. The first is recognition of the universal validity of ethical principles, although this does not mean that the principles involved are necessarily known and accepted equally in all countries. Understanding this discrepancy requires recognition of the cultural differences that exist in different countries and regions. The second element is recognition that knowledge of these differences can provide a useful starting point for adapting principles to circumstances prevailing where they will be applied. We repeat that we are not attempting to encourage research without ethical principles, but rather to familiarize investigators with cultural differences, so that these differences can be taken into account when studies on human subjects are being conducted. In this context, particular differences that seem especially apt to impose limitations on research utilizing human subjects in Latin America and the Caribbean have been underscored.

It should be added that at the moment one of the most effective tools for narrowing the gap between cultural patterns prevailing in Latin American and Caribbean countries and research guidelines issued by developed countries is joint research (12). Such joint efforts tend to secure the cooperation of foreign investigators and their local counterparts in each and every phase of the project. Hence, this involves not only sharing responsibility from a scientific and ethical viewpoint, but also working toward a common objective. The closer this cooperation and the more effective the communication between foreign and national investigators, the greater the chance that the research will be carried out with due respect for the host country, its citizens, its laws, and its authorities. Moreover, the associated exchange of ideas helps to remove many obstacles linked to misunderstanding, thereby in-

creasing the likelihood of successfully concluding research that is mutually beneficial and that respects ethical principles within the contexts of different cultures.

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Ethics and Epidemiology

The ethical dilemmas linked to epidemiology, in both research and application, were discussed at an international workshop on Ethics, Policy, and Epidemiology held at the University of California, Los Angeles (U.S.A.), 3-5 August 1990. The workshop, which preceded the XII scientific meeting of the International Epidemiological Association, attracted 80 practitioners of epidemiology and experts on ethics from 25 countries.

Among the topics discussed at the workshop were the balance between safeguarding confidentiality and using information for analysis and action; the extent to which epidemiologists should communicate research results to the communities and persons studied; conflicts of interest; data ownership and ownership of analyses; intercultural approaches; and ethical review procedures. The case was made for epidemiology to focus more attention on the health needs of disempowered populations and the problems encountered in developing countries and inner-city areas. A positive example of changes in research approaches is the development of codes of community rights by epidemiologists and social scientists in Brazil who work with traditional cultures.

The Council for International Organizations of Medical Sciences (CIOMS) is developing proposals for international guidelines for epidemiologic practice and research, but with the full awareness that guidelines cannot substitute for careful discussion at the local level of ethical dilemmas relating to specific cultural, social, and political factors.

Source: World Health Organization, *Wkly Epidemiol Rec* 65(38):292-293, 1990.