

Overview of Bioethics in Mexico

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In Mexico, as in many other countries, there are numerous situations involving bioethics that are not necessarily covered by officially sanctioned policies or guidelines. In such cases, it is reasonable to describe commonly accepted rules, opinions, and practices in a general way so as to illustrate how bioethical questions are being managed. This article describes certain goals and practices relating to education in bioethics in Mexico. It then outlines Mexican laws and procedures governing research on human subjects, cites certain official rules and activities relating to regulation of human reproduction, quotes literature dealing with intervention in human procreation, discusses artificial prolongation of life, describes laws and practices governing organ transplants, considers ethical issues relating to such transplants, reviews the AIDS situation, and describes how the need for confidentiality is dealt with in managing AIDS cases and related data. In this manner it indicates how bioethical questions in these various areas are being handled and points out certain priority areas needing work.

An ethical person is generally understood to be one who continually shapes his own behavior in terms of a reference group of positive human values, progressively defining himself in this manner to a point where he is seen as exemplifying those values and fostering them in others (1).

One of the most obvious reasons for the accelerated development of medical ethics today is that medicine's outstanding advances have given rise to ethical issues that are often hard to resolve; and the magnitude and complexity of these issues require contributions from disciplines other than medicine.

Among the advances involved, to name only a few of the most prominent, are techniques for successfully making organ transplants, implanting artificial organs, and artificially prolonging life, as

well as genetic selection methods such as that afforded by the combination of amniocentesis and selective abortion. One should also mention the overuse of technological resources in studying patients, an occurrence that tends to mechanize medical care and entail the intervention of several professionals in caring for a single patient, all of which dilutes the personal nature of the physician-patient relationship.

In these and other ways, the complexities of modern medicine's instruments and scientific techniques can often turn against man, raising issues of an ethical nature that urgently need to be resolved. With this in mind, a group of physicians, humanists, sociologists, philosophers, and researchers has founded the Mexican Academy of Bioethics, "dedicated to promote the study, investigation, and reporting of medical and biological ethics" (2).

As set forth in the academy's bylaws, its members are physicians and health professionals with established reputations whose knowledge and experience

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can contribute to development of this field.

Of course, medical ethics goes beyond the dictates of precepts and the behavior of physicians toward ill patients in response to the relentless but sometimes dehumanizing advance of modern technology. For this reason, and in view of the unavoidable need for medical and biological research directed at improving techniques for preserving and restoring health, all workers in the health field should know the basic principles of medical ethics in order to maintain a moral outlook and slow the dehumanizing influence of science when it adopts attitudes and practices that cause physical or mental harm. Within this context, it seems clear that economic utilitarianism, a fundamental goal of medical practice, constitutes one of the greatest ethical threats to modern man.

INSTRUCTION

Although ethical principles have generally been observed in the practice of clinical medicine in Mexico, to date instruction in bioethics has been required by only a few of the country's medical schools; certain others offer it as an elective, while most do not offer it at all. It is therefore encouraging to note that an Institute for Humanism in Medicine was recently organized at the Medical School of Anáhuac University, in order to promote application of the principles of medical ethics in Mexico.

Like many other disciplines, bioethics can be a difficult and "heavy" subject if it is not related to real-life experiences in the world of medicine. Especially today, in our world of advanced technology, philosophical theory in isolation seems dull; but if it is tied to a course on the history of medicine or made a subject for discussion by the professors of all courses, it becomes more attractive be-

cause it can then be seen as a living discipline with practical applications.

In this regard, it is worth noting the following statement by the Director of the Medical School of the National Autonomous University of Mexico: "The teaching of ethics is related to respect for human dignity, and therefore should be imparted through the ethical example of each one of the professors; it sustains itself through the protection of human rights, which is why it should be expounded in a structured and absolutely independent manner with assurance by moral men that they will clarify the questions typical of youth; and it involves commitment, because failure to assume responsibility for attacking moral (and therefore ethical) problems, is to incur discredit . . ." (3).

RESEARCH ON HUMAN SUBJECTS

Ethics has long been a fundamental part of the practice of medicine, especially with respect to the patient's welfare—a matter that should be the main object of the physician's actions. However, real interest in the ethical aspects of medical research on human subjects did not clearly emerge until just after World War II, with the 1947 Nuremberg trials of people accused of performing sadistic research on prisoners in concentration camps. When the accused were found guilty of behavior contrary to universally recognized human values, the foundations were laid for a new phase of medical ethics in which the fundamental principles were patient autonomy and respect for the dignity of man.

Another important step in this same field occurred in 1975, when the 29th World Medical Assembly approved an amended version of the 1964 Declaration of Helsinki, which reaffirmed existing codes of ethics and for the first time proposed creation of ethics committees at all

hospitals where research on human subjects was conducted.

Mexico has encouraged development of many of the ethical rules relating to biomedical research that have been in force up to the present. In 1980 Mexico City was the site of the International Conference of the International Council of Medical Science Organizations. On that occasion Mexico's National Academy of Medicine concerned itself with developing and revising work performed with respect to "Proposed International Guidelines for Biomedical Research Involving Human Subjects" and offering solutions to problems raised in working sessions. The Academy also participated in a similar event organized one year later in Manila, the Philippines, which set the stage for drafting the final version of those standards.

Mexico's General Health Law states in Section 5 that "In the health institutions under the responsibility of the directors or respective representatives and pursuant to the applicable provisions, the following will be formed: a research committee, an ethics committee, and a biosafety committee" (4).

The regulations of the General Health Law pertaining to health research, which were published in 1987, precisely and broadly specify the ethical matters to be considered when conducting research on human subjects. Among other things, Articles 13 and 14 of Chapter 1 make the following points:

In all research where human beings will be the subject of study, the criterion of respect for their dignity and protection of their rights and welfare should prevail.

Research on human subjects should be conducted according to the following principles:

1. It will be in keeping with the scientific and ethical principles that justify it.
2. It will be based on prior experience

with laboratory animals or on other scientific facts.

3. It will be conducted only when the knowledge sought cannot be obtained by other suitable means.

4. The likelihood of expected benefits should always outweigh the foreseeable risks.

5. Aside from exceptions stated in these regulations, informed consent obtained in writing from the subject of the study or his or her legal representative will be required.

6. It [the research] will be conducted by health professionals...with knowledge and experience in safeguarding the integrity of human beings, under the jurisdiction of a health care institution that is supervised by competent health authorities and possesses the human and material resources needed to ensure each research subject's welfare. And

7. It must have the authorization of the head of the health care institution and, when appropriate, the Ministry, in conformity with Articles 31, 62, 69, 71, 73 and 88 of these Regulations. (5)

The Ethics Committee of the General Hospital of Mexico has played an important role in establishing ethics committees in other hospitals throughout Mexico. It has also been involved, through the General Health Council (*Consejo de Salubridad General*), in translating into Spanish ethics handbooks for biomedical experiments—handbooks that are distributed in turn to other Spanish-speaking countries.

As a preliminary step in reviewing proposals for biomedical research on human subjects, it is important to note the desirability of considering the cost/benefit ratio, particularly in our area, in light of the present economic crisis. Therefore, it seems reasonable to propose that before any such research is conducted the following questions should be answered: How valid, from a scientific standpoint, is the research project, and what are its

potential benefits? Is there justification for conducting the research at this time? Is the group on which the research will be conducted adequate and appropriate? What are the potential and identifiable risks involved? And, is the proposed research completely acceptable from the ethical point of view? (6)

REGULATION OF REPRODUCTION

Mexico generally respects a couple's freedom to decide how many children they wish to have and promotes the idea of "responsible parenthood." At the same time, it fosters family planning methods with various measures, including mass social communication campaigns, even though not all these measures can agree with all the criteria applied by the array of diverse family and social groups constituting the Mexican population. The practice of abortion is illegal in Mexico.

Regarding genetic engineering, we believe it has a promising future. However, with regard to human reproduction it appears to have transcended the limits of what is normal in the field of gestation, and so the need for legislation on the subject is imperative. This is especially so regarding *in vitro* fertilization, intratubal transfer of gametes, and all methods related to interventions in human procreation. In this regard we support the moral criteria pertaining to the physician's intervention into human procreation that are contained in the work by Ratzinger and Bovone (7), which reads in part as follows:

The medical act should not be valued solely for its technical dimension, but also and above all for its purpose, which is the good of the people and their physical and psychological health. The moral criteria that regulate medical intervention in procreation derive from the dignity of the human per-

son, from his or her sexuality, and from his or her origin.

Medicine that wishes to serve the integral well-being of the person should respect the specifically human values of sexuality. The physician is at the service of the person and human procreation; he does not have authority to instruct or decide upon them. The medical act is respectful of the dignity of persons when it is directed at helping the conjugal act, whether to facilitate its consummation, or to see that the normally performed act attain its end.

Regarding interventions on the human embryo, these shall be licit as long as they respect the life and integrity of the embryo, do not expose it to uncontrolled risks, and have as their goal its treatment or individual survival; in any case, however, the informed consent of the parents is required. Experimentation on embryos which is not directly therapeutic is unethical, because using an embryo or human fetus as an object of experimentation constitutes a crime against its dignity as a human being.

In vitro fertilization techniques make other forms of biological or genetic manipulation of human embryos possible, such as: plans and projects for fertilization between human and animal gametes, and gestation of human embryos in uteri unnatural to them. These procedures are contrary to the embryo's dignity as a human being and, at the same time, violate the right of a person to be conceived and born within and through a marriage. Also, attempts and plans for obtaining a human being without any connection to sexuality through "gamete fission," cloning, or parthenogenesis should be considered immoral because they are in conflict with the dignity of both human procreation and conjugal union.

Similarly, the freezing of embryos, although done to keep them alive, constitutes an offense to the respect due human beings, inasmuch as it exposes them to serious risk of death or of damage to their physical integrity, deprives them at least temporarily of shelter and maternal gestation, and places them in a situation in which they are susceptible to further injury and manipulation.

Some attempts to intervene in the area of influence of chromosomes and genes are not therapeutic, but seek to produce human beings selected in terms of sex and other preestablished qualities. Such manipulations are contrary to the personal dignity, integrity, and identity of the human being. They cannot in any way be justified by possible beneficial consequences for the future of humanity. Each person deserves respect in his own right; in this resides the dignity and right of the human being from the outset.

In conclusion, it is important to note that any intervention on the human body not only involves tissues, organs, and functions, but also, and at different levels, affects the person. Therefore, such intervention involves a moral significance and responsibility that is perhaps implied but nonetheless real. As Pope John Paul II reminded the World Medical Association:

Each human person, in his unrepeatable singularity, is not made up just of the spirit, but also the body, and for that reason in the body and through the body one reaches the person himself in his concrete reality. Consequently, respecting the dignity of man implies safeguarding that identity of man, as the Vatican II Council affirmed. From this anthropologic vantage point one should find the fundamental criteria for deciding on procedures that are not strictly therapeutic, such as, for example, those that seek to improve the human biological condition. (7)

DEATH

The word death (*muerte*), from the Latin *mors* or *mortis*, means the cessation or end of life. From a biological standpoint it is the cessation of organ function in a living being, beyond a point where revival is possible. In law, natural death ends an individual's civil status in all personal legal relationships, both civil and penal, while all assets and obligations

(including fines) are transferred to the decedent's heirs.

In forensic medicine, the clinical diagnosis of death is based upon cessation of respiration and circulation (functional death). For some time after death, certain other functions persist that can be easily demonstrated, such as electric excitability of the muscles, digestive functions, etc.; the point where such functions cease is termed "tissue death."

Technologic accomplishments and an extraordinary improvement in hospital care resulting mainly from new techniques for diagnosing and treating sudden illnesses that until recently led to death have given rise to situations that require a new approach to treating patients, the principal victims of such illnesses, as well as the patients' relatives who are the secondary victims.

In certain cases it is now possible to prolong a patient's vegetative life for many years—to a point where the extension of life is limited mainly by the economic means available. In such circumstances, the ideal thing would be for the patient himself to choose the time to die. This is a difficult concept to express juridically, however, especially since the patient's choice can have significant repercussions on third parties.

When a patient with a terminal condition is treated, those medically responsible face extremely difficult decisions. Use of artificial life-sustaining equipment and measures, such as respirators, hemodialyzers, etc., can create a serious problem, in that the patient may need them permanently. The decision to suspend use of such equipment under these circumstances is difficult for relatives, doctors, and the attending staff. At the same time, the treatments involved tend to be very expensive for the family, which is obliged to continue them not knowing how long they will be needed or how much it will be required to spend.

Therefore, the physician should be aware of what is involved in prolonging the life of a patient. If there is a reasonable probability that the patient will survive the disease, every effort is justified. But if the doctor knows that the patient will not survive, though sophisticated techniques and procedures might keep him "alive" indefinitely, he should assess what such prolongation of life means in terms of suffering for the patient and cost for the family. He should consider whether the large amounts of money and medical resources involved might better be used to treat several other patients with curable diseases—whose recovery would be emotionally and economically beneficial to their relatives and society.

At the same time, it must be accepted as an ethical principle that the physician has a medical duty to tell the patient and his relatives the truth regarding the patient's status, even when he has not been expressly asked (8).

In general, the patient confronting certain death should be treated with a minimum of measures intended to prolong his "life" and a maximum of measures calculated to alleviate his suffering, even when this means high dosages of tranquilizers and analgesics. That is, we should treat the patient as we would like to be treated and not permit resuscitating maneuvers. We should also keep painful examinations to a minimum and not allow any laboratory studies for academic purposes or for confirmation of what is already a diagnostic certainty.

ORGAN TRANSPLANTS

Mexico already has detailed laws that clearly determine what factors should regulate the use of tissues and organs for therapeutic purposes, particularly for transplants. However, every day sees a greater demand for organs to transplant,

and so there is a need for more volunteer donors and more careful registration.

The Ministry of Health and the Dr. Salvador Zubirán National Nutrition Institute have formally activated the National Transplant Registry, a facility created through joint agreement of the two institutions. This registry coordinates the distribution of organs and tissues throughout the country and maintains a register of the originating donors and patients awaiting organ transplants (9).

Regarding ethical issues relating to transplants, when the recipient and the donor are both humans, there is no doubt that the basic concept of transplanting organs is ethical. Indeed, the transplanting of animal organs to human recipients also appears ethical in concept, assuming that the procedure does not induce significant personality alterations in the receiver.

Allogeneic transplants between relatives involve a deep demonstration of the donor's love and generosity with respect to the recipient, motives that clearly indicate the deeply ethical nature of such transplants.

Allogeneic transplants between unrelated individuals, when the donor's sole motive is charity (as in the case of altruistic blood donations, for example) are richly deserving of social admiration and respect.

In addition, allogeneic transplants from a corpse to a living person, when the donor has just died and appropriate consent has been obtained, are obviously licit and ethical in concept. What is indispensable is an accurate determination that the donor is really dead before the transplant material is obtained; otherwise, the fundamental principle prohibiting homicide should prevail (10).

Without trying to deepen the debate that has emerged regarding determination of the time of death, we would like to cite Kaufer (11), who states that

"death should be considered the suppression of any manifestation of life by the organism as a whole, such that the time of death corresponds to the limit beyond which return and revival are not possible."

In accordance with this definition, once death of the cerebral cortex has been proven it is ethical to perform a transplant, so long as authorization has been obtained from the decedent's close relatives and anything that might be construed as "commerce" or "trafficking" in transplant material is avoided (12).

Especially in view of the fact that Mexico is a developing country, the matter of resource allocation for national transplant programs is important. This issue has a high ethical content because it concerns appropriate distribution of medical resources, particularly in the case of transplant procedures that are still in the experimental stage and that should remain exclusively within the domain of very specialized institutions. On the other hand, the virtues of more routine tissue and organ transplants—of corneas, bones, skin, bone marrow, kidneys, etc.—seem clear; the matter of limiting resources for such transplants has not yet come up for discussion in the developing countries; and we feel from an ethics standpoint that allocation of resources for these procedures is fully justified.

More generally, a presentation by Engelhardt to the Medical Society of Massachusetts (12) stressed that all expenditures made to achieve a life-saving therapy should be prudent—so that they can be justified in response to concern about whether the funds could have been spent better elsewhere. Specifically, Engelhardt asked whether use of such funds to improve prenatal care or reduce hypertension would have ensured greater survival or reduced morbidity in more people.

On the other hand, we believe that the judgment of different societies and social groups should be respected. For example, some societies may freely decide to assign relatively low priority to the transplant program so as to improve the quality of medical care for the poor. At the same time, certain societies with more abundant economic resources might decide to increase the funding and attention given the transplant program. We feel there is every reason to regard such choices freely made as valid.

AIDS

The acquired immunodeficiency syndrome (AIDS) was first identified in the United States in 1981. Since then the disease has been detected in most countries and all continents. In 1983 the first cases appeared in Mexico; since then the number of cases has grown rapidly, and at present it is estimated that this number is doubling every seven months (13).

It now appears that by 1991 there will be between 20,000 and 30,000 AIDS cases in Mexico. As in the United States, the disease in Mexico was initially limited to male homosexuals and bisexuals, but it soon began appearing in women, children, recipients of blood transfusions, and heterosexual males belonging to none of the known high-risk groups.

Extensive studies on AIDS have been performed in Mexico that deal with various clinical, bacteriologic, epidemiologic, economic, and health care aspects of the disease. However, there have been virtually no AIDS studies focusing on ethical questions—which is a principal reason why we recently conducted a survey of who was being informed of AIDS cases by the infectious disease specialists frequently encountering such cases. In a majority of cases the respondents indi-

cated that only relatives interested in the health of the patients were informed, and that appropriate prophylactic measures were provided or practiced only in the case of HIV seropositivity being found in the closest family members.

In general, confidentiality is required. For clinical purposes, AIDS cases are reported to the National Information Center of the National AIDS Council (CONASIDA). This institution follows a procedure directed mainly at voluntary case identification. If the subject agrees, a card is filled out (the overwhelming majority of the subjects do not respond truthfully to the questions asked). Immediately thereafter a social worker reviews the data on the card and a psychologist briefly interviews the subject. Later a medical review is conducted and a blood sample is obtained from the subject. At all times the only means of identification used is a code on the card, which is filed at CONASIDA's information center. No attempt to identify the subject is made at any time, and maximum confidentiality is maintained.

When the subjects are seropositive, they are given their test results in private, along with recommendations and pertinent support.

CONASIDA has adapted an AIDS survey to Mexico that conforms to WHO recommendations and is based on experiences in other countries, primarily the United States (14). The results of this ongoing survey are computerized and analyzed by epidemiologists and infectious disease specialists. The medical records of AIDS cases are always registered with nothing more than a code, never with the names of the patients.

From the standpoint of medical ethics, it can be concluded that thus far no precise methodology has been applied with regard to AIDS patients. Therefore, work needs to be done in this area, proposals

being needed for special treatment and other policies dealing not only with AIDS patients but also with related problems affecting their families and society at large.

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Male Hormonal Contraceptive Efficacy

A study of a hormonal contraceptive for males has shown efficacy comparable to that of female injectable contraceptives and higher than other commonly used methods, including oral contraceptives. Only one pregnancy resulted in 1,486 months of exposure. Previous studies had assessed the effectiveness of this contraceptive on the basis of semen evaluation alone, while other forms of contraception were being used concurrently.

The study was carried out at centers in Australia, China, Finland, France, Sweden, the United Kingdom, and the United States under the auspices of WHO's Special Program of Research, Development, and Research Training in Human Reproduction. Weekly injections of the hormonal preparation testosterone enanthate (already in widespread clinical use for other purposes) suppressed sperm production completely in 70% of the men participating in the study and to residual levels in the rest. There were few side effects directly attributable to the hormone. The efficacy trial lasted 12 months; after injections were stopped, sperm production returned to pretreatment levels in six to nine months.

The need for weekly injections was a major drawback, and a number of volunteers dropped out of the study for that reason. Methods of delivering the hormone that would be more practical for widespread use (such as three injections per year) are being developed.

Source: World Health Organization, Press Release WHO/55, 22 October 1990.