UNITED NATIONS

ECONOMIC AND SOCIAL COUNCIL

Distr.
GENERAL

E/CN.4/1173
18 February 1975

Original: ENGLISH

COMMISSION ON HUMAN RIGHTS
Thirty-first session
Item 10 of the provisional agenda

HUMAN RIGHTS AND SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS

Health aspects of human rights in the light of developments in biology and medicine

The Secretary-General has the honour to submit to the Commission on Human Rights the attached report on health aspects of human rights in the light of developments in biology and medicine, prepared by the World Health Organization.

GE 75-2578

HEALTH ASPECTS OF HUMAN RIGHTS IN THE LIGHT OF DEVELOPMENTS IN BIOLOGY AND MEDICINE

Prepared by the World Health Organization

CONTENTS

1. Introduction

On 19 December 1968 the United Nations General Assembly adopted resolution 2450 (XXIII). The resolution invited the Secretary-General and the executive heads of the competent specialized agencies to carry out a study of a number of problems of which the following (paragraph 1(b) of the resolution) was of special concern to WHO: "Protection of the human personality and its physical and intellectual integrity, in the light of advances in biology, medicine and biochemistry". In pursuance of resolution 2450 (XXIII), WHO prepared a preliminary document[1] which was considered by the Twenty-third World Health Assembly, meeting in Geneva in May 1970, which passed resolution WHA23.41 of which the relevant sections read as follows:

> "The Twenty-third World Health Assembly:
>
> 1. RECALLS the long-standing co-operation between the World Health Organization and the United Nations Commission on Human Rights;
>
> 2. FURTHER RECALLS resolution 2450 (XXIII) adopted by the United Nations General Assembly . . .;
>
> 3. NOTES that the Director-General transmitted to the United Nations a preliminary memorandum on "the protection of the human personality and its physical and intellectual integrity, in the light of advances in biology, medicine and biochemistry";
>
> 4. REAFFIRMS that the right to health is a fundamental human right;
>
> 5. CONSIDERS that the health aspect of human rights in the light of scientific and technological progress is within the competence of the World Health Organization; and
>
> 6. REQUESTS the Director-General:
>
> (a) To reaffirm to the Secretary-General of the United Nations the Organization's willingness to undertake responsibility for the preparation of a document dealing with the health aspects of human rights in the light of scientific and technological developments, and
>
> (b) To study further the implications of this matter for the Organization and to report to the Executive Board at a future session."

The preliminary document prepared by WHO contained the following chapters: Respect for the privacy of individuals in the light of advances in recording and other techniques; Protection of the human personality and its physical and intellectual integrity in the light of advances in biology, medicine and biochemistry (developments in genetics, tissue and organ transplantations, heart transplantations, radical medical techniques in general); Experiments on human subjects (experiments in physiology, pathology and psychology, clinical testing of drugs, use of chemical additives in food and potable fluids); Deterioration of the human environment; Human rights aspects of the delivery of health services; Mental health; and Nutrition.

The present document has been prepared to meet the request made in paragraph 6 of resolution WHA23.41. In this document an attempt has been made to summarize briefly the main situations, whether recent or of long standing, in which interventions, compulsions, or

---

[1] Annex III to document EB47/45. United Nations General Assembly document A/8055/Add.1, dated 30 November 1970.

restraints, performed or imposed on human beings for preventive or curative therapeutic purposes or with a view to advancing knowledge of health and disease, have implications for the rights of the individual. Nothing in this document has any claim to originality. Rather, it should be regarded as a sort of annotated check list of situations involving the intervention of the physician or related professions which may impinge on the rather ill-defined, and often differently interpreted, problems of human rights.

An important question raised by this study is what role an intergovernmental organization such as WHO should play in attempting to arrive at an international consensus as to the point at which certain medical interventions and procedures may offer a threat to human rights. As an example of the role of WHO one could mention the question of research involving human subjects.[2] For this important problem the interest of WHO is not merely theoretical, for it is supporting, directly or indirectly, many medical research activities, all of which must, at one stage or another, find their first applications on human beings. In some countries, governmental organizations funding medical research projects have formulated principles for safeguarding the rights of human subjects, and the scrupulous observance of these principles is a condition for the award of a financial subsidy. So far WHO has not enunciated any similar principles, but it has established an internal secretariat committee to advise on research proposals involving human subjects. However, as medical science becomes ever more potent in the promotion of health and the prevention of disease, so governments tend to become increasingly involved not only in the funding of medical research but also in establishing safeguards for its human subjects.

While it might be considered possible to reach a consensus at the intergovernmental level on the principles that should govern human experimentation, there are quite a number of other fields for which it is difficult to achieve an agreement and thus for an intergovernmental organization the role is at least subsidiary. In some of these matters - such as contraception, sterilization, and induced abortion - ethical, legal, religious and social values are predominant and the possibility of international agreement is very remote. In such areas, however, WHO can and does promote research and organize international discussions on purely scientific aspects and disseminates recently acquired knowledge through its publications. The report of a WHO scientific group on "Spontaneous and Induced Abortion"[3] and the numerous WHO publications on various aspects of human reproductive behaviour are good examples of this type of activity.

These are the limitations and the scope of responsibility of WHO in relation to a number of problems involving ethical considerations. On these problems WHO has also close cooperation with international nongovernmental bodies such as the World Medical Association (WMA) and the Council for International Organizations of Medical Sciences (CIOMS). The World Medical Association has in the course of years issued five codes of ethics, namely, the International Code of Medical Ethics (1949); the Declaration of Geneva (1948); the Declaration of Helsinki containing recommendations guiding doctors in clinical research (1964); the Declaration of Sydney in relation to the determination of the time of death (1968); and the Declaration of Oslo in relation to therapeutic abortion (1970). Also of importance is the sponsoring by WHO and by UNESCO of CIOMS, which has devoted a number of studies and convened different meetings in relation to bioethics. The proceedings of the conferences dealing with human experimentation, heart transplantation, drug evaluation, social and ethical implications of recent progress in biology and medicine, and human rights, have been published. CIOMS has adopted a number of resolutions on these subjects, such as for instance that of the Round Table Conference on human rights (1973) on amniocentesis.[4]

---

[2] The problems raised by human experimentation are dealt with in greater detail in sections 11 et seq.

[3] Wld Hlth Org. techn. Rep. Ser., 1970, No. 461.

[4] See Btesh, S., ed. (1974) Protection of human rights in the light of scientific and technological progress in biology and medicine (Proceedings of 8th CIOMS Round Table Conference), Geneva, pp. 319-320.

As advances in medical science have progressively increased man's power to influence the forces of life and death, writings on the ethical aspects of various medical interventions have become ever more voluminous. This is particularly the case in the United States of America, where the subject of the ethics of biomedical interventions on human beings or material has been given the name "bioethics". The extent of the interest focused on this new discipline is illustrated by the fact that early in 1974 the National Library of Medicine, Bethesda, Maryland, announced that it had awarded a grant of $ 280 000 to the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics, Washington, D.C., to prepare and publish three annual bibliographies on bioethics. If in this report there is a preponderance of references to experiences and discussions in the United States of America, it is because it is in that country that the problems of "bioethics" have been most widely ventilated.

In the pages that follow various situations with greater or lesser implications for human rights have been mentioned without reference to their susceptibility or otherwise to fruitful intergovernmental action. It is obvious that a number of other problems might have been dealt with in the document or that some of the sections might have been expanded. The aim of the present document is therefore only to illustrate a few of the questions which may present particular problems. It is hence not intended to be an exhaustive account and topics such as transsexualism, euthanasia, and orthothanasia are not developed. The present document also does not deal with the rights of minors who are mentally retarded, infirmed, or in other custodial circumstances in which their rights require definition and protection.

1.1 Health as a human right

When referring to health as being a human right, it is essential to consider what is the exact significance of this right, what it involves, and what is its true perspective, while avoiding as far as possible the study of the problem as an abstract concept. It must be demonstrated that the right to health has obvious limitations and it will likewise be necessary to show, in the light of "advances in biology, medicine and biochemistry", what benefits and what parallel potential risks new developments may entail as far as the right to health and possibly other rights are concerned.

Historically, and in contrast with the early introduction of a number of other rights, the "right to health" was one of the last to be proclaimed in the constitutions of most countries in the world. There are no references to the right to health in 18th and 19th century constitutions, whereas a number of other rights are specifically mentioned.

At the international level, the Universal Declaration of Human Rights established a breakthrough in 1948. This Declaration does, in fact, contain two main elements in Article 25:

> (1) "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family including food, clothing, housing, and medical care and necessary social services and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."
>
> (2) "Motherhood and childhood are entitled to special care and assistance. All children whether born in or out of wedlock shall enjoy this same social protection."

The Preamble to the WHO Constitution also affirms that it is one of the fundamental rights of every human being to enjoy "the highest attainable standard of health" and that "governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures".

Adopted by the World Health Assembly in 1970, resolution WHA23.41 goes far beyond these provisions in declaring without qualification that "the right to health is a fundamental human right". At the same time, another resolution, namely resolution WHA23.61, elaborates on what

may be considered as being the philosophy relating to the right to health and gives the latter a specific dimension. This resolution states that "the attainment by all peoples of the highest possible level of health" is the main long-term objective of the World Health Organization and that the most important condition for this is the development of efficient national health systems in all countries. To achieve this, the following recommendations and conclusions are made:

(1) the proclamation of the responsibility of the State and society for the protection of the health of the population, to be based on putting into effect a complex of economic and social measures which directly or indirectly promote the attainment of the highest possible level of health, through the establishment of a nationwide system of health services based on a general national plan and local planning, and through the rational and efficient utilization, for the needs of the health services, of all forces and resources which society at the given stage of its development is able to allocate for those purposes;

(2) the administration of rational training of national health personnel at all levels as a basis for the successful functioning of any health system, and the recognition by all medical workers of their high degree of social responsibility to society;

(3) the development of health services primarily on the basis of extensive measures to foster the preventive approach both for the community and the individual which will require the integration of curative and preventive services in all medical and health establishments and services, emphasizing the protection of health of mothers and children who embody the future of every country and of the whole of mankind, and the establishment of effective control over the condition of the environment as a source of health and life to present and future generations;

(4) the provision for the whole population of the country of the highest possible level of skilled, universally available preventive and curative medical care, without financial or other impediments, by setting up an appropriate system of curative, preventive and rehabilitative services;

(5) the extensive application in every country of the results of progress in world medical research and public health practice, with a view to ensuring conditions that will make it possible to obtain maximum effectiveness from all health measures taken; and

(6) the health education of the public and participation of wide sections of the population in the carrying out of all public health programmes, as an expression of the personal and collective responsibility of all members of society for protecting human health.

The resolution further recommends Member countries, "having regard to their own historical, social economic and other conditions, to take these principles into account in establishing their health services and systems".

Although the "right to health" can be conceived in the sense that a person may not be deprived of his health by the action of another, as by some form of aggression, it would seem that the World Health Assembly was reviewing the right to health rather in the sense of a "right to health care". In this context we have a right that is legally enforceable in that a legal duty to provide such care can be created and applied to individuals and collectivities.

Having considered the situation of the right to health at the international level,[5] it is necessary to examine how the different countries in the world have implemented the principle of the right to health at the national level, in particular through legal ways and means.

---

[5] See also Report of the Special Rapporteur of the Commission on Human Rights, E/CN.4/1131, on page 44, and ECOSOC resolution 1867 (LVI).

In recent constitutions, the "right to health" has in fact been introduced, although not using this precise wording but again rather as a right to health protection. This again circumscribes the right to health for the reason that, even before the birth of any individual, the personal health situation will differ be it only through genetic circumstances and later on for a number of other reasons. It is interesting in this connexion to quote the Constitution of one of the WHO Member States which guarantees to a citizen the "protection of his health and working capacity". This right is to be achieved by "planned improvement of working and living conditions, the fostering of public health, a comprehensive social policy, the promotion of physical culture, of school and popular sports, and of tourism". In the above-mentioned Constitution, the right to health protection is assured by a comprehensive system of social insurance that provides material security in cases of illness or accident, and free medical attention, medicaments, and other necessary materials. Moreover, each citizen has a right to be cared for by society in old age and invalidity.[6]

In a number of other countries, as has already been mentioned, the constitutions do not specify health as a human right. However, the introduction of a whole system of legislative and administrative provisions dealing with therapeutic and prophylactic care shows how the principle of the right to health is implemented in practice.

The right to health has to be considered in relation to a number of other rights, such as the right to food, clothing, and housing, and the right to freedom and privacy, and consequently one may state that in particular circumstances specific human rights may sometimes conflict with one another. In a number of situations, the right of health may involve a number of obligations which may entail limitations on personal liberty. This is the case where, for instance, measures for the control of communicable diseases such as quarantine and/or vaccination may be considered as constituting an infringement of personal liberty, but must be accepted for the sake of the protection of the community. The right to health may thus involve duties to preserve the general welfare and the rights of the community, duties which may override the right of the individual citizen. Moreover, because of differences in standards of living and economic and educational conditions, the attainment of the right to health may vary considerably.

If all the factors which may influence legislative provisions dealing with health protection are studied, it is clear that there are differences which are due, independently of the level of present scientific knowledge, to other important factors. These include religious, moral, ethical, and traditional attitudes that differ from country to country. In respect to matters such as abortion, sterilization, contraception, although such policies and attitudes may well change in the course of time. The role of WHO in the solution of these particular problems is very limited indeed, since decisions lie within the jurisdiction and authority of the different nations. This does not preclude WHO from engaging in the scientific study of these problems, for which as an intergovernmental organization it is well equipped in view of its particular position.

While advances in biology and medicine may promote the attainment of the highest possible level of health and are thus of benefit to mankind, a number of sections in the present document will illustrate how they may sometimes involve a risk to the physical and mental aspects of the "right to health".

Furthermore, the benefits of recent discoveries in the medical field may still be limited to a few persons. A number of reasons may explain why a general application of the benefits of such discoveries is not feasible and why stringent selection of beneficiaries might even be necessary in highly developed countries - obvious examples being renal dialysis and organ transplantation.

---

[6] "Verfassung der Deutschen Demokratischen Republik von 6. April 1968", Gesetzblatt der Deutschen Demokratischen Republik, 1968, Teil I, Nr 8, Articles 35 and 36.

Lack of equipment, financial constraints, and non-availability of highly skilled personnel may constitute powerful barriers to the exploitation of new medical discoveries.

In summary, there exist, in the field of human rights and health, positive aspects for which the State and the community have a duty to ensure that the individual citizen benefits, but those rights may entail negative elements in that the individual citizen has the duty to limit his rights for the benefit of the community, as is the case with respect to pollution, immunization, etc.

There are additional questions such as, are individual citizens sufficiently protected by the State in their fundamental health rights such as, for example, against the indiscriminate advertising of alcohol and cigarettes as opposed to essential health education measures to prevent health hazards. An example of the exploitation of ignorance, which is the result of unethical economic pressures, is the "plasmapheresis problem" against the abuse of which some countries have had to introduce legislative measures in order to avoid damage to the health, and even danger to the life, of their citizens.

2. The beginning of life

While the fertilized ovum is undoubtedly alive in a biological sense, this is equally true of the spermatozoon and the ovum before fertilization. The question arises: At what point in its development should the embryo or fetus be regarded as having acquired human rights? This problem has of course been the subject of controversy;[7] obviously prenatal care in order to preserve the right to health starts at the earliest stage of development. An associated problem is the stage at which the fetus becomes viable in the sense of being able to survive separation from its mother.

In 1972 a national group of experts recommended that a period of 20 weeks of gestation, equivalent to a weight of 400-500 g, should be regarded as presumptive of viability, but added the reservation that advances in medical knowledge might require revision of this period.[8] A WHO scientific group came to different conclusions in 1974, advising that a fetus born before 22 weeks of gestation and weighing less than 500 g had "no possibility of survival today and little more likelihood of survival in the near future".[9] The group recommended

---

[7] In 1973 the Supreme Court of the United States ruled that: "We need not resolve the difficult question of when life begins", giving as the basis for such a ruling the fact that physicians, philosophers, and theologians were unable to reach a consensus on this point and that therefore the judiciary could hardly be called upon to decide it. The court accepted the concept of extrauterine viability as a crucial point of demarcation in fetal development, but also decided that the unborn child was not a "person" for purposes of constitutional protection of its rights. (Supreme Court of the United States. Roe et al. v. Wade, District Attorney of Dallas County. Appeal from the United States District Court for the Northern District of Texas, No. 70-18. Argued 13 December 1971 - reargued 11 October 1972 - decided 22 January 1973). See also Law Commission Report on Injuries to Unborn Children, Cmnd. 5709, and the Lancet, 21 September 1974, pp. 704 and 705.

[8] Great Britain, Advisory Group on The use of fetuses and fetal material for research, London, 1972.

[9] World Health Organization (1974) Report of a WHO Scientific Group on Health Statistics Methodology Related to Perinatal Events, p. 8 (Unpublished document ICD/PE/74.4).

that expulsion from the uterus of a fetus of 500 g or more should be reported as a birth, although it recognized that with periods of gestation of 22-28 weeks, corresponding to birth-weights of 500-999 g, the chances of survival were slender. Such correlations of birth-weights and periods of gestation are evidently approximations, and the differences between various criteria indicate how difficult it is to formulate universally acceptable quantitative standards of viability.

3. Artificial termination of pregnancy

There are few medicosocial questions about which such irreconcilable differences of opinion exist as the justifications or otherwise for induced abortion. In this context the right of the fetus to life and the right of the mother to health or even life may be in direct conflict. In general, when there have been changes in national laws relating to induced abortion these have been in the direction of increased permissiveness, although in a few countries the contrary is true.[10] However, even in countries in which induced abortion is permitted there is reluctance to authorize the operation after the twelfth week of gestation.

The reasons for which induced abortion is performed or requested may vary from a medical judgement that the mother's life will be threatened if the pregnancy goes to term to the wish of the mother not to have any children, or an additional child, or a child of an undesired sex. The last of these "indications" has been made possible by the relatively new technique of amniocentesis, by which the sex of the fetus may be diagnosed. There is at least one case on record in which a pregnant woman who had requested amniocentesis ostensibly to rule out the possibility of Down syndrome sought an abortion on learning that her fetus was a chromosomally normal female.[11]

According to the legislation of a number of countries, induced abortion may be performed for one or more of the following indications:

(a) to safeguard the physical or mental health of the mother;

(b) where a pregnancy results from rape or incest, or occurs in a female who is below a specified age;

(c) where the mother has had rubella at a critical stage of gestation with a resultant risk of congenital imperfections of the child, or has run some other risk, such as from drugs or ionizing radiations, of damage to fetal development;

(d) where Down syndrome or other chromosomal anomaly has been diagnosed by amniocentesis, or by other means;*

(e) where parents are mentally defective and considered to be incapable of caring adequately for a child.

Apart from these indications based on medical, eugenic, or medicosocial considerations, some legal texts provide for the authorization of abortion on socioeconomic or economic grounds. The extreme in the liberal attitude is provided by the so-called "abortion on demand" or "abortion on request".

There is universal recognition that induced abortion is not to be considered a preferred method of family planning.

---

[10] See World Health Organization (1970) Abortion Laws: a survey of current world legislation, Geneva.

[11] Stenchever, M. A. (1972) J. Amer. med. Ass., 221, 408.

* See page 13 under "Preventive medicine in genetic disorders".

An important medical consideration is that wherever artificial termination of pregnancy is illegal, there is likely to be a high rate of clandestine induced abortions performed under conditions offering a serious threat to the health and life of the mother.

New ethical problems are now being raised by the technique described as "menstrual regulation". This has been defined as "the artificial removal of endometrium within two weeks after a missed menstrual period. It is usually performed where pregnancy is suspected but unproven either by pregnancy tests or by clinical examination."[12]

4. Newborn with congenital defects

Acutely difficult ethical problems arise in the case of children born with congenital defects, such as microcephaly or Down syndrome, and who also have purely mechanical developmental defects, such as oesophageal atresia or imperforate anus, that are incompatible with viability. Such mechanical defects can usually be successfully treated by surgical intervention, but for this the consent of the parents is normally necessary. In such a situation, parents and physicians are faced with most painful and difficult decisions. The physician must search his own conscience to decide what degree, if any, of moral suasion he should bring to bear on the parents to agree to a life-saving operation. The life in question is of an imperfect human being capable only of leading a totally impaired existence with a corresponding burden on society, and with a short expectancy of survival. For the parents the dilemma is whether to insist on the passive infanticide of their own child, or to agree that it should be rescued from certain death to lead a subnormal existence of equal certainty. Where the defect is extreme, as in microcephaly, parents and physicians alike would probably agree to let Nature take its course in most cases. Where, as is the case with Down syndrome, the defect is severe but not incompatible with loving parent-child relations, the decision is much more difficult.

No universally applicable criterion can be framed to provide guidance for such a broad spectrum of differing situations, but it is suggested that as a general rule the decision should be that of the parents, the role of the physician being to explain to them as accurately as possible the consequences of the available options. The physician and all other members of the health team are strongly motivated to intervene to save life wherever this is possible. Moreover, for the hospital staff, especially the nurses, the need to tend to an infant inevitably dying from a curable condition is a deeply traumatic experience. Such considerations may induce the physician to persuade the parents to agree reluctantly to surgical intervention, but they may afterwards reject the infant.

5. Use of human fetuses for research

For some investigations the use of human fetal tissue is indispensable. These include, inter alia, the culture of certain pathogenic viruses that do not grow in non-human cells, the manufacture of certain vaccines, immunological and chromosome studies, research on human fetal development, and other fields of research. Physiological and pathological research is sometimes performed on whole fetuses that have been expelled from the uterus but are not sufficiently developed to sustain a separate existence.

The national Advisory Group to which reference has already been made[13] reported on the ethical implications of the use of fetuses and fetal material (amniotic fluid and sac and the placenta). This Group made certain recommendations for the guidance of those involved in research on the human fetus. It unconditionally rejected any experiments on a living fetus in utero even in cases in which arrangements had been made to terminate the pregnancy

---

[12] Lancet, 1974, 1, 84.

[13] See Ref. 8 on p. 7.

artificially. In a "Recommended Code of Practice" the Group rejected any experiments on a fetus presumptively viable after separation from its mother and proposed that whole living but non-viable fetuses should be used for research purposes only when under 300 g in weight. Responsibility for deciding on the use of a fetus for research purposes should, in the view of the Group, rest "with the medical attendants at its birth and never with the intending research worker" and should be subject to the sanction of an ethical committee of the hospital. The Group insisted that there should be no pecuniary considerations involved in the acquisition of fetuses or fetal material for research purposes.

The unconditional rejection of experiments in utero on fetuses to be aborted artificially is not universal, as illustrated by a recent scientific report on the administration to pregnant women, with their consent, of antibiotics in order to determine the concentration of those substances in the tissues of the aborted fetuses.[14]

It may be mentioned that a law severely restricting fetal research came into force in the State of Massachusetts (United States of America) on 26 June 1974,[15] while at the federal level the National Research Act of 1974 (signed into law on 12 July 1974) imposed an interim moratorium on all research on living human fetuses conducted or supported by the United States Department of Health, Education, and Welfare.[16]

6. Sterilization

6.1 Voluntary

Is it a human right for a man or woman to decide to be sterilized by vasectomy or salpingectomy, or comparable surgical intervention, for reasons other than the protection of health? In some countries such a right is recognized, subject to conditions such as the age of the subject, marital status, consent of the other spouse in the case of married couples, a written request for the operation and sometimes a statutory delay between the making of the request and the date of the operation. In other countries an operation for sterilization is a criminal offence unless performed for strictly medical reasons.

In the female, the most common ground for sterilization is to protect the woman from the possibility of pregnancies that will threaten her life. In the male, health considerations may arise on two counts, firstly, when fear of causing pregnancy may cause mental or physical disorder, and, secondly, from the point of view of potential adverse health effects of sterilization.

It may be of interest to cite the following statement, which appears in the Proceedings of an international meeting on the subject held in 1973:[17]

"A MODEL VOLUNTARY STERILIZATION LAW - PREAMBLE

In 1968 the Proclamation of Teheran was adopted by the International Conference on Human Rights: Paragraph 16 provides that '. . . parents have a basic human right to determine freely and responsibly the number and the spacing of their children.'

---

[14] Philipson, A., Sabath, L. D. & Charles, D. (1973) New Engl. J. Med., 288, 1219-1221.

[15] Family Planning/Population Reporter, 1974, 3, 70.

[16] Edwards, C. C. (1974) Science, 185, 900.

[17] Schima, M. E. et al., ed. (1974) Advances in voluntary sterilization (Proceedings of the Second International Conference, Geneva, 1973), Amsterdam, Excerpta Medica, pp. 275-276.

Any law which imposes compulsory sterilization on any individual, is inconsistent with the principles of the Teheran Proclamation. The following provisions of law are recommended to effectuate those principles and provide for freedom of choice in the matter of voluntary infertility.

I. Generally applicable

Every individual of either sex has the right to obtain a procedure that will establish voluntary permanent infertility, and the government has an obligation to make available appropriate services subject to the following.

1. The individual is over the age of legal consent and furnishes evidence of his or her voluntary consent.

2. The individual is fully informed by an appropriate person of the immediate, the possible and the probable long-term consequences of the procedure, and is informed of the various methods of family planning. When appropriate the individual shall also be encouraged to consider carefully over an interval of time the consequences of the different courses of action available.

3. If an individual is a member of a particular ethnic, religious or philosophical group, he or she shall be offered the option of receiving such information (as set out in 2 above) jointly from the person giving the information and a representative of the group concerned, unless the person giving the information belongs to that group.

II. Applicable to incompetents

The following shall apply with respect to any person who does not have legal capacity to consent: if the parents or guardian of such a person, and a physician have decided that temporary measures will be ineffective, they may apply for a procedure to render that person permanently infertile to a Board, duly appointed by the appropriate authority, which may after full consideration, grant their application.

The Board shall consist of at least 5 persons, both lay and professional of both sexes, which shall act by a vote comprised of either a majority, 1/2-1/3, or unanimous, as the appropriate authority may decide.

The Board shall also include a person or persons, representative of the particular ethnic, religious or philosophical group of which the person who is the subject of the application is a member.

III. Performance by individuals

Nothing in these provisions of law shall compel any individual to participate in providing a voluntary infertility procedure, but any individual declining to participate shall have the obligation to inform the requesting individual of another person or facility which offers such procedures. However, every government-supported facility shall be obliged to make such procedures available.

IV. No effect on marriage and divorce laws

Nothing in these provisions of law shall be interpreted to modify the laws on marriage and divorce which shall apply to the question of the consent of the spouse.

V. No liability for non-negligent voluntary infertility procedure

Note. Although there was no time for the workshop to act, it is believed that most members of the workshop would endorse a statement along the lines of the following: 'No physician or other person or health facility shall be held civilly or criminally liable for proceeding in accordance with the foregoing provisions.'"

6.2 Compulsory

In some countries both males and females with severe mental retardation or mental illness may be sterilized for eugenic reasons, or on the grounds that the parents are incapable of giving a child proper care, although the consent of the subject's legal guardian may be required. In other countries such surgical interventions would be regarded as a criminal encroachment on human rights. In certain countries, abortion may be authorized under specific circumstances only on condition that sterilization is likewise performed. It should be mentioned that in countries permitting compulsory sterilization, there is a tendency for the practice to fall into disuse.

7. Castration

Some countries recognize in their legislation the right of a male to be castrated at his own request if he suffers from pathological sexual impulses. This right is usually limited by reference to medical considerations, the age of the person concerned, and his ability to understand the nature and effects of the operation. A written medical opinion by an impartial physician may be required, and this opinion may have to be signed by the person requesting the operation. When submission to this operation is likely to result in earlier release from incarceration in a psychiatric or penal institution, its voluntary character may be regarded as questionable.

8. Contraception

Changes in attitudes, with important consequences for certain human rights now considered fundamental, can be demonstrated by the evolution of ideas relating to contraception.

Up to a few years ago, the legislative provisions dealing with the sale and distribution of contraceptives imposed prohibitions or severe restrictions on these products in some countries. Advertising to the public was even considered to be immoral or indecent. Discussions on such subjects as birth control, fertility regulation, or family planning were difficult if not impossible and the available means were, moreover, unknown or inaccessible to the population.

This situation obtaining at the national level clearly had repercussions on any proposed international programme. During the deliberations of the Committee on Programme and Budget at the Fifth World Health Assembly in 1952,[18] for instance, it was stated that it was not possible for WHO to be engaged in the "health aspects of the population problem". Changes in attitudes were slow to come. The decision that WHO could engage in this type of programme was, in fact, taken only in 1965.

The preamble to resolution WHA18.49 recognizes that "problems of human reproduction involve the family unit as well as society as a whole" and that the size of the family should be the free choice of each individual family. Operative paragraph 2 requests WHO to develop

---

[18] Off. Rec. Wld Hlth Org., 1952, No. 42, pp. 204 and 230.

a programme "in the fields of reference services" involving studies on medical aspects of sterility and fertility control methods and health aspects of population dynamics.[19]

The 1968 Teheran Proclamation constitutes another landmark in the modification of attitudes. This Proclamation expresses the right of the family in the following terms:

> "Couples have a basic right to decide freely and responsibly on the number and spacing of their children and the right to adequate education and information in this respect."

The Proclamation was followed in 1969 by the General Assembly Declaration on Social Progress and Development (resolution 2542 (XXIV)), of which Article 4 states the same principle while, in addition, Article 22(b) implements the principle by requiring "the provision to families of the knowledge and means necessary to enable them to exercise their right to determine freely and responsibly the number and spacing of their children".

Recently, the World Population Plan of Action (adopted during the World Population Conference, Bucharest, 19-30 August 1974) stated (in paragraph 6 of the background to the Plan) that "While the right of couples to have the number of children they desire is accepted in a number of international instruments, many couples in the world are unable to exercise this right effectively. In many parts of the world, poor economic conditions, social norms, either inadequate knowledge of effective methods of family regulation or the unavailability of contraceptive services results in a situation in which couples have more children than they desire or feel they can properly care for."

As recommendations for action, an important aspect is mentioned which interests WHO, namely that basic biological and applied research on the assessment and improvement of existing and new methods of fertility regulation are necessary. Also, that the evaluation of the impact of different methods of fertility regulation on ethical and cultural values and on mental and physical health, both in short-term and long-term effects, as well as the assessment and study of policies for creating social and economic conditions so that couples can freely decide on the size of their families, are essential.

The activities of the World Health Organization cover three main areas, namely, human reproduction, family planning, and population dynamics. The introduction of family planning into health services, provision of appropriate education and training for health personnel at all levels, and research into human reproduction, both biomedical and operational, are the main elements.[20]

One of the important elements of the WHO programme is the integration of family planning into health services. Another important component is the research programme designed to develop a variety of safe, effective, and acceptable methods of human fertility regulation.

It has been repeatedly stressed that population policy remains within the sovereign right of each country. Again, therefore, the role of WHO is to provide advice and assistance on request.

9. Preventive medicine in genetic disorders[21]

The considerable advances that have been made in medical genetics in recent years have given rise to much speculative discussion and writing on the ethical and social implications of "genetic manipulation" or "genetic engineering" as applied to human beings. However, any human applications of such techniques are so far removed from current practical possibilities

---

[19] World Health Organization (1973) Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Vol. I, 1948-1972, Geneva, p. 40.

[20] Zahra, A. & Strudwick, R. (1973) International Journal of Health Services, 3, 701-707.

[21] The question of potential hazards associated with certain types of genetic experimentation is dealt with on page 28.

that it is doubtful whether they can yet be regarded as a matter of legitimate concern at the levels of public health authorities, national legislative bodies, or intergovernmental organizations.

Conversely, in the field of genetic counselling a great practical advance with important medicosocial implications is the prenatal diagnosis of congenital anomalies by culturing fetal cells obtained by amniocentesis, or by biochemical analysis of the amniotic or other fluids. It is generally agreed that there may be risks involved in amniocentesis - including damage to the fetus, infection, and abortion - but that with proper precautions they are negligible, especially at a period of gestation (16 weeks) at which the amniotic fluid is copious.

The techniques of chromosomal analysis of material obtained by amniocentesis are sophisticated, and the number of laboratories equipped to carry them out is relatively small. It has therefore been suggested that the procedure is not justifiable unless the parents are willing and legally able to have the pregnancy terminated if a prenatal diagnosis of abnormality is made. Against this view it has been argued that parents who know in advance that their child will be abnormal are better prepared to deal emotionally with a situation that is in any circumstances painful.

The fact that some genetically determined abnormalities are more common in certain ethnic groups is to be taken into account in deciding whether to adopt systematic screening programmes with a view to eventual termination of pregnancies. It has happened that the limitation of screening programmes to the most susceptible ethnic groups has led to unfounded suspicions of an intention to introduce a discriminatory form of population control.

Recently there have been reports of the successful diagnosis of anencephaly by biochemical analysis of amniotic fluid obtained by amniocentesis. This condition may also be diagnosed by ultrasonic scanning, and, most recently, by analysis of intravenous blood samples for α-fetoproteins.

A congenital disorder that cannot be diagnosed until some days after birth is phenylketonuria, and in some countries routine neonatal screening for this condition is in force. On the question whether such screening should be made obligatory by law there are different opinions. Estimates made both in the United Kingdom and in the United States of America agree that the risk is that about one in 10 000 infants may have this congenital metabolic abnormality. It is evident that only economically developed countries can contemplate nationwide programmes for protecting one in 10 000 infants from developing preventable mental defect and for providing special diets to this end.

10. Artificial insemination

The problems of artificial insemination are predominantly legal rather than medical, but it is incumbent on the physician who performs this procedure to assure himself that both spouses are fully aware of the legal implications of their decision, which may vary from one country to another.[22] When the donor is the husband (AIH), the problem may arise as to whether the marriage has been consummated and whether either of the spouses may later seek a divorce to annul the marriage on the ground of non-consummation.

When the source of the sperm is a donor other than the husband (AID), it is a prime responsibility of the physician to ensure that the donor is free from communicable disease or detectable undesirable genetically determined traits. The Sanitary Code of New York City, as amended in 1950, contained regulations for artificial insemination, specifically requiring

---

[22] The legal implications are fully discussed by Glanville Williams in The sanctity of life and the criminal law, London, Faber, 1958.

that the donor be free from syphilis, gonorrhoea, tuberculosis, or genetic defect. It also required that the donor and recipient should be Rh-compatible. The regulations did not cover non-medical considerations, such as whether donor and recipient should belong to the same ethnic group or whether the physician should attempt to match the physical attributes of the donor with those of the husband.

The legal problems involved in AID are considerable, and one of the most important of them is the legitimacy or otherwise of the infant. Some physicians mix donated semen with that of the husband so that there may be an element of uncertainty as to who is biologically the father. When a marriage has been dissolved after successful AID, the questions of the "father's" right of access to the child or obligation to contribute to its maintenance may arise. The question as to whether AID constitutes adultery in law has also been discussed. In general, religious opinion is strongly opposed to AID.

In recent years, ethical problems have been raised by new artificial insemination techniques leading to so-called "test-tube babies", and by the preservation of human sperm by means of sperm cryobanks.

11. Human experimentation in general

In considering any aspect of the broad and important subject of health aspects of human rights, it should not be forgotten that medical science and practice have made more progress within the life span of many who are still living than was previously made in the whole of human history. This progress has essentially resulted from the growing recognition that new and valid medical knowledge can be won only by scientifically controlled experimentation, and that a point must be reached when for the last - and conclusive - experiment the only possible subject is man. In this sense, human experimentation is inseparable from advances in knowledge of the means and techniques by which disease may be combatted and health promoted.

As regards human experimentation, the Helsinki Declaration of the World Medical Association has been very widely acclaimed as establishing the basic ethical principles that should govern research involving human subjects. This Declaration does not, and was not intended to, cover other situations in which non-experimental medical interventions of one kind or another have ethical or social implications.

The limits of what constitutes human experimentation in medicine are not easy to define. Insofar as each individual patient is unique, every therapeutic intervention, whether medical or surgical, is to a limited extent experimental, and the attending physician must be prepared to modify or change his therapy in accordance with the patient's specific response to it. Drugs of proved value may produce adverse reactions in a small minority of subjects, and every new surgical technique must be tested for the first time on human beings, often after exhaustive animal experiments have led to a virtual certainty of its safety.

In short, all medical progress implies, and has always implied, human experimentation. When Edward Jenner first in 1796 inoculated a boy with pus from a cowpox lesion and subsequently inoculated the boy with smallpox pus, he was conducting a very crucial experiment that could not have been made on a non-human subject. As the boy in question was only eight years of age he can hardly have been considered to have given "informed consent"[23] to this experiment, which might be regarded as unethical by today's standards. Yet, even in modern times, a stage was reached when poliomyelitis vaccine had to be tested for the first time in children of school age. Both these immunoprophylactic experiments on human beings - separated by over 150 years - have conferred incalculable benefits on humanity.

---

[23] See section 12.

Broadly speaking, the options in relation to human experimentation are few, and may be summarized as follows:

(a) No further advances should be permitted in preventive or curative medicine. Such a proposition is clearly untenable.

(b) New therapeutic preparations or procedures should be approved for general use solely on the basis of trials in animals. This would be tantamount to mass uncontrolled human experimentation, many of the experimenters not being fully qualified to assess results. Moreover, suitable animal models are not available for some kinds of prophylactic or therapeutic research.

(c) New therapeutic interventions should not become an established part of medical practice until they have been tested by fully qualified investigators on a statistically significant sample of human patients under experimental conditions that will guarantee an acceptable balance of probability of benefit as opposed to that of risk. This is an option that is, for obvious reasons, more readily applicable to immunoprophylactic or to pharmacotherapeutic than to surgical interventions - such as organ transplants. For example, one successful haemodialysis for renal failure would have justified the use of the technique on others. The word "acceptable" in this context is not susceptible to a universally applicable definition.

(d) Before being made available for controlled clinical trials as in (c) above, the safety of new therapeutic substances should be tested on healthy human volunteers.

As a general conclusion it may be asserted that for most of human history therapeutic interventions were empirical, lacking the statistical and other scientific controls now recognized as essential, sometimes effective and sometimes completely inefficacious. As therapeutic interventions have become progressively more effective, the criteria for their adoption and for safeguarding the interests of the patient have become progressively more stringent.

12. Informed consent of volunteers for experimentation

The Nuremberg Code of 1947 precludes any experiment on a human subject without his "voluntary consent", and this principle has remained absolutely unchallenged. Experiments on healthy human volunteers that involve no greater risk than a mild degree of physical discomfort have not come under criticism. As examples may be cited experimental infections with the common cold or with scabies. Where a more serious disturbance of health is involved, such as experimental infections with malaria in human subjects, opinions are divided, especially on the crucial question of what constitutes consent. While the Nuremberg Code speaks of "voluntary consent", both the Declaration of Helsinki (1964) of the World Medical Association and the International Covenant on Civil and Political Rights (1966) of the United Nations use the term "free consent". More recently the term "informed consent" has been widely used. It is generally agreed that children, mental defectives, and the mentally deranged cannot give valid consent, although their parents or other legal guardians may in certain circumstances give consent on their behalf. Normally such vicarious consent would be given in the expectation of some therapeutic benefit to the subject, but this not invariably so as exemplified by a much-discussed case in which retarded children were deliberately infected with infectious hepatitis on admission to an institution. The disease was endemic in the institution, and there was a very high risk that new inmates would become infected naturally. Specific recommendations as to the age or the level of adult understanding at which consent should be regarded as valid do not seem to have been made.

Criticisms have often been made of the use for human experimentation of special segments of the population, such as students and inmates of prisons. Critics maintain that in such groups there may be special incentives - such as the desire of students to find favour with professors or to avoid the appearance of being uncooperative - that invalidate consent. In the United States of America there has been widespread use of volunteers from among prison populations for the first clinical trials of new pharmaceutical preparations and other investigations. Prisons permitting this practice may have a detailed tariff of cash payments made for various interventions. In one case these range from 25 cents for a stool specimen to $ 12 for a bone-marrow aspiration.

Testifying before a United States Senate subcommittee in 1973, the President of the Pharmaceutical Manufacturers Assocation of the United States of America advanced two main justifications for this use of volunteer prisoners: (i) the subjects were "relatively homogeneous", and living in a constant environment as regards time, place, diet, and exercise; (ii) they were willing to volunteer for a far lower financial reward than would be the case with non-prisoners.[24] The witness testified that "the most important factor behind prisoner participation is financial reward", and gave as additional reasons "to escape the tediousness of prison life; to be part of a commendable effort; to show themselves and others that they can do good and worthwhile things; to gain acknowledgement as individuals deserving respect; to show authorities that they are reforming".

The United States Department of Health, Education, and Welfare has issued regulations to be complied with by organizations seeking grants or contracts from the Department for medical research involving human subjects.[25] According to these regulations, the basic elements of information necessary for "informed consent" include:

> "(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
>
> (2) a description of any attendant discomforts and risks reasonably to be expected;
>
> (3) a description of any benefits reasonably to be expected;
>
> (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
>
> (5) an offer to answer any inquiries concerning the procedures; and
>
> (6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject."

It is increasingly accepted that in addition to the informed consent of the subjects to the investigator responsible for medical research involving human beings there should be a detailed review and approval of the proposed experiment by a committee composed of members not directly involved in the project. Some consider that such committees should include one or more non-medical members, such as lawyers and ministers of religion.

---

[24] United States Congress. Senate Committee on Labor and Public Welfare. Subcommittee on Health. Quality of health care - human experimentation, 1973. Hearings . . . Ninety-third Congress, First Session, Washington, 1973, pp. 864-883.

[25] United States, Code of Federal Regulations, Title 45, Part 46 (Federal Register, vol. 39, No. 105, 30 May 1974, pp. 18913-18920). The Department has also issued proposed rules applicable to fetuses, abortuses, pregnant women, in vitro fertilization of human ova, prisoners, and the institutionalized mentally disabled (ibid., No. 165, 23 August 1974, pp. 30647-30657).

The case for review committees is all the stronger in that printed guides cannot adequately cover all contingencies. For example, the justification for the first community trials of a new vaccine in children calls for ad hoc review by a suitably qualified committee rather than reference to abstract principles.

13. Trials of therapeutic substances in human beings

For almost the whole of the millennial history of therapeutics, pharmacotherapy implied the administration of natural products, whether of animal, vegetable, or mineral origin. Most of these products were, in the doses used, as harmless as they were inefficacious and they were usually prescribed as mixtures supposedly appropriate to the specific symptoms of each individual patient. The sole judge of the adequacy or safety of medicaments was the individual prescriber, who would, in the words of a Victorian physician, write a prescription including "a drug for every symptom, and a few more for the pool". Pharmacopoeias represented, and still represent, an attempt to control the quality of drugs without reference to their effects upon the human body.

Today there is an entirely different situation, in that the manufacture of new substances for therapeutic purposes has become a major industry. Thousands of such substances that never existed before are produced and exhaustively tested on animals for their pharmacological effects. Many, probably the majority, are rejected as not showing any promise of therapeutic effect or as being too toxic. Those that appear to be of potential therapeutic interest are subjected to more exhaustive animal tests, about which recommendations have been made by a WHO scientific group on Principles for Pre-Clinical Testing of Drug Safety.[26] Other WHO scientific groups have made recommendations on Principles for the Testing of Drugs for Teratogenicity,[27] Principles for the Testing and Evaluation of Drugs for Carcinogenicity,[28] and Evaluation and Testing of Drugs for Mutagenicity: Principles and Problems.[29]

Nevertheless, however exhaustive and apparently conclusive may be the results of tests on animals, the final demonstration of the therapeutic efficacy and the safety of a new medicament can only be made on human subjects. As new therapeutic substances have become more numerous, and as their potential for doing good or harm has increased, the conditions under which such a final demonstration should be made have in recent years been the subject of much discussion and, in some countries, of specific legislative provisions aimed at protecting the right of the ultimate consumer not to be exposed to unwarranted risks to health. As Sir Derrick Dunlop, first Chairman of the Safety of Drugs Committee of the United Kingdom, has said: "Modern medicines are now such potent weapons that it is generally agreed that the sole responsibility for their safe production and use can no longer be left entirely to the manufacturer and prescriber".[30] This tendency for legislative bodies to intervene by defining conditions to be satisfied before new therapeutic substances are introduced into medical practice received considerable impetus from the consternation aroused by the teratogenic effects of thalidomide. The fact that such effects were entirely unexpected and, indeed, unprecedented, alerted the whole world to the need for the most scrupulous screening of new compounds before sanctioning their use for medical purposes. However, in 1967 a WHO scientific group on Principles for the Clinical Evaluation of Drugs[31] expressed the opinion that a review of the purpose and design of

---

[26] Wld Hlth Org. techn. Rep. Ser., 1966, No. 341, 1-22.

[27] Wld Hlth Org. techn. Rep. Ser., 1967, No. 364, 1-18.

[28] Wld Hlth Org. techn. Rep. Ser., 1969, No. 426, 1-26.

[29] Wld Hlth Org. techn. Rep. Ser., 1971, No. 482, 1-18.

[30] Dunlop, D. (1971) Good practices in the manufacture and quality control of drugs, Basle, Pharma Information.

[31] Wld Hlth Org. techn. Rep. Ser., 1968, No. 403, 1-32.

a proposed trial of a new therapeutic substance "by local research committees composed of physicians and experienced medical research workers ('peer groups') may actually be more effective than laws in protecting both the patient and the investigator", but added that there had so far been "a failure to consider needs /in terms of financial compensation/ of human subjects who are injured in the course of an ethically irreproachable human experiment". The group suggested that human subjects of experiments should be covered by a special insurance system that would provide appropriate compensation in case of "injury or death during investigation".

Legal requirements in the United States of America for the testing of new drugs on human beings are very stringent, and involve three phases.[32] Phase 1 takes place after all available animal and in vitro data are reviewed and is essentially a "tolerance" trial in a limited number of healthy human volunteers. It is typically for this phase that volunteers from prison populations,[33] usually 10-12 in number or more as indicated, are used. Phase 2 "covers the initial trials on a limited number of patients for specific disease control or prophylaxis", while phase 3 is the period of full clinical trials "conducted by separate groups following the same protocol". These and many other relevant requirements are formulated by the United States Food and Drug Administration, which Dunlop has described as the "pioneer regulatory organization".[34]

Another country in which detailed requirements for testing new medicaments in man have been promulgated is Austria.[35] These requirements, issued as "guidelines", were addressed in a circular of the Federal Ministry of Social Affairs to Provincial Governors with the request that they be brought to the notice of all physicians in charge of hospitals. The guidelines define fully the requirements for preclinical testing and, as in the case of the United States regulations, distinguish between clinical pharmacology (phase 1 and phase 2 in the United States regulations) and clinical trials (phase 3). One provision (11.1) is that only "healthy persons, or at least persons not seriously ill, may be considered as subjects for a clinical pharmacological study". Subjects must be informed of the nature of the study and must have given their consent. "Consent" is not defined.

In most countries physicians have, individually and collectively, considerably more latitude in determining what safeguards are necessary in the interests of the patient or healthy human subject involved in tests of new medicaments. In France, an Order of the Ministry of Public Health of 1972 required that those engaged in clinical trials of medicaments should take into account "the ethical imperatives that govern trials in man".[36] A decree issued in the same year required that pharmaceutical manufacturers should select experts to undertake clinical experiments from a list established by the Minister of Public Health on the advice of a committee of medical and pharmaceutical experts.[37] No distinction is made in either of these documents between clinical pharmacology and clinical trials, and the need for consent of the human subject is not expressly stated, although it may be taken to be implied by the term "ethical imperatives".

---

[32] United States, Code of Federal Regulations, Title 21, Parts 130 to 146e, Washington, 1970.

[33] See section 12.

[34] Dunlop, D. (1971) op. cit.

[35] Mitteilungen der Österreichischen Sanitätsverwaltung, 1970, 71, 17-20. Full English and French translations of these guidelines are to be found in the corresponding editions of the International Digest of Health Legislation, 1971, 22, 18-24.

[36] Journal officiel de la République française, 11 June 1972, p. 5902. Text reproduced in English in the International Digest of Health Legislation, 1972, 23, 740-742.

[37] Journal officiel to la République française, 30 November 1972, pp. 12405-12408. See International Digest of Health Legislation, 1973, 24, 305-315.

Yet another approach has been adopted in the United Kingdom, where the Ministers of England and Wales, Scotland, and Northern Ireland responsible for health, jointly appointed in 1963 a Committee on Safety of Drugs. The functions of this committee were to advise manufacturers whether clinical trials of new drugs were justifiable, and whether the results of such trials were such that the drugs should be released for marketing, to collect and investigate reports of adverse reactions, and to advise the appointing Ministers accordingly. This committee was replaced in 1970 by the Committee on Safety of Medicines, which was appointed under Section 4 of the Medicines Act 1968[38] and 1971 and which reports to the appointing Ministers and also to a "Medicines Commission". Whereas the original committee relied upon the voluntary cooperation of manufacturers, in accordance with a sort of "gentleman's agreement", the new one is the technical advisory body for a statutory licensing system.

The few examples cited above show the different modalities of approach to the solution of the increasingly difficult problem of how to safeguard the rights of the patient and the healthy volunteer without placing vexatious and counter-productive obstacles in the path of therapeutic progress. At one extreme there are rigid, very detailed, and legally enforceable requirements covering not only the various phases by which a new medicament may be tested on humans and ultimately marketed but also specifying the type of information that should be included in labelling and advertising in respect of indications, contraindications and possible adverse reactions. At the other extreme, the highest medical authorities in the country nominate clinical investigators in whom they have confidence, and these are authorized by the government to conduct trials in accordance with their own conscience. An intermediate solution is that in which a panel of experts advises the responsible governmental authority what clinical trials should be authorized and what products should, after such trials, be licensed.

All such solutions have the same objective: to deny to the incompetent or unscrupulous investigator the opportunity of exposing his patients or other human subjects to unjustifiable or unnecessary risks to health. Whatever regulatory system may be adopted, there will always be a few physicians who are not sufficiently sensitive to the innate rights of the fellow human beings to whom they are responsible. Under any system, the justification or otherwise of an experimental procedure performed on human beings must rest ultimately on the technical judgement of the general body of physicians with the participation of the community, which provides the surest safeguard against abuses.

14. Publication of results of human experimentation

A question that has been much discussed is whether editors of biomedical journals should accept for publication articles reporting experiments that may be considered unethical in that they have been carried out without due regard to the rights of the human subjects concerned. The general view appears to be that such articles should be rejected, and this was the position taken by the European Association of Editors of Biological Periodicals at a meeting held in 1972. Beecher[39] and others have advanced in favour of such a policy the argument that a prior knowledge that the results will not be published will discourage investigators from performing unethical experiments.

Be that as it may, it is beyond question that once a scientific investigation on human subjects has been carried out, publication of results and methods in scientific journals offers the only means by which the activities of investigators may be exposed to the judgement of their peers and of society at large.

---

[38] Reproduced in the International Digest of Health Legislation, 1969, 20, 509-557.

[39] Beecher, H. K. (1966) New Engl. J. Med., 247, 1354-1360.

Within recent years Beecher[40] and Pappworth[41] have made thought-provoking studies, based on published results, of allegedly unethical, or questionably ethical, medical investigations on human subjects.

An example of an experiment carried out without due regard to the human rights of the subjects was the deliberate withholding of treatment from some 400 syphilitic males, all of them belonging to an ethnic minority. This experiment, which started in 1932, was continued for no less than 40 years, by which time the survivors numbered less than 80. Participants were not told that they had syphilis, nor that they were the subjects of a longitudinal study on the effects of withholding treatment for the disease, the study lasting until the end of the lives of most of them. Those who had survived did not learn until 1972 that they had been experimental subjects for 40 years. The experiment was terminated as a result of publicity given to it by a journalist in the daily press. Had the details of this investigation been fully reported in the medical press at its inception and during its course, it is inconceivable that it could have continued.

It should in fairness be added that, when the above-mentioned experiment was started, available treatments of syphilis were highly disagreeable and not without danger, involving injections of rather toxic compounds over a period of months. However, when, starting in 1943, the penicillin treatment of syphilis was introduced, the situation changed radically.

15. The moment of death

15.1 The definition of death

Just as the definition of the beginning of life and the acquiring of human rights have given rise to heated controversy, other problems have been raised as to the definition of death especially in circumstances where the use of organs for transplantation purposes is envisaged. (It is of course evident that in most deaths, the diagnosis presents no problem.) In most countries a person is legally dead when certified to be so by a qualified physician, and laws do not normally attempt to usurp the physician's prerogative in this respect by specifying in physiological terms what are the criteria according to which the physician should reach his verdict. An exception is to be found in a law promulgated by the State of Kansas, United States of America, in 1970, which lays down such criteria.* The view has been expressed that this law not only constitutes an encroachment on the responsibility of the physician but is also directed more towards the interests of a prospective recipient of an organ transplant than to those of the involuntary donor.[42]

Where, as is the general rule, society leaves to the physician the task of pronouncing an individual dead, the grounds upon which he may make this decision have much changed well within living memory. For almost all of man's history the absence of any detectable motion of the heart and of spontaneous respiration was synonymous with death. Today, the artificial maintenance of cardiorespiratory function has made this criterion invalid, and it has been replaced by that of irreversible interruption of brain function. This may be due to trauma, a stroke, a cerebral tumour, an acute intoxication, or any cause depriving the cerebral cells of oxygen for more than a few minutes.

---

[40] Beecher, H. K. (1966) op. cit.

[41] Pappworth, M. H. (1967) Human guinea pigs. Experimentation on man, London, Routledge & Kegan Paul.

[42] Kennedy, I. M. (1971) New Engl. J. Med., 285, 946-950.

* The States of New Mexico and Virginia adopted similar legislation.

In 1968 a group at Harvard University, United States of America, under the chairmanship of H. K. Beecher, formulated criteria for deciding on medical grounds what was the point of no return.[43] The approach of this group was pragmatic, in that it did not attempt to define "death" but rather to agree on what were the signs of "irreversible coma". The main sign proposed by the group was the absence of electrical impulses from the brain as measured by the electroencephalograph for at least 24 hours, except in barbiturate intoxication or hypothermia. The tracing obtained in such a state has variously been described as a "flat", "isoelectric", or "linear" electroencephalogram.*

The conclusions of the Harvard group have been widely but not universally accepted. The World Medical Association in its Declaration of Sydney of 1968, while conceding that the electroencephalograph is the most useful of diagnostic aids in establishing the irreversibility or otherwise of coma, deprecated the idea of placing exclusive reliance on one instrument.[44] Beecher has expressed disbelief in claims that there have been instances of recovery after the electroencephalogram was flat for several days, and he supports his scepticism by reference to a study showing that there was not a single recovery in 1662 cases.[45] In a survey conducted by a committee of the American Electroencephalographic Society there were 26 presumed recoveries among 2650 cases of isoelectric encephalogram. However, in 23 of these the electroencephalographic findings were considered to be inconclusive. The remaining three cases resulted from overdoses of a sedative drug, and would therefore have been excluded by the criteria of the Harvard group.[46] The above-mentioned committee used the term "electrocerebral silence" to denote absence of electroencephalographically detectable brain function. It is to be noted that to reach agreement on the criteria for diagnosing irreversible loss of cerebral function is important not only in regard to the use of still-living organs for transplantation. To maintain needlessly the functioning of what has become in fact a physiological preparation is to prolong the distress of the patient's family and possibly to divert skilled personnel and specialized equipment from those who would derive real benefit from them.*

In 1968, the CIOMS Round Table Conference on Heart Transplantation adopted a set of criteria for determining the "complete and irreversible cessation of cerebral function".[47]

15.2 The right to die

There is also the problem of the patient with a terminal illness who suffers great pain or disability and has formed a firm and irrevocable wish to die. It is a widely held opinion that in such a situation, although a physician may in no circumstances deliberately take the life of another, he should do what is in his power to ensure for his patient a painless and dignified death, even in the knowledge that the measures he adopts may slightly accelerate the extinction of life. As an eminent judge has put it: "If the first purpose of medicine - the restoration of health - can no longer be achieved, there is still much for the doctor to do, and he is entitled to do all that is proper and necessary to relieve pain and suffering even if the measures he takes may incidentally shorten life".[48]

---

[43] J. Amer. med. Ass., 1968, 205, 85-88.

[44] The text of this Declaration is reproduced in Wld med. J., 1972, 19, 29-30.

[45] Beecher, H. K. (1970) Ann. N.Y. Acad. Sci., 169, 471-474.

[46] Silverman, D. (1971) Ann. int. Med., 74, 1003-1005.

[47] See Fattorusso, V., ed. (1969) Heart transplantation (Proceedings of 2nd CIOMS Round Table Conference), Liège, pp. 51-52.

[48] The quotation is from Sir Patrick (now Lord) Devlin's summing-up in the trial of Dr J. Bodkin Adams; see Bedford, S. (1962) The trial of Dr Adams, New York, Time Incorporated, p. 245.

* For references to other criteria, see De Moerloose, J. (1974) in Btesh, S., ed., Protection of human rights in the light of scientific and technological progress in biology and medicine (Proceedings of the 8th CIOMS Round Table Conference), Geneva, pp. 338-341.

Another aspect of what is often referred to as "the right to die" might be illustrated by the case of cancer patients with generalized metastases. The following dilemma in cases of attempted suicide may arise for the physician: to maintain at all costs, and against the wishes of the patient, the life of the latter after a suicide attempt, or to let nature take its course.[49]

16. Tissue and organ transplants

Autografts of human tissue - that is, the grafting of tissues from one part of a person's body to another with therapeutic intent, notably in the case of skin-grafting for burns, clearly do not involve bioethical problems. In these, as in any other medical interventions, the physician's judgement may be exercised without reference to the interests of a third person or to social values. Grafts from one identical twin to the other act as autografts, but here ethical problems may be involved. Except in the case of kidney transplants, the possibilities of homografts from one individual to another of the same species (other than an identical twin) are very limited in the present state of knowledge of immunosuppressive therapy. Since 1951, some thousands of kidney transplants have been performed with a reasonable expectation of a five-year survival. The proportion of living donors used is currently estimated at 37% in the United States of America and 21% in Europe.[50] Other grafts are for practical purposes restricted to transfusions of immunologically compatible blood from living donors (although cadaver blood has also been used), for which typing procedures are satisfactory, and to the use of corneas, lengths of artery, and bone or cartilage from human cadavers, in which typing is not necessary.

The bioethical problems posed by organ transplants have already been treated in this report, if only by inference, in the references to the pragmatic definition of the moment of death (section 15) and to the concept of informed consent (section 12). The latter concept is relevant to the decision as to the circumstances in which a healthy identical twin or other immunologically very similar person should sacrifice a paired organ - the kidney - to save the life of another. To attempt to lay down any general rules for such a delicate, and highly personal situation would be an unprofitable exercise, and the only solution to such a problem is to be found in the collective judgement of the subjects - donor and recipient - immediately concerned and the several physicians who would normally be involved in explaining the implications of such a decision.

The ethical problems of transplants of unique organs essential to life, such as the heart or liver, are primarily those of the definition of somatic death (section 15.1) and of the justification of performing such surgical feats when there is still such a limited ability to control the immunological rejection of the grafts.

While surgical and life-supporting techniques have reached such a pitch of perfection that organ transplants that would have been considered inconceivable only a few years ago are now technically feasible, these triumphs of surgical technology have, with the exception of renal transplants, foundered on immunological incompatibility, as well as on the shortage of available donors. Immense as has been the progress of immunotherapy in combatting the phenomena of rejection of kidney transplants, much still remains to be accomplished before patients with defective organs other than kidneys can expect much from "spare part" therapy.

---

[49] For a critical review of the problem of euthanasia, see Jonchères, J. (1974) In: Btesh, S., ed., Protection of human rights in the light of scientific and technological progress in biology and medicine (Proceedings of 8th CIOMS Round Table Conference), Geneva, pp. 362-376.

[50] Brit. med. J., 1974, 1, 589.

A question that has been much discussed is whether interventions that are very costly in terms of skilled manpower and expensive equipment, but which are designed to confer benefit on only a few individuals, are justifiable from the point of view of a cost/benefit analysis. Many more people, it is argued, could benefit from simpler measures more widely accessible, at the same cost. That such simpler measures should be applied as widely as possible is undeniable, but the whole history of biomedical science shows that advances that will ultimately benefit all are necessarily first tried on a very small sample of the whole. The question of the criteria by which the relatively small number of beneficiaries should be selected is a more difficult one. Inevitably a choice may have to be made, even in the most developed countries, between a number of potential beneficiaries of limited and highly expensive facilities.

17. Computerized individual medical records

In recent years concern has been expressed in many quarters that the storage of medical records of named patients might lead to breaches of the confidential nature of the doctor-patient relationship. There is in the medical profession a universal recognition of the need to preserve this confidentiality, although it must be admitted that Courts of Law have not always upheld the right of medical privilege. Apart from the purely ethical aspects of the question, a suspicion that confidentiality might be breached could well discourage patients from seeking necessary treatment for physical and mental ailments.

At the 27th World Medical Assembly of the World Medical Association in Munich, Germany, in October 1973, there was a Conference on Computers and Confidentiality in Medicine, as a result of which two resolutions were adopted. In one of these the "strong opinion" was expressed that "medical data banks should be available only to the medical profession and should not, therefore, be linked to other central data banks".

The World Medical Association was concerned with the personal medical histories of named patients as stored in computerized medical records of hospitals. The storage of such records in computer files raises two problems of invasion of privacy. In the first place, personal information that was previously available only to physicians, nurses, medical secretaries, and medical record librarians becomes, once computerized, theoretically accessible to programmers and other technicians who are so remote from the patient that they can hardly be expected to be imbued with the sense of duty to his interests that is characteristic of the health team. In the second place, there is the problem which was the subject of the resolution of the World Medical Assembly, of the linkage of computerized personal medical records with other computerized data bases. Whether such linkages are compatible with the right to privacy of the patient depends upon the purposes for which they are effected. For example, a matching of holders of, or applicants for, licences to drive motor vehicles with medical histories of neurological or psychiatric disorders, alcoholism, or drug dependence, might help to diminish the alarming toll of death and disability from road traffic accidents. Yet the idea that information derived from the confidential doctor-patient relationship should be automatically available for purposes of law enforcement would be unacceptable to both doctor and patient. There are circumstances in which a physician must urge his patient not to drive a motor vehicle or otherwise place the lives of his fellows in jeopardy. If all persuasion should fail, the physician must make the difficult choice as to whether he should reveal to the licensing authority information that would normally be strictly confidential.

There remains the conclusion that information about a patient derived from a medical consultation should not in ordinary circumstances be regarded as providing a base for legal or administrative sanctions or penalties, unless the physician should be forced to decide that in a particular case the rights of society outweigh those of the individual. The fact that such information enters a computer file should in no way detract from its confidential character for any purpose but that of medical research.

There are applications of the computerization of medical records, including their linkage with other data bases, that have as their object either the welfare of the individual patient, or the advancement of medical knowledge for the benefit of society as a whole, without any detriment to the individual concerned. It is characteristic of epidemiological research that it seeks to establish correlations between data on conditions and events with a view to establishing cause-and-effect relationships. The classical example of such research is the establishment by purely epidemiological reasoning of a relationship between bronchial carcinoma and cigarette smoking. A more recent example is the discovery that daughters of mothers who took diethylstilboestrol some 20 or more years ago have a higher than average incidence of adenocarcinoma of the vagina. For all such studies, especially those involving more than one generation, the investigator must be able to identify the individual subjects and follow their history in order to establish links between events and consequences, and this can be done only by naming them.

The capacity of the computer to permute and match almost instantaneously any of the immense mass of items of information in a data base has added new dimensions to the potentialities of epidemiological research, both on a national and an international scale. There can surely be no doubt of the need to exploit this new technology to the full, especially as an aid to unravelling the multifactorial etiology of the more important noncommunicable diseases. Such applications of the computer may have as a consequence the divulgation to a wider group of information about individual patients that would otherwise have been restricted to members of the immediate health team. It is submitted that such a breach of confidentiality is not in itself to be deplored, and that all depends on the purpose for which such information is made available. To make a computer-aided comparison of data derived from many individual patients with a view to helping those patients or furthering medical knowledge of their condition and its causes, is an entirely unexceptionable procedure. The problem is therefore essentially one of the possible leaking of personal health data for non-medical purposes, and of ensuring that they are not divulged except for strictly medical reasons.

In the United Kingdom the Medical Research Council (MRC) has recently made detailed recommendations for the guidance of those involved in medical research making use of computerized medical records.[51] A basic element of these recommendations was that responsibility for a decision as to the wider availability of confidential information should whenever possible rest with a physician, who would decide whether or not divulgation might be harmful to the patient's interests. To legislate against every possible infringement of privacy that might result from the use of computerized medical records would not only be very difficult but might place irksome obstacles in the path of biomedical progress. The pragmatic attitude of the MRC to this problem implies a recognition that the physician, whether or not his interventions had a favourable outcome, has always been motivated to act in the interests of his patient.

18. Psychosurgery

Psychosurgery may be defined as the selective surgical removal, or destruction by other means, in the absence of evidence of organic cerebral disease, of a part of the brain, or the surgical interruption of nerve pathways between one part of the brain and another, with a view to influencing behaviour. Brain operations not aimed at rectifying some definite organic condition, such as a tumour or a traumatic lesion, have also been performed for the treatment of certain forms of epilepsy and for Parkinson's disease. Destruction of brain tissue may be effected by mechanical cutting instruments, electrodes for inducing coagulation, injection of chemical agents, insertion of radioactive yttrium^{90} seeds, ionizing radiations, ultrasonic beams, or cryotherapy.

---

[51] Brit. med. J., 1973, 1, 213-216.

Although the first such operations were performed by Gottlieb Burckhardt of Switzerland towards the end of the 19th century, psychosurgery did not develop further until the publication in 1936 of the work of A. C. de Egas Moniz of Portugal. As is the case with insulin shock therapy (which still has its protagonists, although there is no proof that it is effective), metrazol convulsion therapy, and ECT (electroconvulsion therapy), psychosurgery is a largely empirical procedure, and its theoretical basis is weak. Advocates of such treatments cannot explain their rationale, but they claim that they "work". The early lobotomies were crude by modern standards, and consisted of applying a technique that can hardly be considered as refined to an organ that Sir John Eccles[52] has described as "the most wonderful organized structure in the universe". Today, when psychosurgical operations are performed use is made of refined stereotactic techniques that make possible an accurate localization of specific areas such as the thalamus, the cingulate gyrus, and the amygdala of the temporal lobes, usually with much less destruction of tissue than was formerly the case. With the introduction of psychotropic drugs, psychosurgical procedures tended to fall out of favour, but there now appears to be a trend for them to be once again regarded in certain medical circles as a valid therapeutic intervention.

Psychosurgery poses one of the most difficult problems of bioethics because of the wide differences of opinion as to its justification within the medical profession. An obvious question that arises is the extent to which a patient with severe mental illness that has not yielded to any less drastic treatment is capable of giving informed consent to a partial destruction of his brain with a view to changing his personality. And if the answer is that he is not competent to give such consent, is his family entitled to give vicarious consent and, if so, what degree of consanguinity is necessary for such consent to be valid?

The most usual indications of psychosurgery have been schizophrenia, severe depressive or obsessional states, or uncontrolled outbursts of aggressivity in inmates of psychiatric hospitals or even prisons. It is generally agreed that the results in schizophrenia are poor, and if a substantial proportion of good results is to be expected, the method is to be used only in extreme and chronic cases in which there is severe mental tension or depression, or a severe obsessional state. A distinguished neurologist and protagonist of psychosurgery, H. Miller, has described it as only a "method of last resort".

If this is the best that can be said for psychosurgery by a very distinguished apologist for it, the ordinary physician, citizen, and legislator may perhaps wonder whether it is permissible to perform on a human brain a surgical operation intended to change the subject's personality favourably, but which does not require a "particular psychiatric diagnosis" and of which the results are "unpredictable". It is clear that the scientific foundation of psychosurgery is at best vulnerable, and the Director of the United States National Institute of Mental Health has gone so far as to assert: "The National Institute of Mental Health staff believes that our knowledge of brain function is inadequate to justify any psychosurgical procedure unless there is a very strong evidence of organic pathology of the brain".[53] In this connexion it is of interest to note that the Minister of Public Health of the USSR in 1950 promulgated an Order prohibiting lobotomy in the treatment of neuropsychiatric conditions.[54]

---

[52] Eccles, J. (1968) In: Fattorusso, V., ed., Biomedical science and the dilemma of human experimentation (Proceedings of 1st CIOMS Round Table Conference), Paris, pp. 19-23.

[53] Quoted by Senator Edward M. Kennedy in United States Congress. Senate Committee on Labor and Public Welfare. Subcommittee on Health. Quality of health care - human experimentation, 1973. Hearings . . . Ninety-third Congress, First Session, Washington, 1973, p. 356.

[54] See International Digest of Health Legislation, 1952, 4, 312.

Some of those who practise psychosurgery have given it the name "stereoencephalotomy", which implies accurately localized surgical division or destruction of certain critical areas in the brain. One advocate of this form of treatment uses the term "sedative neurosurgery" which he defines as "that aspect of neurosurgery where a patient is made quiet and manageable by an operation". Practitioners of this technique do not confine it to adults, and psychosurgical operations may be repeated more than once on the same patient.

It may be said that the numerous opponents of psychosurgery do not accept in any circumstances surgical manipulation of the brain for purely behavioural aberrations of unknown etiology. Protagonists claim that in carefully selected cases psychosurgery enables some otherwise intractable patients to adapt to society or to become more manageable in institutions, while admitting that they cannot guarantee results and that there are many failures.

In view of the wide divergences of opinion that exist within the medical profession on the justification or otherwise for psychosurgery, the uncertainty of its results, and its lack of a firm theoretical basis, it seems that further study is necessary to evaluate such procedures.

19. Environmental protection

The right of the individual to protection against avoidable environmental hazards is probably the most non-controversial of all the health aspects of human rights. There is universal recognition of the desirability of striving to protect the individual against such hazards if not, as yet, universal success in attaining this objective. As older - mainly biological - environmental hazards are successfully combatted in the developed countries, new - mainly chemical and physical - hazards are created by technological developments. The classical example of environmental pollution is the microbial contamination of water supplies, but in the developed countries piped water no longer distributes epidemics. In developing countries the problem of the provision of safe water supplies is economic rather than scientific.

The wilful and fraudulent adulteration of foodstuffs - including such basic articles of diet as milk and bread - is still common, but today the typical risk is of possible harmful effects of intentional food additives intended to improve keeping qualities or consumer appeal or both, and of accidental contaminants such as pesticides. In all countries, the microbial contamination of foodstuffs continues to present a danger against which elaborate safeguards are necessary, and in many cases are prescribed by laws and regulations, often in great detail.

Air pollution became a problem with the growth of towns even before the industrial revolution but, until the development of the chemical and energy industries and of the internal combustion engine, it was rather an aesthetic nuisance than a health hazard.

Noise represents an environmental hazard which has become increasingly recognized as being of both public health and economic importance. It has in fact been estimated that the cost to industry as a result of loss of hearing among workers is probably greater than the cost of any other occupational disease. As far as the public at large is concerned, road traffic and aircraft are regarded as the main sources of offensive noise.[55]

The importance of occupationally conditioned hazards to health was recognized very early, and the first known work on industrial hygiene and toxicology was that of Ulrich Ellenbog, published in 1524. The classical work of Bernardino Ramazzini, published in 1700, described diseases of miners, including pneumoconiosis (often known as "miner's lung"), and of stonemasons and metal workers. It was not, however, until the 20th century that governments were to

---

[55] See WHO Features, 1974, No. 6.

recognize that workers in dangerous but essential trades had the right to the fullest possible protection against health hazards and, if protective measures should fail, to financial support in compensation for their impaired working capacity and life expectancy.

Similarly, as new industrial processes produce new and potentially noxious waste products there is an increasing tendency for governments to intervene by legislation aimed at protecting the integrity of the environment in the interest of the health of the community. The most obvious example of a new potential environmental hazard requiring rigid government control in the interest of community health is the atomic energy industry.

If these comments on environmental protection seem very summary, it is not for want of recognition by WHO of the paramount importance of the subject, which has received far more detailed treatment in more appropriate contexts.[56] But important as is the right of the human being to be able to live in a healthy environment, it is not one that is ever contested in principle, or about which there are differing schools of thought. There are some special situations that require governments to decide whether the benefits of a particular measure outweigh any adverse ecological effects that it may have. An example is that of countries in which arthropod-borne diseases are a major cause of morbidity and mortality. In such a situation the use of persistent insecticides that introduce into the environment an element that may be harmful to non-target fauna and sometimes to man may be the lesser of two evils. In some countries in which arthropod-borne diseases are either rare or non-existent, the mass use of chemically stable pesticides has been outlawed in favour of the application of more costly but biodegradable compounds. It is clear that for such problems no solutions are available that are universally valid, and that each government must decide, often taking into account the views of international groups of experts, what solution is in the best interest of the health of its population.

In connexion with potential dangers to the environment, a call has been made by the United States National Academy of Sciences for a voluntary moratorium on certain types of genetic experiments with micro-organisms. The hazards arising to human health were described as "grave and unpredictable".[57]

20. Compulsory measures for health protection

The Benthamite principle of "the greatest happiness of the greatest number" requires that society should abrogate the right of the individual to unlimited choice in certain special circumstances. Such limitations of personal behaviour may consist of the prohibition of certain actions, such as the procurement of dangerous drugs or of firearms, judged to place the health of the person concerned and/or of others at risk. Conversely, the individual may be obliged to submit to certain procedures or to adopt certain practices in the interest of his own health and/or that of society as a whole. Sometimes, as in the case of compulsory vaccination against smallpox and other communicable diseases, the measure has as its object not only the protection of the health of the individual directly concerned but also the more important one of preventing him from becoming a danger to his fellow-citizens. In other cases, such as the compulsion for drivers and passengers of motor vehicles to wear safety harness, the main object is individual protection, although an important secondary consideration is to relieve the strain on severely taxed hospital facilities, and the economic consequences to society of accidental death or disablement of those with dependants.

---

[56] See, in particular, World Health Organization (1972) Health hazards of the human environment, Geneva.

[57] Brit. med. J., 1974, 3, 483-484.

There is an almost complete lack of consistency internationally in the various prohibitions or compulsory measures (e.g. mass X-ray examinations, water fluoridation, iodization of salt as a prophylactic measure against goitre, etc.) intended to protect health directly or indirectly. Thus, vaccination against a communicable disease may be compulsory in one country and not in an immediate neighbour where the risks are not demonstrably different. This lack of international consistency also applies, for example, to requirements for the compulsory notification of communicable diseases and to the very different periods for which there is an obligatory exclusion from attendance at schools in the case of such diseases.

20.1 Compulsory immunization against communicable diseases

Requirements for compulsory immunization against communicable diseases vary enormously in different countries. For example, in the United Kingdom there have not since 1948 been any such compulsory requirements for the general population, even for smallpox vaccination. Conversely, the legislation of a number of countries, notably Japan and the Eastern European countries, prescribe compulsory immunization against a wide range of communicable diseases.

In almost all countries primary smallpox vaccination in infancy is compulsory, but there are differences in the age-limits between which it should be performed. Revaccination is obligatory in some countries but not in others, and in the former there are differences in the intervals at which it is required that it should be performed. In almost all countries in which immunizations of one kind or another are compulsory exemptions are given on medical grounds on production of a certificate from a physician. Such exemptions may be temporary or permanent. In some countries exemption may be accorded on the ground of conscientious objection. Immunizations that are not compulsory for the general population may be so for certain occupational groups, such as members of the armed forces, medical and nursing students, or workers in certain trades. The legislation of some countries provides for financial compensation by the State for disability or death attributable to a compulsory immunization. Other States do not provide for any compensation for disastrous results of coercive measures.

Apart from smallpox, the diseases against which immunization is most commonly compulsory are diphtheria, pertussis and tetanus (usually as a combined inoculation), poliomyelitis, and tuberculosis.

In the report prepared by participants in the informal technical discussions at the Thirteenth World Health Assembly it was stated:

> "Vaccination is not simply a personal affair. Indeed, it is essentially a community matter, since the objective of most vaccination programmes is to produce a herd immunity."[58]

Participants were unanimous on the need to strengthen by health education public awareness of the benefits both to the individual and the community of active immunization programmes. In the very few countries in which smallpox vaccination has ceased to be compulsory (apart from exemptions) for the whole population the reason for lifting this requirement was that, although serious complications of primary vaccination were very rare, they resulted in a greater incidence of serious illness and death than did smallpox.

---

[58] "The role of immunization in communicable disease control", Publ. Hlth Pap., 1961, No. 8, 107.

As pointed out by De Moerloose (1961), it is difficult to show by a comparison of national morbidity statistics that compulsion plus health education are necessarily more effective than health education alone.[59] Whatever arguments may be advanced in favour of or against compulsion, there can be no question of the necessity to bring about and maintain in the general population as high as possible a level of artificially induced immunity to such communicable diseases as may be held in check by such measures. It is evident that as long as there are communicable diseases that are prevalent in some countries but not in others there can be no international uniformity as to those against which mass immunization is practised - whether compulsorily or voluntarily. But the ever-increasing scale of international travel, whether for business or pleasure, implies a tendency to level out such differences, as exemplified by the sporadic reappearance of cholera in Europe after a long absence.

20.2 Compulsory notification and treatment of diseases

In most countries compulsory notification applies only to diseases that are communicable, although in some countries noncommunicable conditions such as cancer, occupational diseases, and poisoning by insecticides are also notifiable. According to a survey of the relevant legislation of some 50 countries published by WHO, the number of scheduled diseases varies from about 10 to 70, according to the country.[60] Smallpox is compulsorily notifiable in all countries. Sometimes diseases may be compulsorily notifiable only in special circumstances. Thus there may be a requirement to notify suspected salmonellosis or other food-borne infection in food handlers.

Usually it is the physician who has the obligation to notify to the local health authority that he has diagnosed a scheduled disease in one of his patients, although in some cases the head of the family, the spouse, or a landlord is also obliged to notify a known case in his premises. For certain diseases the carrier state is compulsorily notifiable in some countries.

That a physician should be legally obliged, under pain of penalties, to commit an infraction of professional confidentiality is an unusual situation, for which the only justification can be that such an infraction is necessary in the interest of society and sometimes, but not invariably, of the patient himself. Whether the need that health statistics should be as complete and as accurate as possible is an adequate justification is a question upon which opinions might well be divided. But when a disease offers a serious threat to the community, as in the case of smallpox, notification is but the prelude to urgent administrative action by isolation of the patient and vaccination of contacts, and there is no room for differences of opinion as to its necessity. In the case of, for example, tetanus, there is no threat to the community, but this is nevertheless a scheduled disease in a number of countries. Venereal diseases are compulsorily notifiable in some countries but not in others. Even when compulsion exists, it is generally recognized that many cases go unreported. In some countries requiring compulsory notification of venereal diseases there is also legislation enforcing treatment, although such legislation often antedates the general acceptance of the extraordinary effectiveness of antibiotics against both syphilis and gonorrhoea. In pre-antibiotic and, in the case of gonorrhoea, pre-sulfonamide days, treatment was so disagreeable that compulsion may have been important in limiting the spread of the diseases. Today, treatment is so little likely to be shunned by the patient that the case for compulsion is considerably weakened.

---

[59] De Moerloose, J. (1961) "Compulsory or voluntary vaccination", Publ. Hlth Pap., No. 8, 89.

[60] International Digest of Health Legislation, 1958, 9, 603-653.

20.3 Compulsory medical examinations

In some countries couples applying for a marriage licence, or in some cases only the intending husband, are required to have submitted to a medical examination and to produce a health certificate. In most cases the legislation specifies a serological examination and would appear to have been framed primarily with a view to the detection of syphilis. Many of the relevant laws were enacted before the treatment of syphilis with antibiotics was available, and there are no longer such cogent reasons for the obligatory serological screening of all applicants for marriage licences.

Another form of medical examination that may be compulsory is the taking of blood samples from drivers of motor vehicles suspected of being under the influence of alcohol. Where such examinations are not compulsory, refusal to submit to them may be taken as presumptive evidence of guilt. In countries in which a maximum permitted concentration of alcohol in the blood has been fixed by law, to exceed this limit is in itself an offence, and the prosecution is thereby relieved of the necessity of proving impairment of driving ability. Conversely, the fact that a driver has not exceeded the limit does not necessarily exculpate him from having been under the influence of alcohol.

Certain other compulsory examinations have been introduced in some countries. The detection of dependence-producing drugs in blood or urine is an example, as is the detection of amphetamines in persons engaging in competitive sports events.

20.4 Compulsory self-protective measures

It is of course clear that in industry and agriculture a number of self-protective measures are obligatory but in so far as these matters have been dealt with in considerable detail by the International Labour Organisation, they are not covered in this document.

There is a considerable body of evidence that the wearing of protective harness (seat belts) reduces - it has been claimed by 50% - the risk of serious injury or death of drivers and front-seat passengers of motor vehicles involved in accidents. In proceedings for recovery of damages for injuries sustained in traffic accidents, the courts have sometimes ruled that failure to fasten a seat belt constituted contributory negligence and have reduced damages accordingly.[61] Many believe that the wearing of seat belts should be made compulsory by law. A statistical analysis made by the Victorian Office of the Commonwealth Bureau of Census and Statistics of Australia showed that in the State of Victoria, where the wearing of seat belts became compulsory in 1971, it had "greatly reduced the deaths and more serious injuries sustained in road traffic accidents".[62] Opponents of compulsion claim it to be an infringement of personal liberty, since the wearing of a seat belt protects no one but the wearer and plays no role in accident prevention. Moreover, they argue that in certain accidents, as when a car plunges into deep water, a seat belt may hamper efforts at escape.

Other examples of compulsory self-protective measures in non-industrial situations are the wearing of crash helmets by motorcyclists and of life-jackets in small boats.

---

[61] Brit. med. J., 1974, 2, 454.

[62] Pratt, W. N. B., Richardson, D. F. & Yeoh, B. M. (1973) Med. J. Austral., 60, 1109-1112.

20.5 Detention for treatment in medical institutions

Compulsory removal to hospital of patients with dangerous communicable diseases in order to isolate them and give them such medical treatment as is available is so manifestly necessary that there are usually few formalities involved. It is otherwise with patients suffering from non-organic mental disorders, for the compulsory detention of whom most countries have strict regulations (notably as regards the provision of independent legal advice and adequate appeal and review procedures) intended to safeguard the rights of the persons concerned. Such detention is of course only justified if the patient is a risk to himself or to others.

It is generally recognized that if a patient can be persuaded to apply for admission to a psychiatric hospital voluntarily, this is much to be preferred to any form of compulsion. In such cases a written application by the patient himself may be the only formality required, although in some countries a medical certificate is also necessary. Normally a voluntary patient may discharge himself, either at will or after expiry of a statutory period of notice. Should the medical director of the hospital decide that the patient would be a danger to himself or to others if discharged, there may be a procedure for detaining the patient against his will, usually for a limited period in the first instance. Normally such detention requires that the patient shall be certified as not fit for discharge both by the medical director of the hospital and by one or more independent physicians, and a court order may also be necessary.

As for involuntary admission for the purpose of temporary treatment, this is possible in some countries, on the application of the spouse or other near relative, sometimes with authentication by a magistrate or other legal official, on production of certificates by one or more physicians. Usually the period of detention allowable under such a procedure is reckoned in months. Where longer periods of detention are considered necessary, a judicial order may be required. Where emergency admission is required, this may, especially in the case of vagrants, be on the application of the police or other civic authority, usually supported by medical certification. Normally, medical directors of psychiatric hospitals are obliged to report at regular intervals to the competent civic authority on patients detained against their will, and there may be an established procedure for hearing appeals against detention.

Similar measures may also be applicable in a number of countries to alcoholics and drug-dependent persons.

In conclusion, it may be said that while until well into the 19th century persons judged to be of unsound mind were deprived of all rights and often even subjected to degrading physical restraints, there has since been a progressive tendency to regard psychiatric hospitals as centres for treatment and rehabilitation rather than for segregation. This tendency has been much favoured in recent years by the development of psychotropic drugs and the adoption of an "open door" policy by psychiatric hospitals.

SUMMARY

As stated in the Introduction, the present document is intended to survey developments in biology and medicine having an impact on human rights and in particular the right to health.

It is obvious, however, that a number of subjects discussed in the document are of concern to only a limited number of countries. Transplantation of organs, psychosurgery, or computerized medical records are restricted to very few countries indeed, and even within them (as in the case of organ transplantation) to a limited number of citizens. The fundamental questions, viz., how far do countries and citizens benefit from advances in preventive and curative health care and how far is the WHO objective formulated in Article 1 of its Constitution, i.e. the attainment by all peoples of the highest possible level of health, furthered by these advances, are not answered in the present document, which as

requested deals especially with the potential problems posed to human rights and health by developments in biology and medicine. Certain sections have already touched to some extent upon the above-mentioned aspect of the problem as, for instance, that dealing with the availability of contraceptive methods in the world today.

The study deals in particular with a number of bioethical questions and in the Introduction the role of WHO in this connexion is outlined. The role of WHO in a number of fields where moral, religious, and social attitudes may differ so much from country to country is limited. The importance of the links of WHO with the World Medical Association and the Council for International Organizations of Medical Sciences (CIOMS) has been stressed.

Health as a human right has on different occasions been the subject of debate and one may state that as a rule the concept is ill defined. In section 1.1 of the study, the role of governmental authorities and especially health administrations has been mentioned in order to show what part they play in the protection of health and this may lead to giving the right to health its proper perspective. The right to health presents negative as well as positive aspects. For instance, if a positive aspect is the right to health care and protection against communicable diseases, it also entails negative aspects for the sake of the community such as the duty of the citizen to submit himself to a number of requirements, as for example immunization or other compulsory measures, in order to prevent the right to health of other citizens being endangered. As has so frequently been stated, notwithstanding the differences in the current situation from country to country, the achievement of WHO's goal depends on economic, educational, and many other factors. A question may however be raised, namely, do countries do enough to protect their citizens from a number of dangerous influences as, for instance, alcohol or cigarette advertising? In the present document a number of examples are given which certainly provide an incomplete picture of the potential dangers to the right to health created by developments in biology and medicine. A number of examples are also given of the limits on individual liberty which have to be introduced and enforced for the sake of the community and sometimes of the individual himself. This particular aspect of encroachment on individual liberty is developed in the last part of the document under "Compulsory measures". A section which has received major attention in the study because of its present importance is the problem of experimentation involving human subjects.