

CIOMS

Council for International Organizations of Medical Sciences

Organization • Activities • Members



ORGANIZATION ACTIVITIES MEMBERS



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INTRODUCTION

Long before there were international organizations of medical sciences and before medicine could claim to have a scientific basis, medical scholars travelled between countries and shared the information and views of their times with one another. However, it was not until the latter half of the nineteenth century that such exchanges were to be formalized by the convening in Paris in 1867 of the first of the International Medical Congresses. These congresses embraced the whole of medicine, and the published Transactions of the seventeenth and last of them, held in London in 1913, filled thirteen volumes. During the same period there have also been international congresses devoted to the older medical specialties — such as neurology and ophthalmology — in addition to an important series, starting in 1852, on hygiene and demography.

The end of the First World War made possible the renewal of such international medical activities, but it was apparent that all-purpose international medical congresses had had their day and must give way to meetings limited to special fields, the number of which had progressively increased in proportion to the growth of the medical sciences.

The international exchanges referred to above were sponsored by professions rather than governments. However, governments had also begun to enter the international health field by participating, beginning in 1851, in the series of International Sanitary Conferences that was to lead to the founding of the *Office international d'hygiène publique* in Paris in 1908. Afterwards intergovernmental health activities increased enormously, leading first to the creation of the Health Organization of the League of Nations and culminating in the creation of the World Health Organization (WHO) as a powerful instrument for promoting world-wide cooperation in health.

International health activities on professional and governmental planes are complementary, as recognized by WHO's establishment of official relation with approved non-governmental international organizations, but until after the Second World War professional international health activities lacked a focal point that would provide facilities for such coordination as would be desirable. In 1948 Unesco consulted WHO about the possibility of establishing a machinery to help in coordinating the planning and timing of international medical congresses. The result was an agreement between WHO and Unesco for the establishment of a permanent Council for Coordination of International Medical Congresses. The Council was formally constituted at a conference in Brussels in 1949 as a non-governmental organization, with financial assistance from the two parent organizations, WHO and Unesco.

The purpose of the Council was described as being to facilitate the exchange of views and scientific information in the medical sciences by securing continuity and coordination between international organizations of medical sciences, by making their work known, and by furnishing them with material aid where necessary. This was to be achieved through the exchange of information and by the provision of material and financial assistance to congresses and to their participants.

The scope of activities of the Council was gradually broadened to include other forms of international collaboration in medical sciences in addition to coordination of congresses. Consequently, in 1952 its name was changed to Council for International Organizations of Medical Sciences (CIOMS) and its objectives were redefined as follows:

- ☐ To facilitate and coordinate the activities of the international association members of the Council;
- ☐ To act as a coordinating centre between the international associations, and the national institutions adhering to the Council;
- ☐ To maintain collaborative relations with the United Nations and its specialized agencies, in particular with the United Nations Educational, Scientific and Cultural Organization (Unesco) and with the World Health Organization (WHO);
- ☐ To promote international activities in the field of medical sciences whenever the participation of several international associations and national institutions adhering to the Council is deemed necessary;
- ☐ To serve the scientific interests of the international biomedical community in general.

CIOMS was founded on the analogy of the International Council of Scientific Unions (ICSU), which had been established in 1931 and had received financial support from Unesco since the inception of that organization. ICSU includes in its membership international unions representing scientific disciplines including those basic to medicine, such as anatomy, biochemistry, microbiology and physiology. These disciplines, which are of fundamental importance to medicine, cover only certain aspects of medical sciences. Essentially, CIOMS was conceived as an organization to form a link between specialized international medical associations with research interests, analogous with the link that ICSU provides between international organizations of the basic sciences.

Until 1966 the activities of CIOMS were focused on the coordination of international medical congresses; grants and loans to member societies for the preparation of congresses and the publication of their proceedings; travel grants to young scientists, especially from developing countries, to attend medical congresses; organization of symposia on medical subjects; and assistance to member organizations for the standardization of nomenclature in various medical disciplines.

By 1966 political and technological developments were indicating new directions for CIOMS, at a time when for economic reasons it was forced to curtail some of its earlier activities. Large numbers of countries were achieving independence and faced with the task of determining health policies and building health services for rapidly growing population, with very inadequate resources. At the same time, biomedical scientific and technological advances were transforming the practice and potential of medicine, with unprecedented social and cultural, as well as ethical, consequences and implications. CIOMS as a non-governmental organization of medical sciences, with a mandate to collaborate with the United Nations and its specialized agencies, was in a position to provide a forum for representatives of different fields of medicine,

the natural and social sciences, philosophy, and law, as well as lay persons, to make explicit the ethical and other non-technical considerations to be taken into account in determining and implementing health policy.

The adoption by the World Health Assembly in 1977 of the goal of health for all was an assertion of the need for health policy to be informed by ethics and human values, indicating the particular field in which CIOMS could most appropriately complement the work of the World Health Organization, and a dominant theme of CIOMS activity since that time.

A particular aspect of biomedical technology — the development and use of drugs — became another dominant theme of CIOMS in complementing the work of WHO and serving the interests of the international biomedical community. Its independent status permits it to coordinate the contributions of research-based pharmaceutical companies, national drug regulatory authorities, and representative bodies of medical specialties to harmonizing and strengthening drug-safety surveillance measures. A prominent feature of CIOMS activity has been the clarification, mainly for developing countries, of the ethical issues involved in the use of human subjects in drug and vaccine research, and the issuing of international ethical guidelines on the matter.

ORGANIZATION

Membership

The Council for International Organizations of Medical Sciences (CIOMS) consists of International, National and Associate members. Its international membership, consisting of international unions and federations of national associations and societies, represents a substantial proportion of the world's biomedical scientific community. National members are mainly medical research councils and academies of sciences. The membership of CIOMS in 1994 includes 72 international organizations and 30 national bodies.

General Assembly

The supreme body of CIOMS is the General Assembly, composed of representatives of all its members. At its triennial meetings, the General Assembly elects its President and its Executive Committee. It determines general policy and approves programme activities and financial reports.

Executive Committee

The Executive Committee is composed of the President of the Council, the Immediate-Past President, eight representatives of International members and six representatives of National members. It meets every year and reviews and determines programme activities.

Secretariat

The Council has a permanent secretariat headed by the Secretary-General, who is appointed by the Executive Committee. The secretariat is located in Geneva in offices made available by WHO, and in Paris office space is provided by Unesco.

Finances

The regular budget of CIOMS is derived from annual membership dues determined according to a scale of assessment established by the General Assembly. Programme activities of CIOMS are financed through contracts and grants from WHO and a wide range of foundations and funding agencies. In addition, WHO provides a small annual subvention to cover some administrative and office expenses.

CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS
OF MEDICAL SCIENCES

GENERAL ASSEMBLY

EXECUTIVE COMMITTEE

SECRETARIAT

BIOETHICS
AND
HEALTH-POLICY
ETHICS

DRUG DEVELOPMENT
AND USE

INTERNATIONAL
NOMENCLATURE
OF
DISEASES

CONFERENCES AND
COORDINATION
OF MEDICAL
CONGRESSES

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ACTIVITIES

To achieve its objectives, CIOMS has initiated and is coordinating three main long-term programmes: first, an international and intercultural dialogue on bioethics and health-policy ethics, designed to strengthen national capacities for addressing, and making decisions about the ethical and human-values issues involved in health policy, and to pursue deeper understanding of human values across cultural and political lines; second, the medical, social and economic implications of drug development and use, particularly to facilitate international assessment and monitoring of adverse drug reactions and the development of an internationally agreed terminology and classification of adverse drug reactions; third, the provision of an internationally agreed nomenclature of all diseases.

BIOETHICS AND HEALTH-POLICY ETHICS

The remarkable progress of biomedical sciences and biotechnology, and its application in medical practice, are confronting our societies with new ethical dilemmas, extending from traditional medical ethics to the new fields of bioethics and health-policy ethics.

Bioethics, concerned with ethical issues that arise from recent progress in biology and medicine, as distinct from traditional medical ethics, concerned mainly with the doctor/patient relationship, has been the subject of a remarkable surge of interest in the last two decades, both in developed and developing countries. Unlike traditional ethics, with its medical model, bioethics is interdisciplinary, reflecting the reality that medical choices can no longer be made purely on the basis of medical science. Bioethics differs from medical ethics also in that it incorporates a social dimension, being concerned with justice and rights, honesty and respect for human dignity, autonomy of the individual and respect for communities.

Health-policy ethics may be seen as an aspect of bioethics concerned particularly with the organization, financing and delivery of health care. The approach of CIOMS to bioethics and health-policy ethics involves multidisciplinary consultation with a broad range of biomedical specialists, as well as with legal experts, civic and religious leaders, and nongovernmental organizations concerned with human rights. In this role, CIOMS is uniquely placed to assist in and complement the work of the World Health Organization, since it forms a link between, on the one hand, intergovernmental organizations and, on the other, its affiliated societies, other professional groups, the academic world and lay interests.

The particular contribution of CIOMS in this field has been the issuing of international guidelines for the application of ethical principles in various fields and the organization of a series of international, intercultural conferences on health-policy ethics and human values.

The following are summaries of the main activities of CIOMS in relation to bioethics and health-policy ethics.

INTERNATIONAL GUIDELINES AND DECLARATIONS

Principles of Medical Ethics Relevant to the Protection of Prisoners Against Torture

In December 1982, at its thirty-seventh session, the General Assembly of the United Nations formally adopted Principles of medical ethics relevant to the role of health personnel, particularly physicians, in the protection of prisoners against torture or other cruel treatment. The Principles had been elaborated by CIOMS after comprehensive consultation and in 1979, when they were endorsed by WHO, were transmitted to the United Nations.

The Principles were derived from Guidelines for Medical Doctors concerning Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment in relation to Detention and Imprisonment, embodied in the World Medical Association's Declaration of Tokyo of 1975. They provide for the physician or other health worker responsible for the care of prisoners or other detainees an internationally accepted framework for judging whether a specific practice conforms with medical ethics. They postulate that physicians and other health workers are professionally trained solely to maintain or improve the health of those for whom they exercise professional responsibility, and that it is unethical to use their professional skills to allow action that may harm physical or mental health.

In 1983 CIOMS published Principles of Medical Ethics Relevant to the Protection of Prisoners Against Torture, and brought the document to the attention of all nongovernmental organizations concerned, requesting them to inform their members of its existence, contents and spirit.

International Guiding Principles for Biomedical Research Involving Animals

Animal experimentation is fundamental to the biomedical sciences, not only for the advancement of man's understanding of the nature of life and the mechanisms of specific vital processes, but also for the improvement of methods of prevention, diagnosis, and treatment of disease both in man and in animals. The use of animals is also indispensable for testing the potency and safety of biological substances used in human and veterinary medicine, and for determining the toxicity of the rapidly growing number of synthetic substances that never existed before in nature and which may represent a hazard to health. This extensive exploitation by man of animals implies philosophical and moral problems that are not peculiar to their use for scientific purposes, and there are no objective ethical criteria by which to judge claims and counterclaims in such matters. However, there is a consensus that deliberate cruelty is repugnant.

The Principles strongly emphasize that there should not be such restrictions as would unduly hamper the advance of biomedical science or the performance of necessary biological tests, but that, at the same time, biomedical scientists should not lose sight of their moral obligation to have a humane regard for their animal subjects, to prevent as far as possible pain and discomfort, and to

be constantly alert to any possibility of achieving the same result without resort to living animals.

The International Guiding Principles for Biomedical Research Involving Animals were published in 1989.

Human Genome Mapping, Genetic Screening and Gene Therapy — The Declaration of Inuyama

The ethical and human-values implications of research in human genetics, and particularly those of mapping and sequencing of the human genome, were comprehensively discussed at the XXIVth CIOMS Conference held in Tokyo and Inuyama City, Japan in July 1990.

At its final session, the conference agreed on a statement: The declaration of Inuyama, on human genome mapping, genetic screening and gene therapy, which epitomizes the issues and the consensus of the conference.

The conference concluded that some of the public concern about the growth of genetic knowledge stemmed from misconceptions of the nature and uses of genetic technology, and that such misconceptions could be corrected by education of the public and open discussion. For the most part, present genetic research and services do not raise unique or even novel issues, but in view of their implications for reproduction and for personal health and life prospects, as well as the rapidity of bio-technological advances, there is a special need for ethical sensitivity in policy-making.

Some types of genetic testing or treatment not yet in prospect could raise novel issues — for example, whether limits should be placed on DNA alterations in human germ cells. Such alterations, as therapy or prevention, would be technically much more difficult than those affecting somatic cells and would affect the descendants of patients, but could be the only means of treating certain conditions, and therefore must remain under discussion of both their technical and their ethical aspects.

The mapping of the human genome will greatly expand the scope of genetic screening and diagnostic tests, and it is in this regard that the welfare of those who are tested must be safeguarded, as the central concern: test results must be protected against unconsented disclosure, confidentiality assured at all costs, and adequate counselling provided.

Genetic researchers and therapists have a responsibility to ensure that the techniques they develop are used ethically. By insisting on truly voluntary programmes designed to benefit directly those involved they can ensure that no precedents are set for eugenic programmes or other misuse of the techniques by the state or by private parties. One means of ensuring the setting and observance of ethical standards is continuous multidisciplinary and transcultural dialogue.

The needs of developing countries should receive special attention, to ensure that they obtain their due share of the benefits that ensue from the human genome project.

The proceedings of the CIOMS Conference and the Declaration of Inuyama were published in 1991.

International Guidelines for Ethical Review of Epidemiological Studies

The scope and methods of epidemiological research, with its continually expanding potential for the collection, storage and use of data on individuals and communities, and with some inevitable tension between the rights and freedoms of the individual and the needs of society, have led to expressions of societal concern about the risks of abuse and to a demand for the consideration of the ethical issues involved. The need for special ethical guidelines for epidemiological studies has been accentuated by the HIV/AIDS epidemic and the commencement of clinical trials on candidate HIV vaccines and treatment drugs, involving large numbers of research subjects in many parts of the world.

National and international professional associations of epidemiologists have been examining these ethical issues, and some groups have begun to formulate ethical guidelines. However, no international ethical guidelines have yet been drawn up for epidemiological research and practice. In view of the obvious need to address, at the international level, the ethical issues raised by epidemiological studies, CIOMS, in collaboration with the World Health Organization, undertook in 1989 a project to develop such guidelines.

The Guidelines are intended for investigators, health policy-makers, members of ethical review committees, and others who have to deal with ethical issues that arise in epidemiology. They may also assist in the establishment of standards for ethical review of epidemiological studies.

The Guidelines are an expression of concern to ensure that epidemiological studies observe ethical standards. These standards apply to all who undertake any types of activity covered by the Guidelines. Investigators must always be held responsible for the ethical integrity of their studies.

It is recognized that formulating ethical guidelines for epidemiological studies will not resolve all the moral ambiguities that are encountered in everyday epidemiological research and practice. However, they can achieve several useful ends. They can draw attention to the need to consider the ethical implication of professional action; they can thus conduce to high professional standards in regard to both humane attitudes and quality of research.

The guidelines and proceedings of the CIOMS Conference were published in 1991.

International Ethical Guidelines for Biomedical Research Involving Human Subjects

Advances in biomedical science and technology, and their application in the practice of medicine, are provoking some anxiety among the public and confronting society with new ethical problems. Society is expressing concern about what it fears would be abuses in scientific investigations and biomedical technology and devises measures to protect against possible abuses.

The first international code of ethics for research involving human subjects the — Nuremberg Code — was a response to the atrocities committed by Nazi research physicians, revealed at the Nuremberg War Crimes Trials. Thus it was to prevent any repetition by physicians of such attacks on the rights and welfare

of human beings that human-research ethics came into being. The Nuremberg Code, issued in 1947, laid down the standards for carrying out human experimentation, emphasizing the subject's voluntary consent. In 1964 the World Medical Association took an important step further to reassure society: it adopted the Declaration of Helsinki, most recently revised in 1989, which lays down ethical guidelines for research involving human subjects. In 1966 the United Nations General Assembly adopted the International Covenant on Civil and Political Rights, which entered into force in 1976, and which states (Article 7): "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." It is through this statement that society expresses the fundamental human value that is held to govern all research involving human subjects — the protection of the rights and welfare of all human subjects of scientific experimentation.

In the late 1970s, in view of the special circumstances of developing countries in regard to the applicability of the Nuremberg Code and the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) undertook a further examination of these matters, and in 1982 issued Proposed International Guidelines for Biomedical Research Involving Human Subjects. The purpose of the Proposed Guidelines was to indicate how the ethical principles that should guide the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, could be effectively applied, particularly in developing countries, given their socioeconomic circumstances, laws and regulations, and executive and administrative arrangements.

Proposed Guidelines received extensive distribution and, according to a later survey, went into use widely throughout the world, providing valuable ethical guidance in biomedical research involving human subjects. Survey respondents and other users indicated also that the guidelines should be reviewed with particular reference to the ethical issues raised by large-scale trials of vaccines and drugs, transnational research, and experimentation involving vulnerable population groups. A particular indication for their revision was the prospect of field trials of vaccines and drugs to control AIDS. Moreover, in recent years, many people, in developed and developing countries alike, have begun to see the beneficial and not only the threatening aspects of research involving human subjects; indeed such research, particularly related to innovative therapy trials, is now actively sought by potential beneficiaries. For some, participation in research is the only way they can gain access to valuable new treatment or even general medical care; for others, it is the means by which scientists will discover new knowledge that may lead to the prevention or treatment or even elimination of certain categories of disease and disability.

In the revision process special attention was also paid to epidemiological studies owing to the importance of epidemiology, particularly for public health.

After extensive consultation the first draft of the revised guidelines was presented to the CIOMS Conference on Ethics and Research on Human Subjects — International Guidelines, held in Geneva in 1992.

The draft guidelines were revised to reflect the consensus of the conference, but with due regard to minority points of view. The final text has been endorsed by the WHO Global Advisory Committee on Health Research and the Executive Committee of CIOMS, which have recommended its publication and wide distribution.

The text consists of a statement of general ethical principles, a preamble and 15 guidelines, with an introduction, and a brief account of earlier ethical declarations and guidelines. Each guideline is followed by a commentary.

The guidelines reflect the paramount ethical concern for vigilance in protecting the rights and welfare of research subjects and of vulnerable individuals or groups being considered as prospective subjects. The guidelines are designed to be of use, particularly to developing countries, in defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances, and establishing or redefining adequate mechanisms for ethical review of research involving human subjects.

Certain areas of research do not receive special mention in these guidelines; they include human genetic research, embryo and fetal research, and fetal tissue research. These represent research areas in rapid evolution and in various respects controversial. Since there is not universal agreement on all the ethical issues raised by these research areas it would be premature to try to cover them in the present guidelines.

The mere formulation of ethical guidelines for biomedical research involving human subjects will hardly resolve all the moral doubts that can arise in association with such research, but the guidelines can at least draw the attention of investigators, sponsors and ethical review committees to the need to consider carefully the ethical implications of research protocols and the conduct of research, and thus conduce to high scientific and ethical standards of research.

The guidelines and proceedings of the CIOMS Conference were published in 1993.

A Global Agenda for Bioethics — Declaration of Ixtapa

The Council for International Organizations of Medical Sciences (CIOMS) held its XXVIIIth Conference, on "Poverty, Vulnerability, the Value of Human Life and the Emergence of Bioethics", in Ixtapa, Guerrero State, Mexico, on 17-20 April 1994. The Conference was organized in cooperation with the World Health Organization, UNESCO, the Government of Mexico, and the Mexican Foundation for Health. The 110 participants came from 22 countries, representing all continents. In addition to biomedical scientists and physicians, they represented a wide range of disciplines, including philosophy, economics, sociology, epidemiology, law and theology, and brought with them experience from hospital medicine, public health, universities, and the executive branches of governments. Through presentations and discussions in plenary sessions and in working groups, the participants reached broad agreement on a number of issues, and agreed to conclude their deliberations by issuing a Declaration setting forth a Global Agenda for Bioethics.

The participants at the Conference expressed their satisfaction at the substantial and substantive contributions made by CIOMS to bioethics, particularly through the International Dialogue on Health Policy, Ethics and Human Values during its first decade (1984-1994), and welcomed WHO's continuing partnership in this Dialogue; and they acknowledged, with appreciation the strong support accorded by Mexican Governmental and private institutions to the Conference.

1. General Points

1.1 Bioethics in the health sector should be guided by generally accepted principles, and in particular the following:

- an adequate level of health care should be recognized as a universal and fundamental human right;
- equity should be considered a foundational principle for health policy, and such policy should be based on the Alma-Ata principle of Health for All;
- health services should be effective, efficient, accessible, affordable, compassionate, and socially acceptable; and
- mechanisms should be developed to ensure that communities are enabled to meaningfully participate in the development of health policy and services, and communities and individuals should be involved in determining the nature and quality of health care.

Bioethics seeks to define ways and means to ensure that health promotion and health care are in harmony with the protection of life and human values, particularly human dignity; the principles of bioethics entail concrete obligations on the part of international agencies, governments, health care providers, professional associations, and society at large, as well as individuals and specific groups of the population.

Bioethics recognizes that ethical norms and values differ significantly from culture to culture. At the same time, bioethics must seek to identify certain fundamental ethical principles that promote human rights and welfare and that can be applied across all cultures.

1.2 Efforts should be made to promote and strengthen the continuing development of national and international capacities for ethical analysis of current and emerging changes in health care affecting individuals and populations.

1.3 In certain countries and societies, women are rendered vulnerable or potentially vulnerable as a result of customs which may be prejudicial to their health and/or social well-being. Ethical analysis and appropriate remedial action can serve to enhance the status of women, and their personal health and well-being, wherever such a situation obtains.

1.4 With the development of relatively new methods for measuring the burden of disease on human life that constitute potential tools for guiding decisions for improving the cost-effectiveness (efficiency) of resource allocation and health planning, it is essential that the further refinement of these methods be guided

by the principles of equity and non-discrimination, on such grounds as age, sex, ethnic origin, personal status, etc., as well as efficiency, and that countries with an interest in applying these tools be provided with the resources for building capacities for undertaking these analyses in a manner consonant with national and local needs.

1.5 Efforts should be made to promote the further development of national and international protection of the most vulnerable; this will involve organizing and assisting individuals, groups, communities and governments at all levels to enhance their understanding of the causes and the circumstances contributing to different forms of vulnerability and their capacities for corrective action, and fostering a global sense of interdependence among all countries.

1.6 In light of the fact that bioethics has developed primarily, but not exclusively, in the most developed countries, there is a pressing need for the elucidation and universal adoption of basic bioethical principles, in a manner that acknowledges the world's diverse moral and cultural perspectives, priorities and values. A significant step towards this objective would be the setting up of bilateral and multilateral links, such as technical cooperation, exchanges and information, among institutions and professional societies dealing with bioethics in industrialized countries and their counterparts in developing countries; such associations would be mutually beneficial.

2. The Role of National, Regional and International Human Rights Bodies

2.1 Important opportunities exist for applying bioethics concepts in developing the content of human rights relating to health, health protection, and health care. Such rights can be clustered into three categories, viz:

- rights to health care and to the benefits of scientific progress;
- rights relating to information, association, and freedom of action that could empower groups to protect and promote their health; and
- rights relating to self-determination and integrity of the person, including rights to liberty and security and the right to private life.

International and regional human rights treaties, as well as national constitutions, are designed to protect some or all of these rights, and establish mechanisms of accountability for violations of these rights.

3. The Role of Development Banks

3.1 The World Bank and the Regional Development Banks should consider the incorporation of bioethical perspectives into development project design and assessment, particularly as regards health, environment, poverty and education; ethical considerations should likewise be taken into account by these institutions in their health development and other related activities.

4. The Role of International Organizations

4.1 We invite intergovernmental organizations engaged in international health work to pay due attention to bioethical concerns in the planning and

implementation of their policies and programmes. Particular emphasis needs to be placed on the full involvement of all concerned, including scientific and lay organizations, in discussions on the ethical issues raised by the introduction of new health and biomedical technologies. These organizations could help, through international and regional meetings, to sensitize countries to pressing bioethical issues, notably those raised in the primary health care context, and to foster a North-South dialogue in this area, aimed at achieving broad universal consensus on the essential principles of contemporary bioethics and their implementation in the health and related sectors.

4.2 Such organizations as the appropriate United Nations agencies, CIOMS, the World Medical Association, the International Council of Nurses, the International Confederation of Midwives, the International Association of Bioethics, and the International Association of Law, Ethics and Science can play an important role in soliciting and promoting developing-country contributions to their work in the areas addressed by this Declaration. They can likewise serve to arouse the conscience of wealthy countries regarding their obligations to the developing world.

5. The Role of CIOMS

5.1 In recognition of its considerable experience in the field, we invite CIOMS to endeavour to monitor the impact of the International Dialogue on Health Policy, Ethics and Human Values on the emergence and sustainable development of bioethics, particularly in developing countries.

5.2 This Declaration should be distributed to the member organizations of CIOMS, as well as to other relevant international nongovernmental organizations. These organizations and their constituent national societies and associations are invited to give due attention to ethical considerations and issues.

HEALTH POLICY, ETHICS AND HUMAN VALUES — AN INTERNATIONAL DIALOGUE

This major CIOMS programme had its origin in the CIOMS International Conference, held in Athens in 1984, under the same title. The purpose of the conference was to discuss in an international and intercultural context the ethical questions raised by health policy-making and policy decisions. Health policies determine who are to receive health services, how resources are allocated, what criteria are used in setting priorities, what are acceptable forms of health care, when medical care should be begun and ended, and who should take part in making health policy.

These and similar decisions have important ethical components and implications, accentuated today by the remarkable scope and rapidity of advances in science and technology and its application in medicine.

The Athens conference, planned in consultation with WHO, convened health policy-makers, ethicists and philosophers from the world's major cultural and religious groups, as well as secularists; the discussion covered the topics of equity, social justice, community participation, and the dignity of individuals in sickness and health, in the context of health policy-making.

A strong recommendation was for a continuing international intercultural dialogue to improve understanding of the relationship between health policy-making, ethics and human values in different cultures. CIOMS implemented this recommendation by undertaking in 1985 the programme entitled *Health Policy, Ethics and Human Values — An International Dialogue*, with the following objectives:

- ☐ to strengthen national capacities for addressing and making decisions about the ethical and human-values issues involved in health policy;
- ☐ to contribute to improved understanding of the concepts inherent in WHO's goal of health for all, particularly in terms of its values content;
- ☐ to develop transcultural and transdisciplinary approaches and methods for working in this field; and
- ☐ to use improved understanding of the approaches of various societies to the ethical and human-values aspects of health policy, as a way to promote deeper human understanding of human values across cultural and political lines.

The main means of implementing the programme is the organization of international, intercultural conferences with a global orientation. Some are regional conferences, concerned with the interaction of health policy-making, ethics and human values in culturally largely-homogeneous settings.

Health Policy, Ethics and Human Values — Indian Perspectives

The first conference in the framework of the programme, dealing with Indian perspectives, was organized in New Delhi by the Indian Council of Medical Research and co-sponsored by CIOMS. The 258 participants from 72 national organizations of India, representing a diversity of medical specialists, health policy-makers, and religious and political leaders, discussed a great variety of subjects of particular importance for India, such as population

policy, drug policy, medical education, primary health care, quality of life, meaning of life and suffering and death, and health policy planning and administration. The proceedings of the conference were published in 1986.

Battered Children and Child Abuse — International Recommendations

In 1985 CIOMS held a conference on Battered Children and Child Abuse, which formulated a set of recommendations for improving what was considered an alarming situation, to be implemented by national authorities and international governmental and nongovernmental organizations.

Child battering — child abuse in general — is known to be widespread, differing in the forms it takes from one cultural setting to another, but always with medical, social, legal and ethical implications. Public awareness and concern about the problem, in both developed and developing countries, have been stimulated over some years by a dramatic increase in the numbers of reported cases of child abuse, as well as by a better understanding among the public and professionals of the many different forms it takes in different sociocultural settings. Although the reported increase has been particularly noticeable in the industrialized countries, it appears that the problem may be equally extensive but less diagnosed or reported in traditional, rural and agricultural societies.

The conference formulated a set of recommendations which, together with the highlights and proceedings, were published in 1986.

Health Policy, Ethics and Human Values — European and North American Perspectives

This conference, convened in 1987 by CIOMS, in collaboration with WHO, and co-sponsored by the Netherlands Ministry of Welfare, Health and Cultural Affairs, and the Institute of Bioethics of the Netherlands, brought together health policy-makers, ethicists and biomedical experts to consider the critical ethical issues raised by progress in biomedicine and, even in the richest countries, scarcity of resources and the need to reallocate them. The focus was on the industrialized countries, mainly in Europe and North America.

The programme was structured around four areas typifying the ethical and human values issues that confront health policy-makers: screening and counselling, with special reference to genetic engineering and interventions; organ transplantation, including patients' and donors' perspectives; health care of the elderly, with regard to limits of care and quality of life and aging; lifestyles and health hazards, mainly the issues of balance between individual choices and collective interests.

The recommendations of the conference were brought to the attention of the Fifth Summit Conference on Bioethics, entitled Human Genome Sequencing: Ethical Issues, held in Rome in 1988, and the recommendations of the latter were widely based on those of the CIOMS Conference.

The highlights and the proceedings, including the recommendations of the conference, were published in 1988.

Ethics and Human Values in Family Planning

Human reproduction can never be treated merely as an objective, technical subject. No religion and no ethical system has ever been indifferent to the issues involved in reproduction. The recent expansion of the needs for, and the means of, fertility regulation has inevitably raised a host of fundamental ethical concerns.

The complex ethical issues arising from advances in the management of infertility and in molecular genetics were the subject of a conference in 1988 convened by CIOMS, jointly with the WHO Special Programme in Human Reproduction, entitled *Ethics and Human Values in Family Planning*. Its main objectives were: to determine and clarify the ethical issues inherent in family planning from different national and cultural perspectives; and to stimulate transcultural discussion on the ethical issues by policy-makers, health professionals, scientists, ethicists and the public at large. The clarification of apparently conflicting issues was intended to help countries adopt socially and culturally acceptable policies in fertility regulation and family planning. Also, it was hoped to stimulate continued dialogue about these complex topics and encourage tolerance of different views among different cultures.

The conference examined the ethical issues comprehensively, in the light of social norms, legal codes and human values. The highlights and the proceedings of the conference were published in 1989.

Health Policy, Ethics and Human Values: An Islamic Perspective

In November 1988 CIOMS co-sponsored, with WHO, a seminar in Cairo, organized by the Islamic Organization for Medical Sciences, on Islamic perspectives of health policy, ethics and human values.

It had two particular advantages: it prompted the Islamic Organization for Medical Sciences to encourage leading Muslim ethicists and scholars to give major attention to the subject of health policy, ethics and human values; and it provided an opportunity for a number of leading ethicists and policy-makers from other countries, members of the CIOMS Steering Committee on the International Dialogue, to be present and to enter into a dialogue with their Muslim colleagues on these issues.

CIOMS published in 1989 *Reflections on the Cairo Seminar*, which indicates the content of the proceedings and illustrates the nature of the dialogue that took place between the Muslim scholars and their guest ethicists and policy-makers.

Health Technology Transfer — Whose Responsibility?

Advances in the basic medical sciences and their application to clinical medicine have opened the way to new therapies and numerous specialties, demanding new and more specific technologies. Medical research is resulting in new diagnostic, therapeutic and rehabilitative methods, and these have numerous applications in health care in all countries, rich and poor.

Health technology has moral implications and its transfer between different countries raises complex ethical issues. In developing countries large groups are denied the benefits of indirect health technologies (sanitation, housing,

nutrition, education), and have only very restricted access to direct health technologies. They are under heavy pressure to import modern medical technology, and to expend on it scarce resources for buildings, maintenance and staff. Health care technologies need to be assessed and regulated, therefore, but without stifling innovation or local initiative and research. Technology transfer has research implications also. New technology will continue to appear and countries must be prepared to deal rationally with the issues raised by technology transfer.

These and other related issues were discussed at a CIOMS conference entitled "Health Technology Transfer — Whose Responsibility?", held in 1989. The conference discussed the roles and responsibilities of the different parties at present involved in technology transfer, and the perspectives of the developers and users of health-care technology. It indicated the gaps between the offer and the need, and suggested means of bridging them, recognizing the different interests of providers and users, and the need for international collaboration.

The proceedings, including the main papers and a summary of the discussions and recommendations, were published in 1990.

Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Genetic Therapy

Research at present under way into molecular genetics, and particularly into human genome mapping and sequencing, presages a new scientific era in the medicine of the 21st century. However, there is much concern about the implication of advances in human genome mapping, genetic screening and genetic therapy for the right and responsibilities of individuals and societies.

Efforts have begun in the United States of America, Japan and Europe to map and sequence the entire human genome. Over the next decade most of the genes in the human genome are likely to be identified. This knowledge will be important not only for diagnosing, treating, and even preventing diseases caused by single-gene defects but also for better understanding, and even treatment, of those major common diseases that result from the interaction of genetic predisposition with various environmental factors.

These scientific developments will raise difficult ethical issues. Increasingly, single-gene disorders will be diagnosable prenatally and postnatally. But there are questions about the extent to which prenatal screening should be implemented. At present, very few single-gene disorders can be treated. Even if gene therapy becomes feasible, it is very likely for many years to be limited to a few diseases. Hence, results of prenatal and postal screening will be used primarily for genetic counselling or for decisions regarding the abortion of affected fetuses.

Ethical issues are equally important in the case of multifactorial diseases. The possibility of detecting individual predisposition to a given disease must be weighed against the risk of misuse of this information.

Another ethical issue arises when genetic diagnostic advances come faster than advances in treatment. What is the use to an individual of knowing of a predisposition to a disease if there is no treatment? Can genetic screening be justified by the possibility of postponing onset of disease or of lessening its effects?

Other ethical issues include: the extent to which research should be controlled, and who should control it; whether misuse of the knowledge acquired can be precluded, and how; how it will be possible to predict the consequences of genetic intervention and to avoid or mitigate the unacceptable; who should own or otherwise benefit commercially from the products of genetic research; how and from whom is consent to be obtained for genetic interventions, particularly if they may affect future generations; and how are privacy and confidentiality to be protected.

It was in this general context that the XXIVth CIOMS Conference was held in Tokyo and Inuyama City, in July 1990. The Conference, which was co-sponsored by WHO, UNESCO, and the Science Council of Japan, was designed to stimulate an international, interdisciplinary and transcultural dialogue on the ethical implications of research in molecular genetics, and particularly those of the mapping and sequencing of the human genome. The proceedings of the conference, including The Declaration of Inuyama, were published in 1991.

Ethics and Epidemiology: International Guidelines

The potential of modern epidemiology, especially for the collection, storage and use of information, carries with it risks of abuse and gives rise to a certain tension between the rights and freedoms of individuals and the interests of society. These issues are particularly germane to developing countries, which are less well placed than developed countries to prevent abuse or to assure for their people the beneficence of epidemiological research. CIOMS has responded to suggestions of professional epidemiological associations and the World Health Organization, by undertaking a programme of widespread consultation to develop international guidelines for ethical review of epidemiological studies. The need had become pressing because of the special problems raised by the HIV/AIDS epidemic and the imminent commencement of trials of candidate HIV vaccines and new treatment drugs.

It was in this general context that the XXVth CIOMS Conference, entitled Development of International Ethical Guidelines for Epidemiological Research and Practice, was held in November 1990, to consider a set of draft international guidelines for ethical review of epidemiological studies, in the light of biomedical and public-health ethics, and the aspects of epidemiological research and practice, such as informed consent and confidentiality, that impinge upon ethics. The conference discussed the ethical risks associated with epidemiological research in conditions of poverty and scarcity, and the applicability of the guidelines in developing countries, and gave particular attention to the problems posed by the HIV/AIDS epidemic.

The proceedings of the conference entitled Ethics and Epidemiology - International Guidelines, including the international guidelines, were published in 1991.

Ethics and Research on Human Subjects — International Guidelines

To facilitate the revision of the Proposed International Guidelines for Biomedical Research Involving Human Subjects, published in 1982, and to

explore present-day issues in research on human subjects and how ethical principles may guide the conduct of such research, CIOMS organized in 1992 a conference on Ethics and Research on Human Subjects — International Guidelines.

At the conference the draft of the revised guidelines was examined and discussed by some 150 participants from both developed and developing countries, including representatives of ministries of health and of medical and other health-related disciplines, health policy-makers, ethicists, philosophers and lawyers.

The primary themes of the conference were:

- Consent of individuals and agreement of communities to participation in research, including concepts of consent and the communication to prospective research-subjects of information to enable them to give valid informed consent, inducements to consent, selection of subjects, special concerns of disadvantaged or vulnerable populations, and the problems of fully informing and gaining the agreement of communities.
- Ethical review processes, such as national and local committees, practical impediments to ethical review, review of externally-sponsored research, and developing the ethical-review capacity of host countries.
- Obligations of sponsors, with special attention to responsibility for access of subjects to medical services, access to beneficial results of research, care and compensation for injury resulting from research, and development of the research capacity of host countries.

In addition, there was discussion on emerging issues in research, such as the effects of different cultural concepts of ethical principles and values on the conduct of multinational research, challenges to the application of ethical principles in particular research areas such as HIV infection, the influence of ethical principles and guidelines on legislation, and the ethics of research into the human genome.

The three primary themes and the additional topics were explored in plenary presentations and discussed in working groups. A special plenary session was devoted to different cultural perspectives on ethics and research involving human subjects.

The draft guidelines were revised to reflect the consensus of the conference, but with due regard to minority points of view.

The proceedings of the conference, including the revised international guidelines, were published in 1993.

Poverty, Vulnerability, the Value of Human Life, and the Emergence of Bioethics

The first in a series of CIOMS/WHO conferences on Health Policy, Ethics and Human Values was convened in Athens, Greece in October-November 1984. Ten years later, CIOMS and WHO have convened the XXVIIIth Conference in Ixtapa, Guerrero, Mexico, both to commemorate the ten years of work, and to advance consideration of further important issues in this field.

CIOMS and WHO have been partners in probing at the applications of theory and practice of bioethics, often to facilitate consideration in developing countries of concepts formulated in the developed countries, but also to carry back to the developed world the perspectives of the developing world. This conference will provide further opportunities for continuing such probing, and also for reflecting on the particular role of CIOMS and WHO in that process, past and future.

Trends in Bioethics — Regional and Global Perspectives

The emergence of bioethics in the early 1960s in the United States was a result of many social, political, technological and philosophical factors which have a very significant influence on medicine, health policy and public policy in general.

The question should be asked, for every factor that influenced bioethics in the U.S., what was happening in the rest of the world? What would comparable analyses of the developments of bioethics in Europe, Asia, Africa and Latin America look like? Was there mainly a transfer of ideas and experience from the U.S. to other countries, to then be modified according to local circumstances? To what extent has bioethics abroad emerged in original form from the social, political, technological, philosophical, and historical context of those societies? To what extent has bioethics in the U.S. been influenced by happenings abroad in that field? How much room is there for collaborative interaction among countries in the further development of bioethics? How much attention has been given to characterizing the ways in which bioethics is evolving and interacting in different settings around the world?

The agenda of the conference was designed to address the above set of questions. There were presentations on and discussion of the Birth of Bioethics in the United States, followed by perspectives from Europe, developing countries, and related legal and legislative issues.

The Vulnerable in Developed and Developing Countries — A Conceptual Framework

There have been frequent expressions of concern for the vulnerable in previous CIOMS conferences, on Health Policy, Ethics and Human Values. To a considerable extent, the concern was focused on those who are poor, and those whose natural situations in life render them vulnerable.

Two groups of the vulnerable could be distinguished:

- ☐ those who are vulnerable because of their situation in life — mothers, children, and those who are elderly, disabled, or at health risk because of where they live and work or how they live and work;
- ☐ those who are rendered vulnerable because of their socio-economic status and the ways in which society deals with them.

A framework of considering how various factors bear on these forms of vulnerability include:

- ☐ Power and vulnerability;

- ☐ Physicians and the vulnerable in the context of their society;
- ☐ Inter-country efforts for inter-country conflicts;
- ☐ Roles of international organizations.

The conference addressed concerns for the vulnerable through a presentation of the background paper followed by group discussions of the ways in which vulnerability is manifest in both developed and developing countries, leading to reflections in the final session on the possibilities of national and international response to the challenges represented by the vulnerable.

Disability-adjusted Life Years

The disability-adjusted life year (DALY) is a measure of disease burden, combining healthy life years lost because of premature mortality with those lost as a result of disability. A major purpose of using DALYs as a measure of disease burden is to provide policy-makers with guidance for resource allocation.

The key questions focused on comparative valuation given to human lives, and on the extent to which the construction of DALYs has taken equity into account as a moral imperative of development.

The conference addressed these issues through a panel, with a speaker and respondents, and then discussion in small working groups, pointing toward a session at the end that reflected on how far the participants had dealt with the challenges of this important subject.

The three main subjects of the conference were interactive and raised questions that are critical with respect to health and development in societies at all levels of socio-economic development. Each subject can be challenged in terms of the extent to which it takes the others into account. The conference probed at each and explored how they fit into the larger global processes of social development.

The proceedings of the conference were published in 1994.

Impact of Scientific Advances on Future Health

CIOMS cosponsored with WHO a colloquium on the Impact of Scientific Advances on Future Health, held in the United States on 20-25 June 1994. Its objective was to draw attention to, and document, the most critical current and potential developments in science which will have a major impact on medicine and public health over the next 10-20 years. Participants consisted of scientists notable for their research achievements in biology, physics, engineering and applied sciences, and social and behavioural sciences, together with CIOMS and WHO officials.

The colloquium considered two main themes — the future of medicine in the context of advances in natural and engineering sciences, and the future of public health in the context of economics, technology, and the sociocultural and behavioural environment.

The proceedings of the colloquium will be published in 1995.

DRUG DEVELOPMENT AND USE — MEDICAL, SOCIAL AND ECONOMIC IMPLICATIONS

In the early 1980s, in close collaboration with WHO, CIOMS launched its programme on Drug Development and Use — Medical, Social and Economic Implications. The stimulus for this joint programme was a conference, convened in 1977, on Trends and Prospects in Drug Research and Development. The conference recognized that CIOMS, as an independent organization, was well placed to bring policy-makers of research-based pharmaceutical industries into discussion with their counterparts in government and academia, and to convene groups of experts from these constituencies to make recommendations on specific issues. Since then, in collaboration with WHO, CIOMS has undertaken a variety of projects of direct concern to manufacturers and prescribers of drugs. For some years the emphasis of CIOMS activities in relation to drugs has been on the monitoring of drug safety and the reporting of adverse drug reactions.

THE MONITORING AND TERMINOLOGY OF ADVERSE DRUG REACTIONS

This programme was undertaken for two reasons, namely, the intensity of public and media preoccupation with drug safety in highly developed countries, and the need to review the scope and potential of epidemiologically-based approaches and computerized record-linkage systems for drug surveillance.

Its aims were to present objectively and persuasively the benefits that society as a whole derives from access to modern drugs and vaccines, and to make the case that, unless society is prepared to accept the possibility of remote risks to the individual as the corollary of modern medical care and further therapeutic progress, the basis of contemporary drug development will ultimately founder. Society must be assured that a responsible and committed effort is in hand to minimize drug-induced injury, and that the risks of such injury compare favorably to those accepted in other aspects of daily life.

CIOMS convened, as a first step, a group of experts representing universities, drug manufacturers and regulatory agencies, and its report, *Monitoring and Assessment of Adverse Drug Effects*, was published in 1986. During the meeting representatives of both drug regulatory agencies and manufacturers emphasized the urgent need for harmonization of reporting of adverse drug reactions and the relevant terminology, and requested CIOMS to take the necessary steps.

International Reporting of Adverse Drug Reactions — CIOMS I

In 1986 the Adverse Drug Reaction Working Group was convened to explore means of coordination and standardization of international adverse-reaction reporting by industry to regulators. The underlying rationale of the formation of this group was the recognition that adverse drug reaction (ADR) surveillance is critical to assuring that approved drugs are safe in practice, given the inherent limitations of pre-marketing approval processes.

Knowledge of approved products routinely evolves after their initial marketing as experience of their use accrues. The aim of post-marketing surveillance is to capture this knowledge as rapidly and efficiently as possible.

The outcome of the Group's work, was the introduction of an international form and agreed and tested procedure for reporting adverse drug reactions. The form and the reporting procedures are now being used for exchanging reports between regulatory authorities and pharmaceutical manufacturers in a growing number of countries, including the United Kingdom, the United States of America, Germany, and France, which were represented in the ADR Working Group. Also, they are under consideration for use throughout the European Communities and they have been recommended by WHO, on the basis of broader consultation, for international adoption. The report of the Working Group, entitled *International Reporting of Adverse Drug Reactions*, was published in 1990.

Periodic Safety-Update of Drugs — CIOMS II

CIOMS has continued to act as a forum for manufacturers and regulators to meet and continue to facilitate international agreement on procedures for promoting drug safety. Thus a second CIOMS ADR Working Group, consisting of experts from the pharmaceutical industry and regulatory authorities, was convened to explore the possibility of developing internationally agreed approaches to the preparation of safety-update summaries. Such summaries could meet the needs of countries that cannot themselves analyse single cases of ADRs occurring in foreign countries, and at the same time serve as a model of how such data could be presented, so as to forestall any future diversity of safety update regulations.

CIOMS Working Group II set out to develop a satisfactory way for manufacturers to report safety information to regulatory bodies, and to elaborate uniform procedures, for current and future regulatory requirements. The Group concentrated on safety updates required periodically by regulatory authorities after a drug is approved.

It designed and tested a safety-update format, which is being recommended for routine use, and which may be considered also as a basis for periodic or final pre-marketing safety reports. A survey has been made of current safety-update reporting requirements in the nine countries whose regulatory authorities are taking part in the project. The report of CIOMS Working Group II on *Drug Safety Updates* was published in 1992.

Core Safety Data Sheets of Medicinal Drugs — CIOMS III

One of the key obligations for both drug manufacturers and health authorities bearing on the regulatory approval of a medicine is the provision of the most relevant and helpful information for health care professionals on the drug's benefits and risks.

The absence of internationally agreed standards on the format and content of medical product information for prescribers and other health care professionals give rise to discrepancies and inconsistencies from country to

country and manufacturer to manufacturer. This situation is especially unfortunate with regard to the disclosure of important safety information that influences benefit vs. risk considerations in a prescriber's selection and application of a drug. Building on the precedents set by CIOMS Working Group I and II on individual patient and summary safety reporting internationally, Working Group III has developed proposals addressing the preparation and appropriate modification of the Core Safety Data Sheet of Medicinal Drugs: Standards for Good Clinical Safety Labelling Practices. These proposals cover the following aspects: what to include or exclude and how to decide, standard nomenclature and definitions, and general guidance on good clinical safety labelling practices.

The regulatory authorities and manufacturer participants in CIOMS Working Group III strongly endorse these proposed standards and hope they are not only implemented by manufacturers internationally but are adopted by health authorities for application to official data sheets everywhere.

The report of CIOMS Working Group III entitled *The Core Safety Data Sheet of Medicinal Drugs* was published in 1994.

Harmonization of Adverse Drug Reaction Terminology

The advent of international drug monitoring in the late 1960s and the directions that monitoring has taken since then have had as a direct consequence the creation of large data-bases of very heterogeneous origins. This is true not only of an international monitoring system such as that used by WHO, but also of data collected by major pharmaceutical companies with worldwide activities. In several countries companies are also required to transmit reports of adverse drug reactions to the regulatory authorities of other countries in which their products are marketed.

The use and interpretation of certain ADR terms differ considerably in different countries. This can lead to misinterpretation of data or delay their proper evaluation by drug regulatory authorities. The need to establish minimum requirements for the proper diagnosis of a suspected ADR, and thus to describe it with the correct term, is particularly evident in spontaneous reporting of single case reports. Single case reports represent the most important type of information for raising suspicions about drug safety, generating signals and, frequently, even taking action. Single case reports are transmitted by a reporting physician to a collecting centre at either a drug regulatory agency or a pharmaceutical company, and quite often between these organizations as well.

The CIOMS I, II, and III agreements represent useful steps in the harmonization of reporting of adverse drug reactions. The CIOMS I agreement ensures that there will be one form, with one set of definitions, to be completed in one language, for international reporting of ADR. The CIOMS II agreement is concerned with periodic safety updates and provides a format for a single unified report which pharmaceutical companies can send to all regulatory authorities who are willing to participate in the scheme. The CIOMS III agreement sets internationally agreed standards for the format and content of information on medical products.

The need of an international dictionary of ADR terms is recognized as a first priority by both drug regulatory authorities and pharmaceutical companies. Accurate definitions of terms are essential for their valid classification and for recording information from different sources in the same data-base.

In response to this need CIOMS initiated in 1989 a collaborative project aimed at establishing definitions and basic requirements for the use of terms for reporting adverse drug reactions. The model for this work was a series of consensus meetings held in France for defining adverse drug reactions. In the framework of this project CIOMS organized international meetings of experts, of drug-induced liver disorders and on drug-induced cytopenias. In addition, CIOMS with the support of German and Swiss pharmaceutical companies, organized a series of working groups to draw up definitions and minimum requirements for the use of Critical High-level Terms as listed in WHO Adverse Drug Reaction Terminology. The groups consist of medical specialists from different countries and members of national drug surveillance authorities and of drug safety units of pharmaceutical companies. The outcome of these working groups has been published in a series of papers.

There are several classification systems of ADR in extensive use. The most widely used are WHOART (World Health Organization Adverse Drug Reaction Terminology) and COSTART (Codification of Standard Terminology of Adverse Drug Reaction Terms) of the Food and Drug Administration of the United States. Recently a Medical Dictionary for Drug Reaction Terminology (MEDDRA) was developed in the United Kingdom in collaboration with the Medicines Control Agency of the Department of Health of the United Kingdom.

Harmonization of terminology relevant to drug safety is essential for meaningful exchange of information and experience not only between manufacturers and drug regulators, but also between other groups involved in drug safety monitoring. Appreciative of this need and taking into consideration the CIOMS experience in this field, the Food and Drug Administration of the United States (FDA) and WHO have recently requested CIOMS to coordinate the harmonization process of ADR terminology and to prepare the relevant dictionary.

Following this request CIOMS convened, in May 1994, a Planning Committee of representatives of WHO, FDA, EC, Japan and the pharmaceutical industry. The Committee agreed that it is essential that international communication in pharmacovigilance and other regulatory questions require a common terminology and the preparation of definitions and a single dictionary of terms. An overview committee, under the aegis of CIOMS and WHO, has been established in order to: review and consolidate relevant adverse drug reaction terminologies and propose a single terminology; promote the development of a single dictionary to support the terminology and maintain further development of the terminology and dictionary.

DRUG SURVEILLANCE: INTERNATIONAL COOPERATION PAST, PRESENT AND FUTURE

The subject of the XXVIIIth CIOMS conference, the history and future of international cooperation in drug monitoring, is timely because of a resurgence of interest in this scientifically challenging area.

Quality, efficacy and safety are the three criteria which determine the acceptability of drugs for public use. Much attention is given to safety before a drug is registered, but, unlike the evaluation of quality and efficacy, in vitro studies, and animal and controlled human exposure give only a limited picture of safety in general clinical use.

After the limitations of these safety measures were emphasized by the thalidomide tragedy, WHO set up a Programme to coordinate the surveillance efforts of national drug regulatory bodies, including the pooling of case data and producing collated and summarized outputs. The work of the Programme has been much strengthened by the involvement of CIOMS in bringing drug regulators and the pharmaceutical industry together to extend the basic work of the Programme in harmonization of terminology and definitions, which is making communication of drug safety concepts and issues easier, and to explore new areas such as periodic drug safety data sheets and the safety aspects of drug package inserts.

Now there are new challenges and opportunities in drug safety. New drugs are introduced rapidly into the international markets and new biotechnology produces drugs that influence body processes ever more profoundly. The promise is that more selectivity of action will make them safer, but such has to be proven, particularly when therapy may be lifelong. New techniques in pharmacoepidemiology make possible clearer identification of reasons why drugs may have been implicated in causing adverse drug reactions and may give important information for better drug use.

With these examples alone it is easy to see that the cooperative effort begun 25 years ago is still valid, if safety problems with drugs are to be identified and investigated as rapidly as possible, thus giving patients throughout the world the optimal balance of benefit to risk from their treatment, at the most reasonable cost.

The purpose of this CIOMS conference was to review the present position with regard to international drug surveillance, from the perspectives of drug regulatory authorities, the pharmaceutical industry, health authorities, and the research and academic communities, and to indicate the broad lines to be followed in the medium term, at least, and with regard to both developed and developing countries.

The conference participants were representatives of national drug-monitoring centres, drug regulatory authorities, pharmaceutical companies and, as in previous CIOMS conferences, health ministries, CIOMS member organizations, non-governmental organizations in official relations with WHO, medical research councils and universities.

The proceedings of the conference were published in 1994.

ETHICAL CRITERIA FOR MEDICINAL DRUG PROMOTION

The 45th World Health Assembly passed in 1992 a resolution that called upon CIOMS to collaborate with WHO in convening a meeting of interested parties to discuss possible approaches to advancing the principles embodied in WHO's Ethical Criteria for Medicinal Drug Promotion. Pursuant to this request, the CIOMS/WHO Consultation was convened in Geneva in April 1993.

This consultation brought together a wide range of interested parties — governmental drug regulatory agencies, pharmaceutical industry, international pharmaceutical manufacturers associations, consumer groups, journal editors, medical educators, health professionals, and WHO senior staff — to examine the problems associated with implementation of the Ethical Criteria:

- There was unanimous recognition of the need for widespread implementation of the Ethical Criteria as necessary for more appropriate approaches to the promotion or marketing of medicinal drugs, in keeping with rational use of drugs and associated improvements in health.
- Those present generally acknowledged their individual and organization's responsibilities for advancing the implementation of the Ethical Criteria within their spheres of influence and whenever appropriate in a spirit of collaboration.
- All those present also agreed to the importance of activities being undertaken across the broad field of medicinal drug promotion in order to bring practical and operational steps to the implementation of the Ethical Criteria.
- The participants also agreed to report their activities periodically to WHO, and in any case within a year, so these reports could be collectively matters of reference for the World Health Assembly.

A series of topics raised during the Consultation was one of the open dialogue and constructive development of areas for action that could be undertaken by WHO and by participants and their organizations with prospects for substantial advancement in the implementation of the Ethical Criteria.

The participants agreed on Topics Recommended for Further Action and Concluding Statement on the Consultation. The final report, including recommendations, were approved by the WHO Executive Board and the World Health Assembly, in 1994, and Resolution WHA47.11 was adopted, endorsing the report of the Consultation and requesting implementation of its recommendations.

INTERNATIONAL NOMENCLATURE OF DISEASES

Confusion in disease nomenclature is a barrier to communication and to the storage and retrieval of information. Few diseases have a single recognized name: most have several different — often widely different — names, and some have thirty or more. Many of these names are strict synonyms; others, however, are not but may represent only a single clinical manifestation of a given disease rather than the disease itself. The confusion is aggravated by the fact that the same name, or very similar names, may be applied to two or more different conditions, or be used in different ways by different authors. Moreover, very similar names may be used in different senses in different languages. At a time when health is increasingly a matter of concerted international effort, such confusion gives rise to intolerable difficulty in communication and to waste of precious resources.

Following a pilot study, CIOMS, in 1975 undertook, jointly with WHO, the project: International Nomenclature of Diseases (IND). The project is guided by a Secretariat Technical Steering Committee with representatives of both organizations. It was at first funded by the Public Health Service of the United States of America; from 1983 to 1990 it was supported by a grant from the Kuwait Foundation for the Advancement of Sciences and the Kuwait Ministry of Public Health.

The principle objective of the IND is to provide, for every morbid entity, a single internationally-agreed recommended name. The main criteria for selection of this name are that it should be specific (i.e., that it should apply to one and only one disease), unambiguous, as self-descriptive as possible, as simple as possible, and (wherever feasible) based on cause. However, many widely used names do not fully meet these criteria, and to propose new names might well increase, rather than eliminate, confusion. Consequently, names that are in virtually universal usage are retained, even if they do not fully meet the criteria listed above, provided they are not seriously incorrect, misleading, or contrary to the recommendations of international specialist organizations. Eponymous terms are avoided as far as possible, since they are not self-descriptive; however, many of these also such as Hodgkin's disease, Parkinson's disease and Addison's disease, are in such widespread use that they must be retained.

Each disease or synonym for which a name is recommended is defined as unambiguously but as briefly as possible. To the definition is appended a list of synonyms — that is, terms other than the recommended term that have been applied to the morbid entity in question. These lists are very valuable for information retrieval and are made as complete as possible; they are supplemented, where necessary, by notes explaining why certain synonyms are rejected or why a term used as a synonym is not a true synonym.

An additional objective of the IND is that it should serve as a complement to the WHO International Classification of Diseases (ICD). The ICD is a classified list of diseases, arranged systematically and hierarchically, and designed for the reporting of mortality and morbidity. The IND is a list of

recommended names of diseases, with their definitions and synonyms, and is not concerned with their classification. In the preparation of the 10th Revision of the ICD use was made of the experience gained in the preparation of the IND, particularly in regard to the groups of diseases for which volumes of the IND have been published, or are about to be published.

The IND project draws on the services of more than 500 experts in many countries. So far, more than 5000 names of diseases and their definitions have been agreed and more than 20,000 synonymous terms listed.

To date the following volumes of the International Nomenclature of Diseases have been published:

Volume II, Infections Diseases: Part 1 , Bacterial Diseases, 1985

Part 2, Mycoses, 1982

Part 3, Viral Diseases, 1983

Part 4, Parasitic Diseases, 1987

Volume III, Diseases of the Lower Respiratory Tract, 1979

Volume IV, Diseases of the Digestive System, 1990

Volume V, Cardiac and Vascular Diseases, 1989

Volume VI, Metabolic, Nutritional, and Endocrine Disorders, 1991

Volume VII, Diseases of the Female Genital System, 1992

Volume VIII, Diseases of the Kidney, the Lower Urinary Tract and the Male Genital System, 1992

Lexicon of Psychiatric Terms, 1989

Volume I, which will include a general introduction, guiding principles and a historical background of the project, will be published after all other volumes of the nomenclature have been completed.

Other volumes, concerned with diseases of the blood and haemopoietic system including immunological disorders, with neurological disorders and with diseases of the musculoskeletal system, are at different stages of preparation.

It is hoped that the International Nomenclature of Diseases will facilitate communication between health workers throughout the world by providing a truly international language of diseases and thus eliminating one of the barriers to communication.

Due to lack of funds the project was suspended until an eventual availability of funding.

CONFERENCES AND COORDINATION OF INTERNATIONAL MEDICAL CONGRESSES

Annual conferences of CIOMS, on subjects that are both topical and of international significance, serve two purposes: to implement the technical programmes of CIOMS; and to provide an international forum, unhampered by political or administrative constraints, for the exploration of the scientific and technical aspects of new developments in biology and medicine as well as their social, ethical, administrative and legal implications.

Participants in these conferences are prominent representatives of their different fields of medicine and biology, philosophy and theology, sociology and law; it is felt that this multidisciplinary approach can best explore and elucidate the multiple facets of issues that are no longer exclusively the concern of any one profession and are sometimes subjects of wide public interest.

Every year CIOMS organizes such a conference, publishes its proceedings, distributes them to its member organizations, and makes them available generally through the WHO Distribution and Sales Service.

One of the main tasks of CIOMS since its inception in 1949 has been to assist in the coordination of international medical congresses. Once an international or regional organization of medical sciences has notified CIOMS of the subject and proposed date and place of a congress, CIOMS informs the organization concerned of possible overlapping or duplication with other congresses. Since notifications are usually received two or three years in advance, sufficient time is allowed for changes to be made. Each year, CIOMS publishes the Calendar of Congresses of Medical Sciences, covering the current and succeeding years.

CIOMS collaborates in this field with the International Congress and Convention Association (ICCA). ICCA has assisted and co-sponsored with CIOMS several annual conferences and statutory meetings, and has provided, upon request, advice free of charge to CIOMS members.

COLLABORATION WITH THE WORLD HEALTH ORGANIZATION, UNESCO AND THE UNITED NATIONS

By its statutes CIOMS is required to collaborate with the United Nations and its Specialized Agencies, especially WHO and Unesco. During its early years, the organization was located at the Paris headquarters of Unesco and was more actively linked with Unesco activities than with those of WHO. However, with the intensified medical research programme which WHO undertook in the late 1960s, later expanded and oriented towards health research, the objectives of CIOMS became increasingly complementary to those of WHO. Many joint or collaborative activities, as described in the preceding pages, have been undertaken since 1970 when the CIOMS Secretariat was transferred from Unesco in Paris to the Geneva headquarters of WHO.

At present, with regard to bioethics and health policy ethics, CIOMS is acting on behalf of the WHO Global Advisory Committee on Health Research and therefore collaborates particularly with the WHO Secretariat Committee for Research Involving Human Subjects, as well as with the Office of Research Policy and Strategy, Health Legislation, and the WHO special programmes, namely the Global Programme on AIDS; Research, Development and Research Training in Human Reproduction; and Research and Training in Tropical Diseases.

Since 1975 CIOMS has been responsible for the preparation of an internationally agreed terminology of diseases, entitled International Nomenclature of Diseases. CIOMS is the executive agency for the joint project with WHO, and as such collaborates with all technical divisions and units of WHO.

In the field of drug development and use, since the early 1980s CIOMS, in collaboration with the WHO Division of Drug Management and Policies, has been conducting studies which involve the preparation of a series of meetings and the publication of subsequent technical reports, aimed at improving the safety of drugs, in particular the monitoring and assessment of adverse drug reactions.

Collaboration with the United Nations has been largely through its Centre of Human Rights and through the Committee on Crime Prevention and Control, of the Economic and Social Council. As noted above, in 1982 the General Assembly of the United Nations adopted Principles of Medical Ethics Relating to Prisoners, which CIOMS had drafted at the request of WHO.

For some years, the relations between CIOMS and Unesco have been largely consultative, mainly with regard to bioethics. Unesco is regularly informed of CIOMS activities, and its comments have provided welcome guidance. It continues to provide office accommodation for CIOMS at its Paris headquarters, as WHO does in Geneva.

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Metabolic, Nutritional and Endocrine Disorders, Volume VI, 1991

Diseases of the Female Genital System, Volume VII, 1992

Diseases of the Kidney, the Lower Urinary Tract and the Male Genital System, Volume VIII, 1992

Lexicon of Psychiatric Terms, 1989

ANNUAL PUBLICATION

Calendar of Congresses of Medical Sciences

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