

World Health Organization



Human Genetics Programme

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Statement of the WHO Expert Consultation on New Developments in Human Genetics

For urgent consideration by the
WHO Executive Board and the Advisory
Committee on Health Research (ACHR)

A consultation of WHO-invited experts in human genetics and relevant WHO staff was held in Geneva, Switzerland, from 20 to 21 July 2000, to review WHO's current activities in Human Genetics, identify challenges and priorities for WHO, and study the future role of the Organization in Genetics. The following statement was unanimously adopted:

“The advances in human genetics that have occurred during the past twenty years have revolutionized our knowledge of the role of inheritance in health and disease. The genome not only determines the cause of catastrophic single-gene disorders that affect millions of persons worldwide, but also - depending on environment - puts individuals at increased risk of cardiovascular diseases, cancer, and other common diseases. This knowledge has been linked with an equivalent explosion of unparalleled rapidity in the areas of information technology and biotechnology, and a globalisation of technology change. If used appropriately, this knowledge will provide many exciting future opportunities to achieve better health for people in all countries. However, it is clear that many individuals, groups and nations have concerns about the use and exploitation of genetic data and genome technology, and concerns that non-genetic determinants of health will be neglected. Genetic advances will only be acceptable if their application is carried out ethically, with due regard to autonomy, justice, education and the beliefs and resources of each nation and community.”

THE ROLE OF WHO

The World Health Organization is uniquely equipped to consider the new ethical issues that arise from developments in human genetics, by virtue of its mandate to pursue public good and to assist all nations in efforts to improve the health of their populations. It has a shrinking window of opportunity to provide leadership with regard to the key issues facing humankind in the application of genetics to health. WHO has a respected record in both developing and developed countries, and bases its activities on a strong knowledge base. It has a particular role in facilitating health in developing countries, and in narrowing the gap between the “haves” and the “have-nots”. Its experience in quality assessment, setting enforceable international standards of care, education, and promotion of research will be invaluable in developing policies related to genetic procedures and advances in biotechnology. It has a commitment to the preservation of health, to prevention as well as treatment of disease, and to the equitable provision of health care. It has an excellent track record of collaboration with other international bodies, such as the CIOMS¹, the WMA¹ and UNESCO in dealing with relevant issues in medical ethics, and with the OECD¹ in quality control and standards for biotechnology. Most important, it has a long experience of handling ethical issues in the public interest. WHO has the expertise and mandate to lead on behalf of all nations and to take appropriate action in this high profile area. It has a responsibility to provide leadership in health-related ethical issues, and must offer policies on human genetics quickly and decisively.

ETHICAL ISSUES ARISING FROM HUMAN GENETICS

The application of genetic knowledge to communities must be carried out with due regard to the general principles of bioethics. The many issues involved are covered in detail by past WHO efforts. These strong foundations, and the resulting documents (1, 2) which cover the issues in detail should be examined to ensure they are circulated and built upon.

There are many variations of experience and belief in different countries and cultures, but the principles outlined in the documents mentioned above apply to all populations. An appreciation of ethical principles in human genetics should be a part of the professional training of all health personnel, as well as educators and other decision-makers with an interest in health policy.

LEGAL AND EDUCATIONAL IMPLICATIONS OF NEW DEVELOPMENTS IN HUMAN GENETICS

Patenting facilitates the process of product development in genetics as in other medical fields, but patent protection must balance the provision of necessary incentives for invention with protection of public health interests. Gene patenting could impede international collaboration, especially between developed and developing nations, to the detriment of health care and biomedical research. WHO should participate in international debate on the implications of patenting and biotechnology in order to ensure that the health consequences in all countries are taken into account. It should work with key partners to develop a legal and ethical framework for gene patenting.

Genetic knowledge: WHO, working with other organizations, should play a major role in validating authoritative sources of information on human genetics and making these widely available. Education is a two-way process, and health care professionals have much to learn from support groups representing those with genetic disorders, and other citizens, in developing policies and strategies.

1 CIOMS: Council for International Organizations of Medical Sciences;
WMA: World Medical Association;
OECD: Organisation for Economic Co-operation and Development.

PRIORITY ACTIONS FOR WHO

The group recommends that WHO:

- **Develop** the capacity to offer a global response to the ethical, legal and social issues posed by the revolution in human genetics, and the implications of both therapeutic and non-therapeutic use. It should convene an internal Task Force, with urgency, to coordinate activities in this field in an imaginative way, with representation from the highest level and from all relevant departments and regions. This Task Force should recommend the best structure for providing leadership in formulating policies relating to advances in human genetics and in disseminating these to Member States. The Task Force will assess the resources necessary to meet these challenges.
- **Convene** a public, high-level meeting, involving the Director-General, to consider these issues and to stimulate global dialogue among major stakeholders. The meeting could consider whether WHO should create a Standing Commission or an Expert Panel to offer a leading voice on ethical, legal and human rights issues associated with human genetics.
- **Ensure** the establishment of a genetic Resource Centre to coordinate facilities and resources for research, standards, education and development. The Resource Centre could provide protocols and reference samples for simple and inexpensive gene analysis for common mutations, and develop model transferable strategies for training in clinical genetics and genetic counselling. It will coordinate and promote community education programmes in all countries to raise the level of knowledge of genetics, and help in the organization of regional training workshops to provide expertise in diagnostic and therapeutic approaches. Pilot studies on new scientific advances such as gene therapy or accurate sequence-based genome analysis could be initiated, assessed and, if successful, used as models. The Resource Centre will encourage collaboration between developing and developed countries. One area of particular importance is to ensure availability of genomic and bioinformatic resources in all countries to provide a mechanism for involvement in appropriate components of genome studies.
- **Organize** a conference to examine the implications for developing countries of advances in genetics and related biotechnologies.
- **Encourage** all nations to set up genetic services to meet immediate demand and to prepare for future needs. In so doing, the WHO will develop a template of recommended programmes and approaches to integrate basic interventions related to genetics in national health systems.
- **Develop** international norms and standards for genetic testing and other health-related gene technologies.
- **Consider** the implications of use of experimental transgenic animals, possible hazards from xenotransplantation to humans, and relevant issues arising from the development of these and other genetically modified organisms.

REFERENCES

1. Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services. Report of a WHO Meeting, WHO/HGN/GL/ETH/98.1.
2. Report of the Informal Consultation on Ethical Issues in Genetics, Cloning and Biotechnology: Possible Future Directions for WHO. Annex 1, Daar A, Mattei J-F. "Medical genetics and biotechnology: implications for public health", document WHO/EIP/GPE/00.1.

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