



WORLD HEALTH ORGANIZATION

FIFTY-SECOND WORLD HEALTH ASSEMBLY
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Cloning in human health

Report by the Secretariat

1. Resolution WHA51.10 requested the Director-General, *inter alia*, to report to the Executive Board at its 103rd session and the Fifty-second World Health Assembly on action taken by the Organization in the field of cloning in human health. From 12 to 14 October 1998, a small working group of independent and government experts met at WHO headquarters to consider a report containing a first draft of guiding principles and recommendations to WHO and Member States.
2. The Director-General designated two rapporteurs, Professor A.S. Daar (Oman) and Professor J.-F. Mattei (France), to assess the current and potential applications of cloning, considering not just cloning techniques but the overall area of gene manipulation and its implications for human health.
3. Consultation on these draft guiding principles and recommendations has been extended to include governments, international organizations and scientific and professional bodies.¹ Guided by the outcome of this consultation, WHO departments will follow up the specific issues raised and organize meetings in their areas of competence such as genetics, research, reproductive health, organ transplantation, and infectious diseases, in order to reach consensus on guidelines and develop cooperation with countries on these matters.
4. The draft guiding principles are based on fundamental values such as dignity, human rights and freedom, as invoked by the United Nations Charter and other international instruments. They are also inspired by basic principles of medical ethics, including beneficence, non-maleficence, confidentiality, autonomy, equity and access to care for all. The aim has been to ensure that these values can be faithfully incorporated in WHO's policies and cooperation work in areas of genetics related to human health. The draft guiding principles include the following.

GENERAL ISSUES

5. Genetics research and development must be accompanied by public education and debate involving all relevant sectors of society. Negative perceptions of science can detract from the beneficial applications of genetics to human health. Ethical concerns in this area should be given serious consideration and be dealt with carefully at both national and international level.

¹ The full set of draft guiding principles and recommendations "Medical Genetics and Biotechnology: Implications for Public Health" is available on request.

6. Genes interact with environmental, behavioural and other factors. Attention must focus not just on the genetic component of diseases but also on the importance of acting on lifestyles and environmental factors to help prevent diseases such as cancer and to reduce their severity.

7. Hurried or premature legislation in the rapidly-evolving field of genetics can be counterproductive. Legislation and guidelines should be based on a full and sound scientific and ethical assessment of the techniques concerned. They should be general enough to accommodate new developments, and they should be reviewed periodically.

GENETIC MATERIALS AND INFORMATION - RIGHTS AND RESPONSIBILITIES

8. Individuals have the right to retain control over their genetic material and the information derived from it. Access and use must be defined through consent, contract or law. Genetic information should not be used as the basis for refusing employment or insurance. Exceptions would have to be legally defined.

9. Patents are designed to protect intellectual property and stimulate innovation and they are part of the product development process. The private sector, however, also has public responsibilities. A balance must be sought between the need for patent protection and the obligation to ensure society's access to the health benefits of new knowledge and research.

10. The proper conduct of biomedical researchers, including medical practitioners, demands publication at an early opportunity of medical research findings with significant implications for public health. The withholding of such findings for financial or other personal gain is contrary to ethical professional behaviour.

GENETIC INTERVENTIONS

11. Genetic interventions on non-human species may contribute significantly to the improvement of human health and well-being. More data, however, are required to be able to reach objective conclusions on risks and benefits. Research and development must continue, but vigilance and ongoing review of potential harm are also needed.

12. Although genetic interventions hold great promise for the betterment of human health, vigilance should be exercised lest they contribute to racism, stigmatization, discrimination or the development of ruthless social policy.

13. Somatic gene therapy holds promise for improving human health, but possible risks for health must be balanced against possible benefits. In delivering such therapy, care must be exercised that vector/gene components do not contaminate germ lines. At present germ-line therapy is not acceptable, but this should be reviewed with advancing knowledge.

14. The cloning of DNA, genes and cells has been used in many contexts such as research, transplantation and the manufacture of vaccines, pharmaceuticals and diagnostic products over a long period of time, without negative ethical or medical consequences. Existing safeguards, however, must be adhered to and reviewed as new techniques and applications develop.

15. As stated in resolution WHA51.10 "... cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity". Elaboration of the ethical, scientific, social and legal considerations that are the basis of this call for the prohibition of reproductive cloning should continue.

16. As recognized by WHO, major clinical therapeutic benefits may come from the development of cloning techniques for the production of human tissues and organs from non-embryonic cells. Relevant research should be undertaken provided that it does not involve reproductive cloning and that such applications are developed in conformity with ethical and legal requirements.

WHO'S RESPONSE TO THE DRAFT RECOMMENDATIONS

17. As a matter of priority, WHO will take the following action:

% to establish an integrated genetics resource centre within WHO to provide advice and support to Member States in this area of health development, including research, training, and education on ethics;

% to monitor developments and provide support to Member States for establishing the necessary legal and regulatory measures to prohibit human cloning for reproductive purposes;

% to assign to the Special Programme of Research, Development and Research Training in Human Reproduction the task of reviewing and assessing recent technical developments in medically-assisted procreation and their ethical and social implications;

% to implement the recommendations of the WHO Task Force on Organ Transplantation and the WHO Consultation on Xenotransplantation;¹

% to ensure that ethical concerns are given due consideration and visibility in all WHO technical activities and departments with whatever coordination is required for consistency;

% to play a leading role in the international harmonization of guidelines on genetics research and its applications; in particular to coordinate with UNESCO, the European Commission and the Council of Europe; and to collaborate with the relevant bodies in defining and harmonizing fair intellectual property laws that relate to human health;

% to develop a WHO Declaration on the medical, ethical and public health aspects of genetics.

ACTION BY THE HEALTH ASSEMBLY

18. The Health Assembly is invited to note the report.

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¹ Documents ACHR34/INF.DOC./96.3, ACHR35/97.8, WHO/EMC/ZOO/98.1 and WHO/EMC/ZOO/98.2.