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Implementation of resolutions and decisions

Report by the Director-General

This document contains section VII of the Director-General's report on implementation of resolutions and decisions. It reports on implementation of resolution WHA50.37 concerning ethical, scientific and social implications of cloning in human health. The Health Assembly is invited to consider a resolution recommended by the Executive Board.

VII. ETHICAL, SCIENTIFIC AND SOCIAL IMPLICATIONS OF CLONING IN HUMAN HEALTH

1. Resolution WHA50.37 requested the Director-General to clarify the potential applications of cloning procedures in human health and their ethical, scientific and social implications. In view of the diversity of expertise required to deal with such a broad range of issues, several meetings were organized to prepare the ground for a group of experts which would deal with the subject from a global perspective. These preparatory interregional and interdisciplinary meetings focused on the following areas: cloning and human reproductive health, biologicals, organ transplantation, research, and medical genetics. The Director-General has established a study group and designated two rapporteurs to coordinate work on these matters. In addition, WHO has taken part in meetings organized on related issues by international bodies such as UNESCO, the European Commission, OECD and the Council of Europe.

CLONING AND HUMAN REPRODUCTION

2. **Ethical implications.** The main objection to the use of human cloning for reproductive purposes is that it would be contrary to human dignity as it would violate the uniqueness and indeterminateness of the human being. It is also seen as violating the rights of the child. As a decisive step towards the artificial production of human beings, it would increase the risk of reducing people to objects. Associated with new knowledge on the human genome, it could be used to facilitate genotype selection and encourage social and parental intolerance of disability or, potentially, perceived genetic defects. Some, however, consider that reproductive cloning could be acceptable in certain cases, such as otherwise untreatable infertility, or to avoid inherited genetic diseases. The argument is also put forward that reproductive rights should not be curtailed. In terms of existing ethical guidelines for biomedical research involving human subjects, human cloning for reproductive purposes raises concerns about risk in relation to benefit, informed consent, and accountability.

3. **Social implications.** Human cloning for reproductive purposes is seen as having the potential to disrupt intergenerational relations and family structures, with major psychological, social and legal consequences for the individuals and communities concerned. It is thought that it is likely to be used to reinforce rather than to combat society's prejudices, and to increase discrimination, for example, along the lines of gender, ethnic group, caste and financial status. Some also perceive reproductive cloning as a high-technology intervention of little relevance to the health needs of the vast majority of the world's population.

4. Several international health-related professional associations and religious bodies have issued statements calling for the careful monitoring and regulation of scientific developments in the field of cloning and human genetics. The responses from WHO regions stress the importance of taking into account cultural, religious and social values as well as legal implications. They emphasize the need to promote the teaching of ethics in medical education and to establish effective measures to protect developing countries from the risk of unregulated expatriate research involving human subjects.

5. There is widespread concern about the role of commercial interests in the development of such technology, and the way in which its subsequent use could be controlled. Legal provisions in this area need to be accompanied by realistic means of enforcing them at national and international levels. Within its sphere of competence, WHO can contribute technical advice and provide information on the health aspects of issues involved.

6. **Legal provisions.** Before the announcement in February 1997 of the cloning of a sheep by somatic cell nuclear transfer, existing legislation in a number of countries already precluded human cloning for reproductive purposes, sometimes implicitly. Since then, many countries have adopted government decrees or introduced legislation to impose an explicit ban on human cloning for reproductive purposes. Some countries, however,

favour a moratorium to provide sufficient time for multigenerational studies in animals, clarification of the procedure and its safety, and informed public debate.

7. At international level, the potential use of human cloning for reproductive purposes has been condemned by WHO and other organizations and groups. These include: the European Parliament, the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission, the Denver Summit of the Eight, the General Conference of UNESCO, and the Council of Europe. Some documents are of a declaratory nature while others, such as the Council of Europe's Additional Protocol on the prohibition of cloning human beings ("Convention on Human Rights and Biomedicine"), are binding for the signatory States.

8. WHO is preparing an inventory of national and international laws and regulations on cloning to meet the needs of Member States in this area.

HUMAN CLONING FOR NON-REPRODUCTIVE PURPOSES

9. **Time-limited basic research involving cloned human embryos.** Some countries allow research, within prescribed time limits, on "spare embryos" obtained in assisted reproduction programmes and destined to be destroyed. However, many of these countries, and others, prohibit the production of human embryos specifically for research. In some cases this restriction applies to research supported with public funding but does not apply to privately funded research. In other countries, legislation is being considered that would extend to both the public and private sectors.

10. Members of the scientific and medical communities in different countries and regions have expressed interest in the use of somatic cell nuclear transfer techniques to produce cloned human embryos for basic research on ageing and genetic diseases. The value of such research and the likelihood of its yielding useful information need to be assessed in relation to its authorized time-frame.

11. **Production of cloned human tissues and organs.** Interest has been expressed in using cloning procedures to produce tissues and organs for possible future transplantation in the nuclear donor and perhaps other tissue-compatible recipients. No ethical problems are envisaged with the use of somatic cell nuclear transfer techniques which would lead directly to cloned differentiated cells or tissues such as skin. However, ethical problems are envisaged with the production by cloning of fully formed and functioning organs, as it is difficult to see how such organs could be produced without first producing a cloned embryo and allowing it to grow, at least partially, through the fetal stage of development.

CLONING AND THE GENETIC ENGINEERING OF ANIMALS

12. **Xenotransplantation.** Transplantation is a life-saving intervention which has gained general acceptance, but the human donation of organs and tissues has not kept pace with the demand. Research is being conducted on xenotransplantation - the transplantation in humans of animal cells, tissues or organs. There is preliminary evidence that porcine cellular grafts can endure in human recipients. If reasonable standards of safety and efficacy can be ensured, xenotransplantation could become an economical option and help improve equitable access to transplantation. It could also offer the prospect of treatment for diseases with no other effective therapeutic intervention, such as refractory Parkinson's disease or Huntington's disease.

13. To overcome rejection problems, strategies are being developed to modify the recipients' immune systems and to use genetic engineering and cloning techniques to produce animals to serve as sources of grafts. The use of cloned, transgenic, or otherwise genetically engineered animals may be considered acceptable as long as the dignity and identity of humans are respected, human health is protected, and animal welfare is adequately taken into account. Due attention must be paid to ethical and religious values and cultural perceptions. The potential psychological impact of xenotransplants would also call for extensive monitoring and counselling.

14. Xenotransplantation raises important issues of informed consent, human rights and community interests. Basic principles of biomedical ethics should be applied and maximum precaution exercised in the interests of both the patient and the community. This includes the prevention and management of zoonoses - the transmission of potentially infectious agents from animals to xenotransplant recipients and their contacts. WHO has produced a detailed guidance document on this subject.¹ Careful monitoring must be ensured at both national and international levels, to promote safety, efficacy, equity and ethical practice. The same principles must guide the monitoring of other developments in animal cloning and genetic engineering, such as those related to the production of humanized biological substances and vaccines.

CLONING AND MEDICAL GENETICS

15. Rapid development is occurring in the broader field of medical genetics applied to human health. It will be particularly important to monitor and assess the ethical, scientific and social implications of genetic engineering, including cloning technology, within this context. We now know that our DNA is not only associated with severe single gene disorders but also accounts, in interaction with the environment, for predisposition to cancer, heart disease, psychiatric disorders and even susceptibility to infectious diseases. Genetic knowledge can greatly help to improve preventive and therapeutic options and thus achieve better health for all worldwide. However, it must be applied with due regard to principles of medical ethics, such as respect for human dignity, autonomy and justice.

16. Cell cloning or gene cloning can be of great clinical value in the diagnosis and treatment of diseases and should not be confused with reproductive cloning. Somatic cell gene therapy for people with medical conditions is ethically comparable to any other therapy, and research in this promising area should be encouraged. Germ-cell gene therapy, where there is an intention or possibility of altering the genes passed on to the next generation, should not be permitted in the foreseeable future.

17. Genetic screening and testing can be an effective aid to public health planning in any country, but should not be compulsory. Genetic counselling should be made available, within the context of local options and beliefs, and should be as non-directive as possible. Confidentiality and non-discriminatory use of genetic data should be protected, if necessary by legal means.

18. Patenting is part of the normal process of product development, but has the potential to impede international collaboration, to the ultimate detriment of health care for those who need it most, especially in developing countries. Patents on gene sequences should only be granted in the context of inventions of methods or procedures of proven utility.

19. The need is felt for a declaration or code of practice dealing with the new ethical issues arising from the medical and public health applications of genetics. As a starting point for such a declaration, a preliminary statement has been proposed by the WHO Expert Advisory Group on Medical Genetics on fundamental issues such as autonomy, confidentiality, counselling, research, patenting and justice, and their implications for individuals, families and public health. WHO will facilitate global consultation and consensus-building on these issues.

MATTERS FOR THE PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

20. The Health Assembly is invited to consider the resolution recommended by the Executive Board in its resolution EB101.R25.

¹ Xenotransplantation: guidance on infectious disease prevention and management. Document WHO/EMC/ZOO/98.1.