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REPRODUCTIVE CLONING OF HUMAN BEINGS: CURRENT SITUATION

Report of the Regional Director

EXECUTIVE SUMMARY

1. *Cloning* is an umbrella term traditionally used to describe different processes for duplicating biological material. A clone is an organism that is a genetic copy of an existing one. The use of the technique of nuclear transfer for reproduction of human beings is surrounded by strong ethical concerns and controversies and is considered a threat to human dignity. Ethical concerns relate to the risk of causing physical and psychological harm, lack of respect for ethical research standards, exploitation of the poor and conflict of interest if financial interests are involved.

2. Over the years, the international community has tried without success to build a consensus on an international convention against the reproductive cloning of human beings. WHA Resolution WHA50.37 of 1997 argues that human cloning is ethically unacceptable and contrary to human integrity and morality. In February 2005, the Legal Committee recommended to the United Nations General Assembly the adoption of a declaration on human cloning by which Member States were called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life.

3. Creating awareness among ministries of health in the African Region will provide them with critical and relevant information on the reproductive cloning of human beings and its implications to the health status of the general population.

4. The potential benefits of non-reproductive cloning include replacement cells to treat heart disease, Alzheimer's disease, cancer, Parkinson's disease, diabetes and sickle-cell anaemia; as well as diagnostic techniques, drug development and tissue transplantation.

5. Most countries in the African Region have no specific regulations and policies governing genetic manipulations for assisted conception, treatment and research.

6. Priority actions will include development of policy and regulations; strengthening country capacity for monitoring the application of the policies and regulations; establishment of national ethics review committees; data collection and information sharing; and public information programmes.

7. The WHO Regional Committee for Africa is invited to review this document for information and guidance concerning reproductive cloning of human beings.

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ANNEX

INTRODUCTION

1. *Cloning* is an umbrella term traditionally used by scientists to describe different processes for duplicating biological material. A clone is an organism that is a genetic copy of an existing one. Cloning can occur naturally, for example, clones are created when a fertilized egg splits into two to produce identical (homozygous) twins with identical deoxyribonucleic acid (DNA).[1]

2. *Nuclear transfer* is a technique used to duplicate genetic material by creating an embryo through the transfer and fusion of a diploid cell in an enucleated female oocyte.[2] *Cloning* has a broader meaning than *nuclear transfer* as it also involves gene replication and natural or induced embryo splitting (see Annex 1).

3. Media reports on nuclear transfer are usually about one form, reproductive nuclear transfer, also known as *reproductive cloning of human beings*. This technique is surrounded by strong ethical concerns and is considered a threat to human dignity.

4. The international community has tried, over the years to build a consensus on reproductive cloning of human beings. The WHO position was adopted in 1997 through Resolution WHA50.37, which states "the use of cloning for the replication of human individuals is ethically unacceptable and contrary to human integrity and morality."[3] The resolution recognizes the need to respect the freedom of ethical scientific research and to ensure access to the benefits of its application. These developments in genetic procedures have unprecedented ethical implications; related research and developments should therefore be carefully monitored and assessed, and the rights and dignity of patients respected.

5. In 2001, France and Germany requested the United Nations General Assembly to develop international conventions on human reproductive cloning, therapeutic cloning and research on stem cells. An ad hoc committee was created to negotiate such convention. However, consensus on the mandate and scope of the convention was never reached. While some delegations were in favour of a convention prohibiting all forms of human cloning, others were in favour of a convention allowing therapeutic cloning under a strict regulatory regime.[4]

6. In November 2004, the Sixth Committee (Legal) worked on a declaration on this issue, and in February 2005, the Committee recommended to the General Assembly the adoption of a declaration on human cloning by which Member States were called on to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life. Member States were called on to adopt all measures necessary to adequately protect human life in the application of life sciences, as well as measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity.[5]

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[1] WHO, A dozen questions (and answers) on human cloning, http://www.who.int/ethics/topics/cloning/ (accessed on 20 March 2005).

[2] International Society for Stem Cell Research, Glossary of cell-related terms, www.isscr.org/glossary (accessed on 20 March 2005).

[3] Resolution WHA50.37, Cloning in human reproduction. In: *Fiftieth World Health Assembly, Geneva, 5-14 May 1997. Volume III: Resolutions and decisions.* Geneva, World Health Organization, 1997 (WHA50/1997/REC/1).

[4] Development of an African position on International Convention against the Reproductive Cloning of Human Beings (item proposed by the Republic of South Africa), African Union, Executive Council, Fifth Ordinary Session, 25 June–3 July 2004, Addis Ababa, EX.CL/140 (v) Add. 2.

[5] United Nations, "Legal Committee recommends UN Declaration on Human Cloning to General Assembly," press release, GA/L/3271, 18 February 2005.

7. In July 2004, South Africa presented to the Executive Council of the African Union a proposal calling for an African position on the International Convention Against Reproductive Cloning of Human Beings.[6] In this context, the WHO Regional Office for Africa was requested by the African Union to include this issue in the agenda of the fifty-fifth session of the Regional Committee in 2005.

8. This document was developed with technical input from the Regional Reproductive Health Task Force and the African Advisory Committee for Health Research and Development.

9. This paper aims to create awareness among ministers of health in the African Region by providing them with critical and relevant information on the reproductive cloning of human beings and its implications to the health status of the general population.

BACKGROUND

10. The public debate against reproductive nuclear transfer has cited several ethical arguments.[7] The ethical concerns are related to the risk of causing physical, psychological or social harm; lack of respect for ethical research standards and autonomous consent; exploitation of the poor; conflict of interest; and imbalance in the distribution of resources and attention to priority issues, especially in the African Region

11. Concerning the dignity of human beings, the arguments are that reproductive nuclear transfer is an asexual mode of reproduction, limits the gene pool, furthers a mechanical attitude toward human beings and risks turning people into manufactured objects. In addition, there is an argument that the embryo is a human being; consequently, its destruction is morally and ethically unacceptable.

12. The potential benefits of non-reproductive human cloning and nuclear transfer (gene and therapeutic) include the use of stem cells as replacement cells to treat heart disease, Alzheimer's disease, cancer, Parkinson's disease, diabetes and sickle-cell anaemia. Stem cell research could also be used to develop drugs, diagnostic techniques, and new cells and tissues for transplantation.[8]

13. The production of embryonic stem cells allows research projects on cell regulation, growth, development and death. It will also facilitate toxicological and genetic studies using embryonic stem cells as research models.

CURRENT SITUATION

14. Only a few research institutions are currently able to use the technique of nuclear transfer, and the discussion about the impact of reproductive cloning is not yet widespread. Closely related to this issue is the use of assisted reproductive techniques for the management of infertility in the African Region. This technique is controversial because it uses a non-sexual method of

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[6] Development of an African position on International Convention against the Reproductive Cloning of Human Beings (item proposed by the Republic of South Africa), African Union, Executive Council, Fifth Ordinary Session, 25 June–3 July 2004, Addis Ababa, EX.CL/140 (v) Add. 2.

[7] WHO, A dozen questions (and answers) on human cloning, http://www.who.int/ethics/topics/cloning/ (accessed on 20 March 2005).

[8] Fodor WL, Tissue engineering and cell-based therapies from the bench to the clinic: the potential to replace, repair and generate, *Reproductive Biology and Endocrinology*, 1: 102, 2003, http://www.rbej.com/content/; Chan AWS, Transgenic nonhuman primates for neurodegenerative diseases, *Reproductive Biology and Endocrinology*, 2: 39, 2004, http://www.rbej.com/content/

procreation.[9] Arguments against asexual reproduction suggest that it will damage traditional African sociocultural ideas, attitudes, customs and practices, especially those which hitherto lessened the problem of infertility.[10]

15. Most countries in Africa do not have specific regulations and policies regarding genetic manipulations for therapeutic and research purposes, assisted conception or in vitro fertilization.[11] Consequently, there is an increased risk of undertaking illegal or unethical experiments and projects involved with human reproduction in Africa, including procedures that are not permitted in other parts of the world. The capacity to effectively monitor regulations is very weak or absent in many countries.

THE WAY FORWARD

16. Countries are ultimately responsible for the implementation of the following proposed activities, but they will need technical support from WHO.

17. Member States should:

(a) Establish policies and stringent regulations on reproductive cloning of human beings as well as effective mechanisms for monitoring their implementation;

(b) Develop policies and regulations or assist other Member countries to develop their own;

(c) Establish or strengthen national ethics review committees to examine all proposed research protocols to ensure that they follow national policies, regulations and legislation; committees should include researchers as well as religious, legal, social and medical experts;

(d) Develop and implement educational programmes on issues related to human cloning to increase awareness, especially among policy-makers, programme managers and community leaders.

18. WHO and partners should:

(a) Provide assistance to countries for the development and adoption of policies and regulations to protect human life in medical research;

(b) Assist countries in strengthening the capacity to monitor regulations;

(c) Provide technical assistance for strengthening or establishing national ethics review committees;

(d) Facilitate the dissemination of information by creating a regional registry system that includes new developments in medical research;

(e) Support countries to strengthen their capacity to implement the United Nations Declaration.

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[9] Giwa-Osagie OF, Assisted reproductive technology (ART) in developing countries with particular reference to sub-Saharan Africa. In: WHO, *Current practice and controversies in assisted reproduction*, Geneva, World Health Organization, 2002: 22-27.

[10] Tangwa GB, ART and African socio-cultural practices: worldview, belief and value systems with particular reference to francophone countries. In WHO, *Current practice and controversies in assisted reproduction*, Geneva, World Health Organization, 2002: 55–59.

[11] Giwa-Osagie OF, Assisted reproductive technology (ART) in developing countries with particular reference to sub-Saharan Africa. In: WHO, *Current practice and controversies in assisted reproduction*, Geneva, World Health Organization, 2002: 22-27.

MONITORING AND EVALUATION

19. A national health research council or similar body under the Ministry of Health should be responsible for establishing mechanisms for monitoring ethical aspects of research. These include annual or biennial mandatory reporting systems, on-site visits by teams of experts to review the activities of national research centres, and regular revision of approved research protocols and projects.

20. With WHO technical assistance, countries should analyse the situation in relation to the existence of ethics review committees, results of ethics assessments, and the impact of medical research in improving knowledge and contributing to better health of the population.

CONCLUSION

21. There is general consensus that medical research must proceed in an ethical manner. The World Health Assembly agreed almost a decade ago that reproductive cloning of human beings is ethically unacceptable and contrary to human integrity and morality. The United Nations Legal Committee recommended that countries ban the replication of human beings by nuclear transfer cloning. There is general consensus on banning reproductive cloning of human beings but not consensus on banning therapeutic cloning. Concerning the ongoing debate, Member States should be prepared to consider the adoption of all necessary measures to adequately protect human life in the application of medical science and research as well as measures to prohibit the application of genetic engineering techniques that may sacrifice human dignity.

22. The Regional Committee is invited to review this document for information and guidance concerning reproductive cloning of human beings.

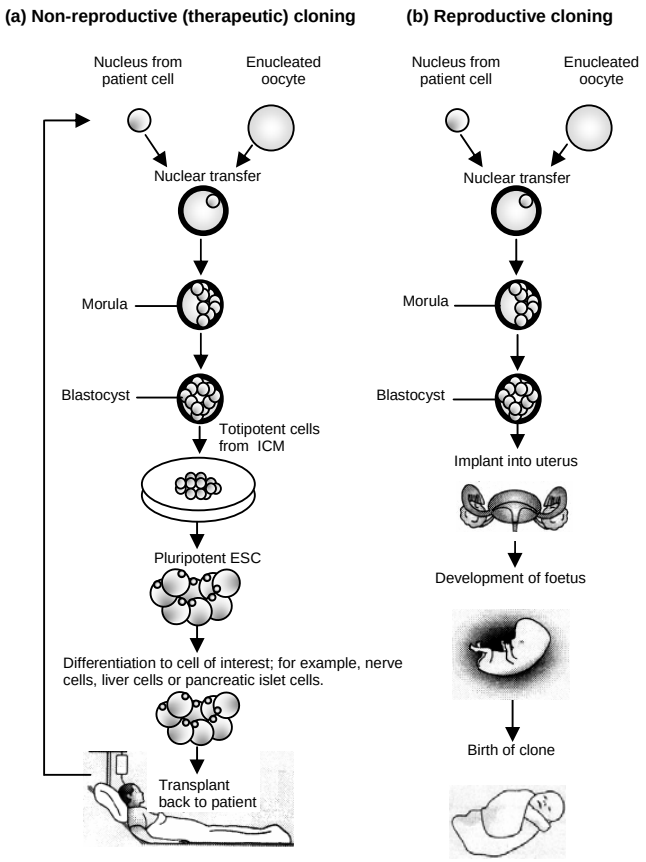
ANNEX 1

Definitions and technical considerations

1. The technique of *somatic-cell nuclear transfer* was first used 40 years ago in research with tadpoles and frogs. Somatic-cell nuclear transfer begins with an adult somatic cell, for example, a skin cell. The nucleus from the somatic cell is transferred to an enucleated egg (that is, one from which the nucleus has been removed). The egg is then activated with electric current or chemicals in order to stimulate it to divide. When the blastocyst stage has been reached, the embryo is transferred into the uterus of a female host, where (if implantation occurs) it can lead to a pregnancy and eventually to the birth of an individual that carries the same nuclear genetic material as the donor of the adult somatic cell.[1]

2. There are four types of identical reproduction (cloning) (see Figure 1). These are (i) deoxyribonucleic acid (DNA) or gene cloning, (ii) natural or assisted splitting (split cloning) of the morula or blastocyst stage of the embryo to create two identical twins, (iii) reproductive nuclear transfer and (iv) therapeutic (non-reproductive) nuclear transfer.

Figure 1: Non-reproductive and reproductive cloning



ESC-Embryonic stem cells
ICM-Inner cell mass

Source: Rhind SM et al, Human cloning: Can it be made safe?, *Nature Reviews Genetics*, 4: 855–864, 2003.

[1] WHO, A dozen questions (and answers) on human cloning, http://www.who.int/ethics/topics/cloning/ (accessed on 20-03-05); Wolf DP et al, Nuclear transfer in the rhesus monkey: practical and basic implications, *Biology and Reproduction* 60: 199– 204, 1999.

3. *DNA* or *gene cloning* involves the transfer of a DNA fragment of interest from one organism to a self-replicating element such as bacterial plasmids. This technology is common practice in most molecular biology laboratories. It has been used in gene therapy and genetic engineering of organisms. Genetically-modified food is produced through this technique.

4. *Embryo splitting* creates two genetically-identical halves, each of which has the potential to develop into a pregnancy.[2] This happens naturally in early embryonic development (two-cell stage) or during hatching of the blastocyst when human identical twins are created and born. This procedure can also be performed in animals with great success.

5. *Reproductive cloning* (or *reproductive nuclear transfer*) involves the generation of a species that has the same nuclear DNA as another currently or previously existing species. Dolly (a sheep) was created through this type of technology. Different species have been duplicated in this way—mice, sheep, rabbits, horses. This technique has the potential for creating human beings, the major concern of all forms of cloning.

6. *Therapeutic nuclear transfer* is the production of human embryos for clinical use and research purposes. The process is not used to create cloned human beings but rather to harvest stem cells that can be used to study human development and treat disease (embryonic stem cell research).

7. The source of the diploid donor cell containing both sets of chromosomes (23 pairs in humans) for nuclear transfer can be twofold: (i) blastomeres (embryonic cells that will give rise to the fetus) from almost any stage of development of the embryo and (ii) adult body (somatic) cells from almost any organ in the body. Reproductive and therapeutic nuclear transferred clones can therefore be produced from both cell sources.[3]

8. Up to day 14 of development of a clone produced from nuclear transfer there is no difference between reproductive and therapeutic nuclear transfer embryos. It is only when a nuclear transfer clone is implanted in the womb of a woman and attaches there that it becomes a reproductive nuclear transfer clone.

[2] Schramm RD, Paprocki AM, Strategies for the production of genetically identical monkeys by embryo splitting, *Reproductive Biology and Endocrinology*, 2:38, 2004.

[3] Mitalipov SM et al, Rhesus monkey embryos produced by nuclear transfer from embryonic blastomeres or somatic cells, *Biology of Reproduction*, 66: 1367–1373, 2002.