

## CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

Presidency of the Council of Ministers

### 44/CNECV/04

## OPINION N.º 44 OF THE NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

# MEDICALLY ASSISTED PROCREATION

(July 2004)



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#### Introduction

The present reflection by the National Council of Ethics for the Life Sciences (CNECV) on Medically Assisted Procreation (hereinafter designated as MAP) arose from the submission to Parliament [Assembleia da Republic] of two Bills addressing this matter – 90/IX (PS –Socialist Party), "Regulates the techniques of medically assisted procreation", and 317/IX (Bloco de Esquerda – Leftwing Block), "Medically Assisted Procreation" –, concerning which the CNECV's opinion was requested. The Council considered that, given the relevance to and impact on Portuguese society of the matter under appraisal, it must not restrict itself to the assessment of the documents proposed, and that it behoves it to reflect more widely on the ethical framing of problems relating to MAP.

In this vast domain, ethical reflection on MAP intersects other areas of biomedical advancement having relevant ethical implications and social impact. Hence, the CNECV cannot ignore them here; yet, they must not be treated subordinately, meriting autonomous, separate opinions. We are referring, firstly, to Pre-Implantation Diagnosis (PID/PGD), which became possible only as a result of the development of reproductive technologies (IVF, ICSI), which the Council intends to analyse soon. We are also referring to stem cell research, specifically to research using embryonic stem cells (ES), which depends partly on *in vitro* embryo production, which may be carried on every known type of stem cell (embryonic, germ and somatic), considering their distinctive potential for differentiation and their different origin, with the respective technical-scientific demands and ethical implications. An Opinion on this matter will be presented soon. We draw attention to the fact that, in previous mandates, the CNECV had attested already to the importance it accords to ethical reflection on MAP through the elaboration of two Opinions on the theme (cf. Opinions 3/CNE/93 and 23/CNECV/97, also available in English). The chief reasons that led to those earlier Opinions are reinforced today:



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- by the advancement of techniques, by the increased rate of conjugal infertility/sterility,
  by the multiplication of institutions practising MAP, by the increasing weight and
  complexity of the ethical issues involved;
- by the prolonged absence of the urgent, necessary specific legislation relating to MAP,
  notwithstanding past legislative efforts namely Bill no. 135/VII of 1997 and the
  decree no. 415/VII of 1999 as well as other studies, reports and opinions;
- by the consolidation of vested interests created around MAP;

Wherefore, with greater reason, the following Opinion is justified.

#### **Previous considerations**

The CNECV, being attentive to what has been exposed above, and aware of:

- the profound suffering that infertility/sterility may cause;
- the possibilities introduced by MAP techniques to overcome infertility/sterility;
- the possibility of unruliness in the practice of MAP techniques and the possibility of abuse in their application;
- the ethical imperative to safeguard the integrity of the parental candidates and professionals involved, and to protect the dignity of the human being in project;
- the embryo's right to ethical-juridical protection, regardless of its ontological status;
- morals, understood as a wide social consensus in the sharing of convictions about what is good and evil, correct and incorrect;



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- the existence of an axiological plurality in Portuguese society often representative of different social sectors (religious, political, ethnic, etc);
- the diversity of moral concepts reflected by the varied international legislation on the matter through the differing norms advanced to date;

#### emits the following Opinion:

- 1. Technical-scientific advancements, in general, and specifically MAP techniques, not only must continue to serve humanity but also they must privilege respect for the human being with regard to the interests of science, by corroborating the ethical principle of the primacy of the human being.
- 2. To be faithful to the original intent of MAP techniques, and in keeping with the principle of beneficence, such techniques must be used for medical reasons, in situations of infertility and/or sterility, perceived as a disease by the couple, and their end must be to attempt to achieve the conception of a human being when alterations in the physiological mechanisms of reproduction will not permit such conception through natural means.
- 3. MAP techniques do not constitute, therefore, procedures alternative to natural reproduction; instead, in accordance with the principle of subsidiarity, they are subsidiary therapeutic methods.
- 4. Exceptionally, and on the basis of well-considered, strictly medical reasons pursuant to the prevention of transmission of serious diseases of genetic or other origin, derogations to the principle of subsidiarity enunciated above MAY BE ALLOWED.



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Such derogations must be authorised by an independent entity, as proposed in Point 28 of the present Opinion.

- 5. In this context, such techniques must be used as an auxiliary to the fulfilment of a parental Project. This involves consideration not only of the desires of the parental candidates but also, above all, of the interests of the future human being that will be conceived eventually through MAP, fully assuming the principle of vulnerability that carries the obligation to care for and protect a fragile, perishable other.
- 6. The beneficiaries of MAP techniques will be heterosexual couples, having a stable relationship, regardless of their having contracted matrimony or living together in *de facto* union.
- 7. MAP techniques must use exclusively gametes from the couple, thus respecting the rule of non-instrumentalisation of human life that follows from the principle of human dignity.
- 8. Exceptionally, and on the basis of well-considered strictly medical reasons, when the couple's reproductive health is at stake, resorting to one-party [singular] donation of gametes be considered. This derogation must be authorised by an independent entity proposed in point 28 of the present Opinion.
- 9. Donation, when authorised, does not permit any type of retribution, and it must remain absolutely gratis, respecting the rule of non-commercialisation of the human body or parts thereof that follows from the principle of human dignity.
- 10. In the case of MAP resorting to a gamete donor, the possibility must be safeguarded of the donor's identification, at the request of the donor's biological child and after the latter's legal majority has been reached, in recognition of the right of the interested



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party to its personal and biological identity. The genetic information of the donor relevant to the health of his/her biological child, permitting no identification, must remain permanently available, and it may be requested, before the biological child reaches legal majority, by the latter's legal representatives.

- 11. Knowledge of the identity of the gamete donor may not entail, on the part of the biological child, the claim to any rights regarding the donor or to duties of the latter towards the child.
- 12. The beneficiaries of MAP techniques must be clearly informed of the technical-scientific nature of the process, including the description of the interventions to which they will be subjected and their potential benefits and risks, especially those that may affect the interests of the child to be born.
- 13. The information conveyed must also cover the following aspects:

psychological – such as worsening of psychological suffering by the intensification of obsessive behaviour or feelings of frustration,

social – such as the presentation of alternatives, namely adoption, legal – particularly in the case of resorting to a gamete donor,

economical – the uncertainty that the financial investment will obtain the desired good and, even in the case of success, the difficulty in estimating the total costs;

and ethical – regarding the couple, the loss of privacy of their intimacy; regarding the future child, the artificialisation of its generation; and regarding the donor.



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- 14. Consent must be given in writing and may be revoked at all times up to the moment of the transfer, in accordance with the general enunciation of the rule of informed consent that follows from the principle of autonomy.
- 15. Likewise, gamete donors must be clearly informed of the nature and implications of the act they propose to do, in compliance with the rule of informed consent implicit in the principle of autonomy.
- 16. All acts involved in the use of MAP techniques must be assured of confidentiality, thus respecting the right to individual privacy, excepting the provisions in point 10.
- 17. Health professionals must be guaranteed the right to conscientious objection regarding the execution of MAP techniques, as provided in the principle of autonomy.
- 18. The implementation of MAP techniques must impede the production of a number of embryos exceeding that assigned for transfer surplus embryos –, attending to the principle of respect for human life, and must also reduce the incidence of multiple pregnancies, taking up the principle of responsibility as the obligation to prevent the negative consequences of the acts one performs.
- 19. Every human embryo has the right to life and to development, to corroborate the universal principle that every existent demands existence, wherefore the embryo originated *in vitro* must always be part of a parental project.
- 20. Promoting embryo adoption is the most appropriate ethical procedure regarding the future of the surplus embryos now existing, as well as the future of such that, due to imponderable circumstances or reasons, might come to be excluded from their original parental project, since this is the only procedure that permits reintegrating such an



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embryo in a parental project, thus fulfilling its original purpose of transfer into the uterus and assuring its right to life and to development.

- 21. Whenever embryo adoption does not take place in useful time, thus compromising the possibility of life and development for the embryo, it is imperative to ponder the possible alternatives of the fate to be given to the surplus embryos, to wit, making them available to scientific research or destroying them.
- 22. Scientific research on human embryos is ethically legitimate when conducted to benefit that same embryo. Derogations to this general enunciate may be considered when the sole alternative fate will be destruction of that embryo. In such a situation, embryos may be used in scientific research that, while it does not act to benefit those same embryos, results in benefit to mankind.
- 23. Any project of scientific research on human embryos must be rigorously scrutinised, by competent organisms already instituted for that purpose, regarding the scientific quality of the project and of the researchers in charge and regarding the extent of foreseeable benefits to mankind. Also, such projects must be subjected to monitoring inspections throughout their several development stages, in compliance with the ethical-juridical guidelines common to all experimentation on human beings.
- 24. None of the researchers involved in scientific research on embryos may belong to any MAP centre and/or institution keeping cryopreserved embryos, in order to prevent a conflict of interests potentially damaging to the life and development of the embryo.
- 25. The creation of embryos solely for the purpose of scientific research is ethically unacceptable.



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26. When, after fertilisation of oocytes, the spontaneous formation of biologically

unviable embryos occurs, such embryos are thereby excluded from any parental

project and they may be made available to research.

27. The institutions, public or private, now practicing MAP must be subjected to a process

of certification, and the new institutions of the same nature, public or private, that are

eventually created must be subjected to a licensing process. Only those requirements

will allow public control of the activity and transparency in its performance.

28. We recommend the creation of an independent entity, of a multidisciplinary nature,

dedicated to the technical, ethical and social monitoring of the application of the

medically assisted procreation techniques provided by law, to the submission of

proposals for the accreditation and licensing of public and private centres of medically

assisted procreation, and to monitoring both people who undergo techniques of

medically assisted procreation and those who are born through such techniques.

Lisbon, the 26th of July 2004

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President

National Council of Ethics for the Life Sciences

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