NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

63/CNECV/2012

OPINION No. 63 OF THE NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

MEDICALLY ASSISTED PROCREATION AND SURROGATE PREGNANCY

(March 2012)

NATIONAL ETHICS COUNCIL FOR THE LIFE SCIENCES

CNECV OPINION ON MEDICALLY ASSISTED PROCREATION AND SURROGATE PREGNANCY

I
INTRODUCTION

This Opinion of the National Council of Ethics for the Life Sciences (CNECV) has been prepared at the request of the Portuguese Parliament.

Although the original request was in regard to the four bills submitted to the Portuguese Parliament on the same subject — medically assisted procreation (MAP) and surrogate "motherhood" — this Opinion refers to the two bills (submitted by the PS [Socialist Party] and PSD [Social Democratic Party] MPs, 131/XII and 138/XII) whose legislative process continues, since the others have been rejected by parliamentary resolution on 20 January 2012.

The CNECV has already issued an opinion on this subject three times, but always before the approval of Law no. 32/2006 of 26 July, which regulates the use of MAP techniques. Although this Opinion is not an overall reappraisal of the issues referred to and focuses on the content of the proposed legislative amendment now submitted, it will also address other ethical issues, some raised directly by the changes that the eventual approval of the bills in question will produce in the existing legislative framework.

First of all, and considering:

a) the lack of national studies with relevant information about the application of MAP techniques;

b) that IVF has already been practised here since 1988 and

c) that previously techniques such as heterologous insemination had already been practised,

the CNECV recommends that longitudinal studies and records are promoted for acquisition of evidence on the information inherent to both the various facets of MAP and the possible surrogacy.

Considering also that:

stakeholders and the general public are not aware of the *efficacy rates* (which should be expressed by the clinical pregnancy rate per oocytes collected and by the rate of healthy newborns per oocytes collected, with an indication of the percentage of twinning, as recommended by the European societies of genetics and reproductive medicine and embryology) of different centres of medically assisted procreation, corrected by age groups and different selection criteria;

the CNECV recommends its public disclosure, as without this information it does not make much sense to talk about free and informed consent by couples who come for MAP consultations.

Considering also that:

a) a large part of the conjugal sterility problems originate, directly or indirectly, in seeking (woman more than 35 years old) evolutionary pregnancy quite late;

b) the various and undeniable biological disadvantages of this late pregnancy,

the CNECV recommends that social measures should be promoted to avoid the increasingly late parenthood, as there may be serious medical and genetic consequences for the future generations.

Finally, the CNECV recommends promoting measures that promote adoption and simplification of these processes.

II

APPRAISAL OF AMENDMENTS PROPOSED IN BILLS No. 131/XII AND No. 138/XII

The bills submitted by PS and by PSD assume, almost entirely, the content of all the proposals that the National Council of Medically Assisted Procreation (CNPMA) submitted to the Portuguese Parliament on different occasions, thus benefiting from the reflection and informed review of that advisory body specially created to rule on the legal, social and ethical issues of medically assisted procreation.

Basically, these proposals aim to introduce improvements, make up for loopholes or overcome some contradictions in the MAP law (Law no. 32/2006 of 26 July), keeping the essential and continuing the principles underlying that law.

Apart from minor alterations which do not raise special ethical concerns, the proposals contained in the two bills mentioned above involve sensitive alterations or relate to ethically relevant aspects in the following areas: beneficiaries of MAP techniques, surrogate pregnancy, heterologous insemination and embryo transfer donated by third parties, cryopreservation period and the fate of embryos created in MAP.

1. Beneficiaries of the MAP techniques

a) <u>The proposals</u>

The PS bill keeps apparently unchanged the delimitation of potential beneficiaries of MAP techniques, since it does not propose any amendment to article 6 of the MAP law which reserves access to married people and those who, being of different sex, have lived together as a couple for more than two years.

However, since 2006, date of approval of the MPA law in force, this has changed, with the legal admissibility of marriages between persons of the same sex, the circle of people who have access to marriage; to leave unchanged the current wording ("... married people... may use MAP techniques") would mean that all married people, therefore regardless of whether same sex or different sexes, could access the MAP techniques. That objective interpretation of rule no. 1 of article 6 would be even more reasonable if the legislator, having had an opportunity to rectify the current wording, had deliberately chosen not to do so. That is, intentionally keeping the current wording could only reasonably mean that it was the legislator's intention that same-sex couples could also access MAP techniques.

However, as is clear from the parliamentary debate, that does not seem to have been the intention of the proponents of the PS bill, so it is imperative that there remain no doubts on this issue and that the legislator's actual intention is clearly passed onto the law.

In turn, this is what the PSD bill unequivocally does, reserving access to MAP techniques to married couples and those in common-law marriage, but in either case only if the couple or marriage is between people of opposite sex.

Thus, despite the changes that have taken place in the matrimonial regime, unions between same-sex persons, married or in unions similar to those of spouses would remain excluded from access to MAP techniques. Single persons remain excluded from access to MAP techniques, with the only exception in article 22, no. 3, which admits the possibility of embryo transfer even after the death of his father.

b) <u>Delimitation of access</u>

The delimitation of the circle of potential beneficiaries of MAP is closely associated to the option to be taken on the nature and purposes of medically assisted procreation, in particular, to understanding it as a subsidiary method, as a complementary method or as an alternative method of procreation.

When it is assumed that there is an ideal model of reproduction that should tend to converge biological parenthood, social parenthood and legal parenthood, the defence of the nature subsidiary MAP seems almost natural: only when there is no possibility of making those three dimensions coincide should one turn to MAP techniques; it is then important to select the criterion or criteria for establishing the access requirements.

The current Portuguese law adopts a subsidiary concept of MAP in which the requirement of a prior diagnosis of infertility appears as the first and general condition for the recognition of access to MAP techniques. However, subsidiarity exclusively based on the diagnosis of infertility is not considered as absolute, since the law itself recognized the access in situations outside the cases of infertility: The situations foreseen in article 4, no. 2, that is, for treatment of serious illness or when there is risk of transmission of disease.

It can be said that, in any case, there is a common element in all those situations: the pre-existence of a real disease or likely to be perceived as such. But what justifies that access to MAP techniques is refused or even prohibited in all other situations?

c) The justification for exclusion

From the moment society has the scientific knowledge and technical means for medically assisted procreation, there are countless people who, while not fulfilling the above requirements (related to infertility or disease), seek access to MAP techniques because in their case, and for reasons worthy of respect, therefore not frivolous or objectionable, procreation by natural means is not an appropriate or acceptable means.

However, the personal interest to procreate, to generate offspring, to start a family, to be a mother or a father to a biologically related being, is a natural interest, a noble one, and may take the utmost importance, sometimes felt as fundamental, in people's lives. If in these circumstances the State not only refuses but also prohibits access to the MAP techniques, then that refusal, and particularly the prohibition, is seen as a serious violation of one's own life plans that only will not be ethically reprehensible if the State can so justify based on strong reasons.

In the situation examined here, on the basis of the existing law and the bills that seek to alter it, there is precisely such a situation, that is, the law is not just about limiting access to the means provided or subsidized by the State - and here the reasons relating to the establishment of selection criteria due to the scarcity of resources could possibly be considered - but prohibits and sanctions, purely and simply, access to MAP techniques to those who are not part of a couple or common-law marriage between persons of different sex, even in situations where the parties intend to do so with their own resources and privately.

That is, to reserve scarce means provided or subsidized by the State to more pressing situations can be considered acceptable, but then it is important to discuss the selection criteria. It is different when the State prohibits and sanctions even when access is achievable through own resources, and in private establishments. Then, if the State prohibits, sanctions and eventually criminalizes, it is because it considers the situation wrong, harmful, ethically unacceptable, but it should at least say why and the reasons must be serious and sustainable.

Not doing so, that is, if the prohibition can be perceived as freely made, arbitrary or, at least, unfounded, the State incurs an ethically objectionable disregard for the autonomy of the individuals, all the more reprehensible when exclusion results in a discriminatory effect.

It turns out that the PS bill presents no justification and the PSD one makes an attempt that cannot be considered sufficient.

It is claimed therein, firstly, that the legal configuration of MAP in these terms would be a constitutional imposition, insofar as the Constitution entrusts the State with the responsibility to regulate assisted procreation for family protection, which would give rise to the need for MAP to be admissible only to treat a disease situation and if the beneficiaries are part of a stable heterosexual couple.

But, given that the Constitution gives the State the responsibility of protecting the family and regulate MAP, it does not seem, firstly, that this mandate determines or requires that the State is obliged to protect only a particular type of family and, above all, even if such discrimination is considered admissible, it would impose not only State deprotection but also the simultaneous prohibition and sanction of MAP access to families or personal situations of other type when it is certain that the State admits and legitimates them through the law itself. On the other hand, there is not even any relation of logical necessity between the constitutional mandate to regulate MAP to protect the family and the access limitation to MAP techniques to situations of illness that have as exclusive beneficiaries heterosexual couples or unions and, much less, prohibition and sanction of access to people outside that framework.

Thus, as the argument for the existence of a secondary legal enforcement of the Constitution is not sustainable, there remains the only justification with ethical relevance claimed for the mentioned exclusions and prohibitions, that is, the claim that access to MAP techniques in such other circumstances would constitute an instrumentalisation of human life, seeming to mean that the new human being would be in those other cases, and only them, to be instrumentalised in the interest of the people who resorted to MAP.

However, the argument is inconsistent, in that, from the standpoint of motivation, intentionality and the interests of those who resort to the MAP techniques — and that is the plan that counts for the diagnosis of existence of instrumentalisation — there is no difference between being part of a couple or not, living together or alone, having a family or wanting to start a family, having one or other sexual orientation.

The motivation, intention and interest of those who resorted to MAP techniques to procreate a new being is always a motivation for the benefit of personal fulfilment or satisfaction, which translates into the intention to procreate, produce offspring, to take on motherhood or fatherhood, to start a family, because they think it will be good for them and, where appropriate, for the parental project shared with someone, accompanied by the conviction - unless one is in the field

of pathology that can occur in any situation - that the parental project will also be good for the new human being.

Therefore, there may be other reasons that determine different treatment depending on the different situations of the people who resort to the MAP techniques, but the claim of instrumentalisation is inapplicable or, alternatively, equally applicable, without differentiations, to any of them, whether those interested are married, in a common-law marriage, single, homosexual or heterosexual.

It is accepted, without reservation, that we are facing complex controversial issues, concerning not only the motivations of stakeholders, but also damage that might be caused to third parties, the interest of the new human being you want to bring to life, the interests of society and their symbolic values, or even relevant ethical principles. It can also be assumed that in areas like this there is no single solution dictated by an ethical imperative that will not admit alternatives and that, differently, other legislative solutions are admissible that are not ethically objectionable, which, incidentally, is empirically confirmed by the existence of very different solutions in the legal systems that we are closer to ours.

However, when the state not only selects in a discriminatory manner the access to the services it provides, but also prohibits and sanctions people for resorting to MAP techniques, even though using their own resources and private facilities, it should, given the importance and seriousness of the violation of options and the autonomy of persons covered by the exclusion and the prohibition, provide a powerful justification for doing so. In this case, this condition seems not have been met so far.

2. Surrogate pregnancy ("motherhood")

Whereas:

a) the semantics chosen is never indifferent in Bioethics;

b) the term "surrogate motherhood", despite being highly publicized and enshrined in our law and the two bills under consideration, may be indicative of misunderstandings and ethical and anthropological ambiguities, by assuming as tacitly accepted the fragmentation of biological motherhood (genetic and uterine), social and legal,

the CNECV opted for the term surrogate pregnancy and surrogate mother, which reflect the objective realities that mediate the process that can elapse between the transfer/uterine implantation of the human embryo and eventual childbirth at the end of evolutionary pregnancy .

As for the core theme, due to the extreme sensitivity of the issues that are raised or are intrinsically involved in the use of this technique, surrogate pregnancy is one of the more ethically complex issues whose resolution is more problematic and controversial in most countries with legal systems that are closer to ours.

Surrogate pregnancy raises objections, doubts or, at least, generates controversy on issues usually related to eventual commodification of an area that should be immune to market logic, exploitation and instrumentalisation of women, commercialisation and objectivisation of babies, degradation or violation of the symbolic value of pregnancy and motherhood, in addition to the difficulties in establishing a proper regulation of conditions to regulate the legal business in terms that meet the various interests at stake.

a) The proposals

In any case, in the bills under consideration, surrogate pregnancy is designed for very exceptional circumstances and with strict eligibility requirements, which largely removes from the proposals the controversial nature that the theme generates in the abstract.

Firstly, according to the bills in question, surrogate pregnancy will only be possible with authorization from the CNPMA and prior hearing of the Medical Association and only in cases of absence of uterus and of injury or illness of that organ that prevents absolutely and definitively the woman's pregnancy or in clinical situations that so warrant (PS bill) or in cases of absence of the uterus or, depending on CNPMA authorisation and prior hearing of the Medical Association in clinical situations that so warrant (PSD bill).

Secondly, the whole process presupposes the fulfilment of the assumptions and general requirements applicable to access to MAP techniques.

Thirdly, both bills require the free nature and therefore exclusively altruistic, of the legal business involved, with prohibition of any payment, benefit or donation, with the exception of proven medical expenses incurred.

The PS bill establishes an additional requirement that does not apply to other situations of access to the MAP techniques and consists in the requirement that the surrogate pregnancy using MAP techniques is made with the use of gametes of at least one member of the couple.

Regardless of the opinion that one has about possible risks from resorting to surrogate pregnancy, such a strict and exceptional delimitation of access conditions and requirements and, in particular, the requirement of its absolutely free nature, may remove from the proposal the controversial nature that the topic potentially presents. Any remaining doubts and risks relate mainly to the different perception of the indeterminate effects of instability that the admissibility,

even if exceptional, of surrogate pregnancy can generate in symbolic and social valuation of pregnancy and motherhood.

Well, as the real and current violation of fundamental principles is not decisively at stake, the existence of those doubts and risks can be offset by substantial benefits that a legally set up surrogate pregnancy in these terms can provide to the actual life of some people; therefore, in these circumstances, there is no absolute ethical objection to the proposals contained in the two bills under consideration.

b) Acceptance with conditions of surrogate pregnancy

Thus, it is considered that a heterosexual couple whose wife has no uterus (or has but is incompatible with evolutionary pregnancy) may have a legitimate desire to ensure the social and legal parenthood of a child procreated with at least one of the respective gametes.

Bearing in mind that there is no wide consensus of positions among bioethicists in this area and, further, that the debate on this topic in the national community is at an early stage, the CNECV accepts, exceptionally, surrogate pregnancy as long as the law ensures compliance of **all the following conditions**:

1. The surrogate mother and the beneficiary couple are fully informed and enlightened, among other things also needed, on the meaning and consequences of the influence of the surrogate mother in the embryonic and foetal development (e.g. epigenetic), such detailed clarification stated in the duly signed written informed consent.

2. Consent may be revoked by the surrogate pregnant at any time up to the start of labour.

In this case, the child should be considered for all social and legal purposes as child of who gave birth.

3. The contract between the beneficiary couple and the surrogate mother should include provisions to be followed in the event of foetal malformations or disease and possible voluntary termination of pregnancy.

4. The surrogate mother and the beneficiary couple should be informed that the unborn child has the full right to know the conditions under which it was procreated.

5. The surrogate mother must not simultaneously be a donor of oocytes in the pregnancy in question.

6. The surrogate mother must be healthy.

7. The altruistic motives of the surrogate mother must first be evaluated by a multidisciplinary health team, not involved in the MAP process.

8. Any health complications occurring during pregnancy (to the foetus or the mother) are entirely decided by the surrogate mother with the support of a multidisciplinary health team.

9. It is up to the beneficiary couple, along with the surrogate mother, to decide the breastfeeding way (in the event of a conflict, the beneficiary couple option should prevail).

10. It is legally unacceptable the existence of a relationship of economic subordination between the parties involved in the surrogate pregnancy.

11. The contract on surrogate pregnancy (made before the pregnancy) cannot impose behaviour restrictions on the surrogate mother (such as constraints on food, clothing, occupation, sex life).

12. The embryo transferred to the surrogate mother has gametes from at least one of the members of the eventual beneficiary couple.

13. The law on this matter and its supplementary regulations must be re-evaluated three years after its entry into force.

c) Ethical reservation regarding the existence of a solution currently provided for

It also has to be mentioned that there is ethical reservation as to the solution contained in the current law, and that the two bills reaffirm, according to which, in situations of a surrogate pregnancy in contravention to the law, the surrogate mother is considered, for all legal purposes, as the mother of the child born in this process (article 8, no. 3 of the current law).

Such a solution, in its rigidity and non-consideration of individual circumstances and not supplemented with other guarantees (as might be the reliance on judicial assessment of the circumstances of the case), can only be justified as a means of sanction and deterrence attempt of illegal behaviours and practices.

However, because of its inflexibility it can mean that, in practical terms, against the interests of the child, you are imposing a filial bond to someone who rejected and never took on an individual parental project or, alternatively, you are determining the possible institutionalization of the child (for example in a situation where the mother was sentenced to imprisonment for the illegal practice of surrogate pregnancy) and always with simultaneous deprivation of the bond with the people involved in the respective parental project and that might even be their biological parents.

3. Heterologous insemination and third-party embryo transfer

As proposed in the two bills, the use of MAP techniques is now admitted using sperm, oocytes or embryos donated by third-parties, not just when a pregnancy is not possible with own gametes (which was already in the current law), but also when it is not possible, with own gametes, to achieve pregnancy without serious genetic disease.

The proposed amendment does not deserve ethical objection to the extent that the reasons justifying a situation (unable to get pregnant) have full ethical equalisation in the other (unable to get pregnant without serious genetic disorder) and because it is considered that the objections that might be raised to one or the other situation (possible moral disturbance caused by the intervention of third-party biological elements in a parental project) have no justification in a situation in which the parties themselves, through free and informed consent, do not have any reservations about the purpose and wish to assume a parental project in the unique conditions under which it can be feasible.

4. Period of cryopreservation and fate of embryos

The two bills foresee the possibility of extension for a further similar period, at the request of the beneficiaries, of the three-year period currently provided for the cryopreservation of embryos created and not transferred through MAP techniques. The two bills also foresee the possibility of the directors of the MAP centres determining the disposal of embryos at the end of those periods when they have not been transferred or donated under the conditions currently provided for and allowed.

Regardless of the opinion one has on the current regime, it is true that the current amendments are a solution for the accountability of the directors of the centres, for which there are no ethical objections to justify the continuation of the situation of uncertainty about the fate of embryos, insofar as, even after the extension referred to, the embryos remain without destination, they are null viability embryos and, without the consent of the beneficiaries, also without the possibility of use for scientific research.

III

CONCLUSIONS

The CNECV has no ethical objections to most of the proposals contained in the PS and PSD bills, taking into account the result of the effective change that its eventual adoption will produce in the legal regime that is currently being practised, but makes the following reservations, conditions and recommendations.

1. The CNECV considers that the exclusion of access to MAP techniques to people who are not married to persons of the opposite sex or in similar unions with people of the opposite sex and, especially, the prohibition and sanction of access to people wanting to do so through own resources constitute a very serious limitation of the autonomy of people that only does not deserve ethical censure if there is an equally powerful justification. The CNECV considers that, since the proponents of the bills under discussion have not presented so far sufficient justifications to substantiate the reasons for that exclusion and, even less, its prohibition and sanction, such a justification must be submitted.

2. The CNECV accepts - with a set of thirteen conditions – surrogate pregnancy in the exceptional circumstances specified in bills no. 131/XII and no. 138/XII, provided that the law guarantees the cumulative compliance with those thirteen conditions transcribed in point 2, paragraph b) of this Opinion.

3. The CNECV expresses, because it could eventually be contrary to the interests of the child and could lead to absurd situations, ethical reservations to the current legislative solution, confirmed in the two bills under consideration, according to which surrogate pregnancy in contravention of the law adamantly determines that, for all legal purposes, the surrogate mother is considered the mother of the child thus procreated, alternatively suggesting leaving it up to the judge to find the most appropriate solution given the circumstances of the case, at least for purposes of guardianship and custody.

4. The CNECV recommends:

a) that longitudinal studies and records are promoted for acquisition of evidence on the information inherent to both the various facets of MAP (not only technical) and surrogate pregnancy.

b) the public disclosure of the *efficacy rates* (which should be expressed by the clinical pregnancy rate per oocytes collected and by the rate of healthy newborns per oocytes collected, with an indication of the percentage of twinning, as recommended by the European societies of genetics and reproductive medicine and embryology) of different centres of medically assisted procreation, of the different sterility centres of the NHS, corrected by age groups and different selection criteria;

c) that social measures are promoted to reverse the achievement of increasingly late parenthood;

d) the promotion of measures that encourage adoption, as well as the simplification of the respective processes

NATIONAL ETHICS COUNCIL FOR THE LIFE SCIENCES

Lisbon, 26 March 2012

Miguel Oliveira Silva (President, rapporteur)
Jorge Reis Novais (rapporteur, with declaration)

Note. Counsellor Michel Renaud was initially designated as rapporteur, together with the President and Counsellor Jorge Reis Novais, having been the author of an alternative draft Opinion that resulted in a minority of votes.

Approved by majority in the 183rd and 184th plenary meetings of the CNECV held on 21 and 26 March 2012, respectively, which were attended, besides the President, by the following Counsellors:

183rd plenary meeting: Agostinho Almeida Santos; Ana Sofia Carvalho; Carolino Monteiro; Duarte Nuno Vieira; Francisco Carvalho Guerra; Jorge Reis Novais; Jorge Sequeiros; José Germano de Sousa; José Lebre de Freitas; Lucília Nunes; Michel Renaud; Raquel Seruca; Rosalvo Almeida.

184th plenary meeting: Ana Sofia Carvalho; Carolino Monteiro; Isabel Santos; Jorge Sequeiros; José Germano de Sousa; José Lebre de Freitas; Lígia Amâncio; Lucília Nunes; Michel Renaud; Pedro Nunes; Raquel Seruca; Rosalvo Almeida.