

Recent Judgement of the Italian Judiciary about medical assisted procreation (MAP): is informed consent valid after parents separation?

N. Di Fazio¹, B. Fineschi², M. Caporale³, Z. Del Fante¹, G. Volonnino¹, P. Santoro¹, R. La Russa^{2,4}

¹Department of Anatomical, Histological, Forensic and Orthopaedic Science, Sapienza University of Rome, Rome; ²University of Siena, AGI medica, Siena; ³Department of Surgical and Medical Sciences and Translational Medicine, La Sapienza University of Rome, Roma; ⁴Institute of Hospitalization and Scientific Care (IRCCS) Neuromed, Pozzilli, Italy

Abstract

Law No 40/2004 regulates in Italy the matter of medically assisted procreation (MAP). Recently, the Tribunal of Capua Vetere expressed its position on the subject of informed consent in a case of MAP. In the specific case, a couple entered the preliminary stages of the PMA procedures, carrying out the fertilization of the ovum and the embryo production.

Afterwards, the couple separated and the man denied consent to the continuation of the MAP. The woman, willing to proceed with the implantation, the woman made an urgent judicial appeal, obtaining the judge's permission to transfer the embryo to the uterus.

This paper analyses the different bioethical positions on MAP's informed consent. In fact, on the one hand, the paper highlight what is set out in Law 219/2017 which provides for the possibility of the patient to revoke at any time the consent to the treatment given. On the other hand, it should be noted that Law 40/2004, willing to protect the embryo, establishes the irrevocability of the position of parental consent after fertilization.

The judgment in question seems to favour this latter position, placing itself in the protection of the cryopreserved embryo and recalling the principle of entrustment following the fertilization of the egg. Nevertheless, the matter is controversial a consistent amount of legal developments are expected to arise in the next future. *Clin Ter 2021; 172 (4):253-255. doi: 10.7417/CT.2021.2325*

Key words: medical assisted procreation, MAP, law 40/2004, informed consent, embryo transfer, embryonal experimentation

Introduction

Law No. 40 of 2004, which rules medically assisted procreation (MAP), over the years, has raised several ethical and legal issues (1-9) In particular, key points in the jurisprudential debate were: the prohibition of heterologous procreation, the prohibition of experimentation on the embryo, the prohibition of pre-implantation diagnosis,

the prohibition of creating more than three embryos per implantation. In this regard the Constitutional Court (10) has expressed its opinion, on the basis of the changes introduced by the European Court of Human Rights (11), which lead to the overcoming of the previously expressed principle of heterologous fertilization prohibition.

Recently, the Italian judiciary has once again pronounced about the subject of the MAP (12). In particular, the Court of Capua Vetere, in its judgement of 27 January 2021, authorized an embryo transfer into the body of a woman despite the fact that she was separated from her husband and his explicit dissent about the MAP procedure.

Case presentation

The couple in full agreement, decided to undergo a cycle of medically assisted procreation (MAP) at the Pertini Hospital in Rome. Following all the legal requirements, they gave formal consent to the procedure. After oocyte fertilization, MAP was interrupted due to woman's health problem, now resolved, with cryopreservation of four embryos that, in agreement between the parties, were moved to another medical centre.

However, in the meantime, the couple had separated and the man refused to give his consent to embryos thawing and, consequently, implantation. Therefore, the woman made an urgent judicial appeal and asked the Court to order the medical centre to proceed with embryos implantation in her uterus, having reached the age of 43 years with a consequent reduction in implantation success chances. (13-14) The man objected that, since no longer existed the parental couple, the subjective requirements of access to the techniques of assisted procreation were lacking.

The former spouse therefore expressed doubts as to the constitutionality of art. 6 paragraph 3 of Law 40, so far as it does not allow consent to be revoked after fertilisation of the ovum. The legislation expressly states that "the willingness of both subjects to access the techniques of medically assisted procreation is expressed in writing together with the

doctor responsible for the facility. A period not shorter than seven days between expression of the will and application of the technique is necessary. The will may be revoked by each of the subjects referred to in this paragraph until the moment of fertilization of the ovum". The Constitutional Court had already expressed itself on this point in its judgment of 22.03-13.04.2016, but did not decide on the merits, considering the issue not relevant to the case under discussion (15-19).

Discussion

In Italian legislation informed consent is mainly ruled by law 2019 of 2017 (20). The provisions of this law relating to informed consent may be applied in different fields of medicine, such as psychiatry, end of life caring and medically assisted procreation procedures (21-22).

The abovementioned law generally allows to revoke informed consent under any circumstance. In particular, Law 219 of 2017 establishes that the patient has the right to revoke given consent at any time, even when the revocation involves treatment interruption (23-26). This provision generally refers to any medical treatment. Otherwise, Law 40, willing to protect the embryo, establishes the irrevocability of the consent given by the couple, which is possible until the time of fertilization (27).

This prohibition is undeniably in conflict, on the one hand, with the principle of free self-determination and, on the other, with the "freedom and voluntariness of the act that allows to become parents and to form a family". This decision-making freedom of the couple must exist until embryo's transfer in the uterus is completed, thus emphasizing all the events following fertilization - formation of a new family, protection of third parties. Instead, Law 40 seems, to opt for the absolute protection of the embryo which, once produced, must follow its destiny until future implantation. Consequently, the couple informed consent cannot be revoked after embryo medical assisted formation (28-29).

The decision of the Court depends on the fact that Law 40/2004 guarantees and attributes to informed consent a different value from the general regulations which rules healthcare subjects. In particular, according to the Court, Law 40/2004 protects not only individuals interests who access MAP procedure, but even public interests concerning the delicate matter (ethical and health) that affects the genesis of life. Indeed art. 1 of Law 40/2004 states that "in order to facilitate solution of reproductive problems arising from human sterility and infertility, using of medically assisted procreation is permitted, under conditions and manners provided by this Law, which ensures the rights of the stakeholders, including the conceived one."

The rule adds that fundamental is the right of the conceived one to be born, so as to justify the irrevocability of parental consent after embryos' production. In particular, art. 6 expressly states the irrevocability of consent after fertilization. The following art. 8 attributes to the manifested will, irrevocable after fertilization, a function consisting of determining motherhood (30), fatherhood and child status. Moreover art. 8 excludes, according to the ratio of the law,

the relevance of behaviours and events following fertilization of the ovum: "the freedom to procreate has been exercised and has been exhausted with fertilization". Thus, the law permits the freedom of rethinking "only until fertilization itself."

According to judges, a diminution in embryo's protection might be admitted only in cases when an interest of equal constitutional importance (such as the right to women's health) results prevalent. Separation of spouses is not included among those cases as it cannot be considered, in fact, on the same level as the single parent or the same-sex couple, which give rise to family models that move away from the traditional one.

According to the Court, the child born from separated parents will have the right to enjoy both parental figures and both father and mother will assume rights and obligations related to parenthood. The legal system provides criminal and civil protection for children rights against parents who are required to safeguard the interest of their children. The judge, in order to his decision, makes a comparison between the possible psychological damage of the two spouses: on the one hand, man's obligation to carry out a parenthood project with a woman who does not longer share a project of life; on the other hand, failure of woman's project of filiation despite successful fertilization. Finally, interests of the parties must balance with the embryo expectancy.

The irrevocability of informed consent, which was given at the time of fertilization, despite the former spouse argumentation, guarantees the protection of delicate involved interests. Furthermore, a mandatory health treatment, in contrast with art. 13 and 32 of the Italian Constitution, is not conceivable. In fact, the prohibition of revocation of informed consent does not impose any unwanted mandatory health treatment, limiting its effects on the assumption of parenthood.

Finally, according to the Court there is no conflict with the general principles of informed consent. In healthcare setting, informed consent does not constitute any agreement; conversely it simply constitutes assent to medical procedures, being always revocable. However, the legislator, within different situations, dictates a specific discipline which, in the present case, is justified for the protection of public interests.

Conclusion

The decision of the Judge is based on two reasons: on the one hand the protection of the cryopreserved embryo, its interest in life and development therefore to be transferred in a woman's body, its expectation to be born. On the other hand, the principle of self-responsibility and legitimate expectation that is expressed in the MAP consent which was given by both parents. Infact, within PMA process, when blastocysts are produced, second thoughts or withdrawals are no longer allowed.

The fact that the family and marital relationship, which constitutes the justification for parental project the couple wanted to carry out, has failed is therefore irrelevant.

The woman can still proceed with the attempt of pregnancy. In case of birth of the child, the former husband will be

recognized as legitimate father by the law. Consequently, the father will be bound to any obligation of education and subsistence towards the child, in application of art. 8 of the law n. 40/2004.

Medical assisted procreation informed consent, which was expressed by the partners, does not constitute mere consent to the execution of a health treatment. Conversely it represents a real expression of the will to become parents, which can no longer be questioned as it was acquired at the moment of embryo's conception.

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The subject is certainly controversial and deserves attention from different points of view. There is no doubt that because of the complexity and delicacy of the, it's recommendable to deal separately with the judgment of the individual case, by adopting the principle of personalized medicine (31).

The decision of the Tribunal of Santa Maria Capua Vetere is surely intended to create a fundamental precedent in a delicate matter such as medically assisted procreation, and several jurisprudential developments are awaited.

Conflicts of Interest

The authors declare no conflict of interest.

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