

A Close Insight into Medical Assisted Procreation (MAP) and related Informed Consent: A Recent Case from Italy

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Abstract

Law n. 40/2004 regulated Medically Assisted Procreation (MAP) in Italy. The case described in this article is part of the many judicial cases that have affected this legislation. Following the marital separation process, the former husband withdrew consent to the implantation of already formed embryos in the uterus of his former wife who turned to the judiciary to obtain permission to initiate such a procedure. This paper consists of an analysis of this judicial process and deals with medical-legal and bioethical issues. In contrast to what is stated in Law n. 40/2004, the subsequent Law n. 219/2017 about informed consent, establishes the general principle of the withdrawal of consent until the healthcare procedure is carried out. Another issue concerns the difficult balance between the guarantee of personal freedom and the embryo's life protection, considering that although the embryo is already formed, it is not a person yet. In light of the existence of previous conflicting judicial sentences, the careful and separate assessment of the case under discussion, together with potential future events, is essential to reach a balanced conclusion, that can resolve disputes in the Italian constantly changing society. *Clin Ter* 2022; 173 (6):507-511doi: 10.7417/CT.2022.2471

Key words: medically assisted procreation, MAP, Law n. 40/2004, informed consent, embryo transfer, embryonal experimentation

Introduction

The publication of Italian Law n. 40/2004 and its guidelines regulated for the first time in Italy the theme of Medically Assisted Procreation (MAP) (1,2). The principles of the original provision, over the years, have been the subject of political and legal debate regarding their contrast with the principles of the Italian Constitution, as well as the European Court of Human Rights (ECHR). In particular, the main topics of discussion were the prohibition of pre-implantation diagnosis, the creation of more than three embryos, embryo cryopreservation, and heterologous fertilization. This has led to the promulgation of numerous judgments by Italian Courts

(3-12), as well as the ruling by the Italian Constitutional Court (13) and the ECHR (14). Therefore, Italian Law n. 40/2004, before reaching its current form, has undergone several changes over the years. The ban on producing a maximum number of embryos during the same procedure, together with the ban on carrying out the pre-implantation diagnosis was abolished (15). In addition, the ban on embryos' cryopreservation was eliminated, except in cases where a maternal disease is present (16). In this context, a clinical case brought before the Court of Rome has once again raised some questions and doubts about Italian Law 40/2004. The subject of the judicial process, similar to what occurred before the Court of Capua Vetere in the same period (17,18), concerns the procedure of embryo implantation which was requested by a couple. After the embryo's creation, the couple separated. The latter event led to the disappearance of the essential requirements needed for carrying out the procedure, that is the union of the couple. In the meantime, the couple's separation led to the weakening of the consent which was previously given by the man.

Case Presentation

A couple consensually decided to enter an medical center in Rome to undergo a MAP procedure. Once the full right of the couple to use this procedure was established, the informed consent of both parents was acquired. Thereafter their gametes were collected. This was followed by the production of an embryo that was suitable for implantation. At this point, due to a medical problem of the woman, the MAP procedure was suspended, and the cryopreservation of gametes was carried out. Subsequently, an emerging marital crisis led to the separation of the couple and, when the woman decided to complete the MAP procedure, the medical center rejected her request because of the marital separation and, referring to the principles of the current Italian legislation in the matter, required further consent from both parents. At the same time, the man affirmed the irregularity of the previously given consent for problems related to the non-validity of

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the same. The woman appealed to the Court, stating that because of her advanced age (45 years) she had a progressive reduction of the embryo's implantation procedure success chances. The man, on the other hand, argued that based on seminograms performed, his condition of reduced fertility did not appear to fall into the cases provided for by art. 4 c. 1 of Italian Law n. 40/2004: "[...] The use of medically assisted procreation techniques is allowed only when it is established that it is impossible to remove otherwise the impeditive causes of procreation and it is, in any case, limited to cases of infertility or unexplained infertility documented by the act as well as to cases of infertility or infertility from established cause and certified by a medical act [...]". The man also affirmed that the MAP previously given consent was not valid because, at the time he had given it, he did not know his clinical condition of fertility. Moreover, the man stated that the couple's separation resulted in the loss of the requirements of art. 5 of Law n. 40/2004 and those of art. 6 c. 3 which reads as follows: "[...] The willingness of both subjects to access the techniques of medically assisted procreation is expressed written together with the doctor responsible for the structure [...] not less than seven days must elapse between the manifestation of the will and the application of the technique. The will may be revoked by each of the subjects referred to in this paragraph until the fertilization of the egg [...]" (19).

Discussion

The present case deals with the delicate issue related to medical treatment informed consent, which is regulated in Italy by Law n. 219/2017. Informed consent concerning MAP procedure is ruled in Italy by art. 6 of Law n. 40/2004 (Fig. 1).

Among the relevant judicial precedents in this field, a similar case led the Constitutional Court not to pass judgment because the woman, before the conclusion of the MAP procedure, had again given her consent to the embryo's implantation (20-24). During the current year, however, the Tribunal of Santa Maria Capua Vetere authorized the procedure of implantation following the marital separation by the couple, under conditions similar to those of the present case. Access to such medical procedures is regulated by article 5 of Law n. 40/2009. This article rules that to access the MAP procedure, couples should be composed of adults of different sex, married or cohabiting, in potentially fertile and living age. The couple dissolved after the birth of the embryo is not, therefore, part of such cases. The Italian Constitutional Court, in its judgment n. 151/2009, introduced the possibility of cryopreserving embryos for subsequent pregnancies, laying the legal basis for the use of such procedures. It is therefore considered that the case presented in this paper showed a legal vulnerability of the current Law n. 40/2009. Well, this legislative vulnerability has led to considerable resonance over time. On the subject of informed consent, the exceptional nature of the MAP procedure within the field of medical and health treatments must be underlined: it constitutes, in fact, regardless of the technique performed (in vivo fertilization, IntraCytoplasmic Sperm Injection (ICSI), in vitro fertilization (IVF)) either a medical act and a parent's act consisting in a disposition of their own body. This act, however, ends with the birth of a new human being. The expression of a will that harms the interests of the new human being, therefore, is a subject of arduous ethical and legal debate. According to the ministerial guidelines on MAP, it is established that: "The information referred to in this paragraph and those concerning the degree of invasiveness of the techniques towards women and men shall be provided for each of the techniques applied and in such a way as to ensure the formation of a conscious and

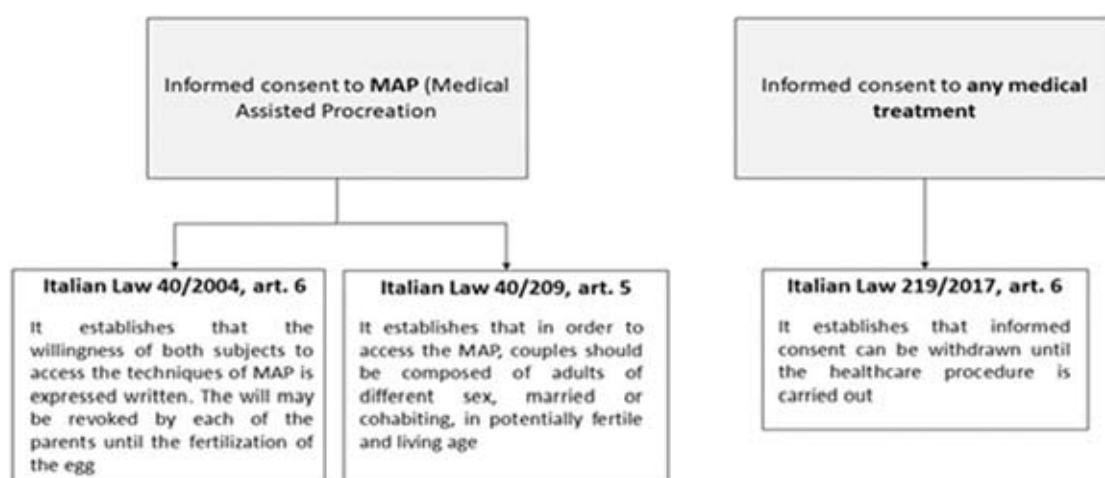


Fig. 1. Italian Laws regarding MAP and informed consent.

consciously expressed will". Therefore, since the different techniques (in vivo fertilization, ICSI, IVF) are characterized by different peculiarities, informed consent must be current, and must be renewed at every stage of the medical procedure. On the other hand, from the formal point of view, the validity of the consent requires the individual manifestation, dated, and signed in written form, limited to the moment of the medical access. The informed consent form completion requires the acceptance and understanding of each medical procedure, limiting to the subsequent stages a confirmation or withdrawal of what was previously expressed. Therefore, according to the Italian legal framework, there should be no interpretative doubt in the present case. Nevertheless, according to some sources of thought, such consent implies: "the will to assume the responsibility of procreation, in a real act of early recognition of the child" (25). This thought is even more emphasized by the provisions of art. 8 which, following the minor protection principles laid down by the ECHR, states that children born through MAP techniques enjoy the status of legitimate or recognized children by the parental couple, who gave consent to MAP procedures (26). Precisely, in the light of the legitimacy of the filiation under the MAP procedure, a legal reference to Law n. 219/2017, which rules the issue of informed consent in Italy, is necessary (27,28). This Law regulates many issues, including mental capacity and end-of-life treatments, as well as MAP procedures (29-31). This Law states: "[...] no medical treatment can be initiated or continued without the free and informed consent of the person concerned [...] Any person able to act [...] has, in addition, the right to revoke at any time, with the same forms as referred to in paragraph 4, the given consent, even when the revocation involves the interruption of the processing". The will of a person, who is mentally capable must be respected. He has the right to withdraw his consent to medical procedures at any time (32,33). This principle applies especially in cases such as the one in the present paper where the reason for the decision to withdraw consent is fully and validly identified. The present case, therefore, faces the right to life of an embryo and the right to self-determination of the biological father who opposed the continuation of the MAP procedure. In addition, further values at stake are represented by the woman's right to filiation and the unborn child's right to life and family (34). Finally, the position taken by the medical center deserves a brief reflection. In the present case, the medical center required further consent from the man after the couple's separation in order to proceed with the MAP procedure. Well, such conduct, may be considered part of the phenomenon of defensive medicine. This practice is constantly growing in all medical areas, especially in high-risk specialties such as obstetrics and gynecology, as well as reproductive medicine (35).

Conclusion

In order to balance the forces at stake, the Court who is in charge of making a judgment in the present case has necessarily to consider the order of the Tribunal of Santa Maria Capua Vetere that, in such a circumstance, decided to authorize the embryo implantation in the woman. This

judgment upheld the appeal of the woman and also supported the principle that the man previously given consent has a validity that is limited to those stages that precede the genesis of a new individual. Moreover, the man was recognized as the legitimate father of the unborn child with consequent full obligations and parental duties (36). In the case reported in the present paper, facing the contrast between what is expressed in terms of informed consent by Law n. 219/2017 and Law n. 40/2004, the principles contained in Law n. 2019/2017 has therefore prevailed. The particular condition of assuming parenthood was not considered by the Court as a real health treatment. However, in the present case, the impossibility of withdrawing consent was framed as an obligation contrary to the constitutional and legislative values of Law n. 219/2017. The objective of this manuscript, however, is precisely to stress this crucial point: the MAP procedure represents in all respects a medical procedure, for which either an act of disposition of one's body and the expression of consent are required. Furthermore, the right to the family mentioned above is based on the assumption of the couple's union. The absence of this condition of parental union constitutes the basis for which the man had withdrawn his consent. Even the heterologous fertilization in Italy, on the other hand, does not represent an exception to the assumption of the existence of a couple of two individuals. The realization of fertilization outside the existence of a couple, therefore, represents a contravention of any legal or even ethical norm so far sanctioned. The existence of a precedent such as the case of the Court of Capua Vetere, therefore, does not allow to affirm with certainty the universal applicability of the criteria adopted therein: the route traced by that judgment should always be integrated with the specific data of the single case, treating them from the perspective of medicine, understood in its all-encompassing, personalized meaning (37-39). Finally, the purpose of the present paper is to arouse reflection on a very topical issue, namely the flexibility of fundamental values such as the family and parenthood, in continuous adaptation to the needs of contemporary society. In the turmoil generated by the judicial events that over the years have crumbled the Law n. 40/2004, the case currently pending highlights the responsibility of the Italian judiciary as guarantor of the fundamental principles of the Italian Constitution, as well as the fundamental contribution it offers to favor a process of sociocultural evolution projected towards the European context of the twenty-first century

Conflicts of Interest:

The authors declare no conflict of interest.

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