Access to medically-assisted procreation: the withdrawal of paternal consent in the maze of law n. 40/2004

G. Napoletano 1, F. Circosta 2, G. Basile 3

1 Department of Anatomical, Histological, Forensic and Orthopedic Sciences, “Sapienza”, University of Rome, Rome, Italy; 2 Department of Clinical, Internal Medicine, Anesthesiology and Cardiovascular Sciences, “Sapienza” University, Rome, Italy; 3 IRCCS Istituto Ortopedico Galeazzi, Milan, Italy

Abstract

The law (No.40/2004) stipulates that consent to Medically Assisted Procreation (MAP) remains irrevocable post ovum fertilization. Cryopreservation introduces complexities, enabling embryo implantation requests after a couple’s separation and the dissolution of the original parenthood plan. Constitutional Court Ruling No.161 in 2023 affirmed that the prohibition of revoking consent to MAP aligns with the Italian Constitution and the jurisprudence of the European Court of Human Rights. This delicate equilibrium of conflicting interests upholds human freedom, allowing consent revocation prior to ovocyte fertilization. Permitting revocation until implantation could inflict more significant harm: the infertile woman can in fact miss the opportunity to become a mother, impacting her psychophysical well-being and freedom of self-determination. Moreover, the embryo loses the chance to live, remaining in cryopreservation, which violates its dignity. Addressing this issue requires thorough communication by medical professionals to inform couples about the limitations on consent revocation. An element of objectivity in terms of standards and evidence-based guidelines, from which norms must originate, is of utmost importance. Relying on broadly shared rules, especially at the international level, is vital in light of the unremitting scientific advances in MAP, as in other areas of medicine, which will open up new opportunities for which current legal/regulatory frameworks are inadequate. Clin Ter 2024; 175 (3):163-167 doi: 10.7417/CT.2024.5057

Keyword: medically assisted procreation, revocation of informed consent, principle of equality, freedom of self-determination, dignity of the embryo, evidence-based guidelines

Introduction

Following the implementation of Law No. 219 in 2017, which regulates informed consent in Italy (1), in various medical fields such as psychiatry and end-of-life care, informed consent can be withdrawn at any time, even if it means stopping the treatment (2). This rule generally applies to any medical procedure. In Italy, Law No. 40/2004, Article 6, paragraph 3, specifies that the desire of a couple seeking assisted procreation “can be withdrawn by either party... until the moment of ovum fertilization.” Initially, the law prohibited storing embryos, requiring the immediate transfer of obtained embryos (up to a maximum of three) into the woman’s body (14, paragraphs 1 and 2) (3). The law aims to legally protect both the parents and the embryo and prevent a significant delay between fertilization and implantation, which could lead to the withdrawal of consent by either the man or the woman. However, several rulings from the Constitutional Court have changed the law, which as a result has been significantly evolved in its restrictions on MAP practices (4). With judgment No. 151 of 2009, the Court declared the obligation of a single and simultaneous implantation of fertilized embryos, not exceeding three, as unconstitutional, allowing the freezing of fertilized but unimplanted embryos (5,6). Furthermore, with judgment No. 96 of 2015, the Court declared unconstitutional the ban on assisted procreation and pre-implantation diagnosis for fertile couples carrying genetic diseases, resulting in a longer period between ovum fertilization and uterine implantation, leading to more cases of storing embryos (7-10).

Historical context

The case under consideration by the Constitutional Court originates not only from the Court’s rulings but also from the absence of necessary interventions by the Italian legislature, which has been notably lacking in matters pertaining to beginning-of-life (11). The scenario involves a married couple who, in 2017, sought assistance from a healthcare facility to initiate the assisted procreation process. Following fertilization, an embryo was formed using the woman’s ovum and the husband’s gamete. The couple had consented to cryopreserving the embryo to facilitate embryonic biopsy before implantation. However, the implantation was delayed due to poor endometrial quality. Consequently, the woman underwent pharmacological therapy, additional analyses, and the so-called “endometrial scratch,” a preparation therapy performed before implantation. However, the in utero transfer of the embryo did not occur because in January 2018, the husband requested separation and revoked consent for embryo implantation. He was no longer interested in the parenthood project stemming from that fertilization, tied to

Correspondence: Giuseppe Basile, email: basilettraumaforense@gmail.com

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a family that no longer existed. In February 2020, a second request from the woman was rejected by the healthcare facility for the same reason. Subsequently, the woman approached the Rome Court, requesting an order for the healthcare facility, where she had initiated the assisted procreation process, to thaw the cryopreserved embryo and proceed with its implantation. The Court, after carefully examining the facts surrounding the incident, referred the matter to the Constitutional Court, expressing doubts about the legitimacy of Article 6, paragraph 3, of Law No. 40/2004.

Reasons for Unconstitutionality of Article 6 of Law No. 40/2004

The Rome Court questioned the legitimacy of Article 6, paragraph 3, citing several concerns. This article permits consent revocation only before fertilization. Notably, even after fertilization, the woman cannot revoke consent but retains the choice not to undergo embryo implantation voluntarily. The law doesn’t enforce coercive implantation. If such a rule were enacted, the Constitutional Court might declare it unconstitutional, as it could violate the dignity and health of the woman. Essentially, the law compels the man, against his will, to become a father if embryo implantation occurs years later, even with changed circumstances since the initial assisted procreation access, violating constitutional articles (12). According to Article 6, paragraph 3, of Law 40/04, “Consent to assisted procreation can be revoked until ovum fertilization,” and neither partner can revoke consent to embryo implantation after that moment. In response to the woman’s request for a blastocyst transfer, the ex-husband cannot legally revoke his previously given consent. Consequently, he is legally unable to prevent his ex-wife from attempting pregnancy. This situation forces the man into legal parenthood, including associated financial and moral obligations, for a child conceived during the marriage but potentially born years after its dissolution. Additionally, Article 5, paragraph 1 (Law 40/2004), allows assisted procreation only for heterosexual married or cohabiting couples of legal age, both potentially fertile and alive. If any prerequisites cease between cryopreservation and implantation, consent revocation should always be allowed. Furthermore, the aspect of formal equality (Article 3 of the Constitution) would be violated because only the man’s freedom would be sacrificed, while the woman could always abstain from implantation, even if initially agreeing to assisted procreation (13). The fact that the familial and marital relationship justifying the intended parenthood project has ceased to exist is therefore irrelevant. The woman can still proceed with attempting pregnancy. If a child is born, the ex-husband will be recognized by law as the legitimate father, and consequently, he will have the duty to raise, provide education, and support for the child (Article 8 of Law 40/04). The Court’s response has essentially pointed to the irreversibility of father consent as sustainable. The Court provides three arguments affirming that the impossibility of revoking consent after ovum fertilization is not unconstitutional.

The Man’s Right to Self-Determination

Firstly, the constitutional judges acknowledge facing a “tragic choice” because it is impossible to reconcile and satisfy two conflicting interests: the protection of the woman’s psychophysical health and her freedom to autonomously become a mother, the man’s freedom to choose not to become a father, the dignity of the embryo, and the rights of the child resulting from assisted procreation. The Court chose to prioritize the protection of the woman’s psychophysical health, her freedom to autonomously become a mother, and the dignity of the embryo while completely sacrificing the opposing interest, namely the man’s right not to become a father against his current will. Regarding the violation of the man’s right to self-determination, the Court observes that it is true that the man, starting from the embryo’s fertilization, cannot revoke his consent. However, when he consented to implantation, he was aware that embryo implantation could occur after several years due to the possibility of cryopreservation. Therefore, he was aware that he could become a father even after a long time compared to when he expressed his consent, even if the couple’s parenthood project had changed in the meantime. Furthermore, the Court emphasizes that the man’s consent affects other constitutionally relevant interests, particularly those of the woman. The woman, due to the man’s consent, undergoes therapies and interventions, including invasive ones, lasting for extended periods and posing serious risks to her health. A potential revocation would have more severe negative repercussions if the woman, due to age or physical conditions (14), could no longer embark on a new assisted procreation path, thus losing her autonomy regarding procreation. Therefore, Law No. 40/2004 stipulates that the given consent is irrevocable to safeguard the woman’s psychophysical integrity because interrupting assisted fertilization, once it reaches the fertilization stage, could negatively impact her psychophysical health (15).

Differential Regulation of Men and Women’s Consent:

Regarding the principle of equality (Article 3 of the Constitution), the constitutional judges argue that the Rome Court’s decision does not violate this principle because there is no disparate treatment, even though it is true that the man cannot avoid becoming a parent while the woman can refrain from implantation. However, this does not constitute gender-based discrimination (Article 3 of the Constitution) since, in this case, the situations of the woman and the man are different. The application of the equality principle must consider these differences because the woman participates with her body, a significantly more relevant involvement compared to the man (16). Indeed, the man’s contribution to generation is exhausted with ovum fertilization, whereas, to realize the shared parenthood project, the woman must undergo demanding cycles of ovum stimulation (17). If this phase concludes successfully, the woman must undergo ovum retrieval, a particularly invasive medical treatment, typically performed under general anesthesia (18). Therefore, it is evident that in the assisted procreation process, the woman is involved to a much greater extent than the man, engaging her body and psyche. If the assisted fertilization
process were interrupted, the woman’s right to health would also be compromised, encompassing both psychological and physical health. On this topic, the Court draws a parallel between assisted procreation and the voluntary termination of pregnancy procedure provided by Law No. 194/78 (18). In both cases, men and women do not have the same rights. The man’s will succumbs because the woman’s decision to terminate the pregnancy deprives the man of the possibility of becoming a father. Similarly, a man who does not want to have a child with a woman cannot obstruct her will to continue the pregnancy. This disparity is justified by the fact that pregnancy involves only the woman’s body, not the man’s. Therefore, neither the continuation nor the termination of the pregnancy can be imposed on her. Similarly, the man’s will to interrupt the in utero embryo implantation has no legal relevance. The highly contentious nature of such dynamics means that the right to conscience-based refusal needs to be upheld as well, within the framework of a process designed to reconcile the rights, needs and aspirations of all stakeholders involved (19,20).

**Protection of Embryo Rights:**

According to the Constitutional Court, the prohibition of revoking consent to assisted reproductive technologies is justified by the need to protect the dignity of the embryo itself. The Court states that the embryo is not reducible to mere biological material; it possesses dignity to be safeguarded as it embodies the principle of life, understood as human life, given that fertilization initiates the development process of a human being. The Court notes that the embryo is generated with the hope that, once transferred to the uterus, it will lead to a pregnancy resulting in birth (21). However, despite this, Law No. 40/2004 has not established the right to be born for the embryo. With these considerations, the Court concludes that when considering the protection of the physical and psychological health of the mother and the dignity of the cryopreserved embryo, it is not unreasonable to limit the self-determination freedom of the individual concerning the perspective of parenthood. The Court argues that assisted reproductive techniques aim to “promote life,” namely new birth, not just fertilization. Therefore, even in the event of a crisis in the couple, the Court deems it possible to prioritize the woman’s request to implant the embryo, even after a prolonged period of cryopreservation, to protect the primary interest of the embryo to be born (21-23). The separation of future parents does not prevent the child from establishing an emotional bond with both. The Court distinguishes between the dissolution of the parental relationship and the indissolubility of the filial bond, ensured by Law No. 40 of 2004. The law aims to guarantee the unborn child parenthood from both the mother and the father (24). The Court believes that between not being born and being born into a family of separated parents (still parents), the latter option should prevail. Parenthood is now considered a concept and a factual situation detached from the connection with marriage and the family, according to the judges.

**European Court of Human Rights**

The decisions of the European Court of Human Rights concerning the alleged violation of Article 8 of the European Convention on Human Rights, which guarantees the right to respect for private life, highlight the broad margin of appreciation granted to states in regulating the possibility and consequences of a man revoking consent. The constitutional judges exclude that in Italian legislation “the irrevocability of consent after embryo fertilization (...) exceeds the margin of appreciation granted to the State” (25). The European Court of Human Rights has consistently emphasized that, in matters of assisted reproductive technology, Strasbourg judges must consider the sensitivity of the issues, especially when ethical choices are involved, there is no generalized consensus among legal systems, and the field of medical science is still evolving. In such cases, the discretion granted to states is considered broader, in light of the complexities arising from highly innovative techniques for which the current regulatory standards may be inadequate from the legal and ethical standpoints (26).

The Evans v. United Kingdom judgment of 2007 (27,28) provides an interesting point of comparison. While the English case bears many similarities to the one examined by the Constitutional Court, it is resolved in the opposite direction because English law (like that of other countries such as Denmark, France, Greece, the Netherlands, Switzerland, and Austria) allowed a man to revoke consent until embryo implantation. Consequently, the woman could not rely on the man’s choice.

The Constitutional Court refers to two contrasting approaches, one Israeli and one Colombian, regarding cases where a man withdraws consent after separating from the woman. In the Israeli case Nachmani v. Nachmani (29), the Court states that parenthood is based on love and mutual respect, and when these elements disappear after separation, the foundation for decisions about the fate of fertilized eggs is lost. In this context, without consent, it is not possible to initiate or continue fertilization treatment. Conversely, the Colombian Constitutional Court has adopted a unique approach. Despite the man’s withdrawal of consent, it allowed the implantation of the embryo, considering a potential refusal by the man as infringing on the woman’s right to reproductive self-determination. However, the Colombian Court determined that the man could maintain anonymity, preventing his contribution to assisted reproduction from generating a filial relationship unless otherwise decided (30).

**Discussion**

The accumulation of cryopreserved embryos, coupled with the rise in separations and divorces, has significant consequences (31). One way to mitigate these serious consequences could be through information dissemination: healthcare professionals should inform couples about the limitations on a man’s ability to revoke consent. All such a process should rely on a set of standards compliant with evidence-based guidelines and best practices sanctioned at the national and international level (32). Even in countries
where consent can be revoked until implantation, it is crucial that the woman is aware that the man can change his mind and no longer want implantation. Similarly, the man should be informed that, after a certain point (varying by different legal systems), he cannot oppose implantation and will be considered the parent of a child he no longer desires. While the law regulates consent revocation, and doctors may assume that couples are aware of it from a legal standpoint, ethically, healthcare providers must act to remedy the disadvantaged and vulnerable conditions of their patients, including any ignorance preventing informed choices. Referring to the Israeli and Colombian court decisions does not seem to provide a solution to rebalance all the delicate interests at play. These judgments appear to absolve the man of the consequences resulting from assisted reproduction, undermining the legitimate expectations of the woman regarding the future (co)parental relationship. Consent revocation would affect the legal status of the future child, depriving them—despite the initially expressed consent—of a parental figure (with significant economic implications) (30).

However, even the radical approach taken by the current Italian legislation does not seem viable. The time between ovum fertilization and implantation could be substantial, allowing the man to have children with another woman in a new ongoing family project. The birth of a child that has remained in cryopreservation for years would disrupt this reality to the detriment of the new partner and her children. The Constitutional Court could not consider this scenario as it was not relevant to the case at hand. Therefore, recognizing the complexity and sensitivity of assisted reproduction, the Court urges Parliament to find a definitive solution. It is necessary to overhaul Law No. 40/2004 and adapt it so that it can effectively meet new societal needs, striving to identify a reasonable balance among the various constitutional interests involved (33,34). Nonetheless, a national legislative approach is not enough in today’s world, where fertility traveling has become increasingly widespread and poses elements of discrimination for those who cannot afford the costs it entails (35). Hence, a viable balance, which must seek to reconcile the core values and priorities of all the stakeholders involved, should be sought at the international level, and shared by countries with common social and moral standards of justice and priorities (35-37). Consent can therefore become even more complex to manage as a result of the greater complexity of the MAP process as a whole (38). The interests of all those involved in reproductive techniques may prove difficult to reconcile: the right of children to know about their biological origins could in fact clash with donor anonymity in case of heterologous fertilization and surrogacy (38-40). Striking such a balance is even more essential in light of the fast-paced scientific advances and technologies, which national medical codes of ethics still do not cover (41,42) and progress faster than the ability of lawmakers and regulators to devise well-balanced standards and norms. Such a rate of progress in fact leads to highly innovative techniques which are bound to outpace the ethical, legal and regulatory standards on which we currently rely (35-43). Moreover, external unpredictable shocks such as the COVID-19 pandemic emergency (44-47). Certainly such adaptability must rely on the potential of breakthrough innovations such as those created by telemedicine, data analysis and, in due time, artificial intelligence-based prognostic and therapeutic avenues, in fertility medicine as well as in other specialties, for which the issue of consent is even more multifaceted and complex (47-51).

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