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Two necessary (and doable) amendments to Law No. 40/2004: Withdrawal of consent and access to assisted reproduction for single women

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Abstract. *Background and aim:* It has been twenty years since the Italian legislator enacted Law No. 40/2004 on medically assisted procreation (MAP). This is a highly ideologized law, which the Constitutional Court has largely modified over the years. The new guidelines issued by the Ministry have incorporated the Court's decisions; however, they have overlooked certain issues that can only be regulated by the legislator: namely, the consent to embryo implantation and the possibility for single women to access assisted reproduction techniques. As has already occurred with end-of-life issues, the legislator has not yet enacted any set of norm aimed at taking into account the demands coming from society and protects the rights of all individuals involved in assisted procreation techniques. In fact, the political direction has gone in the opposite way, even classifying surrogacy as a "universal crime." (www.actabiomedica.it)

Key words: Medical assisted procreation (MAP), informed consent, withdrawal of consent, freedom not to procreate, principle of self-determination, fatherhood, assisted reproduction for singles

Introduction

Twenty years after its approval and after the Constitutional Court has substantially modified its original framework, Law No. 40/2004 (1) continues to create interpretative and applicative problems, particularly concerning the right to parenthood (Art. 5) and consent (Art. 2). Regarding access to assisted reproduction techniques, the law initially allowed access only to heterosexual couples (married or cohabiting), of potentially fertile age, suffering from reproductive issues such as sterility or infertility (Art. 1). Thus, it excluded couples who, even if fertile, were carriers of genetically transmissible diseases. It also did not allow preimplantation diagnosis (Art. 13, co. 3) (2). This was an evidently unreasonable prohibition, given that Law No. 194/1978 (3) already allowed voluntary abortion if prenatal tests found significant anomalies or malformations in the fetus that posed a serious threat to the physical or mental health of the woman. In its original formulation, Law No. 40/2004 also stated that no more than three embryos could be created, and their transfer to the uterus had to occur within a few days (Art. 14, co. 2). Cryopreservation was allowed only in exceptional cases, justified by a serious and documented health reason for the woman that was unforeseeable at the time of fertilization. In any case, implantation had to take place "as soon as possible" (Art. 14, co. 3).

With ruling No. 96 of 2015, the Court declared unconstitutional the ban on access to MAP and preimplantation diagnosis for fertile couples carrying genetic diseases, thus extending the time between fertilization and implantation, and consequently increasing the use of cryopreservation. In ruling No. 151 of

2009, the Court declared the unconstitutionality of the requirement for a single, simultaneous implantation of fertilized embryos, limited to no more than three, thus opening the door to cryopreserving embryos that were not implanted. In ruling No. 96/2015, the Constitutional Court declared the unconstitutionality of Art. 1, co. 1 and 2, and Art. 4, co. 1, in part because they denied fertile couples carrying transmissible genetic diseases access to MAP, thereby legitimizing pre-implantation genetic diagnosis (4-7).

Cryopreservation of embryos has led to a significant increase in the number of frozen embryos (8).

Consent and procreative self-determination

Law No. 219/2017 establishes that consent to medical treatment can be revoked at any time, even when revocation leads to the discontinuation of the treatment (Art. 1, co. 1º, l.) (9). However, the legislator may deviate from this rule, as was the case with Law No. 40, to protect public interests, such as the right to life of the embryo, which can only be sacrificed if there is a risk of violating rights of equal rank. Before starting the assisted reproduction process, the couple must sign a consent form and submit it to the responsible doctor at the medical facility. The doctor, in turn, must thoroughly inform the partners about the methods, possible side effects of the treatment, success rates, and the risks these techniques entail. The doctor must particularly focus on the legal consequences of these techniques for all those involved: the woman, the man, and the unborn child (10-14). The law does not allow for forced implantation; consent can be revoked until fertilization of the egg, but neither partner can withdraw consent for embryo implantation after that moment. In theory, even the woman cannot revoke consent; however, since the law does not allow forced implantation, she may choose not to implant the embryo.

However, after the Constitutional Court's intervention, the embryo can be preserved in liquid nitrogen indefinitely, and, in fact, decades could pass between embryo creation and transfer to the woman's body, leading to births long after fertilization. Over such an extended period, situations may change, such as the death of a parent or the separation of the partners. Even if these situations arise, under Art. 6, implantation must occur because the embryo's right to be born outweighs the revocable consent of the parent who had initially agreed (15).

In our view, the provision in Art. 6 of Law No. 40/2004 is vague because it does not specify what happens if consent is withdrawn after embryo fertilization. Moreover, this rule does not appear to distinguish between the man's and the woman's position, but it is clear that the prohibition applies only to the male partner, while the woman's consent can be revoked at any stage of the procedure. In fact, if the woman's consent were irrevocable, forced implantation of the embryo would be required, which would violate Art. 32 of the Constitution, as MAP would become a mandatory medical treatment. Additionally, this prohibition would be unreasonable, especially considering the content of Law No. 194/1978. The non-implanted embryo would receive far greater protection than the fetus in the first trimester of pregnancy. On the other hand, if the man wants to withdraw his consent, the provision in Art. 6, co. 3 of Law No. 40/2004 should apply, meaning that revocation of consent is entirely ineffective, and implantation can take place. Therefore, the rule in Art. 6 of Law No. 40, which allows for embryo implantation years later under a "different legal situation" from the one that existed when the consent form was signed, would unreasonably force only the man to become a father against his will, effectively nullifying his right to self-determination regarding the decision not to become a parent, a right recognized by Art. 2 of the Constitution and Art. 8 of the ECHR (16).

Discussion

The prohibition on the withdrawal of consent for those accessing MAP techniques made sense (and still does) if the procedures were concluded quickly. In our view, at least in the case of a long delay between fertilization and embryo transfer, with subsequent dissent between spouses, the rights of both parents to parenthood should necessarily be considered equal. This should be the case until the embryo is transferred to the woman's uterus, initiating pregnancy, at which

point the right to maternity certainly prevails over the right to paternity (17).

We believe that to protect the embryo, the consent of the man is also necessary for MAP techniques to continue, otherwise, only the woman will have full decision-making power, as she could choose to indefinitely delay cryopreservation or attempt to have a child whose father is no longer interested in parenthood (and the responsibilities it entails) due to separation or divorce. The non-consenting parent, based on consent given many years earlier, would, therefore, bear parental and financial responsibilities to fulfill someone else's wishes. In our view, just as motherhood cannot be forced, neither can fatherhood. Thus, the law, at the time of giving consent, should provide the possibility for either parent to decide not to proceed with embryo implantation.

Withdrawal of father's consent and its impact on the prospective mother

Under Italian law, access to MAP is conditioned upon an existing stable couple relationship. This situation has negative consequences for the man, the woman, and the child: for the man, who finds himself fathering a child he did not want (with all the economic consequences this entails), for the woman (forced to impose fatherhood on a man who did not want it and with whom there is no longer any emotional connection), and for the child (who will be aware of being unwanted by the father). It is evident that if the woman begins the assisted reproduction process at an advanced age, the only option to become a mother is to proceed, even forcibly, with the implantation of the embryo created with her previous partner. The situation would be different if single women were allowed to access MAP techniques and establish an independent parent-child relationship, giving the child a legal status akin to that of children recognized by a single parent (a situation already present in so-called single-parent families). Legalizing access to MAP for single women would allow women to independently and consciously decide to become mothers and form a single-parent family from the outset. In fact, many European countries (the UK, Ireland, Spain, Portugal, Germany, Greece, Belgium, Denmark, Finland, Sweden, and, more recently, France) (18,19) recognize the right to access MAP for single women – albeit with different prerequisites and conditions. Recognizing this right would also have another significant consequence: it would prevent women from traveling abroad (20), to countries where such access is permitted, to have a child, circumventing Italian law (21). This leads to discrimination against those who, despite having a strong desire for motherhood, do not have the financial means to undergo the long MAP procedures abroad (22-24).

Conclusion

The new guidelines issued by the Ministry of Health (25), which cover both access to assisted reproduction for single women and the withdrawal of consent, do not change the original framework of the law. The Constitutional Court has upheld the irrevocability of the man's consent to embryo implantation in MAP, emphasizing that it is up to the legislator to balance individual rights with the protection of the embryo's health and dignity (26). Therefore, it is necessary to rewrite the law on medically assisted procreation to not only involve couples but to address societal needs and ensure that single individuals also have access to the right to parenthood, while also protecting the dignity of the embryo. A law that reconciles and satisfies the protection of the woman's physical and psychological health, her right to self-determination as a mother, the man's right not to become a father, the dignity of the embryo, and the rights of the child born through MAP.

Unfortunately, in the current political climate, the legislator has enacted laws that do not protect the interests of children and fail to uphold their rights, such as those born through surrogacy, even this technique punishable as a universal crime (27). This, in our view, is an ideological law that may likely prove largely ineffective (28).

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