



## Pre-implantation Genetic Diagnosis in Accordance with Italian Regulations

Aurora Vesto\*

Department of "Scienze della Società e della Formazione di Area Mediterranea" - "Dante Alighieri", University of Reggio Calabria, Italy

### Abstract

A pre-implantation genetic diagnosis allows the identification of any genetic abnormalities in an embryo created *in vitro*; therefore, by exercising this practice, women avoided having to resort to therapeutic abortion, because making such a diagnosis allows you to implant only "healthy" embryos, with diseased embryos being discarded as a result. In Italy there is no legal regulatory body for pre-implantation diagnoses, but, it is possible to find provisions in Law No. 40/2004, "Medically assisted reproduction regulations".

Over the years, practitioners and lawyers have been divided over the interpretation of the provisions laid down for deciding the legality or illegality of DGP; but today this medical practice is a chance for a couple to learn about any malformations and knowingly decide on the path to be taken.

Recently national case law and European have opened a gap in which to perform pre-implant genetic diagnosis even for fertile couples who carry genetically transmissible diseases.

**Keywords:** A pre-implantation genetic diagnosis; Healthy embryos; Illnesses; Termination of the pregnancy; Therapeutic abortion; Procreative choices

### Introduction

The Italian ordinance regulating assisted reproduction with the law of 19 February 2004, No. 40 is entitled [1], "Medically assisted reproduction regulations": for the first comments about this law, among others, we note SESTA [2].

A pre-implantation genetic diagnosis (DGP) is a medical practice that, as generally with prenatal diagnosis techniques, allows the identification of any genetic abnormalities in an embryo created *in vitro* that could potentially jeopardise an existing pregnancy or cause the onset of illness in the unborn; making such a diagnosis, which precedes the pre-implantation phase and detects possible pathologies, allows you to implant only "healthy" embryos, with diseased embryos being discarded as a result [3].

In Italy there is no legal regulatory body for pre-implantation diagnoses; however, it is possible to find provisions and recalls in Law No. 40/2004, as well as various constitutional and jurisprudence measures that have arisen in the practical application of the legislation.

Art. 13 of Legislative Decree 40/2004, which is devoted to "Human Embryo Experimentation", states in paragraph 1 that "any experimentation on any human embryo is prohibited" and in paragraph 2 that, however, "clinical and experimental research on an embryo is permitted providing it pursues therapeutic and diagnostic purposes only, to protect the health and development of that embryo where alternative methods are unavailable." Therefore, paragraph 2 is a derogation from a general ban on experimentation in cases where the research aims to protect the health of the embryo.

In addition, Art. 14, which is entitled "Limits to the application of embryo techniques", at paragraph 5, provides a right for parents, if they so request, to an assessment of their embryo's health status, and the doctor's obligation to inform them about its conditions

### From Illegality to Legality of a Pre-implantation Genetic Diagnosis

Over the years, practitioners and lawyers have been divided over the interpretation of the provisions laid down for deciding the legality or illegality of DGP, although no express prohibition could be identified within Law No. 40/2004: for the first comments about this law, among others,

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#### \*Correspondence:

Aurora Vesto, Department of "Scienze della società e della formazione d'area mediterranea"- "Dante Alighieri" University of Reggio Calabria, Member of OPEGAM (Permanent Observatory of Judicial Events in the Medical Field);  
E-mail: [avesto@unime.it](mailto:avesto@unime.it)

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we note LANNICELLI, since approval of Law No. 40/2004 [4]. With reference to the pre-implantation diagnosis, Art. 13, paragraph 3, letter B), does not explicitly provide such a prohibition.

Traditional prohibitions on a pre-implantation diagnosis forced a woman to receive defective embryos in her uterus, with the risk of fetal malformations; this was in clear contradiction of the rights given to women under Italian statute (Law of 22 May 1978, No. 194), to request the termination of a pregnancy whenever the fetus showed serious anomalies and malformations; it was one of the major aporeae of Law No. 40/2004, which, on one hand, implicitly prohibited a pre-implantation diagnosis, but on the other hand did not forbid the subsequent termination of the pregnancy.

The DGP should then be seen as a chance for a couple to learn about any malformations and knowingly decide on the path to be taken, selecting (if appropriate) from the "healthy" embryos created *in vitro*, those to be transferred to the woman's body without transmitting any illnesses the parents are carrying to the unborn. By exercising this practice, therefore, women avoided having to resort to therapeutic abortion.

On the entry into force of Law 40/2004, a precautionary approach to eligibility for pre-implantation diagnosis prevailed, as argued for in the guidelines of 21 July 2004 (LG 2004), under which "any embryo-related health status study *in vitro*, pursuant to Art. 14, paragraph 5 [5], must be of an observational nature." The 2004 guidelines, apart from constituting an act of secondary education, were alleged to be unlawful by the Tar Lazio [6], which annulled them "in the parts contained in the Embryo Protection Measures, in which it is stated that any *in-vitro* embryo-related health study, in accordance with Article 13, paragraph 5, must be of an observational nature". National case law moreover, has not only stated the full legality of pre-implant diagnosis for non-fertile couples who have decided to undertake PMA, but has also allowed access to this diagnosis to fertile couples who have transmittable diseases (in this sense, Tribunale di Salerno, 9 January 2010). The woman's right to screening for a potential disease in the fetus is therefore considered to be paramount, so she is not subjected to the unreasonable consequences of a diseased fetus being implanted and it then being aborted. In this direction, the order of the Tribunale di Milano (04.03.2015, No. 164, in G.U. 9.9.2015, No. 36), in which a diagnostic study of the embryo was motivated by a dominant autosomal irreversible pathology involving the entire skeletal system of the partner who was affected by multiple hereditary exostoses (MHE) [7]. In this way also European law as well as professional practice-amongst practitioners, those who consider the ban unreasonable, are, non-exhaustively-have thus opened a gap in which to perform pre-implant genetic diagnosis even for fertile couples who carry genetically transmissible diseases [8,9]. In fact, such a limitation is not only a violation of constitutionally guaranteed rights former Articles. 2, 13, 29 and 32 of the Constitution, but also of the self-determination of procreative choices, of the "realization of personhood through parenting" and that, in particular, they breached Art. 9 of the Constitution, since refusal of such diagnostic activity prevents couples from "taking advantage of developments in culture and scientific research"[10].

In favour of permitting such a diagnosis, one should compare the law on PMA and the law on terminating a pregnancy, since one deals with procreation as a positive, consensual procedure by the

pregnant woman, while the other expresses the negative volition of the woman in the course of a pregnancy that has been initiated. Just as the pregnant woman, through a prenatal diagnosis, in the event of "significant anomalies or malformations in the unborn child" which cause a serious threat to the physical or mental health of the woman, may decide to abort the pregnancy, even after the first ninety days" [11], a woman who embarks on the path of assisted fertilization may want to know the health status of the embryo created *in vitro* in order not to exercise her choice for abortion, which anticipates a threshold of knowledge before the embryo is implanted in her uterus, and thus decide to refuse its implantation. In this way, the rest, in perfect harmony with Arts. 3 and 32 of the Constitution, would not oblige a woman to undergo a pregnancy that would then become unwanted, with the possibility of interrupting it by means of IVF, with the potentially consequent psychological developments, capable of altering the sensitivity and behavior of the woman in her sexual and/or procreative dimensions.

In 2015, the Minister of Health, Beatrice Lorenzin, signed the decree updating the new text of the guidelines (Legislative Decree 2015), which, while making significant additions on the matter, confirmed that "any pre-implantation diagnoses for eugenic purposes is forbidden".

With an important pronouncement the judges of Strasbourg censuring the prohibition of pre-implant diagnosis, since in this case they recognized the respective spouses (both Italians, not sterile but healthy carriers of mucoviscidosis) were entitled to conceive a healthy son and thus benefit from the pre-implant genetic diagnosis, thus condemning the prohibition because of its incompatibility, firstly with Italian law, in so far as it authorizes the voluntary termination of pregnancy in the event of a disease of the fetus, and furthermore, because it violates Art. 8 of the ECHR, which protects the "right to respect for private and family life"[12].

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