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# Antenatal Genetic Diagnosis and the New Eugenics: European Vision from Medical, Ethical and Legal Perspectives

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*Abstract-* The objective of this work will focus on the ethical and juridical study of reproductive technologies. We have to recognize the many advantages they bring, but it is also required to foresee and evaluate the consequences that these technologies have for human rights. Antenatal diagnostics are not allowed throughout Europe so the reasonsare the different uses they can have: embryo selection, sex selection, genetic manipulation, etc. Preimplantation diagnosis involve ethical and legal approaches with solutions that are highly criticised by society due to the eugenic component that they entail. Result of this study reflect on the convenience of their practice and a proposal of the guidelines to respect human rights and guarantees.

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# AN TENATA LGENETIC DI AGNOSI SANOTHENEWEUGEN I CSEUROPEANVISI ON FROMME DI CALETHICALAN DLEGALPERSPECTIVES

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# Antenatal Genetic Diagnosis and the New Eugenics: European Vision from Medical, Ethical and Legal Perspectives

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#### I. Antenatal Test and Fundamental Rights

where must place preimplantation genetic diagnosis in the context of assisted reproduction techniques and predictive medicine. This techniqueshas been extended with this preimplantation genetic diagnosis as a solution for those couples in a situation of transmitting a congenital anomaly to their offspring. Due to this technological advance, new constitutional rights are requested.

1. Right to procreate

The fact that we have new reproductive technologies at our disposal raises the question of how far the right to procreation as such extends. Right to have children, which would derive from the right to privacy. If right to have children exists, we would have to analyze whether it is an absolute right that people have or whether, on the contrary, it could be limited to specific cases.

Assisted human reproduction makes it possible to exercise, more than ever before in history, the right of individuals to create a family. Sometimes, age, marital status or biology frustrate people aspirations to have offspring. Assisted Reproductive Technologies (ART) appear as a valuable instrument to satisfy this desire. Spanish Law 14/2014 on Assisted Human Reproduction Techniques says that this right to procreate not only reaches couples but also fertile or infertile single women (art. 6), and people who have died - *post-mortem* fertilization - (art. 9).

Spain has ratified various treaties which proclaim the right to create a family. Right to procreate could be derived from the right to their privacy and right to the protection of their health<sup>1</sup>. However, the fundamental problem with the exercise of this right is that it can compromise two different and sometimes conflicting interests:

- a) the right of individuals to procreate implies the use of assisted reproduction techniques.
- b) the right of the child born to have a father and a mother on an equal conditions with other children born in a naturally way.

Given this approach, the difficulty lies in whether or not to deduce the existence of this right to procreate from the constitutional precepts. Personally, I consider that there exists in the abstract a right to reproduce that couples - married or not have, which is based on the following rights:

- a) In freedom, as a value and in the right to free development of the personality<sup>2</sup> (arts. 1.1 and 10.1 Spanish Constitution), since all persons can freely decide on matters that affect them in their personal and intimate sphere. Right to create a family is based on freedom and the dignity. Right to reproduction is a right to physical selfdetermination. It is a fundamental right of Spanish Constitution- art.17.
- b) In the right to privacy (art. 18.1 Spanish Constitution), in the sense that there can be no state interference in such an intimate sphere as the family and procreation.

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<sup>&</sup>lt;sup>1</sup> GOMEZ SANCHEZ, Y. (1994), *El derecho a la reproducción humana*, Marcial Pons Ediciones Jurídicas/Servicio de Publicaciones de la Facultad de Derecho de la Universidad Complutense de Madrid, Madrid, pp. 42 y.ss.

<sup>&</sup>lt;sup>2</sup> EMALDI CIRIÓN, A. (2015) "El derecho al libre desarrollo de la personalidad y la libertad reproductiva», *Derecho y pobreza*, Álvarez Vélez, Maria Isabel / Rey Pérez, José Luis (Directores), ISBN: 978-84-9098-570-0, Editorial Aranzadi — Thomson Reuters, Cizur Menor, España, (Parte IV, Capítulo 8).

c) In the right to the protection of health (art. 41.3 Spanish Constitution), in the sense that the limitations to founding a family could suppose a psychological problem for people and, on the other hand, the necessary measures should be made available to all those people to solve their health problem. Non-procreation for these people would be a health problem that the State must to solve. It is also intended that the offspring should be healthy.

Consequently, this right to reproduction derives from the right to self-determination of individuals, without the possibility of specific State interferences in the exercise of this right, as these decisions belong to the sphere of private life. It can be concluded that there is a subjective right to procreate that can be limited by the interests of other people:

- a) the right to procreate of one of the partners may entail the deprivation of such a right concerning the other partner. On certain occasions, a woman exercising her right to reproduction may terminate her pregnancy following "
- b) Another limit to this right to procreation would arise when the woman wishes to procreate using assisted reproduction techniques and the husband opposes the insemination of his wife with the reproductive material of both of them- for example, using his cryopreserved sperm. In this case, the insemination would be unlawful. The lack of such consent does not prevent the husband from being the biological and legal fathe. The husband cansue his wife and sue the doctor who carried out the non-consensual insemination.
- c) Another limit to the right to reproduction that we will have to reflect on is when couples who, due to physiological circumstances, are unable to father their children let us think of a male couple but who could provide their reproductive material and resort to surrogate motherhood to have their right to procreate satisfied<sup>3</sup>

In conclusion, I consider that there is a subjective right to procreation recognized in the Spanish constitutional order, which is based on freedom as a value (art. 1.1), and on the dignity of the person (art. 10.1), we, also link it to the right to personal and family privacy (art. 18), right to the protection of health (art. 43.1) and respect for the right to found a family (European Convention). It is not an absolute right and will have the limits derived from the rights of others.

#### 2. Right to health

The right to health is recognized in international Law as a human right, that is, a fundamental right, because its existence allows the exercise of other fundamental rights that are regulated, protected, and guaranteed by the public authorities. In this case, the guarantee of protection of the right is not only internal but also the rest of the Member States undertake to do so. There are several international treaties and agreements that promote health.

In Spain, the right to health is a constitutionally recognized right. Spanish Constitution refers to health in its Title I (On fundamental rights and duties), Chapter III (On the guiding principles of social and economic policy -articles 43 and 50). The right to the protection of health is a fundamental right.

New predictive tools are being made available to people, such as antenatal genetic diagnostics that allow to discard for reproduction those embryos that present some kind of anomaly, disease or predisposition even if this leads to a new and accepted eugenics called "neweugenics"<sup>4</sup>.

These diagnoses will do with all the information and a proper genetic counselling. The doctor will give all the information to people with reproductive problems. Genetic counseling is a requisite for preimplantation genetic diagnosis, - Biomedicine Convention of the Council of Europe signed in Spain in 1997 and Law 14/2007 on Biomedical Research -art. 55-.

On the other hand, we have to think about the posibility to force people to carry out this test. Some cases:

#### A. Health policy reasons

For health policy reasons, certain tests could be considered beneficial so compulsory submission will be justified.We refer to preimplantation genetic diagnosis that brings benefits and the results are relevant for decisions regarding reproduction. One problem arise ifmedical information will be given to thepersonbut he/she prefers not to konw.

B. Economic reasons

Another approach that could justify the compulsory of certain genetic diagnostic would be based on the high social and economic cost of the hándicap people. This argument haven't got ethical value because financial costs are paid by the State and by the parents.

#### C. Descendant Health Protection

In this case, the question arises as to whether it is possible, in the interests of protecting the health of offspring, to compel parents at risk of transmitting

<sup>&</sup>lt;sup>3</sup> EMALDI-CIRIÓN A. (2018) "Surrogacy in Spain and the proposal of a legislative change for its regulation. Global phenomenon in Europe", *Revista de Derecho y Genoma Humano Genética, Biotecnología y Medicina Avanzada-Law and the Human Genome Review* Genetics, Biotechnology and *Advanced Medicine, Ed. Dykinson,* núm.49,pp. 75-99.

<sup>&</sup>lt;sup>4</sup> CARVALHO GONÇALVES ELER / MIRANDA RAMOS y PIRES DE OLIVEIRA, (2019), *Diagnóstico* genético pré-implatacao (DGP): Uma Eugenia mascada?, *Revista iberoamericana de bioética*, núm. 9, pp 60-75.

anomalies to their children to undergo genetic tests to confirm the probability or non-existence of the disease or abnormality in question. To sum up, whether it is possible to force people to know their congenital characteristics and to use this information in relation to their reproductive decisions.

#### D. Special cases imposed by Law

The cases in which genetic tests are compulsory because they are required by Law will be mentioned briefly, as they are outside the scope of the study of preimplantation genetic tests. The most critical cases in which genetic testing could be made compulsory are as follows:

a) Criminal investigation

Scientific and technical developments have introduced new techniques in a criminal investigation, which must be assessed and interpreted by the courts.

#### b) Investigation of paternity

According to the content of the Spanish Constitution -Art. 39.2- "Law shall make paternity investigation". If the subject refuses to undergo this kind of test, he/she cannot be obliged to do so, as there is no rule determining the consequences of such a refusal but this attitude will be interpreted by the judge, not as a *"ficta confessio"*, but when combined with other evidence, it can lead to declare parentage" (Sentence Supreme Court 2017 -ROJ 2815/2017). Nowadays, with these genetic test it is possible to determine the paternity of a person with a 99% probability of success.

c) Public health risks

This approach does not apply during the process of preimplantation genetic diagnosis since diseases of gene origin do not represent a severe risk to public health.

It can be concluded thata person can not be submitted to any type of compulsory genetic test. Firstly, despite the benefits that both predictive and preventive medicine can bring, we must not forget that predictive knowledge can also lead us to consider psycological problems as well as stigmatization or social discrimination of people due to their belonging to a group or category. Secondly, this situation is against the right to privacy.

Finally, privacy would also be violated if the subject have been forced to undergo this type of test, since every subject has a "right not to know". Also, the right to dignity and the right to procreate will be affected, if the knowledge of specific genetic results limits the reproduction.

In defense of the safeguarding of the fundamental rights, no subject can be forced to undergo genetic testing except in two situations: a)concerning the analyses that must be carried out on gametes from donors to prevent them from transmitting specific pathologies when they are used in assisted reproduction techniques; b) the preimplantation analyses whose purpose is to confirm that they comply with the due viability guarantees.

#### II. Preimplantation Genetic Diagnosis in Spain

The regulation of preimplantation genetic diagnosis in our legal system is set out in Law 14/2006 on Assisted Human Reproduction Techniques of 2006<sup>5</sup>.

The Law in the Explanatory Memorandum, states that preimplantationgenetic diagnosis is a complementary technique to assisted reproduction techniques and its purpose is to avoid the transmission of diseases to the offspring. Preimplantation diagnosis must be carried out when the National Commission for Assisted Reproduction gives the authorization.

According to article 12.1.a) this diagnosis reveals the possible presence in the pre-embryo of a monogenic disease. Concerning to the provisions of Article 12.1b) It will usetodetect alterations that may compromise the viability of the pre-embryo. Only the unaffected pre-embryos will be transferred to the woman.

The lawfulness of the diagnosis is conditional upon the authorisation of the competent authority with a prior favourable report from the National Commission on Assisted Human Reproduction, which will evaluate the clinical, therapeutic and social characteristics of each case.

The social and ethical debate is no longer centred on the risk of eugenics that may derive from the practice of preimplantation genetic diagnosis, but on the ethical implications that this embryo selection may entail, since it may be thought that the child born as a result of these processes is instrumentalised, since its conception is caused by the use of its person in favour of another person.

This regulation aims to identify the specific conditions under which it is lawful to carry out preimplantation genetic diagnosis<sup>6</sup>.

#### III. Assisted Reproductive Techniques Framework for Preimplantation Genetic Diagnosis

Predictive genetic diagnosis, and preimplantation genetic diagnosis, has evolved, and its use is increasing in the context of assisted reproduction techniques. It has different purposes<sup>7</sup>:

<sup>&</sup>lt;sup>5</sup> LOZANO ARANA. M. (2016), Diagnóstico genético preimplantatorio. Implantación desarrollo y actualización de un programa de diagnóstico preimplantatorio en un Sistema Sanitario Público, Tesis Doctoral, Universidad de Sevilla, España, 213pp (p.178).

<sup>&</sup>lt;sup>6</sup> FOX, D. (2017)"Reproductive negligence", *Columbia Law Review*, , núm 17, pp. 149-241.

<sup>&</sup>lt;sup>7</sup> EMALDI CIRIÓN,A. (2020), "Derechos constitucionales y análisis jurídico en relación con el diagnóstico genético preimplantatorio en el contexto de la reproducción asistida", *Retos del Derecho ante un* 

#### a) Improve human fertility

The fundamental purpose of Assisted Reproductive Techniques, is to combat human sterility<sup>8</sup>. Woman alone is also allowed to be the beneficiary of assisted reproduction techniques in a public sanitary system, and she may be fertile or, on the contrary, infertile.

## b) To avoid the genetic or hereditary spread of illnesses to future generations

This specific purpose is related to preimplantation genetic diagnosis. Duringthe genetic counseling process, people at risk of transmitting congenital anomalies to their offspring are warned to do sex selection for therapeutic reasons, fetal gene therapy, selection of non-pathological gametes, etc. Carrying out one of these options, people can prevent their offspring from suffering from any type of congenital disease or anomaly.

#### c) Human gametes or fertilized ova used in research

It is necessary to research and experiment with the reproductive material to improve assisted reproductive techniques. The use of the techniques makes possible to produce surplus embryos obtained *in vitro*. Law contemplates and regulates research and experimentation with human gametes and fertilized ova, provided that a series of requirements and controls are met (arts. 14, 15, 16).

Once preimplantation genetic diagnosis has been framed in the context of Assisted Reproductive Techniques, we have to analyze the pre-embryo generated in vitro, prior to being transferred to the woman. The aim is to avoid genetic disorders.

The advantage of this diagnosis is that people who carry it out will accept the discarding of embryos with a pathology<sup>9</sup>.

#### IV. Recommendations for Carrying out a Preimplantation Genetic Diagnosis

The use of this practice is indicated for people who are in a clinical situation that recommends to discard those embryos that haven 't got viability or those that have some predisposition or anomaly.

On the other hand, to use of preimplantation genetic diagnosis, it is also necessary to comply with another requirements that Spanish Law 14/2007 on assisted human reproduction techniques forces to

health professionals: a) the purpose of the predictive genetic analysis; b) the place where it is to be carried out; c) the destination of the biological sample at the end of the analysis; d) access to the results of the analyses when they are not going to be subjected to dissociation or anonymization procedures; e) to ask about the possibility of unexpected discoveries and their possible significance for the subject and for biological family; f) to ask about the implications that the information obtained may have for relatives and the advisability of their transmitting this information to them; g) to offer them genetic counseling, once the results of the analysis have been obtained and evaluated; h) to inform the subject about their rights over their personal data -access, rectification, opposition, and cancellation-. All this information affects the entire biological family.

#### V. Scientific Procedure of Preimplantation Genetic Diagnosis

We shall analyse in detail the phases to proceed with this diagnosis<sup>10</sup>:

Firstly, the couple or the woman alone must consult a genetic counselor when there are possible reproductive problems. Professional will provide information about the preimplantation genetic analyses and the alternatives that the couple or a person-alonewill have depending on the results of these analyses<sup>11</sup>.

#### 1. In vitro embryo fertilization phase

The use of assisted human reproduction techniques will be used, specifically, in vitro fertilization, to obtain embryos to be subjected to preimplantation genetic diagnosis and to rule them out if any type of anomaly, illness, or predisposition is detected in them.

2. Biopsy phase

A cell will extract from the embryo. Cells of the embryo will then continue to divide.Cell stage (6-8) will be the stage chosen for the embryo biopsy prior to be transferred<sup>12</sup>.

#### 3. Genetic analysis phase

The cell obtained will be processed to carry out chromosomal and molecular diagnostics to detect genetic alterations or chromosomal anomalies causing a disease or malformation of the pre-embryo. Two techniques are currently available:

mundo global/ Ed. Tirant lo Blanch, ISBN 9788413558165, pp. 775-808 (p. 800).

<sup>&</sup>lt;sup>8</sup> Spanish Society of Gynaecology and Obstetrics (2018), "Estudios genéticos en la disfunción reproductiva. Diagnóstico genético preimplantatorio. Consejo preconcepcional", *Progresos de obstetricia y ginecología: revista oficial de la Sociedad Española de Ginecología y Obstetricia*, ISSN 0304-5013, Vol. 61, Nº. 4, pp. 403-409 (405)

<sup>&</sup>lt;sup>9</sup> SULLIAN-PIKE, C. / DOKRAS, A. (2018), "Preimplantation genetic screening and preimplantation genetic diagnosis", *Obstetric & Gynecology Clinics of North America*, 2018, núm. 45, pp. 113-125.

<sup>&</sup>lt;sup>10</sup> HODGE C./ SANTOS, M.J. (2017), "Diagnostico Genético Preimplantatorio de embriones humanos: Técnica, ética y teología", Teología y vida, ISSN 0049-3449, pp. 275-300, (285 y ss).

<sup>&</sup>lt;sup>11</sup> GENOFF GARZON / RUBIN / LOBEL / STELLING / PASTORE, (2018), "Review of patient decisión-making factors and attitudes regarding preimplantation genetic diagnosis", *Clinical Genetics*, pp. 1-21.

<sup>&</sup>lt;sup>12</sup> RODRÍGUEZ MARTÍNEZ, K. /REYES MARTÍNEZ, I. /FLORES SÁNCHEZ, RM. / MÉNDEZ VIDAL, J. (2017), "Factores clínicoterapéuticos y su relación con la calidad embrionaria en pacientes sometidas a fertilización *in vitro*", *Rev Cubana Endocrinología*, vol. 28, núm.1, Ciudad de la Habana., p. 15 y ss.

- a) Polymerase chain reaction (PCR), a procedure that allows the amplification of specific DNA sequences *in vitro*, is used to locate specific mutations causing monogenic diseases. Also allows specific detection of diseased embryos, with the advantage of not having to discard potentially diseased embryos simply because of their sex (e.g., in the case of sexlinked monogenic diseases).
- b) The Hybridisation procedure is used for chromosome analysis and involves the use of specific labeled DNA probes that hybridize to specific chromosomes or chromosome fragments. It is used for the diagnosis of X-linked diseases.

Subsequently, the embryo whose genetic analysis shows that it is not affected by an anomaly, disease or predisposition is transferred to the woman. Healthy embryos - or, in the case of X-linked diseases, the female embryos - are transferred to the mother, discarding the rest of the embryo.

Preimplantation genetic diagnosis arises two types of problems. On the one hand, whether the study of a single cell is representative of the totality of the embryo. Second, when the biological guarantees are met, the embryos will be transferred to the mother's uterus, and in a near future, possible anomalies can be detected doing a prenatal diagnostic tests.

#### VI. Different uses of Preimplantation Genetic Diagnosis: Legal and Ethical Aspects

The uses for these predictive diagnostics are expanding, enabling: a) high-risk couples to avoid passing on a disease or genetic predisposition to their offspring; b) embryo selection; c) reducing the number of therapeutic abortions; d) sex selection when there are therapeutic reasons; e) embryo selection for third parties; f) use of discarded embryos for experimental and research purposes; and g) therapeutic techniques on the living preimplantation embryo. Although bioethical approach implies that they are pushing eugenics, these uses are recognized by Spanish Law and they are socially aceptable.

Opponents of this diagnosis have brought up several legal and ethical considerations in support of their objections, which are based on the UNESCO Universal Declaration on Bioethics and Human Rights. Considerations are behind the variety of applications that could result in healthy offspring (2005)<sup>13</sup>.This Declaration proclaims that the impact of life sciences on future generations, and particularly on genetic, must be taken into account. They also consider that there must

be rules governing the decisions to use genetic technology: embryo selection or gene therapy.

Second, some authors question the efficacy of the biopsy techniques on embryos undergoing preimplantation genetic diagnosis.<sup>14</sup>.As a result, they believe that it should have first been approved as an experimental technique before being implemented following the precautionary principle<sup>15</sup>.

Third, lawsuits against professionals may be filed if their careless conduct caused harm that required recompense<sup>16</sup> Professional negligence<sup>17</sup> provides an incorrect diagnosis, which could result in the implantation of embryos carrying a particular anomaly or, conversely, in the rejection of healthy embryos that would otherwise be used for procreation.

Fourthly, it is a practice that is significantly questioned ethically for several reasons, including the following<sup>18</sup>: A) It is possible to think that the methods used are unethical because the blastocyst is endangered during cell extraction, or because it is thought that the extracted cell, being totipotent, should be treated as another embryo once chosen, which is sacrificed for the excellent progress of procreation; B) it is possible to think that using preimplantation genetic diagnosis to rule out the implantation of some embryos is unethical because it prevents the implantation of other embryos.C) This practice will be condemned as tending toward eugenics because embryos will be destroyed.

I'll now examine in detail how ethically and legally acceptable preimplantation genetic diagnosis<sup>19</sup>.

#### 1. Embryo selection for therapeutic purposes

One of the fundamental uses of this diagnosis is to choose healthy embryos for the woman to have an implant because no illnesses or predispositions are found<sup>20</sup>. It is possible to find in the embryo:

<sup>&</sup>lt;sup>13</sup> JIMÉNEZ GONZÁLEZ, J., (2016), "Marco legal Internacional y conflicto étcio del diagnóstico genético preimplantacional y las nuevas técnicas de donación mitocondrial, *lus et Scientia, Revista electrónica de derecho y ciencia*, vol, 2, núm. 2, p. 35.

<sup>&</sup>lt;sup>14</sup> BORINI, A., TAROZZI, N., LAGALLA C. (2016), "Preimplantation genetic diagnosis: Why are obstetric and neonatal risk increased? The need for more data" *Fertility and Sterility*, No. 106-6, pp. 1328-1329

<sup>&</sup>lt;sup>15</sup> KAISER, M. (2010), "El principio de precaución y su importancia para la ciencia", *Ética de la BioTecnología. Una introducción,* Granada, Editorial Comares, pp. 135.

<sup>&</sup>lt;sup>16</sup> DIAS PEREIRA, AG.(2014), "Responsabilidade Civil: o Médico entre o Público e o Privado", *Boletím da Faculdade de Direito*, vol 89, Coimbra, Universidade de Coimbra, 2014, pp. 253-304.

<sup>&</sup>lt;sup>17</sup> MACIA MORILLO, Andrea, Diagnóstico genético preimplantacional y responsabilidad médica por falsos negativos, Ed. Reus, Madrid, 2018, pp. 165 y ss.

<sup>&</sup>lt;sup>18</sup> DE MIGUEL BERIAIN, I. (2021),*Un estudio de impacto ético y social de las nuevas tecnología en la práctica de la biomedicina,* Tesis doctorial, Universidad del País Vasco - Euskal Herriko Unibertsitatea, España, pp.16 y.ss.

<sup>&</sup>lt;sup>19</sup> EMALDI CIRIÓN A. (2017), "Aproximación a un estudio jurídico y ético de la medicina genética predictiva", *Revista Iberoamericana de Bioética*, Número 3, Ed. Universidad Pontificia Comillas, 2017.

<sup>&</sup>lt;sup>20</sup> ENGUER GOSÁLBEZ, P./ RAMÓN FERNÁNDEZ, F. (2018), "Dilemas bioéticos y jurídicos de la reproducción asistida en la sociedad actual en España", *Revista Latinoamericana de Bioética*, ISSN-e 1657-4702, Vol. 18, N<sup>o</sup>. 34-1, pp. 104-135 (p.111).

#### A. Serious diseases

There are some illnesses that, due to their severity might affect a person's future development (Xlinked Alport's Syndrome, Spinal Muscular Atrophy, Huntington's disease, Cystic fibrosis, Haemophilia A, Duchenne muscular dystrophy, and Haemophilia) B. As a result, these diagnoses that identify certain diseases are widely accepted by society and are permitted by law in many nations: Spanish, Greek, Belgian, French, British, Danish, Norwegian, Finnish, and Swedish.

Preimplantation genetic diagnosis is prohibited in some nations since they believe it violates the right to the protection of the embryo and puts people at risk of developing eugenic inclinations. Germany, Austria, Switzerland, and Italy prohibit Preimplantation Genetic Test <sup>21</sup>.

# B. Diseases and Predispositions with Multifactorial and Variable Phenotypic Expression

Preimplantation genetic diagnosis can be used to identify multifactorial disorders or predispositions that manifest in a variety of phenotypical ways. This dispute stems from the fact that a predisposition to a disease does not guarantee that it will manifest in the future; rather, it depends on a variety of environmental and nutritional circumstances, and a person may never get the disease as a result.

Based on this premise, the United Kingdom was the first nation to permit the use of these diagnostics to find predispositions in fetuses to prevent them from being passed on to the mother. Human Embryology Fertilization and Authority (HFEA) authorized the use of preimplantation genetic diagnosis to identify predisposition to several diseases, including familial adenomatous polyposis coli (FAPC) or Cystic Fibrosis, Huntington's disease, Duchenne muscular dystrophy, Beta-thalassemia, and Cystic Fibrosis.

The Biomedical Research Act of 2007 and the Assisted Reproduction Act of 2006 govern this diagnosis and the authorization to perform these analyses when they are used for: a) the detection of serious hereditary diseases that are not amenable to postnatal curative treatment, to carry out embryo selection of unaffected pre-embryos for transfer; b) the detection of alterations that may compromise the viability of the embryo.

As a result, a number of ethical issues are raised in light of this utility. To start, we must be mindful that we are rejecting a pre-embryo that could result in a healthy person. Second, if the couple from whom the embryo with the disease decide the transfer we would be faced with a conflict of interest.

In this view, the question of who should take precedence—the parents who wishes to have children or the medical opinionthat recomend not to transfer the embryo. In these situations, the transfer of these abnormal embryos would be illogical because the couple is using assisted reproductive technology to have healthy children.

Legally, it is advised against transferring embryos with biological traits. It is a serious offense to "transfer gametes or pre-embryos to the woman without the required biological guarantees."

C. Embryo selection for therapeutic purposes for a third party

Cellular transplantation of stem cells can treat several genetic illnesses (FalconiAnemia, Aplastic Anemia, Immunodeficiencies) and diseases (Leukemia, Thalassemia).

The best outcomes in this area occur when the ill person and the donor are histocompatible because this enables the latter to be cured, either through the transplantation of stem cells taken from the umbilical cord or through a subsequent organ or tissue donations<sup>22</sup>.

A couple with a child suffering from Myeloblastic Leukemia would request a preimplantation genetic diagnosis to identify a severe hereditary disease in conjunction with the determination of histocompatibility antigens. He would donate stem cells from the umbilical cord after birth or, if necessary, through a bone marrow transplant.

However, to resolve this clinical case, it is necessary to recognize the significance of the preceding actions since, following a preimplantation genetic diagnosis, any one of the following three scenarios could occur: a) There were healthy embryos - not carriers - that were not immunologically compatible with the sick child; b) there were some embryos that were carriers of the same disease that the first sick child already had; c) the analysis revealed the existence of healthy embryos that were immunologically compatible with the sick child to be treated with stem cells.

In this situation, it is possible that healthy embryos but not immunologically compatible will be eliminated for reproduction.

The current Law in Spain permit this procedure as long as the relevant health authority approves it. Additionally, a prior favorable report from the National Commission for Assisted Human Reproduction is required, which must evaluate the clinical, therapeutic, and social characteristics. It is legal to reject healthy embryos for implantation, even when they are

<sup>&</sup>lt;sup>21</sup> EMALDI CIRIÓN, A. (2017), "La diagnosi genetica preimpianto tra normativa e giurisprudenza", (n. 6/2017 della Collana "Marcopolo. Percorsi di diritto pubblico interno e comparato lungo i confini disciplinari", diretta da S. Prisco) R. FATTIBENE (a cura di), Editoriale Scientifica, Napoli, pp. I-332.

 <sup>&</sup>lt;sup>22</sup> ARANGO RESTREPO, P., SÁNCHEZ ABAD, P. y PASTOR L. (2012),
"Diagnóstico genético preimplantacional y el "bebe medicamento",
*Cuadernos de Bioética*, 23, p. 301.

incompatible with the person to whom the therapy will be applied.

From an ethical point of view, this selection of embryos for therapeutic purposes for a third person would bring up the possible objectification of human beings and their instrumentalization<sup>23</sup> If people are treated with respect from the moment they are born, I believe that they would not be used as instruments. Another situation is when a babyis abandoned or given up for adoption after using the stem cells.

The creation histocompatible embryos with the sick sibling they are trying to cure may be the aspect that inspires the most ethical debate because it is to create twenty or more embryos before finding the best. The rest of surplus embryos will be cryopreserved and used for whatever the couple has decided: donation, research, reproduction, or destruction. We must, however, consider how many times the same couple could repeat this procedurel. This is the reason why this diagnosis raises ethical questions.

2. Positive eugenics: the selection of embryos with an illness or defect

Some couples comprised of individuals suffering from specific pathologies, illnesses, request the selection of embryos with the same condition. This case involved a deaf couple who wanted embryo selection so they might have a kid with the same disabilities they had. The case occurred in the United Kingdom. They felt that an unaffected child might suffer more in a family of affected children, whom they would see as different.

Spanish Law prohibit harming to others. Choosing embryos with defects or illnesses could make parents liable for the harm done. It is possible for a kid to sue his or her parents in civil court.

From an ethical point of view, we reject this practice because people is looking personal interests instead of looking for the baby interest.

3. Sex selection of pre-embryos

Preimplantation genetic diagnosispermit to carry out a sex selection:

a) Sex selection for medical purposes: sex-related illnesses

Preimplantation diagnostics permit to select the embryo preventing the birth of children with a condition associated with the sex chromosome.

From a legal standpoint, this practice is regulated by the Assisted Human Reproduction Techniques Act of 2006 (art. 26) and the Convention on Biomedicine (art. 14), which prohibits the use of medically assisted reproductive techniques to do a sex selection except if it is to avoid a serious hereditary sexrelated disease.

An analysis of this article reveals that we have two possible interpretations

- A. No technique that allows for sex selection, including assisted reproduction methods, should be used.
- B. The Convention states "that the sex of the person to be born cannot be chosen".
- C. The goal of sex selection is "to prevent a significant hereditary sex-linked disease,". So sex selection for therapeutic purposes would not be forbidden under the following two circumstances:
- 1) When sex choice is made to avoid the conception of a child who "may suffer" from a major sex-related hereditary condition.
- Sex selection will be permitted in cases where it is necessary to stop someone from being born "a carrier of a disease".

From an ethical standpoint, sex selection for therapeutic purposes may be acceptable due to this therapeutic goal.

#### Sex preference for non-pathological family factors

Preimplantation genetic diagnosiswill use to select sex for non-therapeutic purposes. In this case, sex selection have not any pathology circunstance. This option can cause gender discrimination, economic discrimination, and population imbalance from an ethical perspective.

#### 4. Pre-embryo in vitro therapy

A preimplantation genetic diagnosis may also be used to identify diseases or anomalies to treat the pre-embryo *in vitro*. If the treatment is posible will be necessary: a) Inform the parents about the processes, diagnostic tests, and hazards;b) confirm that the pathologies have a diagnosis and a cure; c) therapy does not alter non-pathological hereditary characteristics; d) therapy does not seek to select particular people or a particular race.

Although this is currently an exceptional case, it would be a case permitted by Law but would require the authorisation of the corresponding Health Authority, following a favourable report from the National Commission on Assisted Human Reproduction.

5. Research with in vitro embryos

To improve several assisted reproductive techniques will be necessary to research with in vitro pre-embryos. Pre-embryos that will be used in the study could originate from various sources, including:

A. Embryos that are not deemed fit for reproduction based on the findings of preimplantation genetic diagnosis. According to Spanish Law, dead embryos and human embryos that have lost the ability to develop biologically will be donated for scientific research.

<sup>&</sup>lt;sup>23</sup> GARCÍA MOYANO, L. / PELLICER GARCÍA, B. / BUIL TRICAS, B., JUÁREZ VELA, R., GUERRERO PORTILLO, S. /ANTÓN SOLANAS<sup>-</sup>I., (2016), "Bioethical analysis of the generation of saviour sibling", *Rev. Bioética y Derecho*, núm.36, Barcelona, pp. 55-66.

- B. Surplus embryos: These are often viable and come from couples that use *in vitro* fertilization. It is permissible to produce more embryos and cryoconservate them for future situations.
- C. Gametic embryos: The Biomedicine Convention forbids the development of these embryos for the only purpose of study.
- D. Embryos produced by cloning procedures, which entail transferring a somatic cell nucleus from an individual to a human egg cell, to use them for research. There are many authors who consider that this procedure does not involve embryos as the nucleus is not of gametic origin –sperm and egg.

Spain forbids the fertilization of human embryos for any reason other than human reproduction. It treats such a practice as a criminal offense because the Convention on Biomedicine forbids the creation of human embryos to research (art. 18.2). (Penal Code, art. 160.2).

#### VII. LIABILITY FOR FALSE DIAGNOSES

During the practice of preimplantation genetic diagnosis, due to medical negligence, an error occurs in the interpretation of the results.<sup>24</sup> Incorrect information given to the users of such a practice can be of two types:

1) False positives in the preimplantation genetic diagnosis

The information received is erroneous since the diagnosis establishes the existence of a disease in the pre-embryo analyzed that does not exist. Also, the diagnosis may deny the presence in the pre-embryo of specific hisocompatibility characteristics that it does possess.

This error means that the embryos, which are healthy or which do have the histocompatibility characteristics are not implanted, and this is the basis on which a civil liability claim for medical negligence exist.

#### 2) False negative preimplantation diagnosis

The information is erroneous because a preimplantation genetic diagnosis is not given. The diagnosis erroneously denies the existence of a disease. Another situation is that the diagnosis states the presence in the pre-embryo of certain histocompatibility characteristics that it does not possess.

In both cases, the decision on whether or not to implant the embryo is conditioned by the erroneous information that has been transmitted to the couple. The damage for which compensation is claimed is that a child is born suffering from a disease or anomaly. In the other situation, a child who has born does not have the intended histocompatibility characteristics necessary to cure another person.

#### VIII. Conclusions

- Concerning the transfer to the woman of embryos with anomalies when she requests it, this would be a contradiction. If the couple asks for assisted reproduction techniques, the objective is to have healthy children.
- 2) Preimplantation genetic diagnosis is a tool of preventive and predictive medicine. In some cases, it is used as a screening system between healthy and diseased embryos or between healthy embryos but selecting the one that does not have a predispose to a disease. This embryo selection promotes eugenics. We must reflect to what extent we can select pre-embryos with a predisposition. This selection should depend on the type of disease in question.
- It would be interesting to develop researchesto carry out embryo therapies. Ethical problems such as the destruction of pre-embryos would be solved.
- 4) Sex selection for therapeutic reasons may be justified on therapeutic grounds. If sex selection is a technique that can be carried out easily, in a near future sex selection can be allowed. From an ethical point of view is open to criticism and limits should be placed.

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<sup>&</sup>lt;sup>24</sup> BASTIDAS GOYES, L. / RUEDA BARRERA, A. (2020), "La aceptabilidad de las acciones de Wronfgul Birth en el marco de la Teoría Discursiva del Derecho de JÜrgen Habermas", Revista Estudios Socio -Jurídicos, Vol. 22, Núm. 1, pp. 145-174 (150 y ss).

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