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Legal Regulation of Preimplantation Genetic Diagnosis: A Comparative Analysis of the Baltic Sea Region and the Nordic Countries

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This paper examines the concept and regulation of some of the latest research in the field of fertility – preimplantation genetic diagnosis – in Lithuania, Poland, the Baltic States, and the Nordic countries. Preimplantation genetic diagnosis raises many legal and ethical questions regarding the protection of embryos, manipulation of the human genome, selection by sex, and the relation of this diagnosis to other similar studies. International legislation or guidelines define genetic testing, including pre-implantation genetic diagnosis, quite broadly, due to the scope of regulation and nuances, leaving the right to decide to the discretion of each state. National regulation of preimplantation genetic diagnosis should be specific, clearly defining cases in which preimplantation genetic diagnosis is applied.
Keywords: preimplantation genetic diagnosis, embryo, in vitro fertilization, assisted reproduction.

Preimplantacinės genetinės diagnostikos reguliavimas: Baltijos ir Šiaurės regiono valstybių lyginamoji analizė

Šiame straipsnyje nagrinėjama vieno iš naujausių mokslinių tyrimų vaisingumo srityje – preimplantacinės genetinės diagnostikos samprata ir reguliavimas Lietuvoje, Lenkijoje, Baltijos ir Šiaurės šalyse. Preimplantacinė genetinė diagnostika kelia daug teisinių ir etinių klausimų dėl embrionų apsaugos, manipuliavimo žmogaus genomu, selekcijos pagal lytį ir šios diagnostikos santykio su kitais panašiais tyrimais. Tarptautiniuose teisės aktuose arba rekomendacijose genetiniai tyrimai, įskaitant preimplantacinę genetinę diagnostiką, apibrėžiami gana plačiai ir daug sprendimo teisės dėl reguliavimo apimties ir niuansų paliekama kiekvienos valstybės diskrecijai. Preimplantacinės genetinės diagnostikos nacionalinis reguliavimas turėtų būti konkretus, jame turi būti aiškiai apibrėžti preimplantacinės genetinės diagnostikos taikymo atvejai.
Pagrindiniai žodžiai: preimplantacinė genetinė diagnostika, embrionas, fertilizacija *in vitro*, pagalbinis apvaisinimas.

Introduction

All parents-to-be dream of a healthy child. However, some people face a variety of genetically inherited diseases that they can pass on to their child; therefore, they either decide not to have children, run the risk of conceiving naturally, or rely on science and assisted reproduction procedures. One of the

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solutions proposed by science to protect an unborn child from serious genetically transmitted diseases is preimplantation genetic diagnosis (hereinafter the PGD).

PGD is integral to *in vitro* fertilization and has respect toward the embryo, its protection and manipulation of the human genome. Although it has been performed since 1990, preimplantation genetic diagnosis still raises many legal and ethical questions for the reasons mentioned.

In Europe, pre-implantation genetic diagnosis is prohibited only in Malta (Fertility Europe and European Parliamentary Forum ..., 2021). In Lithuania, PGD has been regulated very recently and has been implemented since 2018.

There are no publications in the Lithuanian legal science on the regulation of preimplantation genetic diagnostics. There are a number of scientific publications in English on this topic.[1] Lithuanian scientists have analyzed the legal regulation and nuances of assisted reproduction (E. Kavoliūnaitė-Ragauskienė, "Legislative Initiatives on Assisted Reproduction in Lithuania: Need for a Law and Polemic Issues"; Andrius Narbekovas, Justina Žukauskaitė, Agnė Širinskienė, "The Question of the Extent of Information on Health Risks when Giving Consent to *In Vitro* Fertilization Procedure"; Jonas Juškevičius, "The primacy of the Child's Interests in the Context of Artificial Insemination," and others).

The aim of this article is to analyze, from a legal perspective, what preimplantation genetic diagnosis in general is and what questions it raises, how PGD is regulated in the Baltic States (Lithuania, Latvia, Estonia), Poland and the Nordic countries, how it is regulated by international treaties and bodies, and in which cases the use of PGD is legally unjustified or excessive. To achieve this aim, the tasks of the paper are as follows:

- to define the concept of PGD, the legal and ethical question that it raises;
- to analyze what international legislation governs embryo genetic testing and whether this legislation is sufficient;
- to investigate the regulation of PGD in the Baltic States, the Nordic countries and Poland;
- to analyze the future prospects of PGD and whether it will become a widely used procedure for selective reproduction.

The main methods of the research are *inter alia* systematic analyses of the scientific literature and international legislation, guidelines of international organizations, and a comparison of the national legislation of Baltic countries, Nordic countries, and Poland (comparative method).

The concept of preimplantation genetic diagnostics. The scientific study of genetics makes it possible to analyze the genetic characteristics of an embryo and determine whether an unborn child has genes that cause serious illness or disability. Couples whose children have a genetic abnormality make sure that the disease is not passed on to unborn children and that the health of future generations is not put at risk. In this case, two scientific technologies are possible: prenatal diagnosis, which is performed when the pregnancy develops in a woman's organism, and preimplantation genetic diagnosis (PGD), which involves *in vitro* fertilization.

PGD is a test in which, if one or both genetic parents have a known genetic abnormality, *in vitro* fertilization is performed and the embryo is examined to determine if it also has a genetic abnormality.

[1] Vrijenhoek, T. *et al*. (2021). Clinical genetics in transition – a comparison of genetic services in Estonia, Finland and the Netherlands. *Journal of Community Genetics*, 12(2), 277–290, PubMed. https://doi.org/10.1007/s12687-021-00514-7; Robertson, J. A. (2003). Extending preimplantation genetic diagnosis: The ethical debate. Ethical issues in new uses of preimplantation genetic diagnosis. *Human Reproduction*, 18 (3, March), 465–471. https://doi.org/10.1093/humrep/deg100; Duguet, A-M. et al. (2017). Preimplantation Genetic Diagnosis: The Situation in France and in Other European Countries. *European Journal of Health Law.* 2017 Apr;24(2):160-74. doi: 10.1163/15718093-12420347 and others.

PGD was first clinically applied in the early 1990s and was primarily employed with couples who were at risk of transmitting a recessive inherited disorder in order to distinguish the sex of an embryo. Since then, the number of diagnosed diseases has increased significantly, as well as in the various groups of patients who employ PGD. The International Bioethics Committee identifies three categories of couples who apply for preimplantation diagnostics (Galjaard, 2002):

- couples at high risk of having a child affected by a genetically-caused disease or malformation, and who have an infertility problem;
- couples at high genetic risk who have undergone "conventional" prenatal diagnosis and who did terminate recurrent pregnancies after an affected foetus was found;
- couples at risk of giving birth to a child affected by a genetically-caused disease or malformation and who object to termination of pregnancy.

In addition, older couples referred for IVF because of infertility may request a PGD of chromosomal abnormalities (Galjaard, 2002).

About one quarter of the couples applying for PGD have one or more children affected by a genetically-caused disease or malformation, and an even larger percentage have experienced spontaneous abortions or terminations of pregnancy after "conventional" prenatal diagnosis. [...]The development of new technology during the past two decades has led to a shift in the perception of the purpose of medically assisted reproduction. IVF aims at having a child, PD aims at having a healthy child, and PGD [...] testing aims at having a healthy and helpful child. Undoubtedly, the research and technology related to genetics will further develop in the years to come and will also provide new opportunities for couples to select their offspring (Galjaard, 2002).

1. PGD Regulation in International Legislation

International legislation related to preimplantation diagnosis is The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, Council of Europe) and the declarations and guidelines published by international organizations (UNESCO, World Health Organization).

As the Committee on Bioethics stressed:

> The Convention [*on Human Rights and Biomedicine* – N.G.] represents the outcome of an in-depth discussion at the European level, on developments in the biomedical field, in particular in the field of genetics. This work was guided by the acknowledgement of the positive perspectives of genetic modification with the development of knowledge of the human genome; but also by the greater possibility to intervene on and control genetic characteristics of human beings, raising concern about possible misuse and abuses, in particular the intentional modification of human genome so as to produce individuals or groups endowed with particular characteristics and required qualities (Committee on Bioethics, 2015).

The Convention on Human Rights and Biomedicine sets out two principles concerning embryos (Articles 14 and 18). It forbids the use of techniques of medically assisted procreation for the purpose of choosing a future child's sex (except where serious hereditary sex-related disease is to be avoided) and the creation of human embryos for research purposes. It also stipulates that, where the law allows research on embryos, it shall ensure adequate protection for the embryo (Council of Europe, n.d.). Although the Convention on Human Rights and Biomedicine does not directly regulate preimplantation diagnosis, such research is covered by Article 12 (*Convention on the Protection of Human Rights and Dignity* ..., 1997): "Tests which are predictive of genetic diseases or which serve either to identify

the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling." However, national laws may allow prognostic testing for genetic diseases for reasons outside of healthcare. In view of the potential selection on a variety of grounds during preimplantation diagnosis and the risk of unequal treatment of unborn children on grounds of sex, Article 11 of the Convention precludes this: any discrimination on the grounds of genetic heritage is prohibited. Consequently, the PGD cannot be performed for non-medical or non-scientific purposes.

It can be deduced from these articles that the Convention on Human Rights and Biomedicine takes a rather liberal approach to preimplantation diagnostics. Article 36 states that countries which already have legislation allowing for a wider application of the PGD than the Convention may withdraw.[2] Also, an exception for PDG is determined (Article 18): "1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo. 2. The creation of human embryos for research purposes is prohibited."

The World Health Organization (WHO) in 2021 issued two reports to provide the first global recommendations to help establish human genome editing as a tool for public health, with an emphasis on safety, effectiveness, and ethics (World Health Organization, 2021). "Human genome editing has the potential to advance our ability to treat and cure disease, but the full impact will only be realized if we deploy it for the benefit of all people, instead of fueling more health inequity between and within countries," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General (World Health Organization, 2021). The published reports deliver recommendations on the governance and oversight of human genome editing in nine discrete areas, including human genome editing registries; international research and medical travel; illegal, unregistered, unethical, or unsafe research; intellectual property; and education, engagement, and empowerment. The recommendations focus on systems-level improvements needed to build capacity in all countries to ensure that human genome editing is used safely, effectively, and ethically. The reports also provide a new governance framework that identifies specific tools, institutions, and scenarios to illustrate practical challenges in implementing, regulating and overseeing research into the human genome (World Health Organization, 2021). These reports are tools of "soft law" and are not legally binding.

The Universal Declaration on the Human Genome and Human Rights was adopted unanimously and by acclamation at UNESCO's 29th General Conference on 11 November 1997. The following year, the United Nations General Assembly endorsed the Declaration (UNESCO, 2022). The Universal Declaration on the Human Genome and Human Rights sets forth the basic principles bearing on research in genetics and biology and the application of its results. In order to guarantee the application of these principles, the Declaration recommends that they be made known, disseminated and given shape as measures, especially in the form of legislation or regulations. The Declaration also specifies

[2] Article 36 – Reservations 1. Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article. 2. Any reservation made under this article shall contain a brief statement of the relevant law. 3. Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 35, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs. 4. Any Party which has made the reservation mentioned in this article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

the measures that Member States should take for its application. The implementation of the Declaration is all the more urgent, since scientific progress in genetics and biology is accelerating, both giving humankind hope and creating ethical dilemmas. The declaration is not legally binding, and every member of UNESCO has to adopt its principles in their national legal system.

In 2003, UNESCO's International Bioethics Committee issued the Report on human genome and human rights and in 2015 provided guidelines on the use of this procedure (International Bioethics Committee, 2003 and 2015). The mentioned report recommends preimplantation diagnostics to be restricted to medical indications; thus, selection by sex for non-medical reasons is considered unethical. The recommendation to limit PGD to medical indications means that any studies on normal physical and mental characteristics are excluded. Moreover, the view on embryo selection is also expressed in order to find the most suitable donor who could save a sick brother or sister. The use of PGD to select and implant embryos with a genetic disease or a condition similar to that of one of the parents is considered unethical. At the same time, the International Bioethics Committee recognizes that it is impossible to propose a shared opinion on the moral acceptability of preimplantation diagnosis, as there are several different ethical approaches (for philosophical, socio-cultural, and religious reasons) to the value of human prenatal life:

a) PGD is ethically unacceptable for any indication because it is believed that a human being, described by some as a person, begins to exist from the moment of conception; PGD is thought to require experimental embryo development for selection; PGD is thought to place an excessive burden on the woman;
b) PGD may be ethically acceptable in certain circumstances as it is believed that the overall status of a human being is acquired through gradual development in the womb; an embryo is thought to acquire a soul at some point of its life in the womb; the mother's welfare, health, and prevention of an unborn child's suffering are considered to justify the procedure.

In the Committee's view, as in the cases of embryonic stem cell research or an early termination of pregnancy due to prenatal diagnosis, it should be up to each society to decide on the acceptable stance with regard to preimplantation diagnosis and to regulate this area accordingly.

In 2003, UNESCO adopted the International Declaration on Human Genetic Data (UNESCO, 2004). "The aims of this Declaration are: to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data, and of the biological samples from which they are derived […] in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research; to set out the principles which should guide States in the formulation of their legislation and their policies on these issues; and to form the basis for guidelines of good practices in these areas for the institutions and individuals concerned" (International Declaration of Human Genetic data, 2003). The declaration is not legally binding and has to be incorporated in national laws, regulations and policies of UNESCO's member states.

In 2005, UNESCO adopted the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005). Article 2 of the Declaration states that

> The aims of this Declaration are: (a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics; (b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private; (c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law; (d) to recognize the importance of freedom of scientific research and the benefits derived

from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms; (e) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole; (f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries; (g) to safeguard and promote the interests of the present and future generations; (h) to underline the importance of biodiversity and its conservation as a common concern of humankind (Universal Declaration on Bioethics..., 2005).

As a non-binding instrument, the declaration must be incorporated by UNESCO's member states into their national laws, regulations, or policies in order to take effect.

2. Lithuania, the Baltic, and Nordic Countries

Preimplantation genetic diagnosis is a new test in Lithuania, regulated since 2017 by The Law on Assisted Reproduction and its by-laws. Article 3 (5) of the Law on Assisted Reproduction provides: "Assisted reproduction cannot be used to give a child, who was created by assisted reproduction, certain characteristics, including the desired sex, except when it is needed to prevent a serious illness, the criteria for which are set by the Minister of Health, or to treat it." Article 5 (1) of this Law defines: "Assisted reproduction is permitted only when infertility cannot be cured by any treatment or there is no real chance of success, as well as in cases where the aim is to prevent a severely disabling disease, the criteria for which are set by the Minister of Health, or to treat it" (Law of the Republic of Lithuania on Assisted Reproduction, 2016; Law of the Republic of Lithuania on the Social Integration of the Disabled, 1991).[3, 4]

The website of Vilnius University Hospital Santaros Klinikos (2018) states: "VU Santaros Klinikos is the first and only university-level healthcare institution in Lithuania providing compensated fertilization services in Lithuania. During this time, the Santaros Fertility Center underwent 216 *in vitro* fertilization (IVF) procedures and consulted 1,715 patients; "[…] The Medical Genetics Center of Santara Clinics was the first and the only one in Lithuania to apply a new test – preimplantation genetic diagnosis (PGD). It is a test of genetic diseases performed before implantation on embryos

[3] "Embryo PGD is carried out by a decision of a medical council involving a geneticist, an obstetrician-gynecologist and an embryologist to assess the risk of transmitting a severely disabling disease to one of the partner's germ cells as described in the Procedure, in the following cases:

1) if one or both partners have an inherited disease that causes a severe disability;
2) if one or both partners are carriers of a monogenic mutation;
3) if one or both partners are carriers of chromosome aberration;
4) if there is a risk of spontaneous monogenic mutation and / or chromosomal aberration in the embryo.

A disorder that meets at least one of the following criteria is considered to be a severely disabling disease:

1) it is a health disorder causing a severe permanent disability;
2) it is a life-threatening health disorder. " (Order of the Minister of Health of the Republic of Lithuania on 20 December 2016 ...).

[4] "There are three levels of disability:

(1) "severe disability" means a person's condition in which the person's age-related independence is not acquired at all due to illness, trauma, injury, congenital or acquired health disorders, adverse effects of environmental factors, significantly reduced access to education and is in need of constant care or assistance." (Law of the Republic of Lithuania on the Social Integration of the Disabled, 1991).

created by assisted reproduction. In that study, embryos are examined for genetic diseases inherited from their parents as a result of changes in a single gene, changes in the structure or number of chromosomes." The study can be performed on families where one or both partners are carriers of genetic changes leading to severe, life-threatening, or severely disabling diseases. "The test is performed on the third or fifth day after the in vitro fertilization (IVF) procedure by examining one or more cells of the embryo created by IVF" […] "Depending on the cause of the tested genetic disease, the PGD test is applied to each family on an individual basis, with examination for specific familial disease-causing mutations or chromosomal aberrations."

In Lithuania, the test of preimplantation genetic diagnostics is financed by the state (Order of the Minister of Health of the Republic of Lithuania of 2 January 2018).

In Latvia, which in 2014 was found to have violated Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (Case of A. K. v. Latvia, 2014) by failing to apply prenatal diagnosis in a specific case, preimplantation genetic diagnosis is now permitted and used (Fertility Europe and European Parliamentary Forum ..., 2021). In 2021, according to the European Parliamentary Forum for Sexual and Reproductive Rights, in general, the regulation of assisted reproduction in Latvia is viewed to be better than in Lithuania and Estonia (Fertility Europe and European Parliamentary Forum ..., 2021). In Latvia, assisted reproduction and preimplantation genetic diagnosis are regulated by the Sexual and Reproductive Health Law and by-laws. Section 13 (1) of the Sexual and Reproductive Health Law (2002) defines "medical insemination" as "the artificial fusion of male and female gametes." Assisted reproduction treatment is available only to heterosexual couples or women who have provided a written request to the treatment facility. *In vitro* fertilization is performed "using the germ cells of the donor or genetic parents." Section 15 of Chapter 4 (Sexual and Reproductive Health Law, 2002) states that the Law

> prohibits (1) the fusion of human and animal germ cells nuclei for the purpose of fertilization; 2) to introduce a human embryo into the system of any other species of primate or animal; 3) to obtain a human embryo for research purposes and to use it as a donor for tissues and organs; 4) to use donor's or embryonic gametes for commercial purposes; […] 6) to choose the sex of the child during medical fertilization, except in cases of genetic diseases related to sex; 7) to implant more than three fertilized ovaries in a woman's body at the same time.

Human cloning is prohibited. There is an extensive network of IVF clinics in Latvia, which also perform preimplantation genetic diagnosis. The state finances the artificial insemination procedure in Latvia if the person meets certain requirements: the procedure performed by the medical institution is specified by law; the person has not previously had more than one unsuccessful state-funded artificial insemination procedure; the expectant mother is not older than 37 years old. If these requirements are not met, the state does not fund artificial insemination procedures.

In Estonia, preimplantation genetic diagnosis is regulated by the Law on Assisted Reproduction and Embryo Protection (Salumets, 2019) and by-laws. *In vitro* fertilization and the necessary medicine is reimbursed by the state, but the woman must be under 41 years of age.

Under this law, assisted reproduction procedures require the written consent of both partners receiving this type of treatment. Embryos are allowed to develop for up to 14 days and can be stored frozen for up to 7 years.

In Estonia, the donation of semen, ova, and embryos is permitted and anonymous under this law. Preimplantation genetic diagnostics is allowed in Estonia. Given the country's population (less than 1.3 million), one sperm donor is allowed to produce not more than 6 children. It is not allowed to transfer

more than 3 embryos. The following procedures are prohibited: use of fresh donor semen (only cryopreserved after 6 months of donor control for sexually transmitted diseases); artificial insemination using the accumulated semen of a man after his death; human cloning (Artificial Insemination and Embryo Protection Act, 1997).[5] Article 130 of the Estonian Penal Code ("Prohibited acts on the embryo") fines or imprisons for three years for cloning a human being or creating a human hybrid. Article 131 of the Criminal Code defines that for the creation of a human embryo or fetus *in vitro* without the intention of transferring it to a woman's body or in an unauthorized institution, or without appropriate rights, or for the preservation of a human embryo or fetus unfrozen for longer than the statutory time limit, or for illegal operations on the embryo or fetus, a financial penalty is imposed (NGO Parallel Report on the Republic ..., 2018).

There are six fertility clinics in Estonia, three of which are private. In Estonia, as in Belgium, the Czech Republic, Denmark, Iceland, Slovenia, and Sweden, more than 4% infants are born after assisted reproduction (ART Fact Sheet, 2017). Data on the number of PGD is not available.

The legal regulation of assisted reproduction in Poland is rated poorly (27 percentage points) in the European Atlas of Fertility Treatment Policies and is in line with the Irish legal framework for assisted reproduction. Only Albania is rated worse than Poland (13 percentage points) (Fertility Europe and European Parliamentary Forum, 2021). Poland belongs to a group of more than 30 countries which in 2020 signed the Geneva Consensus Declaration, a commitment to "make the protection of the right to life a key priority." Although the document is not legally binding, the signing symbolized a growing response to the global trend to expand reproductive rights. Since 2020, an extremely strict abortion ban came into force in Poland, when the Polish Constitutional Court ruled against abortion even when there is a high risk of birth defects, which "endangers a woman's health and life." In 1993, The Family Planning Act (hereinafter "the 1993 Act") states: "Protection is provided for the right to life, including the prenatal phase, to the extent provided by law." There were discussions in Poland that the opportunity to choose an embryo without a severe genetic defect allows the avoidance of mental, physical, medical, and moral issues regarding the termination of a pregnancy after prenatal diagnosis. It is believed that PGD should not be permitted for reasons other than medical ones. Therefore, PGD to determine gender or other physical traits; testing for HLA with a view to creating a savior sibling or testing for the diagnosis of a disease that appears later in life (like Alzheimer's) should be precluded. More generally, discussions concerning granting access to the achievements of modern reproductive medicine and a high level of medical care, health safety, and effective medically-assisted procreation treatments have emerged (Analysis of the legal and human rights requirements..., 2019).

The regulation of PGD in the Nordic countries is very similar to the regulation of PGD in the Baltic States. The main regulatory elements for preimplantation genetic diagnosis are similar in the Nordic

[5] "**§ 35. Prohibited acts with embryo**

It is prohibited to perform the following acts in connection with artificial insemination of a woman: 1) artificial fertilisation of an ovum with a sperm which has been selected on the basis of the sex chromosome contained therein, **except in the cases where a gamete is selected in order to avoid transmission of a serious sex-related inheritable disease to the child** (bolded by N. G.);

2) creation, by way of substitution of the nucleus of a fertilised ovum by a somatic cell of another embryo, foetus or living or dead person, of an embryo with genetic information identical to that of the embryo, foetus or living or dead person; 3) fusion of embryos with different genetic information in order to create a cell fusion if at least one of the embryos is a human embryo, or fusion of a human embryo with a cell which contains genetic information different from that of the cells of the embryo and which may develop further together with the embryo;

4) creation of an embryo capable of developing by fertilisation of a human ovum with animal sperm or animal ovum with human sperm."

countries, but availability varies: only Denmark, Finland, and Sweden have national clinics offering PGD. In addition, Denmark and Finland have private clinics offering PGD (Vrijenhoek et al., 2021). PGD are allowed for monogenic disorders and structural chromosome aberrations in all countries but are not performed in Norway or Iceland; candidates from these countries are sent abroad. Both countries are currently preparing to start offering PGD on site. Preimplantation genetic diagnosis is most strictly regulated in Norway, where the national commission evaluates all couples requesting treatment (Hreinsson et al., 2020). The scope of treatment varies across the Nordic countries; Norway and Finland have the lowest rates of treatment. PGD for embryonic aneuploidy differs in the Nordic countries: Finland and Iceland allow this form of treatment, Denmark and Sweden only offer it as a research protocol, and Norway does not allow it at all. As a result, the number of treatment cycles involving embryonic aneuploidy in the Nordic countries is lower than in other countries, where this treatment is more common (Hreinsson et al., 2020). PGD is also allowed in privately funded clinics in all Nordic countries except Norway. There are no significant differences between the forms of PGD allowed in privately funded clinics. Gender selection is not available in any of the Nordic countries and is banned in Denmark, Sweden, Norway, and Finland. PGD-M[6] and PGD-SR[7] are publicly funded in all countries (Hreinsson et al., 2020).

3. Prospects of PGD Usage: Necessary Cases Only or a Road to Eugenics?

In legal science there are competing theories on what is the future of PGD usage. PGD for embryo testing for aneuploidy and genetic diseases is becoming increasingly popular. The available data shows that the PGD success rating is 97% (which means a very high reliability of the test). Due to its specificity, PGD is expected to outperform routine prenatal diagnosis in the future, where the fetus is tested in the mother's womb (no need to terminate the pregnancy due to a positive response to the disease). During prenatal diagnosis, a genetic test is performed using amniotic fluid, and the mother is consulted by a council of doctors in various fields to help parents decide whether to terminate the pregnancy or prepare to have a child who may be disabled or seriously ill.

The possibilities and scope of research are increasing with scientific progress: there is evidence that embryos are being tested for their susceptibility to cancer. PGD is used to diagnose Down syndrome (Zhang et al., 2007) and other diseases that can be diagnosed through routine prenatal diagnosis rather than PGD.

Some scientists express their fear that PGD will become "a road to eugenics." Bioethicists have investigated PGD extensively, mainly because of the speculation that this technology can allow parents to choose their child's traits and give birth to "designer babies." Fears that PGD will lead to a "eugenic drift," promoting a tendency to eliminate any traits perceived as flawed, including minor ones, and select the most desirable physical and intellectual traits, began in the 1980s and later on became more intense (Lowy, 2020). Numerous articles in bioethics journals have discussed the risk of use of PGD for "enhancing" the qualities of future children [...] . Even in countries where this approach is totally unregulated there are no signs of the use of PGD to promote the birth of "designer babies" (Lowy,

[6] A diagnostic tool for the detection of embryos with genetic defects (as an alternative to prenatal genetic diagnosis in families known to contain monogenic mutations) (PGD-M)

[7] A diagnostic tool for the detection of embryos with genetic defects (families at risk of chromosomal aberrations) (PGD-SR);

2020). Jeanne S. Freeman represents the worries people have about PGD, one of them being that "[t] here will be likely an increasing pressure […] on people to take advantage of these techniques and not bring even a mildly disabled child into the world." Freeman believes that the use of PGD will be difficult to control and that will be sought by parents for less and less severe medical conditions as time goes by (Petersen, 2005) . If that is the case, PGD may become a race to a completely healthy child and any parent, even those not knowingly carrying any genetic deceases, may apply for PGD. It also should be noted that many genetic deceases are still unknown to medicine and are undetectable – in cases like these, PGD will not be helpful.

The Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine expressed their negative view of PGD to The European Parliament, fearing that the excessive use of genetic testing, namely prenatal and preimplantation diagnosis, could lead to eugenics (Goodfellow, McPherson, Freeman, & Roses, 2001).

However, there is a different approach. John A. Robertson (2003) has noted: "Although PGD will be increasingly used, only a small percentage of people who will have children will use it, given that a very small proportion of all people who will have children will use assisted reproduction techniques." The author said, "[c]reating an embryo by IVF is expensive and very invasive, and for some people, it raises serious ethical questions. Thus, patients will only do so if they have sufficient grounds to do so, access to PGD infrastructure and health insurance to reimburse such costs" (Robertson, 2003).

The International Bioethics Committee, as well as John A. Robertson, have previously emphasized that only a very small proportion of tests in the future will be performed using preimplantation genetic diagnosis. Thus, this technology will in principle only be used to diagnose life-threatening diseases.

Article 10 of the Universal Declaration on Human Genome and Human Rights states: "no research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of *groups of people*." In 2015, UNESCO's International Bioethics Committee, in the Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights, stated that: "Individuals, families, groups or populations should not be discriminated against or stigmatized on the basis of their genetic characteristics. […] To avoid discrimination and stigmatization, education with adequate norms and information about the objectives of research could be the most prudent avenue to reassure the public and correct their misconceptions about genetic research and techniques" (UNESCO, 2015). Possible overuse of PGD raises a question of tolerance of people with disabilities. When analyzing this issue, it is necessary to establish whether society sees people with disabilities as a burden or sees a whole person with their stronger or weaker traits. According to the principle of non-discrimination, every person needs to be tolerated and equally included into the society, despite any disability. The state shall establish in its legislation that this PGD will only be used to diagnose severe and life-threatening diseases. Issues like sex selection (for non-medical reasons) or overuse of PGD only to assure that the future child is completely healthy (which is also unrealistic during the life span of an average person) shall be attended beforehand in law. Society must be educated not to stigmatize those who suffer from genetic disorders and not to prevent them from participating in society in every sense as its equal members (Shapiro and International Bioethics Committee, 1994). Another dilemma is the subject which decides a disability to be severe. Is this decision made by the state, doctors, or future parents? This paper found that there is a definition of severe disability in Lithuania, and such or similar definition should be used in other countries. The existence of this definition, as defined by the state, makes it easier to distinguish mild or non-life threatening deceases from the severe ones and to reduce number of cases of possible overuse of PGD.

Conclusions

1. Parents with a genetic disease will seek to protect their future offspring from the same fate. Preimplantation genetic diagnosis paves the way for a future child to be protected from life threatening diseases or diseases which cause severe disability. PGD is a test in which, if one or both genetic parents have a known genetic abnormality, *in vitro* fertilization is performed and the embryo is examined to determine if it also has a genetic abnormality. PGD is a very reliable but still a controversial technology due to the question of law and ethics it raises.
2. International legislation, particularly the Convention on Human Rights and Biomedicine, does not not directly regulate preimplantation genetic testing. The Convention on Human Rights and Biomedicine takes a rather liberal approach to preimplantation diagnosis, in particular by leaving much space for the competence of countries which have ratified this Convention. The declarations of UNESCO and recommendations of the World Health Organization are not legally binding rules or protocols, but may be incorporated into laws or regulations of member states.
3. Legislation regarding PGD varies in Baltic states, Nordic countries, and Poland. All countries now have legislation on PGD; Lithuania has adopted this legislation together with the law on assisted reproduction in 2017. The main regulatory elements for preimplantation genetic diagnostics are similar in the Nordic countries and Baltic states, but availability varies. The legal framework in Lithuania should be expanded, as the regulation of preimplantation genetic diagnostics is still quite abstract.
4. Presumably only a small proportion of tests in the future will be performed using preimplantation genetic diagnosis. Thus, this technology will in principle only be used to diagnose severe and life-threatening diseases for a conditionally small number of people. However, the state has to adopt legislation which establishes the scope of PGD in order for it not to become a tool for eugenics. Comprehensive regulation, widespread information, and an appropriate monitoring mechanism for genetic testing would answer legal and ethical dilemmas in the field of preimplantation genetic diagnosis.

Bibliography

Regulatory Legislation

International Treaties and legislation

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine). (4 April, 1997, entered into force on 1 February 2003). Oviedo [interactive]. Online access: http://www3.lrs.lt/pls/inter2/dokpaieska.showdoc_l?p_id=188028&p_query=&p_tr2= [viewed on 22 March, 2022].

Universal declaration on the human genome and human rights. (11 November 1997). Online access: http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html [viewed on 7 October, 2022].

International declaration on human genetic data. (16 October 2003). Online access: http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

Universal Declaration on Bioetchics and Human Rights. (19 October 2005). Online access: http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

*Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights (*2 October 2015). Online access: https://unesdoc.unesco.org/ark:/48223/pf0000233258

Foreign Legislation

Artificial Insemination and Embryo Protection Act. (1997). RT I 1997, 51, 824.

Penal Code (2001). RT I 2001, 61, 364.

Sexual and Reproductive Health Law (2002). *Latvijas Vēstnesis*, 27.

Lithuanian Legislation

Law of the Republic of Lithuania on the Social Integration of the Disabled (1991). *Lietuvos aidas*,|December 13, 249-0.

Law of the Republic of Lithuania on Assisted Reproduction (2016). TAR, 2016-23713.

Minister of Health of the Republic of Lithuania 2016 December 20 order No. V-1452 "On the Approval of the Description of the Procedure for the Provision of Assisted Reproduction Services and Their Funding from the Budget of the Compulsory Health Insurance Fund". TAR, 2016-29271.

Minister of Health of the Republic of Lithuania 2018 January 2 Order on the amendment of the Minister of Health of the Republic of Lithuania 2000 January 28 order No. 49 "On the approval of the lists of reimbursable medicinal products". TAR, 98.

Special Literature

Bayefsky, M. J. (2016). Comparative preimplantation genetic diagnosis policy in Europe and the USA and its implications for reproductive tourism. *Reproductive Biomedicine & Society Online*, *3*, 41–47, https://doi.org/10.1016/j.rbms.2017.01.001

Galjaard, H. (2002, November). Report on the IBC on Pre-Implantation Genetic Diagnosis and Germ-Line Intervention. In: International Bioethics Committee of UNESCO (IBC). (2002, November). 9th session. *Proceedings* (Vol. 1) [interactive]. Access online: http://unesdoc.unesco.org/images/0015/001502/150265eo.pdf [viewed on 25 March 2022].

Hreinsson, J. *et al*. (2020). Preimplantation genetic testing legislation and accessibility in the Nordic countries. *Acta Obstetricia et Gynecologica Scandinavica*, 99(6, June), 716–721. doi: 10.1111/aogs.13831. Epub 2020 Mar 10. PMID: 32103489.

Kemper, J. M., Gyngell, Ch. and Savulescu, J. (2019). Subsidizing PGD: The moral case for funding genetic selection. *Journal of Bioethical Inquiry*, 16(3), 405–414, https://doi.org/10.1007/s11673-019-09932-2

Lowy, I. (2020). ART with PGD: risky hereditary and stratified reproduction. *Reproductive medicine and society online*, 11, 48–55. https://www.sciencedirect.com/science/article/pii/S240566182030023X

Nelson, E. L. (2006). Comparative perspectives: Regulating preimplantation genetic diagnosis in Canada and the United Kingdom. *Fertility and Sterility*, 85(6), 1646–1652, https://doi.org/10.1016/j.fertnstert.2005.11.068

Petersen T S. (2005). Just diagnosis? Preimplantation genetic diagnosis and injustices to disabled people. *J Med Etchics,* 31, 231–234, https://jme.bmj.com/content/31/4/231

Robertson, J. A. (2003). Extending preimplantation genetic diagnosis: The ethical debate. Ethical issues in new uses of preimplantation genetic diagnosis. *Human Reproduction*, 18(3, March), 465–471, https://doi.org/10.1093/humrep/deg100

Vrijenhoek, T. *et al*. (2021). Clinical genetics in transition – a comparison of genetic services in Estonia, Finland and the Netherlands. *Journal of Community Genetics*, 12(2), 277–290, PubMed. https://doi.org/10.1007/s12687-021-00514-7

World Medical Association. (2015). *Medical ethics manual* (3rd ed.) [interactive]. Access online: https://www.wma.net/what-we-do/education/medical-ethics-manual/

Zhang, Y. *et al*. (2007). Preimplantation genetic diagnosis for Down syndrome pregnancy. *Journal of Zhejiang University – Science B. Biomedicine & Biotechnology*, 8(7), 515–521, https://doi.org/10.1631/jzus.2007.B0515

Case Law of International Courts

Case of A. K. v. Latvia [ECHR], No. 33011/08 [24.6.2014]. ECLI:CE:ECHR:2014:0624JUD003301108.

Other Sources

Analysis of the legal and human rights requirements for genomics in and outside the EU (2019) [interactive]. Access online: https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c2e1586f&appId=PPGMS [viewed on 4 October 2022].

Appold, K. (2014). Preimplantation genetic diagnosis. How should labs grapple with ethics? *Clinical Laboratory News* [interactive]. Access online: https://www.aacc.org/cln/articles/2014/january/preimplantation [viewed on 31 January 2022].

ART Fact Sheet. (2017, January). European Society of Human Reproduction and Embryology [interactive]. Access online: https://www.eshre.eu/-/media/sitecore-files/Press-room/ESHRE_ARTFactSheet_2022.pdf?la=en&hash=223AAF16CEC0EC6510EB371B52BE10384892AF49 [viewed on 6 April 2022].

Dirbtinio apvaisinimo reglamentavimas kai kuriose ES šalyse. (21 November 2007). Information and communication department of office of Seimas.

The European Society of Human Genetics [interactive]. Access online: https://www.eshg.org/index.php?id=home [viewed on 4 March 2022].

European Society of Human Reproduction and Embrylology [interactive]. Access online: https://www.eshre.eu/ [viewed on 31 January 2022].

European Society of Human Reproduction and Embryology. (s. a.). *Routine psychosocial care in infertility and medically assisted reproduction – A guide for fertility staff* [interactive]. Access online: https://www.eshre.eu/Guidelines-and-Legal/Guidelines/Psychosocial-care-guideline.aspx [viewed on 4 April 2022].

Fertility Europe and European Parliamentary Forum for Sexual and Reproductive Rights (2021, December). *European Atlas of Fertility Treatment Policies.* ESHRE [interactive]. Access online: https://fertilityeurope.eu/european-atlas-of-fertility-treatment-policies/ [viewed on 4 April 2022].

Goodfellow, P.; McPherson, E.; Freeman, A. and Roses, A. (2001, April 26). *The Science of Genetics and Modern Medicine*. A background paper submitted by GlaxoSmithKline to the European Parliament, Temporary Committee on Human Genetics [interactive]. Access online: http://www.europarl.europa.eu/meetdocs/committees/gene/20010426/436218EN.pdf [viewed on 15 April 2022].

International Bioethics Committee. (2019). Report of the IBC on Assisted Reproductive Technologies (ART) and Parenthood [interactive]. Access online: https://unesdoc.unesco.org/ark:/48223/pf0000367957 [viewed on 20 March].

International Bioethics Committee (IBC). (a. s.). [interactive]. Access online: http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/ [viewed on 15 April 2022].

International Bioethics Committee. (2015). *Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights* [interactive]. Access online: https://unesdoc.unesco.org/ark:/48223/pf0000233258 [viewed on 31 January 2021].

International Declaration on Human Genetics Data. (2003, October 16) [interactive]. Access online: http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html [viewed on 15 April 2022].

NGO Parallel Report on the Republic of Estonia's Third Report on the Implementation of the International Covenant on Economic, Social and Cultural Rights. (2018) [interactive]. Access online: https://tbinternet.ohchr.org/Treaties/CESCR/Shared%20Documents/EST/INT_CESCR_ICO_EST_30826_E.pdf [viewed on 6 April 2022].

Preimplantation diagnosis (PGD). (a. s.). Invicta [interactive]. Access online: https://www.invicta.pl/en/724/idp,9/preimplantation_diagnosis_pgd.html [viewed on 22 April 2022].

Salumets, A. (2019). IVF and reproductive reasearch in Estonia. *Improving Success in ART* [interactive]. Access online: https://www.excemed.org/sites/default/files/l0_salumets_state_of_the_art_in_baltic_countries_1.pdf [viewed on 19 April 2022].

Shapiro, D. and International Bioethics Committee. (1994). *Report on Genetic Screening and Testing* [interactive]. Access online: https://unesdoc.unesco.org/ark:/48223/pf0000132346 [viewed on 12 December 2021].

Vilniaus universiteto ligoninė Santaros klinikos. (2018, sausio 25). *Vaikų norinčioms susilaukti poroms – naujas tyrimas: preimplantacinė genetinė diagnostika* [interactive]. Access online: https://www.santa.lt/naujienos/vaiku-norincioms-susilaukti-poroms-naujas-tyrimas-preimplantacine-genetine-diagnostika/ [viewed on 20 April 2022].

Legal Regulation of Preimplantation Genetic Diagnosis: A Comparative Analysis of the Baltic Sea Region and the Nordic Countries

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S u m m a r y

Preimplantation genetic diagnosis (PGD) is a test in which, if one or both genetic parents have a known genetic abnormality, *in vitro* fertilization is performed and the embryo is examined to determine if it also has a genetic abnormality. The aim of this article is to analyze, from a legal perspective, what preimplantation genetic diagnosis is in general and what questions it raises, how PGD is regulated in the Baltic States (Lithuania, Latvia, Estonia), Poland, and the Nordic countries, how it is regulated by international treaties and bodies, and in which cases the use of PGD is legally unjustified or excessive.

International legislation related to preimplantation diagnosis is The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, Council of Europe) and the declarations and guidelines published by international organizations (UNESCO, World Health Organization). The Convention on Human Rights and Biomedicine does not directly regulate preimplantation genetic testing. The declarations of UNESCO and recommendations of World Health Organization are not legally binding rules or protocols, but may be incorporated into laws or regulations of member states.

Legislation regarding PGD varies in Baltic states, Nordic countries, and Poland. All countries now have legislation on PGD; Lithuania has adopted this legislation together with the Law on assisted reproduction in 2017. The main regulatory elements for preimplantation genetic diagnostics are similar in the Nordic countries and Baltic states, but availability varies. The legal framework in Lithuania should be expanded, as the regulation of preimplantation genetic diagnostics is still quite abstract.

Presumably only a small proportion of tests in the future will be performed using preimplantation genetic diagnosis. Thus, this technology will in principle only be used to diagnose severe and life-threatening diseases for a conditonally small number of people. However, the state has to adopt legislation which establishes the scope of PGD in order for it not to become a tool for eugenics. Comprehensive regulation, widespread information, and an appropriate monitoring mechanism for genetic testing would answer legal and ethical dilemmas in the field of preimplantation genetic diagnosis.

Preimplantacinės genetinės diagnostikos reguliavimas: Baltijos ir Šiaurės regiono valstybių lyginamoji analizė

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S a n t r a u k a

Preimplantacinė genetinė diagnostika (PGD) – tai tyrimas, kurio metu, jei vienas ar abu genetiniai tėvai turi žinomų genetinių anomalijų, atliekamas apvaisinimas mėgintuvėlyje ir tiriamas embrionas, siekiant nustatyti, ar jis taip pat neturi genetinės anomalijos. Šio straipsnio tikslas – teisiniu požiūriu išanalizuoti, kas apskritai yra preimplantacinė genetinė diagnostika ir kokius klausimus ji kelia, kaip PGD reguliuojama Baltijos šalyse (Lietuvoje, Latvijoje, Estijoje), Lenkijoje ir Šiaurės šalyse, kaip tai reglamentuoja tarptautinės sutartys ir organizacijos ir kokiais atvejais PGD naudojimas yra teisiškai nepagrįstas arba perteklinis.

Tarptautiniai teisės aktai, susiję su preimplantacine diagnostika, yra Europos Tarybos Žmogaus teisių ir biomedicinos konvencija ir UNESCO, Pasaulio sveikatos organizacijos tarptautinės deklaracijos ir gairės. Žmogaus teisių ir biomedicinos konvencija tiesiogiai nereglamentuoja preimplantacinės genetinės diagnostikos. UNESCO deklaracijos ir Pasaulio sveikatos organizacijos rekomendacijos nėra teisiškai privalomos taisyklės ar protokolai, tačiau gali būti įtrauktos į valstybių narių įstatymus ar kitus teisės aktus.

PGD reglamentuojantys teisės aktai Baltijos šalyse, Šiaurės šalyse ir Lenkijoje skiriasi nedaug. Šiuo metu visose šalyse galioja teisės aktai dėl PGD, Lietuva 2017 m. priimtame Pagalbinio apvaisinimo įstatyme apibrėžė preimplantacinės genetinės diagnostikos taikymo galimybes. Pagrindiniai preimplantacinės genetinės diagnostikos reguliavimo elementai Šiaurės šalyse ir Baltijos šalyse yra panašūs, tačiau prieinamumas skiriasi. Lietuvoje reikėtų išsamesnio teisinio reguliavimo, nes preimplantacinės genetinės diagnostikos reglamentavimas dar gana abstraktus.

Tikėtina, kad tik nedidelė dalis tyrimų ateityje bus atliekama naudojant preimplantacinę genetinę diagnostiką. Taigi ši technologija iš esmės bus naudojama diagnozuojant sunkias ir gyvybei pavojingas ligas sąlygiškai nedideliam žmonių skaičiui. Tačiau valstybė turi priimti teisės aktus, nustatančius PGD apimtį, kad preimplantacinė genetinė diagnostika netaptų eugenikos įrankiu. Išsamus reglamentavimas, plačiai paplitusi informacija ir tinkamas genetinių tyrimų stebėjimo mechanizmas atsakytų į teisines ir etines dilemas preimplantacinės genetinės diagnostikos srityje.

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