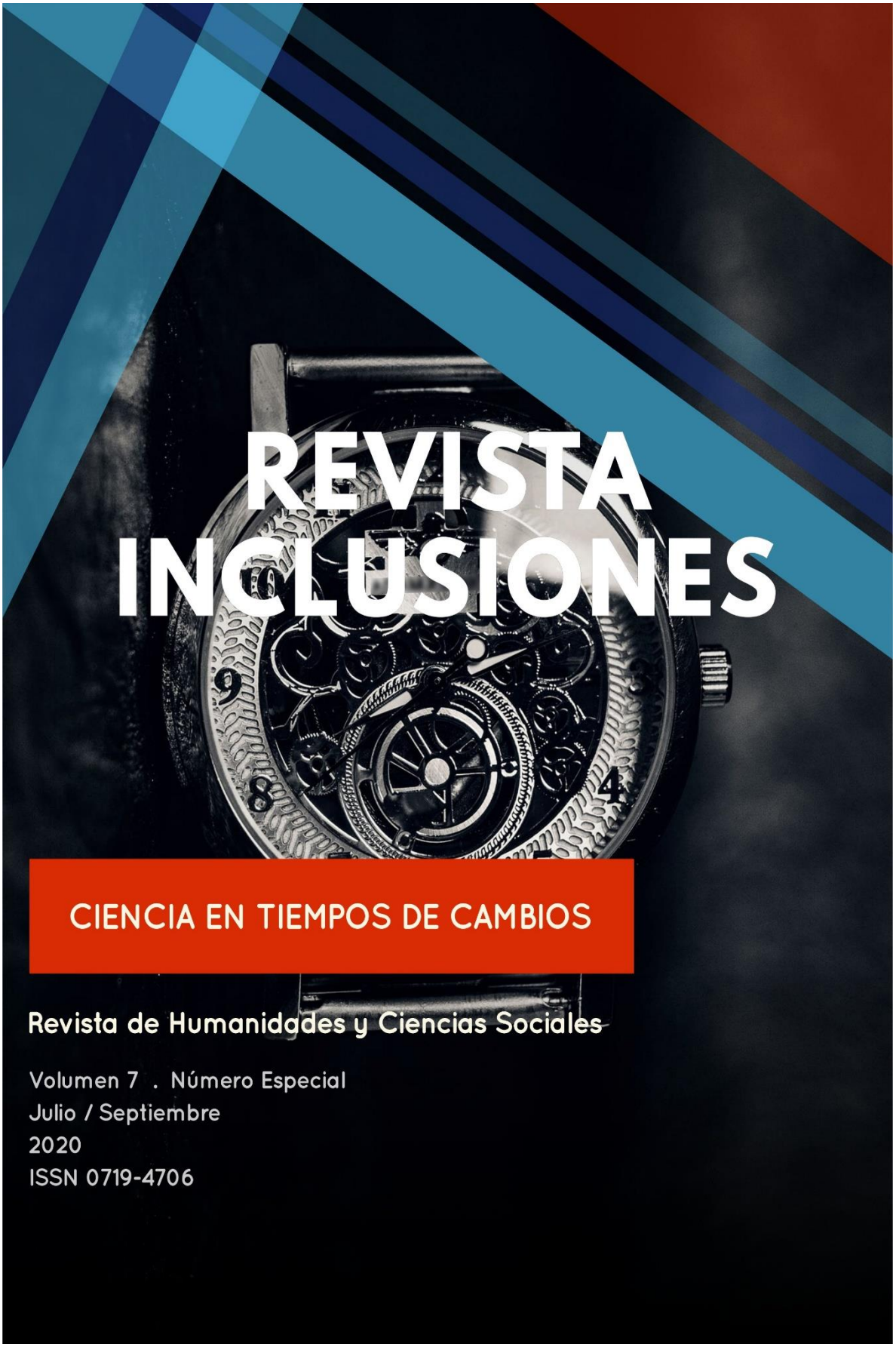

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LEGAL REGULATION OF PRE-IMPLANTATION GENETIC DIAGNOSTICS: THE INTERNATIONAL EXPERIENCE AND ITS APPLICATION IN THE RUSSIAN FEDERATION IN THE DEVELOPMENT OF THE CONCEPT

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Abstract

The relevance of the study of the general principles and patterns of legal regulation of pre-implantation genetic diagnostics in foreign countries is determined by the need to develop a concept of legal regulation of this type of diagnostics in Russia. The *purpose* of this study is to develop the general principles of the concept of legal regulation for pre-implantation genetic diagnostics in Russia. The authors have examined legislative acts, the practice of their application, and the doctrinal sources used in the UK, USA, France, Israel, China, Japan, as well as local regulatory acts of medical organizations. Among the methods used for this study, one can mention general philosophical methods, general and specific scientific methods, special methods (the structural legal method, the comparative legal method, the formal legal method).

Keywords

Patterns – Concept – Ethical and legal problems – Professional community

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Introduction

Ethical problems and the permissible limits of the application of the pre-implantation genetic diagnosis (PGD) procedure as one of the methods for testing embryos obtained through in vitro fertilization (IVF) have remained the subject of ongoing debate in the medical and legal community for a long time. On the one hand, PGD helps to increase the effectiveness of IVF and to avoid abortion, which indicates the need to remove any moral restrictions and legal prohibitions concerning this study, as well as the need to expand the scope of PGD compared to the more usual prenatal diagnosis (to determine the predisposition to cancer, HLA typing, etc.)[1]. On the other hand, there is a fear of the overly subjective perception of the results of PGD and the arbitrary use of the information received to make important decisions in the reproductive sphere, as a result of which arguments are increasingly being heard in favor of the ban on its use for so-called "non-medical purposes" (for choosing the baby's gender due to religious or cultural motives, attempts to conceive children with "pre-defined characteristics", etc.).

Ethical and legal conflicts lead to the fact that all modern legal systems faced with the problem of legal assessment of PGD in any form, adhere to one of the following options: 1) to prohibit this procedure completely; 2) to allow it, accompanied by very strict normative legal regulation with the presence of a large number of administrative permitting procedures and prohibitions; 3) to authorize PGD, providing only minimum prohibitions and restrictions aimed at ensuring the basic rights and freedoms of the individual. Russian legislators, on the contrary, do not pay any significant attention to the ethical and legal problems of the use of PGD. Moreover, the special regulatory legal regulation of professional activity in this area is limited to clinical recommendations on the use of assisted reproductive technologies (ART), the contents of which are limited to the instrumental and laboratory aspects of the analysis. PGD in Russia is not a mandatory component of IVF and is not provided at the expense of mandatory medical insurance (MHI). For this reason, and also due to the lack of clear legal prohibitions, specialists in the field of ART are relatively free to give recommendations on conducting PGD, choosing a research method, and using the diagnostic results[2].

The cost of PGD is influenced by such factors as the number of IVF cycles required in each particular case, the cost of one cycle and the possibility of full or partial payment of the relevant procedures at the expense of MHI; the number of embryos undergoing research and the cost of researching one embryo; the cost of the chosen research method (in Russia the most commonly used methods include FISH, CGH, PCR, NGS); the need for auxiliary genetic tests for parents, their genetic counseling, as well as the cost of these additional services. The difference in the purposes of PGD should be considered. However, when prescribing PGD for reasons not related to factors of female or male infertility (thus, for the initial purpose of identifying the risk of developing genetic diseases), the total cost of the procedure for the patient is very impressive. The cost of conducting IVF cycles in such cases makes up about 75% of the total cost, while the cost of the study itself amounts to about 20%, and additional services and research make up about 5%; for comparison. In case of inclusion of the PGD cost in the cost of the MHI, the additional costs of the public health

[1] C. Sullivan-Pyke y A. Dokras, “Preimplantation Genetic Screening and Preimplantation Genetic Diagnosis”, Obstetrics and Gynecology Clinics of North America Vol: 45 num 1 (2018).

[2] G. B. Romanovsky,” Constitutional personality of citizens in the context of genomic medicine”, Bulletin of Perm University. Jurisprudence num 3 (2017): 260-271.

system amount to about 15-20% per cycle, while foreign studies confirm that the use of PGD to assess the risks of aneuploidy generally reduces the cost of treating one couple by 1.5-2 times by reducing the number of cycles required for fertilization[3]. In this kind of situation, the implementation of PGD is determined not by medical or social indications, but by the patient's readiness to bear the appropriate costs, which cannot be recognized as acceptable.

The purpose of this study is to develop the starting principles of the concept of legal regulation of PDG in Russia as a tool necessary to prevent and resolve ethical and legal conflicts among the professional community and consumers of medical services in the field of ART. Ancillary tasks, in this case, were the identification and consistent study of the general principles and laws of the legal regulation of PGD in foreign countries, since these can be the basis for the development of the desired concept in Russia.

Methods

In this article, based on the application of systemic structural methods, formal legal methods, and comparative legal methods, we performed a comprehensive study of normative legal acts, the practice of their application, and the doctrinal sources used in some foreign countries. We chose the countries mentioned in the study on the following grounds: 1) their experience in using PGD, dynamic normative-legal regulation of this procedure, accompanied by changes in legal doctrine and judicial practice; 2) the legal certainty of the regulations governing the PGD and their justification from an ethical perspective; 3) the ability to trace the trends and patterns of legal regulation of PGD, considering the introduction of ethical and legal restrictions on the procedure at different periods. In total, during the preparation of the article, we studied 11 basic laws in the field of bioethics and genetic research, 27 regulatory legal acts of a by-law level, 11 professional guidelines that disclose indications for the use of PGD, the authorization procedure and general conditions for diagnosing, ethical requirements and the procedure for resolving ethical conflicts in their relationships with patients in the UK, USA, France, Israel, China, and Japan. In addition to the regulatory legal acts, we examined the practice of their application and doctrinal sources, as well as local regulatory legal acts of medical organizations implementing PGD in individual countries, and received comments from specialists on the application of those procedures (in particular, we reviewed about 15 local regulatory acts of medical centers conducting PGD in Israel, the USA, and China). The methodological basis of the study included general philosophical methods (materialistic and dialectical), general scientific methods (logical, systemic structural, axiological), special scientific methods (statistical, hermeneutical, modeling, strategic assessment method), and special methods (structural legal method, comparative legal method, formal legal method). Special focus is made on the application of the comparative legal method. This method was used both in the normative comparison of similar legal norms governing disputed relations in foreign countries and the functional comparison of the desired area of legal regulation, characterized by an ambiguous ethic and legal assessment of the PGD, with the definition of the range of issues requiring their resolution based on existing law enforcement practice, legal doctrine, and opinions of the professional community.

[3] R. J. Paulson, "Mathematics should clarify, not obfuscate: an inaccurate and misleading calculation of the cost-effectiveness of preimplantation genetic testing for aneuploidy", Fertil Steril Vol: 111 num 6 (2019).

Results

A study of the experience of legal regulation of PGD in foreign countries revealed the following general principles and patterns.

First, in states that have the necessary human resources and legal, material, and technical basis for the widespread dissemination of ART, there is a tendency towards a gradual transition to the resolution of PGD procedures for non-medical reasons, provided that the corresponding costs are not a financial burden for the public health system. Medical cases of PGD, on the contrary, are most often provided at the expense of the MHI or the state budget, regardless of whether IVF is prescribed for the treatment of infertility or solely due to the need for genetic research.

The most striking examples of the dynamic development of legislation and legal doctrine in the direction of liberalizing the basis for the implementation of PGD are Israel and China, where an individual approach to the needs and interests of a particular family as a whole prevails over ethical objections to the unacceptability of "eugenic" selection and the need to prohibit interference with the "act of creation"[4].

In Israel, for example, reproductive genetic testing is financed through a national project for expectant parents who carry genetically determined diseases with a frequency of at least 1:60 or an incidence of at least 1 in 15,000 live births[5]. The main theoretical concept substantiating the permissible limits for the use of PGD is the concept of parental autonomy[6]. Its use justifies the choice in favor of an embryo that does not have signs of genetic diseases in the context of preventing the physical suffering of an unborn child and creating confidence in parents about their "normal" life in the future. However, the concept of autonomy of the will of parents does not give unambiguous answers to questions regarding the validity and feasibility of PGD for the so-called "non-medical" selection of embryos, among which the most discussed and demanded among consumers is selection by gender.

The Directive of the Ministry of Health proceeds from the initial premise that PGD is initially performed for medical reasons, while gender selection for non-medical reasons is allowed only in "exceptional, unsystematic, and rare cases" and only after the National Committee for Gender Selection for non-medical reasons will provide written permission for this. The opportunity to appeal to the committee is provided subject to the following conditions: 1) there is a real risk of causing unavoidable moral harm to one or both parents, as well as to the child itself, if the procedure is refused; 2) married applicants have four children of the same gender in common and not of the other (this quantitative criterion is not strict, deviation from it is allowed in "extremely rare" and "having an individual specificity" cases); 3) the applicants were provided with the consultation of a specialist in genetics regarding the content of the PGD procedure, the criteria and the degree of its effectiveness were explained, ethical considerations were expressed with emphasis on the status and fate

[4] J. J. G. Gietel-Habets; C. E. M. Die-Smulders; V. C. G. Tjan-Heijnen; I. A. P. Derks-Smeets; R. Golde y E. Gomez-Garcia, “Professionals' knowledge, attitude and referral behaviour of preimplantation genetic diagnosis for hereditary breast and ovarian cancer”, Reproductive BioMedicine Online Vol: 36 num 2 (2018).

[5] J. Zlotogora, “The Israeli national population program of genetic carrier screening for reproductive purposes”, How should it be continued? Israel Journal of Health Policy Research Vol: 73 (2019).

[6] G. Leiter, “What Israeli policy can teach us about elective gender selection”, Israel Journal of Health Policy Research Vol: 3 num 42 (2014).

of embryos of the unselected gender; 4) it is explained to applicants that in the presence of the remaining healthy embryos of unselected gender, permission for additional IVF cycles for the purpose of gender selection will not be granted until the healthy embryos are used by the couple for reproductive purposes; 5) both parents gave informed written consent to conduct PGD. In the practice of the committee's work, specific examples of exceptions were noted when PGD was allowed when the general quantitative criterion was not met. For example, there were cases when the family already had a child of the opposite gender, but the child suffered from an incurable disease and (or) was disabled, and also cases called "rare idiosyncratic circumstances", when the choice of an exclusively female child was allowed to the priestly families, in which the spouses of the Kohanim fathers could only get pregnant from a sperm donor[7].

In addition to the legal possibility of choosing a gender for social reasons, Israeli law is distinguished by the absence of legal restrictions regarding the stage of development of the embryo at which these diagnostics can be performed. ART medical centers in Israel offer their patients one of three possible biopsy options, such as biopsy directly on the day of fertilization, on the third or fifth day of embryo development (not guided by the status of the embryo at a particular stage of development, but by which of the options will provide the most accurate results and increase the chances of pregnancy for a particular couple or woman). There are no prohibitions that would not allow resorting to the procedure to give birth to an "ideal donor" for a sick family member, provided that the aim of using ART is to give birth to children, and not to donate organs and tissues, while the latter does not harm a baby being born (e.g., with bone marrow donation)[8]. The experience of individual medical centers in Israel shows that about a quarter of all IVF cases are performed in connection with special medical indications for PGD, and not because of infertility.

In China, the field of ART is dominated by the theoretical concept of "yousheng" (the Chinese synonym for the word "eugenics", which does not have a negative connotation), based on which the implementation of PGD to select the most viable embryos is welcomed along with other measures ensuring the health of the future generation, such as giving up bad habits[9]. Of particular interest in this context are the agreed recommendations on the implementation of PGD developed in 2018 by the professional community, the content of which reflects the specifics of the Chinese approach to regulating cases and the procedure for their application. As a special case, which is an indication for PGD, the recommendations consider the determination of the correspondence of human leukocyte antigen (HLA) for couples with children with severe hematological diseases who require bone marrow transplantation. To avoid professional and ethical conflicts associated with a possible refusal to provide a service, situations where PGD is not allowed are separately indicated, for instance, diseases with an unknown genetic component, cases of parents choosing signs that are not related to diseases (gender, appearance, height, skin color, etc.), and some special situations. With the general prohibition of gender selection using PGD, it is not forbidden to provide the patient or couple with information about the gender of the embryo

[7] D. Birenbaum-Carmeli, "Thirty-five years of assisted reproductive technologies in Israel", Reproductive Biomedicine & Society Online num 2 (2016).

[8] S. F. Vitez; E. J. Forman y Z. Williams, "Preimplantation genetic diagnosis in early pregnancy loss", Seminars in Perinatology Vol: 43 num 2 (2019).

[9] M. Qin; X. Zhu; Z. Zhang; X. Li; Z. Yan y Y. Wang, „Genetic analysis and preimplantation genetic diagnosis of Chinese Marfan syndrome patients", Journal of Genetics and Genomics Vol: 46 num 6 (2019).

as part of the diagnosis for other reasons. As a result, scientific literature draws attention to the actual practice of PGD for the selection of embryos by gender[10].

The recommendations specifically define the general conditions for conducting PGD, which include: 1) conducting at least one genetic consultation before deciding on PGD, during which the patient should be explained possible diagnostic methods, their advantages and disadvantages, the content of medical intervention for the chosen option; 2) the reasonableness and sufficiency of clinical indications for PGD (preliminary collection of clinical data and the results of genetic tests of patients and their relatives is required, which allows compiling a genetic family tree, identifying fertile and genetic risks); 3) the choice of the research method depending on the indications for the procedure; 4) an independent evaluation of the diagnostic results (the obtained data should be analyzed and interpreted by two specialists, after which the third specialist should prepare the final conclusion; in the absence of consensus, the embryo is defined as having an unknown diagnosis and is not recommended for transplantation); 5) providing the opportunity to make the final decision on implantation to the patient. In the absence of an embryo, that does not have a deviation, at the patient's choice, implantation is carried out in order of priority of the embryo that has the lowest risk of failure of the transplantation, or a transition to a new IVF cycle is carried out. Studying the experience of China allows us to talk about its yet another important regularity of the legal regulation of PGD in the ART system. One of the prerequisites for the wide and effective application of diagnostics is the development of clear, transparent requirements for the conditions of PGD used to assess the quality of medical care and compliance with licensing requirements by the professional community of genetics specialists or with its participation. The qualified opinion of geneticists also helps to eliminate gaps in the regulation of the content of medical services provided in countries that allow self-regulation of genetic research (here the most striking example is the United States, which does not provide for any legal prohibitions on PGD[11], i.e. the procedure is carried out in the absence of medical indications, to determine gender, intelligence, physical characteristics, etc.), as well as in determining the procedure for approving PGD in rare cases and exceptional cases for countries with strict state regulation in this area. European countries adhere to this approach today, many of which, including Italy and Switzerland, still maintain regulatory requirements for the mandatory implantation of all viable embryos obtained from IVF, which makes the PGD procedure meaningless[12]. We can note the development of law enforcement practice in the direction of a broad interpretation of the grounds for conducting PGD along with the provision to specialized administrative bodies and their advisory councils of the right to authorize diagnosis in exceptional cases. A case in point here is France, where the Agency for Biomedicine (Agence de la Biomédecine), which oversees compliance with the requirements of the law in the field of ART, in 2013, authorized the diagnosis for individual cases of HLA typing[13]. Today, the Agency's advisory functions are performed by the

[10] Ch. Zhou; Ch. Mei y Ch. Xue, "Preimplantation Genetic Diagnosis of Autosomal Dominant Polycystic Kidney Disease Applied in China", American Journal of Kidney Diseases Vol: 72 num 5 (2018).

[11] D. H. Barad; S. K. Darmon; V. A. Kushnir; D. F. Albertini y N. Gleicher, "Impact of preimplantation genetic screening on donor oocyte-recipient cycles in the United States", American Journal of Obstetrics and Gynecology Vol: 217 num 5 (2017): 571-576.

[12] I. Riezzo; S. Bello; M. Neri & P. Cristoforo, "Italian law on medically assisted reproduction: Do women's autonomy and health matter?", BMC Women's Health num 16 (2016): 56-59.

[13] F. Merlet; M. Bergère & T. Heuvel, "Cadre juridique de l'assistance médicale à la procréation en France, à l'aube du processus de révision de la loi de bioéthique", Revue Francophone des Laboratoires num 504 (2018): 63-69.

Multidisciplinary Center for Prenatal Diagnostics (Centre Pluridisciplinaire de Diagnostic Prénatal, CPDPN), which has developed criteria for assessing an individual case. To obtain consent to the procedure, it is required that the disease be sufficiently serious and the chosen research method sufficiently predictive. A similar practice exists in the UK, where the national regulatory authority in the field of human reproduction and embryology (Human Fertilization and Embryology Authority, HFEA) has the right to allow PGD if the disease develops only in adults or does not entail a disability, the genetic diagnosis is difficult, etc. The decision is made after consultation with practicing geneticists and public discussion (the application is published on the HFEA website)[14]. In the USA, where there is no state health insurance system and the question of the reasonableness of the cost of PGD in IVF is not raised in principle, the American Medical Genetics Specialists (ACMG) does not formulate recommendations directly for PGD. However, speaking of prenatal genetic research, it requires so that for diseases developing in adulthood, diseases with a "mild" phenotype, as well as diseases caused by mutations with variable expression and incomplete penetrance, parents should have an opportunity to decide in advance on whether they will get acquainted with the relevant data on the results of the diagnosis or if data on such diseases will not be presented subsequently[15].

In total, the study of foreign experience makes it possible to conclude that when developing a national concept of legal regulation of PGD, several basic moments should be considered, such as the difference in the grounds for conducting PGD, including purely medical ones (taking into account those not related to infertility treatment), and others, accompanied by legal prohibitions and restrictions; the obligation to determine the content of the services provided under medical standards the requirements for the conditions of the PGD, for each research method separately; the desirability of the participation of the professional community in authorizing diagnostics for exceptional cases or in case of absence of an officially approved list of detected diseases.

Discussion

The results can be criticized for several reasons. For instance, the opponents of the widespread adoption of PGD in medical practice, especially through its objective legal regulation, inclusion in the MHI program, and removal of restrictions on diagnostics for non-medical reasons, note that this can lead to a violation of the demographic balance between the genders, can serve as the first step towards the unprecedented interference in the "act of creation" and the appearance of "custom-made children"[16], as well as the irrational and unreasonable use of limited technological and medical resources[17] . One of the most powerful arguments opposing all of the above is that, along with the often prohibited or legislatively limited PGD, genetic screening of embryos and non-invasive fetal testing (NIFT)

[14] M. Heijligers; A. Peeters; A. Montfoort; J. Nijsten; E. Janssen y F. K. Gunnewiek, “Growth, health, and motor development of 5-year-old children born after preimplantation genetic diagnosis”, Fertility and Sterility Vol: 111 num 6 (2019): 1151-1158.

[15] K. Monaghan; N. Leach; D. Pekarek y P. Prasad, “The use of fetal exome sequencing in prenatal diagnosis: a points to consider document of the American College of Medical Genetics and Genomics (ACMG)”, Genetics in Medicine Vol: 1 num 6 (2020).

[16] Ch. Tamura, “Regulation of the preimplantation genetic testing in Japan: challenges for the clinical application”, Reproductive BioMedicine Online Vol: 38 num 1 (2019): 57-58.

[17] J. Cunningham; L. Goldsmith y H. Skirton, “The evidence base regarding the experiences of and attitudes to preimplantation genetic diagnosis in prospective parents”, Midwifery Vol: 31 num 2 (2015): 288-296.

in early pregnancy are widely practiced procedures and, in most cases, are provided at the expense of the MHI[18]. Since each of them allows revealing the gender and some other characteristics of the unborn child, it is believed that in modern conditions it is no longer possible to talk about the full-scale concealment of genetic information from non-medical use.

The concept of reproductive freedom and its analogs continue to develop even in countries with strict regulatory legal frameworks for ART. Here, an expanded interpretation of indications for diagnostics is beginning to take root, and the supervisory authorities, in agreement with the professional community of geneticists, are allowed to authorize PGD in cases not stipulated by law[19]. At the same time, in countries that do not bear the imprint of negative historical experience associated with attempts to introduce eugenic selection (such as China), from the standpoint of theory and practice, the implementation of PGD is justified exclusively in a positive context, for the struggle between society and an individual family for improving the quality of life of the future generation. All of this taken together indicates the impossibility of ignoring the possibilities of PGD and the needs of its legal regulation.

The main difficulty in developing the mechanism of legal regulation of PGD is that its significance and the field of practical application have not yet been fully realized. Many sensitive ethical issues remain unanswered for years, while the required legal regulation should already ensure the adoption of very specific organizational and managerial decisions on the possibility of including PGD in the MHI programs and create a reliable legal mechanism for protecting consumers of medical services in this area.

Conclusion

The concept of legal regulation of PGD should be built on several basic principles. First, the legislators should differentiate the medical grounds for conducting PGD and other cases of "non-medical" research. This is necessary to decide on the inclusion of PGD on medical grounds in the MHI program, which, in turn, must be accompanied by the mandatory determination of lists of chromosomal abnormalities, monogenic genetic diseases, diseases with severe symptoms and genetic susceptibility that can be detected during the procedure. Second, in the content of medical services according to medical standards, the requirements for the conditions of the diagnosis should be determined. This must be done separately for cases of aneuploidy research, diagnosis of couples with a specific genetic diagnosis, and genome-wide sequencing. Such requirements should include, in particular: requirements for conditions providing a choice of a research method, requirements for conditions providing an independent assessment of the obtained results, and requirements for conditions ensuring patient awareness of the procedure, a conscious decision to consent to PGD and the choice of the embryo for implantation according to its results. Third, the advisory board under the supervisory authority in the field of health should be allowed to broadly interpret the grounds for conducting PGD and give consent to decide on diagnosis as an exception or in the absence of an officially approved list of detected diseases.

[18] V. Y. Kuznyetsov; S. Madjunkova; R. Antes; R. Abramov; G. Motamedi y Z. Ibarrientos, “Non-invasive preimplantation genetic testing for aneuploidy (NIPGT-A)”, Reproductive BioMedicine Online Vol: 38 num 1 (2019): 41-42.

[19] E. Kurekci; A. Küpesiz; S. Anak; G. Öztürk; O. Gürsel y S. Aksoylar, “Hematopoietic Stem Cell Transplantation Using Preimplantation Genetic Diagnosis and Human Leukocyte Antigen Typing for Human Leukocyte Antigen–Matched Sibling Donor: A Turkish Multicenter Study”, Biology of Blood and Marrow Transplantation Vol: 23 num 5 (2017): 790-794.

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