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Polygenic Embryo Screening: Ethical Considerations and Recommendations for Clinical Practice On behalf of the Ethics and Good Clinical Practice Group and the Genetics Group of the Spanish Fertility Society

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ABSTRACT

Recent advances in Next-Generation Sequencing (NGS) technologies at the embryonic level have made Whole Genome Sequencing (WGS) a feasible tool for embryo analysis. These findings have enabled the development of Polygenic Risk Scores (PRS), which aggregate information from hundreds or thousands of Single Nucleotide Polymorphisms (SNPs) to estimate an individual's relative risk of developing a given condition compared with the general population.

When PRS are applied at the embryonic stage, the approach is referred to as Polygenic Embryo Screening (PES) or, more specifically, Preimplantation Genetic Testing for Polygenic Disorders (PGT-P)

PGT-P provides a measure of each embryo's relative genetic susceptibility compared with the general population. These estimates rely on statistical models that weigh the contribution of each SNP according to its frequency and estimated disease association. However, interpreting PRS at the embryonic level is challenging. Polygenic risk is probabilistic; thus, an embryo with a high PRS may never develop the disease, while an embryo with a low PRS is not risk-free.

PGT-P raises important ethical concerns, including the need for adequate counseling, realistic patient expectations, issues of distributive justice, the impact of environmental and social determinants of health, and the potential exacerbation of health inequities.

The main objective of this document, prepared by the Ethics and Good Clinical Practice Interest Group of the Spanish Fertility Society (SEF), is to provide guidance to researchers, clinicians, embryologists, regulators, and professional societies as they make decisions regarding the implementation of this emerging technique, with particular emphasis on its ethical implications.

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Introduction

Preimplantation Genetic Testing (PGT) is a reproductive genetic technology that enables the detection of hereditary genetic disorders and chromosomal abnormalities in embryos. It is primarily used by prospective parents seeking to prevent the transmission of a genetic condition or chromosomal alteration to their offspring [1].

A variant of this technique, Preimplantation Genetic Testing for Monogenic Disorders (PGT-M), was specifically designed to identify hereditary diseases caused by mutations in a single gene. These monogenic conditions are generally rare in the general population and include examples such as cystic fibrosis, polycystic kidney disease, and Duchenne muscular dystrophy.

However, most human diseases do not result from single-gene mutations. Instead, they arise from complex interactions between multiple genetic and environmental factors, a type of etiology known as polygenic (or multifactorial). Examples include cardiovascular diseases, hypertension, type 1 and type 2 diabetes, many cancers, autoimmune disorders, dementias, and psychiatric illnesses. Multifactorial polygenic diseases are not suitable for PGT-M.

Recent advances in Next-Generation Sequencing (NGS) technologies at the embryonic level, coupled with decreasing sequencing costs, have made Whole Genome Sequencing (WGS) a feasible tool for embryo analysis. WGS provides comprehensive genomic data, although typically with modest depth of coverage in the embryonic context.

In parallel, Genome-Wide Association Studies (GWAS) have identified Single Nucleotide Polymorphisms (SNPs) that occur more frequently in individuals affected by specific polygenic conditions. These findings have enabled the development of Polygenic Risk Scores (PRS), which aggregate information from hundreds or thousands of SNPs to estimate an individual's relative risk of developing a given condition compared with the general population.

When PRS are applied at the embryonic stage, the approach is referred to as Polygenic Embryo Screening (PES) or, more specifically, Preimplantation Genetic Testing for Polygenic Disorders (PGT-P). PGT-P uses WGS-derived genomic data from embryos to analyze thousands of SNPs associated with various polygenic diseases, thereby assigning each embryo to a PRS for these conditions. Unlike PGT-M, which identifies clearly pathogenic mutations responsible for monogenic disorders, PGT-P seeks to quantify an embryo's predisposition to polygenic diseases and based on these results, prioritize embryos with lower predicted risk for transfer.

PGT-P provides a measure of each embryo's relative genetic susceptibility compared with the general population. These estimates rely on statistical models that weigh the contribution of each SNP according to its frequency and estimated disease association. However, interpreting PRS at the embryonic level is challenging. Penetrance varies widely, and environmental and epigenetic modifiers—often poorly understood—play a substantial role. Furthermore, polygenic risk is probabilistic; thus, an embryo with a high PRS may never develop the disease, while an embryo with a low PRS is not risk-free.

Several technical limitations also affect PGT-P, including the need for large and diverse population datasets to optimize PRS models and the reduced predictive accuracy for individuals of non-European ancestry. This limitation stems from the underrepresentation of non-European populations in major genomic databases such as the Genome Aggregation Database (gnomAD). In addition, the clinical utility of PGT-P depends strongly on the number of embryos available from a single IVF cycle. A larger embryo cohort increases the likelihood of selecting one with lower polygenic risk, but in clinical practice the number of viable euploid embryos is usually small, limiting the effectiveness of polygenic screening.

Embryo selection may also lead to what has been termed the choice dilemma, arising not only from the probabilistic nature of PGT-P but also from the "information overload" it generates. When multiple PRS are evaluated simultaneously, prospective parents may face conflicting trade-offs among embryos with different risk profiles across diseases. In extreme situations, this may result in none of the embryos being considered "acceptable," leading to emotional distress and a sense of failure.

The technical validity and clinical utility of PGT-P have been evaluated in several scientific publications. However, beyond technical limitations, PGT-P raises important ethical concerns, including the need for adequate counseling, realistic patient expectations, issues of distributive justice, the impact of environmental and social determinants of health, and the potential exacerbation of health inequities [2-8].

The main objective of this document, prepared by the Ethics and Good Clinical Practice Interest Group of the Spanish Fertility Society (SEF), is to provide guidance to researchers, clinicians, embryologists, regulators, and professional societies as they make decisions regarding the implementation of this emerging technique, with particular emphasis on its ethical implications.

Ethical Frameworks in the Published Literature

Preimplantation Genetic Testing has long been viewed as ethically sensitive. Over its 30-year history, several ethical concerns have accompanied its applications and the progressive expansion of its use. For example, the use of PGT to detect conditions that manifest only in adulthood has generated debate about its benefits, particularly regarding where to draw the line and how to protect the individual's "right to an open future." Similarly, the introduction of PGT for conditions with incomplete penetrance—such as hereditary breast and ovarian cancer (BRCA1/2 mutations)—has raised ethical questions about making reproductive decisions based on probabilistic estimates of disease occurrence or severity.

Regarding PGT-P, several authors have argued that its potential for risk reduction is limited, and concerns have been raised about its validity, utility, and probabilistic nature. Additional issues include psychological impacts on prospective parents and ethical

concerns related to eugenics, commercialization, stigmatization, and discrimination. While many healthcare professionals in Europe and North America express reservations about introducing PGT-P into clinical practice, surveys indicate that the public and some IVF users in the United States hold a more favorable view [9-18].

Supporters of PGT-P argue that the technique offers parents a means of selecting "the genetically best possible embryo." Such claims have ignited debate regarding the ethical implications and the potential for increased parental anxiety associated with striving for an idealized form of "good parenthood," as well as disappointment when these expectations are unmet [19].

Zappalà et al. highlight how the current commercial narrative promotes these technologies as societal advances capable of reducing the prevalence of chronic diseases and, consequently, healthcare costs. This framing supports applications beyond fertility treatment or disease predisposition, suggesting a future in which genetic selection could become standard practice. Such a shift would fundamentally transform the purpose of IVF—from a treatment for infertility to a means of producing genetically "healthier" children—raising profound ethical and social concerns [20].

Both the European Society of Human Reproduction and Embryology (ESHRE) and the European Society of Human Genetics (ESHG) have stated that clinical application of polygenic disease prediction in prenatal or preimplantation contexts remains unproven and ethically unjustified (ESHRE Position Statement on PRS). Similarly, the American College of Medical Genetics and Genomics (ACMG) declared in 2021 that testing for diseases with multigenic or polygenic inheritance patterns is premature for clinical use and should not be marketed directly to consumers [21].

This view aligns with publications criticizing direct-to-consumer genetic testing models that bypass professional medical consultation, promoting a "self-service" approach to health management that carries risks of misunderstanding and misinterpretation. Furthermore, both the International Society of Psychiatric Genetics and the Polygenic Risk Score Task Force of the International Common Disease Alliance agree that current PGT-P applications remain premature for clinical settings.

In 2024, the Observatori de Bioètica i Dret at the University of Barcelona issued a statement noting [22]:

"There is a market of services surrounding assisted reproduction that offers certainties where none exist. This market covertly promotes eugenics by exploiting the expectations and concerns of individuals and couples."

Growing interest in the evolution of this technology is reflected in a multidisciplinary review by Capalbo et al. which examines the clinical, social, and ethical implications of PGT-P, including potential harm to patients, offspring, and society [23].

According to these authors, potential harms include unnecessary exposure to IVF treatment, elimination of healthy embryos, reduced cumulative live birth rates, inadequate genetic counseling, commercial pressure, information overload, misaligned embryo selection criteria, negative psychological effects, increased risk of undetected disease, and risks associated with the biopsy procedure itself.

At the societal level, concerns include discarded embryos, inequitable access, diversion of resources from more urgent health needs, undermining of public health strategies, a slide toward non-disease-based selection, the threat of non-liberal eugenics, health-related stigmatization and discrimination, and loss of genetic diversity.

Ethical Assessment Based on the Principles of Proportionality, Autonomy, and Justice

Principle of Proportionality

The principle of proportionality requires that the expected benefits of any medical intervention clearly outweigh its potential risks. Thus, ethical arguments for and against PGT-P focus on its benefits and harms—or, more broadly, its implications for the well-being of prospective parents, future offspring, and society. These factors must always be evaluated within each patient's specific context, a notion referred to as contextualized proportionality [24-25].

However, in early phases of technological development, risks are often poorly understood and potential benefits uncertain, making a well-founded assessment difficult. In such cases, the precautionary principle should prevail to avoid accepting serious or poorly understood risks without demonstrable benefit.

The primary anticipated benefit of polygenic embryo selection, as promoted for instance by the company Genomic Prediction, is the reduction of future disease burden, thereby benefiting both families and society at large. However, the actual clinical utility of this technique may be significantly constrained by practical limitations. Given the lack of conclusive data on clinical validity and the long list of potential harms, it is not clear that the benefits of PGT-P outweigh its disadvantages [26-27].

Another frequently cited argument in favor of PGT-P derives from the concept of procreative beneficence, which holds that "couples (or single reproducers) should select, among the possible children they could have, the one expected to have the best life, or at least a life as good as the others, based on the relevant available information". Taking it to its logical extreme, this principle could even be interpreted as implying a moral duty: if technology is available that could improve an individual's life, then society not only has the option to develop and use it but is obliged to do so [28].

Munday and Savulescu propose a welfarist model, limiting embryo selection to circumstances in which it clearly enhances the future child's well-being. They argue that this framework is preferable to a disease-based model (limiting PGT-P to a predefined list of conditions) or a libertarian model (allowing unrestricted selection). Under the welfarist view, PGT-P may be ethically acceptable if it is expected to improve well-being by reducing disease risk [29].

The main counterargument is that there is no guaranteed causal relationship between genetic disease risk and actual quality of life, particularly when disease manifestation is uncertain. Thus, reducing probabilistic genetic risk does not necessarily improve life outcomes [30].

Balancing the ethical principles of non-maleficence ("do no harm") and beneficence ("promote good") requires careful and prudent decision-making that weighs potential benefits against the associated risks. In an environment characterized by limited evidence of clinical validity and substantial uncertainty about the risks, it is difficult to ethically justify the use of PGT-P as a routine or recommended practice.

Respect for Autonomy

One of the main arguments supporting PGT-P (Preimplantation Genetic Testing for Polygenic Traits) derives from the principle of respect for reproductive autonomy, which suggests that, ultimately, parents should decide whether the benefit–risk balance is acceptable from their perspective. In particular, patient autonomy may dictate that parents be provided with any information regarding their embryos that could influence their choices [31,32].

However, respect for autonomy should not be interpreted as granting patients unrestricted access to any treatment they request. Rather, it entails a commitment to shared decision-making based on scientific knowledge (provided by healthcare professionals, preferably a genetic counselor) and on the patient's own values, which should be explored and made explicit through "interpretive" pre-test counseling and a deliberative process. In the case of PGT-P, informed decision-making is particularly challenging, given the high level of complexity and the ease with which statistical data can be misinterpreted. This underscores the importance of training genetic counselors to address the nuances of PGT-P and to enhance their communicative strategies and skills to effectively convey highly complex concepts [33,34].

Shared decision-making, together with policies and guidelines established by professional organizations and regulatory bodies (including restrictions on the circumstances under which reproductive health services may be offered), better upholds reproductive autonomy than a market-based model in which patients are treated as clients to be served on demand.

Furthermore, reproductive decision-making entails responsibility not only toward one's offspring but also toward future generations. Thus, it is unreasonable to leave such decisions solely to prospective parents, as societal responsibility extends beyond individual autonomy.

Principle of Justice

The principle of justice raises several key concerns regarding PGT-P, including:

- Equity and access: PGT-P may be used not only to predict complex disease risk but also to screen traits unrelated to disease. Some companies already offer PRS for intelligence, height, education, income, and subjective well-being. Because reproductive technologies impose significant financial costs, only individuals with sufficient economic means could select offspring based on desirable traits, exacerbating pre-existing social inequalities. One possible solution would be to integrate PGT-P into national health systems to improve accessibility; however, this is not always feasible due to disparities in technological development, healthcare infrastructure, and national priorities. Moreover, widespread use of PGT-P could result in a society where individuals with greater financial means enjoy "better polygenic health" than those without such resources, thereby exacerbating social inequalities rooted in economic disparity. Furthermore, judgment of which traits are desirable is influenced by social norms, including racist, sexist, and ableist biases [35].
- Diversion of healthcare resources: Use of IVF and genetic testing for non-medical purposes may divert resources from more urgent needs, undermining distributive justice.
- Unequal benefits for non-European populations: Due to the predominant bias in existing studies—most of which have been conducted on individuals of European ancestry—PGT-P predictions may be less accurate for other ethnic groups. This could reinforce stigmatization, discrimination, and even reduce self-esteem among underrepresented populations.
- Overemphasis on individual responsibility: PGT-P may overemphasize personal responsibility for health while downplaying the impact of structural injustices and the social and environmental determinants of disease diverting attention and resources away from addressing these fundamental causes. Troubling from a justice perspective is the overemphasis that PRS testing places on genomic factors at the exclusion of environmental ones and the related focus on placing the responsibility for the well-being of their offspring primarily on the prospective parents' hands [36].
- These issues contribute to increased social injustice and form strong arguments against the clinical introduction of PGT-P.

Conclusions

Screening human embryos for polygenic disease risk is technically feasible and could theoretically reduce relative risk. However, at present:

- The reduction in absolute risk remains small. Given the probabilistic nature of polygenic risk, it is essential to recognize that an embryo with a high polygenic risk score (PRS) will not necessarily develop the disease, while one with a low PRS is not free from risk.
- PGT-P could reduce birth rates, since discarding embryos based on polygenic risk rather than embryonic quality may result in fewer embryos available for transfer.
- The instrumentalization of IVF by non-infertile patients and unnecessary exposure to PGT in the absence of clear clinical indications. This shift could drastically alter the logic of IVF—from a treatment for infertility to a tool for producing genetically "healthier" babies, even when no medical justification exists.
- Inaccurate predictions due to environmental confounding in multifactorial diseases.
- Limited precision and clinical applicability for individuals of non-European ancestry, stemming from their underrepresentation in genomic databases.
- Uncertainty regarding the future relevance of prenatal testing for diseases with multigenic or polygenic inheritance patterns.
- Choice dilemmas caused by information overload: when multiple PRS analyses are combined, parents may face the challenge of selecting between embryos with varying probabilities of developing multiple diseases.
- Ethical concerns related to the proportionality of harms and benefits, shared decision-making, and the principle of justice.
- Above all, the false premise of disease predictability, which introduces significant uncertainty, creates unfounded expectations, and opens the door to future consequences driven primarily by economic interests—carrying societal implications that demand careful, collective reflection.

After analyzing the potential advantages and disadvantages and balancing the possible benefits for patients and their offspring, the Ethics and Good Clinical Practice Committee of the Spanish Fertility Society (SEF) believes that the use of PGT-P should be restricted to exceptional cases, specifically for patients undergoing assisted reproductive techniques who are affected by a serious polygenic disease or have a family history of such conditions.

In this context, it is essential to expand polygenic risk research to include individuals from non-European ethnic backgrounds to prevent discriminatory outcomes.

The implementation of PGT-P should always be accompanied by comprehensive counseling provided by specialists in clinical

genetics, enabling patients to make autonomous and well-informed decisions.

In conclusion, the use of PGT-P for detecting the risk of polygenic diseases in embryos should be discouraged at this time, until the technique has matured sufficiently to allow reliable disease prediction, reducing uncertainty and ensuring that expected clinical benefits clearly outweigh potential risks.

The introduction of new technologies that may hypothetically offer parents greater possibilities of improving their children's quality of life must not proceed without broad societal reflection on their consequences. Beyond serving the interests of individual patients, professionals in assisted human reproduction bear a collective responsibility toward both present and future generations.

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Authors Contributions
RNC conceived the idea and wrote the manuscript
JP wrote the introduction and genetic aspects
RT assisted in writing the manuscript and made language corrections
FA reviewed the legal aspects
LF reviewed the ethical aspects of the content
IA, AF, ES, MM, MR, IA and JS, reviewed the content of the manuscript according to the standards of the SEF Ethics Group. All authors read and approved the manuscript.

Conflict of Interest Statement
The authors declare that there is no conflict of interest that are directly or indirectly related to the work submitted for publication.

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