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## SPECIAL ARTICLE

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## FIGO position statement: Gamete donations

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#### **Abstract**

Gamete donation has become a crucial part of Assisted Reproductive Technologies (ARTs), providing hope to individuals, including those who may have no other option for parenthood. This process comes with a wide range of ethical, medical, and legal challenges that need to be carefully addressed to protect the well-being and rights of all parties involved: donors, recipients, and offspring. Navigating these complexities requires strict ethical standards, robust regulatory frameworks, and international collaboration. By standardizing these, the field of gamete donation can continue to develop while ensuring that all parties are well informed and safeguarded. This paper explores the ethical concerns and core principles surrounding gamete donation, offering recommendations to ensure safe, equitable, and ethically responsible practices that protect and support all parties involved.

## KEYWORDS

assisted reproductive technologies, donors, fertility, gamete donation, oocyte, regulation, sperm

See Acknowledgements section for the member of the FIGO Committee on the Ethical Aspects of Human Reproduction and Women's Health and the FIGO Committee on Reproductive Medicine, Endocrinology, and Infertility.

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## 1 | INTRODUCTION

Gamete donation has become a crucial part of Assisted Reproductive Technologies (ARTs), providing hope to individuals and couples struggling with infertility, making it an increasingly essential aspect of modern reproductive medicine. The first documented sperm donation took place in 1884 in the USA and the first oocyte donation in 1983 in Australia. Gamete donation has increased dramatically since then and, in recent years, approximately one-quarter of gamete donor-conceived persons in the USA result from donor oocytes. In Europe, approximately 100000 children resulting from gamete donation are born each year.

However, this process presents a range of ethical, medical, and legal challenges that must be carefully addressed to protect the well-being and rights of all parties involved: donors, recipients, and offspring.

One of the primary concerns is ensuring that ethical standards are consistently upheld. These include providing clear, comprehensive, informed consent, preventing donor exploitation, and addressing issues surrounding donor anonymity. In addition, medical risks to donors and recipients must be carefully managed, with transparent communication about potential short- and long-term impacts.

Navigating these complexities requires strict ethical standards, international collaboration, and transparency. Without a global effort to standardize and regulate practices, discrepancies in legal and medical oversight can lead to inconsistent care and potential harm to donors and recipients.

By standardizing these practices, the field of gamete donation can continue to develop while ensuring that all parties involved are well informed and safeguarded. This paper explores the ethical issues and fundamental principles of gamete donation, aiming to foster a transparent and ethically sound approach to reproductive assistance. In this position statement, the International Federation of Gynecology and Obstetrics (FIGO) provides recommendations for the improved management of gamete donation. These recommendations aim to establish safe, equitable, and ethically sound practices in gamete donation, ensuring that all parties are well informed, protected, and supported throughout the process.

## 2 | ETHICS AND GUIDING PRINCIPLES

Individuals making this altruistic and profound decision of gamete donation must be equipped with the knowledge to make it with full awareness. The issue of gamete exploitation, whether it involves sperm or oocytes, is a profoundly complex and ethically charged concern that transcends borders and necessitates meticulous attention. Therefore, a multifaceted approach is needed to address this global issue responsibly and ethically, preserving the autonomy, dignity, and well-being of all individuals involved.

## 2.1 | Strengthening informed consent practices

Ensure that all parties involved in gamete donation are treated with respect, dignity, and transparency. One key aspect is informed consent, which ensures donors and recipients are fully aware of the implications and risks.<sup>4-7</sup> A comprehensive discussion of counseling protocols and documentation requirements for informed consent is provided in the "Informed consent" section.

## 2.2 | Promoting ethical guidelines

Rigorous enforcement of ethical guidelines for gamete donation practices is essential to ensure that donors are treated with respect and dignity throughout the process.<sup>8-10</sup>

## 2.3 | Regulating commercialization

Supervise the activities of gamete donor agencies and clinics. Financial incentives must not eclipse ethical considerations and the well-being of egg donors. <sup>5,11</sup>

### 2.4 | Raising awareness

Public education is vital to increasing awareness of the ethical challenges surrounding gamete donation. Informed decision making should be encouraged, and a responsible approach to fertility treatments and research should be promoted.<sup>12</sup>

### 2.5 | Exploring alternative options

Research into alternatives such as stem cells could alleviate some of the ethical concerns of human gamete donation and minimize associated risks.<sup>4</sup>

#### 2.6 | Anonymity of donor

Donor anonymity remains a complex issue, with evolving legal and societal trends recognizing the rights of donors and offspring to access identifying information.<sup>7</sup> The rise of publicly accessible DNA databases further complicates the sustainability of long-term anonymity, as discussed in detail in the "Confidentiality and anonymity" section.

## 2.7 | Ethical aspects of gamete donation

Several factors must be considered:



- Rights of the donor: Donors should be free from any responsibility to the biological offspring produced by their gametes.
   The age of the donor, minimizing the risk of infection, and screening for genetic issues are important.<sup>8</sup>
- 2. Number of children: Ethical considerations regarding the number of children a donor can produce should be addressed.<sup>11</sup>
- Criteria for donor selection: Clinics and gamete banks must define their criteria for choosing donors. They cannot guarantee that the gametes are disease-free or free of genetic abnormalities, as diagnostic techniques are not foolproof.<sup>4</sup>
- 4. Recipients' rights: Patients must be aware of the criteria for gamete selection. They have the right to be informed of the limitations and potential complications involved with gamete donation, such as the need for multiple treatments without a guarantee of success. They must be made aware that they are fully responsible for the offspring conceived by using the gametes. 12

## 2.8 | Key recommendations

Key recommendations are as follows:

- Empower informed choices for all parties, ensuring autonomy and dignity.
- Uphold rigorous ethical standards to protect all stakeholders.
- Prevent exploitation by prioritizing ethical considerations over financial incentives.
- Promote public awareness of ethical issues to encourage responsible decision making.
- Recognize challenges to donor anonymity due to advances in DNA testing.
- Protect the rights of both donors and recipients, ensuring a clear understanding of responsibilities and complexities.

## 3 | ACCESS AND EQUITY

During the past few years, the development of ARTs has created new challenges due to cultural, socioeconomic, political, and religious differences around the world. Therefore, it is imperative to provide tools that ensure equitable and fair access to these technologies. Gamete donation is an essential component of ATRs that has become an important tool in the pursuit to improve reproductive outcomes. <sup>6,13,14</sup>

It is important to do the following

 Conduct comprehensive educational campaigns to raise public awareness about gamete donation, including information about the process as well as the risks and benefits for donors, recipients, and offspring. This information should also be easily accessible for marginalized populations and remote geographic areas.

- Provide information that destignatizes gamete donation in various cultural contexts to encourage acceptance and participation, ensuring that ethical standards and best practices are shared and adopted globally.<sup>11</sup>
- Ensure that gamete donation services are accessible to all individuals, regardless of gender, sexual orientation, marital status, ethnicity, or religious beliefs, and implementing anti-discrimination policies. 6,14
- Address financial barriers by advocating for insurance coverage or government funding to make ART, including gamete donation, more accessible to individuals from lower socioeconomic backgrounds.<sup>14,16</sup>
- Develop international guidelines that respect cultural differences while promoting equity and transparency in gamete donation, in order to prevent exploitation and commercialization of gametes. 6,7,11
- Prioritize the rights and well-being of all parties involved in diverse gamete donation policies around the world, including anonymous, open, and identifiable anonymous donations.<sup>6,17</sup>
- Establish clear regulatory frameworks and international agreements that consider legal, medical, and ethical implications to regulate and facilitate safe and equitable access to cross-border reproductive care, including trans-border gamete donation services.<sup>6,7,11,18</sup>

### 3.1 | Key recommendations

Key recommendations are as follows:

- Raise awareness through educational campaigns to combat stigma and improve access for all populations.
- Promote inclusive services with policies addressing financial barriers and supporting insurance or government funding.
- Respect cultural differences while ensuring ethical practices and preventing exploitation in cross-border donations.

## INFORMED CONSENT

The ethical and legal frameworks governing gamete donation underscore the critical importance of informed consent. Indeed, both donors and recipients must be thoroughly informed and their rights safeguarded throughout the process. <sup>19</sup> This process should be carried out in accordance with local laws, ensuring that both donors and recipients fully understand the procedure and the potential implications. Informed consent must be documented in the local language whenever possible, reflecting transparency and compliance with the law.

Counseling plays a pivotal role in ensuring that all parties involved are adequately prepared and informed. It is essential that both donors and recipients receive separate counseling, addressing the complexities of the procedures and ensuring that all relevant information is clearly communicated and documented. This counseling

should be available before, during, and after the procedure to support the emotional and psychological well-being of all individuals involved.<sup>6</sup> Detailed documentation is crucial to prevent misunderstandings or conflicts in the future.

Informed consent forms, based on scientific and medical ethics, are used to formalize the rights of both donors and recipients. <sup>9,10</sup> These forms must be signed by the recipient and verified by their physician, ensuring a mutual understanding of the responsibilities and rights of all parties involved. Adherence to these ethical guidelines is essential for maintaining accreditation from state health departments and national organizations. Failure to comply with these standards can lead to the loss of accreditation, undermining the integrity of the clinic or gamete bank. <sup>8</sup>

Given the competing interests of donors, recipients, and agencies, transparency is paramount. Clear and accurate information must be shared and documented at every stage of the process, in full compliance with the legal and policy requirements of the country. It is also recommended that countries establish and maintain donor registries to promote accountability and transparency in gamete donation practices.<sup>6</sup>

## 4.1 | For donors

- Provide information: Donors must provide information about their personal and family histories, lifestyle, and behaviors.
- Fulfill selection criteria: Donors must fulfill the selection criteria
  according to the legal requirements of individual countries and be
  in good physical and mental health.
- Screening information: Donors must be informed regarding the screening of sexually transmitted diseases and other risk factors that may affect them or the future children born from such a technique.
- Written consent: Donors must provide written consent clearly
  understanding the procedure, its benefits, emotional and psychological consequences, potential short- and long-term medical risks
  on their reproductive health and future parenthood, and the legal
  implications involved. They must also understand that they have no
  dispositional control over the gametes or embryos once procured.<sup>19</sup>
- Nature of donation: Donors must be clearly informed about the nature of the donation, whether altruistic or commercial, and any compensation involved. If compensation is provided, donors should understand its nature and how it relates to their donation.
   The compensation should reflect the costs incurred by the donation process, without constituting an inducement or pressure.<sup>6,20</sup>
- Previous donations: Many countries have legal restrictions on the number of times eggs and sperm can be donated. Donors are expected to inform if they have donated before and the number of times.<sup>21</sup>

## 4.2 | For recipients

Selection criteria: Recipients must be selected for donor programs based on genuine indications.

- Legislation information: Recipients must be informed about the relevant legislation according to the law of the land.
- Anonymity options: Recipients must be informed about the options of anonymous or identity-release donations.<sup>6</sup>
- Procedure information: Recipients must be informed about the procedures, chances of success and failure, and the potential for miscarriage, preterm birth, or any structural or genetic abnormalities even after a pregnancy is achieved.<sup>19</sup>
- Implications of donor gametes: Recipients must be informed about the implications of using donor gametes.<sup>6</sup>
- Legal rights and duties: Recipients must understand that since they procure gametes or embryos, it is their legal right and duty to care for the offspring produced from such donations.<sup>19</sup>
- Confidentiality and anonymity: Though confidentiality and anonymity are intended, they cannot be ensured in the present times
  due to the availability of commercial genetic testing agencies, and
  offspring may try to search for or contact donors in the future.<sup>19</sup>
- Insurance coverage: In some countries, it is mandatory for ART banks to manage the procurement, screening, and documentation processes, along with providing insurance coverage for the donor (egg) by the recipient couple to ensure the health of the donor and cover expenses in case of any unforeseen complications.<sup>21</sup>

#### 4.3 | Key recommendations

- Raise awareness through educational campaigns to combat stigma and improve access for all populations.
- Promote inclusive services with policies addressing financial barriers and supporting insurance or government funding.
- Respect cultural differences while ensuring ethical practices and preventing exploitation in cross-border donations.

## 5 | SAFETY AND QUALITY

Ensuring the safety and quality of gamete donation procedures is paramount. This involves rigorous medical and genetic screening, psychological evaluation, adherence to legal and ethical considerations, and stringent quality control in gamete handling.

## 5.1 | Medical and genetic screening

The following medical and genetic tests are conducted:

- Medical history: A comprehensive medical history is taken to identify any potential hereditary or infectious diseases.
- Physical examination: A thorough physical examination is conducted.
- Genetic testing: Screening for genetic disorders is performed to prevent the transmission of inheritable diseases. It is recommended to screen all oocyte and sperm donors for carrier status

of common genetic diseases, such as cystic fibrosis, spinal muscular atrophy, and thalassemia/hemoglobinopathy. Expanded carrier screening could also be advised to cover a broad range of genetic conditions across diverse populations. 5,19,22

• Age range for donors: Donors should fall within an age range that is consistent with optimal gamete quality. For sperm donors, the recommended age range is typically 21–45 years, while egg donors are generally aged 21–35 years. These age ranges help ensure the highest quality of gametes and minimize the risk of genetic anomalies. <sup>10,19</sup> In exceptional cases, donors aged under 21 years may be considered, provided they undergo a thorough psychological evaluation by a qualified mental health professional, with the final decision made on an individual basis. <sup>19</sup>

## 5.2 | Infectious disease testing

The following tests for infectious diseases are conducted:

 Screening for sexually transmitted diseases: This includes testing for HIV, hepatitis B & C, syphilis, chlamydia, gonorrhea, cytomegalovirus, rubella, and others. 10,19,23,24

## 5.3 | Psychological evaluation

The following tests are carried out for psychological evaluation:

 Mental health assessment: Evaluation of the donor's mental health is conducted to ensure they understand the implications of donation and possess emotional stability.<sup>7,19,25</sup>

#### 5.4 | Legal and ethical considerations

The following legal and ethical considerations must be taken into account:

- Informed consent: Donors must provide informed consent, understanding all aspects of the donation process and future implications.
- Confidentiality: Where applicable, ensuring donor anonymity should be maintained. 5,7,24,26-28

#### 5.5 | Quality control in gamete handling

Laboratory standards should be as follows:

- Good Laboratory Practices (GLP): Laboratories handling gametes must adhere to GLP to ensure the accuracy and reliability of test results.
- Accreditation and certification: Laboratories should be accredited by recognized bodies such as the College of American

Pathologists (CAP) or equivalent organizations in other countries.

## 5.6 | Handling and storage should be managed as follows

- Cryopreservation: Gametes are often cryopreserved, and this process must follow strict protocols to prevent contamination and ensure viability.
- Storage conditions: Proper storage conditions, including temperature control and security measures, must be maintained.

## 5.7 | Gamete quality assessment should be conducted as follows

- Sperm analysis: For sperm donation, parameters such as count, motility, and morphology are assessed.
- Oocyte quality: For egg donation, the quality of oocytes is evaluated by various criteria, including maturation stage and morphology.<sup>10,19,22-24,28</sup>

## 5.8 | Traceability and documentation

Traceability and documentation should be managed as follows:

 Record keeping: Comprehensive records must be kept for each donation, including donor information, test results, and tracking of gametes through the donation process. 8793479, 0, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/jigo.70200, Wiley Online Library on [15/05/2025]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons Licensea

 Traceability systems: Systems must be in place to ensure that gametes can be traced from donor to recipient. 7,25,28

## 5.9 | Key recommendations

- Conduct comprehensive screenings to ensure donor suitability and minimize risks.
- Implement rigorous testing for infectious diseases and assess gamete quality.
- Establish clear age criteria for donors and ensure legal and ethical compliance in all interactions.
- Maintain high standards in laboratory practices, cryopreservation, and traceability.

## 6 | CONFIDENTIALITY AND ANONYMITY

Donor-assisted conception can have important interpersonal ramifications for all parties involved. Since reproduction is linked to sexuality, privacy considerations abound, and perceived stigma may occasionally arise. While public campaigns have been set up for organ and blood donations, no public campaigns have ever been conducted for gamete donations, possibly due to concerns about social acceptability.

Up until relatively recently, fertility specialists discouraged openness in gamete donations, and discretion and donor anonymity were observed. Anonymous donation means that neither the donor, nor the prospective parents, nor the resulting children can obtain information about each other. Before the 1990s, donor records were routinely destroyed.

The possibility of obtaining donor-related information is still limited by several national legislations: Belgium, Brazil, Bulgaria, Canada, Greece, the Czech Republic, Israel, Italy, Japan, Spain, South Africa, and most states in the USA. Currently, however, with changing societal attitudes in many countries, openness, implying non-anonymous donation tends to become the norm. Mandated recording and registration of identifying donor information was enacted in Sweden as early as 1984, and subsequently in Austria, Australia, Finland, France, Germany, Ireland, the Netherlands, Norway, Portugal, Switzerland, New Zealand, and the UK. In many of these countries, non-anonymous donation of gametes with open information about the donor and recipient is the only option. In Victoria, Australia, when the legislation outlawed anonymous donations, it also retrospectively stripped donors of their anonymity, invalidating contracts made before the new nonanonymity legislation. As a mitigating provision, the identified donors at least have the option to veto contact with the other parties.

In some countries or cultures, the move to retain anonymous donations is still gaining traction. Complete anonymity is preferred in China and Iran, and in Middle Eastern countries definite non-disclosure norms prevail. There are also many countries, such as Mexico, where donor conception remains largely unregulated, with each fertility center defining its own policy.

In Spain, the country with the largest number of assistedreproduction cases in Europe and where donor anonymity is protected by law, donor-conceived persons are nonetheless entitled to have access to non-identifiable information about the donor, including medical details. Under extraordinary circumstances that pose a significant risk to the conceived child, even the donor's identity may be disclosed.

Under non-anonymous donation legislations, people conceived from donation—and only them—can access identifying information about the donor only after a certain age (15–18 years) upon formal request. Exceptions to the minimum age requirement exist in Germany, where no age limit is imposed for accessing donor information. It is worth noting that under contemporary fertility industry realities, cross-border reproductive care may circumvent any country-specific provisions, adding an additional level of complexity to an already heterogeneous landscape.

Notably opposed to donor anonymity are the gamete donation offspring, in contrast to parents and donors. Most donor-conceived adults also believe that the sperm donors and parents should be informed about how many children the donor has helped conceive. With anonymous donations, this type of information is often incomplete. At the same time, when it comes to providing information

to the donor, the majority of donor-conceived adults want to be informed and give consent before any information is disclosed. In some countries with identity release donation, such as Finland, donors do not enjoy the same legislated openness as the donor off-spring: donors do not have a right to obtain identifying information about their donor-conceived offspring.

The ethical argument against anonymity in gamete donation is that individuals have a right to know their biological origins and that non-disclosure undermines their autonomy by denying them essential information about themselves, thereby hindering selfdetermination and autonomous decision making.<sup>1</sup> The principle of justice may also be violated if donor-conceived children, compared with non-donor conceived individuals, are disadvantaged in their access to knowledge about their own conception. As a counterargument, it is noted that autonomous actions can be restricted when they risk causing harm to others. In addition, the autonomy of parents must also be considered—their right to make decisions about what they believe is best for their family's well-being and their vision of a "normal family." In recognition of the need to respect the autonomy of donors and recipients, legislation in Denmark, Iceland, some Canadian provinces, and certain states in the USA has adopted a double-track policy, allowing donors and recipients to choose between anonymous and non-anonymous donation.

Practical aspects associated with the growing trend toward nonanonymity have also entered the discussion, including concerns about a shrinking donor pool, given the strong preference for anonymity among most gamete donors, and increasing costs. For example, sperm from donors who agree to identity disclosure is more expensive than that from anonymous donors, not only because of extra financial compensation for identifiable donors but also increased administrative expenses.

It may be surprising that even in identity-release donor contexts, only a minority (7%–33%) of eligible donor-conceived individuals request their donor's information.<sup>29</sup> This can be explained, at least in part, by the lack of disclosure regarding donor conception. Studies have reported that the majority of heterosexual recipient couples choose not to disclose this information.<sup>30</sup> Recently, both the European Society of Human Reproduction and Embryology (ESHRE) and the American Society for Reproductive Medicine (ASRM) endorsed the need for disclosure of donor conception to donors and offspring. However, the ASRM also maintains that the decision to disclose remains the parents' choice, affirming their right to determine what actions best serve the well-being of their children.

A more recent development is the rapid expansion of direct-to-consumer genetic testing aimed at uncovering ancestry information and connecting genetic relatives, particularly across Europe, the USA, and Australasia. This enables donors, recipients, and donor-conceived individuals to identify genetic relatives outside the legal framework. The ongoing proliferation of digital technologies, coupled with increasingly more accessible and sophisticated genetic testing, means that lasting anonymity in third-party assisted reproduction can no longer be guaranteed. Individuals who have



submitted their DNA—or whose relatives have done so—to publicly accessible database, including those participating in global genome research projects, can now be identified. Following DNA finger-printing, genealogy (ancestry) databases can reveal the surnames of potential relatives. Additional non-genetic information (such as location, age, and phenotype) can then be used to further narrow searches, sometimes—though not always—leading to individual identification. In a recent Belgian study, half of the donor-conceived individuals surveyed had registered with an international DNA database to seek information not only about the sperm donor, but also about same-donor offspring. Unfortunately, individuals searching these databases often act on their findings without fully considering the potential impact on others, believing that their personal interests prevail.

Given these developments, donor information agreements should now explicitly address the potential for loss of anonymity and de-identification. Gamete donor registries must further strengthen confidentiality protections through measures such as encryption and controlled access, aiming to balance the legal safeguarding of donors' personal information with recipients' need for access to genetic data. Although there is a societal shift toward prioritizing the rights and interests of donor-conceived individuals, the legal framework should aim to support the autonomy of all parties involved. Donors remain entitled to a reasonable degree of privacy protection, though it must be recognized that privacy is not the same as anonymity or concealment.

Recognizing that, in a three-party reproduction context, competing autonomy interests may arise, future guidelines should aim to protect the best interests of all parties involved, ensuring that all are treated on an equal footing. Policies and guidelines should also take into account religious, ethnic, and cultural norms where applicable.

## 6.1 | Key recommendations

- Balance privacy and autonomy for all parties while acknowledging the challenges to anonymity.
- Promote transparency in disclosure practices and support the rights of donor-conceived individuals to access donor information.
- Strengthen data protection measures and work toward international consistency in privacy standards.
- Provide education and counseling on the implications of disclosure, anonymity, and genetic testing.

# 7 | CULTURAL AND RELIGIOUS CONSIDERATIONS

The ethical acceptance of gamete donation varies significantly, reflecting a broad spectrum of beliefs influenced by religious, cultural, and societal values.

## 7.1 | Religious perspectives

Within major world religions, interpretations can differ widely, often influenced by local customs, individual spiritual guidance, and evolving theological debates. 32-40 This diversity highlights the complexity of addressing gamete donation in a global context. Consequently, it is essential to acknowledge the range of perspectives and the nuanced discussions that occur at the intersection of faith, ethics, and modern reproductive technologies, without generalizing or oversimplifying the stances of entire faith communities.

## 7.2 | Cultural dimensions

Cultural norms significantly influence views on gamete donation, particularly in relation to lineage, family structures, and social acceptance. In patrilineal societies, the emphasis on preserving the paternal bloodline often leads to resistance against sperm donation. In contrast, matrilineal societies may demonstrate less opposition to egg donation. Attitudes toward donor anonymity also vary, with Western cultures increasingly favoring transparency, whereas some Asian cultures tend to prefer anonymity to protect family honor.

Social stigma surrounding gamete donation often correlates with societal attitudes toward infertility and technological interventions. Cultures that stigmatize infertility may also resist gamete donation, viewing it as a threat to traditional family structures. Legal frameworks reflect these cultural values, influencing the regulation and oversight of gamete donation practices. 33,35

Understanding these diverse religious and cultural perspectives is crucial for healthcare providers and policymakers to deliver respectful, informed care in multicultural settings.

## 7.3 Key recommendations

- Respect and accommodate religious perspectives, and understand how these influence attitudes toward gamete donation.
- Recognize cultural norms and tailor counseling and policies to reflect these values.
- Address social stigma through education and develop inclusive legal frameworks that respect cultural diversity.

## 8 | FOLLOW-UP AND MONITORING

Biovigilance is vital in ART, especially with non-partner gamete donations, to ensure the safety of donors, recipients, and offspring. This involves diligent risk monitoring and managing adverse events, as well as proper storage of donor data. Long-term tracking of donor-conceived offspring is essential to identify health issues related to

the donation process. This includes monitoring for developmental and genetic conditions and offering ongoing care.  $^{22}$ 

The 5th edition of the *Guide to the Quality and Safety of Tissues and Cells for Human Application*, published by the European Directorate for the Quality of Medicines & HealthCare (EDQM), emphasizes the need for monitoring both short- and long-term risks. If a genetic condition is discovered in a donor after their gametes have been used, it must be reported as a serious adverse event because of its impact on recipients and offspring. The birth of a child with a genetic disorder inherited from the donor also requires reporting, but as a serious adverse reaction.<sup>10</sup>

The management of donor data varies by country. In Europe, donor information is stored either centrally or locally, with retention in the range of 30–110 years.<sup>22</sup> USA regulations, as per the Food and Drug Administration, require donor records to be maintained for at least 10 years, with some states requiring longer retention. Nevertheless, ASRM advocates for permanent record-keeping and emphasizes documenting clinical outcomes for future medical use.<sup>19</sup>

Donors should update their medical information if new relevant details arise and be aware that they may be contacted for additional information. Donors have the right to access their data under the European General Data Protection Regulation; however, regulations vary and may not cover new issues like direct-to-consumer genetic testing.<sup>22</sup>

Given the international nature of ART, cross-border cooperation is crucial. Effective communication between medical teams in different countries ensures proper follow-up and management of adverse events, addressing issues arising from "reproductive tourism" and varying legal standards. <sup>10</sup>

Recipients of donor gametes must be informed about medical and obstetric risks. Although donor-assisted ART cycles offer higher live birth rates compared to autologous cycles, there remain risks such as the transmission of infectious diseases and genetic conditions, which, although minimized through screening, cannot be completely eliminated.<sup>22</sup> Furthermore, women using donor oocytes should be aware of increased obstetric risks, such as pre-eclampsia and preterm birth.<sup>41-43</sup>

It is also important to highlight the importance of psychoeducational counseling for both donors and recipients, helping them understand the psychological implications of using donor gametes. <sup>19</sup> Counseling should also encourage parents to disclose donor conception to their children from an early age, promoting ongoing, age-appropriate disclosure. <sup>22</sup> Support should be tailored to different family types and cultures, with resources like literature and counseling made available.

Counseling for donor-conceived individuals should address their rights to information about donors, potential changes in anonymity laws, and the implications of contacting donors or discovering siblings. Access to supportive resources and understanding the limitations of information available is crucial.<sup>22</sup>

## 8.1 | Key recommendations

- Implement biovigilance to monitor risks and health issues for donors, recipients, and offspring.
- Report adverse events and reactions, including genetic conditions linked to donations.
- Ensure long-term storage and secure access to donor records, with updates as needed.
- Promote international cooperation among ART teams to ensure coordinated follow-up.
- Educate recipients on medical and obstetric risks and provide psychoeducational counseling.
- Support donor-conceived individuals with counseling and information on donor origins.

#### 9 | CONCLUSION

FIGO strongly advocates for a globally standardized approach to gamete donation that prioritizes ethical, legal, and medical considerations. We emphasize the importance of ensuring equitable access to gamete donation services, minimizing disparities based on economic, social, and cultural factors. We call for rigorous adherence to informed consent processes for both donors and recipients, ensuring transparency and autonomy in all decisions. The safety and quality of gamete donation procedures must be upheld through strict donor screening, quality control measures, and appropriate medical supervision. We recognize the growing challenges around confidentiality and anonymity, particularly with the rise of genetic databases, and advocate for the protection of privacy while balancing the rights of all parties involved. Acknowledging cultural and religious diversity is crucial in guiding respectful practices in gamete donation. We urge continued long-term follow-up of both donors and recipients to address medical, psychological, and obstetric risks, ensuring the ongoing health and well-being of all stakeholders. Through this position, FIGO aims to provide a comprehensive, ethically sound framework that supports safe and equitable gamete donation practices worldwide.

#### **AUTHOR CONTRIBUTIONS**

LH led the writing process. NP initiated the project and, with AA, supervised the work. DF, JM, SP, CS, AV, RZ, and NP contributed to the writing. MLH reviewed and revised the manuscript. All authors reviewed and approved the final manuscript.

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#### DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study

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