

ESHRE position paper: international limits on the number of offspring per gamete donor

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Background

Many people make use of donated gametes (sperm or oocytes) to conceive. Donor gametes may be used for a variety of reasons, such as impaired or absent ovarian function or sperm production, age-related fertility decline, relationship status, among others. While most European countries impose national limits on the number of offspring or families that can be created using gametes from a single donor in their country (see Appendix 1), there is no generally agreed international limit. Since the export of donor gametes to other countries is common practice, the lack of an international limit can lead to large groups of donor-conceived individuals from the same donor.

Recently, the national ethics councils of four Nordic countries (Denmark, Finland, Norway and Sweden) published a joint statement calling for an international limit on the number of children per sperm or oocyte donor [1]. The topic has also received broad public attention following a court case from 2023 in which a Dutch sperm donor was prohibited from making further donations after it was discovered that at least 550 people had been conceived using his sperm [2], and a more recent case whereby sperm from a donor with a rare cancer-causing gene was used for the conception of at least 67 children [3].

This position paper describes the relevant principles that should be considered in debates surrounding international limits on the number of offspring born from a single gamete donor and sets out the position of the European Society of Human Reproduction and Embryology (ESHRE) on this topic. It further proposes a number of policy recommendations on how to regulate the number of offspring per gamete donor, focusing on the European Union (EU) level.

There are implications of the language used when discussing donor conception, since different terms raise different connotations on the relations between the parties involved. Some organisations representing donor-conceived people do not agree with the use of the terms “donor” and “donation”, preferring, for instance, the term “genetic father” rather than “sperm donor” [4]. In contrast, donors and recipients may prefer terms that are not connotated with family relations. Recognising that there is no terminology preferred by all parties, we have opted to use the terms “donor”, “offspring”, “donor-conceived people” and “donor siblings” throughout this paper, since these terms are widely used and expected to be understood by most readers. The term “donor siblings” refers to donor-conceived people from the same donor.

Aspects to take into account when determining donor offspring limits

Psychosocial aspects

Contact between donor siblings: Many donor-conceived people find connections with donor siblings important, leading them to seek contact with each other through direct-to-consumer genetic testing and donor sibling registries with the aim to know the number of donor siblings and/or establish meaningful relationships. This contact is often perceived as positive and rewarding [5, 6]. However, if the search for donor siblings leads to the discovery of a large donor sibling network, it can be overwhelming, distressing, and difficult to navigate [7]. Moreover, not all donor-conceived people are

interested in a relationship with donor siblings. For these people, being found and contacted by a high number of donor siblings may be difficult. It is also important to take into account the time span and geographical spread of donations. Donated gametes can be cryopreserved and used over long periods of time, depending on storage time limits, potentially leading to large age gaps between donor siblings. Furthermore, the export of gametes can lead to a spread of donor siblings across the world. While some donor-conceived people may prefer a geographical spread rather than a concentration of donor siblings in the same area, this can make it more difficult to build a meaningful relationship for those who seek contact.

Contact between donor and offspring: While contact with the donor was not an option for most donor-conceived people a few decades ago, many countries now only allow identity-release donation, giving donor-conceived people access to identifying information on their donor at a certain age [8]. Even if this possibility is not provided, donor-conceived people are often able to identify their donor through genetic testing and internet research [9]. For those who hope to establish (ongoing) contact with the donor, a large number of offspring potentially lowers the chances of establishing such contact. For a donor, it might be difficult to respond to each contact request in a thoughtful way if there are a great number of offspring, let alone invest in an ongoing relationship with each of them. Just like with donor-conceived people, the discovery of a large number of offspring might feel overwhelming to donors. Donors might also be concerned about the impact of large offspring numbers on their own children. There are currently no studies indicating whether donors are more or less comfortable about their donation being used abroad or in their own country. While a certain distance between the donor and the recipient family may be perceived as beneficial to preserve the family unit, a geographical spread across countries could create difficulties for donors and offspring who are interested in contact with each other. Moreover, if donated gametes are cryopreserved and only used after a long time span, there is an increased risk that the donor is already deceased at the time when the offspring is old enough to consider seeking contact.

Uncertainty: The lack of an international donor offspring limit creates uncertainty for all parties. Donors cannot foresee the implications of their donation at the time when they donate and have to accept the possibility that they could always be contacted by additional offspring. Likewise, for donor-conceived people, the gradual discovery of more donor siblings over time and the uncertainty regarding the total number can be difficult to handle and cause stress [5, 10].

Sense of commodification: Some donor-conceived people have expressed feeling “mass-produced” or like a commodity when finding out about large numbers of donor siblings [10, 11].

Access to treatments with donor gametes

If international donor limits similar to current national limits are operationalised, fewer families can be created per donor, and unless donor recruitment can be increased quickly and substantially, patients will likely have to wait longer until they can get access to donor gametes, or they may not be able to access donor gametes at all. Even if the reduction in numbers of families per donor can be compensated for by recruiting more donors, the costs of fertility treatments with donor gametes are expected to increase, since the costs of recruiting and screening a gamete donor are distributed over fewer recipients. Longer waiting times and higher costs will exacerbate inequalities in access to fertility care and leave some patients unable to fulfil their wish for a child. An increase in the number of people who will resort to private donations outside of gamete banks and fertility clinics is also to be expected, which is associated with risks for all parties, such as the transmission of infections or serious genetic conditions, lack of clarity on the legal parental status of the donor and intended parents, and challenges

in upholding the right of donor-conceived people to access information on their genetic origin where this is provided for in the national legislation [12].

Genetic aspects

Consanguinity: The introduction of donor offspring limits at national levels has historically been justified by concerns on consanguinity, i.e., concerns that donor siblings might form romantic relationships without knowing about their genetic relation. Several studies have modelled the risk of consanguinity between donor-conceived people and identified very low risk levels, especially in the context of the international use of gametes where there is a wide geographical spread of donor siblings [13]. The risk of consanguinity is likely to be reduced even further by the increasing openness of parents to inform their children that they are donor-conceived and of donors to inform their own children about their donations, as well as increased access to genetic testing. Therefore, consanguinity is no longer such a pressing concern.

Propagation of genetic diseases: Cases of donors passing on a serious genetic condition to many offspring receive wide media attention and often fuel debates on donor offspring limits. However, for an individual recipient, the risk that a donor has a serious genetic condition is not related to such limits. From a public health perspective, there is also no relation between the number of offspring per donor and the overall prevalence of genetic conditions in the population [13]. While genetic conditions can never be fully prevented, the risk of genetic conditions is in fact often lower for donor-conceived people than for other people, as many (but not all) donors undergo genetic screening. In the EU, testing donors for potentially life-threatening, disabling or incapacitating genetic conditions with a significant prevalence in the donor population will become mandatory as of 2027 under the Substances of Human Origin (SoHO) Regulation. Therefore, the propagation of genetic diseases should not be considered a relevant factor when determining donor offspring limits.

Preferences of affected groups

Research on the preferences of donor-conceived people, donors and recipients regarding offspring limits is scarce and inconclusive. While a study of Danish sperm donors found that 71% of the donors were comfortable with offspring numbers above 100 or considered that the number does not matter [14], only 2.6% of the sperm donors in a Swedish study considered an unlimited offspring number acceptable. This study also included oocyte donors, finding that 15.9% of them considered an unlimited number of offspring acceptable [15]. One American study investigated the preferences of donors, donor-conceived people and recipients and found that a majority of respondents from all of these groups had a preference for having a limit over having no limit in place, with the preference for a limit being strongest among recipients and least pronounced among donors [16]. However, this study did not ask for any details on the preferred limit.

ESHRE has contacted stakeholders for their views on donor offspring limits and received responses from 11 organisations, including organisations representing donor-conceived people, donors and patients, as well as gamete banks. Organisations representing donor-conceived people, donors, and/or patients indicated preferred international limits ranging from two to ten families. In contrast, the gamete banks that were contacted indicated preferred international limits ranging from 60 families to no limits at all. Although not explicitly asked, some organisations have provided their position on the cross-border exchange of gametes. While two organisations of donor-conceived people stated that they oppose the exchange of gametes between countries, one patient organisation has advocated for the need to support access to gametes from other countries to ensure access to treatments for patients from countries with low donor numbers.

Practical aspects on compliance and enforcement

To monitor compliance with an international limit, authorities would have to assess whether donors have donated at different institutions within and across countries and combine information on the number of families resulting from these different donations. Currently, there is no centralised international registry with these data, and building an international donor registry that meets the data protection requirements imposed by the EU General Data Protection Regulation (GDPR) can be expected to be a challenging and time-consuming task. Even if a mechanism to monitor donations within and across different institutions and countries is established, limits can be undermined by the possibility of private donations outside of any institution. An additional challenge for monitoring offspring limits lies in the need to follow up on treatment outcomes, since not all treatments with donor gametes result in the birth of offspring. If only live births are counted that are proactively reported back to gamete banks, this may lead to the limit being exceeded in case of low reporting levels. Therefore, it is important to consider how families are counted and to ensure that clinics follow up with patients and report back on treatment outcomes to gamete banks.

Legal aspects

A worldwide limit could legally only be achieved through an international treaty, which would require immense political efforts and only have limited possibilities of enforcement. Instead of an international treaty, an EU-wide limit could represent a feasible first step towards an international limit. Such a limit could be implemented as an additional standard for offspring protection under the EU SoHO Regulation, which could be added through a delegated act in line with article 58(16). When determining the feasibility of EU legal action, it is important to carefully consider the principles of conferral, subsidiarity and proportionality. A discussion on the application of these three principles is provided in Appendix 2.

ESHRE position and policy recommendations

ESHRE considers that the wellbeing of donor-conceived people should have the highest priority when determining limits on the number of offspring per gamete donor. Such limits will have a direct effect on donor-conceived people by determining the number of genetic relations that they might have. While the same is true for gamete donors, donors consciously choose to engage in gamete donation, whereas donor-conceived people cannot be asked for consent on the conditions of their conception. Nonetheless, other aspects, such as considerations on access to treatment, also need to be taken into account and balanced. Based on these considerations, we have formulated the following position and recommendations:

Setting an international limit

- ESHRE is in favour of setting an international limit on the number of offspring per donor to reduce feelings of uncertainty, overwhelm and commodification among donor-conceived people and donors and provide clarity and security of expectations to all parties. As there is currently no international body that can impose a worldwide limit, we call on the EU to start by introducing an EU-wide limit.
- Any limit on the number offspring per donor should be set in terms of the number of families rather than the number of individual children born. This is important to ensure that recipients can always use their cryopreserved embryos, independent of how many children were born in other families. Moreover, families may prefer using gametes from the same donor for all their

children for various reasons, such as the consideration that this may strengthen the sibling bond or the wish to minimise the number of donors and donor siblings with whom relations may need to be managed in case their children are interested in seeking contact. Allowing families to keep using gametes from the same donor gives them reproductive agency over their own family planning.

- All donors should be offered the possibility to set a lower limit for the number of families that can be created with their own gametes than the one that is mandated by regulations.
- ESHRE is not in favour of restricting the cross-border exchange of gametes. Particularly within the EU, where people, services and goods can move freely between countries, we call for a harmonised EU-wide framework rather than focusing on national borders.
- ESHRE recommends the immediate introduction of an EU-wide limit of 50 families per donor. A 50-family limit is considered feasible for immediate implementation, as it is in line with current self-imposed limits of several gamete banks [1, 17]. At the same time, it would already constitute a major improvement compared to the current situation where some gamete banks apply self-imposed limits as high as 75 families or have no self-imposed limits at all [18]. This international limit is not intended to replace national limits, but rather to complement them. Current national limits should still be upheld if they are lower. Gamete banks that already operate below a 50-family limit are recognised for their good practice and encouraged to maintain it. ESHRE ultimately supports a maximum international limit of 15 families or lower per gamete donor. The initial 50-family limit should be gradually reduced towards this limit, alongside a continuous monitoring of the impact of the limit on access to treatments with donor gametes. A first evaluation on whether the 50-family limit can be reduced further should take place after three years. During the transition period, further research should be conducted on the ultimate ideal limit and if needed, the proposed 15-family limit should be revised in line with updated knowledge.
- Until obligatory international limits are introduced, ESHRE calls on gamete banks to self-impose the recommended limits and on fertility clinics to only collaborate with banks that apply the proposed limits.
- To avoid large age gaps between donor siblings and between donor-conceived people and their donors, gametes should no longer be distributed to new families after 20 years following the first donation (as this can be considered the timespan of a generation).
- Efforts should be made to increase the donor pool to avoid shortages that reduce access to treatments with donor gametes, and to avoid that patients move to unregulated private donations. Similar measures should be taken as for the supply continuity of critical SoHO, e.g., facilitating public participation in donation programmes and putting in place donor recruitment strategies including communication campaigns and education programmes.

Monitoring compliance

- The EU should set a legal basis for an EU-wide donor registry to monitor donations within the EU, including gamete imports from non-EU countries. It should be explored whether this registry could give access to some information to donors on their offspring and to donor-conceived people on their donor and donor siblings, such as the year of birth, country of birth and sex. The option of using this registry to provide access for donor-conceived people to find out the identity of their donor (where allowed in the applicable national legislation) could also be explored.

- Before an EU-wide donor registry is in place, gamete banks should already be obliged to comply with the limit in their own distribution of gametes. This requirement should also apply to banks outside of the EU as a pre-requisite to be able to import gametes into the EU.
- Donors should be required to provide a signed declaration disclosing all previous donations and confirming their commitment to refrain from making private (unregulated) donations. If the number of families resulting from previous donations is not known, banks/clinics should not accept donors for further donations, as there is a significant risk of exceeding the set limits.
- Where monitoring systems across banks are available, e.g., within a group of banks from the same operator or through an existing national registry, it should be ensured that the limit per donor is upheld across all banks that can be monitored together.
- In the absence of knowledge on whether a live birth took place, the number of families to whom gametes were distributed should be counted to ensure that the family limit is never exceeded. Only if it is known that a donation did not result in a live birth and a family has no more cryopreserved embryos created with gametes from the donor should that family be removed from the count and further gametes be distributed to another family. This system is already in place in many gamete banks, who require clinics to purchase a “pregnancy slot” for each recipient, which is then only released if it is known that the donation did not lead to a child.

Counselling and informed consent

- Donors and recipients should be informed about applicable offspring limits prior to the donation/donor treatment. If no international limit is in place at the time of the donation, the possibility of large numbers of offspring should be emphasised [19].

242 **Appendix 1: National donor offspring limits in EU/EEA countries**

Country	Maximum number of children per sperm donor	Maximum number of children per oocyte donor
Austria	3	3
Belgium	Children in 6 families	Children in 6 families
Bulgaria	5	5
Croatia	3	3
Cyprus	Children in 1 family	Children in 1 family
Czech Republic		
Denmark	Children in 12 families	
Estonia	Children of 6 different women	Children of 6 different women
Finland	Children of 5 different women	Children of 5 different women
France	10	10
Germany	15 (recommended)	
Greece	10	10
Hungary	Yes (value not disclosed)	
Iceland	Children in 2 families (in practice, not by law)	Children in 2 families
Ireland	Children in 4 families (recommended)	Children in 4 families (recommended)
Italy	10	10
Latvia	3	3
Liechtenstein	Not known	Not known
Lithuania	5	5
Luxembourg	3	
Malta		
Norway	Children in 6 families	
Poland	10	10
Portugal	Children in 8 families	
Romania	5 (recommended)	5 (recommended)
Slovakia	3–5 (recommended)	3–5 (recommended)
Slovenia	Children in 2 families	Children in 2 families
Spain	6*	6
Sweden	Children in 6 families	Children in 6 families
The Netherlands	Children in 12 families	
* Spain: including children of the family of the donor		

243 Sources: [8] & results of a joint survey of the Council of Europe and ESHRE currently under preparation
244 for publication

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Appendix 2: Discussion on EU legal principles

Conferral: Based on the principle of conferral, the EU can only act within the limits of the competences that EU Member States have conferred upon it in the treaties [20]. Article 168 of the Treaty on the Functioning of the European Union (TFEU) states that “a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities”. Moreover, it assigns a legal competence to the EU to adopt measures setting high standards of quality and safety of organs and substances of human origin. The recently adopted EU Regulation 2024/1938 on standards of quality and safety for substances of human origin intended for human application (SoHO Regulation) is based on this article and already includes a provision on the enforcement of national donor offspring limits in article 58(10), demonstrating that the topic can be considered within the scope of EU legal competence. The SoHO Regulation further states that “[...] SoHO entities shall mitigate any other avoidable risk to the health, including where related to the protection of dignity, in accordance with national law, of SoHO recipients or of offspring from medically assisted reproduction [...] ” (article 58(9)), clearly going beyond the mere protection from physical health risks in its scope.

Subsidiarity: The principle of subsidiarity states that the EU shall only intervene when the objectives of an action cannot be sufficiently achieved by the Member States [21]. Currently, donor offspring limits are set within the national legislations of EU Member States. If all EU Member States adopted a national limit, the sum of these limits would effectively represent an EU-wide donor offspring limit. However, there is an inherent limitation to the maximum limit that can be reached in this manner. Even if each EU Member State implemented a national limit of only one family per donor, this would imply a 27-family limit at EU level, far surpassing the preferred limit of stakeholder groups. Moreover, there are challenges to the enforcement of national limits when donors, recipients, and gametes move between Member States. Recipients frequently travel across borders for treatments with donor gametes, in which case their country of residence has no possibility to enforce the offspring limits in their country. Moreover, when gametes are exchanged between Member States, the competent authority that regulates the distributing gamete bank does not have a mandate to enforce the national regulations of the receiving country. This challenge was demonstrated in a recent case where a Danish sperm bank distributed sperm from the same donor to 14 different fertility clinics in Belgium, leading to a number of families created with sperm from this donor that far surpassed the Belgian national limit of six families [22]. In conclusion, national action is unlikely to be sufficient for effectively limiting the number of offspring per donor in the EU.

Proportionality: Under the principle of proportionality, EU measures must be suitable and necessary to achieve the desired end and must not impose a burden on the individual that is excessive in relation to the objective sought to be achieved [23]. Setting an EU-wide donor offspring limit is likely suitable to reduce feelings of uncertainty, overwhelm and commodification among donor-conceived people and to increase the clarity and security of expectations of all parties. The need for donor offspring limits is already recognised in the national legislations of most EU Member States (see Appendix 1), but as described above, an EU-wide limit is necessary due to the movement of people and gametes across the EU. A donor offspring limit might impose a burden, particularly on individuals who cannot become pregnant without the use of donor gametes. However, the aim to provide access to treatment for these individuals must be balanced against the welfare of the offspring. Access to treatment can also be enhanced through measures to increase the donor pool rather than through unlimited use of gametes from the same donor, thereby respecting the mental health and dignity of offspring.

A proportionality analysis also needs to consider the impact of an EU-wide donor registry on the privacy of donors, recipients and donor-conceived people. An EU-wide donor registry is suitable to monitor adherence to an EU-wide donor offspring limit and it is also necessary, since national registries cannot

account for the movement of donors, recipients and gametes between Member States. In the EU, there are high data protection standards set in the General Data Protection Regulation (GDPR) that ensure that personalised data is handled responsibly and with as little risk for the data subjects as possible. In accordance with the GDPR, an EU-wide donor registry would need to be set up in line with the principle of data minimisation, collecting only those data that are strictly necessary to monitor adherence to the offspring limit. These data would most likely need to include identifiable data on donors to ensure that a donor cannot surpass the limit by donating at several institutions. However, gamete donation is based on a free and voluntary decision and donors who have strong privacy concerns can always decide against donating. In contrast, a strong desire for a child may cause recipients to pursue treatment with donor gametes despite substantial privacy concerns, and donor-conceived people have no choice at all about the data that is recorded about them at birth. It should be explored whether fully anonymous data on these groups could be sufficient to achieve the objective to monitor offspring numbers.

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