

## CONFIDENTIALITY IN ASSISTED REPRODUCTION: ARE THERE EXCEPTIONS?

### CLINICAL CASE

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Marco, and Lucia underwent an assisted reproductive treatment that required an egg donation. The donated oocytes were subjected to genetic analysis to exclude heterozygous mutations in genes associated with significant autosomal recessive disorders. No mutations with a potential phenotypic effect were detected in the regions analyzed. Fertilization was then carried out, and two embryos were transferred. The procedure was successful, resulting in a twin pregnancy. At 20 weeks and 1 day of gestation, a routine ultrasound examination revealed that one of the fetuses presented with Tetralogy of Fallot. Subsequent genetic testing of both fetuses identified two variants in the GDF1 gene-one classified as pathogenic and the other as a variant of uncertain significance (VUS). Genetic counseling recommended carrier testing to determine the origin of these variants. Consequently, genetic studies were performed on the father and the oocyte donor, who had no known prior medical history. The analysis confirmed that the donor was a carrier of both GDF1 variants identified in the affected fetus- the pathogenic variant and the one of uncertain significance. It remains unclear whether the mutation identified is hereditary (inherited from the donor) or spontaneous (de novo, not maternally inherited). Upon receiving the results, the attending gynecologist, Dr Bravo, reviewed whether other couples had received gametes from the same donor and confirmed that Marco and Lucia were the first recipients. Dr Bravo now faces a dilemma of whether he should inform the donor about the genetic alterations detected in her oocytes. His uncertainty is heightened by the fact that the hereditary nature of the mutation has not yet been established.

### ETHICAL ANALYSIS OF THE CASE

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In this case, the principles of privacy and donor data confidentiality come into conflict with the potential need to safeguard the donor's own health or that of her biological descendants. The donor is presumed to be healthy, as no evidence of cardiac pathology was identified at the time of oocyte donation. However, if the mutation were hereditary, a fact that remains uncertain, there is a possibility that her offspring could be affected by the genetic alteration.

Can the confidentiality of egg donors be breached? The Assisted Reproduction Act (Law 14/2006, May 26th, on Assisted Human Reproduction Techniques) stipulates that gamete donation must be anonymous and guarantees the confidentiality of donor identity data. Nevertheless, the law establishes exceptions to this anonymity. In extraordinary circumstances, specifically those involving a risk to the life or health of the child born from the donation, or

when required under criminal procedural law, the disclosure of the donor's identity may be authorized. Such disclosure must be narrowly confined to the relevant context and must not involve any public release of personal data.

Therefore, the law does not explicitly allow for the revelation of a donor's information in cases involving the discovery of a genetic alteration that could potentially affect the donor's own descendants.

### **POSSIBLE COURSES OF ACTION**

- Do not inform the donor, because confidentiality must be protected in this case.
- Locate her by all available means.
- Once located, inform her directly of the results and the possible consequences in the event of pregnancy.
- Once located, ask her if she wishes to know about genetic data found in her oocytes that may affect her future offspring. Respect her decision about whether to be informed.
- If she wishes to be informed, ask her if she has donated more gametes at other centers, in order to locate other possible oocytes affected by the mutation. If so, inform the other centers.
- If there are other families (at the same center or another) who have used gametes from the donor, report the case to the center so that they can inform the recipients.

### **RECOMMEND COURSE OF ACTION**

- Firstly, the center's management must be informed so that the necessary arrangements can be made to locate the donor. The clinic should try to contact her through the official channels of the gamete bank to inform her of the findings, obtain information about other possible donations, and carry out genetic tests to confirm that the mutation is inherited, as it is possible that the mutation occurred spontaneously.
- In any case, the patient's wishes should be respected if she doesn't want to be informed.
- It is advisable to arrange a face-to-face appointment to explain the genetic results found.
- If the patient is a carrier of the mutation and there have been other donations within the same center, the families should be informed.
- If it is confirmed that she carries the mutation, in addition to informing the patient of the consequences for her future offspring, she should be asked about other possible donations she may have made to other centers, so that they can take the appropriate measures, whether fertilization has already taken place (notify the parents) or if it has not yet taken place (do not use these oocytes, or use them after genetic analysis to rule out that they are carriers of the mutation).
- Regardless, throughout the process the donor's privacy will be protected and confidentiality maintained.

## **DISCUSSION**

Law 14/2006 on Assisted Reproduction stipulates that both egg and sperm donation must remain anonymous, and that gamete banks as well as fertility clinics are legally required to protect donor identity. However, the law does allow for narrowly defined exceptions to this anonymity. In exceptional circumstances, such as when there is a serious risk to the health or life of the child born from the donation, or when disclosure is mandated by a judicial investigation, the donor's identity may be revealed.

Based on this legal framework, it's important to note that the health or life of the unborn child is not currently at risk, as the fetus has not been born yet and disclosure of the donor's identity would not alter the prognosis of the fetus affected by Tetralogy of Fallot. However, informing the donor of the genetic mutation she carries could help safeguard the health of her potential offspring. Additionally, it could also benefit other individuals undergoing assisted reproduction who may have received oocytes from the same donor, including those from other centers. Furthermore, identifying and informing the donor would uphold her right to access relevant health information, to receive truthful medical disclosure and to maintain trust in healthcare professionals. Conversely, if she is not informed, her choice to remain as an anonymous donor is fully respected, as is the confidentiality that protects donors and is required in this type of procedure.

When considering this case in its entirety, there are compelling reasons to locate the donor, even though there is no legal obligation to do so. Importantly, before any disclosure is made the donor should first be asked whether she wishes to receive the genetic information related to her donated oocytes. The law does not explicitly require that other couples who have received gametes from the same donor be informed. However, if the mutation is confirmed to be hereditary, it would be appropriate to notify them, given the potential risk to the health of their children. Informing these parents would represent a proportionate and justified measure, as it serves to protect both the health of the children and the parent's right to information.

**Sgd.:** ASISA-Lavinia Bioethics and Health Law Committee  
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