ESHRE position paper on gamete donor compensation



A significant number of patients relying on Medically Assisted reproduction (MAR) pursue gamete donor conception, i.e. conception with donated sperm or eggs. Donor conception may be used for a variety of reasons, such as impaired ovarian function or sperm production, age-related fertility decline, relationship status, etc.

In most EU Member States, gamete donors receive some form of compensation or reimbursement for their donation. The EU Tissues and Cells Directive (Directive 2004/23/EC) states that "Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells". It further elaborates: "Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted." In practice, this has resulted in substantial differences between the levels of compensation offered to donors in different Member States.

On 6 August 2024, the EU regulation 2024/1938 on standards of quality and safety for substances of human origin (SoHO Regulation) entered into force, which states: "Where Member States allow for the compensation of living SoHO donors, in accordance with the principle of voluntary and unpaid donation and based on transparent criteria, including through fixed allowances, or through non-financial forms of compensation, the conditions for such compensation shall be established in national legislation, including by setting an upper limit for compensation that shall endeavour to guarantee financial neutrality" (article 54). This provision will become applicable on 7 August 2027.

The present position paper describes relevant ethical considerations related to gamete donor compensation and principles that Member States should take into account when determining an appropriate upper limit for compensation that gamete donors should receive for their donation.

DEFINITIONS AND TERMINOLOGY: REIMBURSEMENT, COMPENSATION AND FINANCIAL INCENTIVES

When discussing payments to gamete donors, it is important to distinguish between reimbursement, compensation and financial incentives. Reimbursement relates to covering the actual expenses incurred by a donor for their donation, such as costs for travelling to the clinic or gamete bank or the costs of any medication needed for the donation. Compensation relates to covering any additional losses associated with the donation, such as lost earnings, time investment and inconvenience. The aim of reimbursement and compensation is to ensure that donors do not incur any substantial financial gain or loss from the donation (financial neutrality). Any payment beyond reimbursement and compensation would imply a net financial gain for the donor and could therefore constitute a financial incentive to donate.

ETHICAL CONSIDERATIONS

Commodification

Article 3 of the EU Charter of Fundamental Rights prohibits "making the human body and its parts as such a source of financial gain". Thus, donors should never be paid for the donated material itself and compensation should be independent from the amount and quality of the material obtained from them. However, this article does not exclude payment for effort, time investment and inconvenience linked to the donation.

Fair compensation vs undue inducement

Gamete donation is typically altruistic, aimed at benefiting someone else. Nevertheless, since donors invest time and effort and subject themselves to inconvenience when donating, it can be considered fair that they receive some form of compensation. The concern, however, is that when large amounts of compensation are offered for non-financial losses, people with economic vulnerabilities may decide to become a donor against their best judgement to obtain a financial benefit. This is when the



compensation becomes so-called "undue inducement" which may lead to exploitation. The difficulty is that there is no cutoff-point between the two categories, as what one person considers fair compensation can equally be an undue inducement for someone else, creating a grey area. The field of MAR in Europe has traditionally allowed limited compensation in an effort to balance the aim to provide a fair compensation with the aim to avoid undue inducement for donors.

Safety

The offer of a financial incentive might lead donors to conceal relevant information in the assessment of their eligibility to donate. This may reduce the safety of the donation. For example, donors might not inform their clinicians about previous donations or risk factors for complications, or they might conceal information related to an increased risk of transmitting an infectious or genetic disease.

It is important to bear in mind that avoiding a financial incentive alone is not sufficient to achieve safe gamete donation and to avoid exploitation of donors. To maximise safety, donors should be tested for infectious and genetic diseases whenever possible rather than relying on self-reported information. For donor protection, relevant measures also include counselling future donors on benefits and risks, identifying and minimising risks to make the donation as safe as possible, and limiting the number of possible donations per donor. In order to ensure the highest level of safety, comprehensive registries will be required at national and European levels.

ESHRE POSITION AND RECOMMENDATIONS

ESHRE supports the SoHO regulation's aim for financial neutrality. Donation should never be for financial gain, but ESHRE supports compensating donors for losses of income and for their time and effort for reasons of fairness and in order to remove potential barriers to donation.

ESHRE is concerned about the current differences between donor compensation amounts in European countries, since they can lead to cross-border donation. This can increase the risk of insufficient health monitoring and follow-up, language barriers, and targeting of vulnerable populations.

ESHRE also supports countries being obliged to set upper limits for donor compensation under the SoHO Regulation, and recommends that Member States take the following aspects into account when determining these upper limits:

- To offset any losses associated with the donation, compensation should reflect actual expenses, time
 invested and inconvenience incurred by donors.
- Upper limits should be **specific to the type of donation**. For instance, higher compensation for oocyte donors than for sperm donors is justified, since an oocyte donation is usually associated with higher actual costs, requires a bigger time investment, and is more inconvenient for the donor.
- The compensation for time and effort should be determined based on a **transparent indicator**, such as the Gross Domestic Product (GDP) per capita of the country.

ABOUT ESHRE

ESHRE is a European non-profit organisation with international membership, whose main mission is to promote the study and research of reproductive science and medicine as well as the treatment of infertility. Established in 1984, the Society now comprises more than 9.000 members and has become the leading Society in reproductive science and medicine worldwide. Our members are medical professionals, scientists and researchers working in reproductive science, reproductive medicine and embryology. We work in close partnership with the patient organisation Fertility Europe.

For further information, please contact Johanna Tassot, Policy Officer: johanna@eshre.eu

