

DONATION OF OOCYTES

A guide for women
to support informed
decisions



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This guide has been drawn up by the Council
of Europe European Committee
on Organ Transplantation (CD-P-TO).
For more information, please visit
<https://go.edqm.eu/transplantation>.

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INTRODUCTION

Most women can become pregnant and have a child naturally. However, others may need help in their desire to become parents. For some of them, giving birth may only be possible thanks to the generosity of another woman who is willing to donate her oocytes. The aim of this guide is to support informed decisions of oocyte donors, who may be facing questions of whether oocyte donation is safe, about future implications and, in the end, whether it is the right choice for them.

This guide has been prepared by the Council of Europe **European Committee on Organ Transplantation (CD-P-TO)**, composed of internationally recognised experts, in collaboration with the **European Society of Human Reproduction and Embryology (ESHRE)**, to provide clear, accurate and balanced information about the donation of oocytes.

The information included in this guide provides a general overview of the process of oocyte donation. However, practices and national or regional regulations may differ in different countries and women should consult their clinic and/or national Health Authority to find out more about the specific situation in the country where they are considering donating.



WHO NEEDS DONATED OOCYTES?

It is estimated that around 10-15% of individuals or couples of child-bearing age, at some time, have problems in becoming pregnant. There are several reasons for this – of both male and female origin – but a majority of fertility problems can now be treated with the help of modern techniques. Most of these assisted reproduction techniques involve treatment with the woman's own oocytes (also known as egg cells), but sometimes certain fertility problems may prevent women from using their own oocytes. This includes women with no ovaries or functional oocytes (for example women with Turner syndrome or galactosaemia).

Ovarian function may also have been harmed by the use of chemotherapy or radiotherapy when treating certain cancers, or autoimmune conditions such as rheumatoid arthritis. Other conditions in which donated oocytes may be necessary are cases of severe heritable genetic disease in which there is a risk of transmission to the children. Another reason for needing oocyte donation may be premature menopause, usually defined as the stopping of menstrual periods before the age of 40, or the natural reduction of oocytes which comes with age. Studies show that after the age of 36, women experience a marked loss of fertility because the number and quality of their oocytes decline.



Some reasons for needing donated oocytes include:

- ✓ When a woman has no oocytes, or only oocytes of poor quality
- ✓ In premature menopause
- ✓ To avoid transmission of genetic diseases
- ✓ For age-related infertility

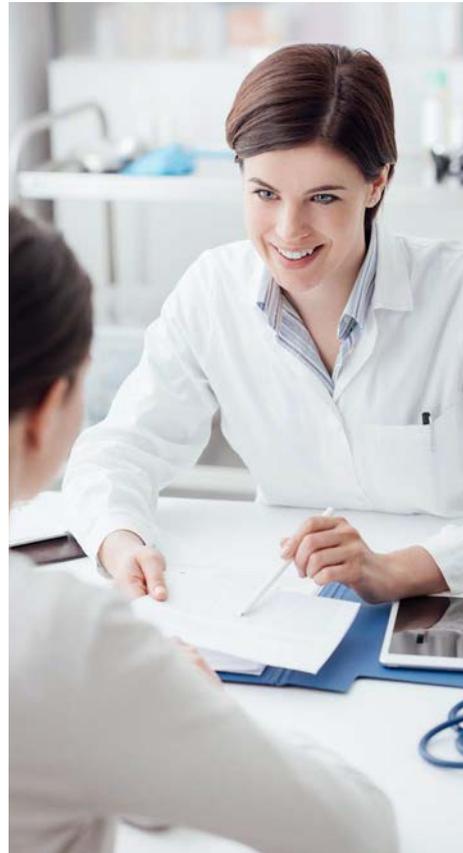
WHAT ARE THE STEPS TO BECOME AN OOCYTE DONOR?

Women contacting a fertility treatment centre to donate oocytes will be interviewed about their personal and family medical history. All potential donors will have to fulfil certain criteria to confirm suitability. These criteria mainly involve general health status (including genetic and infectious disease) and age, but limitations to donation may differ in different countries according to national legislation.

Blood tests and physical examinations are performed to rule out any contraindication for donation. This initial screening is performed to ensure the donors' personal safety, to minimise the risk of transmission of any infectious disease to the recipient, and to maximise the health of babies born as a result of the treatment.

Potential donors should also receive medical and psychological counselling to ensure that all implications and consequences of a donation are fully understood. Counselling should provide details about the procedure and, in particular, about any risks associated with ovarian stimulation and oocyte retrieval. It is also essential for the donor to be informed of and fully understand the legal implications of the donation, which may involve donor identity or anonymity depending on the national regulations. It is therefore important to ask as many questions as possible of the fertility clinic, and in case of any doubt, to contact the national Health authorities.

Oocyte donation is a voluntary and altruistic gesture with the sole aim of helping others.



Nonetheless, financial compensation to cover expenses and time is usually provided.

Before donating their oocytes, and after having received all information, all donors are asked to sign a written consent form. This consent may be withdrawn by the donor up to the moment that the oocytes are used for fertilisation. Thereafter the oocytes belong to the recipient individual or couple.

The use of donated oocytes is a successful and rapidly increasing means for treating certain kinds of female infertility.

56,516 oocyte donation treatment cycles were registered in Europe in 2014, amounting to approximately 7.5% of all assisted reproduction treatments.

CAN ALL WOMEN DONATE THEIR OOCYTES?

Women over 18 may be considered as oocyte donors. Because oocytes become less viable with increasing female age, younger donors are usually preferred. Age limits may vary from country to country, and even between clinics, but donors are seldom accepted above the age of 35.

All donors must be screened as healthy, not suffering from a medical condition that may involve a risk during the ovarian stimulation or oocyte collection procedures. Infectious and genetic diseases must be ruled out to protect the oocyte recipient and future children.

Some European countries have legislation on the maximum number of times a woman can donate oocytes. Some also set limits on the number of children allowed per donor; this is to minimise the risk of these children meeting genetic half-siblings in the future.

WHAT DOES IT MEAN TO BE AN OOCYTE DONOR?

The term ‘donation’ implies an altruistic act of giving without personal gain. The donation of oocytes, which are given for the use of another individual or couple, differs from that of other tissues or cells in that the genetic information (the DNA) of the donor oocytes will be transmitted to any children born as a result of that donation. These children will thereby be genetically related to the donor and her family, including the donor’s own children and their offspring.

The wish to help others become parents through oocyte donation is a personal decision. However, in the end, it often also impacts the present or future partner of the donor, or even other family members. It is therefore important that donors consider their decision carefully and discuss it with those close to them.

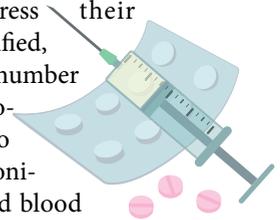


HOW ARE THE OOCYTES OBTAINED?

Hormonal stimulation and maturation of oocytes



To have complete control of the hormonal stimulation process, donors are given medication to suppress their natural hormone production. Once this is verified, hormonal injections are given to boost the number of oocytes produced by the ovaries. This procedure, which is the same as for routine in vitro fertilisation, lasts around 8-12 days and is monitored by vaginal ultrasound examinations and blood samples. These tests help physicians to determine when the oocytes are ready for retrieval. A number of visits to the clinic will be necessary during this time.



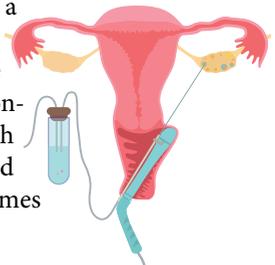
Monitoring and visits to the clinic



Oocyte collection



Approximately 36 hours before oocyte retrieval, donors are given a hormone injection to help the oocytes mature. Oocytes are then collected from the ovaries by insertion of a vaginal ultrasound probe. A needle is guided through the vaginal wall and the oocytes are aspirated one at a time through the needle connected to a suction device. This procedure, which takes around half an hour, is usually performed under local anaesthesia and sedation, or sometimes under general anaesthesia.



Health status of the donor followed up by the medical team of the fertility clinic where the donation was performed.

WHAT ARE THE POTENTIAL RISKS FOR AN OOCYTE DONOR?

Donating oocytes is generally very safe; most women won't experience any health problems beyond the discomfort of having the treatment itself. The only potential risk to be aware of is having a possible reaction to the fertility drugs. Normally if this happens the effects are mild and include hot flushes, feeling irritable or down, headaches and restlessness.

The most important possible medical complication during the ovarian stimulation is ovarian hyperstimulation syndrome, a condition in which the ovaries show an excessive response to the hormonal treatment and become swollen and painful. Up to 30% of women undergoing ovarian stimulation have a mild case of hyperstimulation where symptoms may include a swollen stomach and stomach pains, which can be managed with ordinary painkillers.

In extreme cases, nausea, vomiting, breathlessness, fainting, a swollen stomach and reduced urine may be experienced. However, because of the special stimulation protocol for oocyte donors, the extreme form of ovarian hyperstimulation has now become very rare. In any case, if donors have any reactions to their fertility drugs it is very important that they contact their clinic immediately.

During the oocyte retrieval, removing the oocytes through the aspirating needle can involve a slight risk of bleeding or infection. There can be mild discomfort after the procedure that should disappear within a few hours after the procedure.



There may be other consequences for the donor, such as the psychological impact of any later infertility, or the possible revelation of abnormal medical or genetic results from the donor screening tests.

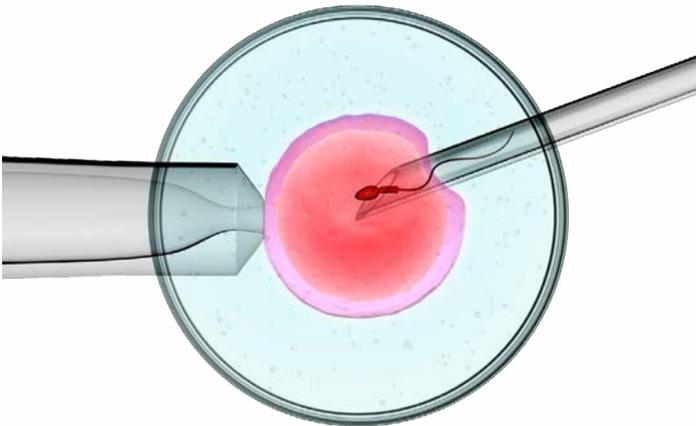
Donating oocytes does not decrease the chances of conceiving and having children in the future. There have been reports of an association between ovarian stimulation and ovarian cancer, but numerous recent studies have found no such link.

HOW CAN DONATED OOCYTES BE USED?

The retrieved oocytes can either be cryopreserved (frozen) directly on the day of retrieval for later use or fertilised directly after collection.

Fresh or frozen-thawed oocytes can be fertilised with sperm from the partner of the oocyte recipient or with donor sperm. Oocytes from one oocyte donation can also be used for several recipients, depending on the number of retrieved oocytes and the policy of the donation programme.

If several embryos of good quality are obtained after fertilisation some can also be frozen for later use by the recipient.



WHERE TO DONATE?

Women who want to donate oocytes will need to contact a fertility clinic which is authorised by the regional or national Health Authorities to perform oocyte retrieval and storage, as well as fertility treatments involving donated oocytes. These clinics must follow strict medical, legal and ethical standards to ensure that the donation procedure is safe and consistent with the legislation in place in that jurisdiction. Information about the authorisation status of each clinic is available from National Health Authorities.

ANONYMITY OR DISCLOSED IDENTITY?

Before donating oocytes, it is important that donors become familiar with the regulations on donor identity and anonymity in the country where they plan to donate, as national regulations are different from country to country (even within Europe). This information can be provided by the clinic where the donation procedure will take place and from the national Health Authority.

In most countries the donation itself is an anonymous procedure, meaning that the donor will not know who receives the oocytes, and the receiving women/couples will not know who the oocytes came from.

In some countries, so-called non-anonymous 'direct donation' of oocytes is allowed. In this setting, the donor donates her oocytes to a relative or friend of hers. Thus, the origin and the destination of the oocytes are known to everyone involved.

Regarding disclosure of the donor's identity to the children born from donated oocytes, the situation varies from country to country. In some countries, persons born from donated oocytes are not able to request any information

about the donor's identity. Nonetheless, it is important to take into account that with the development of new technologies related to genetic testing, it may not be possible to guarantee donor anonymity in the future.

On the other hand, in some countries children born as a result of the donation have the legal right to request information about the donor's identity when coming of age, usually at around 18 years of age.

What does the law say?

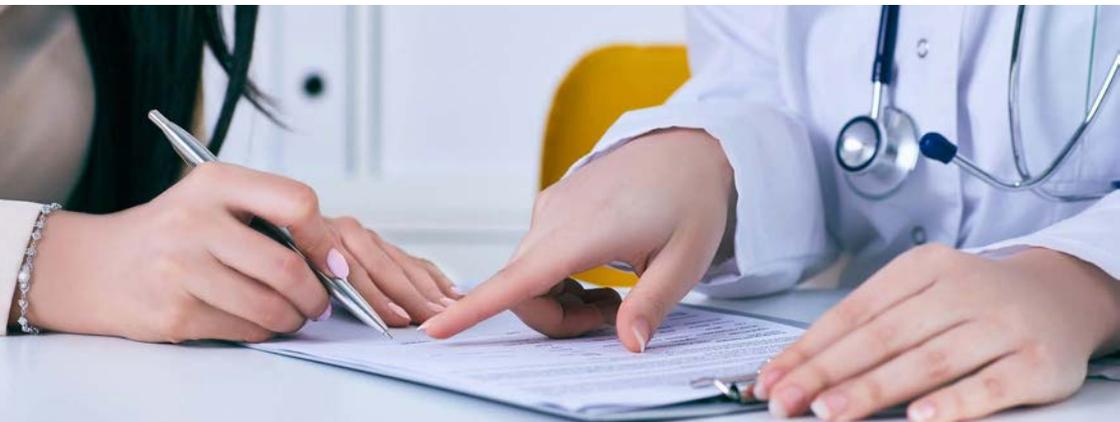
Regulations in Europe concerning oocyte donation vary considerably. What and how donors are allowed to donate may be restricted in some countries.

If you wish to receive further information about the legal provisions in your country, contact your national Health Authority.

WHAT ARE THE RIGHTS AND RESPONSIBILITIES OF AN OOCYTE DONOR?

An oocyte donor should be aware that:

- ✓ she will not be the legal parent of any child born as a result of the oocyte donation
- ✓ she will have no legal or financial obligation to any child born from the oocyte donation
- ✓ she will not be named on the child's birth certificate
- ✓ she will not have any rights over how the child will be brought up
- ✓ in some countries allowing disclosed identity of the donor, children born from donor oocytes may have the right to receive identifying information about the donor



Donors also have a responsibility to disclose accurate information about their own and their family's medical history before, during and after treatment, and to maintain a healthy lifestyle during the donation process.

ARE THERE ANY COSTS INVOLVED IN DONATING?

Donation of cells and tissues must be voluntary and altruistic (i.e. in the absence of any undue influence and without any financial gain or comparable advantage). However, this does not prevent the reimbursement of justifiable expenses related to the donation itself (for example, travel, medication) or compensation for loss of earnings. These costs may be calculated differently in different countries or donation programmes: some will ask for receipts to justify the expenses while others will give a fixed sum per donation to cover all costs.

Information about the regulations regarding reimbursement and compensation of costs that apply in each case should be made available through the clinic and/or the appropriate Health Authority.

SUMMARY OF THE PROCESS FOR DONATING OOCYTES

PREPARATION

1



- ✓ Information about the donation procedure
- ✓ Medical check-up and family and personal history
- ✓ Psychological counselling
- ✓ Decision, signed consent

OVARIAN STIMULATION

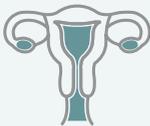
2



- ✓ Suppression of natural hormone production
- ✓ Hormonal injections to boost the production of oocytes
- ✓ Ultrasound examinations, blood sampling
- ✓ Maturation of oocytes

OOCYTE RETRIEVAL

3



- ✓ Local anaesthesia, light sedation
- ✓ Collection of oocytes via vaginal needle
- ✓ Oocytes transferred to special medium
- ✓ Oocytes frozen or fertilised

FERTILISATION

4



- ✓ Fertilisation with sperm (time point where withdrawal of consent is no longer possible)

TAKE-HOME MESSAGE

Choosing to donate oocytes to someone in need is a generous act that gives hope to all the women who are unable to become pregnant using their own oocytes. However, as with any other living donation procedure, it is not without risks and donors need to consider all potential implications. Thus, before deciding to take this step, women need to carefully balance if this is the right choice for them.

We hope the information provided in this brochure will help women through this important decision-making process.

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The Council of Europe is the continent's leading human rights organisation. It comprises 47 member states, including all members of the European Union. The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a directorate of the Council of Europe. Its mission is to contribute to the basic human right of access to good quality medicines and healthcare and to promote and protect public health.