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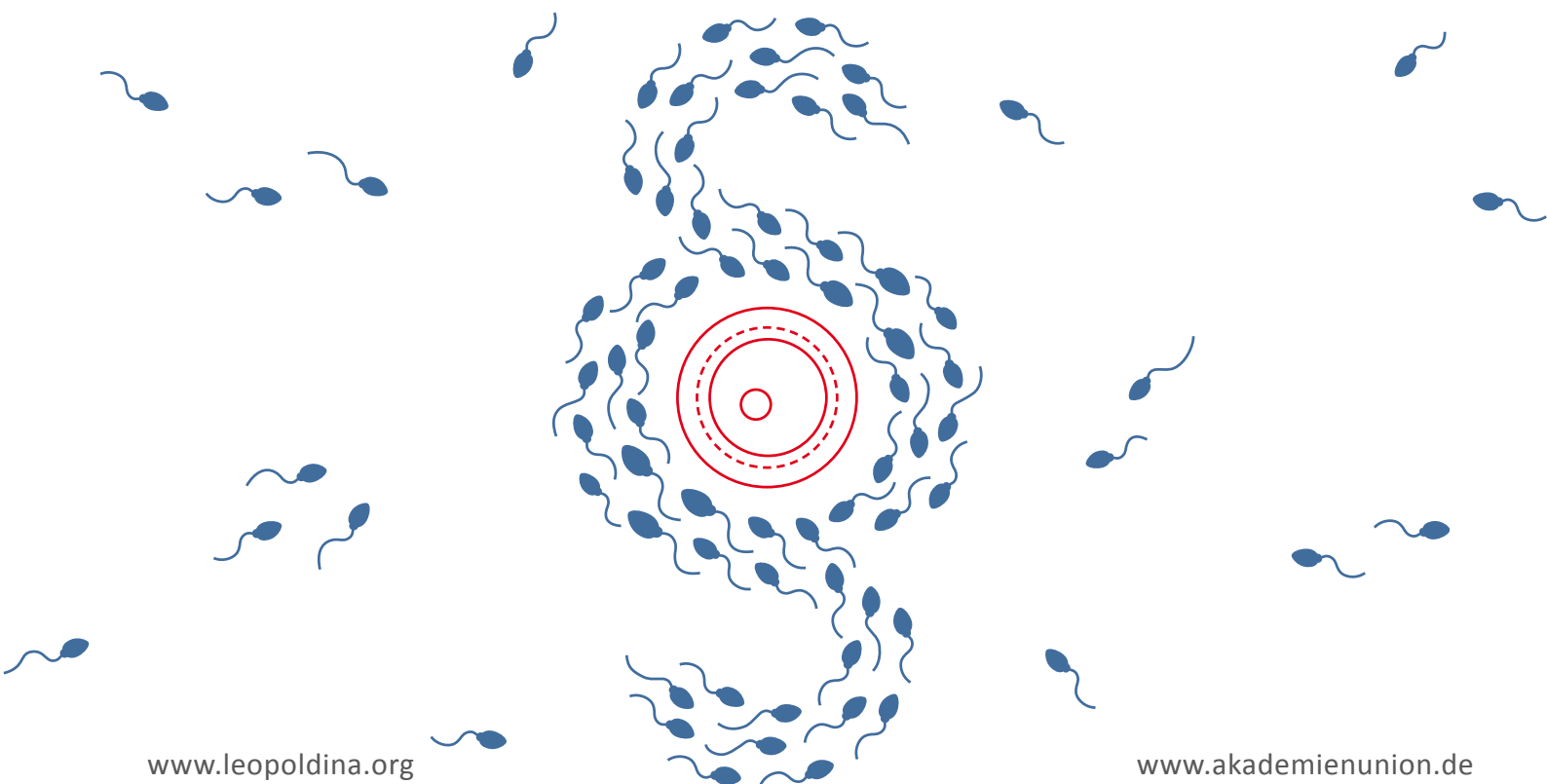


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Summary of statement

Reproductive medicine in Germany – towards an updated legal framework

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Summary and recommendations

I. The background:

For many people, having children and starting a family is one of life's essential experiences and is a fundamental condition for shaping the future of society. Assisted reproduction has been available for several decades. Since Germany's Embryo Protection Act was passed in 1990, assisted reproduction has developed at a rapid pace worldwide and provided new diagnostic and therapeutic measures to aid fertility. The health of all those involved, in particular the children, must always lie at the heart of these treatments. Thanks to high-quality medical and social science studies, reliable empirical statements concerning the effectiveness and tolerability of these technologies can now be made in many areas.

Social concepts of marriage and family have also changed over the last 25 years. In addition, the rights and welfare of children are given greater consideration nowadays. As a result of all this, the legal regulation of reproductive medicine—at the centre of which is still the Embryo Protection Act—is currently incomplete, creates legal uncertainty, contains contradictory values and is partly considered unjust or even harmful to the well-being of children.

Many of these developments could not have been predicted at the end of the 1980s. It is therefore all the more important to have new and comprehensive regulation of the requirements, processes and consequences of reproductive medicine, regulations that offer those involved the best possible and least invasive treatment, and gives due consideration to the rights of all parties, including the future children. The complexity of the material is no reason to further postpone new legal regulations.

II. A future reproductive medicine law should be based on the following principles:

- Creating a family should be made easier and should be supported; reproductive treatments are a part of this.
- Reproductive freedom guaranteed by the German constitution may only be compromised in order to protect other basic rights or constitutional values.
- The welfare and rights of the future child must be given full consideration.
- All medical treatments, in particular third party reproduction, must ensure a binding legal parent-child relationship.
- Discrimination, such as on the basis of a person's relationship status or sexual orientation has to be avoided.
- Measures must be taken to counteract social inequality regarding the access to reproductive treatment and the potential exploitation of vulnerable persons.
- Reproductive health professionals in Germany should not be prohibited by relevant legislation from carrying out treatment in accordance with the latest international scientific standards.
- Legislation in the area of reproductive medicine, like other legal provisions which are particularly dependent on medical innovations and social changes, require regular review.

Ethical and legal aspects

The decision to have children is a central aspect of autonomous and self-determined life. Reproductive freedom is therefore generally considered a fundamental right. However, reproductive decisions affect not just one person, but also their partner and any third parties that may be involved e.g. sperm donors, and in particular the future child, whose rights and interests also have to be taken into account. Reproductive technologies therefore may not, for example, involve any foreseeable serious risks for the physical or mental well-being of the child.

In a freedom-based fundamental order, the state has to provide justification if it wishes to prohibit something.

All regulations concerning reproductive medicine have to be compatible with the German constitution. German constitutional law codifies a comprehensive system of freedom. This means that rather than the individual having to explain and justify their right to act freely, the state has the duty to explain and justify the limitations of this freedom.

However, fundamental and human rights are not without limits.

Legitimate reasons for restricting the freedom of an individual include, in particular, the fundamental rights of third parties or other positions set out in the constitution or considered by legislators to be important rights. Of course, if certain practices violate human dignity, they are automatically excluded.

There are two opposing positions in the debate regarding the ethical status of the embryo—a strict protection of life from the very beginning and a gradual increase in the need for protection as the embryo develops.

For a long time, the debate around assisted reproduction focused primarily on the question from what stage on law and ethics should protect the beginning of human life and what practical consequences arise from this. Fundamentally, there are two positions: One position claims the need for relatively strict protection of the embryo from the very earliest stages. The argument used to justify this position is usually based on the potential of the fertilised oocytes to develop into a human being. The second position, in contrast, argues that protection should increase as the embryo develops, either gradually or in accordance with specific stages. This position approves greater or lesser levels of protection in accordance with later, key phases in the embryonic or foetal development, such as the nidation in the uterus, the development of sentience, the ability to survive outside the uterus, or birth.

In order to do political justice to the plurality of values concerning the embryo's right to protection, it makes sense to permit the parents, donors and doctors involved a reasonable amount of decision-making freedom. In an ideologically neutral state, they ought to have the right to take decisions based on their personal moral, religious and philosophical convictions.

Legal contradictions become apparent when reproductive medicine is compared with pre-implantation genetic diagnostics and with the way nidation inhibitors and induced abortion or termination of pregnancy are dealt with.

For example, with the use of certain legally permitted contraceptive methods such as an IUD (also known as a 'coil'), fertilised oocytes (in other words, embryos) cannot implant and are thus lost. For some years now, the examination of embryos for genetic diseases has been permitted under certain conditions in pre-implantation genetic diagnosis; if the undesired genetic mutation in question is discovered, the embryos are discarded. Termination of pregnancy is legally permitted up to the twelfth week following counselling. In contrast, due to embryo protection laws, it is forbidden to produce several embryos with the aim of selecting the best one for transfer, even though, in the interest of the health of both mother and child, this would help to reduce the number of medical procedures and multiple pregnancies.

III. Future reproductive medicine legislation should consider the following aspects:

▼ The best possible and least invasive treatment:

- Reproductive treatment aims for the birth of a healthy child while minimizing risks and burdens for all parties involved. At the same time, in the interest of embryo protection, it is important to keep the number of surplus embryos low. These aims should determine how many oocytes (egg cells) are fertilised.
- The number of embryos to be transferred should be determined on the basis of individual medical and psychosocial anamnesis and counselling.
- In order to achieve the desired birth of a child while avoiding multiple pregnancies, it should be permissible, in accordance with international scientific standards, to select and transfer from a larger number of embryos the embryo with the best chances of development (eSET). It should be examined whether reimbursement should be linked to the lowest possible number of embryos transferred, depending on the age of the woman and the number of unsuccessful attempts to date.

▼ Appropriate medical, psychosocial and legal counselling:

- Because of the medical, psychosocial and legal consequences for those involved and the future child, informed consent regarding fertility treatment requires detailed counselling. The aim of counselling is to enable self-determined and responsible decision-making.
- In addition to issues of direct medical relevance, counselling should also take into account the rights and the short- and long-term well-being of all parties involved, in particular the future child.
- In principle, this consultation is a medical task. Independent psychosocial counselling and, if necessary, legal advice should be recommended.
- In the case of fertility treatment involving third parties (sperm donor, egg donor, embryo donors) and before preimplantation diagnosis (PGD) is carried out, the offer of independent psychosocial counselling must be mandatory.
- Psychosocial counselling service should be made available to and easy to access for all participants even after the birth of a child.

▼ Ensuring the welfare of the child:

- In all measures of assisted reproduction, the welfare of the child and the rights and interests of the future adult must be paramount. It is true that a child's welfare is not a fixed concept, since families are justifiably guided within certain limits by different life plans when concretising the welfare of the child. However, treatments that entail serious, empirically substantiated risks for the health and/or well-being of the child during pregnancy or after birth should not be permissible. This includes, for example, the avoidable acceptance of higher-order multiple pregnancies.

▼ **Regulation of legal parenthood in the case of families created with the help of third parties:**

- If the gametes of third parties—in the case of sperm donation, egg donation, embryo donation/adoption—are used with the consent of donors and the intended parents, the intended parents should also become the child's legal parents when the child is born. The donor or the intended parents should not have the right to contest legal parenthood. Only the child should have a right to contest maternity/paternity within strictly defined limits, e.g. if the legal father and/or the legal mother pose a considerable risk to the welfare of the child.

▼ **Regulating the consent and the revoking of consent regarding reproductive treatment:**

- Reproductive treatment may only be carried out with the consent of the intended parents and — if a family is created with the gametes of third parties (treatments involving gamete donors) — with the approval of the persons donating the cells.
- In the case of sperm or egg donation, the donor should only be permitted to revoke consent until fertilisation begins.
- In the case of embryo adoption, the consent of the persons donating the gametes must have been obtained at the time of embryo transfer.

▼ **Protecting the right to know one's origins and structuring the donor registry:**

- The right to know one's biological origin for all children conceived by third party reproduction should be guaranteed by appropriate legal provisions and organisational measures, in particular by extending the sperm donor registry to include egg donation and embryo adoption.
- With the consent of the donor and the intended parents, it should be possible for the child and the donor to get to know each other.
- In addition, it should be possible to gain knowledge of the existence of half or full siblings. The disclosure of their identity to half- or full-siblings should be subject to their consent to the register. A child should be able to give such consent from the age of 16; prior to that age, his/her parents should be responsible.
- Psychosocial counselling should be offered to children, donors and their families, especially before contact is established.

▼ **Regulation of the handling and cryopreservation of gametes, pre-nucleus stages and embryos:**

- The duration of cryopreservation of gametes or ovarian tissue, pre-nucleus stages and embryos should be limited to specified timeframes. Such timeframes should be shortened or extended at the request of the persons from whom the gametes originate.
- If, in the case of cryopreserved pre-nucleus stages or embryos, only one of the partners demands an end to the cryopreservation, this should be permitted after a period of reflection.

- The use of gametes or the transfer of embryos in the knowledge of the death of one or both persons from whom the gametes originate should in principle be prohibited. Exceptions to this rule should be permitted if a relatively low number of years — to be determined by law — have passed since the death, and
 - if the surviving genetic parent, after being offered psychosocial counselling, desires to use gametes of the deceased partner and no opposing will on the part of the deceased is discernible
 - when germ cells from third parties are used and the donor(s) has/have not died until after the extracorporeal fertilisation has been initiated.
- Gametes, pre-nucleus stages and embryos must not be traded commercially. Only reasonable expenses may be paid for the donation.
- The number of children conceived per donor via third party reproduction should be limited. Below this limit, donors should be able to individually determine the maximum number of such children and, if desired, be informed of the number of pregnancies and births.

▼ **Appropriate institutional frameworks to ensure quality and enabling innovation:**

- Data on reproductive medicine treatments and their long-term consequences required for the assessment and assurance of quality and innovation should be collected prospectively and more thoroughly, evaluated and made available through a suitable central organisation. This requires adequate funding.
- Systematic long-term medical and psychosocial research needs to be strengthened.

▼ **Adequate funding for fertility treatment:**

- In order to tackle existing social inequalities with regard to accessing fertility treatment, such treatment should be fully covered through the state health insurance system, if it is medically justified and has a realistic chance of success.
- Funding should be independent of marital status.
- Men and women under 25, as well as women over 40 and men over 50 should not be excluded in principle from funding as has been the case up to now.
- There are no medical reasons to limit funding to 3 cycles.
- Cryopreservation of gametes and tissue should be funded if this is necessary to preserve fertility due to a serious disease or its therapy.
- In order to limit multiple pregnancies in assisted reproduction, elective single embryo transfer (eSET), i.e. the selection of the best developing embryo from several embryos, should be promoted. It should be evaluated whether funding of treatment could be linked to keeping the number of transferred embryos as low as possible, depending on the woman's age and the previous number of unsuccessful attempts.
- Psychosocial counselling should be covered by the state health insurance system.

IV. Specific recommendations concerning individual aspects of reproductive medicine:

▼ Sperm donation:

The Sperm Donor Registry Act (SaRegG), which took effect on 1 July 2018, regulates central aspects of sperm donation, such as the duration of documentation, the right to information regardless of age, a central documentation centre, and donor protection. In addition, the following points should be included:

- It should be regulated by law how medical data from sperm donations that predate the Sperm Donor Registry Act can be transferred to the central register.
- Where men donate their sperm outside medical institutions or have done so prior to the Sperm Donor Registry Act taking effect, it should be possible for them to file their data with the Sperm Donor Registry.

▼ Egg donation:

Contrary to previous concerns, children conceived by egg donation do not display any medical or psychosocial peculiarities in comparison with other children conceived via IVF. The concern regarding difficulties in identity development has also proven to be unfounded; family dynamics generally proceed smoothly and resemble those of families following sperm donation. The procedure for retrieving oocytes has become considerably less invasive so that the health risks for donors are low. The risk of exploiting vulnerable donors can be effectively counteracted in Germany.

- Egg donation, which has been prohibited in Germany up to now, should be permitted.
- The type of stimulation and the number of stimulation cycles must be designed to minimise risks for the donor.
- The recipient must be adequately informed of the risks regarding pregnancy via egg donation, in particular regarding high blood pressure and preeclampsia.
- As a rule, the recipient should be no older than approximately 50 years, as the health risks for mother and child increase with age.

▼ Donation of embryos and pre-nucleus stages:

In accordance with existing laws, the donation of so-called surplus embryos is permitted. However, there is no sufficient legal framework. However, the donation of pre-nucleus stages — oocytes which a sperm has already penetrated or been inserted into — is prohibited under the Embryo Protection Act. This unequal treatment is convincing neither from an ethical point of view nor from the point of view of many affected couples.

- With regard to possible donation, pre-nucleus stages and embryos should be legally treated equally.
- Legal regulation should ensure that the process of donating pre-nucleus stages and embryos released for donation by their genetic parents is carried out according to transparent and appropriate criteria. This requires appropriately authorised facilities.

▼ Pre-implantation genetic diagnostics (PGD):

Since 2011, pre-implantation genetic diagnosis (PGD) has been permitted in Germany — however only in the case of a serious hereditary disease in the family or to prevent stillbirth or miscarriage. Whether PGD may be carried out in individual cases is currently up to specialized ethics committees to decide. Several different regional ethics committees have been established. The inconsistent decision-making practice of the various ethics committees does not do justice to the situation of the affected persons.

- In the future, decisions on PGD should be taken in the doctor-patient relationship and include psychosocial counselling but should not require special approval of an ethics committee.
- In any case, the costs incurred in the context of PGD should be borne by the state health insurance system, as is already the case with the costs of prenatal diagnostics.

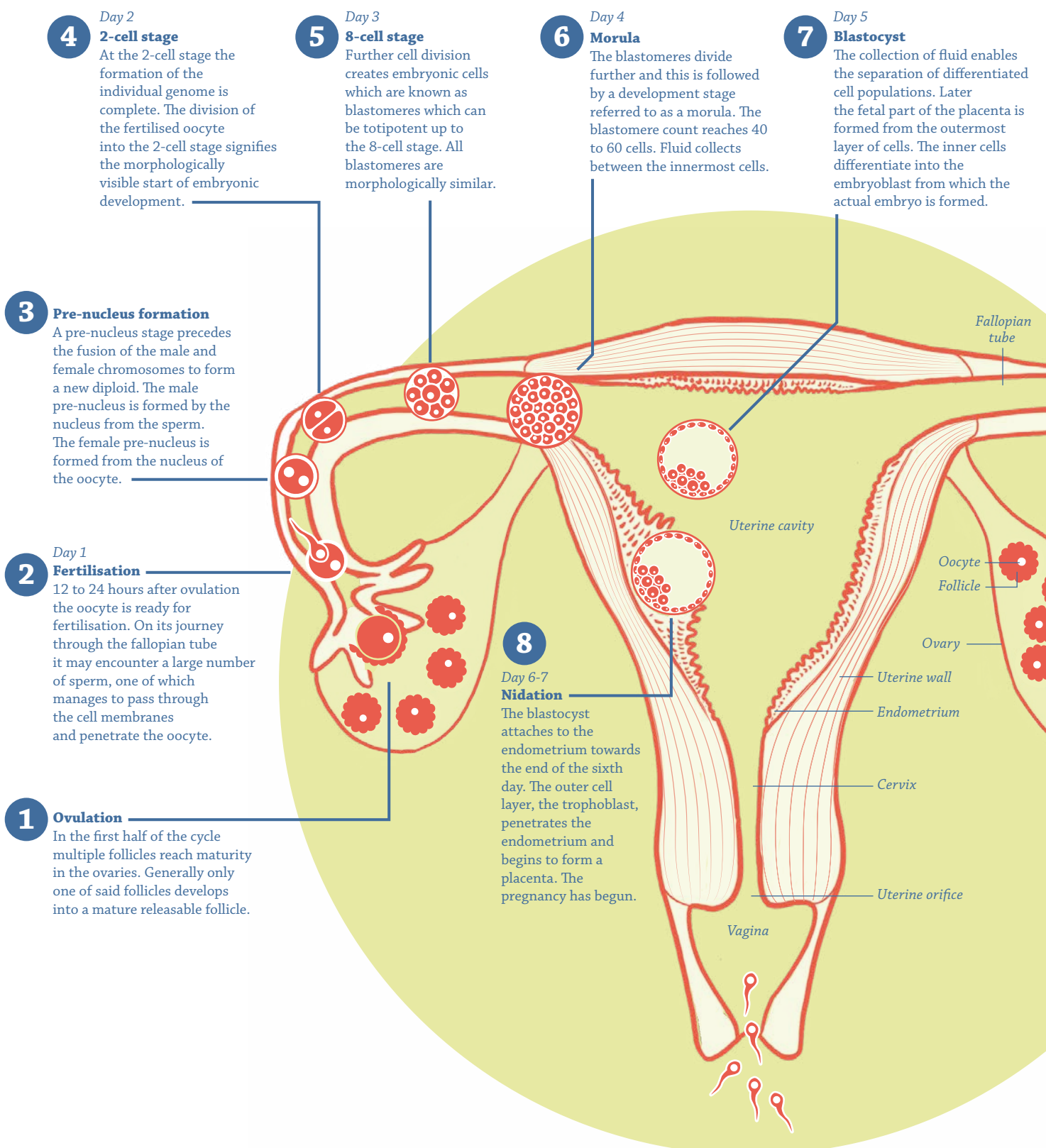
▼ Surrogacy:

Irrespective of the controversy of whether surrogacy should be permitted in the future or not, there is already a need today to introduce regulation for children conceived and born in countries where surrogacy is legal but who grow up in Germany.

- In the interest of the welfare of the child, it should be possible for the intended parents to be legally established as the child's parents, as numerous legal consequences such as parental care, maintenance claims and nationality depend upon them. Resolving individual cases under case law is insufficient. Legal regulations are required.
- Medical and psychosocial counselling offered and carried out in Germany on the issues of surrogacy should not be a criminal offence.

How an embryo develops out of a fertilised oocyte


It takes approximately 6 to 7 days from initial fertilisation to nidation in the womb

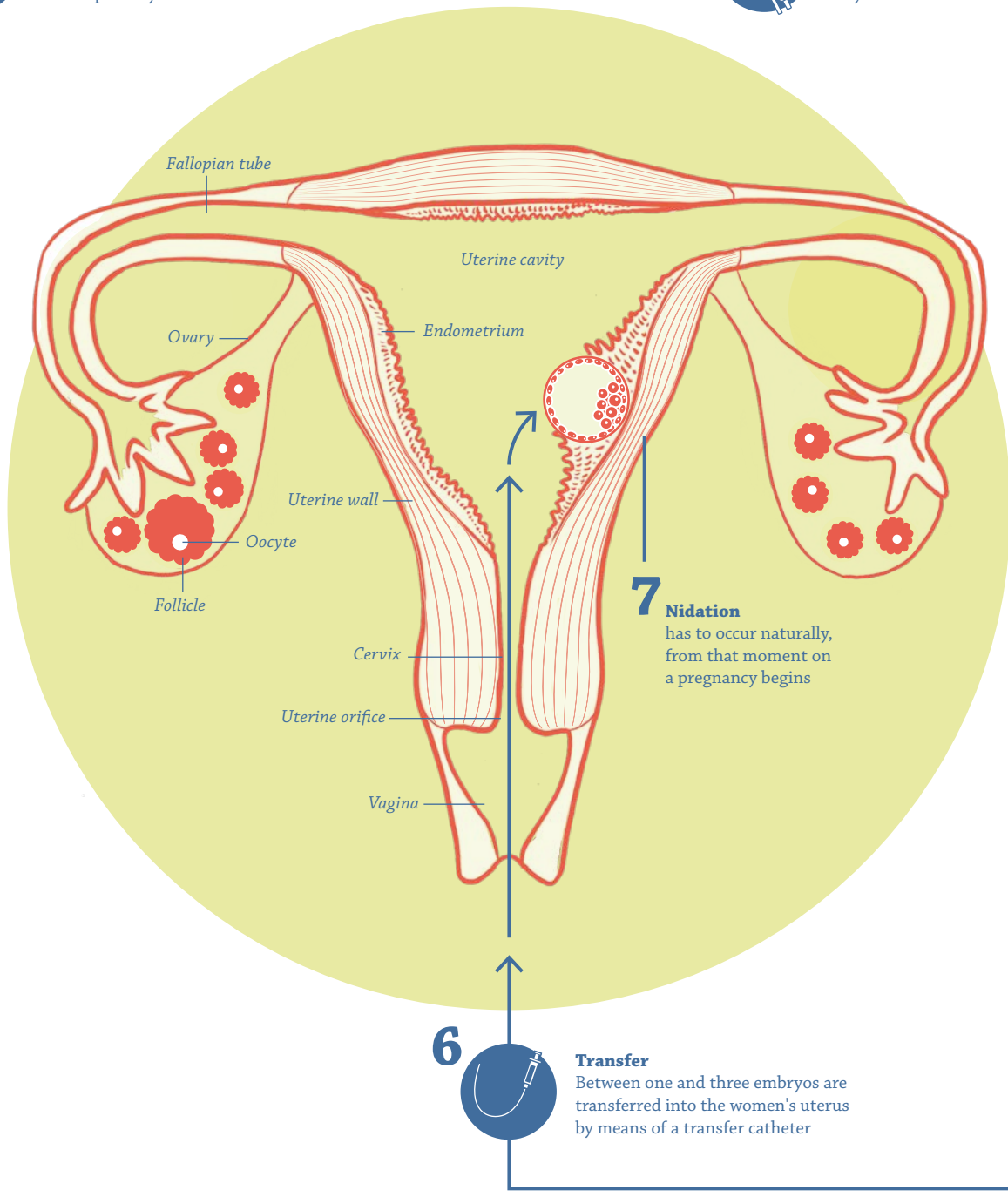


Procedures in Reproductive Medicine

Procedures in reproductive medicine include **insemination** (see above right), **in-vitro fertilisation (IVF)** and **intracytoplasmic sperm injection (ICSI)**

Treatment inside the woman's body

- 1**  **Hormonal treatment (stimulation)**
causes the maturation of multiple oocytes
- 2** **Maturation of follicles**
in the ovary
- 3**  **Retrieval of oocyte (puncture)**
The fluid of the follicle is extracted by a puncture needle and then the oocyte is identified.





Insemination

Insemination is defined as any transfer of male semen into the genital tract of a woman which does not involve sexual intercourse. The aim is the fertilisation of an oocyte which has matured in the woman's body.

Treatment outside the woman's body



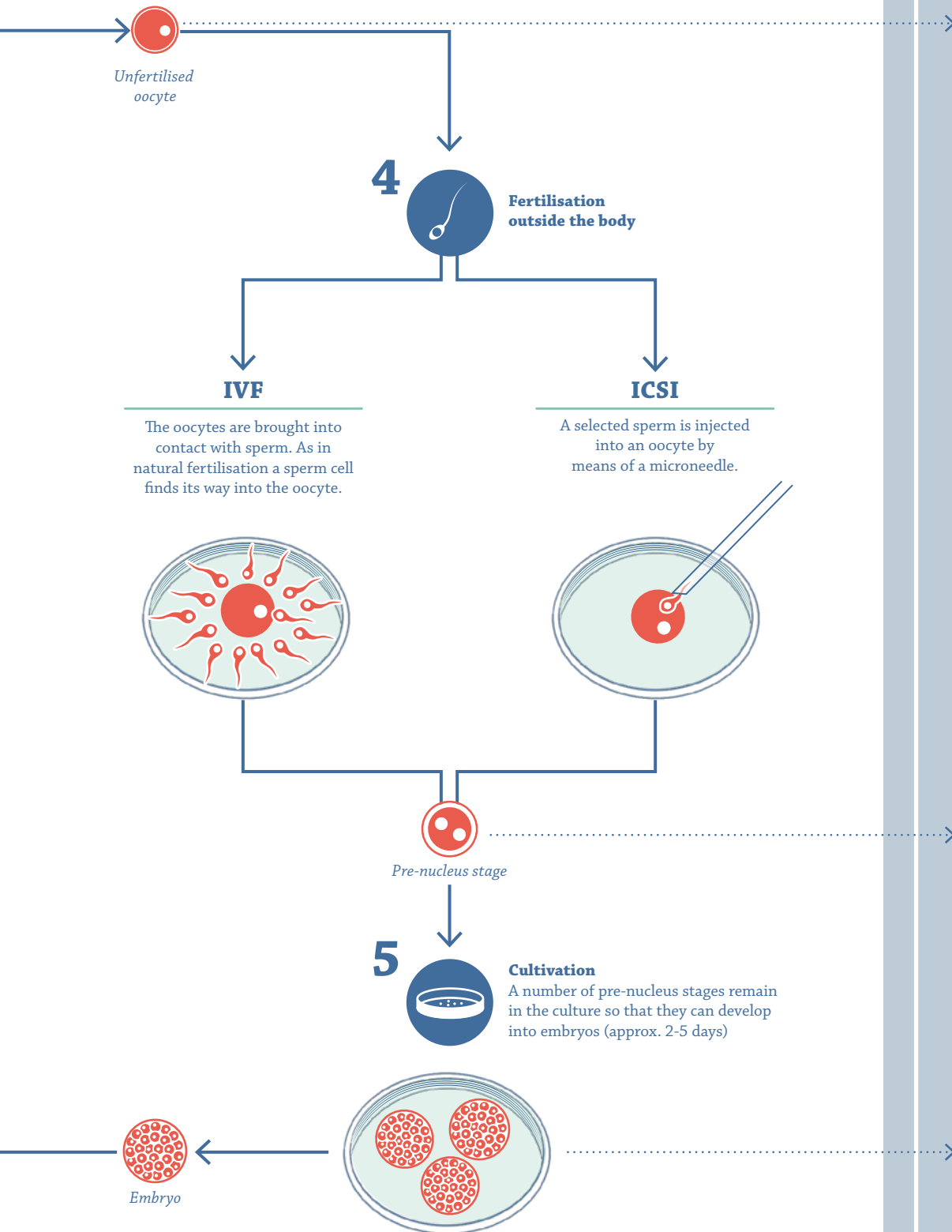
Cryopreservation

Gametes and embryos are frozen in liquid nitrogen at approximately -200° C

Unfertilised oocytes and sperm can be preserved

Pre-nucleus stages can be preserved

Any surplus embryos can be preserved for later use



Elective Single Embryo Transfer (eSET)

A multiple pregnancy increases health risks for both mother and child. eSET reduces this risk and has the same or even better chances of a successful outcome.

The eSET procedure

In eSET the embryos are selected which have the best chance of developing successfully. In order to make the selection a larger number of oocytes are fertilised and their development is observed over several days. However, this procedure is not permitted by the German Embryo Protection Act. It prohibits the deliberate formation of more embryos than can be transferred to a woman in one cycle.



Fertilisation

All of the oocytes removed after hormonal stimulation are fertilised.



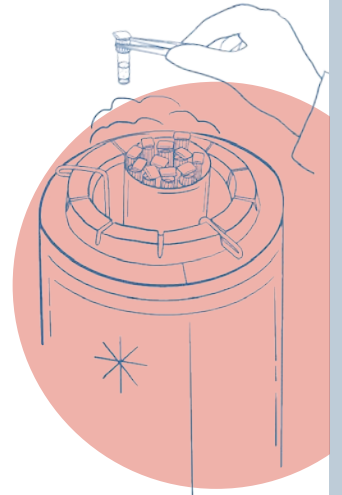
Cultivation

The cultivation extends for a period of 2-5 days. Early-stage embryos vary in their development.



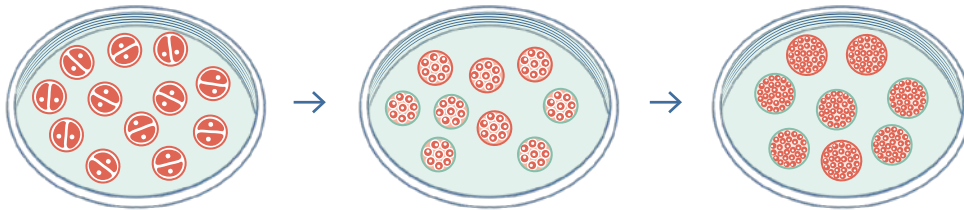
Selection

The development of the embryos is observed. The best developing embryo is selected.



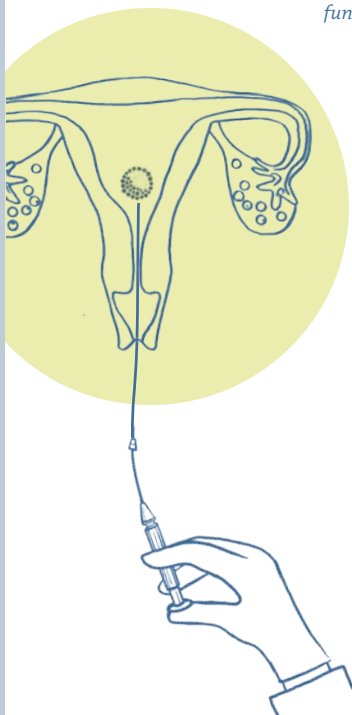
Transfer and preservation

Only this embryo is transferred. The remaining embryos are stored for possible later use.



Women in other countries have fewer multiple pregnancies

A comparison between Germany and countries in which eSET is carried out shows that this procedure considerably reduces the rate of twin births, with a comparable or even better birth rate per oocyte retrieval procedure. To minimise the number of high-risk multiple pregnancies many countries link funding to a restriction of the maximum number of embryos that can be transferred per cycle.



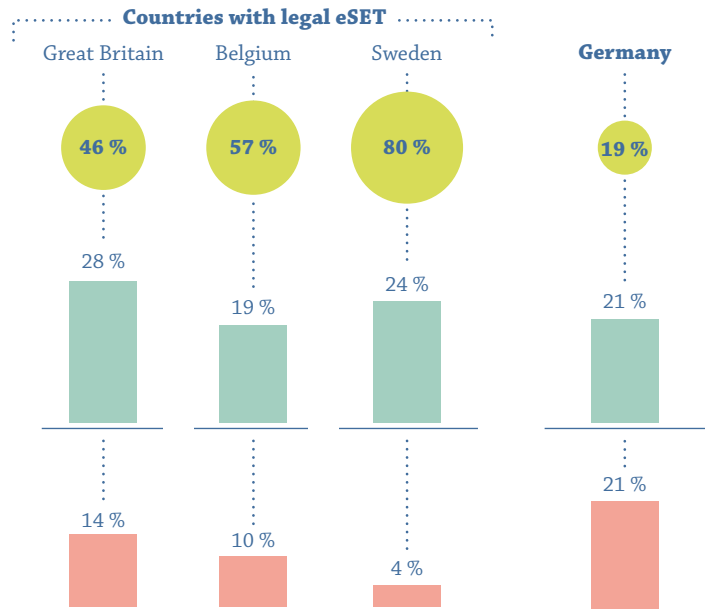
Transfer with only one embryo (IVF and ICSI)



Birth rate per egg retrieval procedure (IVF)



Twin birth rate after IVF/ICSI



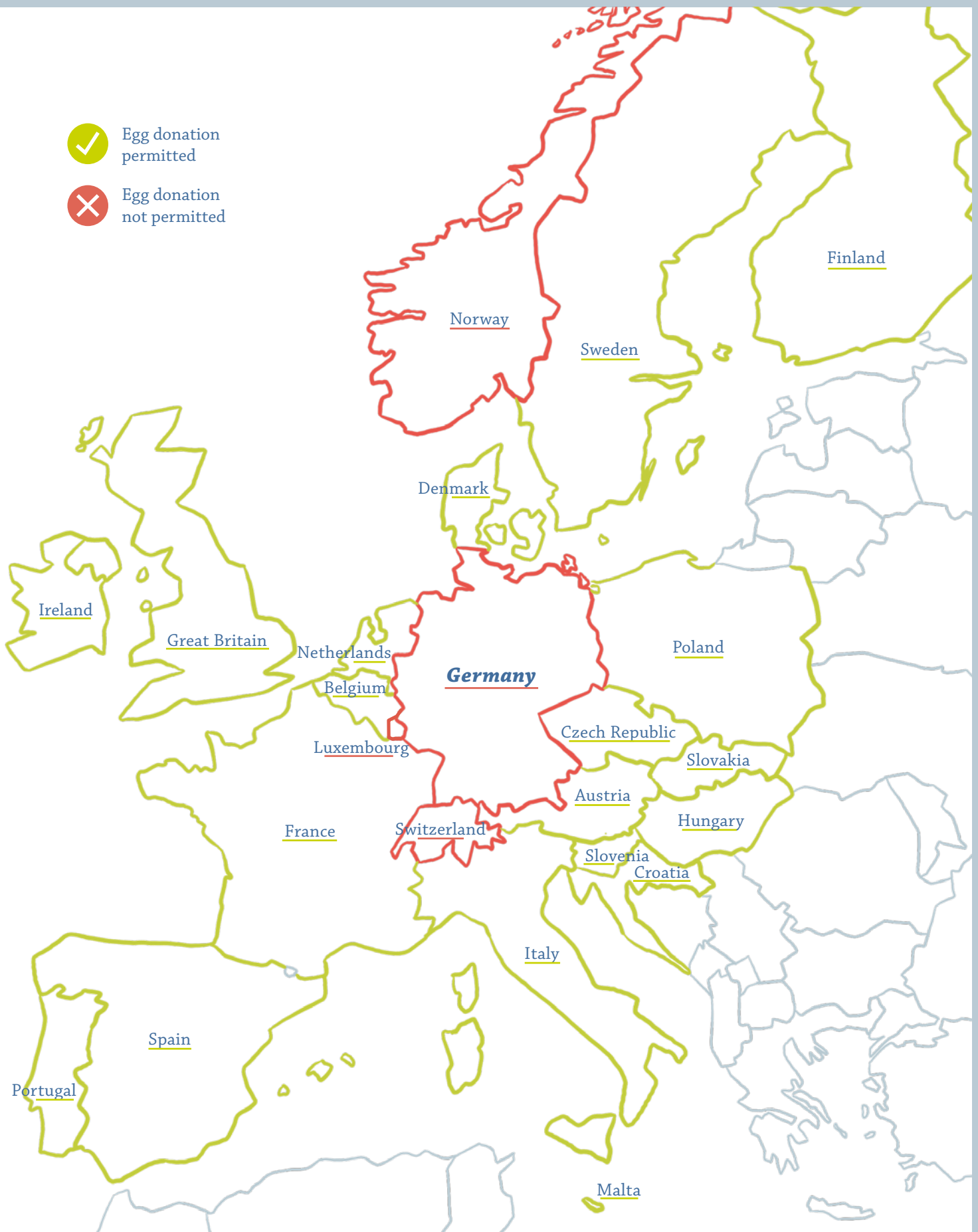
The birth rate for twins in natural pregnancies is 1 %.

Egg donation in Central and Northern Europe

In Germany egg donation is illegal. It is also illegal in Germany for gynaecologists and centres for reproductive medicine to undertake preparatory steps for egg donation

✓ Egg donation permitted

✗ Egg donation not permitted



Funding of insemination and IVF/ICSI by statutory health insurers

Who will receive funding?

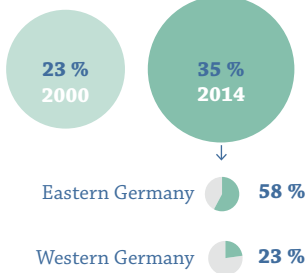


Restricted to married people

Generally only married couples receive funding.

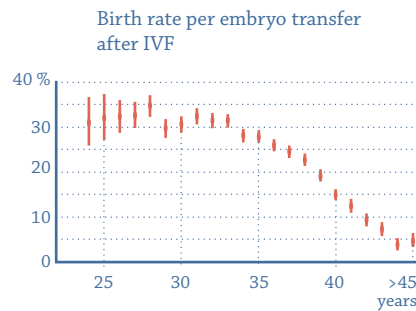
However, this restriction does not reflect current social trends: increasingly more and more children are being born in Germany to unmarried couples (see below), mainly in Eastern Germany.

Children born to unmarried parents



Age restriction

Women under 25 and over 40 years of age and men under 25 and over 50 years of age are not eligible for funding, regardless of individual medical diagnoses and chances of success.



Source: German IVF register (2018b)



Regional inequality

Several German states provide programmes for funding fertility treatments, i.e. Saxony, Saxony-Anhalt, Lower Saxony, Mecklenburg-Western Pomerania, Thuringia, Hesse, Brandenburg and Berlin. This creates regional inequality with regard to funding couples with fertility issues.



What is funded?

50%

Only 50% of the treatment costs is funded

Generally only half of the cost of treatment is paid for.

The cost of each treatment is often several thousand euros, which is a disadvantage for couples with low income.



Only three treatment cycles are partially funded

- regardless of the individual medical situation and the chances of success.

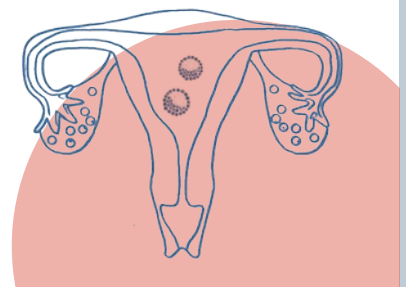
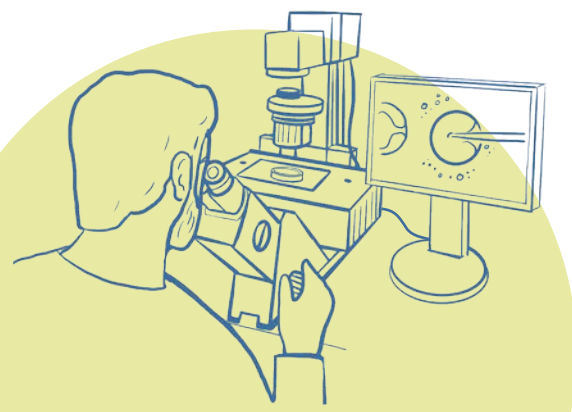


The cost of storage will not be paid for

The cost of preserving oocytes, pre-nucleus stages and embryos is not covered as part of the fertility treatment.

Risks

Due to the method of funding used in Germany, often several embryos are transferred in each treatment cycle (see also eSET graph) to increase the chances of bearing a child. However, this increases the probability of a high-risk multiple pregnancy.



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