

Regulation and legislation in assisted reproduction

1. While patients in Europe have freedom of movement for treatment (under a 2008 European Commission directive), EU member states are free to enact their own medical legislations. This means that different member states have different regulations for the treatment of infertility, but that patients are free to travel abroad for treatment, even if their 'cross border reproductive care' violates domestic legislation. Although some aspects of embryo research and laboratory conditions are regulated by federal law, there is no national legislation for IVF in the USA. Practice is mainly led by guidelines of the ASRM (American Society of Reproductive Medicine), but all clinics are required by law to submit the data of each treatment cycle to a national registry.

2. Every country in the EU (with the exception of Ireland) now has legislation governing assisted reproduction (ART). Nearly all, as the UK, France, Germany, Spain) supplement their legislation with professional guidelines. Legislation has usually been introduced and modified over the past 30 years, sometimes with controversy (as in Poland in 2016, Switzerland 2016, or Italy in 2004).

3. There is no common EU legislation in ART, and the overall picture is often described as a patchwork. The main legal differences between countries relate to:

- embryo selection, particularly by genetic screening
- embryo freezing and embryo transfer
- preimplantation genetic diagnosis (PGD)
- egg donation
- anonymity of gamete donors
- surrogacy
- patient eligibility criteria (eg, sexual orientation, age)

There are also regulatory differences with respect to reimbursement and state funding, and to embryo research. Common EU-wide regulation applies to the use (procurement, storage, transport, traceability) of tissues and cells (which covers eggs and sperm) and to their screening

for infection. These regulations were introduced by the EU as Tissue & Cell Directives in 2004 and 2006, and in ART primarily harmonise procedures in the IVF laboratory.

4. Who can do what in ART?

Embryo freezing. Is now allowed in most EU countries, but has proved contentious in some jurisdictions, notably Italy (where it was banned in 2004 but reintroduced in 2011), Germany (where under embryo protection legislation it is only allowed in emergency but fully allowed for fertilised eggs at the 2PN (two pronuclei) stage), and Poland (where it remains in political limbo).

Embryo transfer. Most EU countries set a legal limit on the number of embryos transferred in a single cycle. In some countries (such as Austria since 2015, or Belgium in patients under 36 years) this may be as few as one, or as many as three (as in Germany, though two are recommended in guidelines in women under 37). Most limits (as in UK or Netherlands) are age dependent, though one is preferred. No more than two embryos can be transferred in France or Sweden.

Genetic embryo screening (preimplantation genetic screening, PGS). Mainly allowed, though with restrictions in Sweden (where PGS is only allowed as part of an ethically approved study), Netherlands (where PGS can be performed at only one national centre), and France

Egg and sperm donation. Egg donation is not allowed in Germany and Norway. Gamete donation may be anonymous (as for example in France, Italy, Slovenia and Spain) or non-anonymous (as in UK, Finland or Sweden), where identities are recorded and made available at a later time point to offspring.

PGD (preimplantation genetic diagnosis). Allowed in most jurisdictions, but still politically controversial in Lithuania and Poland.

Surrogacy. Not allowed in Austria, Bulgaria, Finland, France, Germany, Hungary, Italy, Lithuania, Norway, Serbia, Slovakia, Slovenia, Spain and Sweden.

State funding. Only in France and Belgium are almost all ART cycles (up to a maximum of four in France and six in Belgium) fully funded/reimbursed by the state. In Germany 50% of costs are covered by the state insurance scheme. Only in Cyprus, Ireland and Lithuania are there no public clinics with state funding. Most countries have a mix of private and public services available, where public funding may be dependent on eligibility criteria, usually female age, previous treatment cycles, and previous children. For example, modified legislation introduced

in France in 2011 continued to make treatment 'a right' only when based only on a diagnosis of infertility and in response to a desire for parenthood in a couple 'consisting of a man and a woman'. Treatment of lesbian or single women in France is thus not allowed.

5. ESHRE has publicly opposed the introduction of restrictive ART legislation in Italy, Poland and Lithuania, stating in the latter case:

'As defined by WHO, infertility is a complex pathology that requires appropriate investigation and treatment. One of the most effective treatments is IVF and its related technologies; these techniques cannot be replaced by other procedures and have resulted in the birth of more than 6 million babies throughout the world. Denying the efficacy and accessibility of these treatments to infertile couples is not only unethical, but is also contrary to the principles of evidence-based medicine and good medical practice. All treatments known to be safe and effective should be available to all infertile patients, who should be given the opportunity to make informed reproductive choices on the basis of sound scientific evidence.'