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THE POINT ABOUT MEDICALLY ASSISTED PROCREATION IN EUROPE

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BACKGROUND

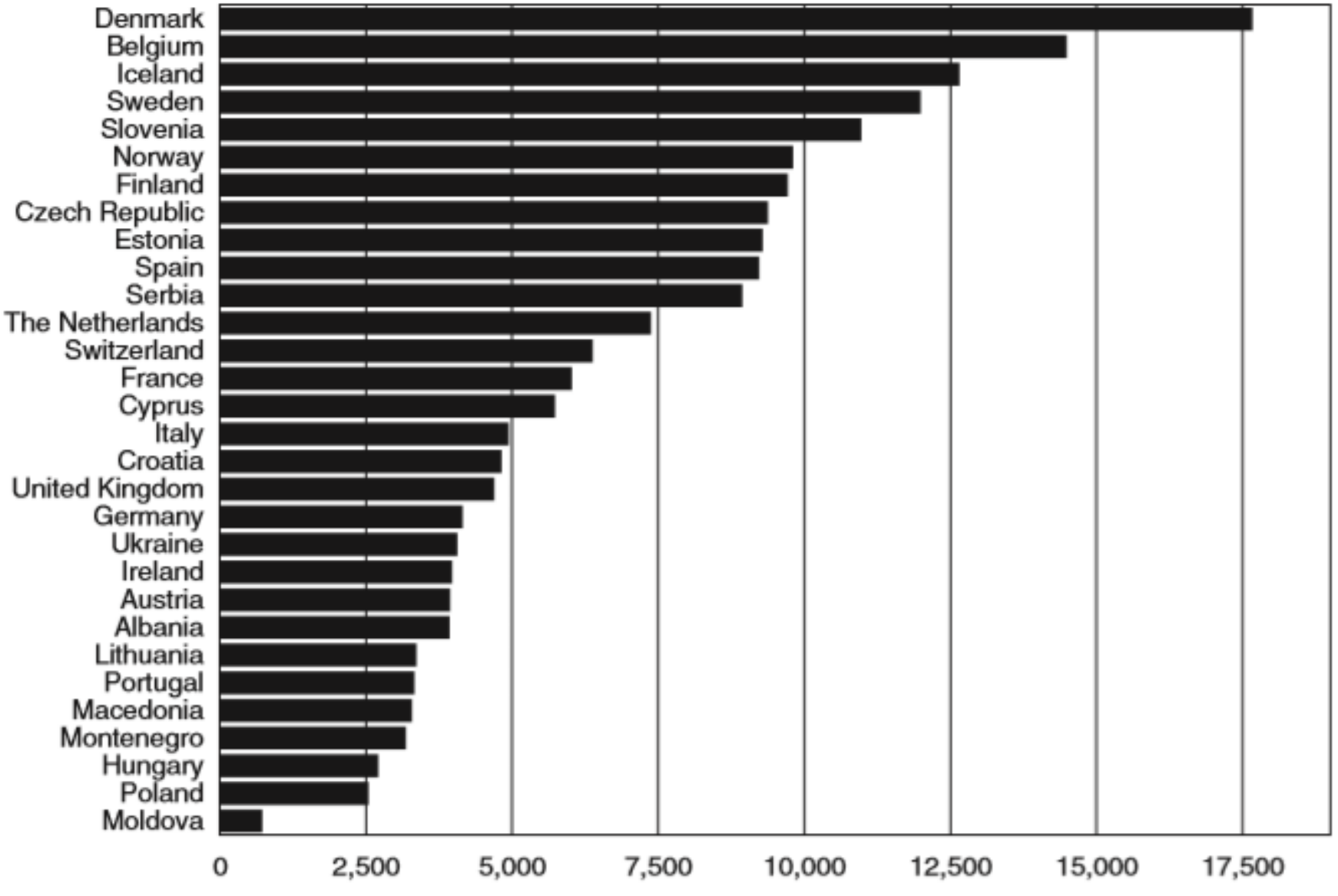
Introduced in Spain more than forty years ago, medically assisted procreation (PMA) has allowed thousands of infertile couples to have a child. But in the European Union its regulation varies a lot from one country to another.

In 2015, 157,500 children were born in Europe from a PMA: this is what the European Society for Human Reproduction and Embryology (Eshere) states. But in this field European legislation is very different. In fact, even if a European directive establishes the rules for the conditions of use of human tissues and cells, the set of ethical and legal questions on PMA continue to depend on national states.

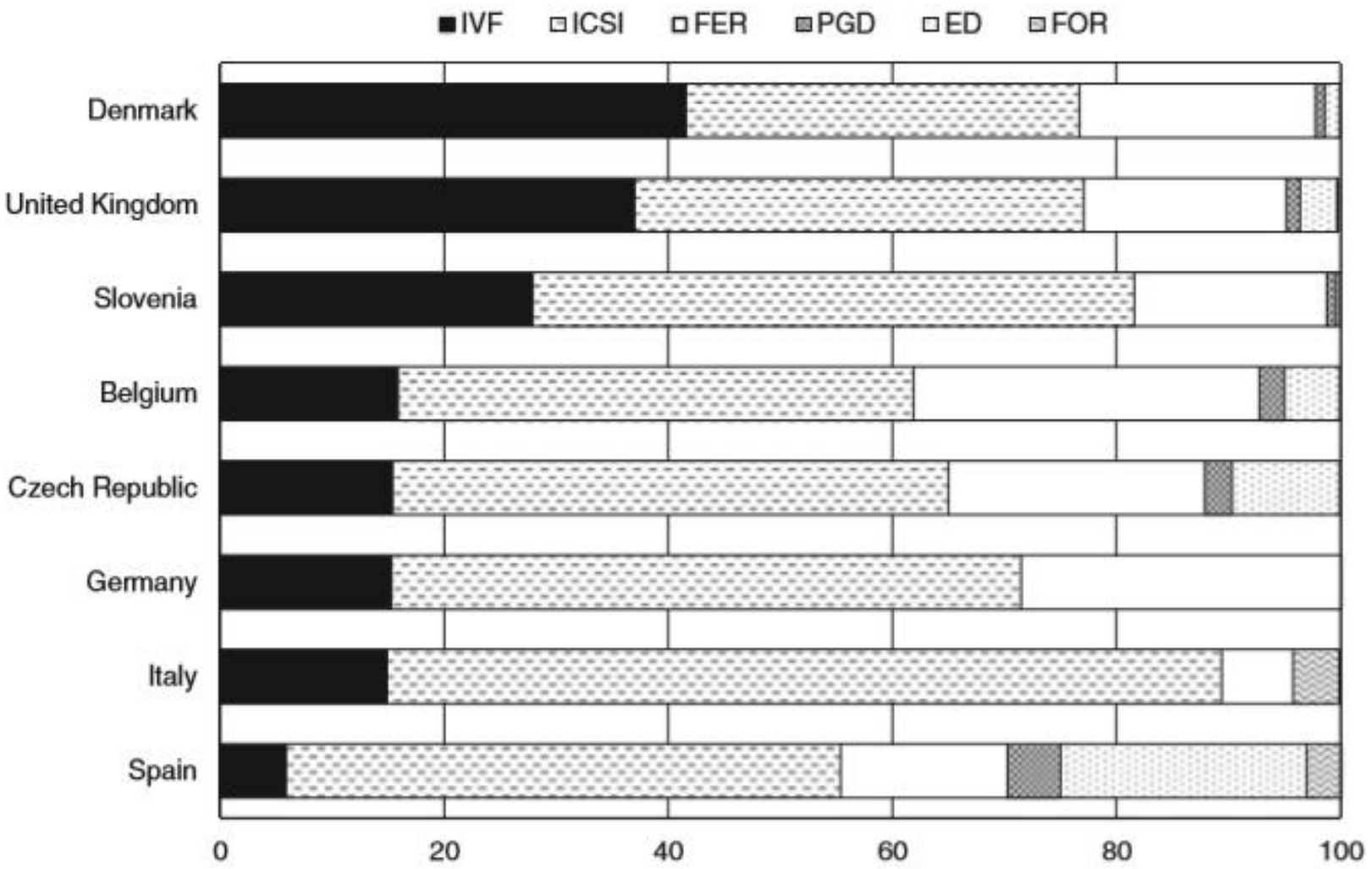
Although diagnostic and treatment services are currently available in all European countries, the variation in ART usage indicates that there are substantial differences in **equity of access**.

Degree of variation in ART usage across Europe

Denmark, Belgium, Iceland, Sweden, and Slovenia are the countries where the largest numbers of ART cycles are initiated. A comparison of these four countries shows that there is substantial heterogeneity at the top of the distribution. ART treatments are considerably more common in **Belgium** and **Denmark** than in Iceland, Sweden, and Slovenia. When we look at the bottom of the distribution, it is apparent that ART is no more widespread in Germany, Austria, or Ireland..




SPERM DONATION
SURROGACY
EGG DONATION
EMBRYO DONATION


IVF
ICSI
FER
PGD
ED
FOR
Denmark
United Kingdom
Slovenia
Belgium
Czech Republic
Germany
Italy
Spain
0
20
40
60
80
100

IVF-ICSI

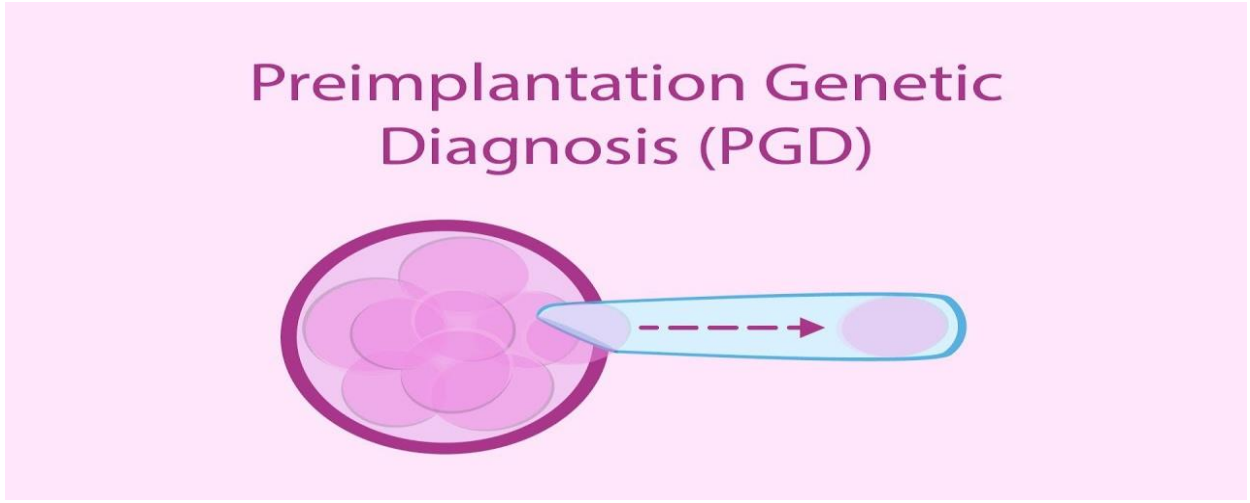
Norms and **beliefs** seem to play an important role for cross-national differences in ART usage.
Beliefs about the moral status of a fertilized egg—whether a human embryo is seen as a human being immediately after fertilization—are associated with ART utilization. Generally, in countries where the belief that an embryo becomes a human being right after fertilization is less widespread, ART is used more often.

In addition to the differences in the extent of ART usage in Europe, there is also considerable variation in the range of ART techniques that are utilized.
The classical form of ART, **IVF,** is no longer the most popular type of ART procedure. The share of IVF treatments among all ART treatments ranges from less than 10% in **Spain** to slightly more than 40% in **Denmark**. **ICSI**, a method invented more recently to treat male factor infertility, has overtaken IVF in recent years as the method of choice for ART:

- Only in **Denmark** the share of IVF treatments is slightly larger (42%) than the share of ICSI treatments (35%).
- In the **United Kingdom**, IVF and ICSI are used to a similar extent (37%-40%).

FROZEN EMBRYO REPLACEMENT

The third-most popular form of ART treatment is **frozen embryo replacement,** making up between 6% (**Italy**) and 31% (**Belgium**) of ART treatments. The low uptake of FER in Italy is attributable to a national law that prohibited embryo cryopreservation (except under exceptional circumstances) from 2004 to 2009. The relative popularity of FER in **Germany** is surprising, as German regulations regarding embryo freezing are fairly restrictive: the non-emergency freezing of embryos is banned, and the freezing of fertilized eggs is allowed only in the earliest stages of development.



PGD

Preimplantation genetic diagnosis (PGD), which has been practiced since the early 1990s, is likely the ethically most controversial form of ART. **PGD** has clear benefits, as it can help parents to avoid passing inheritable disorders to their children, and it is generally considered to be safe and to have a low rate of errors. However, fears about the creation of "**designer babies**" and moral concerns about the use of PGD for non-medical purposes (such as **sex selection**) are often expressed in public discussions about ART. The share of all ART treatments in a country that involve PGD ranges from low number of reported cases (in **Germany** and **Italy**) to 4.7% of cases (in **Spain**). The share is around 1% in Denmark, Slovenia, and the United Kingdom; and is around 2% in Belgium and the Czech Republic.

Denmark and Slovenia restrict its use to screening for specific hereditary disorders.

EGG DONATION

Egg donation is also a technique that is not practiced in all countries. Germany reports no cases, Italy reports very few cases, and in Slovenia and Denmark egg donation makes up less than 2 % of ART procedures. In the United Kingdom and Belgium, the shares are slightly higher (3.3 and 5 %, respectively). In the Czech Republic and Spain a significant share (9.7 and 22 %) of ART treatments involve egg donation.

FOR

Frozen oocyte replacement (FOR), which builds on fertilizing thawed oocytes, is a relatively rare form of ART: FOR treatments are reported only in the United Kingdom, Spain, and Italy (0.1, 3.1, and 4.1 %, respectively). One reason for the relative popularity of FOR in **Italy** is that the cryopreserving of embryos was banned, which created incentives to further develop and refine technologies for cryopreserving oocytes.

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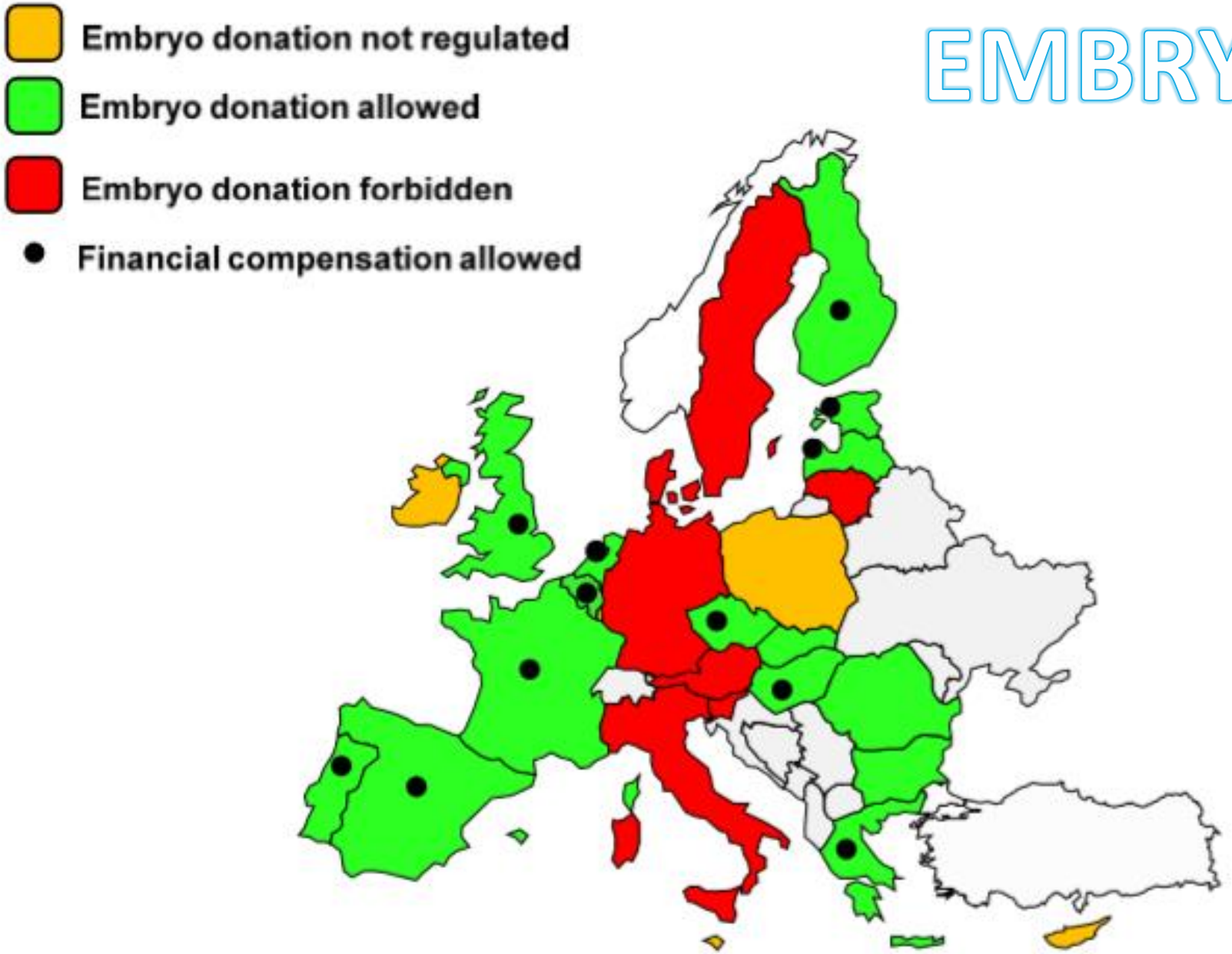
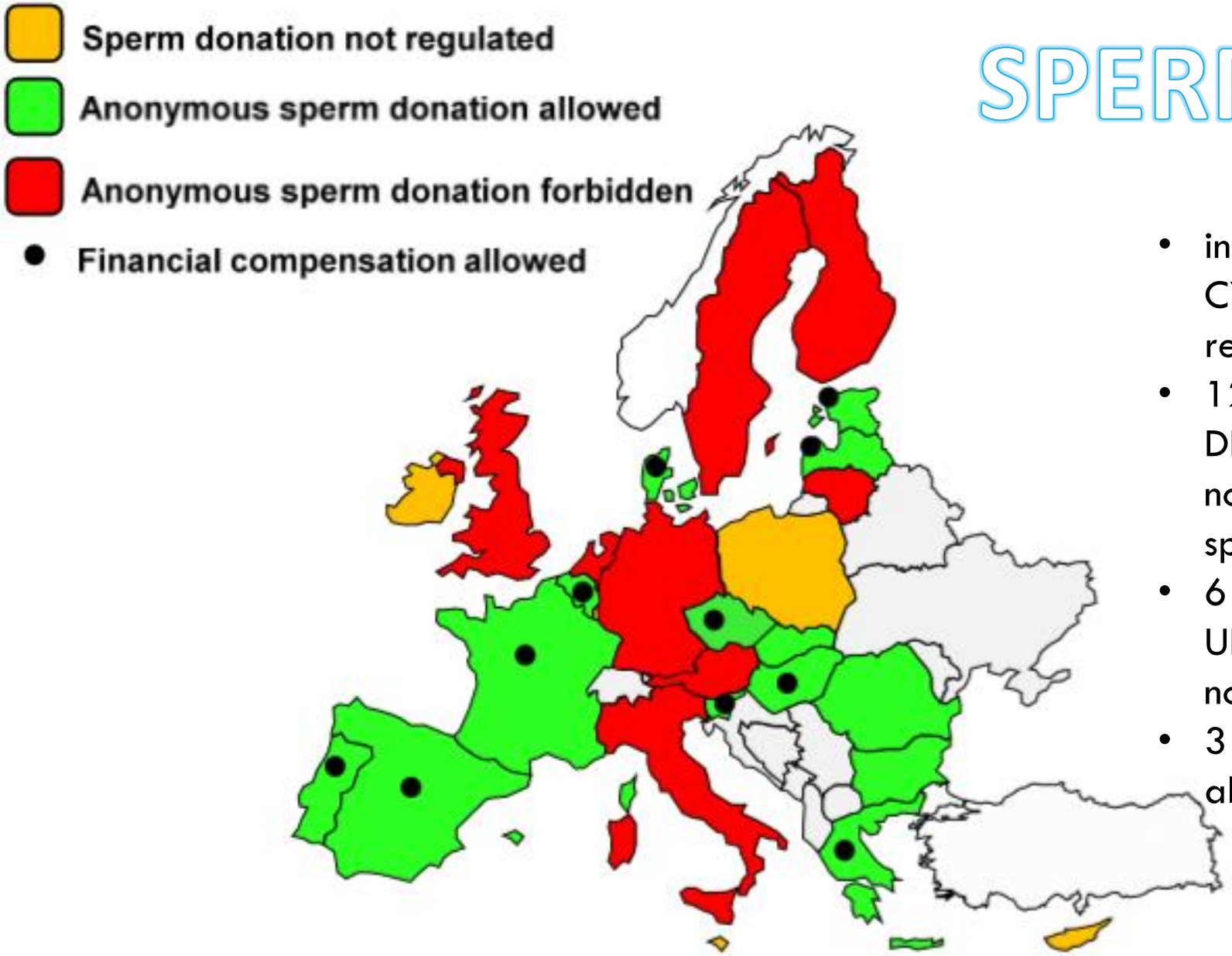
Couples and single women who are unable to obtain the desired treatment in their home country are sometimes willing to travel abroad to obtain that treatment in another country.

EMBRYO DONATION

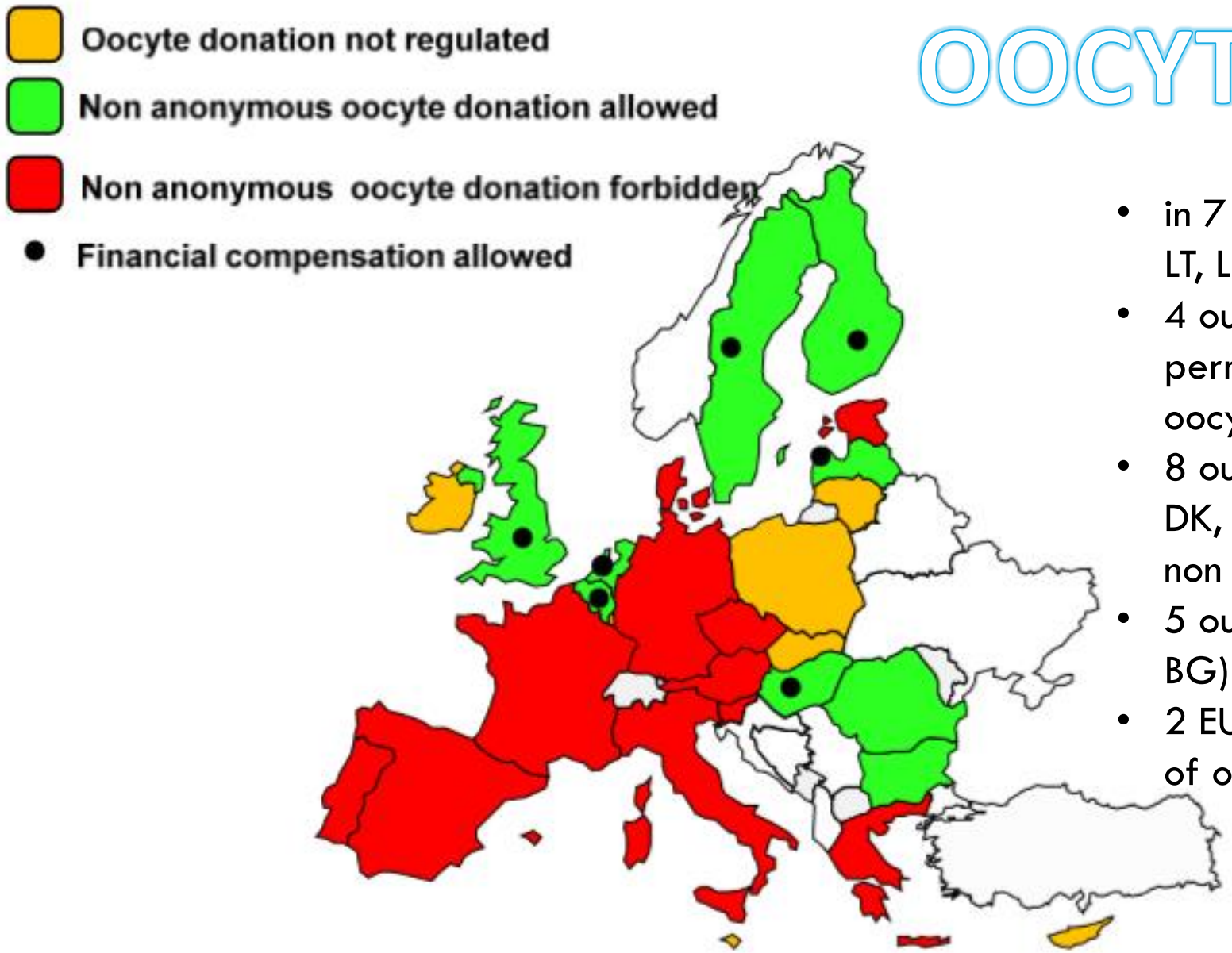


SPERM DONATION



- in 5 out of 28 EU Member States (PL, IE, CY, MT, LU) sperm donation is not regulated;
- 12 out of 28 EU Member States (BG, CZ, DK, FR, ES, PT, GR, HU, SI, EE, SK, IT) forbid non anonymous but permit anonymous sperm donation;
- 6 out of 28 EU Member States (AT, DE, NL, UK, FI, SE) forbid anonymous but permit non anonymous sperm donation;
- 3 out of 28 EU Member States (BE, LV, RO) allow both types of sperm donation.

OOCYTE DONATION



- in 7 out of 28 EU Member States (PL, SK, IE, CY, LT, LU, MT) oocyte donation is not regulated;
- 4 out of 28 EU Member States (UK, NL, SE, FI) permit non anonymous but forbid anonymous oocyte donation;
- 8 out of 28 EU Member States (GR, PT, ES, FR, DK, CZ, SI, EE, IT) permit anonymous but forbid non anonymous oocyte donation;
- 5 out of 28 EU Member States (BE, LV, RO, HU, BG) allow both types of oocyte donation;
- 2 EU Member States (DE, AT) forbid both types of oocyte donation.

REGULATION OF ART IN EUROPE

Europe is the only continent where the legal regulation of ART is widespread. Other major countries where ART is used, such as India, Japan, and the U.S., largely rely on voluntary guidelines.
There are three major ways of regulating the practice of and the access to ART:

- ART can be regulated via **guidelines**, generally issued by professional organizations
- ART is also often subject to **governmental legislation**
- **insurance coverage** as an indirect regulation of access to ART

Virtually all European countries offer some assistance. Only **Belarus, Ireland,** and **Switzerland** do not provide their citizens with any form of coverage. Most countries provide coverage via **national health plans**: 6 countries—Denmark, France, Hungary, Russia, Slovenia, and Spain—offer complete coverage through national health plans. **Marriage** is a requirement for ART treatment in most countries. Only 6 out of 28 European countries report that marriage is not a requirement for ART access. However, apart from Turkey and Japan, all of the European countries also provide treatment to couples who live in a stable relationship.

- Only 10 of these European countries, along with India and the U.S., permit **singles** to utilize ART services.
- Only 7 European countries and the U.S. allow **lesbian** women to have access to ART.

	Marriage required	Stable relationship permitted	Singles permitted	Lesbians permitted
Austria	Yes	Yes	No	No
Belgium	Yes	Yes	Yes	Yes
Bulgaria	Yes	Yes	Yes	Yes
Croatia	Yes	Yes	No	No
Czech Republic	Yes	Yes	No	No
Denmark	Yes	Yes	Yes	Yes
Finland	No	Yes	Yes	Yes
France	No	Yes	No	No
Greece	No	Yes	Yes	No
Hungary	Yes	Yes	Yes	No
Ireland	No	Yes	No	No
Italy	Yes	Yes	No	No
Latvia	Yes	Yes	Yes	Yes
Russia	Yes	Yes	Yes	No
Slovenia	No	Yes	No	No
Spain	Yes	Yes	Yes	Yes
Sweden	Yes	Yes	No	No
Switzerland	No	Yes	No	No
Turkey	Yes	No	No	No
United Kingdom	No	Yes	Yes	Yes
India	Yes	Yes	Yes	No
Japan	Yes	No	No	No
United States	No	Yes	Yes	Yes

SURROGACY

There are several forms of **surrogacy**. The most prominent form is a traditional variant that uses the surrogate mother's egg. By contrast, in gestational surrogacy, the egg is provided by the intended mother or a donor, fertilized via IVF, and then transferred to the surrogate mother's womb.
Surrogacy is prohibited in many countries, such as France, Germany, Italy, Spain, and Portugal. Surrogate motherhood is explicitly allowed in Belgium, Denmark, Greece, Ireland, the Russian Federation, Ukraine, and the United Kingdom.

A second difference refers to **compensation** of the surrogate mother. When surrogacy is permitted, in some countries the prospective parents are not allowed to pay the surrogate mother beyond covering her "altruistic costs." Conversely, commercial surrogacy is legal in certain U.S. states, as well as in India, Ukraine, and Russia.

A third difference between countries relates to **access** to surrogacy. Since some countries require that both partners provide gametes when surrogates are used, singles are generally unable to have a child via surrogacy in these countries.

CROSS-BORDER REPRODUCTIVE CARE

The variation in regulations in Europe has given rise to the phenomenon of **cross-border reproductive care**. Cross-border reproductive care refers to couples or individuals seeking assisted reproductive treatments in a country other than their country of permanent residence.

The main countries of origin of the women seeking care were **Italy** (32%), **Germany** (15%), the **Netherlands** (12%), and **France** (9%). Geographic and cultural proximity is a driving factor in the choice of treatment country.

This phenomenon is also sometimes referred to as "**reproductive tourism**" or "**reproductive exile**"

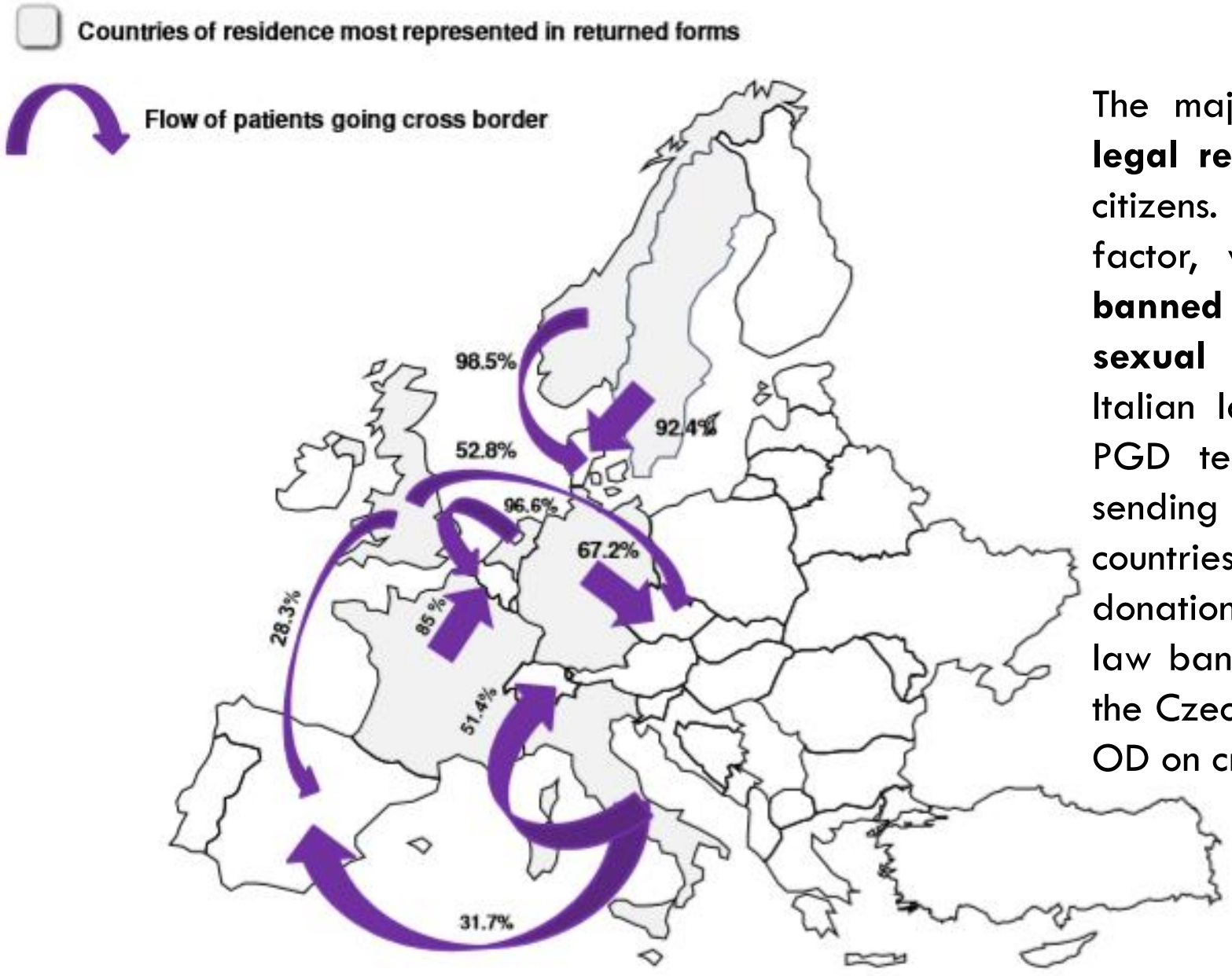
- Some German couples travel to the Czech Republic or Spain for egg donation, that is banned in **Germany**.

- In **France**, single women and lesbian couples lack access to donor sperm. So, these women sometimes travel to **Belgium** to seek treatment.

- Certain countries, like the **United Kingdom**, have long waiting lists for donor gametes, and patients who wish to avoid lengthy waiting periods seek treatment in countries where donor gametes are more readily available. Some countries (Finland, Sweden, and the United Kingdom) have banned anonymous gamete donation, which tends to discourage donation.

- Patients from countries such as **Italy** hope to receive better quality treatments abroad, while other patients go abroad because the previous treatments they received in their country of residence failed.

- Between 57 and 80% of patients from **Italy**, **Germany**, **Norway**, **France**, and **Sweden** cited legal restrictions as one of the reasons why they were seeking fertility treatment abroad. By contrast, only 32% of patients from the Netherlands and 9% of patients from the United Kingdom cited legal barriers. However, 53% of patients from the **Netherlands** reported that they went abroad to obtain better quality treatment, while 34% of the patients from the **United Kingdom** said they went abroad because of access difficulties.



The majority of patients cross borders for **legal reasons,** apart from the Dutch or UK citizens. Thus legal barriers are a major factor, whether because of **age** (France), **banned techniques** (Italy and Germany), or **sexual preference** (France and Norway). Italian law banned all donor gametes and PGD techniques in 2004 (Law 40-2004), sending a ripple of patients to neighbouring countries, like Switzerland, mostly for sperm donation, and Spain for OD. The German law bans OD and patients found its way to the Czech Republic, which performed 62% of OD on cross border women.

Due to the frequent cross-border nature of surrogacy, there is considerable confusion about which laws apply when determining the **citizenship of the child** and the **parental rights** of the surrogate and the adoptive parents. The growth in cross-border reproductive care means that restrictive national regulations can be easily circumvented, but it raises questions about equity of access.

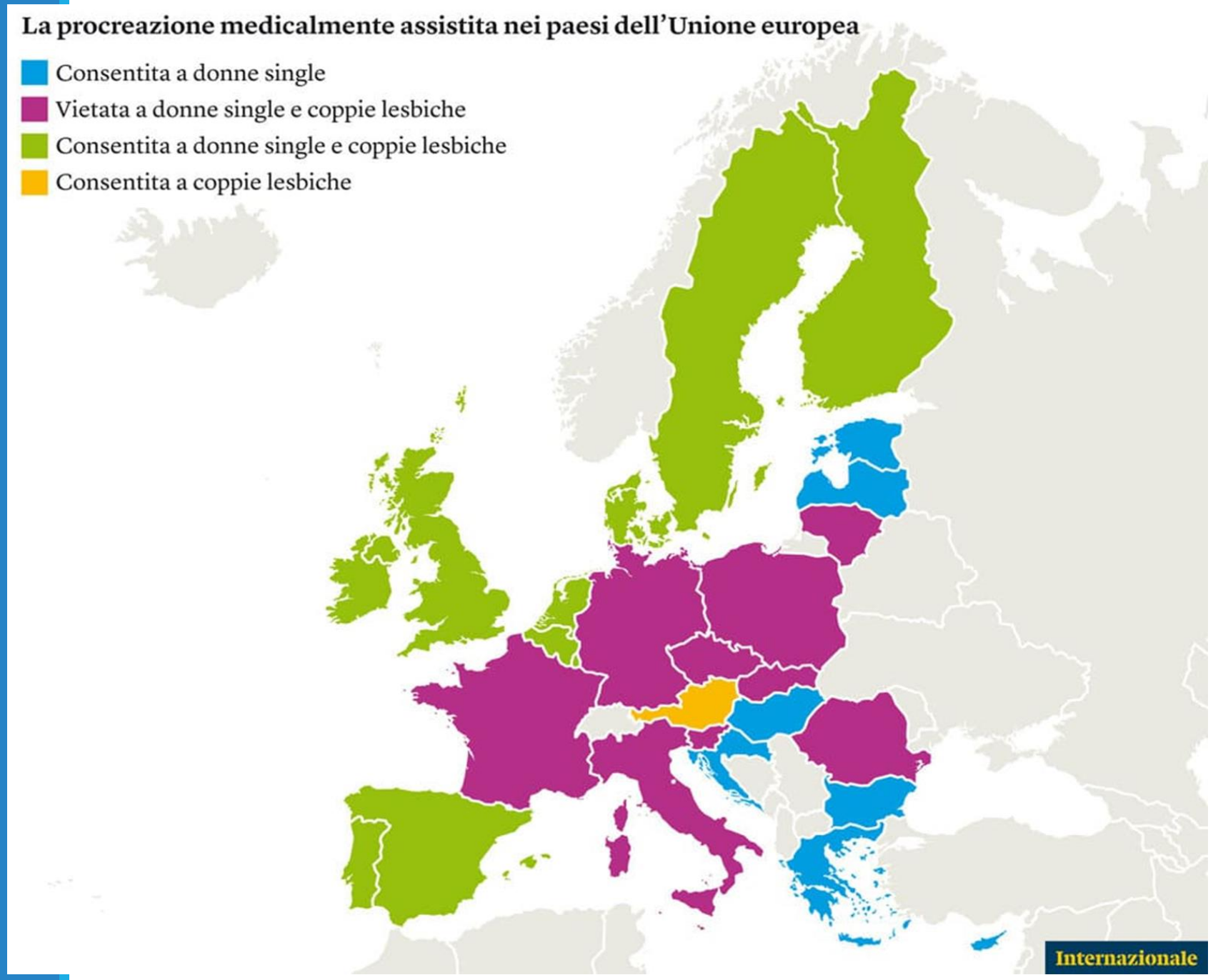
1. WHO HAS ACCESS TO PMA?

In **France** this right is currently granted only to heterosexual couples who can demonstrate medical infertility or serious illness. On the continent the legal criteria are rather heterogeneous: 10 countries have opened this right to all women, 10 others have opened it only to heterosexual couples, 7 have reserved it for single women and only Austria for homosexual female couples.

Spain has historically been the first European country to allow access to PMA for all women since 1977, the year in which the first seed bank was opened in the country. For fifteen years the laws have been evolving quite rapidly and Portugal, for example, has granted the right to medical assistance for procreation in 2006 with provisions very similar to those of France, and then in 2016 it has modified the law to grant it also to lesbian couples or single women.

In 2004 **Italy** came out of a situation of legal vacuum by adopting the strictest legislation in Europe.

- Allowed for single women
- Prohibited for single women and lesbian couples
- Allowed for single women and lesbian couples
- Allowed for lesbian couples



2. IS PMA REIMBURSED BY THE NATIONAL HEALTH SERVICE?

Currently 21 countries partially reimburse the treatments for PMA. Exceptions are 7 countries: Ireland, Cyprus, Estonia, Latvia, Luxembourg, Malta and Romania.

However, these reimbursements are subject to certain conditions. In **Belgium**, a flat rate of 1,073 euros is granted for each complete cycle of IVF. The woman must be less than 43 years old and can perform a maximum of 6 PMA cycles. Furthermore, a maximum number of transferable embryos is established, which changes according to the age and number of cycles performed.

In **France**, PMA is fully reimbursed by the national health system up to the woman's 43 years based on 4 IVF attempts and up to 6 attempts of artificial insemination.

Germany tightened its repayment terms in 2004, which caused a drastic reduction in the number of PMA practiced, from 102 thousand cycles in 2003 to less than 57 thousand in the following year. A number that has not changed much since then.

3. WHAT IS THE AGE LIMIT TO BENEFIT FROM IT?

17 countries restrict access to PMA techniques, imposing criteria relating to the age of women. 10 countries have set a maximum age, ranging from 40, like Finland and the Netherlands, to 50, such as Spain, Greece or Estonia.

In 2017 in **France** the guidance board of the biomedicine agency has pronounced for an age limit of 43 years for women.

Finally, 10 countries have not set an age limit on these medical techniques, including Austria, Hungary, Italy and Poland.

In **Italy**: “the natural age of procreation”.

4. ARE GAMETE DONATION ANONYMOUS?

Most European countries allow the use of a donor's gametes. However, countries have different positions when it comes from eggs or sperm. The **sperm donation** is in fact authorized by 20 European Union countries, including 11 under conditions of anonymity; while the **oocytes donation** is possible in 17 countries, including 8 in conditions of anonymity.

On 12 April 2016, the Council of Europe adopted a recommendation, encouraging an end to anonymity.
In the **United Kingdom**, the anonymity of sperm donation was abolished in 2005 and children can access the donor's identity once they reach legal age.
The principle of the anonymity of the donation of gametes or embryos was maintained in **France** in the bioethical law of 2011, but the new project of bioethical law currently under discussion could change the situation.

THE LAW ON ASSISTED FERTILIZATION IN EUROPE

- **HETEROLOGOUS:**

It is legalized in all the countries of the world. Currently in Italy it is prohibited in public centers and allowed in private centers.

- **POST MORTEM INSEMINATION:**

Unanimously prohibited, even if recently some sentences have authorized it in specific cases.

- **IN VITRO FERTILIZATION:**

With egg donation - Germany, Austria, Norway, Sweden there is a limitation on this technique. In Italy the donation of the oocytes is limited to private centers only.

➢ PRODUCTION OF EMBRYOS FOR RESEARCH:

No country has legalize it. In Great Britain, Sweden, Spain it is possible because cells with less than 14 days are not considered embryos. Experimental studies and research are allowed on these 'pre-embryos'. Great Britain, France, Spain, Sweden, USA, Australia researches are carried out on supernumerary embryos with the right of decision left to the couple.

In **England** heterologous fertilization is allowed and also the homologue fertilization with for 5 embryos, the introduction in utero of 2 and the freezing of the remaining 3 for subsequent pregnancy attempts.
The embryos are selected and classified with a quality index.
Furthermore, singles, lesbian couples, women over 50 and all cases of surrogacy (the so-called "rent womb") have access to assisted fertilization; all banned in Italy.

- ❖ England but also Dutch, Belgium, Spain, France have more open legislation on motherhood.
- ❖ The health of women and the fetus should be a priority.
- ❖ A child must be wanted and must be able to grow well and happy, only this is essential!

Here is what the laws governing assisted procreation in other countries provide for.

AUSTRIA

Both artificial insemination between married or cohabiting couples and the heterologous one is allowed, but not for single women. Post mortem insemination and the uterus for rent are not allowed. Access to donor data is also permitted.

SPAIN

The first law governing the subject is from 1987.

There are no restrictions on access to assisted reproduction. Homologous and heterologous fertilization, donation and cryopreservation of eggs are allowed. Access is allowed to married and cohabiting couples, as well as single and lesbian women.

FRANCE

GERMANY

The 1994 law states that only married or cohabiting couples for at least two years can access artificial insemination. The rented uterus is not allowed. The couple's components must also be both alive. Artificial insemination with donors is allowed only when assisted procreation within the couple has not been successful.

The 1990 law allows homologous and heterologous insemination only for married couples. In vitro fertilization is allowed only if homologous. It is forbidden to transfer more than 3 embryos for an insemination cycle. Post mortem insemination and the uterus for rent are not allowed.

GREAT BRITAIN

NORWAY

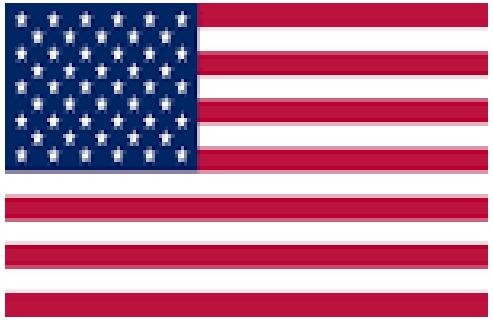
The 1990 law allows both homologous and heterologous insemination to married or cohabiting couples and single women. The uterus for rent is allowed, provided that there is no passage of money, and post-mortem insemination.

The 1987 law states that only stable or married couples can access artificial insemination. Heterologous insemination is allowed only when the woman's husband or partner is sterile or if there is an inherited disease.

SWEDEN

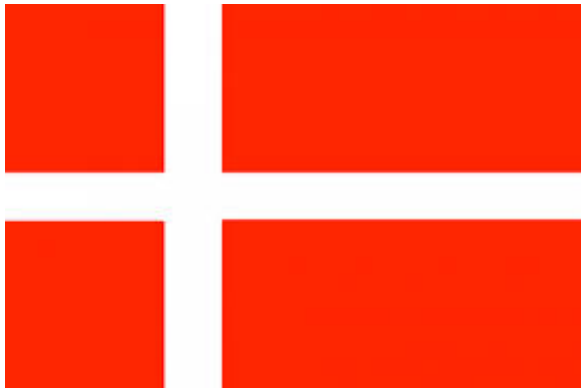
The Law of 1988 allows homologous and heterologous insemination for married or cohabiting couples. They are not allowed for the single women. In vitro fertilization is allowed only with the semen of the couple, that must be married or cohabiting. The rented uterus is not allowed.

USA



There are profound differences between the countries. Generally, both homologous and heterologous insemination are allowed. In California and some other countries the rented uterus is allowed.

DENMARK



Heterosexual and lesbian couples and also single women can request assisted fertilization. Homologous and heterologous fertilization is allowed, as donation and cryopreservation of oocytes.

GREECE

In Greece there is an age limit for women (50 years). For the rest, both homologous and heterologous fertilization are allowed, for married or cohabitants couples and for single women. Surrogacy is also allowed.

ITALY

To regulate the use of PMA in Italy is the **Law 40 of 2004**.

A law widely contested from the beginning, so much that it was the object, in 2005, of an abrogative referendum that was unsuccessful due to the failure to achieve a quorum. Over the years, the law has undergone various and radical changes following interventions by the Constitutional Court, the European Court of Human Rights and the Individual Italian Courts.

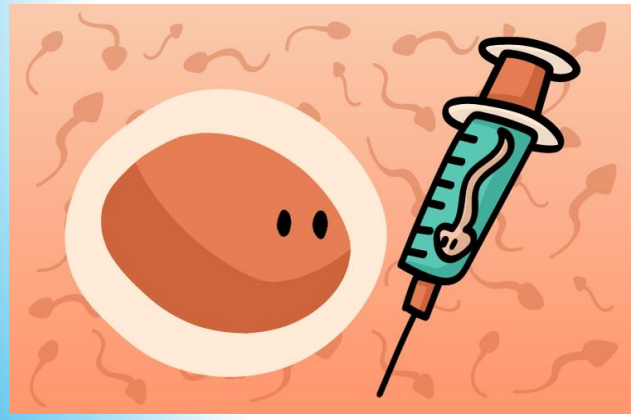
- The techniques of PMA remain prohibited to singles, to homosexual couples, to the so-called "mothers-grandmothers". Post mortem fertilization is also prohibited.
- Today it is also possible to produce more than 3 embryos, thus optimizing the procedures, but it is not necessary to transfer them all at the same time: generally, it is preferred to transfer one or at most two. Those produced in excess and not implanted can be cryopreserved.
- The prohibition of the use of embryos for research and experimentation purposes and that of cloning embryos remain in force.
- Access to heterologous fertilization is allowed only to heterosexual couples, while it is forbidden to homosexual couples.
- Today the technique of PGD is allowed, both for fertile and infertile couples bearing transmissible genetic diseases.

IN CONCLUSION..

- It is clear that 40 years after the introduction of ART, the number of techniques that are available for treatment of infertility have increased in a spectacular way and that the implementation, legislation and reimbursement of these treatments show so much **variation in Europe**.

- **Surrogacy, postmortem** use of embryo's and/or gametes, **PGD** and **embryo donation** are the treatments that are most often forbidden.

- On the other hand **IVF** and **ICSI** are universally accepted.



Age, marital status, previous **children,** the use of **donor gametes,** the type of **service provider** (public or private clinic) allowable **treatment cycles, embryo transfers** and **number** of embryo's transferred are the most common limitations on access to PMA techniques.

WHO IS RIGHT?

THANK YOU FOR THE ATTENTION