

**ACCESS AND DIVERSITY OF MEDICALLY
ASSISTED REPRODUCTION IN EUROPE**

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**PREIMPLANTATION GENETIC DIAGNOSIS (PGD)
LEGAL ASPECTS IN THE EU**

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Declaration of interest

This author reports no conflicts of interest.

This author alone is responsible for the content and writing of this presentation.

Purpose of PGD

- In IVF cycles, PGD seeks to prevent transmission of **serious genetic abnormalities** to a future child.
- Genetic characteristics of embryos are analyzed. Only **embryos free of genetic abnormalities** are implanted in a womb.
- Practiced worldwide **since 1990**.
- Many legal and ethical debates due to **varying legal frameworks** between countries.

Some examples of PGD Use (1)

Monogenic diseases: cystic fibrosis, Duchenne Muscular Dystrophy, Huntington's disease, myotonic dystrophy, spinal muscular atrophy in infants and haemophilia.

Polygenic/Multifactorial diseases: nearly 60 genes implicated in some 40 genetic predispositions to cancer; Li Fraumeni's syndrome, CDKN2A gene and melanoma, BCRA1 gene and breast and ovarian cancer. The HFEA recently authorized PGD for a rare early form of Alzheimer's disease.

Some examples of PGD use (2)

Chromosomal diseases/malformations: Turner syndrome, Down's syndrome.

Preimplantation genetic screening (PGS) for aneuploidy screening, referred to as PGD-AS, to improve IVF outcomes.

Mitochondrial diseases: Leigh's disease, Alpers disease, Barth syndrome.

Human Leucocyte Antigen (HLA) tissue typing: for the benefit of a born and ill sibling.

European Context (1)

→ Texts governing the EU stipulate that **health policies** be determined by **national legislation**.

“Treaty establishing the European Community (Amsterdam consolidated version) - Part Three: Community policies - Title XIII: Public health - Article 152 - Article 129 - EC Treaty (Maastricht consolidated version) - Article 129 - EEC Treaty”: <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:11997E152&from=EN>

→ Consequently, in the realm of **ART** in general and **PGD** in particular, the EU has only a **complementary function**.

European Context (2)

In the same vein, international governmental instruments regarding PGD do not exist apart from recommendations and reports, notably from the Council of Europe, ESHRE, WHO, UNESCO Bioethics Committee, PGDIS, etc.

→ ESHRE Best Practice Guidelines (2005):

<https://academic.oup.com/humrep/article/20/1/35/671600>

→ The Preimplantation Genetic Diagnosis International Society Guidelines for Good Practice (2008):

[http://www.rbmojournal.com/article/S1472-6483\(10\)60567-6/pdf](http://www.rbmojournal.com/article/S1472-6483(10)60567-6/pdf)

European Context (3)

→ Hence, varying national legislations governing PGD can lead to « **cross-border practices** ».

→ Meanwhile, the EU Court of Justice has ruled that health services are included in the provisions of **freedom to provide services within Article 49**.

→ That being said, it **is unclear** whether a Member State **can restrict access of its citizens** to services in other States if it has criminalized such a treatment in its own.

See the **rich and detailed report** on country-by-country PGD legislation. The Council of Europe, “Background Document on Preimplantation and Prenatal Genetic Testing: Clinical and Legal Situation”, **updated 2015**: <https://rm.coe.int/16804583d8>

Case Studies

→ Some countries (5) **prohibit** PGD, *i.e.* Switzerland, Italy (under discussion), Ireland, Austria, Luxemburg.

→ Most authorize **restricted** and/or **strong oversight use**, *i.e.* Belgium, France, Portugal, United Kingdom, Spain, Denmark.

Previously prohibited, Germany passed a very restrictive law framing PGD in July 2016.

→ Other countries have **no** policy or an **unclear** one, *i.e.* Malta, Lithuania, Cyprus. Here one finds the development of **private activities without** supervision or control.

France (1)

→ Since 1994, ART and associated procedures including PGD defined as **treatment for infertile heterosexual couples** only (might change with revision of laws this year).

→ All ART centers are **monitored** by the *Agence de la biomédecine* (ABM): <https://www.agence-biomedecine.fr/>

→ PGD is **regulated** by French Public Health Code amended by Act No. 2011-814, July 2011 and **must be authorized by the ABM** (Article L.231-4 Public Health Code). PGD objective, **avoid the transmission** of a particularly **severe, disabling and incurable** disease.

→ Hence, authorized only in **exceptional cases** as “actions of **prevention** concerning the **child**”. The responsible anomaly must be **previously and precisely identified in at least one** of the parents.

France (2)

→ Four *Centres pluridisciplinaires de diagnostic prénatal* (CPDPN) created in 1994 are **licensed to practice PGD**: Paris, Montpellier, Strasbourg, Nantes.

→ Currently, **209 genetic abnormalities** can be searched for in these centers. Among them **41 new ones** were added in 2014: <https://www.agence-biomedecine.fr/annexes/bilan2015/donnees/diag-prenat/03-preimpl/pdf/dpi.pdf>

→ Not **all** of these 4 centers are able to **diagnose all** genetic abnormalities.

France, final points

- Since 2004, PGD has been **extended to HLA** tissue typing, “savior sibling” (Public Health Code Article L. 2131-4-1).
- “Exclusion PGD” also authorized, *i.e.* a parent **not wanting to know** if s/he is a carrier of a serious disease diagnosed in PGD.
- The 2015 ABM report indicates that **595 PGDs** were accepted in 2014, **up from 438** in 2010.
- French couples **do not have** complete autonomous decision-making. The **CPDPN decides** the severity and incurability of the illness, and **once** that is established, the **couple can consent** to PGD.

Conclusion

→ Clearly, the fact that France's **health care system covers the costs** for patients of ART/associated practices explains the need for **government to regulate and monitor**.

→ In addition, the oldest PGD children today are only in their 20s, early 30s, which **encourages** French public health authorities to **prone caution and follow-up**.

→ This year, France will **revise its bioethics laws**, many topics are on the table, including access to ART by **single women and lesbian couples**.

→ The **outcome** of this revision will definitely have an **impact on PGD practices**. « *Affaire à suivre* ».

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