Regulating Preimplantation Genetic Diagnosis (PGD)

Regulations for Preimplantation Genetic Diagnosis in France

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A commentary on regulations for PGD in France.

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In France, Assisted Reproduction (AR) is regulated by two laws called "Laws of Bioethics" published on July 30, 1994, in the French Government Official Journal. The first one is relating to respect of the human body and the second one to the donation and use of elements and products of the human body for medically assisted procreation and prenatal diagnosis.

All aspects of AR are regulated, including IVF, ICSI, gamete and embryo donation, embryo freezing, research on embryos, and preimplantation genetic diagnosis (PGD). Moreover, a decree of the *Conseil d'Etat* published on March 27, 1998, again in the French Government Official Journal gives more details on specific regulations for PGD.

The laws of bioethics specify that AR is designed to respond to the prenatal demands of a couple. Its aim is to cure infertility for which a pathological cause has been medically identified. It may also aim to prevent the transmission of a particularly severe condition to the child.

The clinical and biological acts involved in AR are carried out under the responsibility of a doctor nominally accredited for this function at each establishment or laboratory authorized to carry out these techniques. Authorization concerns one or several of the activities of AR, with or without a third-party donor. It is issued for a period of 5 years. It is accorded on

the advice of the National Commission of Reproductive Medicine and Biology and of Prenatal Diagnosis (NCRMBPD).

The biological diagnosis based on cells taken from an embryo in vitro is authorized only exceptionally, in the following conditions:

- A doctor practicing in a pluridisciplinary prenatal diagnosis center must declare that the couple, because of familial conditions, has a high probability of producing a child affected by a particularly severe genetic disease recognized as incurable at the time of diagnosis.
- Diagnosis may only be carried out if the abnormality or abnormalities responsible for such a disease have previously been precisely identified in one of the parents.
- Both partners in the couple must give written consent for the diagnosis to be performed.
- The diagnosis must have the sole aim of searching for this condition and the means to prevent and treat it.
- Diagnosis may only be carried out in an establishment specifically authorized for this purpose on the advice of the NCRMBPD, under the conditions defined in the decree issued by the *Conseil d'Etat*.
- Ignorance of the dispositions of the article relating to preimplantation diagnosis is punishable by 2 years of imprisonment and a fine of 200,000 F. (about 31,000 Euros).

The decree issued by the *Conseil d'Etat* mentions specially that the declaration of the indication for

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biological diagnosis, established collectively at a pluridisciplinary prenatal diagnosis center, is signed by a specialist qualified in medical genetics, or with training and experience in this domain.

The couple is informed that only the disease linked to the parental genetic abnormality, for which there is a risk of transmission, may be sought in the embryo during the course of the analyses leading to this diagnosis.

The authorization to carry out biological diagnosis on an embryo in vitro, delivered to an establishment, concerns the following two activities:

- a) Sampling of cells from the embryo obtained by in vitro fertilization
- b) Genetic analysis carried out on the embryonic cell or cells sampled

Establishments receive authorization from the Minister of Health to carry out each of these activities over a 3-year period, on the advice of the NCRMBPD.

All establishments authorized to practice biological diagnosis on cells sampled from embryos in vitro are required to present an annual activity report to the Minister of Health.

If, within an establishment authorized, a lack of compliance with the dispositions of this section is observed, the Minister of Health may, on the advice of the NCRMBPD, revoke the establishment's authorization.

COMMENTS

The French laws and decree *encadre* therefore precisely ART technology, including PGD. Authorizations are given to clinics and to doctors after inspection and advice of the NCRMBPD. For PGD, three authorizations are required: one for the clinical embryologist who performs embryo biopsy, one for the

cytogeneticist who performs FISH analysis, and one for the molecular geneticist who searches for single-gene defects by PCR. To be authorized, doctors must demonstrate that they have diplomas, formation, and experience in animal model and/or on human cells.

The disease to be diagnosed must be particularly severe and incurable at the time of diagnosis. Defining such severe diseases is difficult because of the variable expression of many of them. Moreover, which severity are we talking about? For the child, for the parents, for the society? Does the disease concern the newborn, the child, or the adult? It is generally accepted that the genetic diseases able to be diagnosed by PGD are the same as those diagnosed in the framework of a prenatal diagnosis, on the understanding that the diagnosis on a single cell (or two cells) is available. But contrary to prenatal diagnosis, only abnormalities responsible for a disease previously precisely identified in one of the parents can be searched for. It means that aneuploidy screening in embryos of advanced aged women is not allowed. However, preconception genetic diagnosis performed on the first polar body of the oocytes is not forbidden because in the law, only the biological diagnosis based on cells taken from an embryo in vitro is regulated.

At the moment, although about 100 IVF centers are authorized to do ART in France, only three teams associating an IVF center and a genetic laboratory are allowed to perform PGD and only two are really active. Because of the small number of authorized centers, 1–2 years delay is observed before inclusion of couples and their first PGD cycle. Since 3 years 300 couples have had access to PID and approximately the same number of PID has been practiced. This illustrates the problems of ART in France. A conservative Parliament did not permit embryo research and put all possible obstacles to the PID diffusion. Many French couples have to go in foreign countries in order to obtain PID.