DEBATE

International regulation of human embryo research

Legal aspects of human embryo research and preimplantation genetic diagnosis in France

Stephane Viville1,2,4 and Israël Nisand3

1Institut de Génétique et de Biologie Moléculaire et Cellulaire, 1, Rue Laurent Fries BP163, 67404 Illkirch Cedex; 2Service de Biologie de la Reproduction, Hôpitaux Universitaire de Strasbourg, 1 Place de l'Hôpital, 67000 Strasbourg, and 3Service d'Obstétrique et de Gynecologie, Centre Hospitalier, 78303 Poissy Cedex, France. 4To whom correspondence should be addressed at: IGBMC, 1 rue Laurent Fries, BP163, Illkirch Cedex, France. E-mail: viville@igbmc.u-strasbg.fr

In July 1994 the French parliament adopted a law (no. 94–654) concerning the gift and usage of elements and products of the human body, assisted conception and prenatal diagnosis. This was a highly controversial law which was preceded by 2 years of vigorous debate and subjected to numerous modifications. The issues of assisted reproduction and research on human embryos, and the latter’s eventual application to preimplantation genetic diagnosis (PGD), were strongly debated. The purpose of this article is to present the French legal situation covering research on human embryos and the practice of PGD. In France there is a strong will, both legally and in practice, to separate these two activities, such that each is regulated in their own right. In the following sections we will refer to three articles from the French Bioethical law; a law which was voted for on July 29, 1994, and to a more recent decree, published by the government in May 1997, rendering the law covering research on human embryos applicable. Unfortunately, to enact the pending article covering PGD, a decree still needs to be published. So, for the moment, although we know that PGD will be authorized, the practice of PGD is currently impossible in France.

Research on human embryos in France

Article L152–8 (July 1994) states that ‘the creation of human embryos for study, research or experimentation is prohibited. All experimentation on human embryos is prohibited. In exceptional cases, the man and the woman forming the couple may to consent studies on their embryos. They have to provide written consent. The study must have a medical finality and should not damage the embryo’. A recent decree (no. 97–613; May 1997) specifies under which circumstances research can be performed: ‘the outcome of the study must be one of the following: (i) it must represent a direct benefit for the embryo under study, especially in terms of improving its chances to implant; (ii) it must participate in the improvement of assisted reproductive technology–in-vitro fertilization (ART–IVF) technology by improving the knowledge of the physiology and pathology of human reproduction.’

None of these studies can be performed in order to modify the embryo’s genome or if it represents a risk to alter the development of the embryo.

This decree also indicates that the practice of PGD should not be considered as a study. In addition, before any research is performed, it is necessary to obtain an agreement from the Ministry of Health in consultation with the National Commission of Medicine and Biology of Human Reproduction and Prenatal Diagnosis. Finally, it dictates that any developmental stage, after fertilization has taken place, must be considered as embryonic regardless of either the developmental status, be it developing or arrested, or the presented morphology.

So, in exceptional cases, research on human embryos is ultimately permitted in France, being conditional upon authorization from the Minister of Health. Licensing is needed, therefore, for studies involving, for example, the improvement of culture media or freezing conditions and the determination of chromosomal constitution of arrested embryos.

Unfortunately, the complexity of these texts would not facilitate the development of a good quality research programme, as many issues have been insufficiently addressed. For example, what is meant by ‘damaging an embryo’? Is the biopsy of one or two blastomeres to be seen as damaging an embryo? The notion that the research ‘must represent a direct benefit for the studied embryo’ is also puzzling. Does it mean research on an arrested embryo will be prohibited? If such an embryo is considered dead, how can any research be of any benefit to it?

One could wonder if the complexity of the text does not reflect the fact that the legislator was tempted by a total prohibition of research on human embryos and designed the law in such a way that only the practice of PGD, on live embryos, would be legally feasible. It is interesting to note that France has refused the notion of ‘pre-embryo’, adopted by the British Human Fertilisation and Embryology Act (1990), as corresponding to the developmental stage when the primitive streak appears, or 14 days after fertilization. This measure, thereby allowing research up to this stage, has been adopted by most European countries with the exception of France. Interestingly, in accordance with most of its neighbouring countries, with the exception of the UK, France has banned the creation of human embryos for research purposes.

It is worth noticing that France is one of the many countries to have signed the ‘European convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine’. This Act stipulates in article 18: (i)
where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo; and (ii) the creation of human embryos for research purposes is prohibited. The French law conforms with this European convention, which does not provide precise definitions.

The practice of PGD in France

In most European countries, the practice of PGD is controlled by the law or by recommendations covering research on human embryos. French law links the practice of PGD to prenatal diagnosis (PND) and not to research on human embryos.

Article L162–17 (July 1994) allows the practice of PGD and stipulates that it may only be performed inside a multidisciplinary network licensed for PND. Furthermore, this text defines the conditions under which PGD can be practised: (i) centres must be licensed for PGD and for ART–IVF, and their activity is subject to an annual evaluation; (ii) the consulted couple must otherwise have a high probability of giving birth to a genetically affected child; (iii) the genetic defect must be of a particular severity and recognized as incurable at the moment of diagnosis; (iv) the genetic anomaly must be fully characterized in the parents; (v) only the previously identified defect can be investigated; (vi) the couple must provide a written consent for the diagnosis.

The current legislation in France covering PND (Article L162–16; July 1994) concerns all medical techniques (such as ultrasound screening or fetal cell sampling), allowing the detection in utero of an affection of a particular severity. They can be performed by any relevant specialist, but the decision to terminate a pregnancy has to be taken in connection with a licensed multidisciplinary centre. Relevant specialists include: medical geneticists, sonographists, obstetricians, paediatricians, surgeons, cytogeneticists, molecular biologists and pathologists. Decree no. 97–578 (May 1997) dictates under which conditions a licence may be obtained. By law, the bioethical legislation will be reviewed in 1999.

Conclusions

France has chosen to clearly separate research on human embryos from the practice of PGD. The law covering human embryo research, even if it allows it, has reached such a complexity that it can be interpreted in many different ways, thereby allowing a Minister of Health to permit or prohibit it according to his own beliefs. Even if we are convinced of the necessity of a (strict) law covering this field, we think that clarity is often, if not always, a sign of quality. With regards to French legislation, such clarity is lacking. This certainly reflects the difficulty that the parliament has had in reaching a 'consensus'. It seems that the only procedure that will be legally authorized, on live embryos, is PGD. At least we have avoided a total prohibition.

Concerning the legal details covering the practice of PGD, things are clearer and the law allows such a practice under strict conditions which are easily acceptable, even if PGD for advanced maternal age will not be allowed (which, eventually, can be considered as 'improving the embryo’s chance to implant'). PGD will be allowed for genetic diseases of a particular severity and recognized as incurable at the moment of diagnosis. Furthermore, since there is a clear legal distinction between research and diagnostic activities, we can expect that the prohibition on damaging an embryo will not concern all diagnostic activity. For example, at least the biopsy of blastomere(s) for PGD will not be seen as damaging to the embryo since the ultimate goal is to reach a pregnancy.

Unfortunately, the application of this law (Article L162–17) is still awaiting a decree to be published by the French government; since July 1994 this has not been done! It is dramatic that France has delayed the practice of PGD for so long. This situation is becoming difficult to deal with since some centres have already sent couples abroad in order for them to have access to PGD. All the more, as part of the cost of PGD, the IVF procedure will be payed for by the Social Security since the French legislation states that 'any couple suffering from medically diagnosed infertility or being at risk of transmitting a disease of a particular severity should have access to ART–IVF'. This is, in our point of view, of extreme importance since it potentially allows access to PGD to everyone, regardless of financial status between couples. Furthermore, it has to be mentioned that few teams, such as ours in Strasbourg, are practising and are proficient at the different techniques necessary for PGD on mouse embryos and cultured human cells and are ready to offer PGD when the decree is published.

Acknowledgements

The authors wish to thank Dr Richard Mollard for his helpful comments on the manuscript.

Human embryo research: the Australian experience

Russell Scott

7th Floor, 20 Loftus Street, Sydney, NSW 2000, Australia

Viville and Nisand (1997) highlight the risks and weaknesses of detailed parliamentary lawmaking as the medium for regulating unprecedented medical advances. Their concern is the French parliament’s ambivalence over research on embryos produced by assisted reproductive technology (ART) outside the human body, for example by in-vitro fertilization (IVF).

They cite the French Bioethical Law of July 1994 which states 'the creation of human embryos, for study, research or experimentation is prohibited. All experimentation on human embryos is prohibited'. However the Law itself then weakens its own prohibition: 'in exceptional cases, the man and the woman forming the couple may consent to studies on their embryos... The study... should not damage the embryo' (Article L152–8).

The authors then turn to the practice of preimplantation genetic diagnosis (PGD) which the French parliament,