Regulatory Attitudes to Assisted Reproductive Technology in Europe

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First of all I would like to thank Professor Ono very much for inviting me here. I am very honoured to be here to speak at Daito Bunka University. I would also like to say how much I have enjoyed my visit to Japan, and Tokyo in particular.

Assisted reproduction means providing assistance to those who would otherwise be unable to reproduce. It can include principally 'natural' methods, such as donor insemination and surrogacy, where technological interventions may not be needed and 'artificial' methods which require in vitro procedures. Natural methods of human reproduction are difficult to regulate. Artificial methods require laboratories and skilled technicians and clinicians and are more amenable to legislative control.

Although the first IVF child was born well over twenty years ago, countries have been slow to legislate. Assisted reproduction is a difficult field with conflicting ethical issues arising. There have been long discussions about the status of the embryo, human dignity, the integrity of the individual and clinical and scientific freedom. These are all problems that legislators have to address.

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Over the years she has become an expert on the regulatory and legislative aspects of assisted reproduction, having provided advice both to the European Commission and the British government. During her time at the MRC she was secretary to the Voluntary Licensing Authority for Human in vitro Fertilisation and Embryology, which regulated human embryo research and IVF before statutory regulation was introduced. At the BBSRC, initially, she was seconded to the Department of Health to write a report on the comparative regulation of human IVF and embryo research for use while the Human Fertilisation & Embryology Bill was going through Parliament. Subsequently, she was involved in science policy, developing research assessment methodology and research ethics. She was a Visiting Fellow for 6 years at the Centre for the Analysis of Social Policy at the University of Bath.

She is now working as a Senior Research Fellow in medical law and ethics at Cardiff Law School and as an independent consultant in bioethics and science affairs. She has coordinated a European project on Therapeutic Research in Assisted Conception and has been a partner in two further European projects; Bioethical Aspects of Biotechnology in the Agro-food Sector and Ethnical Function in Ethics Committees. She was a member of the Human Embryo and Fetus Working Group of the European Commission.

In addition to these activities, she sits as a magistrate and is a member of the Avon and Somerset Local Probation Board.

While these discussions have been taking place, clinical and scientific advances in the field have continued to move forward, advancing from simple IVF, use of the embryo, to higher risk and more sophisticated technologies, such as Intra-Cytoplasmic Sperm Injection (ICSI) -this means injecting one sperm into a human egg, using micro-manipulation procedures - or Preimplantation Genetic Diagnosis (PGD). This is where one cell is removed from an embryo to diagnose whether it is normal and free from genetic disease.

Legislators also have to address societal aspects, such as what is a mother, what is a father, what is a family, and who should be allowed to have treatment?

I shall describe how these issues have been tackled in Europe. First of all, by looking at an international legal instrument, the European Convention on Human Rights and Biomedicine, and then I shall look at the legislation in individual countries. The European Convention was open for signature in April 1997. Of the 43 member states of the Council of Europe, 30 states have signed. It required five states to ratify the convention for it to enter into force, and it entered into force with 5 ratifications on 1 December 1999. There are now 10 ratifications.

This Convention took a long time to be drafted and enter into force - at least 10 years deliberation. Of course, the Convention addresses other areas of biomedicine than reproduction, but it was particularly difficult to reach consensus on the articles addressing assisted reproduction. Of interest may be the countries that have not signed. These include the United Kingdom, Germany, and Belgium. The UK and Belgium are very active in IVF and embryo research, but Germany, on the other hand, is quite restrictive.

Article One addresses the purpose and object of the Convention. This, in all cases, protects the dignity and identity of all human beings, and guarantees everyone without discrimination respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Relevant to this talk is Article 13, which addresses interventions on the human genome, and provides that modifications to the human genome may only be undertaken for preventative, diagnostic or therapeutic purposes, nor can the genome of any descendants be modified.

Two articles specifically address assisted reproduction, Articles 14 and 18. Article 14 forbids the use of sex selection for social reasons, and Article 18 prevents the creation of embryos for research. Although in countries where they have existing laws allowing research using embryos surplus to IVF treatments, it requires that they provide adequate protection to the

embryo. The details of what is required under Article 18 are being drawn up in a separate protocol, but this is not yet ready.

Countries signing and ratifying the European Convention will be bound by its articles unless they have law already in place, in which case they can enter a reservation against the relevant article on ratification. At present 15 of the 30 signatories have no assisted reproduction law, nor have 7 of the 10 ratifying states.

The European Convention was open for signature in April 1997 but by the end of 1997, Dolly the Sheep, the cloned sheep, hit the headlines. The Council of Europe acted quickly to address the possibility of human cloning, and an Additional Protocol of the European Convention was open for signature in January 1998. So far, there are 29 signatories to this Protocol and there were 8 ratifications by September 2001.

This Additional Protocol has two principal articles.

The first says that any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.

The second article says that for the purpose of this article the term "human being genetically identical to another human being" means a human being sharing with another the same nuclear gene set.

What this protocol means is that it aims to prevent the reproductive cloning of human beings. But the use of human embryonic stem cells in cloning techniques, or what is called "therapeutic cloning", will be addressed in the protocol to Article 18 of the main Convention. It is considered that cloning humans is a threat to human identity, but the Second Article is trying to say that it does not wish to discriminate against natural monozygotic twins.

Now I come to particular European legislation. I have divided it into two categories. The first category is what I call "permissive legislation". This is legislation that allows IVF technologies and allows embryo research. I shall address these countries in alphabetical order and there is no significance in the order in which they appear.

Table 1: Permissive legislation

Denmark	Law No. 503 24 June 1992 Order No. 650 22 July 1992 Circular No. 108 13 June 1994 Law No. 460 10 June 1997

	Ratified the ECHB 10 August 1999; has signed but not yet ratified the Additional Protocol
France	Order of 20 September 1988 Order of 9 March 1993 Law No 94-654 29 July 1994 Decree No. 97-613 27 May 1997 Order of 12 January 1999 Signed ECHB 4 April 1997–no ratification Additional Protocol signed 12 January 1998–no ratification
Hungary	Act No. CLIV 1997 Chapter VII Signed ECHB 7 May 1999–no ratification Additional Protocol signed 7 May 1999-no ratification
Spain	Law No 35 22 November 1988 ECHB ratified 1 September 1999 Additional Protocol ratified 24 January 2000
Sweden	Law No. 711 of 14 June 1988 Law No 115 of 14 March 1991 ECHB signed 4 April 1997–no ratification Additional Protocol signed 12 January 1998–no ratification
United Kingdom	Human Fertilisation & Embryology Act 1990 HFE (Disclosure of Information) Act 1992 Parental Orders (HFE) Regulations 1994

Denmark

Denmark legislated after a considerable period of public consultation through its national ethics committee. The law in 1992 was enacted specifically with revision in mind. It allows embryo research and IVF treatment. It forbids embryo donation and cloning. It does not allow the return to the womb of embryos that have been used for research. The subsequent Order of 1992 merely addressed issues around freezing embryos and oocytes. It also deals with oocyte donation, where anonymity is required for the use of these gametes.

The 1997 law was the revision of the 1992 law. This is the anticipated revision. esearch was still allowed, and the law is silent about whether embryos may be created for research or not, which would imply that researchers could create embryos for research. The Danes felt that it was unethical to use new IVF technologies if they did not allow research. The law also restricts artificial fertilization to using a partner's gametes. This is looking at a societal aspect for Denmark. The law additionally forbids the use of ovaries from aborted foetuses or stillborn girls. This is an issue that has recently arisen since it has become possible to mature oocytes from ovarian resections. Embryos can be stored for up to two years frozen.

However, Denmark ratified the Convention in August 1999, without a reservation on Article 18. This, in effect, means that the creation of embryos for research is now no longer possible in Denmark.

France

The French discussed the issues related to assisted reproduction for many years. The Order of 1988 was made because many experts in obstetrics and gynaecology wished to enter assisted reproduction, and a very large number of clinics started to be set up. This Order limits the number of clinics to one clinic per 100,00 women between 20 and 40 years of age.

The Order of 1993 was about the regulatory control of laboratories.

The principal legislation in France was enacted in 1994 - the Bioethics Law. This covered counselling and consent procedures. Embryo and gamete donation was also covered. The Law forbids the commercialisation of embryos; establishes a national commission as a regulatory body; and allows preimplantation genetic diagnosis for serious incurable genetic diseases. The Law is ambiguous about research, in that it says that research on embryos can only be undertaken for exceptional reasons, and that it must not harm the embryo. This has effectively stopped research, because French researchers could not see how they could do experiments that were not harmful.

The Decree of May 1997 tried to clarify this a little, and it allowed studies to be conducted on human embryos only to the direct advantage of the embryo concerned.

The Order of 1999 sets out rules for good clinical practice.

France has signed, but not ratified, the Convention, but the law in France complies with its objectives.

Hungary

Hungary was one of the first of the eastern European countries to legislate. The law does allow research on spare embryos. Embryos which have been the subject of experiment cannot be re-implanted and cannot be kept in vitro longer than 14 days

Sex selection is only permitted for prevention of sex dependent hereditary disease.

Spain

Spain is an interesting case. The law was enacted in 1998 and is a comprehensive and liberal law for a Catholic country. It allows treatment of

single women, for instance, and allows research on non-viable embryos, although it does not allow the creation of embryos for research. It makes surrogacy contracts invalid and requires gamete donors to be anonymous.

This law was challenged by the Popular Party, which did not agree with the section on donor anonymity. The law was referred to the Constitutional Court, which delayed its implementation for nine years, when the Constitutional Court declared that there was no conflict with the Constitution, and that donor anonymity was acceptable.

Sweden

In 1984 Sweden was the first country to make a law allowing the identification of sperm donors. This had an interesting effect, both on the donors and on the patients. Patients preferred donors to be anonymous, and sought treatment in other countries. The pool of donors changed from being largely medical students to being married men. This initially caused a sharp drop in the number of treatments, but the situation has now stabilized.

Sweden has continued to revise its laws addressing IVF and related technologies. The first law addressing IVF was in 1988. It was revised in 1991, and currently is undergoing further revision. Swedish law only allows treatments for couples using their own gametes, and they may be treated only in public hospitals unless there is special authorization. Embryo research is allowed, provided there is consent from the originators of the embryo and, again, the law is silent on the creation of embryos for research. This technically means that this is possible in Sweden.

Sweden has signed but not yet ratified the Convention.

United Kingdom

A Committee of Inquiry, the Warnock Committee, was established to address the issues surrounding IVF and human embryo reseach. It filed its report in 1984. Subsequently, a period of regulation by a voluntary authority preceded statutory regulation. The Human Fertilization and Embryology Act came into force in 1990. Its major provisions address in-vitro fertilization, embryo research, donor insemination, and the status of children born as a result of assisted reproductive technologies and surrogacy. The Act also amends the abortion law, and makes surrogacy contracts unenforceable. It sets out prohibited activities, particularly undertaking treatment or research without a licence.

Most importantly, the Act makes provision for the establishment of the Human Fertilization and Embryology Authority (HFEA), which controls assisted reproduction in the UK through its Code of Practice. This allows

flexibility in the light of advancing technology, and the Authority undertakes public consultations. So far, it has consulted on sex selection, with the result that sex selection for social reasons is not permitted. It has also consulted on the use of donated ovarian tissue, with the result that tissue from foetal ovaries cannot be used. There is currently a consultation on preimplantation genetic diagnosis.

In 1992, a new law amended some confusion about confidentiality in the 1990 Act. In 1994, another amendment allowed parental rights and obligations to be transferred from birth to commissioning parents in the case of surrogacy.

Now we come to countries having restrictive legislation. These are countries that either do not allow in-vitro assisted reproduction or they do not allow embryo research.

Table 2: Countries having restrictivelegislation

Austria	Act No. 275 1992
Germany	Law of 13 December 1990–Embryo Protection Law
Norway	Law No 68 12 June 1987 Law No 56 5 August 1994 Law No 52 30 June 1995 ECHB signed 4 April 1997–no ratification Additional Protocol signed 12 January 1998–no ratification
Switzerland	Amendment to the Federal Constitution Section 24, *novies*,17 May 1992 Glarus-Article 33 of Law on Health of 1 May 1988 Base-Law on Human Reproductive Medicine of 18 October 1990 ECHB signed 7 May 1999-no ratificationAdditional Protocol signed 7 May 1999–no ratification

Austria

The Austrian legislation allows no embryo research unless such examination and treatment is necessary to achieve a pregnancy. This would be very unusual. Couples receiving treatment must be married or cohabiting, and an interesting part of this law is that counselling is mandatory; couples have to have counselling.

Germany

The German law is about embryo protection. Eggs may only be fertilised with the object of achieving a pregnancy. The law is very rigid. It allows no embryo research whatsoever, with the end result that it gives higher status to a two-day embryo in vitro, than it does a three-month foetus in the womb. This is because the law implicitly prohibits preimplantation genetic diagnosis while prenatal diagnosis with selective termination of an affected pregnancy is possible.

Norway

Norway was an early legislator. In 1986, a law was passed which limited IVF to state hospitals while a more comprehensive law was considered. Norwegian legislation has subsequently been updated twice. No embryo research is allowed. A couple's own gametes must be used in any treatment, and the 1995 law requires any new technology to have the approval of the Ministry of Health before it can be introduced.

Switzerland

Switzerland is a small country, but it is a federation of even smaller cantons. Individual cantons legislated before the federal state did, and two of the German-speaking cantons, Glarus and Basel do not allow any in-vitro assisted reproduction technologies, nor do they allow donor insemination. The Swiss amended their constitution to address assisted reproduction, and this sets out provisions under which assisted reproductive technology (ART) may be used. ART is only allowed for alleviating sterility or for preventing the transmission of serious genetic disease. No embryo research is allowed, and no surrogacy is allowed. Children may have access to a donor's identity only if the donor has given consent. Otherwise they may only have access to other non-identifying information about their donor father.

Wherever there is legislation, the penalties for infringing these laws, whether permissive or restrictive, usually involve imprisonment, but the terms of imprisonment vary considerably between legislations, and of course fines are also possible. In Norway, persons who deliberately breach the law may be imprisoned for up to three months.
In Germany, violation of the law may be punished by imprisonment of up to five years or a fine. In the United Kingdom, persons guilty of an offence involving the mixing of human and animal gametes, or introducing animal embryos or gametes into a women may be liable to imprisonment for up to ten years, or a fine or both. Other offences are punishable by up to two years imprisonment. In this case, where a country has relatively liberal laws, it has actually more severe penalties than a country with more restrictive law.

Thank you very much for listening.

Thank you so much Dr. Gunnning