Oocyte donation: the legislative framework in Western Europe

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Relatively few countries have legislation addressing oocyte donation. Where such legislation does exist it is entirely in the context of broader legislation concerned with the regulation of in-vitro fertilization (IVF) or assisted reproduction more generally. Within Western Europe only nine countries so far have passed Acts addressing assisted reproduction. These countries fall into two groups in their approach to oocyte donation: those which do not allow gamete donation, and hence oocyte donation, in the context of IVF (Austria, Germany, Norway and Sweden) and those which specifically permit the use of donor oocytes in the treatment of infertility or to avoid the transmission of disease (Denmark, France, Spain and the UK). In Switzerland, a federation of cantons, where legislation relating to assisted reproduction is primarily a cantonal matter, except where it affects constitutional rights, the picture is similar. The Canton of Aargau does not allow gamete donation in the context of IVF, the Cantons of Glarus and Basel do not permit gamete donation at all and the remaining cantons follow the guidelines of the Swiss Academy of Medical Sciences.

Key words: donation/gamete/legislation/oocyte/regulation

Comment on those technical, ethical or social aspects of oocyte donation which have not been the subject of legislation and which are the subject of a paper by another author.

For women with dysfunctional or no ovaries, the only way to achieve a pregnancy is through the use of a donor oocyte or embryo. This has only become possible during the last 15 years or so through the development of in-vitro fertilization (IVF) techniques. In contrast, donor insemination (DI) has been practised since the 19th century and has become a common method of alleviating male infertility in the second half of the 20th century. Whereas there is widespread legislation addressing DI (primarily with regard to filiation and eligibility for treatment), there is no legislation solely addressing issues relating to the donation of oocytes. Rather, where countries have introduced more general legislation addressing assisted reproduction, the provisions may extend to the use of donor oocytes.

Only nine Western European states have so far introduced comprehensive legislation addressing assisted reproduction. These tend to fall into two groups with respect to their attitude to oocyte donation; those which permit oocyte donation and those which prohibit it.

Legislation permitting oocyte donation

Only four countries specifically permit oocyte donation, Denmark, France, Spain and the UK. In each case this is addressed within broader legislation covering assisted reproduction. While eligibility for oocyte donation varies there is a consensus that donors should not be paid for their oocytes.
Table I. Legislation in Western Europe permitting oocyte donation

<table>
<thead>
<tr>
<th>Country</th>
<th>Legislation</th>
<th>Comment</th>
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| Denmark | Act No. 503 24 June 1992  
| France | Law 94-654 29 July 1994 | Requires donor anonymity; requires donors of oocytes or spermatozoa to be part of a fertile couple and their written consent is obligatory; requires partners to give consent before a judge or notary. Treatment is reserved for heterosexual couples. |
| Spain | Law 35 November 1988 Health: Assisted Reproduction | Gamete donation must be free and anonymous. Donors must be consenting adults. No more than six offspring per donor. Single women eligible for treatment. Law currently declared unconstitutional and not implemented. |
| Switzerland | Section 24 novies of Constitution (May 1992) | Guarantees access to information relating to parentage. Access to treatment only for infertility or to avoid transmission of serious disease. Oocyte donation prohibited in some Cantons – see Table II. |
| UK | Human Fertilisation and Embryology Act 1990 | Donors must be anonymous although identifying information collected. Child may have access to non-identifying information at age 18. Single women eligible for treatment. |

Table I summarizes legislation within Western Europe specifically permitting oocyte donation.

**Denmark**

The Danish Act No. 503 of 24 June 1992 was derived from a report from the National Ethics Council entitled *Protection of Human Gametes, Fertilised Ova, Embryos and Fetuses*. The Act primarily addresses access to assisted reproduction and the issue of research in this context. Treatment is available to single women as well as to couples. A further order under the Act (No. 650 of 22 July 1992) specifies that oocyte donation must be anonymous and stipulates that frozen oocytes, fertilized or unfertilized, may be stored for a maximum of one year. There is a statutory obligation for the Act to be reviewed by 1995–1996. This review is nearing completion and a new Act is likely to be adopted during the summer of 1997.

**France**

The recent French law on bioethics, Law 94-654 of 29 July 1994, was a long time in gestation and followed a number of reports from the National Ethics Committee, the Conseil d'Etat and, finally, a report commissioned by the government from the lawyer Madame Noelle Lenoir. The French approach to oocyte donation mirrors that to DI and the new law enshrines many of the regulations formerly imposed by CECOS (Centres d'Etude et de Conservation du Sperme) which carries out ~90% of all inseminations in France.

Treatment is reserved for couples who must be of procreative age and is only to be provided to alleviate infertility or to avoid the transmission of disease. Couples have to consist of a man and a woman and have to be married or to show proof that they have been living together for two years. Although not explicit in the law, this has the effect of excluding from treatment single or lesbian women. Treatment centres must be non-profit making and must be licensed. Licences are for five years.

As with sperm donation, oocyte donation must be free and anonymous. The donors must be of proven fertility, part of a stable couple and are required to give written consent. The law requires that embryos must be created with the gametes of
at least one member of the couple undergoing treatment. This means that where donor oocytes are used they must be fertilized with the spermatozoa of the male partner. Whenever donor gametes are used, the couple undergoing treatment must give their consent before a judge or notary. This consent may be withdrawn at any time before treatment.

Spain

The Spanish Law 35 Health: Assisted Reproduction Techniques received Royal Assent on 22 November 1988 and was the first legislation of its kind in the European Union. It made provision for the establishment of a regulatory body, the National Committee of Assisted Reproduction, as well as addressing issues such as eligibility for treatment, gamete donation and embryo research. Any woman, whether married or not, is eligible for treatment. The donation of both gametes and embryos is authorized and must be free with not more than six children allowed to be born from one donor. Donors must be aged >18 years and gamete donation, and so oocyte donation, must be anonymous. The freezing of oocytes is prohibited.

The required anonymity of gamete donation led to the law being challenged as unconstitutional immediately upon its enactment. It was contested that, as a law addressing human rights (in this case to know one's origins) it was not enacted according to the correct procedure. The Constitutional Court is still considering the issue. In the meantime the regulatory body has yet to be established and the provision of assisted reproduction, including oocyte donation, is subject to professional self-regulation.

UK

The Human Fertilisation and Embryology Act (1990) is probably the most comprehensive of all the European legislation addressing assisted reproduction. One of the principal elements of the legislation is the establishment of a statutory regulatory body, the Human Fertilisation and Embryology Authority (HFEA) which is charged with licensing centres and drawing up a Code of Practice. The requirements of the HFEA with regard to gamete donation are dealt with in a separate paper. While oocyte donation is permitted, the Act requires that a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as the result of treatment (including the need of that child for a father). This discourages but does not preclude the treatment of single women. The Act requires that the woman/couple being treated is offered appropriate counselling but this is not mandatory.

Gamete donation must be anonymous though centres providing treatment are required to supply identifying information to the HFEA. The Act makes provision that persons attaining the age of 18 can seek information from the HFEA about whether they were born as a result of assisted conception techniques and obtain non-identifying information about the donor. This provision ensures that sibling marriages are avoided but also would allow the retrospective removal of donor anonymity.

The Act also clarifies the status of the couple being treated with regard to the child. The woman bearing the child is defined as the mother. However, the Act allows parental orders to be made in favour of the gamete donors in the case where the child is borne by a third party. That is, where a woman has functioning ovaries but no womb and her embryos are carried by another woman, she is technically donating her oocytes to the surrogate who, in the terms of the Act, is the mother. This section allows the infertile woman, together with her husband, to claim entitlement to legal parenthood. The application must be made within 6 months of the birth of the child.

Legislation not permitting oocyte donation

There are more laws prohibiting than permitting oocyte donation. These laws do not specifically address oocyte donation but deal with gamete donation in general or in the context of IVF. The restrictive point of view towards sperm and oocyte donation is characteristic of the German-speaking and some Nordic regions of Western Europe. While sperm donation may be seen as an acceptable way of addressing male infertility, gamete donation in the context of IVF is perceived as being unnatural and oocyte donation is thus precluded. The Cantons
Oocyte donation: Western European legislation

Table II. Legislation in Western Europe not permitting oocyte donation

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<thead>
<tr>
<th>Country</th>
<th>Legislation</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Austria</td>
<td>Act No. 275 1992</td>
<td>Gamete donation prohibited in the context of IVF or</td>
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<tr>
<td></td>
<td></td>
<td>GIFT – no oocyte donation</td>
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<tr>
<td>Germany</td>
<td>Embryo Protection Act 1990</td>
<td>Prohibits oocyte donation</td>
</tr>
<tr>
<td>Norway</td>
<td>Act No. 68 12 June 1987</td>
<td>Gamete donation prohibited in the context of IVF</td>
</tr>
<tr>
<td>Sweden</td>
<td>Law No.711 14 June 1988</td>
<td>Gamete donation prohibited in the context of IVF</td>
</tr>
<tr>
<td>Switzerland:</td>
<td></td>
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<tr>
<td>Canton of Glarus</td>
<td>Law on Health 1 May 1988</td>
<td>Permits AIH only, forbids IVF – no oocyte donation</td>
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<tr>
<td>Canton of Basel</td>
<td>Law on Human Reproductive Medicine 18 October 1990</td>
<td>Permits AIH only, forbids IVF – no oocyte donation</td>
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<tr>
<td>Canton of St Gallen</td>
<td>Decree 24 February 1988</td>
<td>Prohibited IVF but declared unconstitutional</td>
</tr>
<tr>
<td>Canton of Aargau</td>
<td>Law on Health 10 November 1987</td>
<td>Allows homologous IVF only – no oocyte donation</td>
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</tbody>
</table>

IVF = in-vitro fertilization; GIFT = gamete intra-Fallopian transfer; AIH = artificial insemination by husband.

of Glarus and Basel in Switzerland consider all use of donor gametes as unacceptable.

Table II summarizes the legislation in Western Europe not permitting oocyte donation.

Austria

In 1992 the Austrian government passed a broad and generally restrictive Act on Procreative Medicine, Act No. 275. While permitting IVF, the Act does not permit the use of donor gametes in conjunction with the technique and thus prohibits oocyte donation.

Germany

The German Embryo Protection Act went through a number of drafts before becoming law on 24 October 1990. As implied by its title, the Act focuses on the protection of the embryo and centres almost entirely on penal provisions. The Act prohibits the fertilization of a human oocyte for any purpose other than to start a pregnancy in the woman who produced it. Oocyte donation is therefore not allowed.

Norway

Norway was the first European country to introduce legislation concerning artificial fertilization in the Act No. 68 of 12 June 1987. Like the Austrian legislation, the Norwegian Act also prohibits the use of donor gametes in the context of IVF and so prevents oocyte donation.

Sweden

In 1984 Swedish law removed the principle of anonymity in the context of DI (Law No. 1140 of 20 December 1984). In contrast, the Law No. 711 of 14 June 1988 on fertilization outside the human body forbids the use of donor gametes in the context of IVF. The use of oocytes from a third party woman is considered contrary to the human biological process.

Switzerland

There is a divergence of approach among the Swiss Cantons with regard to assisted reproduction. It represents in microcosm the varying attitudes in the rest of Europe. The German speaking Cantons of Glarus and Basel have both introduced laws allowing artificial insemination by husband only so that both DI and oocyte donation are forbidden. A similar decree introduced by the Canton of St Gallen in 1988 was declared unconstitutional. The Canton of Aargau allows only homologous IVF and hence no oocyte donation.

Other Cantons allow treatment according to the guidelines of the Swiss Academy of Medical Sciences, thus delegating regulation to the profession. These restrict treatment to married couples or unmarried couples living in similar conditions, such that gamete donation is allowed but, like the French law, provided that donor gametes are not used from both sexes simultaneously. Donation must be free of charge and the number of offspring from one donor is limited to ten. Gametes may be stored up to five years.

In May 1992 the Federal Constitution of Switzerland was amended (Section 24 novies) to restrict access to assisted procreation techniques. Access is permitted where infertility or the risk of transmis-
sion of serious disease cannot be avoided in any other manner. The amendment also guarantees a person access to data relating to his or her parentage.

Conclusion

In considering the legislative framework which exists in relation to oocyte donation it is difficult not to make comparison with contrasting attitudes to DI. The latter has a long history and consequently there is widespread legislation addressing aspects related to the use of donor spermatozoa, primarily with respect to filiation but also with regard to eligibility for treatment and donor anonymity. Oocyte donation did not become available until the 1980s and is only possible in the context of IVF. Many countries have delayed introducing legislation addressing IVF and, where they have, there is little uniformity of approach particularly to gamete donation.

Differences exist between upholding the right to know one's origins and the right to donor anonymity and between permitting access to oocyte donation as opposed to DI. In Austria and Sweden children may have access to identifying information about sperm donors and DI is an acceptable treatment, yet gamete donation in the context of IVF, and hence oocyte donation, is forbidden. In this case oocyte donation is seen as contravening the human biological process. That is, DI is seen as a 'natural' form of assisted fertilization whereas IVF, and so oocyte donation, is not. A distinction would seem to be drawn between fertilization in vivo, even if the means of introduction of the spermatozoa are mechanical, and fertilization in vitro. The Cantons of Glarus and Basel are at least consistent in viewing all use of donor gametes as unacceptable. In Spain, where legislation allows oocyte donation but requires donor anonymity the law has been contested as unconstitutional, largely because it is considered by some parties that there should be a constitutional right to know one's origin. The Swiss Federal Constitution has been amended precisely to this effect. Denmark, France and the UK permit oocyte donation and preserve donor anonymity.

Other conflicts arise in the context of eligibility and access to treatment. Most countries where legislation exists restrict IVF treatment to married or cohabiting couples but in Denmark, Spain and the UK it is within the law for single women, or even lesbian couples, to receive treatment and, by extrapolation, oocyte donation.

Regulation of the practice of IVF and so, where permissible, oocyte donation appears to be left mainly to professional self-regulation and specifically so in Switzerland. The UK is the only country where a statutory body is required to lay a Code of Practice before Parliament. The Spanish law does make provision for a regulatory body but this has not been established due to the delay in implementing the law. In countries where there is no legislation, the practice of IVF and the provision of oocyte donation is guided by professional standards or left to the discretion of clinicians.

One may question why such inconsistencies of approach exist in an area of medicine which holds such great public interest. The legislative debate has focused around the status of the human embryo rather than the details of infertility treatment. Where legislation has been introduced it restricts clinical freedom to a greater or lesser extent but in those countries where no legislation has been introduced, by default, the environment for assisted reproduction is more permissive. It is inappropriate to speculate on the reluctance of some countries to introduce legislation addressing assisted reproduction but in an area of medicine where new ethical issues seem to arise with each technological advance it may be wise not to rush into inappropriate legislation. Laws are easier to make than to repeal and, in some contexts, it is difficult to separate arguments about the status of the human embryo from the thorny issue of abortion.