Legal and ethical responsibilities of gamete banks

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In the UK, following many years of consultation and debate, Parliament passed the Human Fertilisation and Embryology Act in 1990. This introduced a system of detailed regulation of banks and clinics undertaking the storage and use of gametes and embryos in the UK. The law established the framework for the system and set up the Human Fertilisation and Embryology Authority (HFEA) to implement it from 1991. The HFEA is required to license and monitor centres which store or use donated gametes, and to provide them with guidelines in a Code of Practice. The Code of Practice contains guidance on practical clinical matters and also the HFEA’s policy on a number of social and ethical issues. The regulatory system was set up to reassure the public, to protect the interests of potential children, patients and donors, and to promote good practice in fertility research and treatment. It works by consultation and cooperation between the HFEA and the scientists and clinicians being regulated, although sanctions do exist for use where needed. The HFEA is notable in regulating an area of medical practice in such a detailed way. It has established itself as an effective regulator and adviser, and has provided a basis for the development of policy in the field of fertility treatment.

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Background on guidelines in the UK

In the UK, we now have a tried and tested regulatory system controlled by the law which has proved to be a good basis on which to develop policy. Some 15 years ago the government responded to public anxieties about new methods of assisted conception by initiating a public debate. It was recognized that these new methods affected family life and that it was important to consider the legal, social and ethical implications. Following 7 years of wide-ranging debate and consultation (with the ‘Warnock Report’ of 1984 acting as a particular focus), the government brought forward a Bill in 1989 to regulate certain fertility treatments, as well as aspects of abortion, research and genetics, in considerable detail. This was a new departure, and fertility treatment remains the only area of medicine subject to such detailed legal control.

Fertility treatment is mentioned here because, in the UK, storage banks for donated gametes are not often separated from the provision of donor insemination treatment itself (there are 105 treatment and storage centres, 33 of which recruit donors, and a further 10 banks store semen for medical reasons). In order to protect the potential child, patients, donors and the wider public interest, it was decided that centres undertaking storage and use of donated gametes must be licensed and monitored by an independent body accountable to Parliament. Interestingly, the organizations representing fertility scientists and clinicians also favoured some regulation. They recognized that reassuring the public was essential if developments in fertility research and treatment were to remain generally acceptable.

Human Fertilisation and Embryology Act (1990)

The regulatory framework for fertility treatment using donated gametes was established by Parlia-
ment in 1990 with the passing of the Human Fertilisation and Embryology Act. This Act is important for things it does not do, as well as for things that it does. A fundamental point is that it does not seek to establish gametes and embryos as either persons or things in law. Instead, the law recognizes that special status is due to gametes and embryos, and their storage or use is made to depend on the effective consent of the people providing gametes. A further point is that the Act does not restrict access to licensed fertility treatment. No category of woman is prevented by law from being offered treatment. The risks to public health of people resorting to do-it-yourself arrangements, or using unscreened donors, were of prime concern here. For the same reason surrogacy arrangements were not made illegal. They were not, however, particularly encouraged, since contracts were made unenforceable.

Amongst many other things, the 1990 Act did the following: (i) it established the requirements for obtaining legal consent from a donor to store or use gametes (donors must be given proper information and a suitable opportunity to receive counselling about the implications of their actions); (ii) it established the legal parentage of children produced from donated gametes and embryos (the carrying mother is legally the mother, her husband or the male partner treated with her is the father); (iii) it stated clearly that there was a requirement for the welfare of the potential child (including the need of that child for a father), and of any other child who might be affected, to be taken into account before people were provided with treatment using donated gametes; (iv) it established the maximum period for which donated gametes may be stored (now 10 years); (v) it set up the Human Fertilisation and Embryology Authority (HFEA) and gave it powers to license and regulate centres offering storage of gametes and any treatment using donated gametes. The 21 Authority members are appointed by the UK Health Ministers. They have a broad range of experience and interests. Neither the Chairman, Deputy Chairman nor a majority of members may be by law doctors or scientists researching infertility; (vi) it required the HFEA to collect from centres identifying information about every donor, patient, treatment and child born and to keep it securely in a register. The prime purpose of the register is to allow people to inquire when they are grown-up about whether they are related to someone they wish to marry. And of course it also allows treatment services to be monitored, both nationally and at individual centres; (vii) it required the HFEA to issue a Code of Practice containing guidelines for centres on the proper conduct of licensed activities.

Regulatory system

The Human Fertilisation and Embryology Act (1990) sets the legal and ethical framework, but the regulatory system has two further elements: (i) directions to licensed centres which the HFEA has power to issue to make detailed provisions under the law; and (ii) the Code of Practice issued by the HFEA to licensed centres which contains guidance on good practice and the Authority’s policy on a number of social and ethical issues.

The 1990 Act, being primary legislation, could be altered only by Parliament. The Directions and the Code of Practice can more easily be changed and so provide the flexibility that is needed to regulate such a fast moving area of medical practice.

Ultimately a regulatory system needs sanctions to deter and punish wrongdoing. In the UK, failure to abide by particular sections of the Act is a criminal offence, subject to fines and/or imprisonment. Failure to follow Directions or the Code of Practice can lead to refusal or removal by the HFEA of that clinic’s licence. This may sound draconian but in practice the HFEA seeks to work with licensed centres, not against them, and the use of sanctions is rare. Cooperation from practitioners is much more effective in making the system work.

The HFEA Directions and Code of Practice together contain the Authority’s policy on ethical issues and they expand on the law by explaining the way in which licensed activities should be carried out. The Code of Practice contains the answers to most questions that clinics ask. It was first issued after wide consultation with clinicians, patient groups, religious and ethical bodies. It must be approved by the Secretary of State for Health and laid before Parliament. Both Directions and
the Code of Practice can be regularly updated to take account of new developments in clinical practice and changes in public opinion.

Legal and ethical issues
Some of the obligations which the Directions and the Code of Practice impose on banks which recruit donors and store gametes are given below.

Practical obligations
Practical matters such as the minimum professional qualifications required for practitioners and staff are set out in the Code of Practice guidelines. Requirements relating to laboratory and treatment facilities at clinics are also covered. These include security and guidance on avoiding contamination (an HFEA working group is currently looking further at safe cryopreservation). There is also guidance on such matters as proper security of records and dealing with complaints. Keeping records confidential is a particular obligation of centres because the 1990 Act, as amended in 1992, makes it a criminal offence to disclose identifying information about patients and donors except in specified circumstances.

Assessment of prospective donors
The Code of Practice sets out the normal age range for gamete donors: 18–35 years for women and 18–55 years for men. If a centre wishes to make an exception to this range it must justify its decision in the individual case. Using donors known to the recipients is allowed, but full consideration must be given to the implications for all concerned, especially for the welfare of the potential child. Centres are required to assess a donor’s personal and family medical history and attitude to donation. They are required to follow the British Andrology Society’s guidelines on clinical screening of donors as a minimum. This means that semen must be stored frozen for a 6 month quarantine period to allow testing for human immunodeficiency virus (HIV).

Payment of donors
At present, centres can pay donors a maximum of £15 in money per donation plus expenses. Donors can also receive free or cheaper fertility treatment, or free sterilization, in exchange for donation. This is known as receiving benefits-in-kind. In July 1996, the HFEA announced in its Annual Report that it intended to withdraw all payments and benefits in kind other than expenses. Our decision was preceded by three years of debate and consultation in the UK. The HFEA commissioned a survey of donors and clinics which indicated that in the UK the motivations of current and potential donors differ according to gender: men admit to an interest in money, women have a primary interest in helping other women to produce a child. The survey results showed that most semen donors are recruited from the student population and may receive £300–500 over the period of time they donate.

The debate in the UK is between those who say that it is wrong to pay for the building blocks of life, and those who say that if donors are not paid they will disappear, along with treatment services. The HFEA decided that it was opposed to payments for donors in principle as it risked the quality of the consent that was given and was inconsistent with the view that gamete donation should be a gift, freely and voluntarily given. However, concerns for the practical impact of its decision on treatment services in the UK has meant that a further period of consultation with clinics has been embarked on. Issues such as the expenses that will be paid and alternative methods of recruiting donors will be taken into account by the HFEA in deciding how, and when, payments to donors will be withdrawn.

Information
It was mentioned earlier that prospective donors must be given full information about the screening, procedures and consequences of donating before they give their consent. Centres must also give patients full information including their chances of having a baby if they have treatment at that particular clinic.

Counselling
Centres must offer prospective donors and patients counselling about the implications of what they are proposing to do. Counselling is not obligatory but is strongly recommended. It is not a psychological assessment. It is an opportunity for donors
or patients to explore their motives and the possible consequences of what they are planning to do with a trained third party.

**Consent**

Centres must obtain legal consent from donors to the storage and use of their gametes, which must include what is to happen to their stored gametes if they die. Centres must obtain consent which specifies whether the semen or eggs may be used to treat a woman, to make embryos for treatment or for research. Centres must tell those providing gametes that their consent may be varied or withdrawn before particular gametes or embryos are used.

**Number of offspring per donor**

The Code of Practice guidance on this states that a maximum of ten live children may be produced from the gametes of one donor. This limit is not related to consanguinity, but emerged from a long period of public consultation as to the maximum number of children that was regarded as proper for one person to produce by donation. Keeping to the limit when one bank or centre supplies another with gametes requires good cooperation and feedback between all those concerned.

**Import and export of gametes**

Guidance on import and export may be particularly relevant in a European context. Centres in the UK may export gametes in any quantity but may import them only by special permission from the HFEA for the use of particular patients. However, Parliament did not envisage a commercial trade in gametes. Charges paid or received must be at a level to cover reasonable costs only. Gametes may not be imported or exported for purposes which would not be allowed in the UK. This means, for example, that centres are not allowed to import or export semen from a donor who has already produced ten offspring, the maximum number permitted per donor in the UK. A special direction from the HFEA is needed for the import or export of embryos.

**Supplying gametes to other centres**

As with import and export, supply of one centre with donated gametes by another is allowed, but is not expected to be a profit making business. Full matching and screening information must be supplied with the gametes.

**Advertising**

Advertising for donors is allowed, subject to the general laws on advertising.

**Conclusions**

The regulatory system in the UK, including the Code of Practice guidelines, represents a comprehensive effort to protect potential children, patients and donors, to reassure the public and to encourage best practice. While the guidelines may seem a good deal more far-reaching than other countries would feel comfortable with, it should be noted that because centres must comply with the Code of Practice, the HFEA is always aware of the need to ensure that the guidelines are practicable. The guidelines define expected practice, but they are framed in a way which allows clinicians to make different decisions in individual cases where these can be justified. The regulatory system has now been running for >6 years. Both the HFEA and the clinics it licenses have learnt by experience and there is general agreement that the system is effective.