

Ethics Framework

Introduction

This Ethics Framework is a non binding tool for the Ethics and Law Advisory Committee (ELAC) of the Human Fertilisation and Embryology Authority (HFEA). ELAC is a subcommittee of the Authority and considers the ethical, social and legal aspects of the Authority's work. It is an advisory group with no decision making powers ¹.

The Framework is designed to:

- set out the moral principles which guide ELAC's deliberations and which frame the advice it offers to the Authority, the Executive or other committees;
- help ELAC make explicit the moral principles underpinning its advice and the approach it takes to ethical deliberation.

ELAC recognises that the HFEA operates in a society where there are deep moral divisions over the areas it regulates and recognises that the principles set out in this framework will not necessarily address the concerns of all of its stakeholders.

Moral principles

The Framework takes as its starting point the criteria set out in the Human Fertilisation and Embryology Act 1990 (as amended). Subject to those criteria, ELAC will be guided by the following moral principles:

- *Special status of the embryo*
- *Respect for persons*
- *Welfare of the child*
- *Reproductive autonomy and respect for family life*
- *Public Good*
- *Community, altruism and social trust*
- *Justice, equality and non-discrimination*

Where relevant, ELAC will make explicit how these principles were weighed in its deliberations and advice.

Special status of the embryo

The human embryo and the human admixed embryo have a special status, warranting protections safeguarded by law. However, these do not amount to human rights, which are only afforded to (born) persons. They are also different to the legal protections afforded to the foetus.

The Warnock report states that:

'...a collection of four or sixteen cells (is) so different from a full human being, from a new human baby or a fully formed human foetus, that it might quite legitimately be treated differently. Specifically ... unlike a full human being, it might legitimately be

¹ <http://www.hfea.gov.uk/1126.html>

used as a means to an end that was good for other humans, both now and in the future.’²

The report also states that the nature of this special status is not linked to the ‘potentiality’ argument whereby the embryo could, ‘if certain conditions were satisfied, become human beings’. Rather, it is based ‘on the consideration of what the embryo (is) at a particular time, its actual mode of existence immediately after fertilisation’³.

Thus, for example, it is justifiable for the embryo to be used (and be specially created to be used) for medical research purposes, since such practices could provide important benefits to mankind.

However, embryos can only be used for such purposes subject to various conditions and limitations (prescribed by law). For example,
The research must address a question relevant to a ‘serious medical condition’
Research cannot be carried out on embryos beyond the appearance of the primitive streak (or no later than 14 days after the embryo was created)
Various activities, such as genetic manipulation of the embryo, are prohibited

Respect for Persons

This principle has two components: autonomy and welfare. It recognises that people have various rights and interests that should be respected.

This principle therefore encompasses the practices of:

- informed, un-coerced consent. This includes the right to withdraw or place conditions on consent, subject to certain special limits⁴;
- privacy and confidentiality⁵
- access to information (subject to any confidentiality restrictions). This includes, for example, the information access rights of donor-conceived children
- respecting individuals’ right ‘not to know’ certain information. This applies in the context of respecting a patient’s wishes not to be informed that they carry a genetic condition (not yet manifest). This may arise, for example, where a child born as a result of donation has a rare heritable disease⁶ or where a patient at risk of a particular condition (e.g. Huntington’s) wishes not to know their carrier status but want to ensure that any offspring they have will be free from that

² ‘Embryos and Ethics: the Warnock Report in Debate’ Edited by Nigel M. de S.Cameron, Rutherford House Books, Edinburgh. The report only considered the ethics of research using human (only) embryos.

³ *ibid*

⁴ These limits include the requirement that any conditions placed on consent should not be discriminatory and, in certain cases, it might be unpractical to seek consent to the use of patient identifying information for research purposes

⁵ subject to certain special exemptions, including ones relevant to medical research using patient identifying data

⁶ See HFEA Code of Practice (8th edition), G.11.21.

condition. In such cases, they may wish to have PGD with exclusion ⁷ or non-disclosure ⁸ testing. The 'Welfare of the Child' test, which ensures that the interests of any children born as a result of treatment (and of any existing children who may be affected by the birth) are taken into consideration when deciding on the appropriateness of providing treatment.

The Welfare of the Child

It is important to note that the statutory duty to consider the 'welfare of the child (including the need for that child to have 'supportive parenting')' ⁹ is one which applies to centres (rather than the HFEA) when considering whether treatment should be provided in a particular case. However, the welfare of any existing or future children (born as a result of ARTs) is an important consideration for ELAC when deliberating over relevant policy issues.

Reproductive autonomy

Assisted reproductive techniques (ARTs), including in vitro fertilisation (IVF); IVF with intra-cytoplasmic sperm injection (ICSI); pre-implantation genetic diagnosis (PGD) and donation, can all help extend reproductive choice and can be viewed as part of the reproductive process.

The principle of reproductive autonomy includes some (limited) rights to change one's mind about procreating or to change one's mind about (or opt out of) becoming a parent. This right is enshrined in the legislation and applies to: donors; the husband or civil partner of women undergoing treatment ¹⁰ and people (neither married to nor in a civil partnership with a woman undergoing treatment) who have previously consented to parenthood ¹¹.

The limits to the pursuit of reproductive choice include:

- the welfare of the child test;
- the prohibition of sex selection for non-medical purposes and
- the prohibition of preferring 'abnormal' embryos for implantation.

⁷ Exclusion testing involves testing the embryos for the (affected) grandparental DNA and only selecting embryos which have not inherited this DNA for treatment. (In this scenario, the clinical staff would be unaware of the patient's genetic status)

⁸ Non-disclosure testing involves directly testing the embryos for the affected condition and for the clinical staff to withhold the test results from the patient

⁹ Human Fertilisation and Embryology Act 1990 (as amended), S.13(5)

¹⁰ In cases where donor sperm is used, there is a (legal) presumption that the husband or civil partner will be the child's legal parent (unless they registered their opt-out prior to gamete or embryo transfer)

¹¹ The right to change one's mind or to opt out can only be exercised up until the stage of gamete or embryo transfer. Thus, for example, the husband of a woman using donor sperm for treatment can opt out of being the child's legal father (as long as he registers this prior to transfer) but he cannot veto continued treatment. If, however, his gametes are being used, the gamete or embryo transfer cannot proceed.

Public good

A public good can be defined as a good that anyone can benefit from and whose availability is not diminished, however many people consume it. Examples of public good include clean air and safe drinking water.

This principle is concerned with facilitating, encouraging or promoting practices that further the public good. HFEA-relevant examples of such goods include:

- public health measures (such as drives to reduce the multiple pregnancy rate following ART)
- the outcomes of medical research (including embryo research and research using data from the HFEA register)
- encouraging public debate of fertility matters and contributing to the development of a social environment where support is more readily available

Community, altruism and social trust

This principle is concerned with facilitating, encouraging or promoting practices that address the needs of those with medical or fertility problems. This includes helping those who need fertility treatment and contributing to or facilitating good quality medical research. It can be understood to include the practices of:

altruistic gamete or embryo donation for treatment, research or training purposes; consent to the use of patient identifying data from the HFEA Register (research involving patient-identifying HFEA Register data requires explicit consent (from October 2010) or the absence of a withdrawal of consent (pre October 2010)

It is important to note that the outcomes of medical research can potentially benefit many, although not necessarily the research participants themselves.

Justice, equality and non-discrimination

Nobody should be denied access to treatment on discriminatory grounds. Any policy decision to restrict treatment from a particular group should be based on medical reasons or where the 'Welfare of the Child' test could never be met.

Conclusion

This Framework may be subject to review and amendment in the future. This version was adopted by ELAC in February 2011.