
Assisted Reproduction, the Law and Public Attitudes: A Danish Perspective

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Assisted reproduction has been carried out within the Danish health care system since the beginning of the 1980s. The first independent act on artificial reproduction was adopted in Denmark 15 years later, in 1997. The issue of assisted reproduction is still a subject of debate in Denmark. The main driving forces in Danish society when establishing legal regulation in this area are existential, social and cultural/religious. The involvement of both scientific and lay voices and the timing of the ethical debate are important factors in the creation of the Danish legislation on assisted reproduction.

Novel assisted reproduction technologies (ARTs) raise a large number of difficult questions – political, ethical and legal. We are faced with a melting pot in which ethics, the law, and the rights of different individuals and groups intermingle and become interdependent.

For example, many religious people object to in-vitro fertilisation technologies on the principle that they can involve the creation – and destruction – of possibly viable embryos. ARTs that involve surrogates – eggs, sperm or wombs – throw up not only ethical problems but legal challenges too – ‘ownership’ of the unborn child, custody and financial responsibility issues. Pre-implantation Genetic Diagnosis carries, to some, the uncomfortable whiff of eugenics, and the issue of human cloning raises a myriad of issues from safety to personal identity. The ethical principles have to be weighed against each other and regulated appropriately. This process is exceptionally difficult, but is increasingly necessary, I argue, in an increasing number of areas.

Fundamental Ethical Principles

Autonomy, Dignity, Integrity and Vulnerability

Human rights criteria and the existence of rules regarding informed consent arise mainly from the ethical principle of autonomy. Dignity and integrity are fundamental drivers when formulating rules of the type that incorporate ethical principles directly, and which often override more specific principles, for example the right to privacy, data protection and so forth.

The current act from 2006 (Act no 923/2006), which is the newest revision of the former act mirrors the Danish approach of trying to solve some of the ethical dilemmas that is raised by ART. The act is applicable for medicinal treatment, diagnostics and research that is conducted by a medical doctor or under the responsibility of a medical doctor, where a pregnancy is induced in a woman in other ways than between sexual intercourse between a woman and a man.

The act restricts the offer of medically assisted artificial reproduction to single women with no children and couples with no children of their own. Prohibitions against treatment are set out in a number of situations in order to protect the child: for example, the prohibition of inducing a pregnancy via ART unless the ovum stems from the woman who is giving birth to the child or the sperm stems from her partner – this prohibition mirrors the principle that the child should be genetically related to at least one of the parents. Another prohibition states that ART must not take place in the case where the woman giving birth to the child is older than 45 years.

The European Convention on Human Rights and Biomedicine contains a large number of rules for protecting especially vulnerable groups of individuals. To these should be added the rules comprised by national regulation for the protection of children, including future generations, people with dementia and other vulnerable individuals. Denmark has ratified the European Convention on Human Rights and Biomedicine and the principles of autonomy, dignity integrity and protection of vulnerable groups are mirrored in Danish law.

Economic and Qualitative Benefits

The Convention on Human Rights and Biomedicine and the UNESCO Declaration both stipulate that the interests and welfare of the human being are to ‘prevail over the sole interest of society or science’. This principle also guides The Danish Scientific Ethical Committee System.

Just Distribution of Benefits and Burdens

Unlike the first two principles, this ethical principle has not achieved the same fixed, prominent status in regulation on ethics in biotechnology. However, isolated occurrences do exist: the UNESCO Declaration proclaims: ‘Advances in biology, genetics and medicine, concerning the human genome, shall be made available to all’. The Council of Europe’s Convention on Human Rights and Biomedicine refers to ‘equitable access to health care’. This principle is a basis of the Danish health care system, which incorporates universal free access to health care. For a short period of about two years (2010–2011) the government decided that one had to pay for the different treatments of ART. From January 2012, the principle of free treatment was reinstated in the area of assisted reproduction.

Co-determination and Openness

The European Commission’s document, *Life Sciences and Biotechnology – A Strategy for Europe*, emphasises the importance of societal dialogue – proactive civic responsibility – and

monitoring, as well as regulation based on scientific principles. However, it is far from clear what the concept of ‘co-determination’ actually means.

Public consultation would appear to be a given, yet it is difficult to discern what actual influence the consultative response and/or outcome of public dialogue is intended to have.

In Denmark there is a long tradition of addressing ethical concerns in public dialogue and consultations.

The Legislative Picture

At the national level in the different European countries there is variation in the extent to which any actual legislation is applied. If we look at ‘first generation’ regulation of medically assisted reproduction we can identify the following models.

- *Laissez-faire* means that there is no legislative regulation or only very limited legislation or other form of regulation.
- *Liberal attitude* means that legislative regulation (hard law) exists only to a limited extent, but that regulation is effected through professional standards or similar (soft law).
- *Cautious legislative* regulation means that relatively well-developed regulation exists, also in the form of hard law (in some cases in the form of framework legislation).
- *Prohibitive legislation* means that full legislation exists, and is focused principally on prohibition and punitive measures.

In Denmark, the legislative approach in the area of assisted reproduction is mostly cautiously legislative.

Ethics When?

In Denmark, the discussion often centres on when to apply the ethical deliberations. What is the right mode of operation when an ethical problem arises? What are the tools available in order to ensure openness and collaboration in the lawmaking process? And how do we time the ethical debate, so that it is not too early and not too late in order for society to react to the challenges raised by new technologies?

The tools used by government to secure the law-making process, which have been used in Denmark over the last 20 years, include: risk assessment, risk management and risk communication, which can be effective tools in order to combine the scientific approach to the problem with the efforts of ensuring the principles of openness and co-determination. An example of this is the work of the health research ethics committees who are commissioned to assess the risk in relation to trials involving assisted reproduction.

In the process of elaborating ethical principles, the involvement of different interested parties (the scientists, the politicians, the administrators, the media and the general public) are taken into account in a variety of ways. In Denmark, there are several public and private organisations commissioned to initiate public debate and deliberation in the area of Bioethics, for example: The Danish Council of Ethics, The Danish Scientific Ethical Committees, The Animal Ethics Council, and The Danish Board of Technology.

These organisations have over the years collaborated in raising the different ethical issues in the public debate, thus securing the more narrow experts' view within the different areas as well as the broader view, by securing interdisciplinarity in the debate.

Dialogue and Timing

Ethics are no longer formulated by a single proponent (for example the Church) but have evolved in an interaction of forums and actors. It is therefore important to link up the debate ongoing at the different centres – who will be talking to whom, so that we can be sure that an opinion is generated on the issue to be settled. Moreover, it is important to sustain debate and dialogue – how do we ensure that debate and dialogue do not peter out – how is momentum sustained?

Ethical principles can now be formulated taking into account a number of disparate views and institutions. The ethical principles are distilled through a polycentric debate. For example, in previous times religious views may have been the single reference when making ethical decisions and formulating laws, for instance those relating to reproductive matters. Today, religious views (of all kinds) form only one part of a patchwork quilt of inputs that guide lawmakers and physicians in Denmark.

A polycentric debate can be seen as a phase devoted to settling issues and discussing them, and thereby as the precursor of a process to arrive at an enhanced regulation strategy based on a clear perspective of the general public's and the actors' attitudes to an issue prior to legislation. The debate phase calls for both an interdisciplinary component and recourse to the opinions embodied by the general public. In this context, the media have an important role to play as the media will bridge the dialogue between scientists, politicians, government and the public. The various forms of debate models can be employed depending on culture, traditions and so forth.

Timing is an element that is essential to stress in connection with ethical debate. The Danish Council of Ethics has adopted the motto 'Ethics Just-in-Time'. As the words suggest, this means that ethical debate must not happen too late, nor must it start too early. If ethical debate comes too late, products will already be placed on the market, and the risk is that there is no issue left to debate. If it happens too early the risk is that no one will have any feel for the issues. The questions will not be taken seriously and ethical debate will fall by the wayside.

Two examples serve to illustrate the problem.

In the mid-1980s, the then Danish Ministry of Health produced a report for the Danish Parliament on gene therapy. This was met by deafening silence – simply because the issue had been raised too early. The same was the case with the debate regarding Dolly, the first cloned sheep. Everyone claimed that the public was astonished that cloning was even possible, despite the fact that a study of newspaper cuttings revealed that the capability had been reported in newspaper articles for several years previously.

In Denmark, the experience has been that it is important to plan carefully the timing of ethical debate and the putting into practice of ethical principles. This should be based on an assessment of when the debate will be sufficiently newsworthy and merited. Perhaps it should be conceded that what is really needed is 'Ethics All the Time' – when research is planned, when it is carried out, when its results are studied, and when it is applied.

In summary, the scientific advances over the last 30 years in Assisted Reproduction have created a number of intense moral, legal and ethical debates. We can summarise the way forward using a (hopefully) snappy mnemonic – DIALOGUE.

- D** *Debate* – make room and time for public polycentric debate within the forums between scientists, between decision-makers and between lay people. Make sure that there is room for disagreement and promote ‘cooperation despite disagreement’.
- I** *Interdisciplinarity* – academics from different disciplines must exchange views and work on the implementation of ethical principles in concepts involving biotechnology.
- A** *Agora: The Marketplace* – governance and decision-makers should facilitate the creation of an agora where stakeholders can meet and exchange views among themselves and with the public. In ancient Greece, the public administration, the court, the philosophers and the traders met in the Agora to govern, exchange views and do business. In a time where science and the application of science is multinational and will have an impact on future generations, the creation of agorae should be local, national and international alike.
- L** *Learning* – children, young persons and laymen as such should be trained in decision-making with regard to ethical issues, and researchers should be trained in merging ethical deliberations in their fields of research.
- O** *Optimise* – ensure the operationalisation of ethical principles in politics, regulation and debate.
- G** *Gradualism* – when we are to go forward then we should do so step by step. The principle of gradualism should be considered each time we have to make decisions that may be irreversible or may have an impact on the environment and future generations.
- U** *Update* – ethics ‘just in time’: renew and update the deliberations and decisions. Choose the right time for the debate of a special issue, not too early and not too late.
- E** *Evolution* – ensure the evolution of ethical principles and their specific application to new areas.

About the Author

Berit Faber is at present an independent consultant specialising in biolaw, dialogue-processes, executive coaching and mentoring, see Biolaw, Faber Advisors, <http://www.biolaw.dk>. Earlier he served as Executive Director, Danish Council of Ethics; Special Consultant at the Centre for Bioethics and Risk Assessment, the Royal Veterinary and Agricultural University; Senior Consultant, The National Committee on Health Research Ethics and the Committees for Scientific Dishonesty. She does consultancy work for the Management Secretariat at the University of Copenhagen, including university faculty networking, interdisciplinarity in teaching biotechnology and bioethics.