

## Ethics, social, legal, counselling

# International evolution of legislation and guidelines in medically assisted reproduction



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### Abstract

The most noticeable characteristic of the legal situation in Europe regarding medically assisted reproduction is the enormous variety of rules. It is hard to find two countries with the same rules regarding a topic like embryo research or donor insemination. Moreover, there has been a rapid evolution of the law and regulation of medically assisted reproduction in the last 15 years. This legal mosaicism is threatened by increasing pressure from politicians and international societies. Three topics are discussed in this article: (i) the relationship between ethics and politics, and the impact on national legislation; (ii) the evaluation of international legal harmonization; and (iii) alternative solutions to some of the problems. It is concluded that consensus and harmonization only has moral value when it is brought about by discussion and persuasion, not by force.

**Keywords:** *assisted reproductive technology, ethics, legislation*

### Introduction

In their overview of the existing legislation on assisted reproductive technology (ART), Jones and Cohen raised two important questions: why does society want to oversee ART as opposed to other medical procedures? And what exactly does society want to oversee? (Jones and Cohen, 2007). In the past, the interest of society and lawmakers in ART was, to a large extent, generated by religious groups with a strong interest in the protection of the human embryo. ART directly and indirectly leads to the creation and possible destruction of embryos.

More recently, some legislation has been triggered by a negative motive: the fear of abuse and of a derailing technology. The lawmakers want to prevent the application of some techniques in certain circumstances because they consider them morally unacceptable. One of the clearest illustrations of this tendency is the attempt to introduce a worldwide ban on reproductive cloning. France and Germany, which originally suggested this initiative at a moment when some dubious figures announced the birth of the first human clone, wanted to avoid the application of cloning anywhere in the world. Not surprisingly, some legislation is triggered by media reporting on 65-year-old mothers, post-

mortem fatherhood and sex selection. The old adage 'hard cases make bad law' seems to be true. The focus on specific individual cases hampers the formation of a broader picture of the problem. It also leads to mainly restrictive legislation because cases generally make the news when they generate negative reactions and because the original goal is to prevent future abuses and aberrations by covering all possible loopholes.

Most legislation on ART is based on fundamental moral values or principles, such as the protection of human life, the non-commercialization of the human body and reproduction, and responsible parenthood. However, as will be discussed later, although everyone agrees on the general principles, disagreements begin as soon as these principles are applied and specified in real-life situations.

### Legal mosaicism

The first finding from the analysis of the legislation and regulation on ART is the legal mosaicism that exists. There is an enormous variety and diversity in laws on all the different

aspects of ART. To extend the observation further, if one were to take a biopsy of the legal situation in one country in Europe, one would know nothing about the legal situation in the neighbouring countries or European legislation as a whole.

One example is the legislation on donor anonymity. The whole spectrum of possibilities is present, ranging from complete anonymity over double track systems to complete identifiability. France, Denmark, Greece, Spain, Portugal and Norway have legally imposed anonymity. Iceland has a double track system, which allows identifying information to be disclosed to the child at the age of 18 years if the donor consents. The new law in Belgium has made anonymity mandatory, but allows known donation when donor and recipient agree. Finally, Austria, Germany, Sweden, Switzerland, The Netherlands and the UK only accept identifiable donors.

The second example is more crucial for the practice of ART, that is, the laws and regulations on embryo transfer also vary. From 2003, the UK Human Fertilisation and Embryology Authority (HFEA) limits the number of embryos for transfer to two in women under 40 years and to three for older women. Belgium introduced a reimbursement system in 2003 that links funding for six IVF cycles to the compulsory use of elective single embryo transfer (eSET) in the first cycle for women below 36 years. The number of embryos transferred in the following cycles depends on the age of the woman and the quality of the embryos. Finland, Norway, Denmark and The Netherlands have no state regulation on this issue; however, the clinics have successfully moved to the widespread application of eSET. France, Spain, Portugal and Greece have no state regulation, but in these countries there is no evidence of increasing numbers of eSET cycles. Finally, Germany, Switzerland, Austria and Italy have a restrictive law that forbids culturing of more than three oocytes beyond the pro-nucleus stage and demands the transfer of all embryos without selection (Expert Group on Multiple Births after IVF, 2006).

Underlying these laws are various moral principles that are related to the value of life, the welfare of the child, good clinical practice and safety. Most countries find all general moral values and principles important. The difference between countries is attributed mainly to a different ranking of these values. This leads in some cases to largely different or even opposing policies. While some countries introduce rules to prevent multiple pregnancies, others, such as Germany and Italy, have adopted laws that increase the risk of having multiple live births. The latter are based on a much higher moral status of the embryo *in vitro* compared with the well-being of the future child(ren) and the health of the mother.

The legislation on ART within a country is rarely a monolithic and coherent set of rules. There are several possible explanations, for example other factors beside substantive coherence play a determining role. A different political coalition for instance may lead to different legislation. The general economic situation may affect rules on access and reimbursement. There are also several internal causes for the complexity. Firstly, multiple criteria apply simultaneously. The lawmakers want to promote the welfare of the future child, cost-effectiveness, safety and equity in access. Balancing these criteria may lead to complex compromises. Secondly, the field of ART is broad and one has to be a specialist to oversee all the existing rules. However,

since the members of parliament change regularly and the preparatory commissions do not always communicate with each other, this can mean that new laws contradict, or at least do not fit, existing laws. In Belgium, for instance, the provisions for informed consent for the donation of cryopreserved embryos for research, in the law on medically assisted reproduction of 2007, combined with the clauses in the law on research on embryos *in vitro* of 2003 create considerable practical and unintended difficulties (Pennings, 2007). The law of 2007 states that every couple or patient before the start of the treatment should indicate the disposition of their embryos at the end of the normal storage period (5 years). The law of 2003, however, says that patients who want to donate their embryos for research should receive full information on the research project. Since almost all research projects in Belgium run for a period of 4 years, the two clauses cannot be fulfilled simultaneously.

## The interaction between law and ethics

The law of a country expresses the moral position of the majority of the citizens on acceptable family building (post-mortem insemination and lesbian couples), the safety of patients (regulation of centres and quality standards), justice and equality (reimbursement of treatment) and the welfare of the child (donor anonymity, health and embryo transfer). The basic problem for all democracies is how to deal with the moral views of the minority. How should the legislator in a post-modern society, characterized by a multitude of groups holding different moral outlooks, react to moral conflicts?

Two general positions can be adopted regarding the right of the majority to express its views in a binding law. The first position states that the legislation in a pluralistic society should not reflect the substantive moral position of one group. Legal restrictions need a strong common basis in society. The main solution for the proponents of this view is a legal compromise between the diverse preferences and interests. The second position holds that the majority of the citizens have the political right to impose their view of the 'good life'. This should be taken as a theoretical position, since the law, even in democracies that function perfectly, does not necessarily reflect the view of the majority. In some countries, such as Norway, small political parties with relatively extreme moral views may influence the law much more than their number justifies because they are indispensable units in a larger coalition. However, generally speaking, the law is supported by the majority. This is perfectly acceptable since political parties in a democratic system try to organize society according to their goals, values and principles. If one ideological or religious group has the majority, they can, and should, use this power to mould the law according to their convictions.

The main cause of friction between ethics and law is that democracy is based on the majority rule whilst ethics (that is, what is ethical) is not decided by the majority. Nevertheless, although the majority has the political right to impose its views on the minority, a number of ethical values urge the majority to tread cautiously. Among these values are autonomy, tolerance and respect for other moral positions. Imposing a moral opinion on people who do not share this view increases the risk of conflicts. For example, the Italian law is strongly

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