

Assisted reproductive technology in Europe: research, legal and ethical aspects

Abstract

Aim. Infertility, its treatment and family planning affect the fundamental right to procreate. For this reason, discussions on developing the legislative framework governing these matters are highly sensitive and subject to ethical controversy. At a European level there are numerous ethical challenges related to assisted reproductive technology (ART) but none related into uniform manner to be acceptable by all member countries. **Methods.** In this respect, we review the current legislation of the following twenty-six European countries which are also into Shengen Area: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxemburg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweeden, Switzerland, other four European countries that do not form part of the Schengen Area, Bulgaria, Croatia, Cyprus and Romania and other two like Ireland and the United Kingdom. **Results.** Twenty-four of the European Union member states (i.e. Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Liechtenstein, Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain, Sweeden, Switzerland, Bulgaria, Croatia and United Kingdom) have reported the existence of specific legislation, while 8 countries (i.e. Cyprus, Ireland, Lithuania, Luxembourg, Malta, Poland, Romania, Latvia) have reported that no specific legislation exists, only general legislation covering ART procedures. **Conclusions.** We propose that legal systems should supplement the existing laws and adapt it to the unique challenges presented by ART, so that society may benefit from the application of ART advancement in a socially responsible and uniform ethical manner.

Keywords: assisted reproduction, Europe, research, ethical aspects

Introduction

Assisted reproduction technology (ART) has evolved in the past thirty-five years, allowing for in vitro human embryo of better quality. The improvement of ART and increased accessibility have provided new opportunities for more and more infertile couples in most European countries, couples which could not have found therapeutic solutions to reproductive problems before this technological development. This massive development of ART has brought up for discussion ethical issues regarding the applicability of the ART methods. These methods should be applied according to legislation, selection criteria and patient treatment protocols, which are intended to set rules and limits, and the contribution from the state budget^(1,2).

Public debates were conducted in several European countries targeting issues related to ART regulation by law, the right to ART treatment, the cost and availability of resources, and the monitoring the quality of ART practice. Edwards's pioneering work⁽³⁾ and the unprecedented subsequent development in the field of genetics and ART have brought up in discussion the importance of reviewing the ethical and legal aspects involved in the regulation of ART. The major European countries do not easily accept a common principle, having different opinions and strategies for ART application.

The impact of the ethical aspects and regulations on ART practice has been discussed by many authors, the issue being analyzed by the experts from the European Commission⁽⁴⁾.

In some European countries the legislative regulations come only from various statutes, where there are no specific human reproductive health laws, although the legislation of ART practice has been under scrutiny by important forums of our continent, such as the Parliamentary Assembly of the Council of Europe ever since 1989^(5,6). From another perspective, however, ART policy could be described as rather restrictive, setting some limitations for the use of ART⁽⁷⁾. However, many European countries have not yet established a uniform law on the various aspects of using ART.

The purpose of the present paper is to present the current legislation of the European countries, including those from Shengen Area which are presenting numerous ethical challenges related to the development of a legislative framework which should be uniformly applicable and acceptable to all member countries.

Methods

Here we summarize the information available regarding the current legislation of the twenty-six European countries which are also in the Shengen Area: Austria,

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Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxemburg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and other four European countries which are not in the Schengen Area, Bulgaria, Croatia, Cyprus and Romania - including Ireland and the United Kingdom.

Reproductive policies can address different dimensions of regulation and these dimensions should be combined in order to regulate the legal aspects in Europe. In this context, we take into account three analytical dimensions like autonomy stated to the medical community to practice ART and abortion, constraints on patient access to treatment, and availability of expense coverage for the treatment of reproductive disorders⁽⁸⁾.

These dimensions stated above can be combined to find a solution to the legal application of ART techniques, but each of these dimensions should be first individually evaluated⁽⁹⁾. However, it is well known that the medical community impact on regulation is

slow, and physicians and specialists in this field are compelled to reach a compromise.

Results

The estimated population of Europe is approx. 600 million, which is less than 15% of the world's total population. Nevertheless, there are 516 ART centers in all Europe, which represent 60% of the world's ART program. Although the percentage of this program is very high comparing to other non-European countries, the number per units per head of population is different. This can be explained by the difference in the standard of living between the population.

Twenty-four of the European Union members (i.e. Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Liechtenstein, Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, Bulgaria, Croatia and United Kingdom) have reported the existence of specific legislation until present (Figure 1, green), while other 8 countries (i.e. Cyprus, Ireland, Lithua-

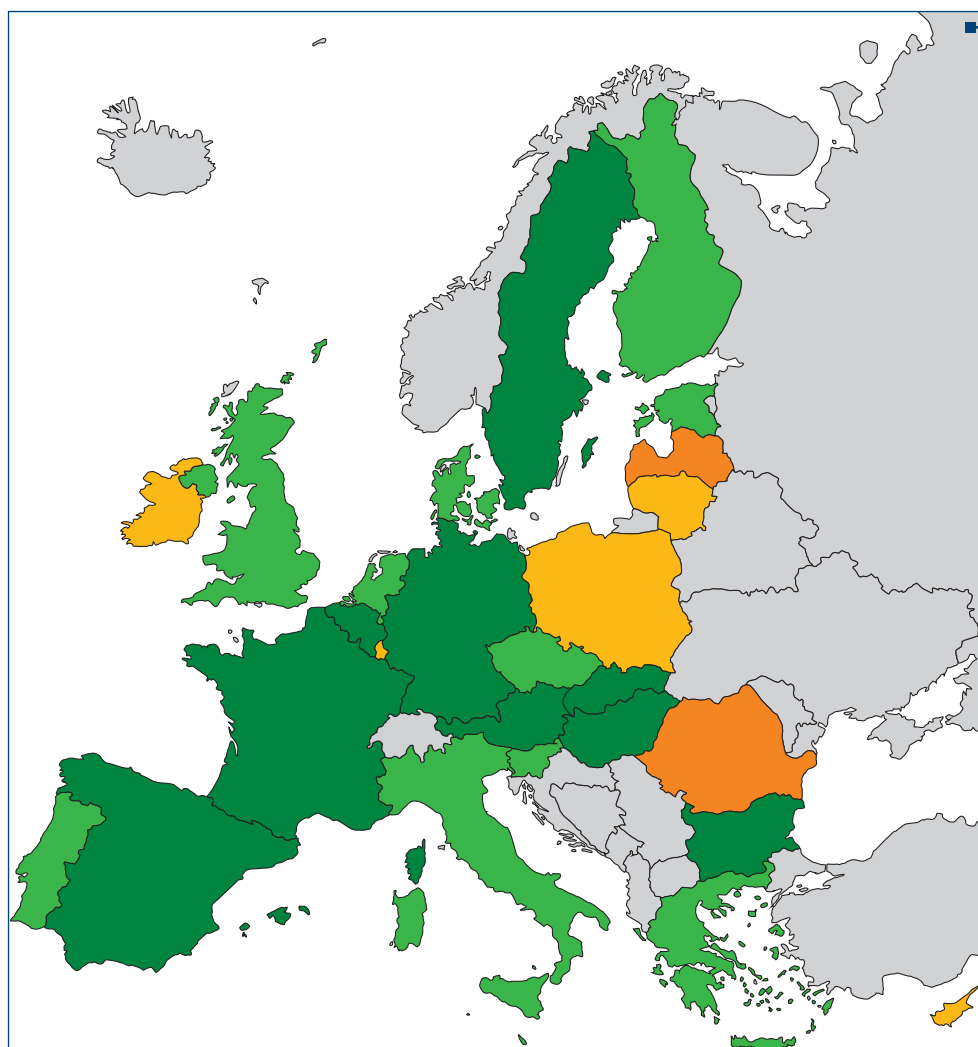


Figure 1. Overview of ART application and specific legislation in European countries (green = ART specific legislation which is not transposed to Directive 2004/23/EC; dark green = ART specific legislation which is transposed to Directive 2004/23/EC; orange = general legislation applicable to ART which is not the result of transposing Directive 2004/23/EC; dark orange = general legislation applicable to ART which is the result of transposing Directive 2004/23/EC) (adapted from 10)

nia, Luxembourg, Malta, Poland, Romania, Latvia) have reported that no specific legislation exists, only general legislation covering ART procedures (Figure 1, orange)⁽¹⁰⁾.

For Romania, although no specific ART legislation exists, there is a general law based on Tissues and Cells Directive for all types of cell and tissue transplants (Law no. 95/2006, Art. 153 to 164 and the guiding lines of health law from 25.10.2006 with all amendments) which covers all ART treatments. The same rules are applying for Bulgaria, Croatia and Cyprus. Although a general understanding of the moral issues involved has been reported, the legislation is still in the process of being established in countries which are not included yet into Shengen Area⁽¹⁰⁾.

In many other countries from Shengen Area the field of ART and the change of ethical concepts have been showed to bring up in discussion the ethics of limiting the use of ART to certain categories of patients selected according to the marital status of the couple, the gender of the two partners, or the application of the ART techniques to a couple including a transsexual⁽¹¹⁾. In this respect, in other countries like Denmark, Netherlands and UK couples with genetic diseases or inability to procreate with their own gametes represent another distinct category of patients that could benefit from ART support by donation of oocytes or embryos. All these situations showed to be distinct challenges in the perspective of developing a legislative framework which should take into account both the ethical and societal acceptance and those which concern the individual's fundamental right to procreation⁽¹²⁾.

Whatsoever, regulations on the ART practice in European countries have been showed in the last decades to affect the ethical dimension of ART practices worldwide.

In this context, Table 1 present twenty-one countries where assisted reproduction is already applied⁽¹³⁾.

At these countries where ART is already applied, the law still doesn't include the discrimination of using ART techniques, the access to counseling ART techniques for all persons regardless of income including protection for the right of women to decide on matters of birth, including genetic diagnosis methods⁽¹⁴⁾.

Discussion

The problem of defining a single legislative framework at the European level to regulate the application of ARTs including embryo research has frequently been discussed by many official organizations.

Moreover, cultural diversity and differences of opinion among the member countries of the European Community have not allowed a uniform legislation so far. Under these circumstances some of the member countries have developed a range of legislative regulations of their own and personalized on infertile couples⁽¹⁵⁾.

In this respect, the law could be based on the fact that many infertile couples appeal to specialists in order to obtain counseling and ART treatment. The goal of infertility services is to help people with fertility problems by finding solutions to their reproductive plans and counseling must always be the first step that precedes the use of ART^(16,17).

Our study shows that only twenty-four of the European countries members have reported the existence of specific legislation until present, while other eight countries like Cyprus, Ireland, Lithuania, Luxembourg, Malta, Poland, Romania, Latvia have reported that no specific legislation exists, only general legislation covering ART procedures.

Table 1 European countries where assisted reproduction techniques are applied

Austria	France	Poland
Belgium	Germany	Portugal
Bulgaria	Greece	Slovenia
Czech Republic	Hungary	Spain
Croatia	Italy	Sweden
Denmark	Netherlands	United Kingdom
Finland	Norway	Romania

Indeed, it is necessary to underline that this is a field in constant evolution from the scientific to the juridical and ethical aspects⁽¹⁸⁾. Due to some common elements like the protection of health and liberal access to un-married couples, it is possible to show that in the European countries there are many ways to analyses the ART application, as every country has own cultural, social, political and religious culture⁽¹⁹⁾. In Germany, the legislation shows that it is illicit to use the ART techniques.

Cloning, pre-implantation, genetic diagnosis and embryo research are forbidden⁽²⁰⁾. In contrast, France and Italy allow pre-implantation for diagnosis purposes, without the embryo implantation following a husband's death, the production of hybrids and chimeras, cloning and the surrogate motherhood. In France also the legislation permits cryopreservation, the donation of sperm and the research on embryos⁽²¹⁾.

In the United Kingdom there is an Human Fertilization and Embryology Authority that evaluate case by case and have it's own model of authorization⁽²²⁾.

The European legislation can be distinguished into two groups: rigid and liberal⁽²³⁾. In the first category are included France, Italy, Germany, Sweden and Austria law, while the second represents United Kingdom and Spain⁽²⁴⁾.

In particular, Sweden and Austria admit the donation of sperm under specific medical control, with free informed consent by sperm donator. These countries are

considered liberal because they allow a liberal utilization of these practices. In this context, they use embryos for research purposes like post-mortem reproduction and cryopreservation. In contrary, Spain forbids the surrogacy, the production of hybrids and chimeras and the unlimited use of embryos^(25,26).

Technological advances in the field of ART and the related scientific areas use specialists which take into consideration the type of disease and the treatment aggressiveness. Further, each case should be individually assessed, having in the view the fact that the law in these countries is still not uniformly applicable⁽²⁷⁾.

Conclusions

Despite the cooperation of European countries from political and economic point of view, there are still important differences in the legislation concerning the practice of ART. It is quite clear that a European consensus on legislation cannot be achieved because the whole area of infertility ART treatment concerns fundamental problems of life structures, family and society, which are influenced by tradition which vary greatly among the ethnic groups which make up the population of modern Europe.

Given the complex and sensitive issues implied by the ART practice, we propose that each European country's national institutions should exercise a clear and systematic impact on ART ethics, in view of the widespread applicability to infertile couples. ■

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