



Review

Current regulatory arrangements for assisted conception treatment in European countries



Luca Gianaroli^{a,b,*}, Anna Pia Ferraretti^a, Maria Cristina Magli^a, Serena Sgargi^a

^aS.I.S.Me.R. Reproductive Medicine Unit, Bologna, Italy

^bPast Chairman of ESHRE

ARTICLE INFO

Article history:

Received 14 October 2016

Accepted 14 October 2016

Keywords:

IVF legislation

Assisted conception treatments

Cross border reproductive care

Access to treatments

ABSTRACT

Infertility is a condition affecting an increasing number of individuals all over the world. In recent years, this phenomenon has spread across both western countries and developing countries, thus developing the features of a pandemic. For this reason, the World Health Organization (WHO) acknowledged that infertility should be considered a disease to all intents and purposes, as it diminishes the health and wellbeing of the individuals who suffers from it. At present, the most effective means to contain the spread of infertility are essentially prevention and Assisted Reproductive Technologies (ART). With reference to the latter, although most of these techniques are routinely used in the majority of countries, they are still subject to medical, ethical and political debates. There are huge variations noted when the regulatory legislation adopted by different countries to govern infertility treatment in various countries all over the world are reviewed. In fact, it has to be recognized that ART legislation depends on a variety of factors, such as social structure, political choices, ethical issues and religious beliefs. This makes it apparently impossible to create a standard regulation for different countries, especially in case of controversial issues like gamete and embryo donation, embryo cryopreservation or surrogacy.

© 2016 Elsevier Ireland Ltd. All rights reserved.

Contents

Introduction	211
Criteria for access to treatments	212
Legitimacy of preimplantation genetic diagnosis/preimplantation genetic screening	212
Legitimacy of gamete donation, reimbursement policies for gamete donors and donors' anonymity	212
Provision of Assisted Reproduction Treatments by national healthcare services	212
Surrogacy	213
Cross border reproductive care	213
Conclusions	213
Funding	213
Conflicts of interest	213
References	213

Introduction

Infertility is a condition affecting an increasing number of individuals all over the world. In recent years, this phenomenon has spread across both western countries and developing countries

(although with different characteristics), thus developing the features of a pandemic.

For this reason, the World Health Organization (WHO) acknowledged that infertility should be considered a disease to all intents and purposes, as it diminishes the health and wellbeing of the individuals who suffers from it [1].

At present, the most effective means to contain the incremental rise in the number of cases of infertility are essentially through

* Corresponding author.

E-mail addresses: luca.gianaroli@sismer.it, segreteria@sismer.it (L. Gianaroli).

prevention and by offering Assisted Reproductive Technologies (ART). With reference to the latter, although most of these techniques are routinely used in the majority of countries, they are still subject to medical, ethical and political debates.

There are huge variations noted when the regulatory legislations adopted by different countries to govern infertility treatment in various countries all over the world are reviewed [2]. In fact, it has to be recognized that ART legislation depend on a variety of factors, such as social structure, political choices, ethical issues and religious beliefs. This makes it apparently impossible to create a standard regulation for different countries, especially in case of controversial issues like gamete and embryo donation, embryo cryopreservation or surrogacy.

While legislators struggle to keep the pace with scientific advancements, the demand for Assisted Reproduction Treatments is dramatically and relentlessly rising. This is due to a variety of factors, among which the most important being an increase in the average age of women at first birth worldwide (which has on average, increased by 3.7 years in the past four decades) due to the postponement of parenthood [3].

Consequently, the number of ART cycles performed all over the world is incrementally rising. The European IVF Monitoring consortium has been collecting data produced by IVF registries throughout Europe since 1999 and according to the most recent data available, the number of ART treatments performed has skyrocketed from 203,893 in 1997 [4] to 609,973 in 2011 [5] in Europe.

While analyzing these data, however, it has to be considered that the availability of these treatments differs significantly from one country to another. In 2011, the average number of cycles available per 1 million inhabitants within Europe was 1269. However, this value ranged between 469 cycles in Hungary to 2793 cycles carried out in Belgium [5].

This variability is mainly due to the regulations in place in each country. In fact, it has been demonstrated that different legislation and different reimbursement policies for infertile couples affect the number of cycles performed and the types of treatments provided.

The most controversial issues influencing ART legislations are:

- Criteria for access to treatments (woman's age, fertility status, marital status, sexual orientation, etc.);
- Legitimacy of Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS);
- Legitimacy of gamete donation, reimbursement policies for gamete donors and donors' anonymity;
- Provision of Assisted Reproduction Treatments by national healthcare services, and
- Surrogacy.

Criteria for access to treatments

Most European countries allow access to treatments to heterosexual couples of legal age, married or in a stable relationship.

With reference to women's age, limitations are usually set (especially for treatments provided by National Healthcare services) to keep it within the frame of biological reproductive age.

Certain countries, among which Spain, Belgium and the UK, allow single women access to ART.

Homosexual couples are allowed access to Assisted Reproduction Treatments only in some countries (Spain, Denmark and Belgium among others), whilst it is forbidden in others (for instance in Italy).

In Italy, access to treatments is restricted to infertile couples or to couples affected by or carriers of a disease whose transmission

to the offspring can only be avoided through Assisted Reproduction.

Legitimacy of preimplantation genetic diagnosis/ preimplantation genetic screening

PGD and PGS are increasingly used to detect abnormalities in gametes and embryos, thus allowing the selection of normal cells.

These techniques are particularly useful whenever prospective parents suffer from or are carriers of a genetic disease transmissible to potential offsprings.

Some countries allow the application of PGD/PGS only on oocytes, prohibiting it on embryos (e.g. Switzerland). In other countries, PGD/PGS can be performed only in specifically licensed Centres upon completion of a specific procedure by couples (e.g. Germany).

In Italy PGD/PGS were not feasible until 2009 [6], and their application was extended to fertile couples suffering from or carriers of genetic diseases only in 2015.

PGD/PGS for sex selection for non medical reasons is prohibited everywhere in the EU.

Legitimacy of gamete donation, reimbursement policies for gamete donors and donors' anonymity

There are variable national policies within Europe as regards gamete donation: gamete donation has become available in the vast majority of European countries, although some of them only allow sperm donation (e.g. Switzerland, Germany, Austria) and in Italy, the ban on gamete donation was removed only in 2014 following a ruling of the Italian Constitutional Court.

National regulations also differ with reference to donors' anonymity and reimbursement policies.

While some countries guarantee donors' anonymity (e.g. Belgium, France, Italy, etc.), others allow recipient couples and/or children to get information about donors and vice versa (e.g. The UK, The Netherlands, Sweden, etc.). In these countries individuals who are born following gamete donation are allowed to get access to information about the donor once they reach a certain age, normally 18.

With reference to reimbursement policies for gamete donors, reimbursement is allowed in the majority of countries and in most cases its amount is defined by law (e.g. The UK, Spain, etc.). In other countries (such as Italy and France) gamete donation is a voluntary act and reimbursement is not allowed. Of course, this affects the number of donors available.

A study carried out by ESHRE [7] analysed socio-demographic and fertility-related characteristics and motivations of oocyte donors in eleven European countries. The study documented a considerable variation of donor characteristics and motivations among European countries; the general donor profile in this study was a well-educated, 27-year-old woman living with her partner and a child who mainly donated to help others.

Of course, the type of donor that is attracted depends on the rules of the donation practice, i.e. whether anonymity is guaranteed, whether reimbursement/payment is provided, etc., but in general it was observed that most donations are based on altruism.

Provision of Assisted Reproduction Treatments by national healthcare services

The provision of ART by national healthcare services varies among countries in terms of modalities and number of cycles available.

The provision of a limited number of treatment cycles, as well as restrictions to access (age, income, etc.), long waiting lists and

restrictions on reimbursement can lead to a shift to the private sector in the same country or abroad for those who can afford it or to involuntary childlessness for those who cannot.

Surrogacy

Commercial surrogacy is illegal in almost all EU countries, while it is allowed in Eastern countries such as Ukraine or Russia.

Altruistic surrogacy is allowed in countries such as Belgium, the Netherlands or Greece under specific conditions.

Cross border reproductive care

Throughout the years it has been shown that legal restrictions to access to ART lead couples in need of specific treatments to seek medical assistance in countries where legislation is more permissive. This phenomenon, which has been defined as “cross border reproductive care”, was the subject of a study carried out by the ESHRE Task Force on cross border reproductive care to assess the extent of this practice [8].

Analyzing the results obtained, it was estimated that every year, approximately 20,000 couples are forced to travel abroad to gain access to ART treatments forbidden or not reimbursed in their country of residence, facing all the costs, difficulties and risks that this choice entails.

In most cases, treatments performed abroad are neither reimbursed by national healthcare systems nor by insurance companies. Moreover, patients are charged for the drugs, especially those which cannot be obtained through their national healthcare system. Having considered the additional costs involved for travel and accommodation expenses, the overall cost of ART procedures performed out of the country of residence becomes extremely burdensome for couples, especially if the treatment fails and it has to be repeated.

From a medical point of view, patients treated abroad cannot count on the assistance of a specialist in their country of origin, making it difficult to deal with potential complications. This exposes them to a greater risk, which can be further increased by language barriers.

The study was carried out in 2010, when one of the strictest ART legislations on ART in Europe was still in place in Italy. In fact, the results showed that approximately 32% of all couples seeking treatment abroad came from Italy [8]. Most common recipient countries were Belgium, Czech Republic and Spain.

Following several rulings of the Constitutional Court, the Italian legislation on ART was modified to include PGD (also for fertile couples affected by or carriers of genetic diseases) and gamete donation [9,10]. However, this did not significantly reduce the flow of couples seeking treatment abroad, as access to specific treatments is still very difficult. In particular, this applies to gamete donation due to the worrying shortage of oocyte donors, for whom reimbursement is not allowed [10].

Moreover, in the last few years, the recession pushed patients to self refer to clinics located in countries where treatments are cheaper and legislation is more permissive, to the detriment of safety and quality standards, as shown by reports of incidents related to ART procedures performed in these countries.

Conclusions

In the early Nineties, it was acknowledged that infertility is a disease, therefore couples should have the right to get access to the

treatments they need in their country of origin without any discrimination related to their pathology and irrespective of their income.

However, ART regulations can significantly differ among countries due to a variety of socio-economic factors and at present the introduction of homogeneous Pan European legislation seems unlikely. Further difficulties are caused by the recent surge of restrictive legislative proposals (similar to the Italian Law 40/2004) in some countries (e.g. Poland, Lithuania, Malta, etc.).

The social and healthcare costs of infertility treatments, as well as those of involuntary childlessness due to the impossibility of getting access to Assisted Reproduction Techniques are often ignored by policy makers, but their impact on a socio-economic level should not be underestimated [11].

In fact, macroeconomic studies show that, although the provision of Assisted Reproduction Treatments can be onerous for healthcare systems, in the long term it turns out to be cost-effective in terms of the tax contribution provided by children born thanks to these techniques [12].

Funding

The authors declare no personal funding or other financial support for this publication.

Conflicts of interest

None.

References

- [1] World Health Organization Programme of Maternal and Child Health and Family Planning Unit. Infertility: a tabulation of available data on prevalence of primary infertility. Geneva: World Health Organization; 1991.
- [2] IFFS Surveillance. Available at: http://c.ymcdn.com/sites/www.iffs-reproduction.org/resource/resmgr/iffs_surveillance_09-19-13.pdf.
- [3] Mills M, Rindfuss RR, McDonald P, te Velde E. Why do people postpone parenthood? Reason and social policy incentives. *Hum Reprod Update* 2011;17:848–60.
- [4] Nygren KG, Andersen AN. Assisted reproductive technology in Europe, 1997. Results generated from European registers by ESHRE. *European IVF-Monitoring Programme (EIM)*, for the European Society of Human Reproduction and Embryology (ESHRE). *Hum Reprod* 2001;16:384–91.
- [5] European IVF-Monitoring Consortium (EIM), European Society of Human Reproduction and Embryology (ESHRE), Kupka MS, et al. Assisted reproductive technology in Europe, 2011: results generated from European registers by ESHRE. *Hum Reprod* 2016;31:233–48.
- [6] Gianaroli L, Crivello AM, Stanghellini I, Ferraretti AP, Tabanelli C, Magli MC. Reiterative changes in the Italian regulation on IVF: the effect on PGD patients' reproductive decisions. *Reprod Biomed Online* 2014;28:125–32.
- [7] Pennings G, de Mouzon J, Shenfield F, et al. Socio-demographic and fertility-related characteristics and motivations of oocyte donors in eleven European countries. *Hum Reprod* 2014;29:1076–89.
- [8] Shenfield F, de Mouzon J, Pennings G, et al. Crossborder reproductive care in six European countries. *Hum Reprod* 2010;25(6):1361–8.
- [9] Benagiano G, Gianaroli L. The Italian Constitutional Court modifies Italian legislation on assisted reproduction technology. *Reprod Biomed Online* 2010;20:398–402.
- [10] Benagiano G, Filippi V, Sgargi S, Gianaroli L. Italian Constitutional Court removes the prohibition on gamete donation in Italy. *Reprod Biomed Online* 2014;29:662–4.
- [11] Hoorens S, Clift J, Staetsky L, et al. Low fertility in Europe: is there still reason to worry? Rand Corporation. Available at: http://www.rand.org/content/dam/rand/pubs/monographs/2011/RAND_MG1080.pdf.
- [12] ESHRE Capri Workshop Group. Economic aspects of infertility care: a challenge for researchers and clinicians. *Hum Reprod* 2015;30:2243–8.