

## **Assisted reproductive technologies in European Union: Findings of the Reproductive Health Report**

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### **Abstract**

**Objectives** The aim of this paper is to present and compare the data on assisted reproductive technologies (ART) legal regulations, reimbursement and ART birth rates per national births in European Union Member States.

**Methods:** Data were retrieved from the Report on medically assisted procreation in European Countries national documents, European Society of Human Reproduction and Embryology report for year 2006 and national health statistics.

**Results:** The majority of EU countries have adopted some legal regulations on ART, six countries have not. The legal regulations and guidelines prepared by medical professionals differ in extent and content from country to country. For instance in 13 countries ART procedures are only used for heterosexual couples, in others also for other (lesbian couples and/or single women). In the majority of countries national health systems fully or partially

reimburse ART treatments. For a small minority no reimbursement exists. The percentage of ART births per national births in 2006 ranged from 0.5% in Malta to 4.1% in Denmark.

**Conclusions:** In the EU, as for ART regulations and policies is concerned, there are many disparities existing among countries and even within countries. These disparities contribute to inequalities in access to sexual and reproductive health services, which does not always contribute to a readily availability of ART in the EU.

## Introduction

Infertility is defined “a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse”<sup>1</sup>. Estimates, from existing population surveys, show that the prevalence of lifetime infertility ranges from 3.5% to 16.7% in more developed nations and from 6.9% to 9.3% in less-developed nations, with an estimated overall median prevalence of 9%<sup>2</sup>. Postponement of childbearing, sexually transmitted infections, increased obesity, smoking and alcohol consumption seem to contribute to a decrease in female and male fertility<sup>3-5</sup>.

Assisted reproductive technology (ART) is an important part of infertility treatment (besides counselling, pharmacotherapy and surgery) in developed e.g. high income countries. In the countries with low fertility rates, accessibility and availability of ART probably plays a role in increasing fertility rates of European countries<sup>6</sup>.

In all European Union (EU) Member States, total fertility rates (TFR) are below the replacement level. The replacement level, in developed countries, can be taken as requiring an average of 2.1 children per woman<sup>7,8</sup>. According to national statistics the TFR in EU countries in 2008 were: Ireland (2.10), France (2.01), the United Kingdom (1.96), Sweden

(1.91), Denmark (1.89), Belgium (1.86), Finland (1.85), the Netherlands (1.77), Estonia (1.65), Luxembourg (1.61), Slovenia (1.53), Greece (1.51), Czech Republic (1.50), Bulgaria (1.48), Lithuania (1.47), Cyprus (1.46), Spain (1.46), Latvia (1.44), Malta (1.44), Italy (1.42), Austria (1.41), Poland (1.39), Germany (1.38), Portugal (1.37), Hungary (1.35), Romania (1.35), Slovakia (1.32)<sup>9</sup>.

In the EU ART procedures are used for heterosexual couples (e.g. infertility, risk of transmission of a disease), but sometimes also for single women and lesbian couples.

Treatment criteria and availability of ART in EU Member states were one of the five areas covered by The Reproductive Health Report, the project under the EU Health Programme for the period 2008-2013. Other areas covered were: teenage sexuality, reproduction and youth friendly clinics; use of contraception and associated policies (e.g. reimbursement, accessibility); childbearing support and public policies; policies, practices and trends related to induced abortion. The Reproductive Health Report is now the first comprehensive Report with high public health relevance that describes the current state of sexual and reproductive health (SRH) within the EU. The aim of this paper is to present and compare data on ART in EU Member States from the project Reproductive Health Report in terms of legal regulation, reimbursement of ART and the rates of births from ART per national births.

## **Methods**

Data on ART regulations were retrieved from the Report on medically assisted procreation in European Countries made by the Steering Committee of Bioethics of the Council of Europe in 2005<sup>10</sup> and from national data supplied by collaborating partners from each EU country. Data on reimbursement policies were collected through national documents and data from the report on MAP in European Countries made by the Steering Committee of Bioethics of the Council of Europe<sup>10</sup>. Data on the percentage of ART births were delivered from ESHRE report for year 2006<sup>11</sup> and national health statistics, when available.

## Results

### *Regulations on ART*

In the majority of EU countries the availability of ART is regulated in terms of law or professional guidelines and/or recommendations (Table 1).

HERE TABLE 1

ART regulations differ in extent and content from country to country. From the 27 countries of the EU, 21 have adopted some legal regulations about ART, six countries have not done it yet. In Austria, Cyprus, Czech Republic, France, Hungary, Ireland, Italy, Lithuania, Malta, Poland, Portugal, Slovakia and Slovenia, 13 countries, the ART procedures are available for medical reasons. The medical reasons for ART treatment include infertility and the risk of transmission of a disease (e.g. serious genetic disease, sexually transmitted diseases). ART procedures are legally available for lesbian couples and/or single women (non-medical reasons) in Belgium, Bulgaria, Denmark, Estonia, Finland, Germany, Greece, Latvia, Luxembourg, the Netherlands, Spain, Sweden and United Kingdom; in Romania there is no prohibition. For the majority of EU Member States semen and/or ovum donation is allowed, except for Ireland, Italy, Lithuania, Malta and Poland. In addition, embryo donation is allowed in Belgium, Czech Republic, Estonia, Finland, France, Greece, Hungary, Latvia, Luxembourg, the Netherlands, Slovakia, Spain, Sweden and United Kingdom. Surrogacy is allowed in Greece and in the United Kingdom and not prohibited in Belgium and the Netherlands. There are some peculiarities, e.g. in Italy the law prohibits the gamete donation, pre-implantation genetic diagnosis (PDG) and research on human embryos. Some countries, such as Bulgaria and the United Kingdom, do not have any age limits for ART procedures. On the other hand, there can be a legal upper female age limit, which is high, as

in Estonia and Greece, 50 years. In Greece, according to the law, post-mortem insemination is legal.

In some countries there are only minimal and/or old ART legislations: in Bulgaria, the Czech Republic, Hungary and Slovakia. In Cyprus, Ireland, Malta and Poland there are only some professional guidelines, but in Luxemburg and Romania there are no professional guidelines ART at all.

### ***Reimbursement of ART***

In some countries national health systems or social security systems fully or partially reimburse ART treatments (Table 1). The highest reimbursement rates for ART treatment (three or more ART treatments) in EU Member States occur in Slovenia, Estonia (since 2008), Belgium, Hungary, France, Luxembourg, Czech Republic, the Netherlands and Portugal. Moderate reimbursement rates for ART treatment (less than three ART treatments) are found in Austria, Denmark (from 2010 no reimbursement), Finland, Greece, Germany, Italy, Sweden and the United Kingdom. Low reimbursement rates for ART are found in Cyprus and Romania, where public reimbursement for infertile couple is provided only for one ART cycle. No reimbursement on ART procedures exists in Bulgaria, Ireland, Latvia, Lithuania, Malta and Poland.

### ***Rates of births from ART***

The highest percentage of ART births per national births in 2006 was found in Denmark (4.1%), Slovenia (3.6%), Belgium (3.3%), Finland (3.3%), Sweden (3.3%) and Netherlands (2.4%). Moderate percentage of ART births per national births was seen in Hungary (2.0%), United Kingdom (1.7%), France (1.6%), Germany (1.6%), Bulgaria (1.4%, data for 2005) and Austria (1.3%). Low rates were seen in Italy (1.0%), Estonia (0.9%) and Malta (0.5%, data for 2005). There are no data available for the other Member States.

## Discussion

ART discussion is linked to other SRH issues, namely childbearing policies and also to several reproductive health determinants, namely maternity postponing. In a certain way, some people wonder if it would be wise or advisable, as far as possible under different social, cultural and economic perspectives, to advise people to have their children earlier. Earlier motherhood should be promoted in order to avoid unnecessary infertility treatments and because its positive effects to childbearing (less complications)<sup>12</sup>.

If ART itself will increase the total fertility rate is debatable<sup>13</sup>. Nevertheless, in some countries of the EU, ART births represent more than 3% of all births which, in countries with low fertility rates represent important numbers.

By gathering and analyzing data concerning ART regulations and policies, we came into the conclusion that a lot of disparities exist among countries and even within countries, which is the case, for example, in Sweden and Italy. These disparities often represent obstacles for accessing ART and can, indeed contribute to inequalities in access to SRH care services. This is probably the reason why sexual and reproductive health is fertile ground for the so called “health tourism” or, in this specific case “reproductive tourism”.

“Reproductive tourism”, also called “cross-border reproductive care”, refers to the travelling of citizens from their country of residence to another country in order to receive fertility treatment through ART. The main drivers for fertility tourism are legal regulations of the sought procedure in the home country, or lower price and higher success reported by foreign centres<sup>14</sup>. Not in all centres are clear regulations regarding safety of the procedures and number of embryos transferred in IVF. Therefore, “reproductive tourism” is often associated with a high risk of health dangers for mothers and eventually their newborns,

frustration and disparities. At present there are no reliable data available on the magnitude of this undesired phenomenon but we believe that this is an important issue that should call the attention of EU, especially in terms of trying to harmonize regulations and policies.

The majority of the data on ART regulations and reimbursement policies were delivered from the report on MAP in European Countries made by the Steering Committee of Bioethics of the Council of Europe in 2005<sup>10</sup> and through national documents. One fifth (six out of 27) of EU countries had no legal framework for ART procedures. In some of these six Member States, national medical guidelines and recommendations are used to describe the framework of ART procedures. But in rare occasions, as in Romania, the absence of law reflects the lack of prohibitions against most ART practices and high probability to provide ethically questionable or inappropriate ART procedures and lack of upper age limits.

Twenty one EU Member States have some ART regulations; among others, some older and some new ones and some incomplete. Therefore this Report should be used to encourage Member States without legislations (or with old or inappropriate ones) to establish or improve the legal framework for ART procedures in their country.

A division among EU Member States is seen when ART indications are considered: in one half of them (13 countries) ART procedures are used in heterosexual couples (e.g. infertility or a risk of transmission of a disease), and in the other half (14 countries) ART procedures are used also in lesbian couples or single woman and in some countries (Greece, United Kingdom) surrogacy is allowed, which can lead to the ethical discussions in some cultures and religions. The dilemma exists, as in some countries ART procedures are used for the other (social) purposes by legislation, in spite of the fact, that in the same law there is a legal stipulation, that ART is permitted if it is justified by medical indications.

For the present and future development of legislation on ART in EU it would be useful to check current legislations with some ethical values and reference documentation, e.g. the Human Rights and Biomedicine Convention (The Oviedo Convention)<sup>15</sup> and its Protocols, which in several Member States became even lawful.

Considering the reimbursement policy in ART there are huge differences among EU Member States. The availability and levels of reimbursement and the proportion of reimbursement are critical predictors of the use of ART in a given country: the highest percentages of births from ART are in the countries with high reimbursement rates. On one hand, some national policies support ART and therefore reimburse a large part of ART costs. On other hand, some Member States provide no support for ART procedures, even not for infertility treatment. In any case, “the rights or privileges of infertile patients to receive State support for their treatment”<sup>16</sup> have to be considered. In fact, “there are dangers of an economic selection of patients for fertility treatments when national funds allotted for this purpose are very limited”<sup>16</sup>. In this case, when a minimum level of purchase is not defined, “some treatments will be restricted to the wealthier sections of populations”<sup>17</sup>.

The practices from EU Member States have shown that clear legislation is a prerequisite to increase the availability and accessibility of ART; legislation on ART procedures is a must for every EU country. Freezing, thawing and transferring the embryo in uterus is an example of an important area where a clear legislation is necessary. Whatever one thinks about the moral status of the human embryo and the embryonic human stem cells research, it is at least essential to have a transparent legal framework for this. Sometimes the absence of law can be worse than an imperfect law. Furthermore medical guidelines for ART procedures are warranted to prevent maternal and perinatal morbidity and mortality, for instance the advice on single embryo transfer in order to reduce the number of multiples<sup>18</sup>.



The data on the percentage of ART births were delivered from the ESHRE report for year 2006<sup>11</sup> and were found to be very useful. These data show that in some EU Member States ART procedures could contribute an important part to fertility rates in particular country, even more than 3% per year. ART births are obvious and prominent especially in the countries with low fertility rates. Due to the latest changes in reimbursement policies in some countries, percentage of ART births in some counties is expected to rise in the future (e.g. in Estonia).

Regarding data quality, we are aware that the collected data in present study are not always equally robust, not always retrieved from the same time period and therefore not always comparable between countries. But the project put a lot of effort to collect the best and most updated data and we feel that presented data are “the best you can get”.

To collect ART data across all EU member states regularly and in a standardised, validated way would be of great help in the discussion on ART. The establishment of the ESHRE registry<sup>11</sup> is a good example that this is possible.

In conclusion, ART births rates represent important numbers in the countries with low fertility rates. In EU, regarding ART regulations and policies, a lot of disparities exist among countries and even within countries. These disparities often represent obstacles for accessing ART and can, indeed contribute to inequalities in access to SRH care services, which does not always contribute to a readily availability of ART in the EU.

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Table 1 – Laws and /or other regulations on ART, reimbursement policy and the percentage of ART births per national births in EU countries in 2006

Country	Law on ART (year)	Comments	Reimbursement	ART births per national births (%)
<b>Austria</b>	Yes (1992)	Available to heterosexual couples, semen donation allowed only in insemination	70% of costs of IVF treatments under specific conditions, 4 cycles of IVF	1.3
<b>Belgium</b>	Yes (2007)	There are no specific criteria for ART; available to heterosexual couples, lesbian couples, single women; embryo donation allowed; surrogacy not forbidden	6 procedures of ART reimbursed, women aged less than 42 years	3.3
<b>Bulgaria</b>	Yes (1987)	Available to women in or without heterosexual relationships ; no age limits	No	1.4*
<b>Cyprus</b>	No	Available to heterosexual couples, no other prohibition	1 cycle of ART reimbursed, women aged less than 40 years	
<b>The Czech Republic</b>	Yes (1982)	The law regulates only insemination; other ART procedures are regulated by professional recommendations. ART available to heterosexual couples, embryo donation allowed	IUI reimbursed without any restrictions, women aged less than 40 years, 3 completed IVF cycles reimbursed	
<b>Denmark</b>	Yes (2007)	Available to heterosexual couples, lesbian couples, single women	No reimbursement (Until 2010 3 ART cycles reimbursed)	4.1
<b>Estonia</b>	Yes (1997/2011)	Available to heterosexual couples and single women; embryo donation allowed, surrogacy not	Unlimited number of ART cycles fully covered, women aged less than 40 years, reimbursement system for medicines (since 2008)	0.9.**
<b>Finland</b>	Yes (2007)	Available for heterosexuals, lesbian couples, single women, embryo donation allowed	Partially covered, woman aged less than 42 years	3.3
<b>France</b>	Yes (2004)	Available to heterosexual couples, embryo donation is allowed	4 cycles of IVF reimbursed, woman aged less than 40 years	1.6
<b>Germany</b>	Yes (1990)	Available to heterosexual couples. Sperm donation is legal. Oocyte donation and surrogacy are illegal. Treatment of lesbian couples and single women not clearly specified by law. Cryopreservation of embryos is legal only in emergency situations. Polar body biopsy is legal, blastomere biopsy is illegal.	50% of up to 8 cycles of IUI and/or up to 3 cycles of IVF covered by federal insurance, for married couples, women aged less than 40 and men less than 50 years. Private insurance companies have to pay as long as the couple's individual pregnancy chance is > 15%/ET regardless of marital status and age.	1.8
<b>Greece</b>	Yes (2005)	Available for heterosexuals, lesbian couples, single women, embryo donation and surrogacy is allowed; legal post-mortem insemination; upper female age limit is 50 years	Variable reimbursement	
<b>Hungary</b>	Yes (1981)	Available to heterosexual couples, embryo donation is allowed	Up to 5 cycles of IVF reimbursed	2.0**
<b>Ireland</b>	No	Only professional guidelines: ART available to heterosexual couples, no gamete or embryo donation	No	
<b>Italy</b>	Yes (2004/2009)	Available to heterosexual couples; no gamete donation, no PGD	Partial reimbursement, individual policy in each region	1.0
<b>Latvia</b>	Yes (2002)	Available to heterosexuals, lesbian couples, single women, embryo donation is allowed	No	
<b>Lithuania</b>	Yes (1999)	Available to married couples, no gamete donation	No	

Country	Law on ART (year)	Comments	Reimbursement	ART births per national births (%)
<b>Luxembourg</b>	No	No specific professional guidelines. ART available also for lesbian couples, single women; embryo donation allowed	4 cycles of IVF fully paid for woman aged less than 42 years	
<b>Malta</b>	No	Not prohibited, available to married couples	No	0.5*
<b>Poland</b>	No	Available as infertility treatment	No	
<b>Portugal</b>	Yes (2008)	Available to heterosexual couples, anonymous gamete donation and PGD allowed.	3 cycles of IUI, 3 cycles of IVF	0.9
<b>Romania</b>	No	No prohibition	1 procedure of ART reimbursed, woman aged less than 40 years	
<b>Slovakia</b>	Yes (1983)	The law regulates only insemination; other ART procedures are regulated by professional recommendations. Available to heterosexual couples; embryo donation is allowed	2 cycles of ART, woman aged less than 38 years	
<b>Slovenia</b>	Yes (2000)	Available to heterosexual couples, anonymous gamete donation and PGD allowed	4 cycles of IUI, 6 cycles of IVF for the first child in IVF and 4 cycles of IVF for any further child in IVF, woman aged less than 43 years	3.6
<b>Spain</b>	Yes (2006)	Available to all women since 18 years, embryo donation is allowed	Free in Public Health system for women aged less than 40 years (but long waiting lists: 4-5 years)	
<b>Sweden</b>	Yes (1998)	Available to heterosexual couples, lesbian couples (only insemination), not single women, embryo donation is allowed only in public hospitals	Some County Councils covers three ART procedures and others cover no treatments at all	3.3
<b>the Netherlands</b>	Yes (2002)	Available to heterosexual and homosexual couples, single women; embryo donation is allowed; surrogacy is not prohibited	Maximum 3 cycles of IVF	2.4
<b>United Kingdom</b>	Yes (1990)	Available to heterosexual couples, single women, lesbian couples, embryo donation is allowed, surrogacy allowed	Some services are available free of charge, depending on local authority	1.7

\* data for 2005

\*\* data from national birth registry