Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologies

(SANCO/2008/C6/051)

FINAL REPORT

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I. General introduction

In 2004, a broad range of legislative quality and safety requirements for the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells was introduced by the European Parliament and the Council with the launch of the Directive 2004/23/EC[1]. Implementation of this Directive requires clinics in all 27 EU Member States, specialized in Medically Assisted Reproductive (MAR) technologies, including fertility treatment and pre-implantation genetic diagnosis, to adapt to stringent measures and to implement systems and operating procedures concerning accreditation, designation, authorization, licensing, inspection and registration of MAR-treatments. However, once the Directive came into force, it became apparent that the field of medically assisted reproductive technologies should be considered as a field quite distinct from the field of tissue and cell transplantation because MAR in most cases (except for oocyte donation cycles) does not concern transplantation of tissues and cells from one person to another: it involves auto- transplantation. Consequently, due to the wide coverage of the Directive in comparison to the very specific nature of MAR treatments including numerous repeated procedures on the same patient, execution of some of the areas in the Directive are problematic for the MAR community. Based on this information ESHRE published in 2007 a position paper (see Annex 9) describing problems and new initiatives with regards to quality and safety in MAR treatments[2].

Work Package 1 of this study was set up to analyse in a comparative perspective the different regulatory frameworks at Member State level for MAR and to compare reimbursement issues among Member States whereas **Work Package 2** was organized with the aim to gather more information on the scale and scope of MAR institutes in the EU Member States.
Details on the methods of information collection are explained in paragraph II and VI (Introduction to Work package 1 and 2). Analyzing the results of the two surveys conducted, one should be aware of the chosen reference periods for data collection. In WP1 data collection was closed on 30 October 2009 and data represent the current legislative situation in the 27 EU Member States. For WP2 however, Member States could only deliver data for treatments between 1st of January 2006 and the 31rd of December 2006.

Although the European Society of Human Reproduction and Embryology (ESHRE) organized 2 surveys among 27 EU Member States, not all Member States could deliver the data requested, especially not when quantification was required in Work Package 2. The observed lack of data (indicated in all further figures and tables as 'not reported') is Member State – specific and is due to several reasons:

- Quantified data are mostly unavailable for Estonia, Malta, Romania and Slovakia due to:
  - EE, SK: Inexistence of a National/Local registration nor could individual clinics provide data on treatments;
  - MT: Existence of a voluntary National Registry but clinics apparently do not report;
  - RO: Registration became compulsory in 2008. No data are available for 2006.
- Quantification is possible but incomplete for Greece, Lithuania and Poland due to:

[1] DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of Human tissues and cells.

[2] ESHRE Position Paper on the DIRECTIVE 2004/23/EC , November 2007 (see Annex 9)

- PL, GR: Inexistence of a National/Local registration but data are available through voluntary participation of some of the individual clinics;
- LT: has a Local Registry in place on voluntary basis but not all clinics report.

As can be seen throughout this report, ESHRE used different information sources (competent authorities and contacts from ESHRE Consortia) to gather the requested data and to validate the obtained data. This report therefore provides the European Commission with an outline and evaluation of the topics addressed in the first and the second Work Package during the maintained timeframe. However, observed differences between the situation 'as is' and the 'official' situation (reported by Competent Authorities) with regard to MAR treatments in the European Union, need to be interpreted with caution as ESHRE was obliged for some countries to contact individual experts due to the lack of response from the competent authorities. Therefore in certain countries 'official' information is not available and a comparison between 'as is' and 'official' data cannot be made. ESHRE is able to provide an outline based on cross checked information (official and/or from the field) but is not able, with information obtained throughout this study, to one on one compare 'official' with 'as is' data in each country. More elaborate research would be required to make relevant conclusions. However, this study already gives a first clear indication of the situation in each country and of current issues within the field of MAR.

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Report Work package 1 – Legal Aspects and Reimbursement Issues

II. Introduction to Work Package 1

Work Package 1 of this study was set up to analyse in a comparative perspective the different regulatory frameworks at Member State level for MAR and to compare reimbursement issues among Member States. A survey was conducted among 27 EU Member States using different contact persons in each Member State. The survey for Member States (questionnaire see Annex 1) for WP1 was put online at the ESHRE-website *after formal approval of the content of the questionnaire* by DG SANCO (Anna Pavlou, Isabel De la Mata). Contact lists for all 27 Member States were established and the contact persons were sent an e-mail in April 2009 with access codes (allowing them to enter the online survey) and were requested to complete the forms by 1 May 2009. A second and third data gathering round was organized to cross check data and validate data for each specific Member State. In general, contact persons (see Annex 2 for contact list) could be divided into 3 groups: Competent Authorities, regulators being member of ESHRE's European Assisted Conception Consortium (EACC)[3] and members of ESHRE's Committee of National Representatives (CNR)[4].

The current report reviews the 2009 – legal situation concerning MAR in 27 EU Member States. As legislation in the different Member States may vary, it may be that in the meanwhile there were some adaptations, not included here. Data collection for WP1 was closed on 30 October 2009.

[3] The aim of the EACC is to bring together national ART regulators and practitioners within the European Union for professional cooperation and joint action. Some of the objectives are : to provide an organisational framework for developing and presenting joint positions to the European Commission on matters concerning the regulation of assisted reproduction services in the EU; To share learning during implementation of the EU Tissue & Cells Directive and to develop solutions to common problems where possible; To help improve consistency and share best practice approaches to promoting safety and quality through open communication between Member States.

[4] Members of the CNR advice ESHRE from a national perspective on strategic decisions, policy, local regulatory developments and should be aware of current legal situation in their home country.

III. Analysis of legislation regulating MAR in 27 EU Member States

1. Implementation of the Tissues & Cells Directive (2004/23/EC) in 27 EU Member States

1.1 Status on implementation of the Tissues & Cells Directive (2004/23/EC) (September 2009)

Data were collected for all 27 EU Member States and describe the legal situation as currently (October 2009) present in each Member State. As can be seen in Figure 1, 26 countries have implemented the EU Tissue and Cells Directive (hereinafter referred to as EUTCD), 1 country (BE) did, up till now, not implement this Directive.

23 of 26 EU Member States that have implemented the EUTCD have a Competent Authority installed (see Table 1), as well as Belgium that did not yet implement the EUTCD. Inspection and licensing has started in 18 EU Member States.

Different situations occur among the Member States:

- 18 of 27 EU Member States have implemented EUTCD, have installed a Competent Authority and licensing/inspection procedures are taking place: AT, BG, CY, CZ, DK, DE, EE, FI, FR, HU, IE, LV, LU, RO, SI, ES, NL, UK.
- 5 of 27 EU Member States have implemented EUTCD, have installed their Competent Authority but did not start licensing/inspection procedures: GR, IT, PT, SE, LT.
- 1 of 27 EU Member States has not yet implemented EUTCD, but has installed its Competent Authority. Licensing and inspection has not started: BE.
- 2 of 27 EU Member States have implemented EUTCD, but have not installed a Competent Authority and licensing/inspection procedures have not yet started: PL, SK.
- 1 of 27 EU Member States has implemented EUTCD, but has not yet installed a Competent Authority and has not started licensing/inspection procedures: MT

Belgium[5] (Figure 1 remark (1)), Greece, Italy, Lithuania, Portugal and Sweden have a Competent Authority installed, but inspection and licensing did not start yet. Slovakia and Poland (Figure 1 remark (2) & (3)) are the only two EU Member States who implemented the EUTCD and did not install a Competent Authority or start inspection/licensing procedures.

Worthwhile mentioning is that in Spain, the Directive was transposed into national legislation (Royal Decree 1301/2006) with different levels of practical implementation in the different regions, since inspection and licensing are under Autonomous Governments competence.

[5] For Belgium (see Figure 1 remark (1)), the EUTCD has been transposed into the Belgian Law of 19/12/2008 dealing with the use of and access to human tissue material for medical use and/or use in scientific research. The Decree implementing the law still needs to be published. However, an additional law (16/06/2009) states that Law 19/12/2008 will become effective anyway at the latest on 14 July 2010. Belgium has installed a Competent Authority, Agency for Medicines and Health Products, and has started inspection and licensing.

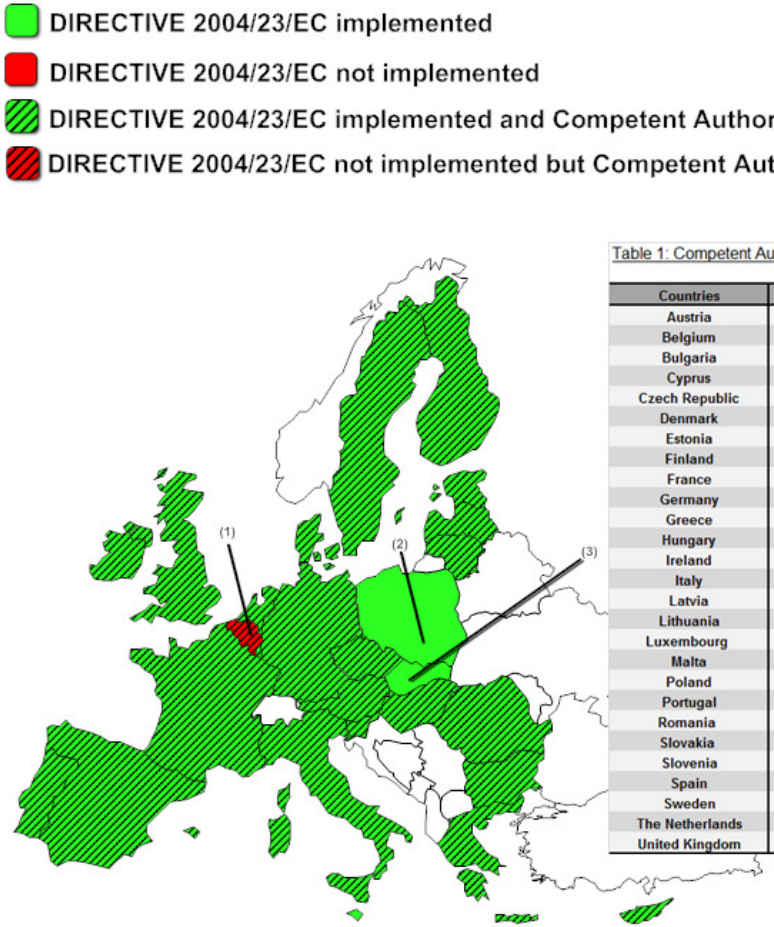


Table 1: Competent Authority and Inspection in 27 EU Member States

Countries	Competent Authority installed	Inspection/Licensing started
Austria	+	+
Belgium	+	-
Bulgaria	+	+
Cyprus	+	+
Czech Republic	+	+
Denmark	+	+
Estonia	+	+
Finland	+	+
France	+	+
Germany	+	+
Greece	+	-
Hungary	+	+
Ireland	+	+
Italy	+	-
Latvia	+	+
Lithuania	+	-
Luxembourg	+	+
Malta	-	-
Poland	-	-
Portugal	+	-
Romania	+	+
Slovakia	-	-
Slovenia	+	+
Spain	+	+
Sweden	+	-
The Netherlands	+	+
United Kingdom	+	+

Figure 1: Implementation of DIRECTIVE 2004/23/EC and establishment of Competent Authority in 27 EU Member States (2009)

1.2 Specific MAR – legislation in 27 EU Member States

19 EU Member States (FI, SE, UK, DK, NL, DE, BE, FR ES, PT, IT, AT, SI, CZ, SK, HU, BG, GR, EE) have reported the existence of MAR- specific legislation in their country (Figure 2: green), whereas 8 countries (CY, IE, LT, LU, MT, PL, RO, LV) report not to have MAR- specific legislation but general legislation covering MAR-procedures (Figure 2: orange).

For Romania, although no MAR- specific legislation is in place, there exists a general law based on Tissues and Cells Directive for all kinds of cell and tissue transplants (Law no 95/2006 art. 153 till art. 164 and law guidelines /25.10.2006 with all later amendments) that covers MAR treatments. The same counts for Latvia, Poland, Luxembourg, Lithuania, Ireland and Cyprus.

Malta reported that a parliamentary committee has just met to discuss MAR-related legislation. Although there is reported a general agreement on most of the moral issues involved, legislation still is in the process to become established.

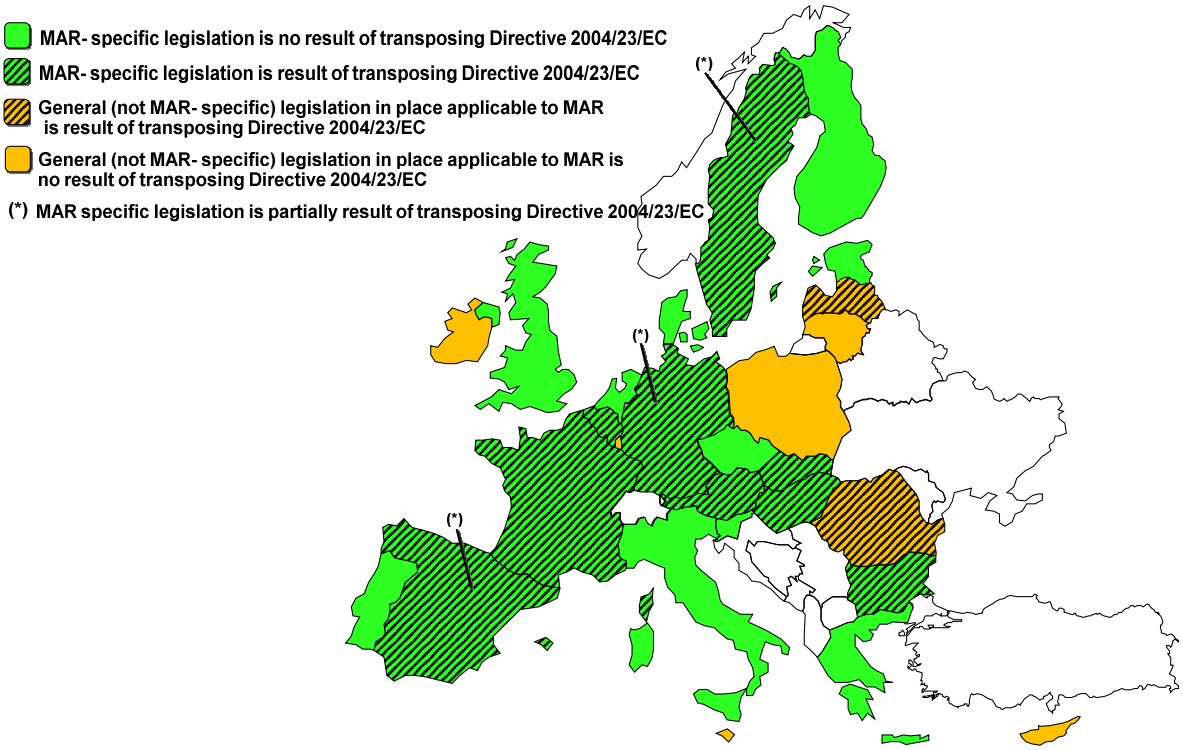


Figure 2: Overview of existence of MAR- specific legislation in 27 EU Member States

The different national laws are reviewed in Table 2. Remark that some of them were already in place before the EUTCD came into force. Details on date and content of national laws in each of the Member States are listed in Table 2, except for the Czech Republic and Slovakia, which did not report details on their specific legislation.

Table 2: Specific legislation for MAR-treatments

Country	Legislation References
Austria	Law: Gewebesicherheitsgesetz-GSG (Tissue safety Law), 19.3.2008 "Fortpflanzungsmedizingesetz" (no manupulation of the embryo; in addition, no PGD, no egg donation, no surrogacy, no heterologous IVF/ICSI)
Belgium	Law of 15 February 1999: regulation of IVF centres; Law of 11 May 2003: law on embryo research; Law of 4 June 2003: conditions reimbursement laboratory; Law of 14 September 2006: reimbursement gonadotrophins; Law of 6 July 2007: informed consent regulations; Law of 24 July 2008: inspections; Law of 6 October 2008: reimbursement inseminations; Law of 19 December 2008: tissue and cell directives.
Bulgaria	Law for the Health
Cyprus	**No specific legislation in place. MAR is covered by a general health law (see figure 2)**
Czech Republic	No details reported[6]
Denmark	Lov om krav til kvalitet og sikkerhed ved håndtering af humane væv og celler (vævsloven, nr. 273 af 1. april 2006, som ændret ved lov nr. 534 af 17. juni 2008) Bekendtgørelse nr. 1266 af 15. december 2008 om tilladelse til, kontrol med samt indberetning af alvorlige bivirkninger og alvorlige uønskede hændelser ved håndtering af humane væv og celler Bekendtgørelse 984 af 2. august 2007 om kvalitet og sikkerhed ved testning, forarbejdning, konservering, opbevaring, distribution, import og eksport af humane væv og celler Standard for oprensning af sædceller med henblik på partner- og donorinsemination (Fra bilag 4 i Bekendtgørelse nr. 633 af 28. maj 2008 om Danske Lægemiddelsstandarder 2008.2) Bekendtgørelse nr. 753 af 3. juli 2006 om kvalitet og sikkerhed ved donation, udtagning og testning (humane væv og celler) Lovbekendtgørelse om kunstig befrugtning i forbindelse med lægelig behandling, diagnostik og forskning m.v. nr. 923 af 04.09.2006 Bekendtgørelse om kunstig befrugtning nr1724 af 21.12.206

[6] No data could be obtained on the existence of MAR- specific legislation in CZ and SK.

	Bekendtgørelse om indberetning af IVF-behandling m.v. samt Præimplantationsdiagnostik og Svangerskabsreduktion nr. 1522 af 16.12.2004
Estonia	The law **"Assisted fertilization and Protection of the embryo"** was ratified in Estonia in July 1997. The law includes 5 parts and 36 paragraphs and regulates artificial insemination, IVF, connected with those procedures manipulations with the embryos and all legislative problems.
Finland	Act of Assisted Reproduction (http://www.finlex.fi/fi/laki/ajantasa/2006/20061237) Laki hedelmöityshoidoista 22.12.2006/1237 Act of Medical use of human organs, tissues and cells (http://www.finlex.fi/fi/laki/ajantasa/2001/20010101) Laki ihmisen elimien, kudoksien ja solujen lääketieteellisestä käytöstä 2.2.2001/101 (http://www.finlex.fi/fi/laki/alkup/2007/20071302) Sosiaali- ja terveysministeriön asetus ihmisen kudoksien ja solujen lääketieteellisestä käytöstä Sosiaali- ja terveysministeriön päätöksen mukaisesti säädetään ihmisen elimien, kudoksien ja solujen lääketieteellisestä käytöstä 2 päivänä helmikuuta 2001 annetun lain (101/2001) 24 §:n, sellaisena kuin se on laissa 547/2007
France	The 1rst laws on Bioethics have been voted in 1994 founding the key ethical principles. Revision was scheduled to take place at five year intervals in order to take into account the experiences and the latest developments in legislation, clinical practice and evolving public concerns. Actually, the 1994 laws were revised in 2004 (Law 2004-800 6 August 2004) and then in 2008 transposing the EUTCD. Currently France organised in may-june 2009 a large public debate for the further revision of the 2004 Law. It is planned that the new law will be voted at the end 2010.
Germany	Penal law (embryo protection law): "ESchG" (abbr.): Gesetz zum Schutze von Embryonen: 13. Dezember 1990 (BGBl. I S. 2746 and BGBl. I S. 2702, 2705) Law that have converted the EU tissue directive (EU-Richtlinie 2004/23/EG & Durchführungsrichtlinien 2006/17/EG and 2006/86/EG)into national law: "Gewebegesetzes" (Gesetz über Qualität und Sicherheit von menschlichen Geweben und Zellen): 20. Juli 2007 (BGBl. I S. 1574) Rechtsverordnungen (=executive order law) to the Gewebegesetz: 1) "Arzneimittel- und Wirkstoffherstellungsverordnung" (abbr.: AMWHV) (§ 54 of the "Gesetz über den Verkehr mit Arzneimitteln" (abbr.: AMG), 14. August 1976, BGBl. I S. 2445, 2448, zuletzt geändert: Art. 1 VO vom 28. September 2009, BGBl. I S. 3172) 2) Transplantationsgesetz (abbr. TPG) (1. Dezember 1997, in der Fassung der Bekanntmachung vom 4. September 2007 (BGBl. I S. 2206), das durch Artikel 3 des Gesetzes vom 17.

	Juli 2009 (BGBl. I S. 1990) geändert worden ist You can check these laws for further details under: http://bundesrecht.juris.de/tpg/BJNR263100997.html (this, for example is the Transplantationsgesetz)
Greece	Legislation 3305/2005
Hungary	Act on Health, Chapter IX., 20/2007. (IV.19.) Ministerial Decree (EüM), 30/1998 (VI.24) Ministerial Decree (NM)
Ireland	**No specific legislation in place. MAR is covered by a general health law (see figure 2)**
Italy	Law 40/2004: Regulations on access to ART and on ART activity, embryos' rights, institution of a national ART registry.
Latvia	**No specific legislation in place. MAR is covered by a general health law (see figure 2)**
Lithuania	**No specific legislation in place. MAR is covered by a general health law (see figure 2)**
Luxembourg	**No specific legislation in place. MAR is covered by a general health law (see figure 2)**
Malta	**No specific legislation in place. MAR is covered by a general health law (see figure 2)**
Netherlands	Planningsbesluit In Vitro Fertilisatie (Act on In Vitro Fertilization) (1 april 1998) Embryowet (Embryo Act) (20/06/2002) Wet donorgegevens kunstmatige bevruchting (Law on data from donors for artificial reproduction) (25 april 2002) Wet veiligheid en kwaliteit lichaaMember Statesmateriaal (Law on safety and quality of human tissues) (6 februari 2003)
Poland	**No specific legislation in place. MAR is covered by a general health law (see figure 2)**
Portugal	Law 32/2006 (26th July)
Romania	**No specific legislation in place, only a general law based on Cell and Tissue Directive for all kinds of cell and tissue transplant (Law no 95/2006 art. 153 till art. 164 and law guidelines /25.10.2006 with all later amendments)**
Slovakia	No details reported[7]
Slovenia	Act on infertility treatment and procedures of biomedical-assisted procreation since 28.7.2000: it includes provisions on donation of gametes, recipients, procedures for MAR, data included in registry, local and national council for MAR.

[7] No data could be obtained on the existence of MAR- specific legislation in CZ and SK.

	Act for quality and safety of tissues and cells for the medical treatment since 2.7.2007: it includes provisions to provide quality and safety of tissues and cells for the medical treatment.
Spain	14/2006 26 de mayo sobre técnicas de Reproduccion humana asistida Royal Decree 1301/2006
Sweden	1st july 2008 (Lag 2008:286 om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler) Other Laws based on: SFS 2005:39, SFS 2006:351, SFS 2009:262, SOFS 2002:13, SFS 2008:286
United Kingdom	HFEA Act 1990 with changes concerning parenthood, PGD in 2008

Besides showing the existence of MAR-specific legislation (Figure 2: green) in 19 EU Member States and general legislation applicable to MAR in 8 countries (Figure 2: orange), Figure 2 (hatched) also explains that in 11 of 27 EU Member States (SE, LV, DE, BE, FR, ES, AT, SK, HU, RO, BG) implementation of some of their national law has been (at least partially) the result of transposing the EUTCD. 16 of 27 EU Member States (FI, EE, LT, PL, CZ, DK, NL, LU, PT, UK, IE, IT, SI, GR, CY, MT) do have specific legislation in place, which is not resulting from the EUTCD.

As the situation appears to be quite different in each Member State we explain a bit more in detail the current situation in the countries where legislation is (partially) the result of transposing the EUTCD below.

For **Austria, Belgium and Bulgaria**, the current law (see Table 2) is the result of transposing the EUTCD.

Spain, Sweden and Germany (Figure 2 (*)) do have more than one law regulating MAR- procedures and only part of these laws came into force due to the EUTCD.

- **Spain:** EUTCD was transposed into national legislation (Royal Decree 1301/2006). Note that Law on Assisted Reproduction (14/2006) in Table 2 is not resulting from the EUTCD.
- **Sweden:** Law 2008:286 is a result of the EUTCD, not the other laws/regulations mentioned in Table 2.
- **Germany:** The laws on MAR are a result from the Tissues and Cells Directive if it concerns the Gewebesicherheitsgesetz [8] and its executive laws, but not the Embryo protection law.

For France, the law in se is no result of EUTCD. The 1st laws on Bioethics have been voted in 1994 founding the key ethical principles. Revision was scheduled to take place at five year intervals in order to take into account the experiences and the latest developments in legislation, clinical practice and evolving public concerns. Actually, the 1994 laws were revised in 2004 (Law 2004-800 6 August 2004) and in 2008 transposing the EUTCD. Currently France has organised in May-June 2009 a large public debate for the further revision of the 2004 Law. It is planned that the new law will be voted at the end 2010.

[8] Gewebesicherheitsgesetz-GSG (Tissue safety Law), 19.3.2008 is the result of the directive. The law requires QC and QA systems and inspections by the assigned agency.

For Hungary, Ministerial Decrees have been added to the law (Act on Health Chapter) after the EUTCD came into force.

Romania, Latvia and Slovakia report to have general legislation in place regulating MAR and being the result of transposing EUTCD into national law.

1.3 MAR – specific soft regulation in 27 EU Member States

Additional to country-specific MAR legislation, also soft regulation is reported in EU Member States. Soft regulation is defined as guidelines, not laws, which help countries to act in the most appropriate way. These include good clinical practice guidelines, good laboratory practice guidelines and ethical guidelines.

Table 3: Soft Regulation in 27 EU Member States

Country	Good Clinical Practice Guidelines	Good Laboratory Practice Guidelines	Ethical Guidelines	Other
Austria	+	+	+	-
Belgium	+	+	+	-
Bulgaria	+	+	+	-
Cyprus	-	-	-	-
Czech Republic	-	-	-	+
Denmark	+	-	-	-
Estonia	-	-	-	-
Finland	-	-	-	-
France	+	+	-	-
Germany	+	+	-	-
Greece	+	+	+	-
Hungary	-	-	-	+
Ireland	+	-	-	-
Italy	+	+	+	-
Latvia	+	-	-	-
Lithuania	-	-	-	-
Luxembourg	+	+	+	-
Malta	+	+	+	-
Poland	-	-	-	-
Portugal	-	+	-	-
Romania	+	+	+	-
Slovakia	+	+	-	-
Slovenia	+	+	+	-
Spain	+	+	-	-
Sweden	+	+	+	-
The Netherlands	+	+	+	-
United Kingdom	+	+	+	-

22 of 27 EU Member States have reported that there is some soft-regulation in place in their country, while 5 of 27 indicated that no soft-regulation at all is applicable (CY, EE, FI[9], LT, PL). Note that Malta is in the process of drafting ethical guidelines for reproductive technology.

- One can remark that for the **Czech Republic** no guidelines are reported, although there is a certain form of soft- regulation (Table 3: indicated as 'Other'). More specifically, there exist professional society recommendations.
- Also regarding to **Hungary**, no good clinical/laboratory/ethical guidelines exist. The only types of soft regulation reported are PGD guidelines.
- For **Ireland**: The Irish Fertility Society is in the process of producing good clinical practice guidelines. The ICE[10] has a professional Code of Conduct. The Medical Council has guidelines on IVF for many years now.
- Note that although Table 3 indicates for **Romania** the existence of good clinical/laboratory/ethical practice guidelines. However, these guidelines are not yet available but will be soon provided by the Romanian Embryology Association (AER).

[9] In Finland no national consensus has been reached yet, but the procedures concerning soft-regulation are being debated.

[10] ICE = Association of Irish Clinical Embryologists

2. Establishment of Registries for MAR procedures in 27 EU Member States

2. 1 Establishment of National and Local registries for MAR-treatments

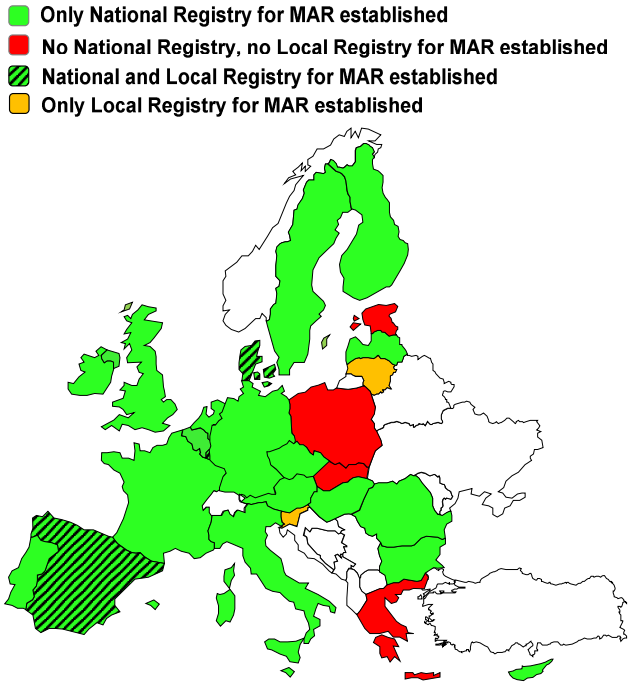


Table 4: Existence of National and Local Registries in the EU

Countries	National Registry		Local Registry	
	Voluntary	Compulsory	Voluntary	Compulsory
Austria		x		
Belgium		x		
Bulgaria	x	x		
Cyprus	x	x		
Czech Republic		x		
Denmark		x		x
Estonia				
Finland	x	x		
France		x		
Germany	x			
Greece				
Hungary		x		
Ireland	x			
Italy		x		
Latvia	x			
Lithuania			x	
Luxembourg	x		x	
Malta	x			
Poland				
Portugal	x			
Romania	x	x		
Slovakia				
Slovenia				x
Spain	x			x
Sweden	x			
The Netherlands		x		
United Kingdom		x		

Figure 3: Overview of the establishment of National and Local Registries for MAR-treatments in 27 EU Member States

Figure 3 shows that nowadays (de dato 2009) in 21 of 27 EU Member States (AT[11], BE[12], BG[13], CY, CZ, DK, FI, FR[14], DE, HU[15], IE, IT, LV, LU[16], MT[17], NL[18], PT, RO, ES[19], SE[20], UK[21]) a National

[11] Competent Authority: AGES - The Austrian Agency for Health and Food Safety; National Registry: GÖG/ÖBIG, IVF-Register.
[12] Competent Authority: FAMHP - Federal Agency for Medicines and Health Products; National Registry: BELRAP (Belgian Register for Assisted Procreation)
[13] Competent Authority: the Bulgarian Transplantation Agency
[14]Two systems exist for France: 1) Annual report: each ART centre provides an annual report of aggregated data to the Competent Authorities (Agence de la biomedecine and regional hospitalization agencies) on a mandatory basis. Collected data are exhaustive. The Competent Authority (Agence de la biomédecine) publishes a national report describing all the MAR activities performed in France each year (IUI, IVF, ICSI, FET, Cryopreservation of gametes, germinal tissues or embryos, gamete and embryo donation) (Law 2004-800 on Bioethics 6 August 2004, Decree 2005-420 4 May 2005 on Agence de la biomédecine, Decree 2006-1660 on ART and gamete donation 22 December 2006);
2) Registry of individual IVF attempts: the aggregated data can not lead to enough accurate studies. That is the reason why the Competent Authority has been organizing a supplementary collection of IVF, ICSI, FET and ED cycles, one record per attempt. The registry is currently in progress;
[15] The Hungarian Competent Authority is Committee of Human Reproduction of the Hungarian Research Council and its Ethical Committee of the Ministry of Health.
[16] Hospital Direction and Ministry of Health is Competent Authority of Luxembourg.

[17] Malta has a National Registry on voluntary basis and apparently clinics do not report data.

[18] The Registry is organized by the "LIR foundation", supervised by the Dutch Society of Gynaecology and Obstetrics and by the Dutch Society of Clinical Embryology. It is limited to IVF and ICSI treatment and cryo cycles. Name of the National Registry is 'Nederlandse IVF registratie'.
[19] The Spanish registry has been put in place by the Spanish Fertility Society.

[20] Competent Authority is National Board of Health and Welfare.

[21] Competent Authority is 'Human Fertilisation and Embryology Authority' (HFEA).

Registry has been established (Figure 3: green countries) and is maintained by The Competent Authorities. In 6 of 27 EU Member States (EE, GR, LT, SI, SK, PL) the inexistence of a National Registry (Figure 3: red and orange countries) was reported, with 2 of 6 (LT, SI) having a Local Registry in place (Figure 3: orange countries).

In 13 of 21 countries (AT, BE, BG, CY, CZ, DK, FI, FR, HU, IT, RO, NL,UK) having a National Registry in place, reporting to the National Registry is under legal obligation, whereas it appears to be voluntary in 8 countries (DE, ES, IE, LV, LU, MT, PT, SE). Note that in 4 countries (BG, CY, FI, RO) more than one National Registry exists and a voluntary as well as a compulsory reporting system appears to be in place. Reasons for both systems, obligatory and voluntary, simultaneously being in place were not highlighted in the questionnaire approved by DG SANCO and therefore no complete data can be used to explain this phenomenon. One possibility however, is that at first a voluntary system was organized by some medical Society to monitor output of MAR, and that later on, due to pressure from certain laws and/ or the Tissues and Cells Directive, a second registry was organized by the relevant authority and that both systems kept on operating.

Country-specific details are listed below or can be found in footnotes.

- For **Bulgaria**, the National Registry is compulsory and organized by Bulgarian Transplantation Agency. There also exists a National Registry on voluntary basis, organized by S. Kurkchief, which is used for data collection in the second Work Package of this report (EIM).
- In **Cyprus**, a National Registry on voluntary basis, organised by Ministry of Health just has started. It is under legal obligation to report to the Competent Authority.
- For **Denmark,** a National Registry and a Local Registry exist, both being compulsory and ran by respectively the Competent Authority and by the Danish Fertility Society.
- Note that for **Germany**, the National Registry is called 'Deutsches IVF Register' (www.deutsches-ivf-register.de) and is organized by the medical association "Artzekammer".
- For **Ireland**, the National Registry is organized by the Irish Fertility Society on voluntary basis.
- Note that for **Romania** there exist both, a National Registry on voluntary basis organized by Romanian Embryology Association (AER), and a National Registry under legal obligation ran by the Competent Authority, since 2008. Before, reporting was not compulsory and data have not been collected before 2008.
- Theoretically there should be a register in **Latvia**, where all private clinics send information, about patients with fertility problems, but unfortunately nobody in the government makes any summary.
- In **Spain,** the National Registry is organized by the Spanish Fertility Society. Local registries for MAR treatments exist and there is a legal obligation by the local Competent Authority in Catalonia to report. Remind that in Spain, the EUTCD was transposed into national legislation (Royal Decree 1301/2006) with different levels of practical implementation in the different regions, since inspection and licensing are under Regional Governments competence (see paragraph 1.1)
- For **Sweden** there is no legal obligation to report to the National Registry. Previously (until 2006) Swedish clinics were obliged to report to the 'National Board of Health and Welfare' (until 2006). However, in 2007 Sweden established a new National Registry, handled by the IVF profession. Although reporting to the new National Registry is not obligated by law, it does become compulsory if clinics do not report properly. Not voluntarily to the National Registry reporting clinics are 'forced' by 'the Board of Health' to deliver relevant data to them instead. Therefore, in Sweden it is compulsory to deliver data, but not to this New Registry. In practice, all MAR- clinics have agreed to deliver their data to the registry.

- For **Finland**, a National Registry on voluntary basis and a compulsory registry[22] exist.
- For **Greece** no National Registry is established. There exists a law (Law 3305/2005) which states that the establishment of a Local Registry is required. However, up till now, no such registry is in place yet.
- For **Slovenia:** no National Registry is in place. A local registry is in the process to be established on legal obligation by the Competent Authority. MAR Centres should organize their own registry and transfer personal clinical data for each cycle (related to quality control) online to the Medical chamber and provide a summary of the ART programme to Ministry of Health (each year).
- For **Lithuania,** no National Registry is organized, only Local Registries for MAR treatments exist on voluntary basis (local registering in clinics).
- **Estonia** has no local nor National Registry, neither have **Poland** and **Slovakia**.

22 Compulsory registry organized by Competent Authority i.e. licensing body is Lääkelaitos -National Agency for Medicines. The other registries are organized by 'THL - National institute for Health and welfare '– annual MAR statistics and 'VALVIRA – National supervisory authority for welfare and health' – donor registry.

2. 2 Establishment of National and Local registries for donors

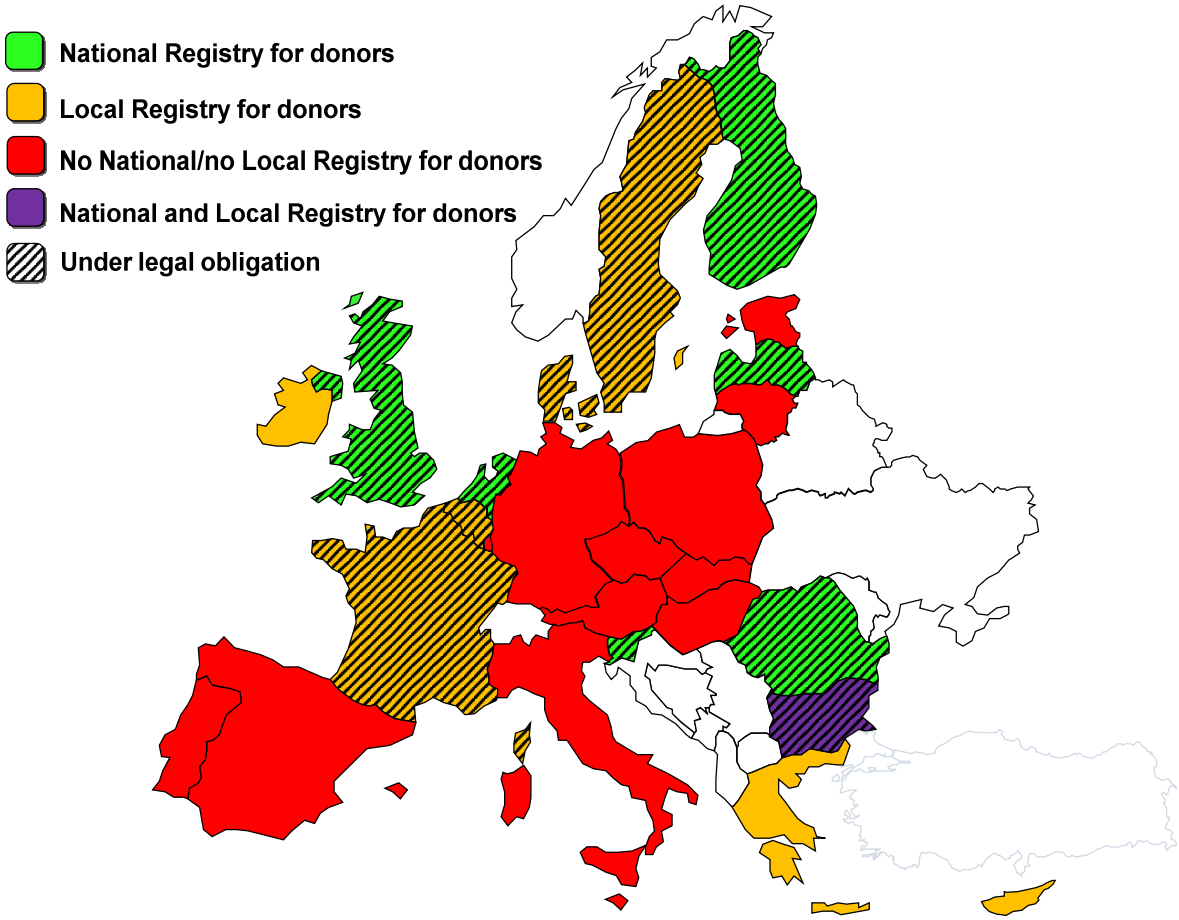


Figure 4: Overview of the establishment of National/Local Registries for donors

14 of 27 EU Member States (IE[23], UK, FR, BE, NL, DK, SI, BG, RO, GR, CY, LV, FI, SE) do have a Registry, National or Local, for donors (green, orange and purple in Figure 4), while the other remaining 13 countries (AT, CZ, DE, EE, ES[24], HU, IT, LT, LU, MT, PL, PT, SK) do not have any registry for donors in place (red in Figure 4).
6 of 14 EU Member States (FI, UK, NL, SI, RO, LV) having a registry for donors appear to have a National Registry for donors, 7 of 14 EU Member States have Local Registries in place, while Bulgaria has both, a Local and a National Registry for donors.

Note that in 11 of the 14 (UK, BE[25], NL, FR[26], SI[27], RO, BG[28], LV, FI[29], SE, DK[30]) countries that have established a National or Local Registry for donors, this is under legal obligation (see hatched countries in Figure 4). More country-specific information can be found in footnote.

[23] In Ireland, local registries on voluntary basis exist. A number of clinics receive donor sperm from other countries. There is no local register organized by the Competent Authority but the clinics are tracking live births from these donors.

[24] In Spain the Royal Decree for Donor Registry is currently under development (National Legislation).

[25] For Belgium a Local Registry for donors with Legal obligation is organised by the indivual centres, and is required by the law of 19.12.2008.

[26] France has no National Registry for donors. Data related to the donors are recorded at the local level under the responsibility of the authorized centres because they must assure the traceability of the donation (it means that all the useful information is available including the conditions of the donation, the donor's testing and other medical donor's data). According to the French law, please note that records do not provide any identifying information.

[27] For Slovenia, the data received were confusing. Under legal obligation a National Registry for donors should be in place. Licenced centers for donors have to report their identity in this Registry. Apparently the National Registry is in the process to be established.

[28] Bulgaria has both, a National and a Local Registry for donors. Note that the National Registry is only for oocyte donors and organised by Competent Authority, whereas the locally each centre collects the data for sperm donors.

[29] For Finland the National Registry for donors is organised by the Competent Authority.

[30] Denmark has a Local Registry under legal obligation. Licensed MAR centres have a legal obligation to ensure traceability from donor no. to recipient (Article 8 Directive 2004/23/EC). Licensed sperm banks have a legal obligation to record the specified information related to donors (Annex IV of Directive 2006/17/EC).

2. 3 Authorization and registration of different MAR-treatments, post-mortem use of embryos/gametes and surrogacy in the EU

Table 5: MAR - treatments: Legal situation in 27 EU Member States

	AID	AIH	ED	FET	ICSI	IVF	IVM	MESA	NIVF	OD	PGD	PGS	SET	SD	TESE	Postmortem use of embryos/gametes	Surrogacy
Austria	P	P	F	P (*)	P(*)	P(*)	P	P(*)	P(*)	F	F	P	P (*)	F	P(*)	F	F
Belgium	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(**)	P
Bulgaria	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	F	F
Cyprus	P	P	P	P	P(*)	P(*)	P	P	P	P	P	P	P	P	P	P	P
Czech R	P	P	P(*)	P(*)	P(*)	P(*)	P	P	P	P(*)	P(*)	P(*)	P(*)	P(*)	P	P(**)	F
Denmark	P(*)	P(*)	F	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	F	F
Estonia	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Finland	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	F	F
France	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	F	P(*)	P(*)	P(*)	F	F
Germany	P	P	F	P(*)	P(*)	P(*)	P	P	P	F	F	F	P	P	P	F	F
Greece (1)	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	F	P
Hungary	P	P	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	F	P	P(*)	P(*)	P (**)	F
Ireland	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P	P	P	P	P
Italy	F	P(*)	F	P(*)	P(*)	P(*)	P(*)	P	P(*)	F	P(*)	P(*)	F	F	P	F	F
Latvia	F	P(*)	P(*)	P(*)	P(*)	P(*)	P	F	F	P	F	F	F	P(*)	F	F	F
Lithuania	F	P(*)	F	P(*)	P(*)	P(*)	F	P(*)	F	F	F	F	P	F	P(*)	P	F
Luxembourg	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P	P	P(*)	P	P	P	P(*)	P(*)	P(*)	P	P
Malta	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Netherlands	P	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P	P(*)	P(*)	P(*)	P(**)	P(**)
Poland (1)	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Portugal	P	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	F	F
Romania	P	P	P(*)	P(*)	P(*)	P(*)	P	P	P	P(*)	P	P	P	P(*)	P	P	P
Slovakia	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Slovenia (1)	P	P	F	P	P	P	P	F	P	P	P	F	P	P	P	F	F
Spain	P	P	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(**)	F
Sweden	P	P	F	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	F	P(*)	P(*)	P(*)	F	F
UK	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P	P(*)	P(*)	P(*)	P(*)	P(*)	P(*)	P	P(**)	P(**)

Legend: **P:** Permitted, **F:** Forbidden, **(*):** Registered in National/Local MAR – Registry, **(**):** Allowed and registered in National/Local MAR – Registry, but WITH existing legal limitations, **(1):** No data available on registration as registry is not yet implemented

Table 5 shows which of the 15 considered MAR treatments[31] are legally allowed ('P' in Table 5) in the different EU Member States and which of them already have been registered ((*) in Table 5) in the existing National/Local Registries. Table 5 (last 2 columns) comments also on the legal status of surrogacy and postmortem use of gametes/embryos in each of the 27 EU Member States.

Remind that in 6 EU Member States (CY, IE, LT, LU, MT, PL) no MAR-specific legislation is in place (Figure 2: orange). For RO, LV, IE, CY, LU and PL there exists a general law based on Cell and Tissue Directive for all kinds of cell and tissue transplants. Malta however, is in the process of drafting legislation (see 1.2 'Specific MAR-legislation).

Analyzing the registration of the MAR-techniques, one can conclude that if the Member State has a National/Local registry established, IVF, ICSI, FET, MESA, NIVF, PGD, SD and TESE are in most countries being registered. Remind that Estonia (1), Greece (1), Poland (1) and Slovakia (1) do not have their own registry established yet and so no registration of treatments is mentioned in Table 5.

- France commented that PGS is forbidden in France. The law on Bioethics stipulates that PGD can only be performed in order to diagnose a severe familial genetic disease in the embryo (Law 2004-800 article L 2131-4).
- In Austria, Lithuania and Latvia PGD was reported to be forbidden (Table 5). For Latvia data refer to the existence of the 'Sexual and Reproductive Law' saying that it is not allowed to choose embryo gender (unless for genetic disease).

Further in Table 5 it is reported that in 12 of 27 EU Member States (AT[32], BG, DK, FI, FR, DE, GR, IT, LV, PT[33], SI, SE) post-mortem use of gametes/embryos is forbidden. 15 of 27 EU Member States (BE, CY, CZ, HU, IE, LT, NL, PL, RO, ES, UK) allow post – mortem use of gametes and embryo's, with legal restrictions in 6 of 15 EU Member States (BE[34], CZ, HU[35], NL, ES, UK). Legal basis when forbidden or restricted by law can be found, where provided by the individual Member States, in footnotes.

Surrogacy is forbidden in 15 of 27 EU Member States. 12 EU Member States allow surrogacy ('P' Table 5) and there are legal restrictions[36] to surrogacy in 2 ('P**' in Table 5) of those 12 countries (NL, UK).

[31] These 15 MAR techniques are the 15 most used techniques concerning MAR in Europe.

[32] In Austria, postmortem use and surrogacy is forbidden by Fortpflanzungsmedizingesetz Reproduction Law 2004.

[33] Postmortem use and surrogacy is prohibited in Portugal by Law 32/2006.

[34] In Belgium, postmortem use is allowed, but restricted by Law of 6 July 2007.

[35] Only if the IVF- process was started before the partner died, Hungary allows post-mortem use of gametes and embryos.

[36] Information on the kind of restrictions was not asked for in the questionnaire approved by DG SANCO and is therefore outside the scope of this study.

3. Eligibility and reimbursement criteria for MAR treatments in 27 EU Member States

3.1 Overview of existing eligibility and reimbursement criteria

Objective of research summarized in this paragraph is to analyse the existing eligibility criteria for obtaining access to MAR-treatments in each of the 27 EU Member States and to compare these criteria with the criteria for reimbursement of MAR- treatments. First of all we need to distinguish between Member States having public as well as private MAR clinics and Member States having only private or only public MAR centres. Ireland and Lithuania only have private MAR clinics, whereas Luxembourg, Slovenia and The Netherlands have solely public institutes (see Annex 5 for List of reporting establishments. 'PU' refers to Public Institutes, 'PR' refers to Private Institutes).

Table 6a indicates what eligibility criteria are used in each Member State for **access** to MAR treatment and to what extent these criteria differ between private and public institutes in countries where both types of institutes provide MAR treatment.

Table 6a: Limitations on **access** to MAR - treatments in 27 EU Member States

Country	Are there limitations for access to MAR-treatments in public institutes ?	Criteria						*Do the same criteria apply to private MAR-centres?*
		Marital status	Max. age of woman	Max. age of man	Welfare of Child conditions (HIV parents, criminal record,…)	Number of assessed cycles	Number of embryos transferred	
Austria	Yes	+	-	-	-	-	-	*Yes*
Belgium	Yes	-	+	-	-	-	-	*No (*)*
Bulgaria	Yes	-	+	-	-	-	-	*Yes*
Cyprus	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Czech Republic	Yes	+	+	-	-	-	-	*Yes*
Denmark	Yes	-	+	-	-	+	+	*No (*)*
Estonia	Yes	-	+	-	-	-	-	*Yes*
Finland	Yes	+	+	-	-	+	-	*No (*)*
France	Yes	+	+	+	-	-	-	*Yes*
Germany	Yes	-	+	-	-	-	-	*Yes*
Greece	Yes	+	+	-	-	-	-	*Yes*
Hungary	Yes	+	-	-	-	-	-	*Yes*
Ireland	Only private MAR centres exist	-	+	-	+	-	-	*NA, Only private MAR centres exist and criteria on the left refer to criteria maintained by private centres*
Italy	Yes	+	-	-	-	-	-	*No (*)*
Latvia	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Lithuania	Only private MAR centres exist	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Luxembourg	Yes	-	+	-	-	-	-	*Only public centres exist*
Malta	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Netherlands	Yes	-	+	-	-	-	-	*Only public centres exist*
Poland	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Portugal	Yes	+	+	-	-	-	-	*No (*)*
Romania	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Slovakia	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Slovenia	Yes	+	+	-	-	-	-	*Only public centres exist*
Spain	Yes	-	+	-	-	+	-	*No (*)*
Sweden	Yes	+	+	+	-	-	-	*No (*)*
United Kingdom	Yes	-	+	-	+	+	-	*No (*)*

20 of 27 EU Member States report the existence of limitations (criteria) **for access** to MAR-treatments. In 7 of 27 EU Member States (CY, LV, LT, PL, RO, SK, MT) no criteria at all are to be met in order to be eligible for MAR-treatment. Therefore MAR treatment in these countries is open to all citizens without any restriction regarding marital status, number of cycles, embryo's, ...

With regards to the reimbursement (public health insurance) of MAR treatment, criteria additional to the ones to be met for access to MAR treatment appear to exist in some countries and are displayed in Table 6b. However several countries did not provide information upon the existence of specific criteria for reimbursement and in these cases Table 6b only shows the minimum criteria, i.e. the criteria for access to MAR treatment.

Table 6b: Criteria limiting **reimbursement f**or MAR - treatments in 27 EU Member States

Country	Are there limitations for reimbursement to MAR-treatments in	Criteria						*Do the same criteria apply to private MAR-centres?*
		Marital status	Max. age of woman	Max. age of man	Welfare of Child conditions (HIV parents, criminal record,…)	Number of assessed cycles	Number of embryos transferred	
Austria	Yes	+	+	+	-	+	-	*Yes*
Belgium	Yes	-	+	-	-	+	+	*No (*)*
Bulgaria	Yes	-	+	-	-	+	-	*Yes*
Cyprus	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Czech Republic	Yes	+	+	-	-	+	-	*Yes*
Denmark	Yes	-	+	-	-	+	+	*No (*)*
Estonia	Yes	-	+	-	-	-	-	*Yes*
Finland	Yes	+	+	-	-	+	-	*No (*)*
France	Yes	+	+	+	-	+	-	*Yes*
Germany	Yes	+	+	+	-	+	-	*Yes*
Greece	Yes	+	+	-	-	+	-	*Yes*
Hungary	Yes	+	-	-	-	-	-	*Yes*
Ireland	Only private MAR centres exist	-	+	-	+	-	-	*NA, Only private MAR centres exist and criteria on the left refer to criteria maintained by private centres*
Italy	Yes	+	-	-	-	-	-	*No (*)*
Latvia	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Lithuania	Only private MAR centres exist	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Luxembourg	Yes	-	+	-	-	-	-	*Only public centres exist*

Malta	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Netherlands	Yes	-	+	-	-	-	-	*Only public centres exist*
Poland	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Portugal	Yes	+	+	-	-	+	-	*No (*)*
Romania	No reimbursement in any case							
Slovakia	No	NA	NA	NA	NA	NA	NA	*There are no criteria at all*
Slovenia	Yes	+	+	-	-	+	+	*Only public centres exist*
Spain	Yes	-	+	-	-	+	-	*No (*)*
Sweden	Yes	+	+	+	-	+	+	*No (*)*
United Kingdom	Yes	+	+	-	+	+	+	*No (*)*

(+): means that a specific criteria is commonly checked for reimbursement to MAR-treatments

(-): means that a specific criteria is commonly not checked for reimbursement to MAR-treatments

NA: Not Applicable

(*): In private clinics criteria are in general less strict then in public centres. Details on criteria specifically maintained in private centres have not been asked for in the questionnaire approved by DG SANCO and are outside the scope of this study.

No detailed information was provided in the questionnaire answers. However minimum criteria for reimbursement are the criteria that apply to access to MAR treatments.

In general, criteria checked for are marital status (married or legally living together), maximum age of the woman, maximum age of the man, number of assessed cycles, number of transferred embryos and welfare of child conditions (HIV and criminal record of the parents to be). As can be seen from Table 6a, the major selection criterion for access to MAR treatment is woman's age, followed by the couples' marital status.

For the criterion 'woman's age' three legal situations occur throughout the European Union:

- countries with a defined maximum woman's age by law (10[37] of 27 EU Member States);
- countries with age restriction but without specified age. In those cases, the law defines the maximum age as "within the natural reproductive age of the woman" (7[38] of 27 EU Member States);

[37] BE, BG, DK, EE, FI, GR, LU, SI, IE, NL apply strict age limits for woman. Max. woman's age is 45 years for BE, BG (ICSI), DK (in public institutes), IE; 43 years for Slovenia, Luxembourg and 40 years for Finland (public institutes) and The Netherlands, Greece and Estonia have a woman's age limit of 50 years.

[38] Laws in CZ, FR, DE, PT, ES, SE, UK mention a woman's age restriction, but do not specify the maximum age.

- countries where MAR-treatment is not restricted by age on legal basis (10[39] of 27 EU Member States).

Note that even if countries do not have strict age limits, often age – restrictions do apply as they are required by National MAR- Societies and/or competent authorities (some examples are given in footnote)[40]. Moreover, woman's age is almost in every country a limiting factor for reimbursement of MAR- treatment (see Table 6b).

Reason for the age limitation obviously is the maintenance of acceptable success rates of MAR-treatment: the so called "take home baby rate" declines drastically with age.

Only in a minority of countries (France and Sweden) the age of man is regarded a limiting factor for access.

It can be seen from Table 6a that marital status is a criterion in 10 of 27 EU Member States (AT, CZ, FR, GR, IT, PT, SI, SE, FI, HU) whereas it is not in 17 of 27 EU Member States (BE, BG, DK, DE, EE, ES, IE, RO, UK, PL, CY, NL, LT, LV, LU, MT, SK). As previously discussed, although marital status might not form a limitation for access to MAR- treatment, it often is used to select for reimbursement (see Table 6b).

Furthermore the sexual orientation usually needs to be heterosexual. Single women and lesbian couples often cannot access MAR-treatment in countries having marital status as criterion. There is no access to MAR-treatments for lesbians and single women in Austria, Czech Republic, France, Italy, Portugal and Slovenia. Sweden allows access for lesbians, but not for single women since 2005 and for Finland the situation remains unclear. Although the questionnaires revealed for FI that nor singles nor lesbians are allowed to seek MAR treatment, we could find a publication[41] saying the exact opposite. This needs further investigation.

(There might be some discussion for CZ as the law states that a female has to be in "reproductive period of her life", meaning she has menstruation, or she is in the age below 50.)

[39] No laws for restriction by woman's age for AT, IT, LV, LT, RO, CY, PL, HU, SK, MT in place.

[40] For Spain, no maximum age of the women specified by law. By consensus, 50 years of woman's age with donor oocytes in private centers is used whereas public centers follow recommendations of ESHRE, SEF and ASRM (<40 years with own oocytes) . In the UK, no woman's age limit specified, but to obtain reimbursement the upper limit is defined as 50 years by the HFEA.
ASRM = American Society for Reproductive Medicine

SEF = Spanish Fertility Society

41

Finland passes new fertility legislation
Dr. Kirsty Horsey, *Progress Educational Trust,* 20 October 2006
[BioNews, London] The Finnish Parliament has voted in favour of new fertility legislation, after years of debate and delays. Until now, fertility treatment in Finland has been practised without a background of regulation, although many aspects have been self-regulated by treatment providers.
The key features of the proposed new legislation said that fertility treatment should only be performed by fertility clinics authorised by the Ministry of Health; treatments should be available for single women and lesbian couples, as well as to heterosexual couples; that there will be no age limit imposed on the treatment of women or men - decisions on whether treatment is medically indicated or not will be left to patients' doctors; gamete donors will be identifiable and their names kept on a register of donors, accessible by donor-conceived offspring when they reach the age of 18; and embryos currently in storage created using anonymous egg or sperm donations will either have to be used or destroyed within six months of the new law coming into force.

In Greece and the UK single women/lesbians do have access, whereas in Hungary MAR-treatment for lesbians is forbidden and single women are legally allowed to receive MAR-treatment if infertility is proven.

Reason for the existence of marital status as criterion for access/reimbursement of MAR might have a political and/or religious background.

3.2 Reasons for limitations posed by national legislations and reimbursement schemes

There are limitations on the access to and reimbursement of MAR treatments in general and on the number of treatments in particular. In many countries it is not clear which arguments have been used to decide on a restrictive policy, concerns around the cost, efficacy, and safety or ethical and religious objections. For some the sanctity of life is closely related to natural conception.

The picture is very heterogeneous throughout Europe. Some countries like Spain for example provide full coverage but patients are only reimbursed if treated in public centres. In other countries not all woman who are infertile are eligible for reimbursement. For example in Ireland reimbursement schemes are almost non- existent. In countries with restrictions demographic, social or economic circumstances are taken into account. Economic factors are assumed to play a major role. In most countries the reasons for restrictions on treatments are the cost-(in) effectiveness. However, in many cases the evidence that is necessary for evidence based decision does not exist.

Eligibility criteria on reimbursement include age, marital status, previous children, the use of donor gametes, the type of service provider (i.e., public or private clinic) and allowable treatment cycles or embryo transfers.

MAR treatments might be excluded from coverage on the grounds that treatment is not medically necessary. In a number of countries the clinical definition of infertility is strictly medical and excludes single and lesbian women ('socially infertile') from coverage, while in others it is not. However, an increasing number of these groups of women request MAR treatments. The Swedish government has supported this with a bill that does allow lesbian couples (but not single women) to have access to publicly funded assisted reproduction. According to the bill, the partner or cohabitant of the biological mother is regarded as a parent of the child on condition that she has consented to the treatment and it is 'likely' that the child was conceived via MAR treatment.

In the vast majority of countries age is an important criterion to restrict access and funding, which means that coverage is limited to younger women while older women, who are having a greater need and urgency to be treated are excluded. The reason for having an age limit has to do with the fact that a lot of evidence suggests that a declining effectiveness and increasing costs as well as safety issues are associated with MAR in women aged 40 and older.

Besides patient age there are medical limitations on the use of MAR treatments. Sometimes weight or BMI is evaluated and medical decisions are also based on hormonal findings. A restriction on the basis of the smoking status is under debate. In some countries the limitations on the use of testicular sperm and in many on the access to donor gametes are reflected in the reimbursement schemes.

Some of the reimbursement and regulatory frameworks are connected to safety concerns.

Sometimes feministic arguments have been used in this respect: women undergoing these treatments are unfairly manipulated to undergo treatment and are exposed to serious risks associated with hormonal stimulation for superovulation and oocyte retrieval (One example is: Ovarian Hyperstimulation syndrome. Symptoms are set into 3 categories: mild, moderate, and severe. Mild

symptoms include abdominal bloating and feeling of fullness, nausea, diarrhea, and slight weight gain. Moderate symptoms include excessive weight gain (weight gain of greater than 2 pounds per day), increased abdominal girth, vomiting, diarrhea, darker urine and less in amount, excessive thirst, and skin and/or hair feeling dry (in addition to mild symptoms). Severe symptoms are fullness/bloating above the waist, shortness of breath, urination significantly darker or has ceased, calf and chest pains, marked abdominal bloating or distention, and lower abdominal pains (in addition to mild and moderate symptoms). This illustrates the need of developing more patient friendly stimulation methods. The Belgian government has coupled reimbursement of the laboratory costs for IVF/ICSI to restrictions on the number of embryos used for transfer related to age of the woman.

In some countries the right to access to infertility treatment does not necessarily mean that there is also a right to public funding of that infertility treatment, since not paying does not constitute a violation of that right. In many countries with publicly funded ART services, a large proportion, if not the majority, of IVF cycles are provided by the private sector and population groups, including those currently often excluded from public provision, such as single, lesbian and older women from within the country or from abroad make use of it.

The access and reimbursement of PGD is not allowed according to the law in a number of countries, while others have a more liberal law. For instance the German Embryo protection law is very restrictive. In countries where there are no principle objections to PGD, there might be restrictions with respect to the indications used. This is for instance the case in France and the Netherlands and reflects ethical points of view in these countries.

Finally there are European countries that have concerns about the demographic changes that have taken place. These concerns have influenced the reimbursement schemes. A good example of this is Denmark.

4. Legislation for gamete/embryo donation

Figure 5a indicates that embryo donation is allowed in 15 of 27 EU Member States (UK, FI, LV, CZ, HU, RO, GR, NL, BE, FR, ES, PT, EE, SK, BG), forbidden in 7 of 27 EU Member States (IT, DK, SE, AT, DE, SI, LT) and not regulated in 5 of 27 EU Member States (IE, LU, PL, CY, MT). Financial compensation is foreseen in 12 of 20 countries allowing (= not forbidden means allowed + not regulated) embryo donation. In Romania, every kind of reimbursement and financial compensation for MAR- treatment is forbidden.

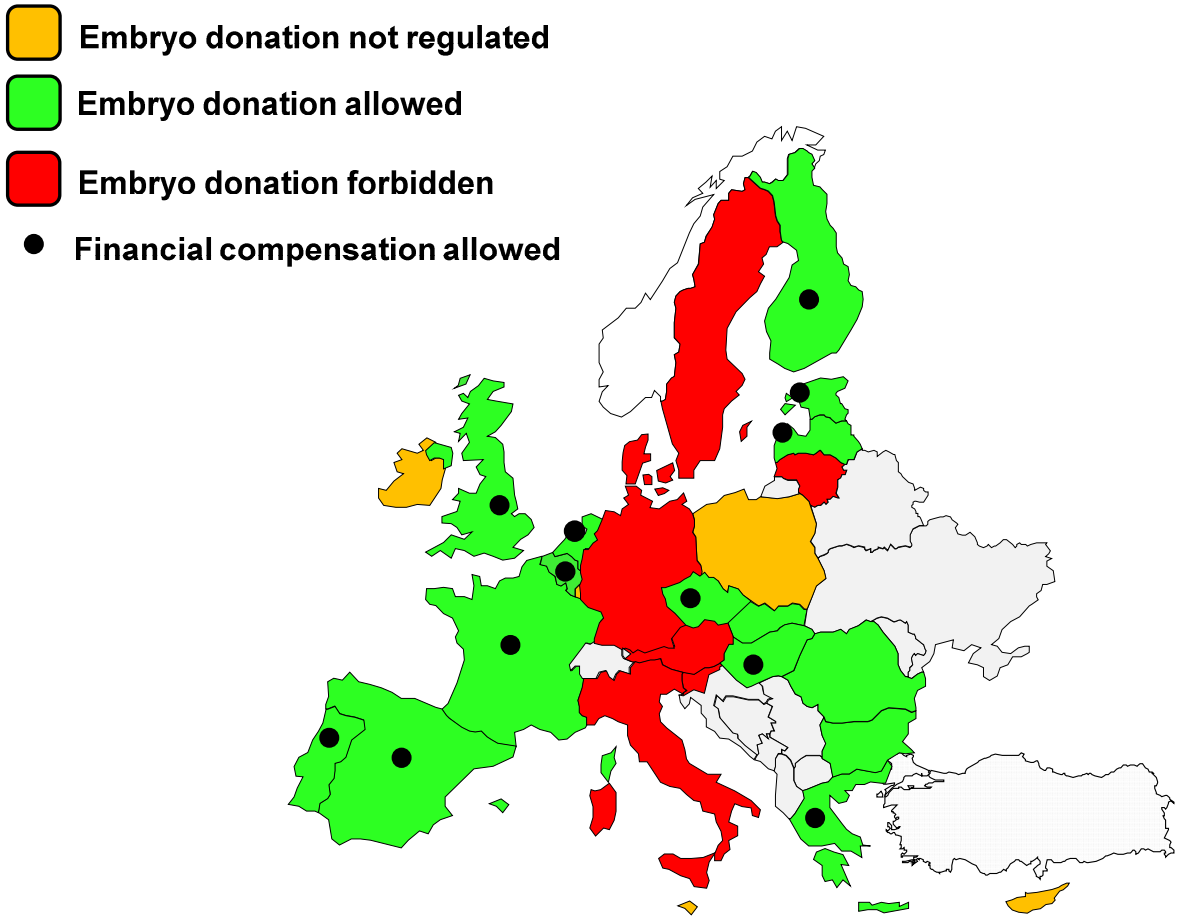


Figure 5a: Legislation regulating embryo donation in 27 EU Member States

Figure 5b indicates that anonymous sperm donation is forbidden in 8 of 27 EU Member States (FI, SE, UK, NL, DE, AT, IT, LT) allowed in 14 of 27 EU Member States (LV, DK, CZ, BE, FR, ES, PT, SI, HU, RO, BG, GR, EE, SK), not regulated in 5 EU Member States (IE, PL, MT, , LU, CY). Note that financial compensation is foreseen in 11 of 14 countries legally allowing anonymous sperm donation, with no financial compensation for SK, RO and BG.

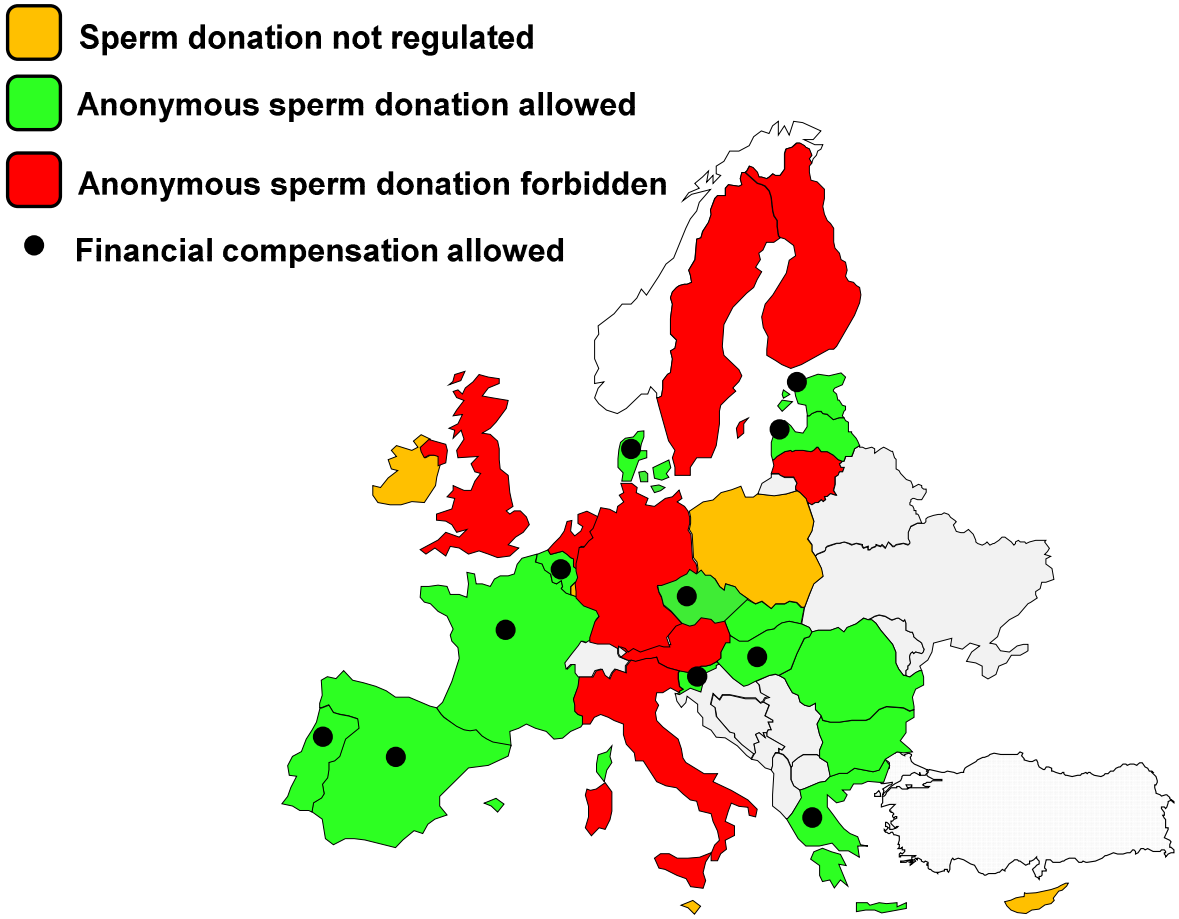


Figure 5b: Legislation regulating anonymous sperm donation in 27 EU Member States

Figure 5c indicates that non anonymous sperm donation is forbidden in 13 of 27 EU Member States (PT, ES, FR, IT, CZ, SI, SK, BG, GR, DK, EE, LT, HU) allowed in 9 of 27 EU Member States (FI, SE, UK, NL, BE, DE, AT, RO, LV), not regulated in 5 EU Member States (PL, CY, IE, MT, LU).

Note that financial compensation is foreseen in 6 of 9 countries legally allowing non anonymous sperm donation, with no financial compensation in DE, AT, RO.

Summarizing the legislative situation in the European Union for non anonymous and anonymous sperm donation one can conclude that:

- in 5 of 27 EU Member States (PL, IE, CY, MT, LU) sperm donation is not regulated;
- 11 of 27 EU Member States (BG, CZ, DK, FR, ES, PT, GR, HU, SI, EE, SK) forbid non anonymous but permit anonymous sperm donation;
- 6 of 27 EU Member States (AT, DE, NL, UK, FI, SE) forbid anonymous but permit non anonymous sperm donation;
- 3 of 27 EU Member States (BE, LV, RO) allow both types of sperm donation;
- 2 EU Member States (IT, LT) forbid both types of sperm donation.

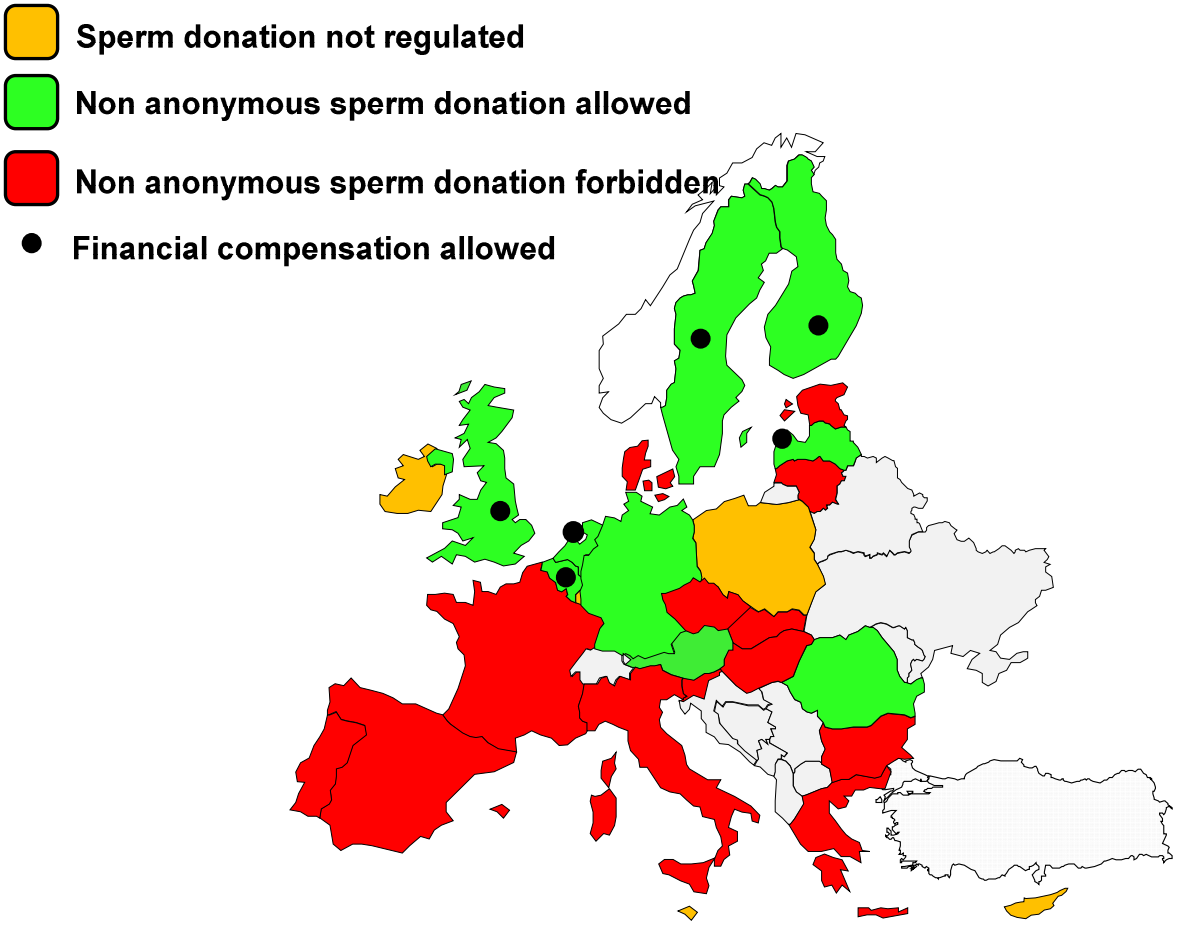


Figure 5c: Legislation regulating non anonymous sperm donation in 27 EU Member States

Figure 5d indicates that anonymous oocyte donation is forbidden in 7 of 27 EU Member States (UK, NL, SE, FI, IT, DE, AT), allowed in 13 of 27 EU Member States (BE, LV, HU, RO, BG, GR, PT, ES, FR, DK, CZ, SI, EE), not regulated in 7 EU Member States (PL, CY, IE, SK, MT, LU, LT). In table 5, Lithuania: oocyte donation not allowed

Financial compensation is foreseen in 10 countries (BE, LV, GR, PT, ES, FR, DK, CZ, SI, EE).

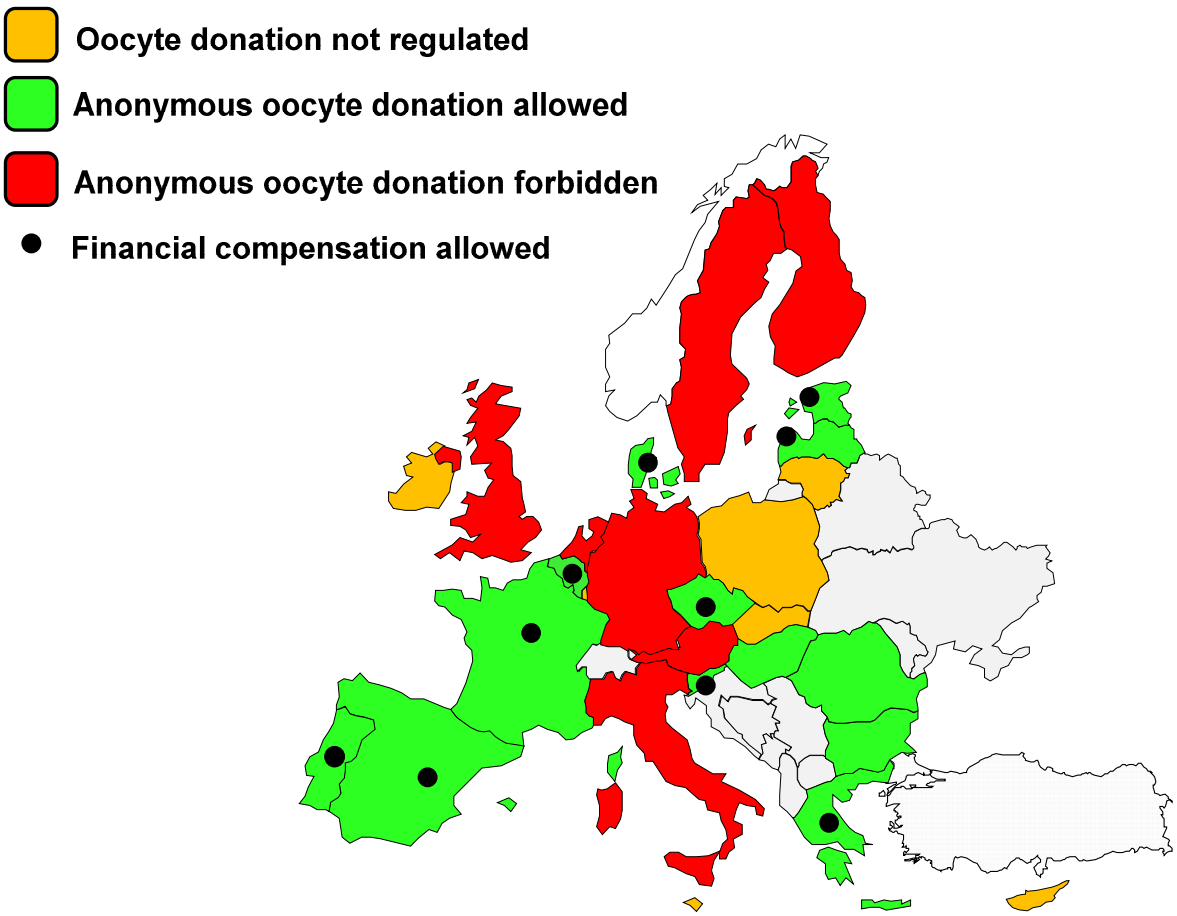


Figure 5d: Legislation regulating anonymous oocyte donation in 27 EU Member States

Figure 5e indicates that non anonymous oocyte donation is forbidden in 11 of 27 EU Member States (GR, PT, ES, FR, IT, DE, DK, CZ, AT, SI, EE), legally allowed in 9 of 27 EU Member States (UK, BE, NL, SE, FI, LV, HU, RO, BG), not regulated in 7 EU Member States (PL, CY, IE, SK, MT, LU, LT).

Financial compensation is foreseen in 7 countries (FI, SE, UK, NL, BE, HU, LV).

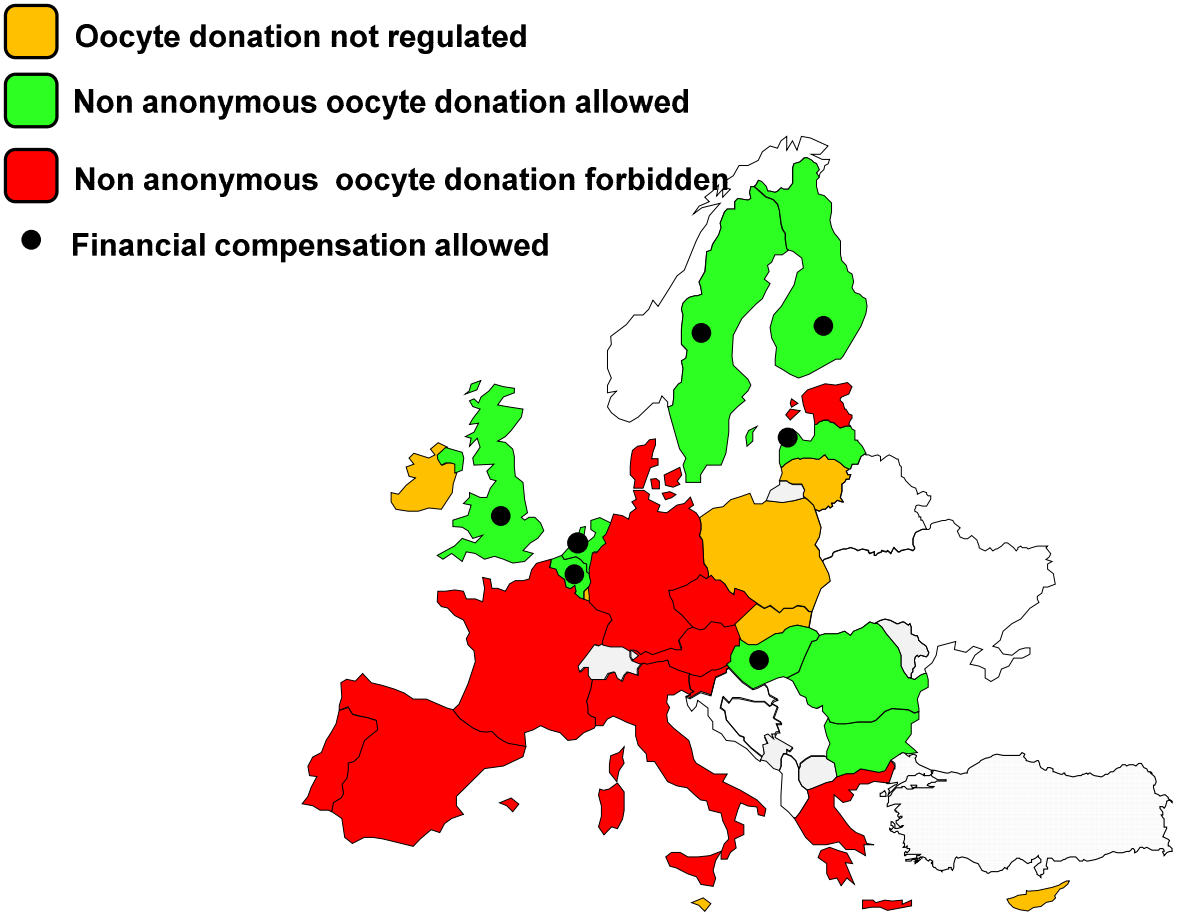


Figure 5e: Legislation regulating non anonymous oocyte donation in 27 EU Member States

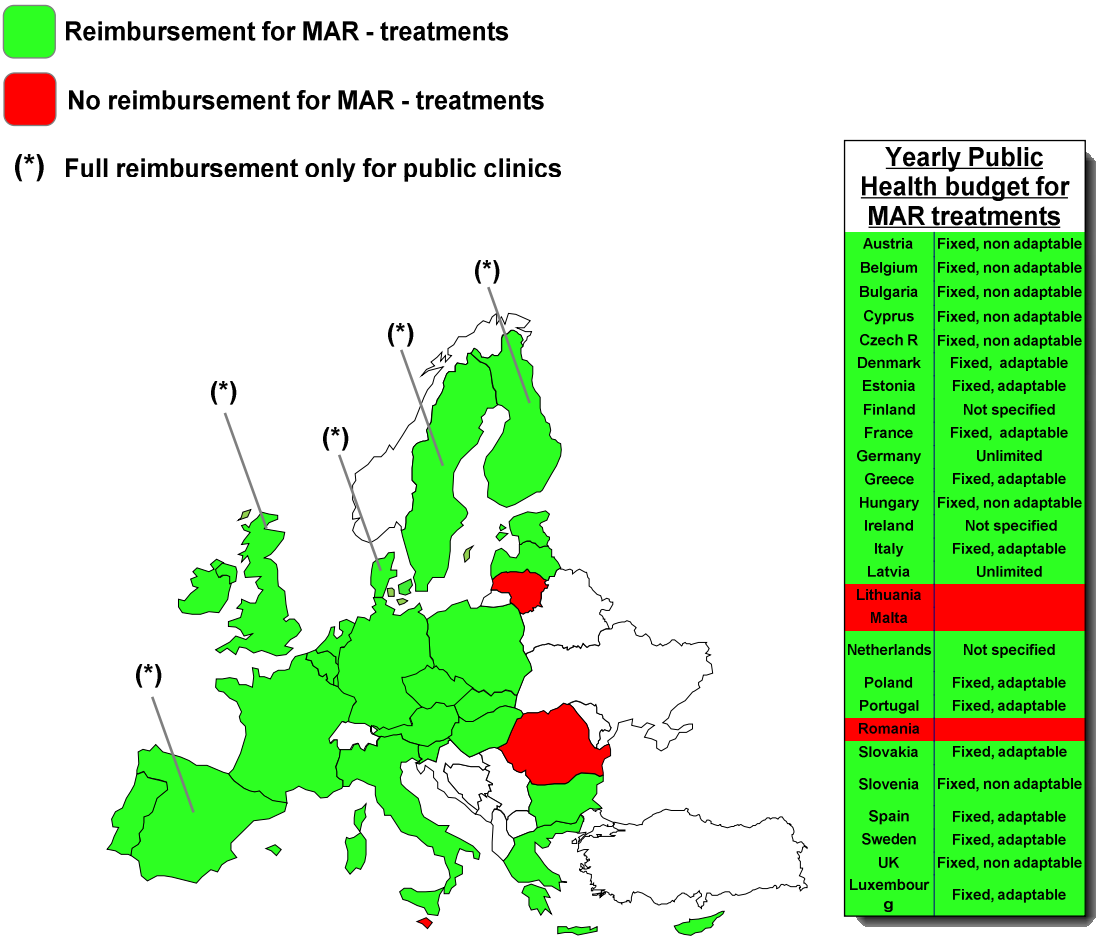
Summarizing the legislative situation in the European Union for non anonymous and anonymous oocyte donation, one can conclude that:

- in 7 of 27 EU Member States (PL, SK, IE, CY, LT, LU, MT) oocyte donation is not regulated;
- 4 of 27 EU Member States (UK, NL, SE, FI) permit non anonymous but forbid anonymous oocyte donation;
- 8 of 27 EU Member States (GR, PT, ES, FR, DK, CZ, SI, EE) permit anonymous but forbid non anonymous oocyte donation;
- 5 of 27 EU Member States (BE, LV, RO, HU, BG) allow both types of oocyte donation;
- 3 EU Member States (IT, DE, AT) forbid both types of oocyte donation.

In general, Belgium, Latvia and Romania appear to be the most tolerant countries with regards to embryo/gamete donation. Italy forbids any type of donation for MAR-treatment.
Analyzing above results, there appears to be a trend: countries that allow non anonymous oocyte donation but forbid anonymous oocyte donation, allow (if any type of oocyte donation is allowed) anonymous oocyte donation and forbid non anonymous oocyte donation and vice versa.

IV. Analysis of reimbursement[42] schemes for MAR treatments in 27 EU Member States

1. Reimbursement in EU Member States and available budget within the Public Health Budget



Yearly Public Health budget for MAR treatments	
Austria	Fixed, non adaptable
Belgium	Fixed, non adaptable
Bulgaria	Fixed, non adaptable
Cyprus	Fixed, non adaptable
Czech R	Fixed, non adaptable
Denmark	Fixed, adaptable
Estonia	Fixed, adaptable
Finland	Not specified
France	Fixed, adaptable
Germany	Unlimited
Greece	Fixed, adaptable
Hungary	Fixed, non adaptable
Ireland	Not specified
Italy	Fixed, adaptable
Latvia	Unlimited
Lithuania	
Malta	
Netherlands	Not specified
Poland	Fixed, adaptable
Portugal	Fixed, adaptable
Romania	
Slovakia	Fixed, adaptable
Slovenia	Fixed, non adaptable
Spain	Fixed, adaptable
Sweden	Fixed, adaptable
UK	Fixed, non adaptable
Luxembourg	Fixed, adaptable

Figure 6: General overview of public reimbursement for MAR-treatments in 27 EU Member States

In 24 of 27 EU MS public reimbursement is foreseen, 3 countries (RO, LT, MT) do not foresee public reimbursement. Ireland maintains a specific reimbursement scheme based on tax relief for the costs involved in IVF treatment, including the drugs used as part of fertility treatment.

In half of the countries the budget for MAR treatments is adaptable; in the other half it is not adaptable. Germany and Latvia claim that the budget is unlimited while for Finland and the Netherlands it was not specified. In Ireland the reimbursement is given by a TAX reduction. Remark that an unlimited budget is unusual and probably due to incorrect data provision by both countries.

[42] The study means 'public' reimbursement. Private insurance systems do not belong to the scope of this study as 'reimbursement' was not specified within the questionnaires. Participants considered reimbursement as 'public reimbursement' and no data are available on private insurance companies.

The table in Figure 6 indicates for 8 countries a yearly fixed, not adaptable budget. This means that social insurance decides upon the number of fully paid cycles per centre annually and that this number is then fixed. Costs for a cycle are fixed for each centre.

2. Financial mechanism in place for MAR- reimbursement in EU Member States

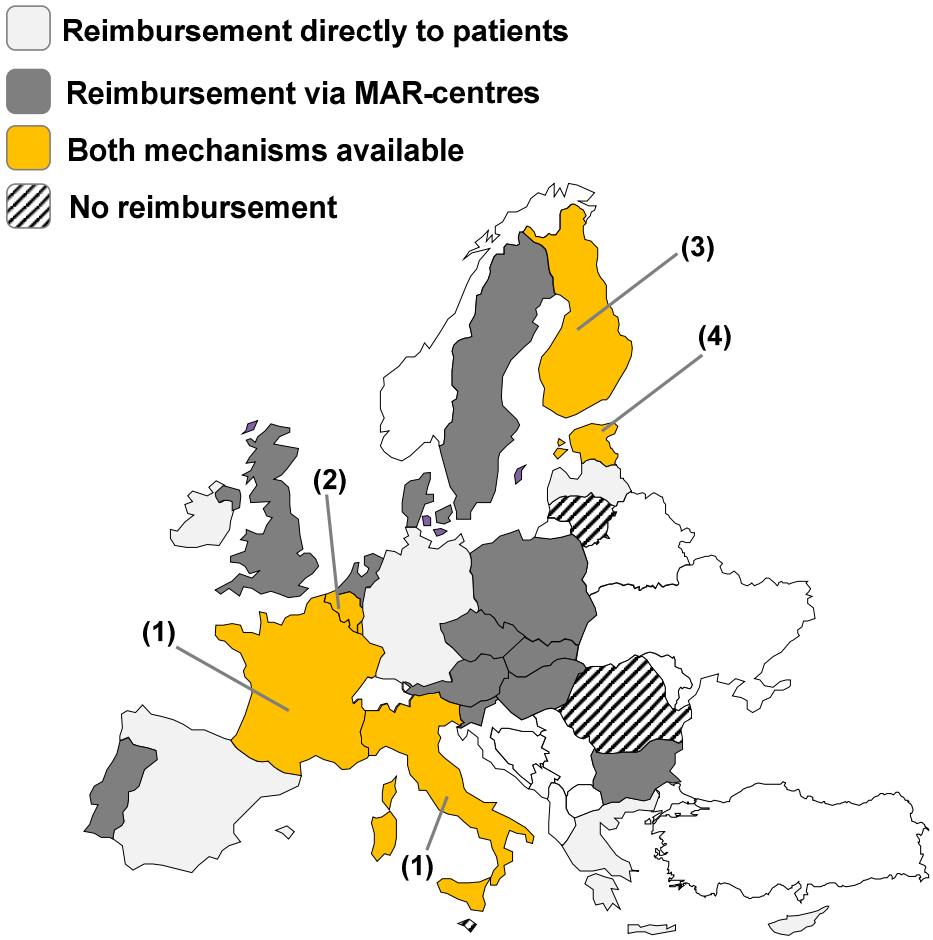


Figure 7: Different possibilities of reimbursement in 27 EU Member States

In 24 of 27 EU Member States reimbursement is foreseen for MAR-treatments (clinical as well as laboratory phases), under certain conditions as are explained in figure 7. Three countries (LT, RO, MT) forbid any reimbursement. Actual reimbursement is mainly executed in two different ways:

1. Payments are executed directly to the patients or
2. Payments are executed directly to MAR- centres which implement the amount of reimbursement in their price-setting towards patients.

Five countries, France & Italy (1), Belgium (2), Finland (3) and Estonia (4), maintain a combination of the above mentioned reimbursement schemes (payment directly to patients and/or MAR clinics).

- ***In France and* Italy (1)** both mechanisms appear: direct reimbursement to patients for the laboratory phase and to MAR centres for the clinical phase of a MAR-treatment.

- ***In Belgium (2)*** too both mechanisms (payment to patients and to MAR-centres) exist. For the clinical phase (blood, consultation) reimbursement is executed directly to patients, whereas for the rest of the clinical phase and for the laboratory phase MAR centres receive the payment.

- ***For Finland (3)*** payment directly to patients or MAR clinics is optional. Clinics can have a direct reimbursement agreement with KELA – Kansaneläkelaitos - Social Insurance Institution of Finland. In this case KELA reimburses the clinic. Alternatively, the patient submits himself a reimbursement application to KELA.

- ***In Estonia (4)*** payments concerning medications are executed directly to patients per cycle of treatment, whereas reimbursement for clinical and laboratory phases is directly to MAR centres per cycle of treatment.

It is also reported that requirements exist for entrance to reimbursement procedures. Most countries require a specific document from social insurance (or a valid National Insurance Card) and/or Public Health Department to be filled out in order to start the reimbursement procedure. 4 of 27 EU Member States (LV, SE, DK, PL) do not require specific documents to be filled out. For Ireland, reimbursement is in the form of tax relief and requires a Med 1 form to be completed and sent to the department of finance for reimbursement of taxes. Austria was the only country that reported other administrative requirements for reimbursement: a 'proof of civil status and medical diagnosis' and a legal confirmation for unmarried couples is needed to conform to the IVF-Fonds-Gesetz-Novelle 2004- Law.

3. Reimbursement of specific MAR-treatments in each EU Member State

3.1 Reimbursement situation for ICSI/IVF treatments

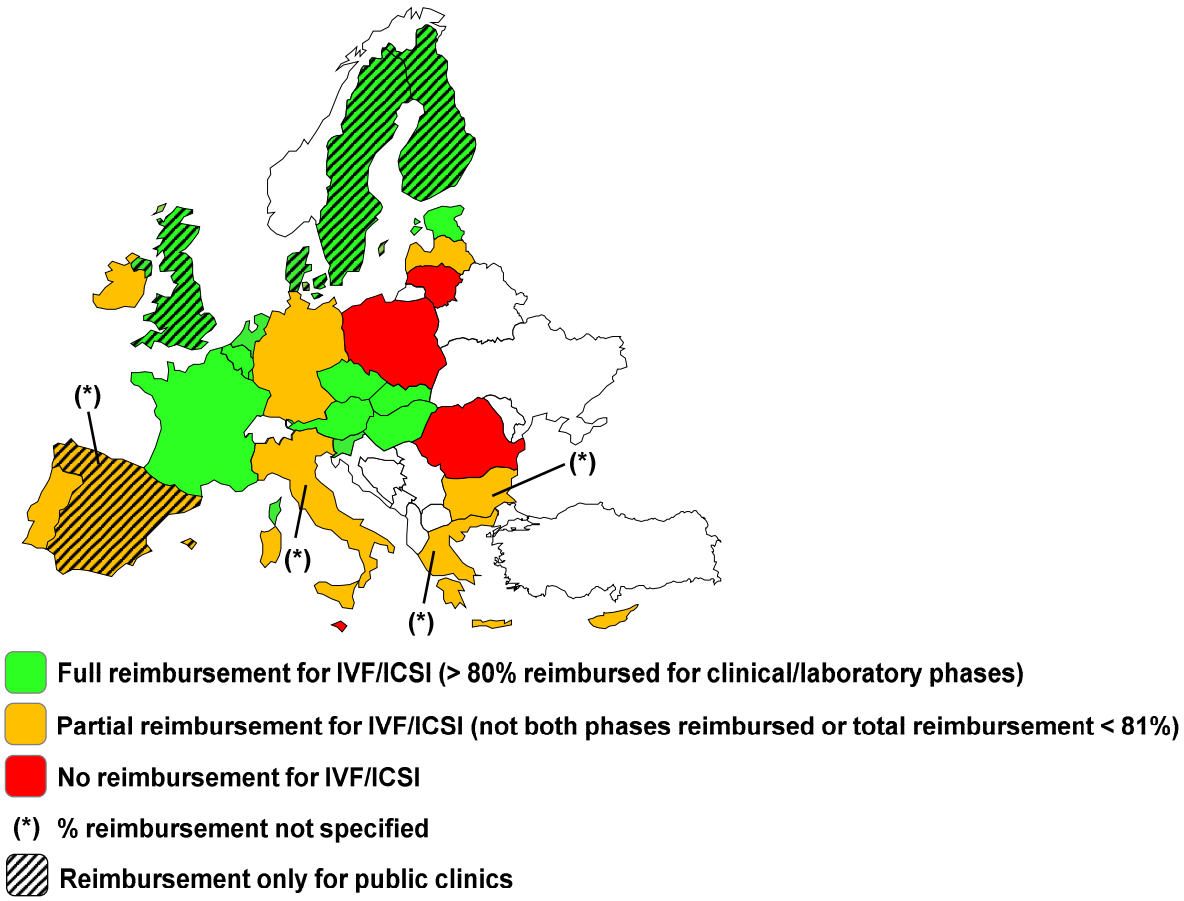


Figure 8: Reimbursement of ICSI/IVF treatments in EU Member States

Although ICSI and IVF are allowed techniques in all EU Member States, reimbursement may vary among different Member States as can be seen in Figure 8.

13 of 27 EU Member States (FI, SE, DK, EE, NL, BE, FR, UK, CZ, SK, HU, AT, SI) reimburse both clinical and laboratory phases of IVF/ICSI treatments for more than 80%. Details on exact reimbursement amounts can be found in Table 7. Hatched countries in figure 8 indicate that reimbursement is only applicable to treatments performed in public MAR – clinics (FI, ES, SE, UK, DK).

9 of 27 EU Member States (LV[43], DE, IE, PT, ES, IT, BG, GR, CY[44]) do foresee reimbursement but only partial (not both phases reimbursed or reimbursement less than 81%).

[43] Latvia only reimburses laboratory phase of IVF/ICSI treatments.

[44] Cyprus only reimburses laboratory phase and gonadotrophic drugs of IVF/ICSI treatments.

4 of 27 EU Member States (LT, PL[45], RO, MT) do not reimburse IVF/ICSI at all. Note that LV, RO and MT do not reimburse MAR - treatments at all (see Figure 8).

As earlier mentioned, **Ireland** only reimburses via tax relief. These tax reductions are related to costs for drugs used during treatment and not for the cost of the cycles.

[45] In Poland, only IUI is reimbursed.

3.2 Reimbursement situation for IUI treatments

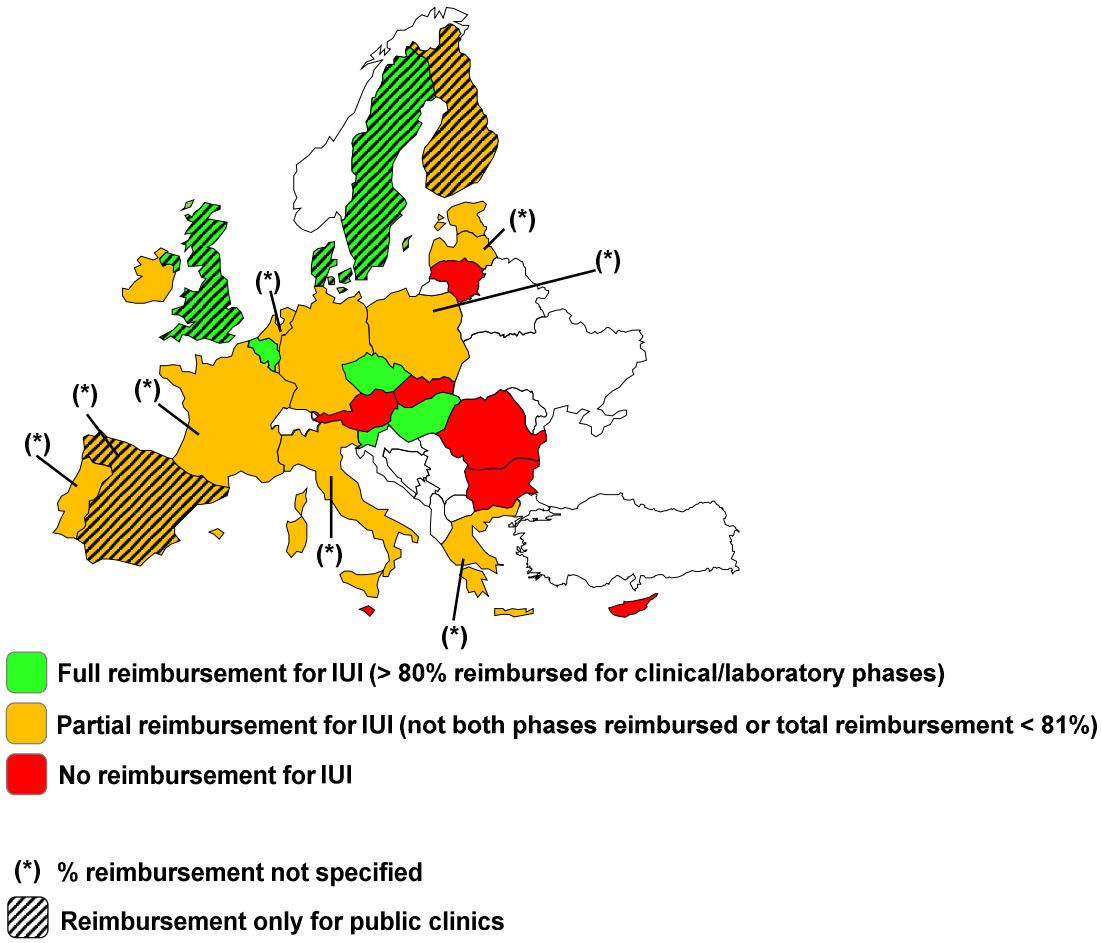


Figure 9: Reimbursement of IUI - treatments in EU Member States

IUI is allowed in all EU Member States However, reimbursement is different in each Member State.

Only 7 of 27 EU Member States (SE, DK, BE, UK, CZ, SI, HU, SI) reimburse both clinical and laboratory phases of IUI treatments for more than 80% (Figure 9 green). Details on exact reimbursement can be found in Table 7. Hatched countries in figure 9 indicate that reimbursement is only applicable to treatments performed in public MAR – clinics (FI, ES, SE, UK, DK).

At least 13 of 27 EU Member States (EE, LV, PL, DE, NL, IE, FR, ES, PT, IT, GR, LU, FI) reported to have some reimbursement system in place for some part of the IUI treatment. These countries are all orange colored in Figure 9, but one should keep in mind that specifications may differ in each Member State. Details on exact amounts of reimbursement in each Member State can be found in Table 7.

7 of 27 EU Member States (LT, SK, AT, RO, BG, CY, MT) do not reimburse IUI. Remind that RO, MT and LV do not reimburse any MAR – treatment and Ireland only reimburses via tax relief. These tax reductions are related to costs for drugs used during treatment and not for the cost of the cycles.

Table 7 : Reimbursement for ICSI/IVF and IUI- treatments in 27 EU Member States

Country	ICSI/IVF						IUI				
	Laboratory phase	Clinical Phase					Laboratory phase	Clinical Phase			
		agonist/antagonist drugs	gonadotrophic drugs	consultations	blood	echographies		gonadotrophic drugs	consultations	blood	echographies
Austria	70%	70%	70%	100%	100%	100%					
Belgium	100%	95%	95%	95%	95%	95%	100%	95%	95%	95%	95%
Bulgaria	(*)	(*)	(*)	(*)	(*)	(*)					
Cyprus	(*)		(*)								
Czech Republic	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Denmark (**)	100%	75%	75%	100%	100%	100%	(*)	75%	75%	100%	100%
Estonia	100%	90%	90%	100%	100%	100%		10%	100%	100%	100%
Finland (**)	75%	42-100%	42-100% (***)	60%	75%	75%	75%	42-100% (***)	60%	75%	75%
France	100%	100%	100%	100%	100%	100%	(*)	(*)	(*)	(*)	(*)
Germany	(*)	50%	50%	50%	50%	50%	(*)	50%	50%	50%	50%
Greece	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)
Hungary	100%	(*)	70%	100%	100%	100%	100%	30%	100%	100%	100%
Ireland	tax relief for drugs (21%)						tax relief for drugs (21%)				
Italy	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)
Latvia	(*)							(*)	(*)	(*)	(*)
Lithuania											
Malta											
Netherlands	100%	100%	100%	100%	100%	100%	(*)				
Poland							(*)	(*)	(*)	(*)	(*)
Portugal (****)	(*)	69%	69%	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)
Romania											
Slovakia	75%	75%	75%	100%	100%	100%					
Slovenia	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Spain (**)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)	(*)
Sweden (**)	100%	100%	100%	100%	100%	100%	(*)	100%	100%	100%	100%
United Kingdom (**)	100%	100%	100%	100%	100%	100%	(*)	100%	100%	100%	100%
Luxembourg	100%	100%	80%	100%	100%	100%		80%	100%	100%	100%

	Reimbursement available
	No reimbursement
(*)	% (amounts) not specified
(**)	Full reimbursement only foreseen for public MAR centres
(***)	If expenses in a calendar year exceed the treshold of EUR 672.70, the exceeding part is reimbursed in full, if annual less than there are three different categories (42% - 100%)
(****)	IVF/ICSI: Reimbursement applies to the public centres plus to a few couples (after a long waiting time in public institutions) that get the same kind of governmental support in private centres. IUI: No reimbursement outside public centres except for drugs; those are reimbursed in 69% of costs even if they are used in a private centre.

As can be seen in Table 7 some Member States reimburse IVF/ICSI/IUI treatments, others don't and in a few Member States certain parts of the treatments are excluded from reimbursement. In general it can be seen that IVF/ICSI is more often reimbursed than IUI.

With regards to IVF/ICSI:

- 20 of 27 Member States do reimburse IVF/ICSI, although not always for the full cost (no 100%);
- 4 of 27 Member States (LT, MT, PL, RO) do not reimburse IVF/ICSI at all;
- 3 of 27 Member States (CY, IE, LV) do reimburse IVF/ICSI although some parts of the treatment are excluded from reimbursement. More specifically, in these countries some parts of the clinical phases are excluded from reimbursement.

With regards to IUI:

- 16 of 27 Member States do reimburse IUI, although not always for the full cost (no 100%);
- 7 of 27 Member States (AT, BG, CY, LT, MT, RO, SK) do not reimburse IUI at all;
- 4 of 27 Member States (EE, IE, LV, LU) do reimburse IUI although some parts of the treatment are excluded from reimbursement. More specifically, in 3 countries (EE, LV, LU) the laboratory phase is excluded from reimbursement, whereas Ireland only reimburses via tax relief for drugs.

3.3 Reimbursement situation for PGD treatments

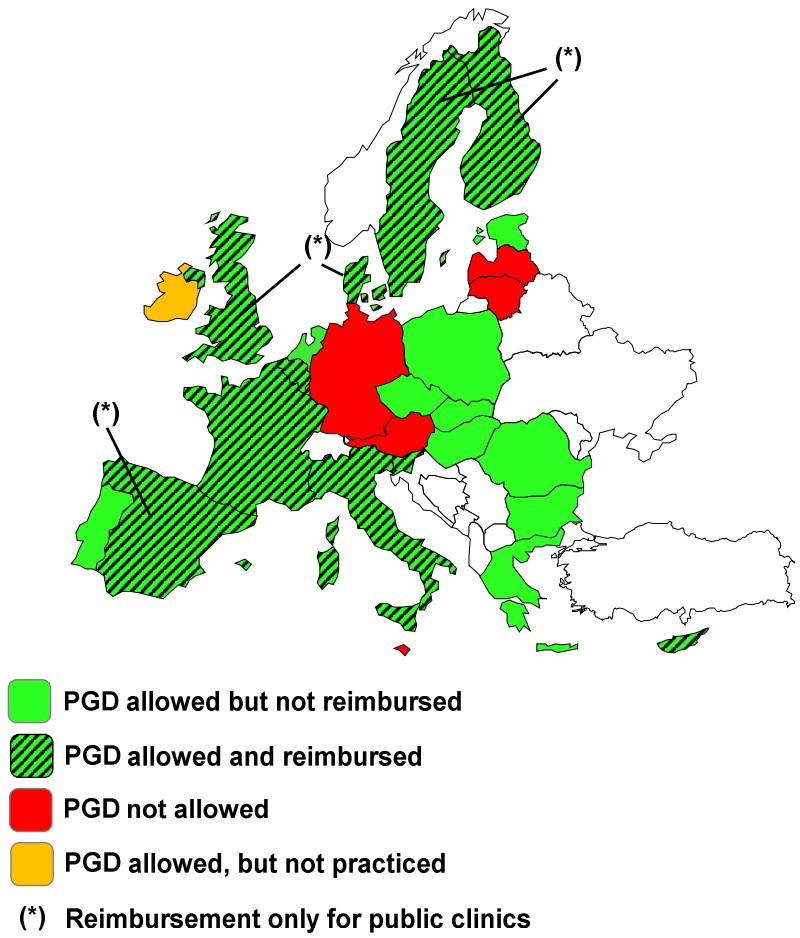


Figure 10: Additional Reimbursement for Pre-Genetic Diagnosis in EU Member States

Pre- implantation Genetic Diagnosis (PGD) is not allowed (red countries in Figure 10) in 4 of 27 EU Member States (LV, LT, DE, AT) and allowed in 23 EU Member States.
10 of 23 EU Member States (FI, SE, DK, UK, BE, FR, ES, IT, SI, CY) reimburse PGD, with reimbursement only for public clinics in ES, FI, ES, DK, UK.

Italy previously prohibited PGD, but recently allowed this MAR-treatment. The Law on PGD has changed as a consequence of the verdict 151/2009 of the Constitutional Court that stated that parts of the Law 40/2004 on assisted reproduction (including the one concerning PGD) are unconstitutional.

Ireland reported that PGD is not practiced, although it is not forbidden.

In Spain PGD is reimbursed when performed in public centres, however most PGD activity is executed in private clinics.

3.4 Reimbursement situation for IVM treatments

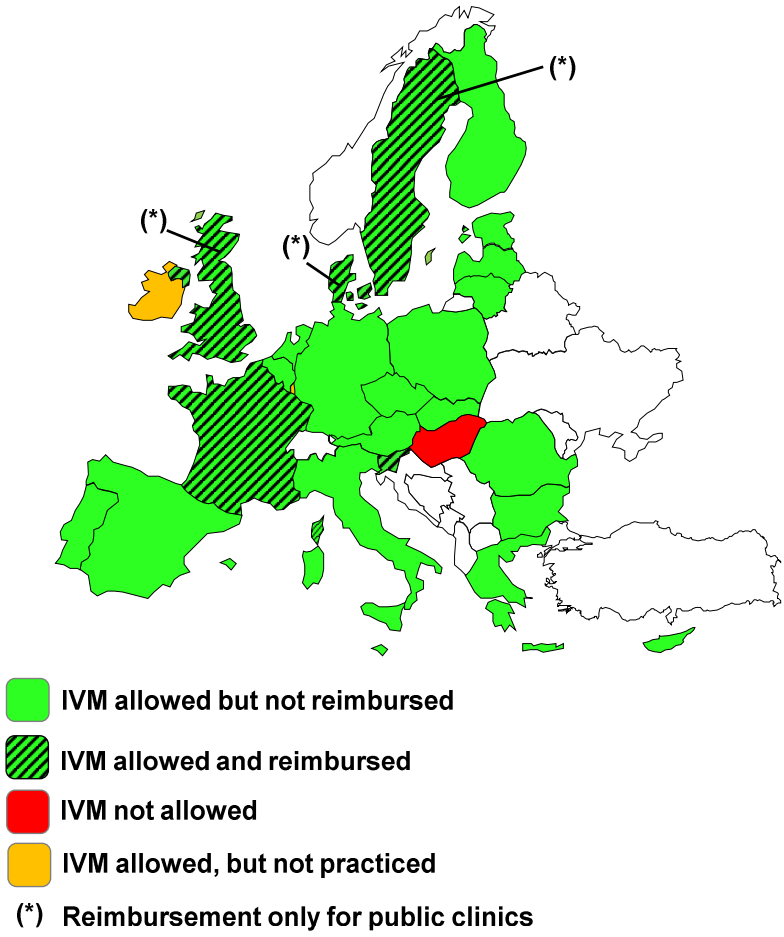


Figure 11: Additional reimbursement for IVM phase in EU Member States

In Vitro Maturation (IVM) is allowed in 26 of 27 EU Member States (green on map) and is forbidden in Hungary. Ireland has no IVM in practice, nor has Luxembourg although the technique is not be forbidden by law (orange in Figure 11).

In 5 Member States (UK, FR, DK, SI and SE) of 26 that allow IVM, additional reimbursement (green, hatched) for IVM is foreseen:

- In France, IVM is not yet recognized by the national health insurance. However, the ICSI attempt is fully reimbursed and there is no supplementary cost for the couple needing IVM treatment.
- In the UK, the ICSI attempt is fully reimbursed and there is also no supplementary cost for the couple needing IVM treatment.

19 Member States (BE, CZ, DE, FI, AT, IT, GR, BG, RO, LV, LT, CY, ES, NL, PT, EE, SK, PL, MT) do not foresee additional reimbursement for IVM.

Note that for Spain IVM could be reimbursed when performed in public centres, however IVM is not performed in public centres and is therefore never reimbursed.

V. Legislation for cross border MAR – care in 27 EU Member States

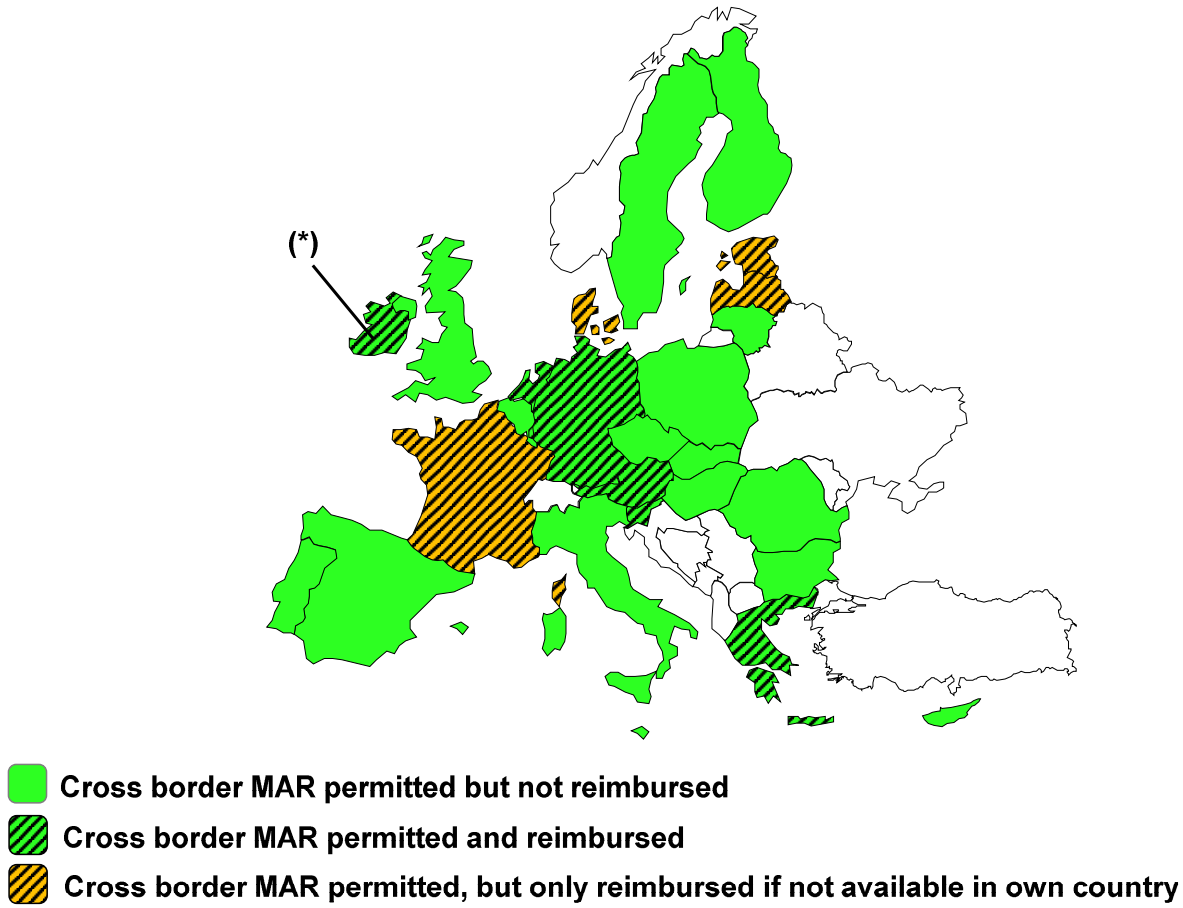


Figure 12: Legislation and reimbursement for cross border MAR treatments in 27 EU Member States

All EU Member States allow inhabitants to seek cross border MAR care. Reimbursement is allowed in some Member States without any limitation, other Member States only reimburse treatments that are not available in the country of origin.

Figure 12 shows that 16 Member States do not reimburse foreign MAR- treatments (UK, SE, FI, LT, PL, BE, CZ, SK, ES, PT, IT, MT, HU, BG, RO, CY). Remember that Malta, Romania and Latvia do not reimburse l MAR- treatments at al.

Although reimbursement for cross border MAR care is reported to be theoretically legally allowed for 11 countries (FR[46], IE[47], NL, LU, EE, AT, SI[48], GR, LV, DK, DE[49]), no data upon real payments following cross border MAR care could be obtained in the scope of this study.

[46] Reimbursement for oocyte donation is foreseen because of the long waiting list for oocyte donation in France.
[47] Ireland only reimburses via tax relief. These tax reductions are related to costs for drugs used during treatment and not for the cost of the cycles.

[48] Slovenia only reports reimbursement for cross border oocyte and sperm donation.

[49] Germany: IVF, ICSI and IUI will be reimbursed abroad (for example Austria) but only in a few federal states (for example Bavaria).

Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologies

(SANCO/2008/C6/051)

Report Work package 2 – Analysis of establishments, practices and cross-border aspects of MAR in EU Member States

VI. Introduction to Work Package 2

Work Package 2 of this study was set up to gather more information on the scale and scope of MAR institutes in the EU Member States. A survey of current practices, including information on establishments, registration and reporting procedures, procedures' outcomes, quality and safety standards and cross-border flow of patients was conducted among 812 MAR-clinics in 27 EU Member States on their activity in 2006. Based on information asked for in the questionnaire (see Annex 3), ESHRE used its European IVF Monitoring (EIM) Consortium (contact persons representing data collection programmes in participating countries are attached in Annex 4) as platform for data collection. Questionnaire 2 was used after formal approval concerning content by DG SANCO (Anna Pavlou, Isabel De La Mata).

The European IVF Monitoring Program (the EIM program) is already active since 1999 and was raised with the aim to collect, process and finally publish regional data for Europe on direct clinical results, but also on side-effects, follow-up of children's well-being and also on the availability and the structure of services in the different countries. The EIM nowadays covers 24 of 27 EU Member States, with Estonia, Luxembourg and Malta being the 3 countries not participating to the EIM data collection. Estonia, Luxembourg and Malta appear to have respectively 3, 1 and 2 MAR-centre(s) in place. For these countries data were collected through additional contacts ESHRE has within these countries (see Annex 4 for contact details).
The report excludes data for Romania[50] and Slovakia, as Romania nor Slovakia were reporting data to any Registry or Authority in 2006.

The present report summarizes data from MAR-treatments, including IVF, ICSI, FER, IVM, ED and PGD started between the 1st of January 2006 and the 31rd of December 2006 (reference period). Follow-up data on pregnancies and deliveries are based on those treatments carried out during the reference period.

Note that data in this study should be interpreted with caution as for some topics an incomplete European Union dataset is provided. The current report includes data from 812 of 971 (84%) of all MAR- centres in the 27 EU Member States. However, we believe that those clinics that do not report are likely to be smaller in size than those that do report. Also based on previous surveys of the EIM Consortium a positive trend related to reporting clinics can be seen, especially for Greece, Italy and Spain, where the number of reporting clinics increased considerably the past few years.

The current report will review the 2006 - situation on establishments performing MAR treatments in the European Union. Main characteristics of institutes, registries in place and outcomes of MAR-treatments will be quantified and presented in this report.

[50] Romania recently (2009) became member of the EIM. No data for 2006 available.

VII. Analysis of establishments performing MAR in the European Union

1. Characteristics of institutes for MAR treatments in EU Member States

1.1 Geographical distribution

In 2006 **971** clinics (see Table 8) were performing MAR-treatments in the European Union, from which **812** are reporting to the National Registries or to the EIM (on a voluntary basis). 13 of 27 countries (SE, EE, LV, LT, LU, IE, NL, CY, BG, SI, HU, SK, MT) appear to have maximum 15 MAR- clinics, 9 countries (AT, BE, CZ, DK, FI, GR, , PO, PT and UK) count between 16 and 100 MAR- clinics, whereas in 4 countries (D, FR, IT, ES) more than 100 MAR- clinics are executing MAR- treatments (see Figure 13 and Table 8). A detailed list of establishments reporting in 2006 is available in Annex 5. However, information for Romania and Slovakia is missing. Estonia and Luxembourg provided incomplete data. Therefore all four countries (RO, SK, LU, EE) were not taken into account in all further quantifications on treatments in this Work Package.

The list of reporting clinics in the European Union in 2006 comprised **812** clinics, public as well as private institutes[51], and can be found in Annex 5. The list provided in Annex 5 indicates the name and location of each MAR-centre reporting to a Registry.

[51] The existence of monitoring by government on the activity of private establishments was not covered by the questionnaires approved by SANCO. Conclusions concerning this topic would therefore need further investigation.

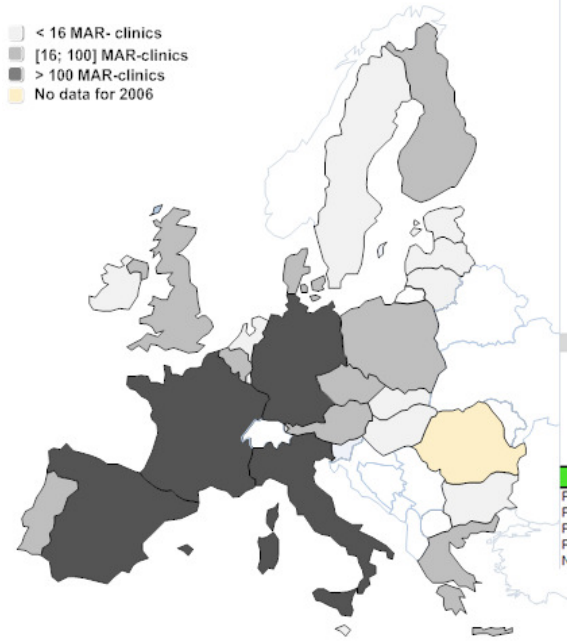


Table 8: MAR - clinics in the European Union in 2006

Country	MAR - clinics			Type of clinics
	Total N° of Clinics in the country	N° of Clinics reporting to Registry	total #cycles/year	
Austria	25	25	5.177	PU+PR
Belgium	18	18	22.864	PU
Bulgaria	15	8	1.387	PR (*)
Cyprus	7	7	1.436	not reported
Czech Republic	21	21	13.851	PU+PR
Denmark	22	22	12.622	not reported
Estonia	3	0	0	PU+PR
Finland	18	18	8.774	PU+PR
France	102	102	65.404	not reported
Germany	122	122	54.695	PU+PR
Greece	50	9	3.989	PU+PR
Hungary	10	5	3.280	PU+PR
Ireland	7	6	3.233	PR
Italy	202	202	37.771	PU+PR
Latvia	1	1	280	PR (**)
Lithuania	3	2	236	PR
Luxembourg	1	1	0	PU
Malta	2	0	0	PU+PR
Poland	32	17	6.260	PU+PR
Portugal	21	19	3.876	PU+PR
Romania	not reported			not reported
Slovakia	7	0	0	not reported
Slovenia	3	3	2.804	PU
Spain	182	107	50.335	PU+PR
Sweden	14	14	14.845	PU+PR
The Netherlands	13	13	17.770	PU
United Kingdom	70	70	44.097	not reported
TOTALS	971	812	374.986	

PU = Public institute
PR = Private institute
PR (*) = PU and PR institutes exist, but only PR are reporting.
PR(**) = Only PR institutes exist, athough PU are not forbidden.
Not reported means that we do not have data on the nature of the institutes.

Figure 13: Geographical distribution of institutes for MAR in 27 EU Member States in 2006

As can be seen in Table 8, only in 15 of 27 EU MS (AT, BE, CY, CZ, DK, FI, FR, DE, IT, LV, SI, SE, NL, UK, LU) the total of clinics in place is reporting to the Registry, whereas for the other 12 countries, not all clinics in place report to the Registry and data from non reporting institutes could not be included in the study.

1.2 Size of reporting clinics

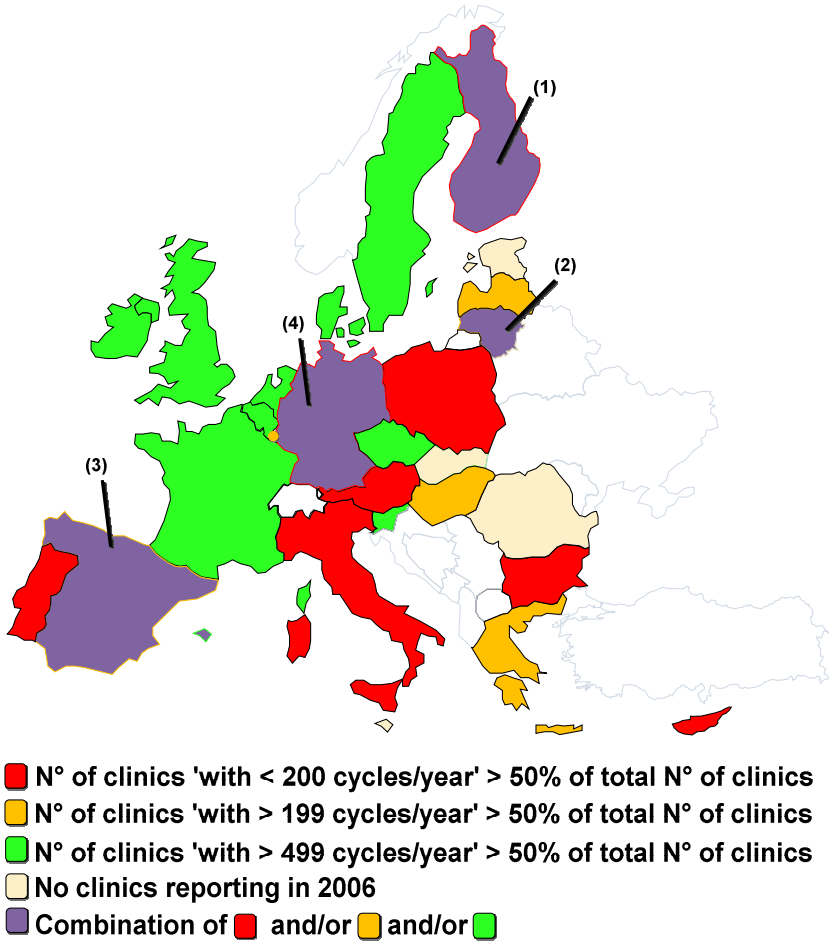


Figure 14: Size of reporting MAR- clinics in 27 EU Member States in 2006

Figure 14 displays the size distribution of reporting clinics in 2006. In 2006, Malta, Estonia, Romania and Slovakia did not have any reporting system in place, so these countries are indicated as 'no clinics reporting in 2006' in Figure 14.

For the other countries, the distribution of clinics according to the number of cycles performed varies considerably among the different countries.

6 countries (AT: 68%, BG: 75%, CY: 57%, IT: 69%, PL: 71%, PT: 58%) appear to have more small- (< 200 cycles/year) than large-sized clinics(> 199 cycles/year) (Figure 14 red), whereas 15 countries (BE: 100%, CZ: 95%, DK: 73%, FI: 78%, FR: 87%, DE: 66%, GR: 100% , HU: 80%, IE: 83%, LV: 100%, SI: 100%, ES: 60%, SE: 100%, NL: 100%, UK: 90%, LU: 100%, SK: 57%) contain more large - (>199 cycles per year) than small-sized clinics (Figure 14: green and orange).

- Clinic distribution in Finland (1) is as follows: 22% (<200 cycles) , 33% (>199 cycles) and 45% (>499 cycles);
- In Lithuania (2) only 2 MAR-clinics are in place with 1 clinic performing less than 200 cycles/year, the other clinic providing more than 199 cycles/year (see Figure 2: purple);
- Spain (3) counts 40% clinics < 200 cycles, 36% clinics > 199 cycles and 24% clinics > 499 cycles;

- Germany (4) counts 34% clinics < 200 cycles, 30% % clinics > 199 cycles and 37% clinics > 499 cycles.

Note that Italy has the highest number of clinics (202) and 69% of this total are clinics with less than 199 cycles per year (small). France, Germany and Spain also do have more than 100 clinics in place, but in these countries most of the clinics are medium-sized or large, with respectively 87%, 66% and 60% of the clinics performing annually more than 200 cycles.

1.3 Actual and future collaboration between establishments

The questionnaire approved by SANCO did not ask for data on collaboration between establishments. Therefore we do not have official prove from the different Member States themselves that centres are collaborating. Within ESHRE, however, based on for example the different data collection initiatives (European IVF monitoring Consortium, PGD Consortium, cross border reproductive care taskforce, …) we do see a close collaboration. This collaboration is not limited to centres within one country, but also cross-border collaboration is a frequent fact.

Centres with a specific and good knowledge of certain techniques often collaborate with centres where this technique is not available, due to technical or legislative reasons. We believe that this is a very positive setting. Sharing knowledge and skills can only improve the service to the patients.

1.4 Quality assessment systems: accreditation, quality control, quality assurance systems

Article 6 in the Directive 2004/23/EC foresees that all MAR- clinics in each EU Member State are accredited, designated, authorized or licensed by the Competent Authority. Accreditation procedures may involve quality control and quality assurance systems. Inspection and control measures should be executed by the Competent Authority in order to ensure compliance with the requirements in the Directive. In the frame of this study all EU Member States were asked whether they had a centre accreditation system in place and whether Quality Control and Quality Assurance systems were part of the accreditation evaluation in 2009.

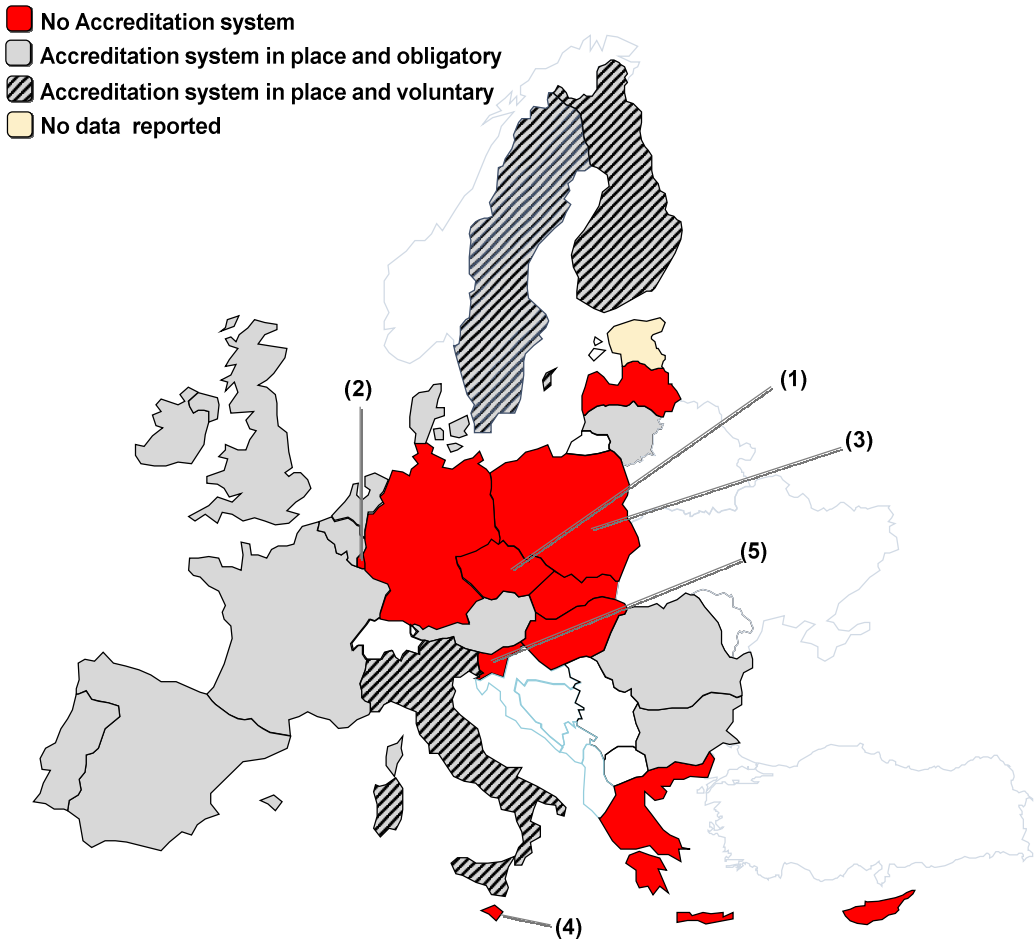


Figure 15: Accreditation of MAR - centres in 2009 in the European Union

As can be seen in figure 15[52], 11 countries (DE, CZ, PL, LV, HU, CY, SI, LU, SK, MT and GR) do not have accreditation systems in place.

- Although for ***Poland (3)*** no accreditation system is in place, the Polish Society of Reproductive Medicine (PTMR) is now working on a voluntary system for

[52] No detailed information available for Estonia.

accreditation. PTMR will obligate IVF- centres to run quality management systems until 2011.

- For ***Slovenia (5)***, under provisions of the national law and EU directives for quality and safety of tissues and cells, every tissue establishment (including MAR/IVF centres) should get a working permit issued by Competent Authority. In order to get working permit every tissue establishment (including MAR/IVF centres) is subject of verification processes (QC and QA systems).

- ***Malta (4)***: No accreditation, but there is a system whereby all private hospitals and clinics have to reach certain standards.

- ***Czech Republic (1)*** has partially established an accreditation system: new centres must fulfill criteria concerning the staff and equipment but there are no Quality Assurance and Quality control systems

- ***Luxembourg (2)*** is currently implementing its accreditation system.

15 countries have implemented an accreditation system being compulsory for all institutes in 12 of 15 countries (AT, BE, BG, DK, FR, ES, PT, IE, UK, BG, RO, LV) performing MAR-treatments and being voluntary in 3 of 15 countries (SE, FI, IT).

Below an update on the exact status of the inspection processes in each Member State is summarized including details of relevant legislation.

- ***In Austria,*** AGES 'The Austrian Agency for Health and Food Safety' investigates all running centers. The new centers also need to be approved by this agency. QC system is required from each center as well as the assignment of a QC responsible person (may have other functions too). The structure of this system and its ability to avoid and manage errors is inspected by the above authority.

- ***In Bulgaria,*** the Ministry of Health and Bulgarian Transplantation Agency give accreditation for work in MAR - institutes.

- ***In Denmark,*** Quality Systems are required by Article 16 of Directive 2004/23/EC and are evaluated and the Danish Medicines Agency has a public register of MAR centres.

- ***In France,*** accreditation of all hospitals by an independent authority (HAS) is legally required since 1996. Accreditation should be renewed every 4 years. MAR Centres do not have any supplementary obligation which would be specific to MAR activities. However, most of the MAR laboratories or Centres has developed an ISO certification on a voluntary basis. Also, it should be noted that a new accreditation procedure will apply to all laboratories, including MAR labs, either private or public by 2015. Obviously, QC and QA systems are part of the accreditation evaluation done by external visitors. Finally, evaluation of professional practices is also mandatory for all physicians, including those working in the MAR field.

- ***In Portugal***, every MAR centre needs to establish a quality system. Portuguese rules impose ISO 9001:2000 for this. However, the whole system of inspection of centres still is under construction.

- ***In Ireland***, the IMB (Legal authority responsible for the EU Directive) accredits the laboratory for all IVF centres. All authorized clinics are listed on the IMB- website and QC and QA systems are part of the inspection process. The legislation came into force as follows: European legislation 2004/23/EC and 2006/17/EC was transposed into

Irish National legislation as SI 158 of 2006 (in force since 7th April 2006 & 1st November 2006), while 2006/86/EC was transposed as SI 598 of 2007 (in force since 31st August 2007). QC and QA are compulsory part of the accreditation.

- ***In Lithuania,*** Accreditation is supervised by the Ministry of Health. They provide the certification of all public and private hospitals and laboratories. All Clinics (private and public) should have the Certificates and Licenses to work. MAR- clinics or laboratories also should have the licensing for the "Assisted reproduction" work.

- ***In the UK***, centre accreditation is executed by the HFEA, no one can practice without a license, and labs will be inspected prior to opening as well as soon afterwards opening. QA and QC are part of the accreditation process.

- ***In Romania***, MAR centres must have accreditation in order to be able to function and part of the accreditation is the necessity of the clinics to have in place a quality system (for example ISO 9000 family).

- ***In the Netherlands (7)***, there is an accreditation system in place for MAR laboratories. It is a cooperation of the Dutch society of clinical embryology and CCKL/Dutch Council of Accreditation (compatible with ISO 15189). Accreditation involves a license plus inspection by National Health Inspectorate (www.IGZ.nl). QC schemes are mandatory where available. Qa & Qc: National Accrediation organisation for IVF lab (www.CCKL.nl).

- Accreditation according to ISO9001 or other system is optional ***in Finland***. Some clinics have been accredited, most clinics not. Most clinics use the Tissue & Cell Directives as standards for their quality system. All clinics have initially been licensed by the Competent Authority. Next round of inspection is planned for spring 2010.

- ***For Sweden***, no central accreditation system in place. It is not compulsory for Swedish clinics to be certified/accreditated. However, all clinics are doing it. Most clinics are certified and two are accreditated.

- ***Concerning Italy,*** accreditation systems are in place, but are not compulsory.

- ***Spain:*** Accreditation system in place licensed by local competent authorities (Autonomous Governments)

2. Main characteristics of registries on MAR - establishments in 27 EU MS

Implementation of the Directive 2004/23/EC introduced reporting and registration obligations for MAR-establishments in the European Union (article 10). Recording activities, including procurement, testing, preservation, processing, storage and distribution have become compulsory and MAR-institutes shall submit an annual report to the Competent Authority summarizing their activities. The Competent Authority should establish and maintain a National Registry for MAR-clinics, specifying status on accreditation, authorization and licensing.

Figure 16 and Table 9 give an overview of the situation regarding reporting requirements of treatments for MAR-clinics in 2006. Note that already in 2006 in 15 of 27 EU Member States (AT, BE, CY, CZ, DK, FI, FR, DE, IT, LV, SI, SE, NL, UK, LU) all clinics seem to report to a National/Local Registry. For those countries with incomplete reporting, the number of reporting clinics is less than 50% of the total number of clinics in place for Greece, between 50% and 80% for Bulgaria, Hungary, Lithuania, Poland and Spain and more than 80%, but less than 100% for Ireland and Portugal. As mentioned earlier in this study, Romania and Slovakia did not have in place any data collection system in 2006 and are excluded in the scope of Work Package 2. Malta and Estonia are excluded as well.

In 5 of 27 EU MS (AT, BE, DE, UK, LU) data are reported to the Registry for individual cycles, whereas in 18 countries summaries of cycles are reported by clinics. (Are excluded: SK, RO, EE, MT)

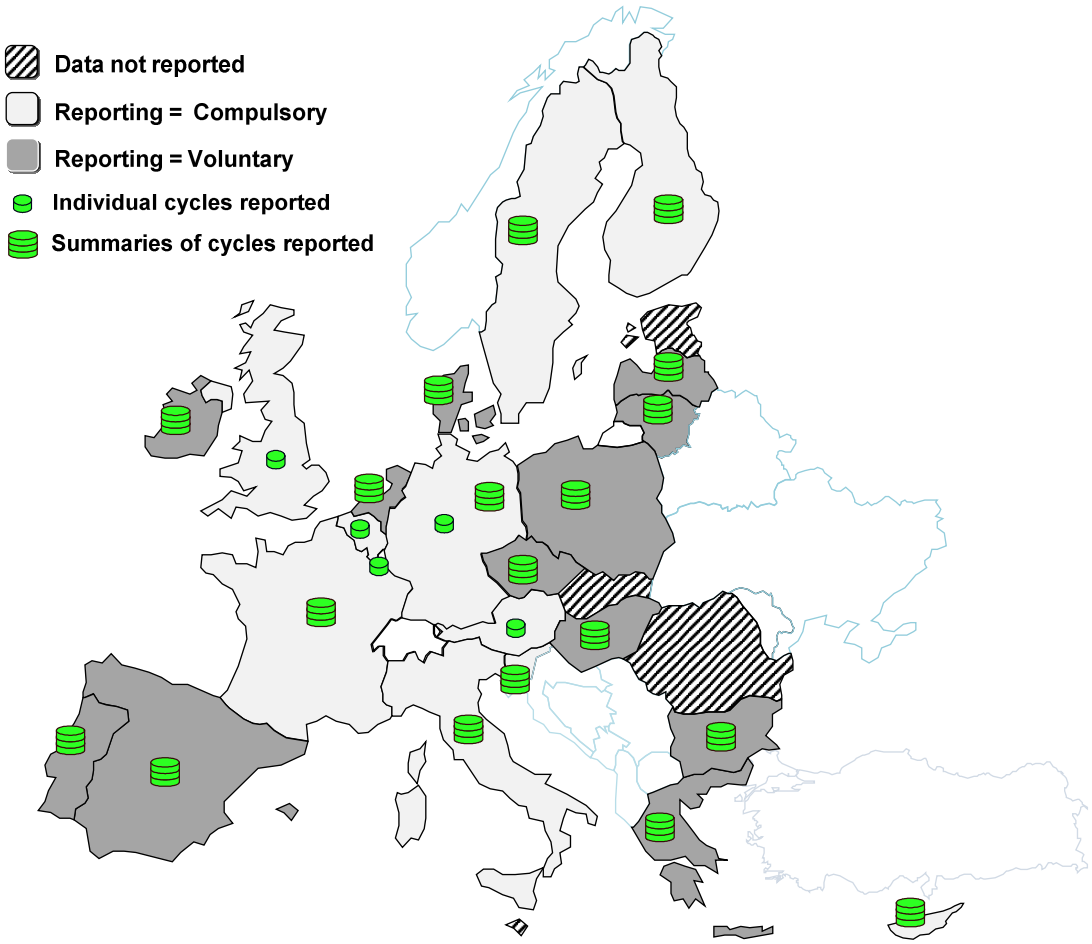


Figure 16: Reporting requirements of MAR-clinics in the European Union in 2006

Table 9: Reporting Requirements of MAR-clinics in the European Union in 2006

Country	Reporting requirements of MAR- clinics in the EU				
	Total N° of Clinics	N° of Clinics reporting to the Registry	Result Reporting Requirements	% Clinics Reporting	Reporting Methods (Cycles + Deliveries)
Austria	25	25	Compulsory	100	Individual cycles
Belgium	18	18	Compulsory	100	Individual cycles
Bulgaria	15	8	Voluntary	53	Summaries of cycles reported by the clinics
Cyprus	7	7	Compulsory	100	Summaries of cycles reported by the clinics
Czech Republic	21	21	Voluntary	100	Summaries of cycles reported by the clinics
Denmark	22	22	Voluntary	100	Summaries of cycles reported by the clinics
Estonia	3	0	not reported	not reported	not reported
Finland	18	18	Compulsory	100	Summaries of cycles reported by the clinics
France	102	102	Compulsory	100	Summaries of cycles reported by the clinics
Germany	122	122	Compulsory	100	Individual cycles
Greece	50	9	Voluntary	18	Summaries of cycles reported by the clinics
Hungary	10	5	Voluntary	50	Summaries of cycles reported by the clinics
Ireland	7	6	Voluntary	86	Summaries of cycles reported by the clinics
Italy	202	202	Compulsory	100	Summaries of cycles reported by the clinics
Latvia	1	1	Voluntary	100	Summaries of cycles reported by the clinics
Lithuania	3	2	Voluntary	67	Summaries of cycles reported by the clinics
Luxembourg	1	1	Voluntary	100	Individual cycles
Malta	2	0	Voluntary	0	not reported
Poland	32	17	Voluntary	53	Summaries of cycles reported by the clinics
Portugal	21	19	Voluntary	90	Summaries of cycles reported by the clinics
Romania	not reported	0	no requirements	no requirements	no requirements
Slovakia	7	0	no requirements	no requirements	no requirements
Slovenia	3	3	Compulsory	100	Summaries of cycles reported by the clinics
Spain	182	107	Voluntary	59	Summaries of cycles reported by the clinics
Sweden	14	14	Compulsory	100	Summaries of cycles reported by the clinics
The Netherlands	13	13	Voluntary	100	Summaries of cycles reported by the clinics
United Kingdom	70	70	Compulsory	100	Individual cycles

Comparing the data on reporting requirements in 2006 (Figure 16, Table 9) with data summarized in Work Package 1 Figure 3 (data from 2009) on requirements of clinics towards National and Local Registries following conclusions can be drawn:

- Nowadays (de dato 2009) in 21 of 27 EU Member States (AT[53], BE[54], BG[55], CY, CZ, DK, FI, FR[56], DE, HU, IE, IT, LV, LU, NL[57], MT, PT, RO, ES, SE, UK[58]) a National Registry has been established. In 6 of 27 EU Member States (EE, GR, LT, SI, SK, PL) the inexistence of a National Registry was reported.

  In 13 of 21 countries (AT, BE, BG, CY, CZ, DK, FI, FR, HU, IT, RO, NL,UK) having a National registry in place, reporting to the National Registry is under legal obligation, whereas it appears to be voluntary in 8 countries (DE, ES, IE, LV, LU, MT, PT, SE). Note that in 4 countries (BG, CY, FI, RO) more than one National Registry exists and a voluntary as well as a compulsory reporting system appears to be in place.

  Country-specific details are listed below or can be found in footnote.

  - For **Bulgaria**, the National Registry is compulsory and organised by BTA. There also exists a National Registry on voluntary basis, organised by S. Kurkchief, which is used for data collection in this report (EIM).
  - In **Cyprus**, a national registry on voluntary basis, organised by Ministry of Health just has started. It is under legal obligation to report to the Competent Authority.
  - For **Denmark**, a National Registry and a Local Registry exist, both being compulsory and ran by respectively the Competent Authority and by the Danish Fertility Society.
  - Note that for **Germany**, the National Registry is called 'Deutsches IVF Register' (www.deutsches-ivf-register.de) and is organised by the medical association "Artzekammer". Data (summary reports) need to be reported to the medical association of the individual federal state, but not necessarily to the computerized registry (individual cycle data).
  - For **Ireland,** the National Registry is organised by the Irish Fertility Society on voluntary basis.
  - Note that for **Romania** there exist both, a National Registry on voluntary basis organized by AER Embryology Association, and a National Registry under legal

[53] Competent Authority: The Austrian Agency for Health and Food Safety; National Registry: GÖG/ÖBIG, IVF-Register.
[54] Competent Authority: Agency for Medicines and Health Products; National Registry: BELRAP (Belgian Register for Assisted Procreation)
[55] Competent Authority : the Bulgarian Transplantation Agency
[56] Two systems exist for France: 1) Annual report: each ART centre provides an annual report of aggregated data to the Competent Authorities (Agence de la biomedecine and regional hospitalization agencies) on a mandatory basis. Collected data are exhaustive. The Competent Authority (Agence de la biomédecine) publishes a national report describing all the MAR activities performed in France each year (IUI, IVF, ICSI, FET, Cryopreservation of gametes, germinal tissues or embryos, gamete and embryo donation) (Law 2004-800 on Bioethics 6 August 2004, Decree 2005-420 4 May 2005 on Agence de la biomédecine, Decree 2006-1660 on ART and gamete donation 22 December 2006);
2) Registry of individual IVF attempts: the aggregated data can not lead to enough accurate studies. That is the reason why the Competent Authority has been organizing a supplementary collection of IVF, ICSI, FET and ED cycles, one record per attempt. The registry is currently in progress;
[57] The Competent Authority and the registry are organized by another body, "LIR foundation", supervised by the Dutch Society of Gynaecology and Obstetrics and by the Dutch Society of Clinical Embryology. It is limited to IVF and ICSI treatment and cryo cycles.
[58] Competent Authority is '***Human Fertilisation and Embryology Authority' (HFEA)***

obligation ran by the Competent Authority, since 2008. Before, reporting was not compulsory and no data were collected for 2006.

- In **Spain,** National registry is organized by the Spanish Fertility Society. Local registries for MAR treatments exist and there is a legal obligation by local Competent Authority in Catalonia to report. Remind from WP1 that in Spain, the EUTCD was transposed into national legislation (Royal Decree 1301/2006) with different levels of practical implementation in the different regions, since inspection and licensing are under Autonomous Governments competence (see paragraph WP1 §1.1).

- For **Sweden** Table 9 explains that reporting in 2006 was compulsory, whereas Figure 3 shows that there is no legal obligation to report to the National Registry nowadays. Previously (until 2006) Swedish clinics were obliged to report to the 'National Board of Health and Welfare' (until 2006). However, in 2007 Sweden established a new National Registry, handled by the IVF profession. Although reporting to the new National Registry is not obligated by law, it does become compulsory if clinics do not report properly. Not voluntarily to the National Registry reporting clinics are 'forced' by 'the Board of Health' to deliver relevant data to them instead. Therefore, in Sweden it is compulsory to deliver data, but not to this New Registry. In practice, all MAR- clinics have agreed to deliver their data to the registry.

- For **Finland**, a national registry on voluntary basis and a compulsory registry[59] exist.

- For **Greece** no National Registry is established. There exists a law (Law 3305/2005) which states that the establishment of a Local Registry is required. However, up till now, no such registry is in place.

- For **Slovenia**: no National Registry is in place. A local registry is organised on legal obligation by the Competent Authority. MAR Centres should organize their own registry and transfer personal clinical data for each cycle (related to quality control) online to the Medical chamber and provide a summary of the ART programme to Ministry of Health (each year).

- For **Lithuania,** no National Registry is organized, only Local Registries for MAR treatments exist on voluntary basis (local registering in clinics). In 2006 2 of in total 3 clinics were registering data (see Table 9).

- **Poland** has no local nor national registry, neither have **Estonia** and **Slovakia**.

59 Compulsory registry organized by Competent Authority i.e. licencing body is Lääkelaitos -National Agency for Medicines. The other registries are organised by 'THL - National institute for wealth and welfare '– annual MAR statistics and 'VALVIRA – National supervisory authority for welfare and health' – donor registry.

3. Main characteristics: outcomes of MAR-procedures in 27 EU MS

3.1 Number of procedures undertaken in institutes in 27 EU MS

Table 10 'MAR - treatments in the European Union in 2006' shows that from 27 EU Member States, 812 clinics reported **374.986** treatment cycles including: IVF (**97.834**), ICSI (**186.517**) frozen embryo replacement (**74.787**), oocyte donation (OD, **11.822**), pre- implantation genetic diagnosis/screening (**3.838**) and in vitro maturation (**188**). (LU, MT, EE, SK and RO were not taken into account as data for 2006 were not available).

Table 10: MAR - treatments in the European Union in 2006

Country	Initiated cycles						
	IVF	ICSI	FER	OD	IVM	PGD	TOTALS
Austria	1.218	3.733	226	NA	not reported	NA	5.177
Belgium	3.619 (*)	11.928	6.620	697	not reported	not reported	22.864
Bulgaria	642	634	93	18 (***)	0	0	1.387
Cyprus	402	780	143	84	not reported	27	1.436
Czech Republic	2.331	6.891	3.560	655	not reported	414	13.851
Denmark	5.500	4.436	2.515	35	52	84	12.622
Estonia	not reported	not reported	not reported	not reported	not reported	not reported	not reported
Finland	2.849	1.927	3.561	388	22	27	8.774
France	20.409(*)	30.367	14.064 (***)	228 (*)	69	267	65.404
Germany	11.082	28.687	14.926	NA	not reported	NA	54.695
Greece	1.222	2.287	310	170	not reported	0	3.989
Hungary	522	2.086	641	28	0	3	3.280
Ireland	1.588	1.004	636	5	0	not reported	3.233
Italy	8.680	28.186	905	NA	not reported	not reported	37.771
Latvia	105	63	87	25	0	NA	280
Lithuania	not reported	168 (**)	68 (***)	NA	NA	NA	236
Luxembourg	not reported	not reported	not reported	not reported	not reported	not reported	not reported
Malta	not reported	not reported	not reported	not reported	not reported	not reported	not reported
Poland	336	3.790	1.737	353	6	38	6.260
Portugal	1.161	2.225	380	42	3	65	3.876
Romania	not reported	not reported	not reported	not reported	not reported	not reported	not reported
Slovakia	not reported	not reported	not reported	not reported	not reported	not reported	not reported
Slovenia	687	1.512	590	5	0	10	2.804
Spain	4.178	28.360	8.203	7.080	36	2.478	50.335
Sweden	5.304	4.784	4.659	98 (*)	not reported	not reported	14.845
The Netherlands	8.365	6.485	2.920 (***)	0	not reported	not reported	17.770
United Kingdom	17.634	16.184	7.943	1.911	not reported	425	44.097
TOTALS	97.834	186.517	74.787	11.822	188	3.838	374.986

NA: Not allowed
(*) Number of oocyte recoveries was used as number of initiated cycles was not available.
(**) Number of embryo transfers was used as number of initiated cycles was not available.
(***) Number of embryo transfers was used as number of thawings was not available.

Zero's in Table 10 mean that no cycles are performed, whereas 'not reported' indicates that in 2006 these data were not collected or that the technique was not performed (which is the case for LT – IVF and for IE - PGD.

Last column 'Totals' in Table 10 shows the number of all treatment cycles recorded in each country. The cycles are subdivided into treatment modalities such as IVF, ICSI, FER, OD, IVM and PGD.

For Belgium, France, Lithuania, Sweden and the Netherlands the number of initiated cycles, thawings and donation cycles mentioned in Table 10 are underestimated as aspirations and embryo transfers

were used instead of initiated cycles, thawings and donation cycles because these data are the only one available in these 5 countries.

First of all, the trend towards an increase in the use of ICSI has been observed throughout the world, as was recently reviewed by Nyboe Andersen et al., 2008 (Nyboe Andersen A, Carlsen E, Loft A (2008). Trends in the use of intracytoplasmatic sperm injection – marked variability between countries. Hum Reprod Update 14, 593 – 604.)

Within Europe, there exists a marked regional variation in terms of ratio between IVF and ICSI. As can be seen from Table 10, certain countries such as BE, DE, PL, IT, PT, SI, ES use ICSI frequently, whereas the Nordic countries (SE, FI) as well as NL, UK, LV, BG and IE use IVF more frequently. The marked increase in the use of ICSI cannot be explained by a similar increase in male infertility in the countries but rather to a more frequent use of ICSI in cases with mixed causes of infertility, unexplained infertility and male factor infertility. This is however unlikely to explain the differences between countries, which can only be explained by professional experience, as was reviewed in Nyboe Andersen A, Carlsen E, Loft A (2008). Trends in the use of intracytoplasmatic sperm injection – marked variability between countries. Hum Reprod Update 14, 593 – 604.

Among 284.351 fresh cycles, the distribution between IVF (97.834) and ICSI (186.517) was respectively 34.4% and 65.6%. The amount of fresh cycles is 284.351 and 74.787 frozen cycles have been performed.

Table 11 shows data from those 15 of 27 EU Member States where all clinics have reported to the National Registry in 2006. Overall, 352.725 cycles were undertaken in 15 countries, in a population of 379 million, resulting in a mean of 1201 cycles per million. On average, 5.4 cycles were performed per thousand women of reproductive age (15-49 years).

Table 11: MAR in those countries where all clinics reported to the National Registry in 2006

Countries	Total N° cycles	Population (mio)	Females of reproductive age (thousands)	Cycles/mio	Cycles/thousand females of reproductive age
Austria	5.177,0	8,3	1.697,4	623,7	3,1
Belgium	22.864,0	10,5	2.422,5	2.177,5	9,4
Bulgaria					
Cyprus	1.436,0	1,0	273,7	1.436,0	5,2
Czech Republic	13.851,0	10,3	2.208,7	1.344,8	6,3
Denmark	12.622,0	5,4	1.245,3	2.337,4	10,1
Estonia			not reported		
Finland	8.774,0	5,3	1.164,7	1.655,5	7,5
France	65.404,0	61,2	14.822,5	1.068,7	4,4
Germany	54.695,0	82,4	19.241,0	663,8	2,8
Greece					
Hungary					
Ireland					
Italy	37.771,0	59,0	13.613,2	640,2	2,8
Latvia	280,0	2,3	431,9	121,7	0,6
Lithuania					
Luxembourg			not reported		
Malta			not reported		
Poland					
Portugal					
Romania			not reported		
Slovakia			not reported		
Slovenia	2.804,0	2,0	365,8	1.402,0	7,7
Spain	50.335,0	45,5	10.110,4	1.106,3	5,0
Sweden	14.845,0	9,1	1.786,3	1.631,3	8,3
The Netherlands	17.770,0	16,4	3.526,3	1.083,5	5,0
United Kingdom	44.097,0	60,5	14.463,5	728,9	3,0
TOTALS	**352.725,0**	**379,2**	**87.373,2**	**18.021,3**	**81,4**
MEAN				**1.201,4**	**5,4**

= not all clinics are reporting and data are incomplete

3.2 Pregnancies and deliveries after MAR- treatments in 27 EU Member States

Figures 17a-c, 18a-c and 19 (as well as Tables 12, 13 and 14) show the number of pregnancies and deliveries in relation to the number of initiated cycles (exceptional: number of aspirations and transfers) for IVF, ICSI and frozen embryo replacement (FER; IVF+ICSI) in 812 reporting clinics in the EU in 2006. Note that the data used for 'pregnancies' refer to the WHO/ICMART definition of clinical pregnancy: evidence of pregnancy by clinical or ultrasound parameters (ultrasound visualization of a gestational sac). ?). Zegers-Hochschild F, Adamson GD, de Mouzon J, Ishihara O, Mansour R, Nygren K, Sullivan E, van der Poel S; International Committee for Monitoring Assisted Reproductive Technology; World Health Organization. The International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) Revised Glossary on ART Terminology, 2009. Hum Reprod. 2009;24:2683-7. The definition includes ectopic pregnancy. Multiple gestational sacs in one patient are counted as one clinical pregnancy. Deliveries include those resulting in a live birth and/or stillbirth.

Success rate is calculated as number of pregnancies resulting from MAR-treatment divided by total number of initiated cycles.

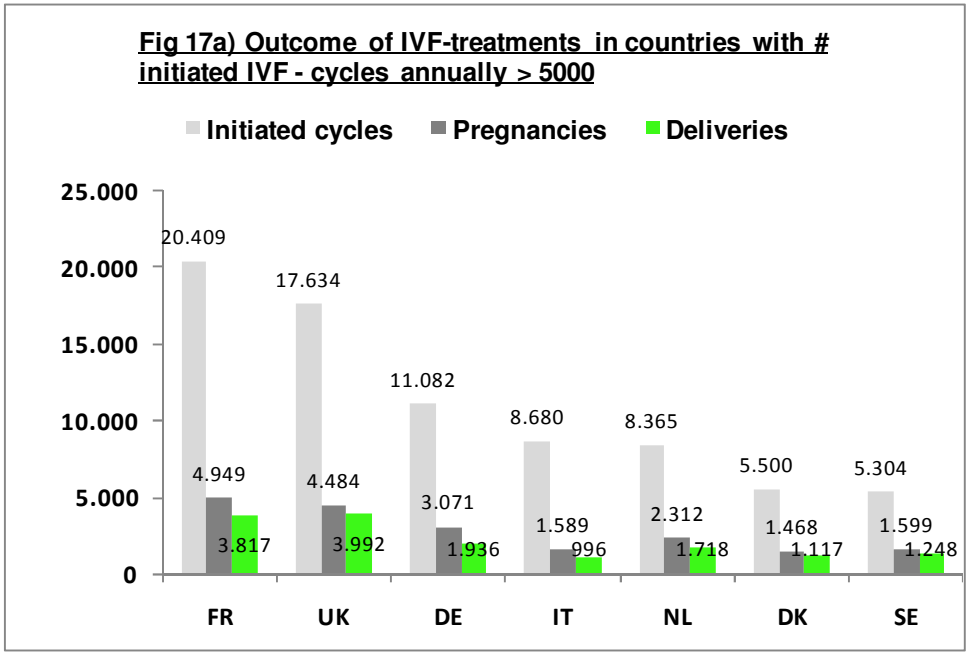
IVF-treatments in 27 EU Member States in 2006

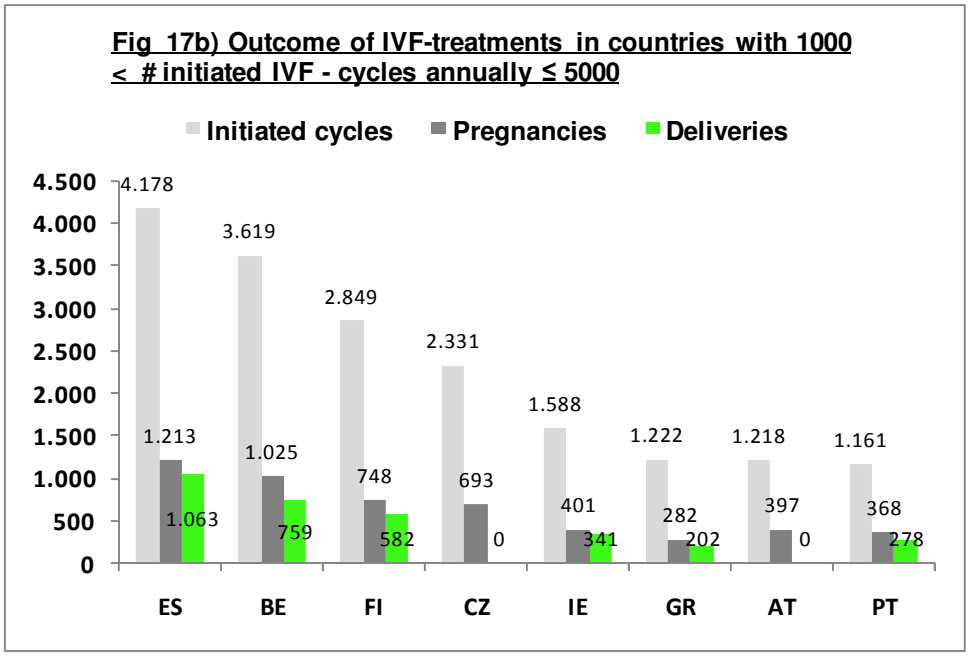
Table 12: Pregnancies and deliveries after IVF in 2006 in EU Member States

Country	Initiated cycles	Pregnancies	Deliveries
# initiated cycles > 5000 (Figure 7a)			
France	20.409	4.949	3.817
United Kingdom	17.634	4.484	3.992
Germany	11.082	3.071	1.936
Italy	8.680	1.589	996
The Netherlands	8.365	2.312	1.718
Denmark	5.500	1.468	1.117
Sweden	5.304	1.599	1.248
1000 < # initiated cycles ≤ 5000 (Figure 7b)			
Spain	4.178	1.213	1.063
Belgium	3.619	1.025	759
Finland	2.849	748	582
Czech Republic	2.331	693	not reported
Ireland	1.588	401	341
Greece	1.222	282	202
Austria	1.218	397	not reported
Portugal	1.161	368	278
# initiated cycles ≤ 1000 (Figure 7c)			
Slovenia	687	201	168
Bulgaria	642	174	128
Hungary	522	102	83
Cyprus	402	113	not reported
Poland	336	107	94
Latvia	105	72	not reported
Lithuania	not reported	53	10
Luxembourg	not reported	not reported	not reported
Romania	not reported	not reported	not reported
Slowakia	not reported	not reported	not reported
Estonia	not reported	not reported	not reported
Malta	not reported	not reported	not reported
ALL	**97.834**	**25.368**	**18.532**

Table 12 shows that after IVF in 22 EU MS **25.421** pregnancies (25.368 without LT) resulted from **97.834** initiated cycles. The mean clinical pregnancy rate was **26% per cycle** of IVF-treatment in 21 EU MS.

Lithuania was not taken into account as there are no data on the number of cycles initiated. Romania and Slovakia do not report data. Data on deliveries are incomplete as AT, CY, CZ and LV do not report deliveries to the registry.





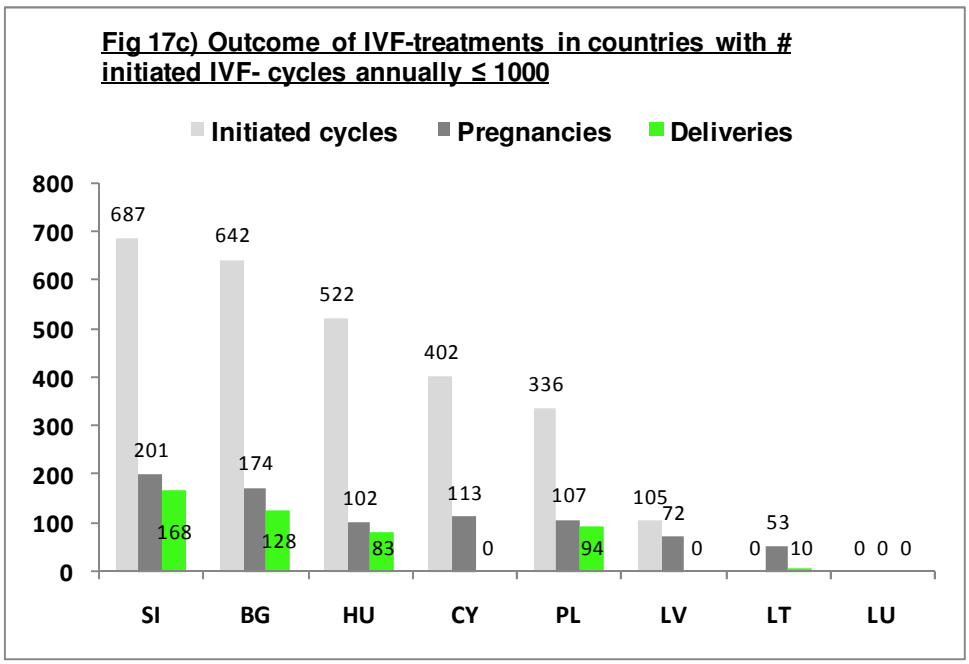


Figure 17: Pregnancies and deliveries after IVF in 2006 in EU Member States

ICSI - treatments in 27 EU Member States in 2006

Table 13: Pregnancies and deliveries after ICSI in 2006 in EU Member States

Country	Initiated cycles	Pregnancies	Deliveries
# initiated cycles > 10.000 (Figure 8a)			
France	30.367	7.847	6.165
Germany	28.687	7.772	5.104
Spain	28.360	8.836	4.574
Italy	28.186	5.361	3.133
United Kingdom	16.184	4.856	4.284
Belgium	11.928	3.245	2.194
1000 < # initiated cycles ≤ 10.000 (Figure 8b)			
Czech Republic	6.891	2.496	not reported
The Netherlands	6.485	2.000	1.570
Sweden	4.784	1.382	1.093
Denmark	4.436	1.127	876
Poland	3.790	1.306	1.065
Austria	3.733	1.171	not reported
Greece	2.287	605	340
Portugal	2.225	580	464
Hungary	2.086	649	543
Finland	1.927	505	407
Slovenia	1.512	394	325
Ireland	1.004	256	214
# initiated cycles ≤ 1000 (Figure 8c)			
Cyprus	780	282	not reported
Bulgaria	634	186	152
Lithuania	168	58	14
Latvia	63	26	not reported
Luxembourg	not reported	not reported	not reported
Romania	not reported	not reported	not reported
Slowakia	not reported	not reported	not reported
Estonia	not reported	not reported	not reported
Malta	not reported	not reported	not reported
ALL	**186.517**	**50.940**	**32.517**

Table 13 shows that after ICSI in 22 EU MS **50.940** pregnancies resulted from **186.517** initiated cycles. The mean clinical pregnancy rate was **27.3 % per cycle** of ICSI-treatment in 22 EU MS.

Romania and Slovakia do not report data. Data on deliveries are incomplete as AT, CY, CZ and LV do not report deliveries to the registry.

Fig. 18a) Outcome of ICSI treatments in countries with # initiated ICSI cycles annually > 10.000

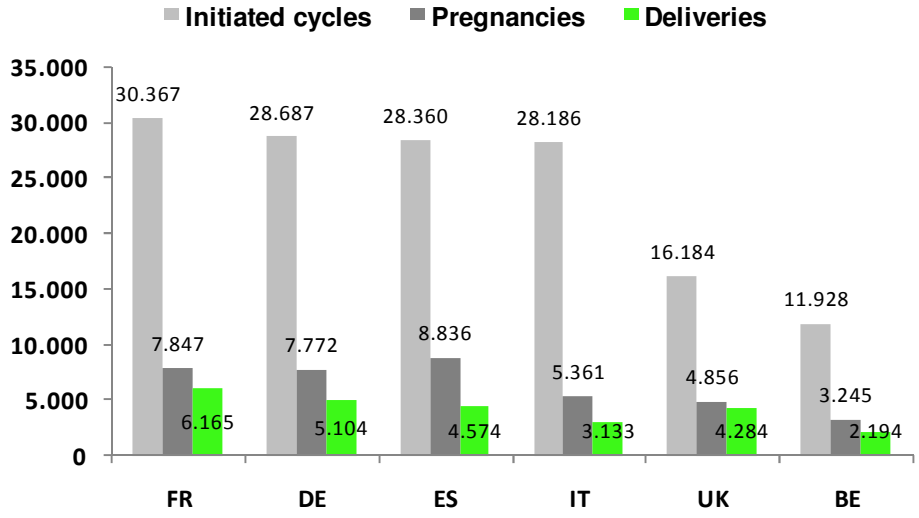
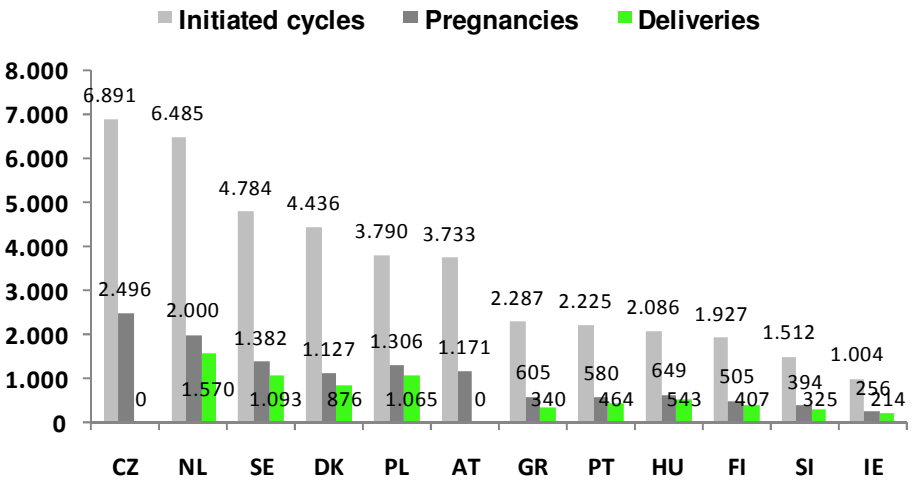


Fig 18b) Outcome of ICSI treatments in countries with 1000 < # initiated ICSI cycles annually ≤ 10.000



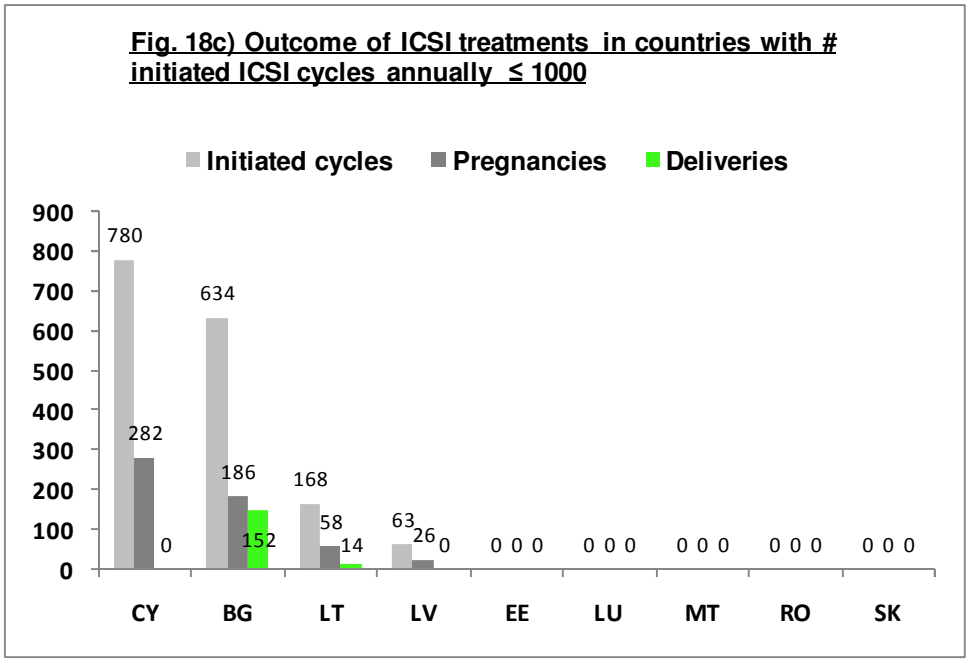


Figure 18: Pregnancies and deliveries after ICSI in 2006 in EU Member States

FER - treatments in 27 EU Member States in 2006

Table 14: Pregnancies and deliveries after FER in 2006 in EU Member States

Country	Thawings	Pregnancies	Deliveries	Children born
Austria	226	71	Not reported	Not reported
Belgium	6.620	899	575	635
Bulgaria	93	21	7	7
Cyprus	143	31	Not reported	Not reported
Czech Republic	3.560	829	Not reported	Not reported
Denmark	2.515	391	257	288
Estonia	not reported	not reported	not reported	not reported
Finland	3.561	709	541	591
France	14.064 (***)	2.458	1.829	1.911
Germany	14.926	2.696	1.616	1.872
Greece	310	67	52	53
Hungary	641	114	61	75
Ireland	636	112	81	96
Italy	905	145	84	97
Latvia	87	9	Not reported	Not reported
Lithuania	68 (***)	8	2	2
Luxembourg	not reported	not reported	not reported	not reported
Malta	not reported	not reported	not reported	not reported
Poland	1.737	291	236	281
Portugal	380	73	54	61
Romania	not reported	not reported	not reported	not reported
Slovakia	not reported	not reported	not reported	not reported
Slovenia	590	111	75	84
Spain	8.203	1.776	991	1.184
Sweden	4.659	1.109	793	908
The Netherlands	2.920 (***)	740	561	630
United Kingdom	7.943	1.598	1.388	1.653
ALL	**74.787**	**14.258**	**9.203**	**10.428**

(*) Number of oocyte recoveries was used as number of initiated cycles was not available.

(**) Number of embryo transfers was used as number of initiated cycles was not available.

(***) Number of embryo transfers was used as number of thawings was not available.

From Table 14, it can be seen that after FER **14.258** pregnancies resulted from **74.787** thawings including data for 22 EU MS. This results in a clinical pregnancy rate of **19% per thawing**.

No data are reported for RO, SK, MT, EE and LU. Data on deliveries and children born are incomplete as there is no reporting requirement for them in AT, CY, CZ and LV.

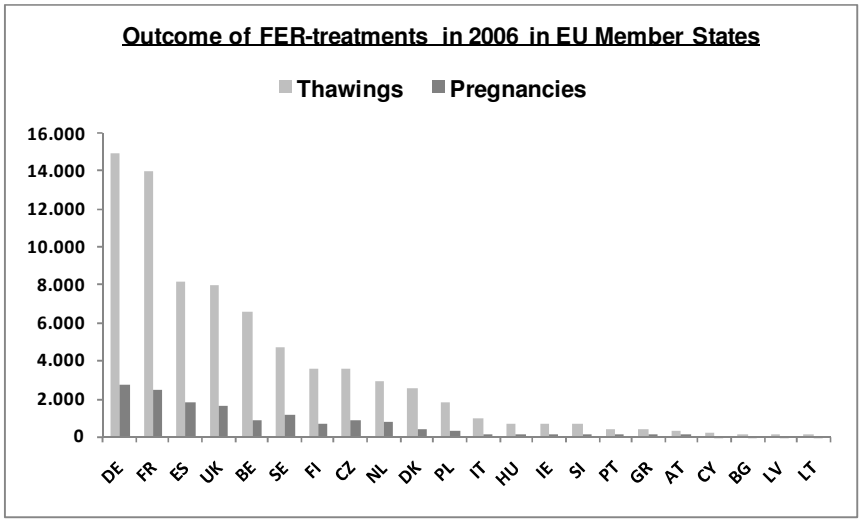


Figure 19: Pregnancies and deliveries after FER (IVF+ICSI) in 2006 in EU Member States

As can be seen from data in figures and tables 17/18/19 and 12/13/14, the number of ICSI cycles is in many countries higher than the number of regular IVF cycles. The ratio between both has changed during the last ten years from 65% IVF cycles versus 35% ICSI cycles in 1997 to the opposite, 35% IVF cycles versus 65% ICSI cycles in 2006 (data EIM report 2006). Nyboe Andersen A, Goossens V, Bhattacharya S, Ferraretti AP, Kupka MS, de Mouzon J, Nygren KG; European IVF-monitoring (EIM) Consortium, for the European Society of Human Reproduction and Embryology (ESHRE). Assisted reproductive technology and intrauterine inseminations in Europe, 2005: results generated from European registers by ESHRE: ESHRE. The European IVF Monitoring Programme (EIM), for the European Society of Human Reproduction and Embryology (ESHRE). Hum Reprod. 2009;24:1267-87.

We believe that in some countries ICSI is used to ensure fertilization, even when not necessary.

However, the pregnancy rates for IVF and ICSI remain similar (26% and 27.3% respectively).

Data on FER show us that the overall pregnancy rate after freezing (19%) is much lower than after fresh IVF or ICSI cycles (26% and 27.3% respectively).

Comparison of success rates between 27 EU Member States and for IVF, ICSI and FER

All results are reported as pregnancy rate per initiated cycle (number of clinical pregnancies/number of initiated cycles). The number of cycles performed (related to the size and number of clinics in each country) should be taken into account when analysing the results in terms of pregnancy rates.

Table 15: Pregnancy rates for IVF, ICSI and FER treatments in 27 EU Member States in 2006

Country	IVF			ICSI			FER		
	Initiated cycles	Pregnancies	Pregnancy rate	Initiated cycles	Pregnancies	Pregnancy rate	Thawings	Pregnancies	Pregnancy rate
Austria	1.218	397	32,59%	3.733	1.171	31,37%	226	71	31,42%
Belgium	3.619	1.025	28,32%	11.928	3.245	27,20%	6.620	899	13,58%
Bulgaria	642	174	27,10%	634	186	29,34%	93	21	22,58%
Cyprus	402	113	28,11%	780	282	36,15%	143	31	21,68%
Czech Republic	2.331	693	29,73%	6.891	2.496	36,22%	3.560	829	23,29%
Denmark	5.500	1.468	26,69%	4.436	1.127	25,41%	2.515	391	15,55%
Estonia	not reported	not reported	-	not reported	not reported	-	not reported	not reported	-
Finland	2.849	748	26,25%	1.927	505	26,21%	3.561	709	19,91%
France	20.409	4.949	24,25%	30.367	7.847	25,84%	14.064	2.458	17,48%
Germany	11.082	3.071	27,71%	28.687	7.772	27,09%	14.926	2.696	18,06%
Greece	1.222	282	23,08%	2.287	605	26,45%	310	67	21,61%
Hungary	522	102	19,54%	2.086	649	31,11%	641	114	17,78%
Ireland	1.588	401	25,25%	1.004	256	25,50%	636	112	17,61%
Italy	8.680	1.589	18,31%	28.186	5.361	19,02%	905	145	16,02%
Latvia	105	72	68,57%	63	26	41,27%	87	9	10,34%
Lithuania	not reported	53	-	168	58	34,52%	68	8	11,76%
Luxembourg	144	not reported	-	211	not reported	-	287	122	42,51%
Malta	not reported	not reported	-	not reported	not reported	-	not reported	not reported	-
Poland	336	107	31,85%	3.790	1.306	34,46%	1.737	291	16,75%
Portugal	1.161	368	31,70%	2.225	580	26,07%	380	73	19,21%
Romania	not reported	not reported	-	not reported	not reported	-	not reported	not reported	-
Slovakia	not reported	not reported	-	not reported	not reported	-	not reported	not reported	-
Slovenia	687	201	29,26%	1.512	394	26,06%	590	111	18,81%
Spain	4.178	1.213	29,03%	28.360	8.836	31,16%	8.203	1.776	21,65%
Sweden	5.304	1.599	30,15%	4.784	1.382	28,89%	4.659	1.109	23,80%
The Netherlands	8.365	2.312	27,64%	6.485	2.000	30,84%	2.920	740	25,34%
United Kingdom	17.634	4.484	25,43%	16.184	4.856	30,00%	7.943	1.598	20,12%

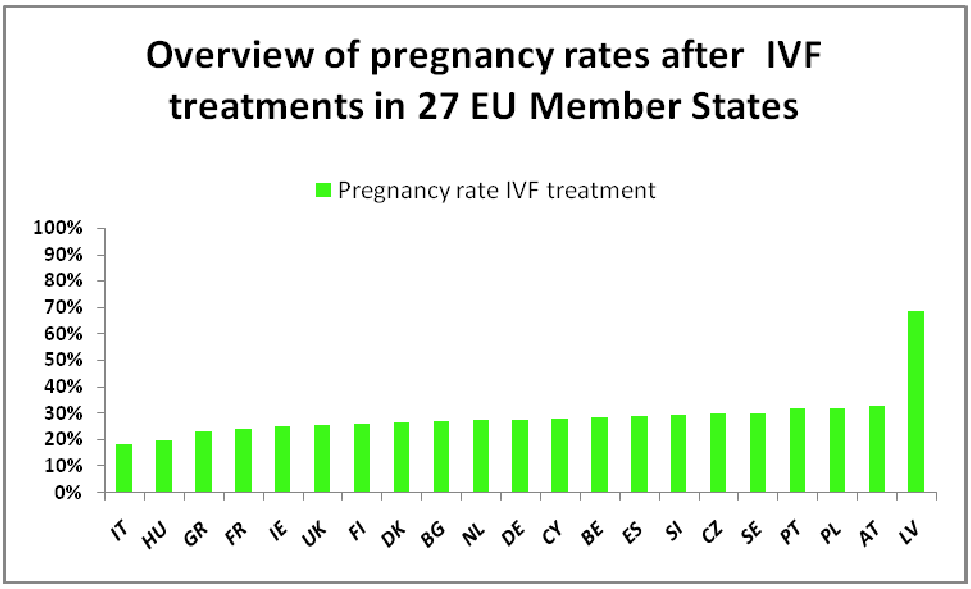


Figure 20a: Succes rate of IVF treatments in 27 EU Member States in 2006

Similar pregnancy rates are observed after IVF between different countries, ranging from 20 to 30% (see also Table 16a for the exact values) .

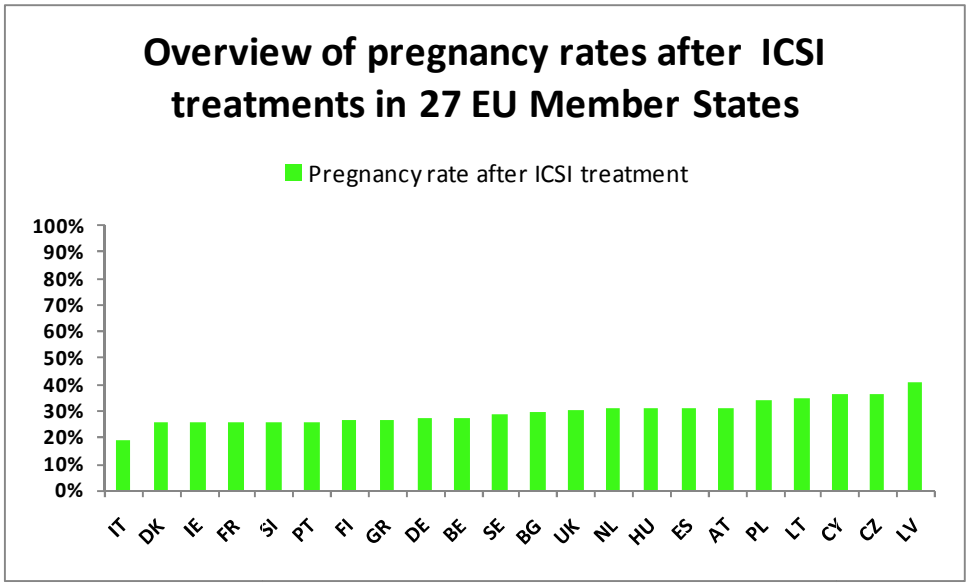


Figure 20b: Succes rate of ICSI treatments in 27 EU Member States in 2006

Similar pregnancy rates are observed after ICSI between different countries, ranging from 25 to 35% (see also Table 16b for the exact values).

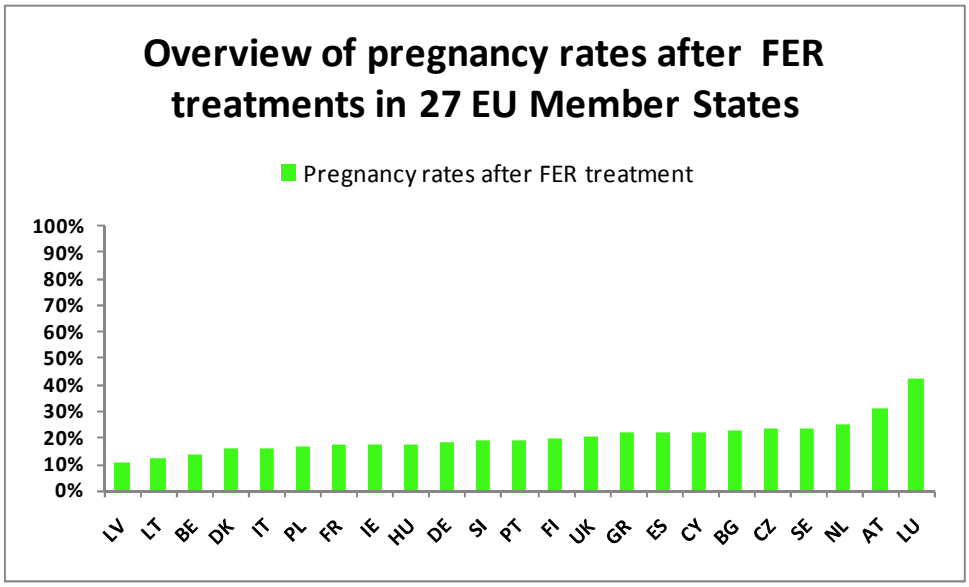


Figure 20c: Succes rate of FER treatments in 27 EU Member States in 2006

The pregnancy rates after FER are lower than the ones achieved after fresh embryo transfer and range from 10 to 30% (see also Table 16c for the exact values).

Table 16a: Pregnancy rates after IVF treatments in 27 EU Member States in 2006		Table 16b: Pregnancy rates after ICSI treatments in 27 EU Member States in 2006		Table 16c: Pregnancy rates after FER treatments in 27 EU Member States in 2006	
Country	**Pregnancy rates**	**Country**	**Pregnancy rates**	**Country**	**Pregnancy rates**
Italy	18,31%	**Italy**	19,02%	**Latvia**	10,34%
Hungary	19,54%	**Denmark**	25,41%	**Lithuania**	11,76%
Greece	23,08%	**Ireland**	25,50%	**Belgium**	13,58%
France	24,25%	**France**	25,84%	**Denmark**	15,55%
Ireland	25,25%	**Slovenia**	26,06%	**Italy**	16,02%
United Kingdom	25,43%	**Portugal**	26,07%	**Poland**	16,75%
Finland	26,25%	**Finland**	26,21%	**France**	17,48%
Denmark	26,69%	**Greece**	26,45%	**Ireland**	17,61%
Bulgaria	27,10%	**Germany**	27,09%	**Hungary**	17,78%
The Netherlands	27,64%	**Belgium**	27,20%	**Germany**	18,06%
Germany	27,71%	**Sweden**	28,89%	**Slovenia**	18,81%
Cyprus	28,11%	**Bulgaria**	29,34%	**Portugal**	19,21%
Belgium	28,32%	**United Kingdom**	30,00%	**Finland**	19,91%
Spain	29,03%	**The Netherlands**	30,84%	**United Kingdom**	20,12%
Slovenia	29,26%	**Hungary**	31,11%	**Greece**	21,61%
Czech Republic	29,73%	**Spain**	31,16%	**Spain**	21,65%
Sweden	30,15%	**Austria**	31,37%	**Cyprus**	21,68%
Portugal	31,70%	**Poland**	34,46%	**Bulgaria**	22,58%
Poland	31,85%	**Lithuania**	34,52%	**Czech Republic**	23,29%
Austria	32,59%	**Cyprus**	36,15%	**Sweden**	23,80%
Latvia	68,57%	**Czech Republic**	36,22%	**The Netherlands**	25,34%
Estonia	not reported	**Latvia**	41,27%	**Austria**	31,42%
Lithuania	not reported	**Estonia**	not reported	**Luxembourg**	42,51%
Luxembourg	not reported	**Luxembourg**	not reported	**Estonia**	not reported
Malta	not reported	**Malta**	not reported	**Malta**	not reported
Romania	not reported	**Romania**	not reported	**Romania**	not reported
Slovakia	not reported	**Slovakia**	not reported	**Slovakia**	not reported

Table 16 shows the pregnancy rates related to three different MAR treatments: IVF, ICSI and FER for treatments in 27 Member States. Countries are ranked from lowest to highest pregnancy rate.

IVM - treatments in 27 EU Member States in 2006

Table 17: Pregnancies and deliveries after IVM in 2006 in EU Member States

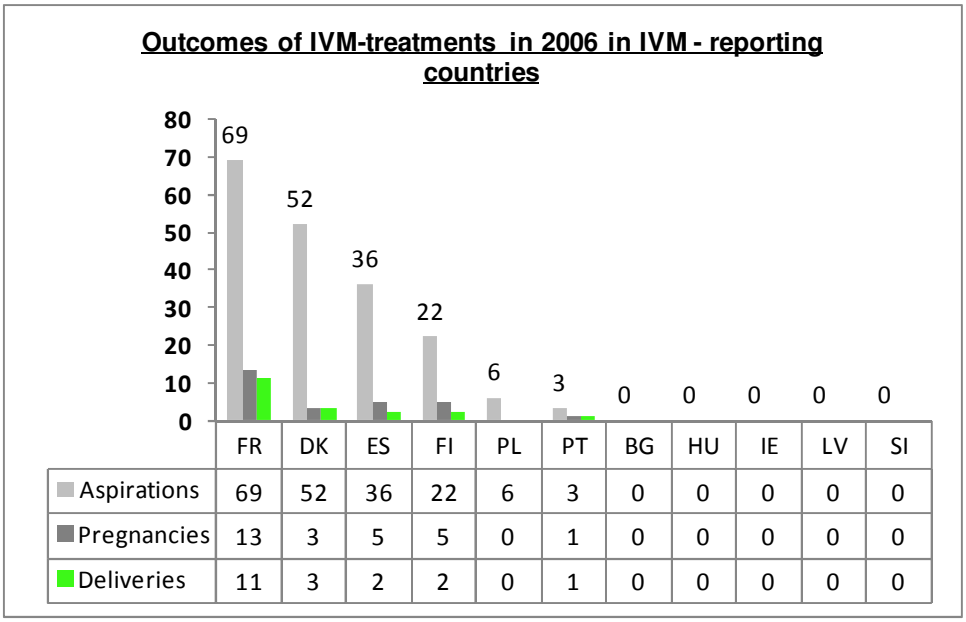
Country	Aspirations	Pregnancies	Deliveries
Austria	not reported	not reported	not reported
Belgium	not reported	not reported	not reported
Bulgaria	0	0	0
Cyprus	not reported	not reported	not reported
Czech Republic	not reported	not reported	not reported
Denmark	52	3	3
Estonia	not reported	not reported	not reported
Finland	22	5	2
France	69	13	11
Germany	not reported	not reported	not reported
Greece	not reported	not reported	not reported
Hungary	0	0	0
Ireland	0	0	0
Italy	not reported	not reported	not reported
Latvia	0	0	0
Lithuania	not reported	not reported	not reported
Luxembourg	not reported	not reported	not reported
Malta	not reported	not reported	not reported
Poland	6	0	0
Portugal	3	1	1
Romania	not reported	not reported	not reported
Slovakia	not reported	not reported	not reported
Slovenia	0	0	0
Spain	36	5	2
Sweden	not reported	not reported	not reported
The Netherlands	not reported	not reported	not reported
United Kingdom	not reported	not reported	not reported
ALL	**188**	**27**	**19**

Table 17, shows that after IVM **27** pregnancies resulted from **188** aspirations including data for 6 EU MS. This results in a clinical pregnancy rate of **14. 3 %** per aspiration. Please note that 13 of 27 MS are not reporting data and that the above means and totals should be interpreted with caution as they cannot not represent the situation in the other countries. For BG, HU, IE, LV and SI no IVM is performed.

Zero's in Table 17 mean that no cycles are performed, whereas 'not reported' indicates that in 2006 these data were not collected or that the technique was not performed in the selected country.

This fertility treatment was developed to provide an alternative to conventional IVF for certain groups of patients, at risk for OHSS (Ovarian Hyper Stimulation Syndrome) after ovarian stimulation. This group is mainly constituted by polycystic ovaries patients. Improved IVM techniques are developing rapidly and an increasing number of fertility clinics are offering IVM. However, its introduction in routine clinical IVF program is, at present, a distant goal.

As can be seen from these data (see Table 17 and Figure 21), only few clinics in the EU are offering the technique already. The efficiency of the technique is much lower than the one reported for conventional IVF or ICSI and this is due to the fact that the process of in vitro maturation of the oocytes is still not optimized and results in a low quality of the embryos generated by IVM oocytes.



	FR	DK	ES	FI	PL	PT	BG	HU	IE	LV	SI
Aspirations	69	52	36	22	6	3	0	0	0	0	0
Pregnancies	13	3	5	5	0	1	0	0	0	0	0
Deliveries	11	3	2	2	0	1	0	0	0	0	0

Figure 21: Pregnancies and deliveries after IVM in 2006 in IVM-reporting EU Member States

Table 18: Pregnancies and deliveries after OD in 2006 in EU Member States

Country	Donation Cycles	Pregnancies	Deliveries	Children born	% Multiple deliveries
Austria			**NA**		
Belgium	697	158	94	111	20.2
Bulgaria (1)	18	6	6	6	
Cyprus	84	43	Not reported	Not reported	Not reported
Czech Republic (**)	655	242	Not reported	Not reported	Not reported
Denmark (**)	35	6	3	4	33.3
Estonia (**)	Not reported	Not reported	Not reported	Not reported	Not reported
Finland (*)	388	136	106	120	13.2
France (**) (2)	228	138	93	74	21.3
Germany			**NA**		
Greece (**)	170	74	40	49	28.9
Hungary	28	11	8	9	13
Ireland	5	4	3	4	33.3
Italy			**NA**		
Latvia	25	7	Not reported	Not reported	Not reported
Lithuania			OD not performed		
Luxembourg	Not reported	Not reported	Not reported	Not reported	Not reported
Malta	Not reported	Not reported	Not reported	Not reported	Not reported
Poland	353	119	105	226	Not reported
Portugal (**)	42	15	7	9	28.6
Romania	Not reported	Not reported	Not reported	Not reported	Not reported
Slovakia	Not reported	Not reported	Not reported	Not reported	Not reported
Slovenia (**)	5	2	1	1	Not reported
Spain (**)	7.080	3.269	2.019	2.619	29.3
Sweden (*) (2)	98	46	35	35	Not reported
The Netherlands (*)	Not reported	Not reported	Not reported	Not reported	Not reported
United Kingdom (*)	1.911	586	518	648	24.7
ALL	**11.822**	**4.862**	**3.038**	**3.915**	

NA Non anonymous as well as anonymous oocyte donation are forbidden in IT, DE, AT.

(*) Anonymous Oocyte Donation forbidden in NL, UK, SE, FI. Data are only for non anonymous Oocyte Donation.

(**) Non anonymous Oocyte Donation forbidden in DK, CZ, EE, FR, ES, PT, SI, GR. Data are only for Anonymous oocyte Donation.
(1) Number of transfers was used as number of initiated cycles was not available.
(2) Number of oocyte recoveries were used as number of initiated cycles was not available.

Table 18 shows that after OD (Oocyte Donation) **4.862** pregnancies resulted from **11.822** aspirations including data for 17 EU MS. This results in a clinical pregnancy rate of **41. 1% per donation cycle**. Remind that OD is not allowed in AT, DE and IT. Data on deliveries, children born and % of multiple pregnancies are incomplete. Please note that since only 17 of 27 Member States are reporting data the above means and totals should be interpreted with caution as they cannot not represent the situation in other countries.

SK, RO, LU, EE, MT did not report data in 2006 and are excluded here. In Lithuania OD is not performed and in the Netherlands OD data are not collected. Therefore no data were included in Table 18 for these two countries.

Table 19: Pregnancies and deliveries after PGD in 2006 in EU Member States

Country	Initiated cycles	Pregnancies	Deliveries	Children born
Austria		**NA**		
Belgium	Not reported	Not reported	Not reported	Not reported
Bulgaria	Not reported	Not reported	Not reported	Not reported
Cyprus	27	6	Not reported	Not reported
Czech Republic	414	128	Not reported	Not reported
Denmark	84	14	12	Not reported
Estonia	Not reported	Not reported	Not reported	Not reported
Finland	27	6	4	4
France	267	43	37	46
Germany		**NA**		
Greece	Not reported	Not reported	Not reported	Not reported
Hungary	3	2	1	1
Ireland	Not reported	Not reported	Not reported	Not reported
Italy	Not reported	Not reported	Not reported	Not reported
Latvia		**NA**		
Lithuania	Not reported	Not reported	Not reported	Not reported
Luxembourg	Not reported	Not reported	Not reported	Not reported
Malta	Not reported	Not reported	Not reported	Not reported
Poland	38	10	9	Not reported
Portugal	65	8	7	9
Romania	Not reported	Not reported	Not reported	Not reported
Slovakia	Not reported	Not reported	Not reported	Not reported
Slovenia	10	1	1	1
Spain	2478	497	362	441
Sweden	Not reported	Not reported	Not reported	Not reported
The Netherlands	Not reported	Not reported	Not reported	Not reported
United Kingdom	425	112	100	Not reported
ALL	**3838**	**827**	**533**	**502**

Table 19 shows that after PGD **827** pregnancies resulted from **3.383** initiated cycles including data for 17 EU MS. This results in a clinical pregnancy rate of **21. 5% per cycle**. Remind that PGD is not allowed in AT, DE and LV.

Data on deliveries, children born are incomplete. Please note that since only 11 of 27 MS are reporting data the above means and totals should be interpreted with caution as they cannot represent the situation in the other countries. As only a small number of countries are reporting PGD it is of no use to compare the technique between the countries. Too many details are missing.

Table 27: Complications related to MAR-treatments in 2006 in the EU Member States

Country	Hyperstimulation syndrome	Complications to oocyte retrieval	Maternal death	Fetal reduction
Austria	not reported	not reported	not reported	not reported
Belgium	154	231	0	not reported
Bulgaria	19	5	0	6
Cyprus	5	0	0	6
Czech Republic	142	2	0	89
Denmark	not reported	not reported	not reported	not reported
Estonia	not reported	not reported	not reported	not reported
Finland	61	9	0	6
France	not reported	not reported	not reported	not reported
Germany	173	278	0	not reported
Greece	25	7	0	9
Hungary	36	2	0	7
Ireland	21	6	0	0
Italy	161	142	0	0
Latvia	3	2	0	0
Lithuania	not reported	not reported	not reported	not reported
Luxembourg	3	0	0	0
Malta	not reported	not reported	not reported	not reported
Poland	71	19	0	0
Portugal	30	3	0	0
Romania	not reported	not reported	not reported	not reported
Slovakia	not reported	not reported	not reported	not reported
Slovenia	22	3	0	3
Spain	236	46	1	95
Sweden	not reported	not reported	not reported	not reported
The Netherlands	not reported	not reported	not reported	not reported
United Kingdom	589	65	0	102
ALL	**1751**	**820**	**1**	**323**

Table 20 presents the incidence of ovarian hyper stimulation syndrome (OHSS) recorded from registries in 17 of 27 EU Member States (BE, BG, CY, CZ, FI, DE, GR, HU, IE, IT, LV, , PL, PT, SI, ES, UK, LU). It is seen that 1751 cases of OHSS were recorded in 2006. The number of fresh IVF and ICSI cycles performed in those 17 countries was 193.582, corresponding to a risk of OHSS of 0.9 % of all stimulated cycles. Other complications are also shown in the table, with i.e. a total of 323 fetal reductions being recorded in 2006 in 15 of 27 EU Member States.

Notice that in 10 of 27 EU Member States (AT, DK, FR, LT, SE, NL, EE, SK, RO, MT) data on complications are not being registered.

VIII. Analysis of cross-border MAR - tourism in 27 EU MS

Member States have only recently started to collect data on cross – border MAR – treatments and up till now data are incomplete or not collected at all. ESHRE therefore decided to discuss the already obtained results of a survey among 6 European countries (5 being EU Member State) as this information is the only one available at the moment.

1. Data collection for Cross border Reproductive Care in 5 EU Member States

Taking into consideration the multiple press releases one should recognize that, although large-scale data on cross border reproductive care never have been collected before, a substantial number of couples travel to another country than their own to obtain MAR - treatments. The problem at present is the lack of empirical data on the extent of this phenomenon. No large-scale data collection nor country-specific data collection programmes are existing, but will be required to obtain a complete picture of the phenomenon of cross-border reproductive care. The collection of data on the numbers of patients moving from one country to another for certain MAR-treatments will be a first and important step. More elaborate research in the future should also include experiences of patients, difficulties they experience, impact of movements on the national healthcare systems, effects of portability of insurances.

Due to the lack of data collection systems in EU Member States, ESHRE decided to address the cross border fertility questions in the questionnaires by compiling results from two recently executed studies (set up in the frame of ESHRE' s taskforces 'Ethics and Law' and 'Cross border reproductive medicine') investigating cross-border MAR-tourism. It should be noted that to evaluate and conclude on the phenomenon properly a full picture has to be patched together in the near future. As these data are not yet available nowadays and below summary involves two studies of voluntary nature, one should be aware that the provided picture only shows 'trends' and that evidence is still partial.

The first study (Pennings et al., 2009[60]) gives an overview of the intake of foreign patients in Belgium for infertility treatment, whereas in the second study (Shenfield et al., 2009 – in press[61]) the analysis is made for 6 countries: Belgium, Czech Republic, Denmark, Slovenia, Spain (and Switzerland) and gives a first indication on trends in EU Member States. Data discussed below are derived from the second study, as this study in most recent and also includes data for Belgium.

Purpose was to get an estimation of the number of women/couples who cross borders, and of the reasons for them to make such a choice. In practice, it appeared to be impossible to obtain an estimate of the proportion of patients exiting their own country, as no data are kept in countries of

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60 Pennings et al. (2009) 'Cross border reproductive care in Belgium' represents Belgium incoming flow of foreign patients during the period 2000-2007. (Pennings G, Autin C, Decleer W, Delbaere A, Delbeke L, Delvigne A, De Neubourg D, Devroey P, Dhont M, D'HoogheT, et al. Cross border reproductive care in Belgium, Human Reprod 2009, 24 in press doi:10.1093/humrep/dep300).

A survey was conducted among 18 Belgian centres for reproductive medicine. Data were collected on the nationality of patients and the type of treatment for which they attended during the period 2000 - 2007.

[61] In Shenfield et al. (in press, 2009) Shenfield, F ., de Mouzon, J ., Pennings, G., Ferraretti, A.P.F., Andersen, A.N., de Wert, G., Goossens, V. and Van den Eede, B. , on behalf of the ESHRE Taskforce on Cross border reproductive care. (2009) Cross border reproductive care in six European countries. Hum. Reprod. In press.

'Cross border reproductive care in six European countries' a multinational prospective study of all foreign women coming from abroad to attend the 44 participating centres for assisted conception (IVF, ICSI, SD, OD, PGD and PGS) in six collaborating countries: Belgium, Czech Republic, Denmark, Slovenia, Spain and Switserland is performed. It should be noted that this study only represents one month's activity.

origin. It was therefore decided to concentrate on recipient countries (1 country in the 1st study, 6 countries in the 2nd study) and mostly on the reasons patients have to cross borders and the help they may obtain in their country of origin (reimbursement).

This prospective, anonymous, one-month study is believed to be the first to present a set of hard data concerning this subject at European level and includes several countries known to be recipient of foreign patients. However and due to the limited number of countries, centres and patients analysed, the study is biased and limited in many ways.

The major methodological limitation is the lack of representativity. In effect, it was impossible to get data from all European countries and, moreover, in 4 countries, data were obtained from voluntary clinics. Thus, we found in our sample that French patients were going mainly to Belgium as single women seeking IUI, whereas it is known that many of them go to Spain for oocyte donation, but mostly to centres that were not included in this study. This limitation also makes it impossible to calculate accurate estimates of the number of couples obliged to cross their country's border to obtain treatment. However, this study shows the great extent of the phenomenon, which is also of interest to public health authorities, and we can make some rough estimates according to the following hypothesis: we collected 1230 cycles over one month from 46 clinics in 6 countries, which may represent 12 000 to 15 000 cycles annually in those centres, taking into account seasonal variability and annual closures.

If we assume that, in each country, the selected centres are, on average, more concerned by patients who cross borders patients than others, and as the selected countries were chosen because they are known to be recipient (even if some other such known countries like Greece were not included), the total number of cycles in Europe can be estimated to be at least, 25 000 to 30 000 cycles per year.

If we then apply the treatment distribution observed in this study (75% ART, 25% IUI), and make the reasonable hypothesis that, on average 1 to 6 cycles are performed for IUI and 1 to 4 cycles for ART (averages 3 and 2 respectively), this leads **to a minimum estimated number of concerned patients of 11,000-14,000**. Such quantity confirms the importance of the cross border phenomenon, and also clearly calls for the necessity of evaluating it more accurately, with methodologically correct tools.

2. Characteristics[62] of Cross border Reproductive Care in 5 EU Member States

In total, 1230 forms (see Annex 10) were received by ESHRE Central office, from 46 clinics participating in the 6 treating countries (Table 21): 29.7% from Belgium, 20.5% from the Czech Republic, 12.5% from Denmark, 16.3% from Switzerland, 15.7% from Spain, and 5.3% from Slovenia. In Denmark and Slovenia, all clinics collaborated, in Belgium 50% of clinics, whereas in the other countries, only a few self-selected centres participated. The forms concerned patients coming from 49 countries. However, four countries were particularly represented, with more than 100 forms returned to Central office each (Table 16): Italy (31.8%), Germany (14.8%), the Netherlands (12.1%) and France (8.7%), followed by 3 countries returning more than 50 forms each: Norway (5.5%), the UK (4.3%) and Sweden (4.3%). The remaining 42 countries of origin represented less than 19% of the received forms (n=233).

Thus, only the 7 main contributors are presented in Table 21 and Figure 22. Figure 22 also shows that most Italians went to Switzerland and Spain, most Germans to the Czech Republic, most Dutch and French patients to Belgium and to Spain and most Norwegians and Swedish to Denmark.

Table 21: Percentage of patients crossing borders to the six treating countries

Country of residence	Received forms		Forms per treating country (%)					
	n	%	Belgium	Czech republic	Denmark	Slovenia	Spain	Switzerland
Italy	**391**	31.8	13.0	2.6	0.3	1.0	31.7	51.4
Germany	177	14.4	10.2	67.2	11.9	0.0	10.7	0.0
Netherlands	149	12.1	96.6	0.0	0.0	0.0	3.4	0.0
France	107	8.7	85.0	7.5	0.0	0.0	7.5	0.0
Norway	67	5.5	0.0	1.5	98.5	0.0	0.0	0.0
UK	53	4.3	7.55	52.8	11.3	0.0	28.3	0.0
Sweden	53	4.3	0.0	5.7	92.4	0.0	1.9	0.0
Total: n	**1230**		365	252	154	65	193	201
%	100		29.7	20.5	12.5	5.3	15.7	16.3

[62] Shenfield, F ., de Mouzon, J ., Pennings, G., Ferraretti, A.P.F., Andersen, A.N., de Wert, G., Goossens, V. and Van den Eede, B. , on behalf of the ESHRE Taskforce on Cross border reproductive care. (2009)Cross border reproductive care in six European countries. Hum. Reprod. In press

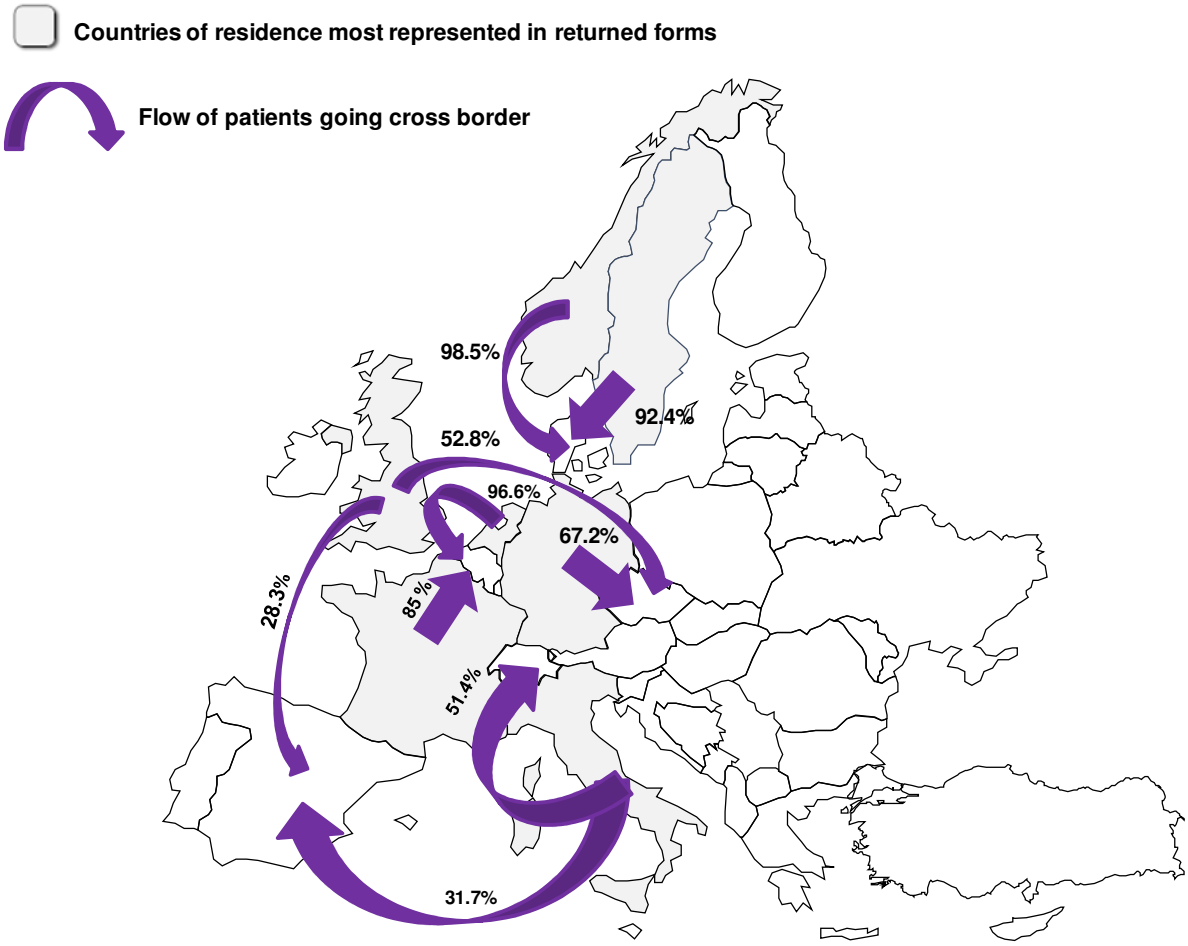

Figure 22: Flow of patients in cross border Reproductive care

2. 1 Socio-demographic characteristics

The mean age (Table 22) was over 37.3 for all countries (range: 21 to 51 years). The proportion of women aged 40 or more was 34.9% for all patients, and reached 51.1% for Germany and 63.5% for the UK, compared to 32.2% for Italy and 30.2% for France.

Table 22: Age of the women crossing borders from the 7 most represented countries

Country of residence	Women's age (%)					
	Mean ± SD years	<35 (%)	35–39 (%)	40-44 (%)	≥ 45 (%)	Range
Italy	37.4 ± 5.0	27.3	40.5	24.7	7.0	21-50
Germany	38.8 ± 5.0	21.0	27.8	40.3	10.8	23-49
Netherlands	35.4 ± 5.1	44.3	34.9	17.4	3.4	23-51
France	36.6 ± 5.8	32.1	37.7	20.8	9.4	21-49
Norway	35.8 ± 4.6	38.8	43.3	16.4	1.5	21-47
UK	40.8 ± 5.4	11.5	25.0	32.7	30.8	21-49
Sweden	37.4 ± 5.5	26.4	32.1	37.7	3.8	24-45
Total	37.3 ± 5.1	29.5	35.6	26.8	8.1	21-51

Civil status was also very different according to the countries of residence (Table 23). In total, 69.9% of women were married, 24.0% cohabiting and 6.1% single. However, most Italian women were married (82.0%), whilst 50% French women, and 34.9% Dutch women were cohabiting and 43.4% Swedish women were single. Furthermore, many same sex couples travelled from France and Sweden.

Furthermore, 57.9% women and 53.3 % partners had a university degree, and 29.3% (31.7% partners) had secondary education.

Table 23: Civil status and sexual orientation of patients' residence

Country of residence	Civil status (%)			Sexual orientation (%)
	Married	Cohabiting	Single	Homo/ Bisexual
Italy	82.0	17.2	0.8	1.5
Germany	72.0	25.7	2.3	11.2
Netherlands	62.3	34.9	2.7	8.5
France	33.6	50.0	16.4	39.2
Norway	47.6	28.6	23.8	21.3
UK	62.0	30.0	8.0	0.0
Sweden	32.1	24.5	43.4	32.7
Total (%)	69.9	24.0	6.1	9.7

2. 2 Reasons for crossing borders

Reasons varied from one "outgoing" country to another. Legal reasons were predominant for patients coming from Italy (70.6%), Germany (80.2%), France (64.5%), and Norway (71.6%). Access was more often noted for UK patients (34.0%) than for the other countries, and quality was an important factor for most countries (Table 24).

Table 24: General reasons for travelling according to the country of patients' residence

Country of residence	Legal reason	Access difficulty	Better quality	Previous failure
Italy	70.6	2.6	46.3	26.1
Germany	80.2	6.8	32.8	43.5
France	64.5	12.1	20.6	18.7
Netherlands	32.2	7.4	53.0	25.5
Norway	71.6	0.0	22.4	16.4
UK	9.4	34.0	28.3	37.7
Sweden	56.6	13.2	24.5	5.7
Total %	54.8	7.0	43.2	29.1

Before reviewing the different reasons for crossing borders, note that many patients (about one in 3 in our sample) indicated more than one reason to travel abroad.

General reasons

An average of 29.1 % of patients had *previous failure of treatment* (Table 24), with Germans and UK residents above average (respectively 43.5% and 37.7%). In the case of Germany, this higher percentage may be due to recent decrease in the funding of cycles by insurances, as it may be cheaper to cross the border to the Czech Republic rather than having a cycle in the private sector at home. In the case of the UK, regions have autonomy in prioritising the funding ART or not, resulting in vastly different waiting lists, and inequity of access (Shenfield F.. Justice and access to fertility treatments, in Shenfield F and Sureau C (eds) Ethical dilemmas in assisted reproduction. 1997. Parthenon , New York and Carnworth USA pp 7-14 / Shapps, G. The IVF postcode lottery: Don't promise what you can't deliver, Bionews, ***09 August 2009, www.bionews.)***

Interestingly, this was the opposite for Swedish, Norwegian and French residents, where only respectively 5.7%, 16.4%, and 18.4 % gave this extra reason, well below average. Indeed, we know that access in general is liberal in the Nordic countries, and good in France, with the exception of oocyte donation due to a dearth of donors and bans on advertising (Law "Bioethique", 2005), and of sperm donation outside heterosexual couples.

Vicinity is also a common factor between all patients. Ease of access via common borders explains why so many French women go to Belgium, for sperm donation mainly (Pennings G, Autin C, Decleer W, Delbaere A, Delbeke L, Delvigne A, De Neubourg D, Devroey P, Dhont M, D'HoogheT, et al. Cross border reproductive care in Belgium, Human Reprod 2009, 24 in press doi:10.1093/humrep/dep300). It is however surprising to note the relatively small number of French women going to Spain for OD, which is probably due to the low proportion of Spanish participating centres (see limitations of study under III.1). Swedes and Norwegians go to Denmark (>90%), again within a short distance, and Germans go mostly (67.2%) to the Czech Republic. Furthermore 50% Italian women go to Switzerland for sperm donation.

Legal barriers to treatments

In practice, our findings show that the majority of patients cross borders for legal reasons (Table 24), apart from the Dutch or UK citizens. Thus legal barriers are a major factor, whether because of age (France), banned techniques (Italy and Germany), or sexual preference (France and Norway). Italian law banned all donor gametes and PGD techniques in 2004 (Italian law 40-2004), sending a ripple of patients to neighbouring countries, like Switzerland (51% of our sample), mostly for sperm donation, and Spain for OD (31.7%). The German law bans OD and 67.2 % of our sample found its way to the Czech Republic, which performed 62.2 % of OD on our cross border women (Table 25).

Table 25: Sought treatment according to the country of patients' residence

Country of residence	Infertility treatment*		PGD-PGS	Donation		
	ART	IUI		Semen	Oocyte	Embryo
Italy	76.5	32.6	2.1	17.4	17.9	2.3
Germany	90.5	10.3	8.5	10.2	44.6	6.2
Netherlands	78.1	27.4	3.4	11.4	9.4	0.7
France	46.7	61.7	2.8	43.0	20.6	5.6
Norway	62.7	41.8	1.5	38.8	1.5	1.5
UK	90.6	9.4	3.8	15.1	62.3	11.3
Sweden	37.7	62.3	0.0	43.4	5.7	1.9
Total	77.9	27.1	3.2	18.3	22.8	3.4

Patients sought mostly IUI (Table 26) in Denmark (56.5% in total) and Switzerland (54.1%), whereas they sought ART in Slovenia (100%), the Czech Republic (98.4%) and Spain (98.4%). Spain (62%) and the Czech Republic (52%) were mainly concerned by oocyte and embryo donation. Denmark (40.9%), Switzerland (27.4%) and Belgium (20.5%), received many patients seeking sperm donation.

Table 26: Treatment sought according to the recipient country

Recipient country	Forms (n)	Infertility treatment*		PGD/ PGS	Donation*		
		ART	IUI		Semen	Oocyte	Embryo
Belgium	359	71.9	33.4	5.2	20.5	6.8	0.3
Czech Republic	251	98.4	1.6	5.6	9.5	52.4	11.9
Denmark	154	46.8	55.5	0.6	40.9	1.3	0.6
Slovenia	64	100	0.0	0.0	0.0	0.0	0.0
Spain	190	98.4	5.8	2.1	4.1	62.2	4.7
Switzerland	196	59.7	54.1	0.5	27.4	1.0	0.5
Total		73.0	22.2	3.2	18.3	22.8	3.4

For Denmark, receiving its Scandinavian neighbours, almost 41 % of cycles were donor inseminations. Again local lack of donors may be a factor, but 18.9 % of Swedish and 16.4% Norwegian patients stated they did not merely want donor insemination, but that they sought "*anonymous*" donation. Thus,

for Sweden, this exodus may also relate to the 1985 legislation requiring non anonymous donation as a primary cause, but also to the fact that they must be in a couple, thus excluding single women.

Another important legal reason is related to the civil status and sexual orientation of the patient. In Sweden only couples have access, whether homosexual or heterosexual, which explains the high proportion of single Swedish women (43.4%) seeking treatment abroad. In France the legal requirement to be in a heterosexual couple in order to have access to ART explains why 39.2% of French patients were homosexual and 16.4% single. By contrast no British woman left because of sexual orientation as the HFE Act 1990 never forbade access to homosexual women. For the Dutch patients the main reason was the search for “quality” (53%) which may relate to ICSI with testicular sperm being only accessible in a research setting in The Netherlands, and in fact be a kind of legal barrier.

Finally, for the patients originating from the UK legal reasons were the lowest of our sample, with only 9.4%, the main reason being difficulty of access (37.7%). Indeed the UK legislation is one of the most open and tolerant to differences in Europe (HFE Act 2008).

This is also the case for Spain which makes it a natural recipient for patients seeking OD, and where oocyte donors are more prevalent because of a strong tradition of donation reflected in the high rate of organ donation, and the compensation offered to oocyte donors (about 900 euros). In the Czech Republic, the compensation is in the order of 500 euros per donation. For both countries, the compensation may facilitate the recruitment of donors and explain a fairly large cross border movement.

2. 3 Reimbursement of Cross border Reproductive Care in 5 EU Member States

Cross border patients are poorly reimbursed (Table 27). Only 13.4% received partial reimbursement, and 3.8% total. The most generous country is the Netherlands, with a partial or total reimbursement of respectively 44.4% and 22.1% of patients.

Table 27: Reimbursement according to the country of patient's residence

Country of residence	No	Partial	Total	Unspecified
Italy	74.9	10.7	0.3	14.1
Germany	81.9	8.5	2.3	7.3
Netherlands	16.8	44.3	22.1	16.8
France	77.6	12.2	3.7	6.5
Norway	79.1	10.4	1.5	9.0
UK	92.6	1.9	1.9	0.00
Sweden	73.6	3.8	0.00	22.6
Total	71.7	13.4	3.8	11.1

3. Conclusion Cross border Reproductive Care

Above summarized study is the first evidence based picture of a phenomenon, cross border reproductive care between several European countries, which is now well entrenched. It belies some of the misgivings expressed by the public, puzzled if not outraged when women over the age of 60 go for treatment abroad as no one was > 51 in our sample, all be it incomplete. This does not mean we must rest assured that this may not be sometimes risky for the recipient and future child, as shown by a recent study showing that UK residents having conceived by ART abroad are less likely to reduce a multiple pregnancy of high order than if they had treatment at home (McKelvey A, David AL, Shenfield F and Jauniaux ER , The impact of cross-border reproductive care or 'fertility tourism' on NHS maternity services, BJOG 2009: 116; 1520-1523).

Furthermore, there is a dearth of research on the welfare of donors in several contributing countries. It is thus important that we continue looking at the evidence, including the rate of multiple pregnancy, where our patients travel (Nyboe Andersen A, Goossens V, Bhattacharya S, Ferraretti AP, Kupka MS, de Mouzon J, Nygren KG, and The European IVF-monitoring (EIM) Consortium, for the European Society of Human Reproduction and Embryology (ESHRE). Assisted reproductive technology and intrauterine inseminations in Europe, 2005: results generated from European registers by ESHRE: ESHRE. The European IVF Monitoring Programme (EIM), for the European Society of Human Reproduction and Embryology (ESHRE) Hum. Reprod 2009:24;1267-1287.), inform them, and as professional strive to common standards to protect patients, the future child(ren) and the generous gametes donors. It is also illusory to think of "common European law", a contradiction in terms in a field where there are some practical directives pertaining to our field (like the Tissue directive), but which is much prone to the influence of national tradition and history. Indeed the principle of devolution applies to many EU fields, and it seems that will be the case for the future implementation of the directive which will enable patients to travel between European countries to seek treatment in general (BMJ news Aug 2009).

The danger of legal harmonisation would actually be a "lowest common denominator", no gametes donation, no embryo research or freezing, no openness to different ways of life for access to ART. It is therefore up to professional societies to ensure that safety standards are agreed by its members, and to make this information available.

Patients and the profession may have little effect on national policy, or at least have to wait a long time before they see improved access at national level. Indeed "at present, the movements by patients to other countries can be seen as a form of civil disobedience, which intends to change the existing legislation", but which also "may have the opposite effect: politicians may accept the movements of some citizens to clinics abroad as a safety valve which decreases the pressure for law reform internally".

Clearly there is inequality of access to fertility treatments in Europe, and, whilst this cross border movements can increase the autonomy of our patients, it must be stressed that in many instances it is only available to those with the financial means of travelling, apart from the cases where patients state that a private cycle abroad is cheaper, including travel, than at home. This may be particularly so in some Eastern European countries not included in this study.

IX. Conclusion

ESHRE, European Society for Human Reproduction and Embryology, was contracted by the European Commission to outline the situation 'as is' regarding MAR legislation, reimbursement and MAR establishments in the European Union. ESHRE's ability to organise data collection covering most of the 27 EU Member States together with its previously shown MAR-related expertise, has been essential for the collaboration with the European Commission in the scope of this study. This MAR-study was initiated to significantly improve quality and safety of MAR treatments for patients in the European Union. Two surveys were conducted among all 27 Member States and this conclusion summarizes the main findings of both surveys.

It is clear that 30 years after the introduction of in vitro fertilization, the number of techniques that are available for treatment of infertility have increased in a spectacular way and that the implementation, legislation and reimbursement of these treatments show so much variation in Europe that no two EU Member States are alike.

Implementation of the EU Tissues and Cells Directive (EUTCD, Directive 2004/23/EC[63]) has taken place in 25 of 27 EU Member States. Most of them have installed a Competent Authority and also have started inspections. Two countries are lagging behind (BE, MT) but as far as the analysis permits there are no grounds to suspect that these will not catch up in the foreseeable future.
With the exception of a few, mostly small countries (CY, IE, LT, LU, MT, LV, RO, PL), the vast majority of EU Member States have specific legislation regarding medically assisted reproduction (MAR) in place. Countries without MAR-specific legislation report to have general legislation in place, applying to MAR- treatments. In 11 of 27 EU Member States implementation of MAR-legislation resulted from transposition of the EUTCD. On top of legislation, there is also soft regulation reported in 22 of 27 EU Member States: good clinical/laboratory practice and ethical guidelines. However, for the latter the European situation is more heterogeneous. National registries for the collection of clinical activities do exist in more than 20 countries. Besides that a few countries have local registries as well. Regarding the establishment of national and local registries for donors, the European pattern shows a clearly mosaic pattern. The full spectrum of the presence and / or absence of national and / or local registries emerge. Gamete donation is regulated by law in most countries and non anonymous donation is as often allowed as it is forbidden. Surrogacy, postmortem use of embryo's and/or gametes, PGS and PGD and embryo donation are the treatments that are most often forbidden (in this order of frequency). On the other hand IVF and ICSI are universally accepted.

However, this does not mean that all women in Europe have the same access to treatment. Apart from financial hurdles also eligibility criteria are in place for the inclusion of patients in MAR programs in different countries. . Eligibility criteria on reimbursement include age, marital status, previous children, the use of donor gametes, the type of service provider (i.e., public or private clinic) and allowable treatment cycles, embryo transfers and number of embryo's transferred. Of these, marital status and the maximum age of the mother to be are the most common limitations on access to MAR techniques. It is clear that almost all EU Member States have some reimbursement scheme in place and that the majority have a fixed, non adaptable yearly budget for MAR treatments. However, for many countries it is not clear which arguments have been used to decide on a restrictive policy, but possible reasons for such a policy include cost, efficacy, and safety or ethical and religious objections. For some the sanctity of life is closely related to natural conception.

[63] DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of Human tissues and cells.

Some countries like Spain for example provide full coverage. In other countries not all women who are infertile are eligible for reimbursement. For example in Ireland reimbursement schemes are almost non-existent. In countries with restrictions demographic, social or economic circumstances are taken into account. Economic factors are assumed to play a major role. In most countries the reasons for restrictions on treatments are the cost-ineffectiveness. However, in many cases the evidence that is necessary for evidence based decisions does not exist.

MAR treatments might be excluded from coverage on the grounds that treatment is not medically necessary. In a number of countries the clinical definition of infertility is strictly medical and excludes single and lesbian women ('socially infertile') from coverage, while in others it is not. However, an increasing number of these groups of women request MAR treatments. The Swedish government has for example supported this with a bill that does allow lesbian couples (but not single women) to have access to publicly funded assisted reproduction. According to the bill, the partner or cohabitant of the biological mother is regarded as a parent of the child on condition that she has consented to the treatment and it is 'likely' that the child was conceived via MAR treatment. In the vast majority of countries age is an important criterion to restrict access and funding, which means that coverage is limited to younger women while older women, who are having a greater need of being treated are excluded. The reason for having an age limit has to do with the fact that there is an overwhelming body of evidence that there is a declining effectiveness and increasing costs together with safety issues in women aged 40 and older.
Besides patient age there are medical limitations on the use of MAR treatments. Sometimes weight or BMI is included and medical decisions are also based on hormonal findings. A restriction on the basis of the smoking status is under debate. In some countries the limitations on the use of testicular sperm and in many on the access to donor gametes are reflected in the reimbursement schemes. Some of the reimbursement and regulatory frameworks are connected to safety concerns. Sometimes feministic arguments have been used in this respect: women undergoing these treatments are unfairly manipulated to undergo treatment and are exposed to serious risks associated with hormonal stimulation for superovulation and oocyte retrieval. This illustrates the need of developing more patient friendly stimulation methods. The Belgian government has coupled reimbursement of the laboratory costs for IVF/ICSI to restrictions on the number of embryos used for transfer related to age of the woman.

In some countries the right to access to infertility treatment does not necessarily mean that there is also a right to public funding of that infertility treatment, since not paying does not constitute a violation of that right. In many countries with publicly funded ART services, a large proportion, if not the majority, of IVF cycles are provided by the private sector and population groups, including those currently often excluded from public provision, such as single, lesbian and older women from within the country or from abroad make use of it. The access and reimbursement of PGD is not allowed according to the law in a number of countries, while others have a more liberal law. For instance the German Embryo protection law is very restrictive. In countries where there are no principle objections to PGD, there might be restrictions with respect to the indications used. This is for instance the case in France and the Netherlands and reflects ethical points of view in these countries. Finally there are European countries that have concerns about the demographic changes that are taking place. These concerns have influenced the reimbursement schemes. A good example of this is Denmark.

Both public and private MAR centres are in charge of the treatments in the different countries. The information was obtained mainly through the ESHRE European IVF Monitoring Consortium that constitutes a reliable source of information, mostly collected from National Registries. It has been difficult to get access to the information in the cases where no National Representative for the EIM existed. This inventory shows that there is considerable variation in size of the clinics performing MAR treatment. The highest number of clinics is situated in countries with the highest number of inhabitants such as Germany, France, Spain and Italy. Differences in the size of the clinics are observed. However, as long as European data collection is not at the level of the individual clinic but aggregated

per country, it is impossible to come to a conclusion with respect to the optimal size of a treatment centre. Accreditation systems are in place in most of EU countries but it is not yet possible to correlate the results with the results of accreditation of the laboratories and / or clinics.

In most EU countries, the reporting system is made through the reporting of cycles summary and most of the information is processed by National registries. The most correct and precise way of collecting the data would be through individual cycle collection but most of the data provided are global centre data.

The number of MAR treatment cycles in the EU in 2006 is approaching 0.5 Million. The mean number of treatments per million inhabitants varies among countries and ranges from 120 to more than 2.000. The data collected show that more than 100.000 European citizens are born in the EU as the result of MAR techniques. In some countries like Denmark and Slovenia on average more than one child in every school class is the result of these treatments.

Looking at the success rates per country and per MAR technique, the pregnancy rates after IVF range from 20 to 30% with similar rates between different countries but with lower rates for Italy probably due to the restrictive use of only 3 oocytes per cycle and 60% for Latvia with a very low number of cases performed. The same situation is repeated for ICSI with slightly increased pregnancy rates. When performing the analysis of the data, one should of course take into account, the number of clinics and the number of cycles performed per clinic.

The pregnancy rates after FET are, as expected, lower than in fresh cycles and vary from 10 to 30%.

There are no data available regarding multiple pregnancies, which is an essential parameter to be considered when analyzing the success rate. It is preferred to have a reasonable pregnancy rate after mild stimulation and single embryo transfer rather than a higher rate obtained after very high stimulation and transfer of 2 or more embryos, with multiple pregnancies as a result. Unfortunately these data are not available. The reduction of multiples with the complete elimination of high order multiple pregnancies should be the goal while maintaining adequate pregnancy rates.

Correlations of the success rates with different clinical and laboratory parameters might help to identify the variables that affect success in the different countries.

As only a small number of countries are performing and reporting IVM and PGD, it is of no use to compare the technique between the countries. Too many variables exist, too many data are lacking.

Among 284.351 fresh cycles, the distribution between IVF (97.834) and ICSI (186.517) was respectively 34.4% and 65.6% The amount of fresh cycles is 284.351 and 74.787 frozen cycles has been performed.

The use of ICSI has increased in certain countries. This is not related to an increase of male infertility but is mostly due to the fact that some clinics in certain countries use ICSI to ensure fertilization even it is not needed. The unnecessary use of such a complex technique should be considered both in safety and economical terms.

The extent of gamete donation should be evaluated, especially with respect to oocyte donation. This technique is increasingly used in women over 40 because of poor oocyte quality. The increasing age of the women treated makes it a frequently requested and used technique. Few countries allow for the compensation of oocytes and, as a consequence, in the countries where this happens the oocyte donation programs activities are concentrated (i.e. Spain).

Diagnosis and treatment in the area of reproductive medicine is practically unavailable in some countries. This is one of the reasons for patients to seek cross border reproductive care. Other

reasons are legal restrictions or eligibility criteria. Furthermore, long waiting lists and costs are also reasons to explain inaccessibility. This study provides, a first evidence based picture of the cross border MAR care. This phenomenon is raising interest due to the inequality of access to fertility treatments in Europe, but has been poorly documented up till now. Indications on patient flows, e.g. Italians travelling to Switzerland and Spain, most Germans to the Czech Republic, Dutch and French patients to Belgium and to Spain and most Norwegians and Swedish to Denmark, are observed. However, conclusions about reasons for patient flows are premature and should be interpreted with caution. More elaborate research is necessary to analyse in more detail all cross border MAR care-related aspects.

As far as the safety and risks are concerned it is justified to conclude that air quality and the transmission of viruses, which are one of the main points of attention of the EU Tissues and Cells Directive, cannot be held responsible for the observed complications after MAR. A big debate is being held on the frequency of viral screening assessment frequency and annual screening seems to be the most recommended option by most experts. The major complications of MAR techniques are iatrogenic. They involve the occurrence of the ovarian hyper stimulation syndrome (OHSS), complications due to oocyte retrieval and fetal reductions. “Mild stimulation” which has been introduced recently will greatly influence the incidence of OHSS. Other options include the use of In Vitro Maturation Techniques. Fetal reduction is used to reduce multiple pregnancies after multiple embryo transfer. Single embryo transfer should be recommended whenever possible while avoiding the reduction in pregnancy rates. It would be most optimal to incorporate the transfer policy in the legal regulations and the reimbursement policies as it should be addressed in all soft regulation by professional bodies.

Conclusion: Safety and quality are the main concerns when treating patients with MAR techniques. Adequate legislation, reimbursement schemes and good clinical practice are crucial to achieve this goal. Reliable data collection regarding the results obtained should allow improvement in the field. The recognition of ESHRE by the EU as ‘the expert’ European organization in the area of MAR and the collaboration of ESHRE with the European Commission will significant improve quality and safety of MAR treatments for patients in the European Union.

Annex 1: Questionnaire WP1

Annex 2: Contact list WP1

Annex 3: Questionnaire WP2

Annex 4: List EIM members – contact information

Annex 5: List of MAR-establishments in 27 EU MS

Annex 6a: Pilot studies on cross- border MAR tourism

Annex 7: Definitions Assisted Reproductive Technology

Annex 8: Abbreviation list

Annex 9: ESHRE Position Paper

Annex 10: Cross border questionnaire

Annex 1 : Legal Aspects and Reimbursement Issues on MAR

QUESTIONNAIRE

EUROPEAN CELL AND TISSUE DIRECTIVES

1. Have the European Cell and Tissue Directives been implemented in national legislation in your country?	❒ yes	❒ no

2. Has/have a Competent Authority(ies) for inspecting and licensing been installed?	❒ yes	❒ no

3. Has inspection and licensing of medically assisted reproduction (MAR) Centres started?	❒ yes	❒ no

4. Are there public and private MAR Centres?	❒ yes	❒ no

5. Is there a **national** registry for MAR treatments?	❒ yes	❒ no
If yes: ❒ On voluntary basis ❍ registry organized by organization, society, individual, other, please specify: ..... ❒ Legal obligation ❍ registry organized by Competent Authority ❍ registry organized by other body, please specify:		
If no, are there **local** registries for MAR treatments? ❒ On voluntary basis ❍ registry organized by organization, society, individual, other, please		

specify: ..... ❒ Legal obligation ❍ registry organized by Competent Authority ❍ registry organized by other body, please specify:		

6. Is there a **national** registry for donors?	❒ yes	❒ no
If yes: ❒ On voluntary basis ❍ registry organized by organization, society, individual, other, please specify: ..... ❒ Legal obligation ❍ registry organized by Competent Authority ❍ registry organized by other body, please specify:		
If no, are there **local** registries for donors? ❒ On voluntary basis ❍ registry organized by organization, society, individual, other, please specify: ..... ❒ Legal obligation ❍ registry organized by Competent Authority ❍ registry organized by other body, please specify:		

7. If there is a national/local registry for MAR treatments, which are/have to be registered?
Choose from list of treatments:

- ❒ AID Artificial insemination Donor sperm
- ❒ AIH Artificial Insemination Husband sperm
- ❒ ART Artificial (Assisted) Reproductive Technology (Treatment)
- ❒ ED Embryo Donation
- ❒ FET Frozen Embryo Transfer
- ❒ ICSI IntraCytoplasmatic Sperm Injection
- ❒ IVF In Vitro Fertilisation
- ❒ IVM In Vitro Maturation
- ❒ MESA Microsurgical Epididymal Sperm Aspiration
- ❒ NIVF Natural Cycle In Vitro fertilization
- ❒ OD Oocyte Donation
- ❒ PGD Preimplantation Genetic Diagnosis
- ❒ PGS Preimplantation Genetic Screening
- ❒ SET Single Embryo Transfer
- ❒ SD Sperm Donation
- ❒ TESE Testicular Sperm Extraction

SPECIFIC LEGISLATION ON MEDICALLY ASSISTED REPRODUCTION (MAR)

8. Does specific legislation relating to MAR exist in your country? If yes, what is the content?	❒ yes	❒ no

9. Is there soft regulation relating to MAR available (such as guidelines by national or international societies)?	❒ yes	❒ no
If yes, what is the content: ❒ good clinical practice guidelines ❒ good clinical practice guidelines ❒ good laboratory practice guidelines		

❒ ethical guidelines ❒ other, please specify:		

10. Which MAR technologies are legally allowed?

- ❒ AID Artificial insemination Donor sperm
- ❒ AIH Artificial Insemination Husband sperm
- ❒ ART Artificial (Assisted) Reproductive Technology (Treatment)
- ❒ ED Embryo Donation
- ❒ FET Frozen Embryo Transfer
- ❒ ICSI IntraCytoplasmatic Sperm Injection
- ❒ IVF In Vitro Fertilisation
- ❒ IVM In Vitro Maturation
- ❒ MESA Microsurgical Epididymal Sperm Aspiration
- ❒ NIVF Natural Cycle In Vitro fertilization
- ❒ OD Oocyte Donation
- ❒ PGD Preimplantation Genetic Diagnosis
- ❒ PGS Preimplantation Genetic Screening
- ❒ SET Single Embryo Transfer
- ❒ SD Sperm Donation
- ❒ TESE Testicular Sperm Extraction

11. Are there limitations for getting access to MAR treatment:

- ❒ No limitations
- ❒ Marital status, please specify: .....
- ❒ Maximum age of the women
- ❒ Maximum age of the man
- ❒ Maximum number of cycles that can be accessed
- ❒ Decision by MAR centre not to give access
- ❒ Are access criteria for public and private centres the same?
- ❒ Patients coming from other EU member state
- ❒ Other, please specify: .....

<u>Please note</u> that this question is not about limitations on financial reimbursement (although they may be linked); questions on reimbursement will follow

12. What level of anonymity is applied in case of gamete/embryo donation?
    - ❒ Full anonymity obligatory (without any possibility of tracing donor(s) to acceptor(s) or vice – versa)
    - ❒ Non-anonymity obligatory (the donor's identity must be disclosable at least to the child if wanted by the child at majority)
    - ❒ Known gamete /embryo donation based on consent of donor(s) and acceptor(s) allowed
    - ❒ Other, please specify: .....

13. Financial compensation for gamete/embryo donation
    - ❒ Every kind of compensation forbidden
    - ❒ Compensation allowed, maximum amount specified
    - ❒ Compensation allowed, maximum amount not specified

14. Postmortem use of gametes /embryos
    - ❒ Allowed, not regulated
    - ❒ Allowed, regulated by law
    - ❒ Not allowed
    - ❒ Unclear

15. Surrogacy
    - ❒ Allowed, not regulated
    - ❒ Allowed, regulated by law
    - ❒ Not allowed
    - ❒ Unclear

REIMBURSEMENT FOR MAR

16. Does reimbursement for MAR exist in your country?	❒ yes	❒ no

17. Are there limitations for getting access to reimbursement to IVF/ICSI ?:

- ❒ No limitations
- ❒ Marital status, please specify: .....
- ❒ Maximum age of the women
- ❒ Maximum age of the man
- ❒ Maximum number of cycles that can be accessed
- ❒ Limitation on maximum number of embryos to be transferred
- ❒ Private versus public
  - ❍ Reimbursed only for public
  - ❍ Reimbursed for public and private
    - ❒ to the same extent
    - ❒ differently, please specify: .....
- ❒ Going cross the border (see also questions 22 and 23)
- ❒ Other, please specify: .....

<u>Please note</u> that a treatment may well be accessible but possibly not reimbursed

18. Which of the following are reimbursed for IVF/ICSI

- ❒ Clinical phase:
  - ❍ agonist/antagonist drugs for …%
  - ❍ gonadotrophic drugs for …%;
  - ❍ consultations for ..%
  - ❍ blood for …%
  - ❍ echographies for ..%
- ❒ Laboratory phase for …%

19. If IUI is reimbursed which of the following are reimbursed
    - ❒ Clinical phase
        - ❍ gonadotrophic drugs for …%;
        - ❍ consultations for ..%
        - ❍ blood for …%
        - ❍ echographies for ..%
    - ❒ Laboratory phase

20. If pre-implantation genetic diagnosis (PGD) is practiced in your country
    - ❒ reimbursement is foreseen for the IVF/ICSI cycle
    - ❒ additional reimbursement is foreseen for the genetic work up of the patients
    - ❒ additional reimbursement is foreseen for genetic screening of the embryos
    - ❒ other, please specify:.....

21. If in vitro maturation (IVM) is practiced in your country
    - ❒ reimbursement is foreseen for the IVF/ICSI
    - ❒ additional reimbursement is foreseen for the in vitro maturation phase
    - ❒ other, please specify:.....

22. Are patients allowed to seek treatment in another EU country
    - ❒ yes
    - ❒ no
    - ❒ only for treatments not available in their own country

23. If yes, for which of the MAR treatments in another EU country is reimbursement foreseen
    - ❒ none
    - ❒ all
    - ❒ other, please specify:.....

24. Financial mechanism of reimbursement: entry
- ❒ Specific entrance document needed from social insurance /public health department
- ❒ no specific document needed

25. Financial mechanism of reimbursement: payment
- ❒ directly to patients per cycle of treatment
  - ❍ For clinical phase
  - ❍ For laboratory phase
- ❒ directly to MAR centres per cycle of treatment
  - ❍ For clinical phase
  - ❍ For laboratory phase

Please note that a treatment may well be accessible but possibly not reimbursed

26. Financial mechanism of reimbursement: public health's yearly budget
- ❒ Fixed, non-adaptable budget
- ❒ Pre-fixed budget but adaptable budget
- ❒ Unlimited

THANK YOU FOR YOUR COOPERATION!

Annex 2: Contact list WP1

ANNEX 2

Survey Work Package 1: Contact list for 27 EU Member States

Country	Competent Authority (*)	EACC Regulator	CNR Member	Other/specify
Austria	Kurz J, Tel +43 171100 4643, johann.kurz@bmgf.gv.at		Ebner, T, Tel +43 732 6923 24605 thomas.ebner@gespag.at	Strohmer, H (EIM), Tel +43 1 40111 1400 heinz.strohmer@kinderwunschzentrum.at
			Wildt, L, Tel +43 512 504 23276, ludwig.wildt@i-med.ac.at	
Belgium	Muylle, L, Tel +32 2 524 83 77, ludo.muylle@fagg.be		Heindryckx, B, Tel +32 93324748 bjorn.heindryckx@ugent.be	Van den Abbeel, E (Executive Committee), Tel +32 2 477 66 94, etienne.vandenabbeel@uzbrussel.be,
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				Griesinger, G (FSGD Consortium), Fax +49 451 500 5764, griesing@uni-luebeck.de
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Hungary	Kovacs, Z, Tel +36 1 215 5327, kovacs.zsolt@oth.antsz.hu		Urbancsek, J, Tel +36 1 266 01 15, UrbJan@Noi1.sote.hu	
Ireland	Costello, P, Tel +353 1 676 49 71, patrick.costello@imb.ie		Mocanu, EV, Tel +353 1 80 72 732, emocanu@rcsi.ie	Cunningham, G (Irish Medicine Board), Tel +353 16764971, grace.cunningham@imb.ie
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				Gudleviciene, Z (EIM), Tel +370 52 34 2020, zivile.gudleviciene@gmail.com
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Malta	Zammit, R, Tel +356 22992655, richard.zammit@gov.mt			Mallia, P, Tel: 00356 21347787, bioethicscentre@onvol.net
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Slovakia	Valky, J, Tel +421 2 5441 4410, Jozo@iscare.sk	Marsik, L, Tel +42 1 905 251 904, taco@marsik.sk		Koller, J (Ministry of Health of Slovak republic), E-mail koller@nspr.sk
Slovenia	Tivadar, A, andrijana.tivadar@jazmp.si	Letonja, D, Tel +386 1 3006864, danica.avsec@slovenija-transplant.si	Vrtacnik-Bokal, E, Tel +386 1 5226013, eda.bokal@guest.arnes.si	Vlaisavljevic, V (Executive Committee), Tel +386 23 21 24 60, vlai@ukc-mb.si
			Kovacic, B, Tel +386 1 5226013 eda.bokal@guest.arnes.si	
Spain	Garrido Cantarero, G, Tel +34 91 822 49 15 ggarrido@msc.es			Veiga, A (Executive Committee), Tel +34 93 316 0360, aveiga@cmrb.eu
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			Saldeen, P, Tel +46 40 98 70 52, pia.saldeen@curakliniken.se	
The Netherlands	Kok, L, Tel 0031 70 340 50 78 l.kok@minvws.nl			Welma, S (ESHRE Member), Tel +31 88 755 8472 s.welma@umcutrecht.nl
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United Kingdom	Davies, T, Tel +44 207 291 8240, trish.davies@hfea.gov.uk		Braude, P, Tel +44 207 1884138, peter.braude@kcl.ac.uk	Shenfield, F (Executive Committee), Tel +44 207 380 94 35, mfi@easynet.co.uk
			Hartshorne, G, Tel +44 2476 968867, geraldine.hartshorne@warwick.ac.uk	

Legend

	No answers received
	Contact person 1 = first data input
	Contact person 2 = contacts used for cross check of data received from contactperson 1
X	**Contactperson 2 did not reply**
EACC	European Assisted Conception Consortium
CNR	Commitee of National Representatives
(*)	List of Competent Authorities provided by DG SANCO

Annex 3: Establishments involved in MAR technologies

QUESTIONNAIRE

Name of country : .....

Name of contact person : .....

Full address of contact person : .....

.....

.....

Reference period for this questionnaire is **2006**

Number and size of clinics

a/ IVF clinics (units) in the country

Total number of clinics in the country **Private** **Public**	
Location of the clinics (provide list of clinics by area)	

b/ Size of the reporting clinics.

total annual number of initiated cycles for the purpose of

IVF, ICSI, FET,PGD/PGS,IVM, OD,SD (Gamete Donation,GD) and ED

	Number of clinics
< 100 cycles	
100 - 199 cycles	
200 - 499 cycles	
500 - 999 cycles	
≥ 1.000 cycles	

Is there a centre accreditation system in place?	
Are QC and QA systems part of the accreditation evaluation?	
Is there a result reporting requirement in place?	

What % of clinics are reporting results?	
Is there a national registry for gamete donation reporting?	
Reporting methods :	
Cycles. 1. Individual cycles; 2. Summaries of cycles reported by the clinics	
Deliveries. 1. Individual cycles; 2. Summaries of deliveries reported by the clinics	
National number of deliveries in the same year in the country	
National number of infants born in the same year in the country	
Comments	

Number of treatments, pregnancies and deliveries.

Frozen embryos stored

	IVF	ICSI	FET	PGD/PGS	IVM	GD/ED
4. Initiated cycles						
5. Pregnancies						
% of multiple pregnancies						
6. Deliveries						
Children born						
Frozen Embryos stored						

Please use the WHO/ICMART definition of clinical pregnancy: evidence of pregnancy by clinical or ultrasound parameters (ultrasound visualisation of a gestational sac). It includes ectopic pregnancy. Multiple gestational sacs in one patient are counted as one clinical pregnancy.

Deliveries include those resulting in a live birth and/or stillbirth.

Complications to treatments and foetal reduction

Complications with admission to hospital

	Number of occurrences
Hyperstimulation syndrome	
Complications to oocyte retrieval	
Maternal death	
Foetal reductions	

Cross border reproductive care

Number of cycles performed **Number of patients treated**	
Reasons (cycles performed)	**Legal**
	Anonymity
	Availability of the technique
	Financial
Countries of origin	
MAR Technique (IVF, ICSI, FET,PGD/PGS,IVM,GD, ED	
Follow-up of treatment (including pregnancy and delivery)	**Yes/no**

Annex 4: Contact persons representing data collection programmes in participating European countries

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Annex 5: List of establishments for Medically Assisted Reproduction[64] in the European Union in 2006

PR= Private centres

PU= Public centres

Austria (Total N° clinics = 25 // N° reporting clinics = 25) clinics)

Both private and public centres

1. Bregenz: Institut für Reproduktionsmedizin und Endokrinologie (PR)
2. Dobl: Kinderwunschinstitut Schenk (PR)
3. Graz: Institut für In-Vitro-Fertilisierung und Endokrinologie (PR)
4. Graz: Institut für Hormonstörungen Wechselbeschwerden und Kinderwunsch (PR)
5. Graz: A. ö. Landeskrankenhaus Graz (PU)
6. Horn: Landesklinikum Waldviertel Horn (PU)
7. Hohenems: Landeskrankenhaus Hohenems (PU)
8. Innsbruck: Landeskrankenhaus-Universitätskliniken Innsbruck (PU)
9. Innsbruck: Private Kinderwunschklinik Dr. Josef Zech GmbH (PR)
10. Innsbruck: WOMED Therapiezentrum Kinderwunsch GmbH (PR)
11. Klagenfurt: Sterignost Kinderwunschbehandlungs GmbH (PR)
12. Krumpendorf: Privatkrankenanstalt Parkvilla (PR)
13. Linz: Landes-Frauen- und –Kinderklinik (PU)
14. Oberpullendorf: 23 A. ö. Krankenhaus Oberpullendorf (PU)
15. St. Pölten: Landesklinikum St. Pölten (PU)
16. Salzburg: St. Johanns Spital (PU)
17. Vienna: Allgemeines Krankenhaus der Stadt Wien (PU)
18. Vienna: Goldenes Kreuz (PR)
19. Vienna: GYNANDRON Dr. Freude (PR)
20. Vienna: Krankenhaus Hietzing (PR)
21. Vienna: Wunschbaby-Zentrum (PR)
22. Vienna: Adebar – Institut für Reproduktionsmedizin und Psychosomatik der Sterilität (PR)
23. Vienna: 22 Tagesklinik (PU)
24. Wals-Himmelreich: Babywunsch-Klinik Dr. Zajc GmbH (PR)
25. Wels-Thalheim: Die KinderWunschKlinik Dr. Loimer GmbH (PR)

Belgium (Total N° clinics = 18 // N° reporting clinics = 18)

Only public centres

1. Antwerpen: Dienst Fertiliteit, Algemeen Ziekenhuis Middelheim (PU)
2. Braine - L'alleud : Centre de Fécondation C.H. Interregional Edith Cavell (CHIREC), (PU)
3. Brugge: BIRTH – Fertiliteitskliniek, Algemeen Ziekenhuis Sint-Jan (PU)
4. Brussel: Centrum voor Reproductieve Geneeskunde, UZ Brussel (PU)
5. Brussel: Clinique de Procréation Médicalement Assistée, Hôpital Universitaire Saint- Pierre - U.L.B. (PU)
6. Brussel: Service de Gynécologie, Cliniques Universitaires Saint-Luc - U.C.L (PU)
7. Brussel: Centre de FIV de l'U.L.B. – Hôpital Erasme (PU)
8. Charleroi : Service Gyn/Obst, Clinique Notre Dame (PU)

[64] Establishments only performing IUI are excluded in this list.

9. Edegem: Centrum voor Reproductieve Geneeskunde, Universitair Ziekenhuis Antwerpen - U.I.A. (PU)
10. Genk: Centre for Reproductive Medicine, Ziekenhuis Oost-Limburg - St. Jan (PU)
11. Gent: Vrouwenkliniek- Infertiliteitscentrum, U.Z. – Gent (PU)
12. Gent: Centrum voor Fertiliteitstherapie, A.Z. Jan Palfijn (PU)
13. Leuven: dienst Gynaecologie, Universitaire Zieknhuizen K.U.Leuven Gasthuisberg (PU)
14. Leuven: Unit Reproductieve Geneeskunde, Regionaal Ziekenhuis Heilig Hart (PU)
15. Libramont: Centre d'Infertilité, Centre Hospitalier de l'Ardenne (PU)
16. Liege : Centre de FIV, Centre Hospitalier Régional de la Citadelle (PU)
17. Namur : Service Gynéco, Centre Hospitalier Régional de Namur (PU)
18. Rocourt : Centre Liégeois pour l'étude et le traitement de la stérilité, Clinique Saint Vincent (PU)

Bulgaria (Total N° clinics = 15 // N° reporting clinics = 8)

Both private and public centres, but reporting centres only private

1. Sofia: In Vitro Medical center "Bratya Todorovi" (PR)
2. Sofia: Ob/Gyn Center "Dimitrov" (PR)
3. Sofia: Medical center "Reprobiomed" (PR)
4. Sofia: IVF Unit, Ob/Gyn Hospital "Dr. Shterev" (PR)
5. Varna: ART Centre "Varna" OOD (PR)
6. Varna: In Vitro Center "Olimed"; (PR)
7. *Plovdiv: In Vitro Center, Ob/Gyn Hospital "Selena" (PR)*
8. Plovdiv: Clinic of Sterility, BORA Medical (PR)

Cyprus (Total N° clinics = 7 // N° reporting clinics =7)

Only private centres

1. Limassol: Centre of Genetics (PR)
2. Nicosia: Akeso Fertility Centre (PR)
3. Nicosia: Pedieos IVF Centre (PR)
4. Pafos: Iaso Fertility Centre (PR)
5. Areteio Hospital (PR)
6. Akeso IVF unit (PR)
7. Lyda Clinic (PR)

Czech Republik (Total N° clinics = 21 // N° reporting clinics = 21)

Both private and public centres

1. Brno: MUDr. Ales Bourek (PR)
2. Brno: REPROMEDA, s.r.o. ; (PR)
3. Brno: Sanatorium HELIOS, s.r.o (PR)
4. Brno: CAR 01 Brno, Gyn. - por. klinika FN Brno (PU)
5. Brno: UNICA, s.r.o. (PR)
6. Ceské Budejovice: Sanatorium ART, s.r.o. (PR)
7. Hradec Kralove: SANUS, s.r.o. (PR)
8. Jihlava: Sanus Jihlava (PR)
9. Olomouc: Fakultni nemocnice Olomouc, CAR, Por.-gyn. Klinika (PU)
10. Olomouc: FERTIMED, s.r.o. (PR)
11. Ostrava: GYNCENTRUM Ostrava, s.r.o. (PR)

12. Pardubice: Sanus Pardubice (PR)
13. Plzen: IVF-institut, s.r.o. (PR)
14. Plzen: NATALART (PR)
15. Praha: APOLINAR CAR – VFN, Gyn.-por. Klinika 1. LF UK (PU)
16. Praha: Fakultni nemocnice v Motole, CAR, Gyn.-por klinika 2. LF UK (PU)
17. Praha: GEST, s.r.o. (PR)
18. Praha: UPMD Praha (PU)
19. Praha: Gennet Praha (PR)
20. Praha: Iscare IVF (PR)
21. Praha: Pronatal, s.r.o. (PR)

Denmark (Total N° clinics = 22 // N° reporting clinics = 22)

1. Aabenraa: Alexander Laschke gyn/obst
2. Aalborg: Faurskov Fertilitet og Ultralyd;
3. Aarhus: Privathospitalet Ciconia (PR)
4. Fertilitetsklinikken Skejby Sygehus;
5. Aarhus: Maigaards Fertilitetsklinik
6. Brædstup: Fertilitetsklinikken Brædstrup Sygehus
7. Copenhagen: Dansk Fertilitetsklinik;
8. CPH: Fertilitetsklinikken Riberhus;
9. CPH: Fertilitetsklinikken Herlev Sygehus;
10. CPH: Fertilitetsklinikken Hvidovre Hospital;
11. CPH: Fertilitetsklinikken Rigshospitalet;
12. CPH: Fertilitetsklinikken Trianglen;
13. CPH: Gentofte Fertilitetsklinik;
14. CPH: Nordica Fertilitetsklinik
15. Dronninglund: Fertilitetsklinikken Dronninglund
16. Fredericia: Fertilitetsklinik-SYD
17. Holbæk: Fertilitetsklinikken Holbæk Sygehus
18. Horsens: Horsens Fertilitetsklinik
19. Randers: Randers Amtssygehus
20. Odense: Fertilitetsklinikken Odense Universitetshospital;
21. Odense IVF-Klinik
22. Skive: Fertilitetsklinikken Skive Sygehus

Estonia (Total N° clinics = 3 // // N° reporting clinics = 0)

Both private and public centres

1. Women's Clinic of Tartu University (PU)
2. Private clinic Nova Vita Tallin (PR)
3. Tallinn's National Eastern Hospital (PU)

Finland (Total N° clinics = 18 // N° reporting clinics = 18)

Both private and public centres

1. Helsinki: Diacor (PR)
2. Helsinki Family Federation of Finland Helsinki (PR)
3. Helsinki Felicitas (PR)
4. Helsinki Fertinova (PR)
5. Helsinki University Central Hospital (PU)
6. Joensuu: Northern Carelia Central Hospital (PU)
7. Jyväskylä: In-Tiimi Jyväskylä (PR)
8. Kuopio:In-Tiimi Kuopio (PR)

9. Kuopio University Central Hospital (PU)
10. Lappeenranta: Felicitas (PR)
11. Oulu: Family Federation of Finland Oulu (PR)
12. Oulu University Central Hospital (PU)
13. Tampere: AVA Tampere (PR)
14. Tampere Family Federation of Finland Tampere (PR)
15. Tampere University Central Hospital (PU)
16. Turku: AVA Turku (PR)
17. Turku: Family Federation of Finland Turku (PR)
18. Turku University Central Hospital (PU)

France (Total N° clinics = 102 // N° reporting clinics = 102)

1. Abymes : C.H.U. De Pointe a Pitre/Abymes
2. Aix en Provence : Centre Hospitalier du Pays d'Aix
3. Amiens: Clinique v Pauchet de Butler;
4. Amiens: Centre De Gyneco Obstetrique CHU Amiens
5. Angers: C.H.U. D' Angers
6. Avignon: Polyclinique Urbain V
7. Bagnolet: Clinique de La Dhuys
8. Bayonne: Clinique Lafargue
9. Beaumont : Clinique La Chataigneraie
10. Besancon: CHU Saint Jacques;
11. Besancon Polyclinique Franche-Comté
12. Blanc Mesnil: Hopital Privé de la Seine Saint Denis
13. Bois-Guillaume : Clinique Saint Antoine Bois Guillaume
14. Bondy : Hopital Jean Verdier
15. Bonneville : Hopital de Bonneville
16. Bordeaux : CHU de Pellegrin
17. Brest : CHRU hopital Morvan;
18. Brest : S.A. Clinique Pasteur Saint Esprit
19. Bruges : Polyclinique Jean Villar
20. Caen: CHR Georges Clemenceau Caen
21. Calais : CH Calais
22. Cayenne: Centre Hospitalier de Cayenne
23. Chambray-Les-Tours: Clinique « Le Parc »
24. Charleville-Mezieres: Hopital Manchester CH Charleville
25. Chesnay : Centre Medico Chirurgical de Parly II
26. Clamart : Hopital Antoine Béclère
27. Clermont-Ferrand : C.H.U. Hotel Dieu
28. Cormeilles En Parisis : Clinique du Parisis
29. Courbevoie : CH de Courbevoie Neuilly/Seine
30. Créteil : CHI de Creteil
31. Dijon : Hopital Le Bocage CHU Dijon
32. Dreux : Centre Hospitalier de Dreux
33. Ecully : Clinique du Val d'Ouest Vendome
34. Epinal : Clinique L'Arc en ciel
35. Equeudreville Hainneville :Polyclinique du Cotentin
36. Guilherand-Granges : Clinique Pasteur
37. Kremlin Bicetre : Hopital de Bicetre
38. Lens : CH Lens
39. Lille : Polyclinique du Bois;
40. Lille : Hop Jeanne de Flandre CHR Lille
41. Limoges : CHU Dupuytren Limoges
42. Lorient : Centre Hospitalier Bretagne Sud
43. Lyon 3ieme : Hopital Edouard Herriot
44. Lyon 8ieme: Clinique Montplaisir;
45. Mans : Clinique du Tertre Rouge
46. Marseille 5ieme: Hopital de la Conception
47. Marseille 6ieme : Clinique Bouchard

48. Marseille 8ieme: Hopital Saint Joseph
49. Metz : Maternité Hopital Sainte Croix Metz
50. Montivilliers : Hopital Jacques Monod CH Le Havre
51. Montpellier : Hopital Araud de Villeneuve CHU MPT;
52. Montpellier : Polyclinique Saint Roch
53. Mulhouse : Clinique du Diaconat
54. Nancy : Polyclinque Majorelle;
55. Nancy : Maternité Régionale A Pinard
56. Nantes : C.H.U. Nantes;
57. Nantes : Clinique Breteche Viaud Site Breteche;
58. Nantes : Clinique J. Verne Pole Hosp mutualiste
59. Neuilly sur Seine: Centre Chirurgical Pierre Chérest;
60. Neuilly sur Seine Hôpital Américain
61. Nice : Hopital de L'Archet;
62. Nice : Clinique Saint Georges
63. Nimes : Groupe Hospitalier Caremeau CHU Nimes
64. Paris 11ieme : Hopital des Métallurgistes
65. Paris 12ieme : Hopital des Diaconesses
66. Paris 13ieme : Groupe Hosp. Pitié Salpétrière
67. Paris 14ieme : Hopital Cochin;
68. Paris 14ieme Hopital Saint Vincent de Paul;
69. Paris 14ieme Institut mutualiste Montsouris
70. Paris 16ieme : Clinique de La Muette
71. Paris 18ieme : G.I.H. Bichat/ Claude Bernard;
72. Paris 20ieme : Hopital Tenon
73. Pau : Polyclinique de Navarre
74. Perigueux : Polyclinique Francheville
75. Perpignan : Clinique Saint Pierre
76. Poissy : C.H. Int. De Poissy/St Germain en Laye
77. Port : Clinique Jeanne D'Arc
78. Reims : Polyclinique de Courlancy;
79. Reims : Hopital Maison Blanche CHR Reims;
80. Rennes : C.H.R. Hopital Sud;
81. Rennes : ET. Soins La Sagesse Rennes
82. Roanne : CH de Roanne
83. Rochelle : Clinique du Mail
84. Rouen : Hopital Charles Nicolle CHU Rouen
85. Saint Etienne : Centre Hospitalisation privé de la Loire
86. Saint Herblain : Polyclinique de L'Atlantique
87. Saint-Jean : Nouvelle clinique de L'Union
88. Saint-Martin de Boulogne : Centre M.C.O. Cote D'Opale
89. Saint Martin d'Heres : Clinique Belledonne
90. Saint Priest en Jarez : Hopital Nord
91. Saint-Saulve : Clinique Maternite du Parc
92. Schiltigheim : Centre Medico Chirurg Obstetrical
93. Schoelcher: Clinique Sainte Marie
94. Senlis : Centre Hospitalier de Senlis
95. Sevres : CH Jean Rostand Sevres
96. Toulon : Clinique Saint Michel
97. Toulouse :Clinique Saint Jean Languedoc;
98. Toulouse : Hopital Paule de Viguier CHU Toulouse
99. Tours : C.H.R.U. Bretonneau
100. Tronche : Hopital de la Tronche
101. Villeurbanne : Clinique du Tonkin
102. Vitry Sur Seine : Clinique des Noriets

Germany (Total N° clinics = 122 // N° reporting clinics = 122)

Both private and public centres

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3. Aalen: IVF-Zentrum Aalen, Dr. med. Rainer Rau, Dr. med. Ute Burk, Petra Hetzel, Dr. rer. nat. Said Hassan, Dr. rer. nat. Roland Eid (PR)
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5. Augsburg: Dr. med. D. Steinfeld-Birg (PR)
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8. Bayreuth: Klinik am Hofgarten, Kinderwunschzentrum Bayreuth, Dr. phil. Dr. med. S. Todorow (PR)
9. Bedburg/Erft: Gemeinschaftspraxis Frauenheilkunde und Reproduktionsmedizin, Dr. med. Dieter Struller, Dr. med. Christof Etien (PR)
10. Berlin: Arbeitsgruppe Reproduktionsmedizin, Gemeinschaftspraxis im Lützow Center, Dr. med. Detlef H. G. Temme, Dr. med. Rolf Metzger (PR)
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12. Berlin: Gemeinschaftspraxis FERA im Wenckebach-Klinikum, Dr. med. Kay Moeller, Dr. med. Andreas Jantke, Dr. med. Peter Rott (PR)
13. Berlin: Kinderwunschzentrum Berlin, Dr. med. Reinhard Hannen, Dr. med. Christian F. Stoll (PR)
14. Berlin: Kinderwunschzentrum an der Gedächtniskirche, Dr. med. Matthias Bloechle, Dr. med. Silke Marr (PR)
15. Berlin: Kinderwunschzentrum am Innsbrucker Platz, Babette Remberg, Dr. med. Susanne Tewordt-Thyselius (PR)
16. Berlin: PraxisKlinik für Fertilität Am Gendarmenmarkt, Dr. med. David J. Peet, Dr. med. Peter Sydow (PR)
17. Berlin: Zentrum für Reproduktionsmedizin Helle Mitte -, Dr. med. M. Zaghloul-Abu Dakah, Swetlana Hoffmann (PR)
18. Bielefeld: Bielefeld Fertility-Center, Gemeinschaftspraxis Paul A. Ebert, Dr. med. Karl Völklein, Beata Szypajlo, Dr. med. Gabi Pfab-Völklein (PR)
19. Bielefeld: BIF - Bielefelder Institut für Fortpflanzungsmedizin (BIF), Städt- Kliniken Bielefeld gem. GmbH, -Klinikum Mitte-, Leitung: Chefarzt Prof. Dr. med. Joachim Volz (PU)
20. Bocholt: Fertility Center Münsterland, Dr. med. Ulrich Hilland (PR)
21. Bochum: FERTI-MED, Zentrum für Reproduktionsmedizin Bochum, Yvonne Giesner (PR)
22. Bonn: Praxisklinik für Gynäkologische Endokrinologie und Reproduktionsmedizin, PD Dr. Dr. med. Gernot Prietl (PR)
23. Bonn: Universitätsklinikum Bonn, Abteilung für Gynäkologische Endokrinologie und Reproduktionsmedizin, Prof. Dr. med. Hans H. van der Ven, Prof. Dr. med. Kathrin van der Ven, PD Dr. med. Christoph Dorn, Dr. med. Benjamin Rösing, Dipl. Biol. PD Dr. Markus Montag (PU)
24. Bremen: Bremer Zentrum für Fortpflanzungsmedizin (BZF) im Ev. Diakonie-Krankenhaus gGmbH, Prof. Dr. Ernst Heinrich Schmidt, Dr. Olaf Drost (PU)
25. Bremen: Gynäkologische Endokrinologie und Reproduktionsmedizin, Dr. A. von Stutterheim (PR)
26. Chemnitz: Chemnitzer IVF-Zentrum, CIZ, Frauenklinik-Chemnitz, Prof. Dr. med. Thomas Steck (PR)
27. Cottbus: Prof. Dr. med. habil. H.-H. Riedel, Carl-Thiem-Klinikum Cottbus gGmbH, Zentrum für Reproduktionsmedizin und gynäkologische Endokrinologie (PR)
28. Darmstadt: Reproduktionsmedizinisches und Endometriose Zentrum Darmstadt, Frauenklinik des Klinikum Darmstadt, Prof. Dr. G. Leyendecker (PR)

29. Deggendorf: Kinderwunschzentrum Niederbayern, Dr. Hans J. Kroiss, Dr. med. Elfriede Bernhardt (PR)
30. Dortmund: Kinderwunschzentrum Dortmund, Gemeinschaftspraxis PD. Dr. med. Stefan Dieterle / Dr. med. Andreas Neuer, PD Dr. med. Robert Greb (PR)
31. Dresden: Praxisklinik Dr. med. Hans Jürgen Held (PR)
32. Dresden: Universitätsklinikum Carl Gustav Carus, Klinik und Poliklinik für Frauenheilkunde und Geburtshilfe, Prof. Dr. med. W. Distler, Dr. rer. nat. G. Keck (PU)
33. Düsseldorf: Frauenklinik Benrath, Abteilung für Reproduktionsmedizin, Dr. B. Milcat-Drozdzynski, Dipl-Biol. E. Halbe (PU)
34. DD: Unikid-Universitäres-Interdisziplinäres Kinderwunschzentrum Düsseldorf, Prof. Dr. H. G. Bender, PD Dr. J. Krüssel (PU)
35. DD: Zentrum für Reproduktionsmedizin Düsseldorf, Dr. (B) Hugo Verhoeven, Dr. med. Michael Scholtes (Ph. D.), Dipl.-med. Kersten Marx, Dr. med. Martina Behler, Dr. med. Manfred Schulte (PR)
36. Erlangen: Gemeinschaftspraxis der Frauenärzte Dr. M. Hamori, Dr. R. Behrens, Dr. A. Hammel (PR)
37. Erlangen: Kinderwunschzentrum Erlangen, Dres. Jan van Uem und Madeleine Haas, Gynäkologische Endokrinologie und Reproduktionsmedizin (PR)
38. Erlangen: Universitätszentrum für Fortpflanzungsmedizin Franken, Prof. Dr. med. M. W. Beckmann, Dr. med. H. Binder (PU)
39. Essen: NOVUM – Zenrum für Reproduktionsmedizin, Prof. Dr. med. Thomas Katzorke, Dr. med. Dirk Propping, Dr. med. Susanne Wohlers, Prof. Dr. med. Peter Bielfeld (PR)
40. Esslingen: IVF-Zentrum Esslingen, Praxis Dr. med. J. E. Costea (PR)
41. Esslingen: Zentrum für Reproduktionsmedizin an der Städtischen Frauenklinik Esslingen, Prof. Dr. med. Dr. med. habil. H. W. Mickan, Dr. med. Chr. Stoll (PR)
42. Frankfurt/Main: Kinderwunschzentrum Frankfurt, Krankenhaus Nordwest GmbH, Prof. Dr. E. Merz (PU)
43. Frankfurt: Prof. Dr. med. Ernst Siebzehnrübl, Zentrum für Reproduktionsmedizin (PR)
44. Frankfurt: Schwerpunkt Gynäkologische Endokrinologie und Reproduktionsmedizin, Universitätsfrauenklinik Frankfurt, PD Dr. med. S. Kissler, PD Dr. med. I. Wiegratz (PU)
45. Freiburg: Centrum für gynäkologische Endokrinologie und Reproduktionsmedizin Freiburg (CERF),Gemeinschaftspraxis Dr. Weitzell, Dr. Thiemann, Prof. Dr. Geisthövel (PR)
46. Freiburg: Department Universitäts-Frauenklinik, Klinik für Endokrinologie und Reproduktionsmedizin, Dr. med Stephanie Friebel (PU)
47. Gelsenkirchen: Kinderwunschpraxis Gelsenkirchen, Dr. med. Ute Czeromin, Dr. med. Ina Walter-Göbel, Dr. med. Anke Beerkotte (PR)
48. Göttingen: Georg-August-Universität Göttingen, Frauenklinik, Kinderwunschsprechstunde, Prof. Dr. med. Dr. Bernd Hinney; Kinderwunschpraxis Göttingen, Dr. med. Monica Tobler, Reproduktionsmedizin / Gynäkologische Endokrinologie (PU)
49. Göttingen: Kinderwunschzentrum Göttingen, Dr. Sabine Hübner, Dr. Rüdiger Moltrecht, Dr. Thomas Welcker, Dr. Stephanie Mittmann, Dr. Peter Schulzeck (PR)
50. Grevenbroich: Praxisklinik und Zentrum für Familienplanung, gynäkologische Endokrinologie & Reproduktionsmedizin, Dres. Tigges, Friol, Gnoth (PR)
51. Halle/Saale: Universitätsklinikum Halle (Saale), Zentrum für Reproduktionsmedizin und Andrologie (ZRA), Univ.-Prof. Dr. med. Herrmann M. Behre, OÄ Dr. med. Petra Kaltwasser, Oass Dr. rer. nat. Ewald Seliger (PU)
52. Hamburg: BKS Zentrum für Hormondiagnostik und Kinderwunschbehandlung, Prof. Bohnet, PD Dr. Knuth, PD Dr. M. A. Graf (PR)
53. Hamburg: Endokrinologikum Hamburg, Zentrum für Hormon- und Stoffwechselerkrankungen, Reproduktionsmedizin und Pränatale Medizin, Ludwig & Partner (PR)
54. Hamburg: Fertility Center Hamburg, Praxisklink Fischer, Naether, Rudolf (PR)
55. Hamburg: Gynäkologicum Hamburg, Gemeinschaftspraxis Dres. med. Bispink, Horn, Michel & Seeler (PR)
56. Hmaburg: Kinderwunschzentrum Fleetinsel Hamburg, Dr. S. Kocak, Dr. H. P. Kohnen und Dr. U. Weidner (PR)
57. Hannover: Kinderwunschzentrum Langenhagen, Dr. M. Müseler-Albers, H. P. Arendt, Dr. K. Bühler, Dr. Th. Schill (PR)
58. Hannover: Medizinische Hochschule Hannover, Prof. Dr. H. W. Schlösser (PU)
59. Hannover: Team Kinderwunsch Hannover, Dr. Saymé und Kollegen (PR)

60. Heidelberg: Kinderwunschzentrum Heidelberg, Dr. Partra-Kehry, Dr. Parta,Tesarz, Dr. Seehaus (PR)
61. Heidelberg: Universitätsklinikum Heidelberg, Abt. Gynäkologische Endokrinologie und Fertilisationsstörungen, Prof. Dr. T. Strowitzki, PD Dr. M. v. Wolff, Dr. C. Thoene, Dr. S. Rösner, Dr. R. Popovici (PU)
62. Hildesheim: Zentrum für Reproduktionsmedizin und Humangenetik, Dr. F.-J. Algermissen, Dr. P. F. Justus, Dr. G. Wilke, Dr. N. Graf (PR)
63. Homburg: Klinik für Frauenheilkunde, Geburtshilfe und Reproduktionsmedizin, Universitätsklinikum des Saarlandes, Dr. P. Rosenbaum (PU)
64. Jena: Universitätsklinikum Jena, PD Dr. med. W. Starker, Dr. rer. nat. I. Hoppe (PU)
65. Jena: Reproduktionsmedizines Zentrum, PD Dr. med. H. Fritzsche, Dipl. med. J.-P. Reiher, Dr. med. A. Hoffmann (PR)
66. Karlsruhe: Karlsruher IVF-Programm, AG für Fortpflanzungsmedizin, Dr. V. Wetzel, H. J. Gräber, E. Wetzel, Dr. F. Tetens, Dr. G. Zoulek und Kollegen (Laborärzte), Dr. G. Schlüter (Humangenetikerin) (PR)
67. Kassel: Najib N. R. Nassar, Dr. med. Marc Janos Willi, Dr. med. Urte Reinhardt, Medizinisches Versorgungszentrum für Reproduktionsmedizin am Klinikum Kasse (PR)
68. Kiel: Kinderwunsch Kiel, Dr. med. Kurt Brandenburg, Dr. sc. agr. A. Bonhoff (PR)
69. Kiel: Sektion Reproduktionsmedizin, Universitätsfrauenklinik UK-SH, Campus Kiel, Christian-Albrechts-Universität Kiel, Prof. Dr. med. L. Mettler, Dr. med. A. Schmutzler (PU)
70. Köln: Kinderwunschzentrum Köln, Praxisklinik Schönhauser Straße, Eva Schwahn, Dr. med. Markus Merzenich (PR)
71. Köln:Klinik und Poliklinik für Frauenheilkunde und Geburtshilfe der Universität zu Köln, Funktionsbereich Gynäkologische Endokrinologie und Reproduktionsmedizin, OÄ PD Dr. med. Dolores Foth (PU)
72. Köln: PAN Institut für Endokrinologie und Reproduktionsmedizin, Gemeinschaftspraxis Dr. S. Palm, Dr. I. Pütz, Dr. M. Dannhof, Prof. Dr. Ch. Keck, c/o PAN-Klinik am Neumarkt (PR)
73. Leer: Zentrum für Fortpflanzungsmedizin Leer, Dr. med. Wolfgang von der Burg, Dr. med. Jutta Hoang (PR)
74. Leipzig: Praxisklinik City Leipzig, Dr. med. Astrid Gabert, Dr. med. Katharina Bauer (PR)
75. Leipzig: Praxisklinik für Gynäkologische Endokrinologie und Reproduktionsmedizin, Dr. med. F. A. Hmeidan, Dr. med. P. Jogschies & Partner (PR)
76. Leipzig: Universitätsfrauenklinik Leipzig, Zentrum für Reproduktionsmedizin, Gynäkologische Endokrinologie und Sexualmedizin, Prof. Dr. med. H. Alexander, Doz. Dr. med. D. Baier, Dipl. Biol. W. Weber (PU)
77. Lübeck: Universitäres Kinderwunschzentrum Lübeck, Prof. Dr. med. K. Diedrich, Dr. med. A. Schultze-Mosgau, Dr. med. G. Griesinger (PU)
78. Magdeburg: Klinik für Reproduktionsmedizin und Gynäkologische Endokrinologie, Otto-von-Guericke-Universität Magdeburg, Prof. Dr. med. J. Kleinstein, Dr. med. A. B. Brössner (PU)
79. Mainz: Johannes-Gutenberg-Universität, PD Dr. med. Rudolf Seufert M.Sc., Prof. Dr. med. Franz Fischl (PU)
80. Mainz: Kinderwunsch Zentrum Mainz, Dr. Robert Emig, Dr. med. Silke Mettlin (PR)
81. Marburg: Universitätsklinikum Gießen und Marburg GmbH, Standort Marburg, Klinik für Gynäkologie, Gynäkologische Endokrinologie und Onkologie, Reproduktionsmedizin und Osteologie, Prof. Dr. U. Wagner, Dr. Karin Bock, Dr. Klaus Baumann, Prof. Dr. Peyman Hadji, Dr. Volker Ziller (PU)
82. Mannheim: Kinderwunschzentrum, Universitätsfrauenklinik Mannheim, Prof. Dr. med. M. Sütterlin, Dr. med. T. Schmidt (PU)
83. Minden: Gemeinschaftspraxis Dr. med. Dipl.-Biochem. Onno Buurman, Dr. med. Michael Dumschat, Dr. med. Barbara Heidecker – privat - , Dr. med. Ralf Menckhaus (PR)
84. Mönchengladbach: Kinderwunschzentrum Mönchengladbach, Dr. med. Georg Döhmen, Dr. med. Thomas Schalk (PR)
85. Mühlheim a. d. Ruhr: Fertilitätszentrum Mühlheim, Evangelisches Krankenhaus Mühlheim an der Ruhr, Prof. Dr. H. von Matthiessen (PR)
86. München: Arbeitsgruppe Kinderwunsch Reproduktionsmedizin & Endokrinologie, Ludwig-Maximilians-Universität, Frauenklinik Innenstadt, PD Dr. Markus S. Kupka (PU)
87. Munchen: A.R.T.-Bogenhausen, Prof. Dr. med. Dieter Berg, Dr. med. Bernd Lesoine (PR)
88. Munchen: Hormonzentrum München, PD Dr. med. H.-U. Pauer, Dr. med. H. Lacher, Dr. med. J. Puchta, Dr. med. S. Michna (PR)
89. Munchen: Kinderwunsch Centrum München-Pasing ehem. an der Frauenklinik Dr. Krüsmann, Dr. med. Klaus Fiedler, Dr. med. Irene von Hertwig, Dr. med. Gottfried Krüsmann, Prof. Dr. Dr.

med. habil. Wolfgang Würfel, Ina Laubert, Dr. med. Claudia Santjohanser, Sabine Völker, Dr. med. Susann Böhm (PR)

90. Munchen: Kinderwunschzentrum der LMU-München-Grosshadern, Prof. Dr. med. Christian J. Thaler (PU)
91. Munchen: Zentrum für Reproduktionsmedizin, Dr. med. Walter Bollmann, Dr. med. Thomas Brückner, Dr. med. Ulrich Noss (PR)
92. Münster: IVF-Zentrum Münster, Dr. Dr. med. L. Belkien, PD Dr. med. B. Krause (PR)
93. Munster: Universitätsklinikum Münster, Klinik und Poliklinik für Frauenheilkunde und Geburtshilfe, Dr. med. Andreas Schüring, Prof. Dr. Ludwig Kiesel, Institut für Reproduktionsmedizin, Prof. Dr. med. Eberhard Nieschlag (PU)
94. Neubrandenburg: Prof. Dr. med. R. Sudik, Kinderwunschzentrum Neubrandenburg, Dietrich Bonhoeffer Klinikum Neubrandenburg (PU)
95. Neuwied: Kinderwunschzentrum Mittelrhein Neuwied & Koblenz, Dr. med. J. Beran, Dr. med. B. Mueller, A. Weber-Lohrum (PR)
96. Nürnberg: Gemeinschaftspraxis, Dr. med. J. Neuwinger, Dr. med. B. Munzer-Neuwinger (PR)
97. Nurnberg: Prof. Dr. P. Licht (PR)
98. Oldenburg: Tagesklinik Oldenburg, Zentrum für Kinderwunschbehandlung, Dr. med. Jörg Hennefründ, Dr. med. Heike Ochs-Ring, Dr. med. Michael Heeder (PR)
99. Oldenburg: Team Kinderwunsch Oldenburg, Dr. med. Saif Jibril, Dr. med. Gerhard Pohlig (PR)
100. Osnabrück: Zentrum für Kinderwunschbehandlung Osnabrück, Irene Coordes, Dr. med. Manfred Schneider (PR)
101. Pforzheim: Centrum für Reproduktionsmedizin, Praxis Verena Peuten (PR)
102. Prien am Chiemsee: Priener Centrum für Reproduktionsmedizin, Dr. med. Mathias Lehnert, Diana Krüger, Dr. rer. nat. Viktoria von Schönfeldt, Embryologin (PR)
103. Recklinghausen: Reprovita, Dr. med. Cordula Pitone (PR)
104. Regensburg: Kinderwunschzentrum Regensburg, Prof. Dr. med. habil. Bernd Seifert, PD Dr. med. Monika Bals-Pratsch (PR)
105. Remscheid: Institut für Gynäkologische Endokrinologie und Reproduktionsmedizin am Klinikum Remscheid, Dr. med. Johannes Luckhaus (PR)
106. Rostock: Praxiszentrum Frauenheilkunde, Gemeinschaftspraxis, PD Dr. med. H. Müller und A. Busecke (PR)
107. Saarbrücken: Gemeinschaftspraxis Dres. med. M. Thaele, L. Happel, A. Giebel, Zentrum für Gynäkologische Endokrinologie und Reproduktionsmedizin (PR)
108. Schwäbisch Gmünd:Klinikum Schwäbisch Gmünd, Abteilung Fortpflanzungsmedizin, Dr. med. R. Rau, Dr. rer. nat. R. Eid (PR)
109. Stuttgart: Frauenarztpraxis mit Tagesklinik Reproduktionsmedizin, Prof. Dr. med. Ute Fuchs (PR)
110. Stuttgard: Gynäkologie und Reproduktionsmedizin, Dr. med. Fred Maleika, Dipl. Biol. Dr. Silvia Harrer (PR)
111. Stuttgard: Praxis Villa Haag, Dr. D. B. Mayer-Eichberger, Zentrum für Reproduktionsmedizin (PR)
112. Trier: Kinderwunsch-Praxisklinik Trier, Dr.med. Mohsen Satari (PR)
113. Tübingen: Kinderwunsch- und Hormonsprechstunde, Universitäts-Frauenklinik Tübingen, OÄ Dr. Cosima Zeeb (PU)
114. Tubingen: Kinderwunschpraxis, Dr. med. Ulrich Göhring (PR)
115. Ulm: IVF-Zentrum Ulm, Dr. med. Friedrich Gagsteiger (PR)
116. Ulm: Praxisklinik Frauenstraße, Prof. Dr. med. K. Sterzik (PR)
117. Ulm: Universitätsfrauenklinik und Poliklinik, Zentrum für Reproduktionsmedizin und Gynäkologische Endokrinologie, Prof. Dr. med. J. M. Weiss (PU)
118. Viernheim: Viernheimer Institut für Fertilität, PD Dr. med. Stefanie Völz-Köster, Dr. med. Christina Nell, Dr. sc. Hum. Brigitte Hauff (PR)
119. Wetzlar: Kinderwunschzentrum Mittelhessen, Dr. med. Amir Hajimohammad (PR)
120. Wiesbaden: Kinderwunschzentrum Wiesbaden, Dr. med. Th. Hahn, Dr. med. M. Schorsch, Dr. med. G. Adasz, K. Schilberz (PR)
121. Würzburg: Gemeinschaftspraxis Dr. med. Reinhard Mai, Dr. med. Wolfgang Schmitt, Dr. med. Lore Mulfinger (PR)
122. Wurzberg: Universitäts-Frauenklinik Würzburg, Abteilung Gynäkologische Endokrinologie und Reproduktionsmedizin, Leiterin: Dr. med. Silke Blissing, OA Dr. T. Frambach, OA Dr. Th. Benar, OA PD L. Rieger (PU)

Greece (Total N° clinics = 50 // N° reporting clinics = 9)

Both private and public centres

1. Athens: Neogenesis IVF Center (PR)
2. Athens: Embryoland IVF (PR)
3. Athens: Eugonia - Medical Research (Iatriki Erevna) (PR)
4. Athens: Fertility Institute (PR)
5. Athens: IVF Unit, Alexandra Maternity Hospital (Pu)
6. Crete: Mediterranean Fertility Center& Genetic Services, Chania (PR)
7. Ioannina: IVF Unit, University of Ioannina (PU)
8. Thessaloniki: Infertility & IVF Center, Biogenesis Unit (PR)
9. Thessalia: Dept of OB/GYN, Medical School, University of Thessalia (PU)

Hungary (Total N° clinics = 10 // N° reporting clinics = 5)

1. Budapest: 1st Departement of OB/GYN, Semmelweis University, Faculty of Medicine; department of OB/GYN, 'Nuiro Gyula Hospital;
2. Budapest: Departement of OB/GYN, St. John's Hospital;
3. Budapest: Devai Institute;
4. Budapest: Forgacs Institute
5. Pécs: Departement of OB/GYN, Pécs University of Medicine

Ireland (Total N° clinics = 7 // N° reporting clinics = 6)

Only private centres

1. Clane: Assisted Conception Unit, Clane General Hospital, Clane, Co Kildare (PR)
2. Cork: Cork Fertility Centre, ¾ Fernhurst Villas (PR)
3. Dublin: Human Assisted Reproduction Ireland (HARI) Unit, Rotunda Hospital (PR)
4. Dublin: Merrion Fertility Clinic (PR)
5. Galway: Galway Fertility Unit, University College Hospital Galway (PR)
6. Kilkenny: The Kilkenny Clinic, Greens Hill, Kilkenny (PR)

Italy (Total N° clinics = 202 // N° reporting clinics = 202)

Both private and public centres

1 ABANO TERME (PD), Centro PMA - Casa di Cura Abano Terme (PU)

2 ANCONA (AN), Centro PMA - Presidio Ospedaliero G. Salesi (PU)

3 AOSTA (AO), Centro Sterilità – PMA (PU)

4 APPIANO GENTILE (CO), Le Betulle Casa di Cura s.r.l. - Poliambulatorio di Procreazione Medico Assistita (PR)

5 ARCO (TN), Centro Provinciale per la Procreazione Medicalmente Assistita - Ospedale Alto Garda e Ledro (PU)

6 AVELLINO (AV), Fisiopatologia della Riproduzione e Sterilità di Coppia - A.O.R.N. San Giuseppe Moscati di Avellino (PU)

7 BARI (BA), Centro di Fisiopatologia della Riproduzione Umana e PMA – U.O. Ostetricia e Ginecologia - Ospedale "Di Venere" di Carbonara (PU)

8 BARI (BA), Centro Medico "San Luca" (PR)

9 BARI (BA), Centro PMA - Casa di Cura Santa Maria (PU)

10 BARI (BA), U.O. di Fisiopatologia della Riproduzione Umana e Congelamento Gameti - A.O. Policlinico Consorziale di Bari (PU)

11 BENEVENTO (BN), Centro di Fisiopatologia della Riproduzione Umana - A.O.R.N. "G. Rummo" di Benevento - BENEVENTO (PU)

12 BERGAMO (BG), Centro PMA - U.O. Ostetricia e Ginecologia – A.O. Ospedali Riuniti di Bergamo - P.O. Ospedali Riuniti (PU)

13 BOLLATE (MI), Centro dell'Infertilità di Coppia - U.O. Ostetricia e Ginecologia – A.O. "G. Salvini" di Garbagnate - P.O. Caduti Bollatesi (PU)

14 BOLOGNA (BO), Centro di Sterilità e Fecondazione Assistita - A.O. di Bologna – Università degli studi di Bologna - Policlinico S.Orsola – Malpighi (PU)

15 BOLOGNA (BO), Poliambulatorio Privato GYNEPRO (PR)

16 BOLOGNA (BO), SISMER - Società Italiana Studio Medicina Riproduttiva (PR)

17 BOLOGNA (BO), Tecnobios Procreazione s.r.l. (PR)

18 BOLZANO (BZ), Centro Sterilità - Ospedale di Bolzano (PU)

19 BRA (CN), Centro PMA - Casa di Cura "Città di Bra" (PU)

20 BRESCIA (BS), Centro di Fecondazione Medicalmente Assistita – U.O. Ostetricia e Ginecologia - Casa di Cura "Istituto Clinico Città di Brescia" (PU)

21 BRINDISI (BR), Casa di Cura SALUS (PU)

22 BRINDISI (BR), PROBIOS s.r.l. Ginecologia (PR)

23 BRUNICO (BZ), Centro Sterilità - Ospedale di Brunico (PU)

24 CAGLIARI (CA), Centro per la Diagnosi e Cura della sterilità di Coppia – Università degli Studi di Cagliari - Ospedale S. Giovanni di Dio di Cagliari (PU)

25 CAGLIARI (CA), PROMEA - Casa di Cura Villa Elena (PU)

26 CAGLIARI (CA), Servizio Ostetricia e Ginecologia - Diagnosi Prenatale e Preimpianto –Opedale Regionale per le Microcitemico di Cagliari (PU)

27 CAMPOBASSO (CB), Centro Procreazione Medico Assistita - Ospedale Cardarelli (PU)

28 CARMAGNOLA (TO), Lisa srl (PR)

29 CASERTA (CE), CARAN - Medicina e Biologia della Riproduzione s.r.l. (PR)

30 CASERTA (CE), Centro GENESIS (PR)

31 CASERTA (CE), U.O. Fisiopatologia della Riproduzione - A.O. San Sebastiano di Caserta (PU)

32 CASTEL VOLTURNO (CE), I.D.F. Clinica Pineta Grande (PR)

33 CASTELFRANCO VENETO (TV), Promea srl - Ambulatorio Polispecialistico (PR)

34 CASTELVETRANO (TP), Hermes srl Servizi Sanitari Selinuntini (PR)

35 CATANIA (CT), A.O. "Cannizzaro" - U.O. Ginecologia e Ostetricia - Servizio di PMA (PU)

36 CATANIA (CT), ARNAS Garibaldi S. Luigi "Unità di Fertilizzazione in Vitro" – U.O. di Andrologia ed Endocrinologia della Riproduzione - P.O. Garibaldi (PU)

37 CATANIA (CT), Azienda Ospedaliera Universitaria V. Emanuele - Ferrarotto S. Bambino – Unità Operativa di Patologia ostetrica del P.O.S. S. Bambino (PU)

38 CATANIA (CT), Casa di Cura Falcidia srl (PR)

39 CATANIA (CT), Centro di Medicina della Riproduzione e Infertilità (PR)

40 CATANIA (CT), CRA s.r.l. Centro di Riproduzione Assistita (PR)

41 CATANIA (CT), G.M.R. - Ginecologia e Medicina della Riproduzione (PR)

42 .CATANIA (CT), Societa' Cooperativa U.M.R. - Unita' di Medicina della Riproduzione (PR)

43 CATTOLICA (RN), Ospedale Cervesi di Cattolica PU)

44 CHIANCIANO TERME (SI), Chianciano Salute - Centro di Chirurgia Ambulatoriale (PU)

45 CHIETI (CH), Casa di Cura Spatocco (PR)

46 CHIETI (CH), Centro di Medicina della Riproduzione - Clinica Ginecologica ed Ostetrica - Ospedale S.S. Annunziata - Università D'Annunzio (PU)

47 CITTA' SANT'ANGELO (PE), Casa di Cura Villa Serena del Dott. L. Petruzzi s.r.l. (PR)

48 CITTADELLA (PD), Centro di Fecondazione Medicalmente Assistita di Cittadella – U.O.A. Ostetricia e Ginecologia - Dipartimento Materno Infantile - P.O. di Cittadella (PU)

49 COMO (CO), Centro Terapia Infertilità di Coppia - Ospedale Classificato Valduce (PU)

50 CONEGLIANO (TV), Centro Regionale Specializzato di Fisiopatologia della Riproduzione - Ospedale Civile di Conegliano (PU)

51 ERICE (TP), Casa di Cura Sant'Anna Centro di PMA (PR)

52 FARA NOVARESE (NO), Poliambulatorio "I Cedri" (PR)

53 FERMO (AP), Casa di Cura Palmatea (PR)

54 FIRENZE (FI), Centro di Procreazione Assistita "Demetra" (PU)

55 FIRENZE (FI), Florence - Centro di Chirurgia Ambulatoriale ed Infertilità (PU)

56 FIRENZE (FI), Futura Diagnostica Medica - Procreazione Medicalmente Assistita s.r.l. (PU)

57 FIRENZE (FI), Servizio di Fisiopatologia della Riproduzione Umana – Università degli Studi di Firenze - A.O. Careggi (PU)

58 FOSSANO (CN), Centro per la Riproduzione Umana Assistita - Ospedale di Fossano (PU)

59 FRATTAMAGGIORE (NA), Centro Fecondazione Assistita - P.O. "S. Giovanni di Dio" - ASL N. di Napoli (PU)

60 FROSINONE (FR), Centro Medico Life (PR)

61 GENOVA (GE), Biotech (PR)

62 GENOVA (GE), Centro di Fisiopatologia della Riproduzione Umana – Dipt. Ostetricia ed Ginecologia Padiglione I Ospedale San Martino (PU)

63 GENOVA (GE), S.S. Medicina della Procreazione - Ospedale Galliera (PU)

64 GIOIA TAURO (RC), Gatjc S.a.s. (PR)

65 GIUGLIANO IN CAMPANIA (NA), Clinic Center HERA - Centro HERA srl (PR)

66 GRAGNANO (NA), Studio A.G.O.I. del Dott. A. M. Irollo(PR)

67 LAMEZIA TERME (CZ), C.I.S. Medicina Della Riproduzione (PR)

68 L'AQUILA (AQ), Centro di Procreazione Medicalmente Assistita - U.O.S. Dip. FIVET - Ospedale "San Salvatore" (PU)

69 LATINA (LT), U.O. Dipartimentale di Andrologia e Fisiopatologia della Riproduzione (PU)

70 LIVORNO (LI), Arca Service s.r.l. (PU)

71 LUGO (RA), Servizio di Fisiopatologia della Riproduzione Umana - P.O. di Lugo (PU)

72 MADDALONI (CE), IATREION s.r.l. - Medicina Polispecialistica (PR)

73 MANERBIO (BS), Dipartimento di PMA - U.O. Ostetricia e Ginecologia – A.O. di Desenzano del Garda - P.O. di Manerbio (PU)

74 MANTOVA (MN), Centro di Medicina della Riproduzione ed Endicronologia Ginecologica - U.O. Ostetricia e Ginecologia - A.O. Carlo Poma (PU)

75 MAZARA DEL VALLO (TP), Terzo Millenio s.r.l. (PR)

76 MERANO (BZ), EUBIOS (PR)

77 MERCOGLIANO (AV), Centro di Fisiopatologia della Riproduzione (PR)

78 MESSINA (ME), Centro Riproduzione Umana - Chirurgia Ambulatoriale - CRU s.r.l. (PR)

79 MESSINA (ME), U.S. Fisiopatologia della Riproduzione Umana - Centro PMA - Azienda Ospedaliera Papardo (PU)

80 MILANO (MI), "DANAEDONNA" - Studio Medico Associato A. e G. Testa (PR)

81 MILANO (MI), Andrologia e Riproduzione Assistita - U.O. Urologia II – A.O. "San Paolo" di Milano - P.O. San Paolo (PU)

82 MILANO (MI), Athena Lodovica s.r.l. - Lodovica Medical Center s.r.l. (PR)

83 MILANO (MI), Casa di Cura "Città di Milano s.p.a." (PR)

84 MILANO (MI), Casa di Cura IGEA - Sezione Procreazione Medico Assistita - U.O. Urologia (PU)

85 MILANO (MI), Centro di Fisiopatologia della Riproduzione Day Surgery – U.O. Ostetricia e Ginecologia-I.R.C.C.S. Ospedale San Raffaele (PU)

86 MILANO (MI), Centro di PMA - U.O. Ostetricia e Ginecologia - Casa di Cura "Santa Rita s.p.a" (PU)

87 MILANO (MI), Centro Endocrinologia, Sterilità e PMA (ESPA – U.O. Ostetricia e Ginecologia - A.O. Fatebenefratelli e Oftalmico - P.O. Macedonio Melloni (PU)

88 MILANO (MI), Centro per i disturbi della fertilità - U.O. Ostetricia e Ginecologia- A.O. Ospedale Niguarda Ca Granda - P.O. Ospedale Niguarda Ca Granda (PU)

89 MILANO (MI), Centro Sterilità - U.O. Ostetricia e Ginecologia - A.O. Luigi Sacco - P.O. Luigi Sacco (PU)

90 MILANO (MI), Fondazione Policlinico Mangiagalli e Regina Elena – Unità Operativa Complessa "Sterilità di Coppia e Andrologia" (PU)

91 MILANO (MI), MATRIS - Medici Associati per la Terapia e la Ricerca dell'Infertilità e Sterilità (PR)

92 MILANO (MI), SARA - Studio Associato Riproduzione Assistita (PR)

93 MILANO (MI), Servizi Sforza s.r.l. - Medicina della Riproduzione (PR)

94 MODENA (MO), Centro di Medicina della Riproduzione – Dip.to Integrato Materno Infantile - Sez. di Ginecologia ed Ostetricia - A.. Università di Modena (PU)

95 MOLFETTA (BA), One Day Surgery di Ginecologia - Ostetricia – Infertilità (PR)

96 MONTERIGGIONI (SI), Centro Servizi Montearioso s.r.l. (PR)

97 MONTICHIARI (BS), Centro di Procreazione Assistita - U.O. Ostetricia e Ginecologia –A.O. "Spedali Civili" di Brescia - P.O. di Montechiari (PU)

98 MONZA (MI), Centro di Medicina della Riproduzione - U.O. Ostetricie e Ginecologia - Istituto Clinici Zucchi (PU)

99 NAPOLI (NA), Biologia della Riproduzione "Crm - Napoli" presso casa di cura Villa del Sole (PR)

100 NAPOLI (NA), Casa di Cura Clinica Tasso Spa Centro Gynekos (PR)

101 NAPOLI (NA), Centro di Sterilita' - Az. Univ. Policlinico - Università degli Studi di Napoli Federico II° (PU)

102 NAPOLI (NA), Centro Mediterraneo di Fecondazione Assistita (PR)

103 NAPOLI (NA), Centro PMA del Dipartimento Assistenziale di Ostetricia, Ginecologia e Neonatologia – A.O.U. Policlinico - Seconda Università degli Studfi di Napoli (PU)

104 NAPOLI (NA), Centro Sterilità - Casa di Cura C.G. Ruesch S.P.A. (PR)

105 NAPOLI (NA), U.O.S.C. Ostetricia e Ginecologia - A.O.R.N. "A. Cardarelli" (PU)

106 NAPOLI (NA), U.O.S.D. Medicina della Riproduzione - P.O. "S. Giovanni Bosco" (PU)

107 NOVENTA VICENTINA (VI), Centro di Procreazione Medico Assistita - Presidio Ospedaliero II – Ospedale di Noventa Vicentina (PU)

108 ODERZO (TV), Centro per la Procreazione Medicalmente Assistita "Gianluigi Beltrame" - Ospedale di Oderzo (PU)

109 PADOVA (PD), Analisi Mediche Pavanello s.a.s. (PR)

110 PADOVA (PD), Centro di Procreazione Medicalmente Assistita - Università di Padova –A.O. di Padova - Clinica Ostetrica e Ginecologica (PU)

111 PADOVA (PD), Diaz s.r.l. - Casa di Cura Privata - Centro di PMA "GEMMA" (PR)

112 PADOVA (PD), Poliambulatorio Euganea Medica (PR)

113 PALERMO (PA), Casa di Cura Candela Spa (PR)

114 PALERMO (PA), Centro Andros s.r.l. (PR)

115 PALERMO (PA), Centro di Biologia della Riproduzione (PR)

116 PALERMO (PA), Centro di Fisiopatologia della Riproduzione - U.O. di Ostetricia e Ginecologia – Ospedale Ingrassia (PU)

117 PALERMO (PA), Centro di PMA Policlinico di Palermo - A.O.U.P. Giaccone – Clinica Ostetrica Ginecologica Universita' di Palermo (PU)

118 PALERMO (PA), Centro Procreazione Medicalmente Assistita Villa Serena (PR)

119 PALERMO (PA), Centro Procreazioni Assistite DEMETRA (PR)

120 PALERMO (PA), Centro Venezia - IVF SERVICE (PR)

121 PALERMO (PA), Genesi - Centro Chirurgia Medicina Riproduzione (PR)

122 PALERMO (PA), Nuova Casa di Cure Demma - A.M.B.R.A. (PR)

123 PALERMO (PA), Servizio di Fisiopatologia della Riproduzione Umana della Casa di Cure Orestano s.r.l. (PR)

124 PARMA (PR), Centro Incapacità Riproduttiva CIR - Clinica Ostetrica e Ginecologica – Azienda Ospedaliera -Universitaria di Parma (PU)

125 PAVIA (PV), Centro di Ricerca per la PMA - IRCCS Policlinico San Matteo - Università degli Studi di Pavia (PU)

126 PERUGIA (PG), Centro di Sterilità e Fecondazione Assistita – Struttura Semplice di Fisiopatologia della Riproduzione Umana - A.O. di Perugia – Università degli studi di Perugia (PU)

127 PESARO (PU), Azienda Ospedaliera San Salvatore di Pesaro (PU)

128 PIEVE DI CADORE (BL), Ospedale di Pieve di Cadore (PU)

129 PISA (PI), Casa di Cura Privata San Rossore (PR)

130 PISA (PI), Centro di Fisiopatologia della Riproduzione e Procreazione Assistita – Università degli Studi di Pisa - Ospedale Santa Chiara - A.O. Pisana (PU)

131 PONTE SAN PIETRO (BG), Centro di Medicina della Riproduzione BIOGENESI – U.O. Ostetricia e Ginecologia - Casa di Cura Policlinico San Pietro (PU)

132 PORCIA (PN), Villa Esperia (PR)

133 PORDENONE (PN), Struttura Operativa Semplice di Fisiopatologia della Riproduzione Umana e Banca del Seme (PU)

134 POTENZA (PZ), Servizio di Fisiopatologia della Riproduzione - c/o Ospedale San Carlo (PU)

135 QUARTU SANT'ELENA (CA), Casa di Cura Policlinico Citta' di Quartu (PU)

136 RAGUSA (RG), Centro PMA "ASTER" c/o Casa di cura "Clinica del Mediterraneo" (PR)

137 REGGIO NELL'EMILIA (RE), Centro per la Diagnosi e Terapia della Sterilità – A.O. Arcispedale S. Maria Nuova (PU)

138 REGGIO NELL'EMILIA (RE), Studio Diagnostico Raoul Palmer s.r.l (PR)

139 RENDE (CS), LIFE LAB - Studio Medico Specialistico di Riproduzione e Andrologia (PR)

140 ROMA (RM), A.S.I.C. - Associazione per lo Studio dell'Infertilità di Coppia (PR)

141 ROMA (RM), Alma Res (PR)

142 ROMA (RM), Ambulatorio Sterilità della "Fabia Mater" (PU)

143 ROMA (RM), ARS Biomedica srl (PR)

144 ROMA (RM), ARTEMISIA (PR)

145 ROMA (RM), Biogenesi - Clinica Villa Europa (PR)

146 ROMA (RM), C.I.P.A. - Centro Italiano Procreazione Assistita (PR)

147 ROMA (RM), Casa di Cura " Villa Salaria" - Servizio di Fisiopatologia della Riproduzione (PR)

148 ROMA (RM), Centre for Reproductive Medicine - Casa di Cura Nuova Villa Claudia (PR)

149 ROMA (RM), Centro Biofertility (PR)

150 ROMA (RM), Centro di PMA Umana - Ospedale S. Andrea – Università degli Studi di Roma "La Sapienza" – II° Facoltà di Medicina e Chirurgia - U.O.C. Ginecologia e Ostetricia (PU)

151 ROMA (RM), Centro di Sterilità - Istituto di Ginecologia ed Ostetricia presso Prof. Lanzone – Policlinico A. Gemelli - Università Cattolica del Sacro Cuore (PU)

152 ROMA (RM), Centro Genesis (PR)

153 ROMA (RM), Centro LEDA (PR)

154 ROMA (RM), Centro Procreazione Medicalmente Assistita - A.O. "San Filippo Neri" (PU)

155 ROMA (RM), Fisiopatologia della Riproduzione Umana - U.O. di Ginecologia e Ostetricia – Azienda Ospedaliera S. Camillo – Forlanini (PU)

156 ROMA (RM), GISPeS (Gruppo Italiano di Studio Permanente sulla Sterilità di Coppia e la Poliabortività (PR)

157 ROMA (RM), Grimaldi Medical srl - Centro Studi Fertilità di Coppia (PR)

158 ROMA (RM), Grimaldi Studi Medici - Centro Studi di Ginecologia, Fertilità e Parto (PR)

159 ROMA (RM), IRI - Istituto Romano di Infertilità e Sessuologia (ex-Villa Mafalda) (PR)

160 ROMA (RM), Machiavelli Medical House (PR)

161 ROMA (RM), Medicina e Biologia della Riproduzione - European Hospital (PR)

162 ROMA (RM), Praxi ProVita Centro di Fertilità (PR)

163 ROMA (RM), RAPRUI - Day Surgery - Ristemo Medica srl (PR)

164 ROMA (RM), Servizio Fisiopatologia della Riproduzione e Fecondazione - ASL RM A - Centro della Salute della Donna S. Anna (PU)

165 ROMA (RM), Servizio Speciale di Sterilità Coniugale (PU)

166 ROMA (RM), U.O.C BG Az. Policlinico Umberto I - Day Surgery, Laparoscopia e Riproduzione Assistita

(PU)

167 ROMA (RM), Unità Operativa Fisiopatologia Riproduzione e Terapia Infertilità - Ospedale Sandro Pertini (PU)

168 ROZZANO (MI), IRCCS Istituto Clinico Humanitas - U.O. Ostetricia e Ginecologia –Sezione di Patologia della Riproduzione (PU)

169 SALERNO (SA), C.M.R. s.r.l - Centro di Medicina della Riproduzione (PR)

170 SALERNO (SA), Fertilitas M.R.D.S. (Medicina della Riproduzione Day Surgery s.r.l. (PR)

171 SALERNO (SA), GEA Medicina della Riproduzione del Dott. Mario Cirmeni (PR)

172 SALERNO (SA), Mediterraneo Medicina della Riproduzione (PR)

173 SASSARI (SS), Centro per PMA - Istituto di Ginecologia e Ostetricia – Ospedale SS. Annunziata di Sassari - Università di Sassari (PU)

174 SELVAZZANO DENTRO (PD), Poliambulatorio Tencarola (PR)

175 SIENA (SI), Centro Diagnosi e Cura Sterilità - Università degli Studi di Siena –U.O. Ostetricia e Ginecologia - Policlinico Le Scotte - P.O. Senese (PU)

176 SONDRIO (SO), Centro Sterilità della Coppia - U.O. Ostetricia e Ginecologia – A.O. della Valtellina e della Valchiavenna - P.O. Ospedale Civile (PU)

177 SORA (FR), Centro S.T.S. di Polsinelli Francesco & C. s.a.s. (PR)

178 TARANTO (TA), CREA S.R.L. Centro Riproduzione e Andrologia (PR)

179 THIENE (VI), Centro di Procreazione Medico Assistita - Ospedale di Thiene (PU)

180 TORINO (TO), C.M.R. Centro di Medicina Riproduttiva e Procreazione Assistita (PR)

181 TORINO (TO), Centro Medicina della Riproduzione - Dipt. Disciplina Ginec. e Ostetriche – Univ. degli Studi di Torino (PU)

182 TORINO (TO), Centro Clinico San Carlo di Fecondazione Assistita e Ginecologia (PR)

183 TORINO (TO), Centro di Fisiopatologia della Riproduzione Ospedale "Maria Vittoria" (PU)

184 TORINO (TO), Ginecologia Endocrinologica - Centro FIVER Torino - Ospedale Sant'Anna (PU)

185 TORINO (TO), Livet s.r.l. (PR)

186 TORINO (TO), Promea s.p.a. (PU)

187 TRECENTA (RO), Centro PMA - Presidio Ospedaliero S. Luca - Trecenta - ULSS di Rovigo (PU)

188 TRENTO (TN), Gynepro srl (PR)

189 TREVISO (TV), Salute e Cultura - Centro satellite SISMER (PR)

190 TRIESTE (TS), SSD Procreazione Medicalmente Assistita - IRCCS Burlo Garofalo (PU)

191 UDINE (UD), Casa di Cura "Città di Udine" (PR)

192 VALLO DELLA LUCANIA (SA), Centro di PMA - U.O. Ostetricia e Ginecologia – P.O. San Luca di Vallo della Lucania (PU)

193 VARESE (VA), Centro Diagnostico Varesino (CDV). (PR)

194 VENEZIA (VE), ARC STER - Centro Studi per la Terapia della Sterilità della Coppia SRL (PR)

195 VENEZIA (VE), Centro di Procreazione Medicalmente Assistita P.O.di Mestre – U.O. Ostetricia e Ginecologia Azienda U.L.S.S. Venezia (PU)

196 VENEZIA (VE), Venice Fertility (PR)

197 VERONA (VR), Centro Athena (PR)

198 VERONA (VR), Centro per la Diagnosi e Cura della Sterilità di Coppia - Ospedale Policlinico G.B. Roma (PU)

199 VERONA (VR), Studio Medico "Tethys" (PR)

200 VIAREGGIO (LU), Centro di Riproduzione Assistita - U.O.C. Ostetricia e Ginecologia - Ospedale Versilia (PU)

201 VICENZA (VI), Centro Medico Palladio (PR)

202 VIGNOLA (MO), San Tommaso Day Surgery (PR)

Latvia (Total N° clinics = 1// N° reporing clinics = 1)

Only private centres (public are allowed)

1. Riga : Clinic EGV (PR)

Lithuania (Total N° clinics = 3 // N° reporting clinics = 2)

Only private centres

1. Vilnius: Fertility Center (PR)
2. Vilnius: Fertility Clinic (PR)

Luxemburg (Total N° clinics = 1 // N° reporting clinics = 0)

Only public centres

1. Luxembourg: Centre hospitalier Luxembourg (PU)

Malta (Total N° clinics = 2 // N° reporting clinics = 0)

Both private and public centres

1. Zabbar: St. James Hospital (PR)
2. Msida: Mater Dei Hospital (PU)

Poland (Total N° clinics = 32 // N° reporting clinics = 17)

Both private and public centres

1. Bialystok: Department of Reproductive Medicine and Gynecological Endocrinology, Medical University of Bialystok (PU)
2. Bialystok: Center for Reproductive Medicine "Kriobank" (PR)
3. Gdansk: „Invicta" Fertility and Reproductive Center (PR)
4. Katowice: 'Provita' Centrum Leczenia Nieplodnosci i Diagnostyki Prenatanej (PR)
5. Krakow: "Maternity" Infertility Diagnosis and Treatment Centre (PR)
6. Krakow: In Vitro Centrum Jaroslaw Janeczko MD (PR)
7. Lodz: "Gameta" Fertility Center (PR)
8. Lodz: "GRAVITA" Diagnosis and Infertility Treatment Wojciech Gontarek MD (PR)
9. Lublin: Family Health Center 'AB OVO'- Infertility treatment (PR)
10. Lublin: 'OVUM' Rozrodczosc I Andrologia (PR)
11. Myslowice: Fertility Center "Novomedica" Ltd. (PR)
12. Opole: GMW-Embrio Sp.Zo.o (PR)
13. Poznan: Division of Infertility and Reproductive Endocrinology, Karol Marcinkowski University of Medical Sciences (PU)
14. Poznan: Infertility Center "MEDART" (PR)
15. Warsaw: Center for Reproductive Medicine, I Clinic of Obstetrics and Gynecology, University Medical School in Warsaw (PU)
16. Warsaw: Private Clinic "NOVUM (PR)
17. Wroclaw: POLMED Nonpublic Health Center 'POLAK' CP (PR)

Portugal **(Total N° clinics = 21 // N° reporting clinics = 19)**

Both private and public centres

1. Coimbra: FERTICENTRO (PR)
2. Espinho: COGE (PR)
3. Guimarães: Hospital N. S. da Oliveira (PU)
4. Lisboa: Ava Clinic (PR)
5. Lisboa British Hospital (PR)
6. Lisboa CEMEARE (PR)
7. Lisboa CLINDIGO (PR)
8. Lisboa Hospital de Santa Maria (PU)
9. Lisboa CLIFER (PR)
10. Lisboa Imoclinica (PR)
11. Lisboa IVI-Lisboa (PR)
12. Oporto: Centro de Genética Prof. Alberto Barros (PR)
13. CEIE (PR)
14. CETI (PR)
15. Hospital de Santo António (PU)
16. Hospital de S. João (PU)
17. Maternidade Júlio Dinis (PU)
18. Ponta Delgada: Clínica do Bom Jesus (PR)
19. Vila Nova de Gaia: Centro Hospitalar (PU)

Romania List of establishments not provided

Slovakia List of establishments not provided

Slovenia **(Total N° clinics = 3 // N° reporting clinics = 3)**

Only public centres

1. Ljubljana: Univerzitetni klinični center Ljubljana (PU)
2. Maribor: Klinika za ginekologijo in perinatologijo, UKC Maribor (PU)
3. Postojna: Bolnišnica za ginekologijo in porodništvo (PU)

Spain **(Total N° clinics = 182 // N° reporting clinics = 107)**

Both private and public centres

1. A Coruña: IRAGA (PR)
2. A Coruna: Maternidad Belén (PR)
3. Albacete: Hospital General de Albacete (PU)
4. Alicante: Hospital General de Alicante (PU)
5. Alicante: Clínica Vista Hermosa de Alicante (PR)
6. Alicante: Clínica Ufeal (PR)
7. Alicante: H. General de Elche (PU)
8. Alicante:IVI Alicante (PR)
9. Almeria: IVI Almería (PR)
10. Almeria:Unidad de Reproducción Hospital Virgen del Mar (PU)

11. Almeria:Roquetas FIV (PR)
12. Almeria:CIRA Mediterráneo (PR)
13. Asturias: CEFIVA Oviedo (PR)
14. Asturias:CEFIVA Gijón (PR)
15. Asturias:Hospital Central de Asturias (H UCA Unidad de Reproducción) (PU)
16. Badajoz: Instituto Extremeño de Reproducción Asistida (PR)
17. Badajoz: Complejo Hospitalario Infanta Cristina (CERHA) (PU)
18. Baleares: Instituto Balear de Fertilidad (PR)
19. Baleares:CEFIVBA (PR)
20. Baleares:Hospital Universitario Son Dureta (PU)
21. Barcelona: Institut Dexeus (PR)
22. Barcelona:IVI Barcelona (PR)
23. Barcelona:CERHVO (PR)
24. Barcelona:Hospital Clínic de Barcelona (PU)
25. Barcelona:CIRH (Centro de Infertilidad y Reproducción Humana, Dr. Brassesco) (PR)
26. Barcelona:Instituto Pous (PR)
27. Barcelona:Centro MédicoTeknon Dr. Nadal (PR)
28. Barcelona:Centro Médico Teknon Dr. Bachs (PR)
29. Barcelona: Fertilab (PR)
30. Barcelona:Gine-3. IMER (PR)
31. Barcelona:Fecunmed (PR)
32. Barcelona:Hospital de la Santa Creu i San Pau-Fundación Puigvert (PU)
33. Barcelona : Unitat Endocrinología Ginecológica (PR)
34. Caceres: Clínica Norba (PR)
35. Cadiz: Consulta Dr. Enciso (PR)
36. Cadiz: Clínica Serman Unidad de Reproducción (PR)
37. Cadiz:UltraFIV-Bahía (PR)
38. Canarias: Instituto Canario de Infertilidad S.L. (Ali Mashlab) (PR)
39. Canarias: Centro de Asistencia a la Reproducción Humana de Canarias (Angela Palumbo) (PR)
40. Canarias: Hospital Universitario Materno Infantil de Las Palmas de Gran Canaria (PU)
41. Canarias: CIRA Las Palmas (PR)
42. Canarias: Hopital Universitario de Canarias-Tenerife (PU)
43. Cantabria: Unidad de Reproducción del Hospital de Valdecilla (PR)
44. Ciudad Real: FIV Recoletos (PR)
45. Cordoba: Clinica BAU (PR)
46. Gipuzkoa: Clínica El Pilar de San Sebastián (PR)
47. Gipuzkoa:Clínica Quirón San Sebastián (PR)
48. Gipuzkoa:Policlínica Guipuzcoana (PR)
49. Granada: Hospital Virgen de las Nieves (PU)
50. Granada:Clínica Sanabria (PR)
51. Granada:Clínica Inmaculada (PR)
52. Granada:CRH Granada (PR)
53. Guadalajara: FIV Recoletos (PR)
54. Huelva: Fertimed (PR)
55. Jaen: H. Ciudad de Jaén (PU)
56. La Rioja: Clínica Ginecológica Juana Hernández (PR)
57. La Rioja: Centro Ginecológico Manzanera (PR)
58. León: Centro Ginecológico de León (PR)
59. León: FIV Ponferrada (PR)
60. Lleida: CIRH (PR)
61. Madrid: IVI Madrid (PR)
62. Madrid:Instituto de Ginecología y Reproducción ”La Cigüeña » (PR)
63. Madrid:FIV Madrid (PR)
64. Madrid:GINEFIV Madrid (PR)
65. Madrid:Clínica Tambre (PR)
66. Madrid: U.R.H García del Real (PR)
67. Madrid:Hospital Universitario Madrid-Montepríncipe (PU)
68. Madrid: Hospital de Alcorcón (PU)
69. Madrid:Centro de Reproducción Jose Mª Nava (PR)

70. Madrid:Hospital Gregorio Marañón (PU)
71. Madrid:Hospital La Paz (PU)
72. Madrid:IGMR Ordás y Palomo (PR)
73. Madrid:Clínica Ruber Internacional (PR)
74. Madrid:Hospital 12 de Octubre (PU)
75. Malaga: Malaga FIV (PR)
76. Malaga:Clínica Rincón (PR)
77. Malaga: Centro de Reproducción Asistida de Marbella (CERAM) (PR)
78. Malaga:Centro Gutemberg (PR)
79. Malaga:Hospital Materno-Infantil Carlos Haya (PR)
80. Malaga:Clínica Fertia (PR)
81. Malaga: Hospital Xanit (PR)
82. Malaga: CEMAR (PR)
83. Murcia: IVI Murcia (PR)
84. Murcia:IMFER (PR)
85. Pontevedra: Hospital Xeral Cíes (PR)
86. Pontevedra: Hospital Nuestra Señora de Fátima (PU)
87. Pontevedra:Centro Médico Pintado (PR)
88. Pontevedra:IVI Vigo (PR)
89. Sevilla: IVI Sevilla (PR)
90. Sevilla:GINEMED (PR)
91. Sevilla: Hospital Universitario Virgen del Rocio (PU)
92. Sevilla:CEHISPRA (PR)
93. Sevilla:Instituto Génesis (PR)
94. Sevilla:CIVTE (PR)
95. Valencia: IVI Valencia (PR)
96. Valencia: HU La Fe (PU)
97. Valencia:IMER (PR)
98. Valencia:Clínica Quirón Valencia (PR)
99. Valencia: Unidad de Reproduccion del Hospital General Universitario (PU)
100. Valladolid: FIV Recoletos (PR)
101. Vizcaya: Clínica Euskalduna (PR)
102. Vizcaya:Clínica Ginecológica de Bilbao (PR)
103. Vizcaya:Consultorio Ginecológico Elkano (PR)
104. Vizcaya:Quirón Bilbao (PR)
105. Vizcaya:Hospital de Cruces (PU)
106. Zaragoza: Hospital Miguel Servet (PU)
107. Zaragoza: Clínica Montpellier (PR)

Sweden (Total N° clinics = 14// N° reporting clinics = 14)

Both private and public centres

1. Falun: IVF unit, Falu Hospital (PR)
2. Göteborg: Fertility Center, Carlanderska Hospital (PR)
3. Reproduktionsmedicin, Sahlgrenska University Hospital (PU)
4. Linköping: IVF unit, RMC, Linköping University Hospital (PU)
5. Malmö: Curakliniken (PR)
6. Öresundskliniken (Ideon) (PR)
7. Örebro: IVF unit, Örebro University Hospital (PU)
8. Stockholm: IVF Stockholm; St Görans Hospital (PR)
9. IVF unit, Huddinge University Hospital (PU)
10. IVF unit, Sophiahemmet (PR)
11. Lucinakliniken; RMC Karolinska University Hospital (PR)
12. Umeå: IVF unit, Norrlands University Hospital,Umeå (PR)
13. Uppsala: Carl von Linné Kliniken (PU)
14. Reproductive center, Academic Hospital (PR)

The Netherlands (Total N° clinics = 13// N° reporting clinics = 13)

Only public centres

1. Amsterdam: Academisch Medisch Centrum (PU)
2. Vrije universiteit Medisch Centrum (PU)
3. Eindhoven: Catharina Ziekenhuis (PU)
4. Groningen: Universitair Medisch Centrum Groningen (PU)
5. Leiden: Leids Universitair Medisch Centrum (PU)
6. Leiderdorp: MCK (PU)
7. Maastricht: Universitair Medisch Centrum Maastricht (PU)
8. Nijmegen: Universitair Medisch Centrum Nijmegen (PU)
9. Rotterdam: Erasmus Medical centre (PU)
10. Tilburg: St. Elisabeth Ziekenhuis (PU)
11. Utrecht: Universitair Medisch Centrum Utrecht (PU)
12. Voorburg: Reiner de Graaf Groep (PU)
13. Zwolle: Isala (PU)

United Kingdom (Total N° clinics = 70// N° reporting clinics = 70)

1. Aberdeen: Aberdeen Fertility Centre
2. Aldridge: Midland Fertility Services
3. Bath: Bath Fertility Centre
4. Belfast: Origin Fertility Care;
5. Belfats: Regional Fertility Centre, Belfast
6. Birmingham: Birmingham Women's Hospital;
7. Birmingham: BMI Priory Hospital
8. Brentwood: Brentwood Fertility Centre
9. Bristol: Centre for Reproductive Medicine, University of Bristol (now closed);
10. Bristol: Southmead Hospital
11. Burton Upon Trent: Burton Hospitals NHS Trust
12. Cambridge: Bourn Hall Clinic;
13. Canterbury: BMI The Chaucer Hospital
14. Cardiff: IVF Wales
15. Cheshunt: Herts and Essex Fertility Centre
16. Colchester: Isis Fertility Centre
17. Coventry: Centre for Reproductive Medicine, Coventry
18. Darlington: London Women's Clinic, Darlington
19. Dorchester: The Winterbourne Hospital
20. Dundee: Ninewells Hospital
21. Eastbourne: Sussex Downs Fertility Centre
22. Edinburgh: Edinburgh Assisted Conception Unit
23. Exeter: Peninsular Centre for Reproductive Medicine
24. Gateshead: The Gateshead Fertility Unit
25. Glasgow: Glasgow Nuffield Hospital;
26. Glasgow: Glasgow Royal Infirmary;
27. Glasgow: Glasgow Centre for Reproductive Medicine
28. Great Missenden: The Chiltern Hospital Fertility Services Unit
29. Hartlepool: Hartlepool General Hospital
30. Hull: Hull IVF Unit
31. Leeds: Assisted Conception Unit, St James' University Hospital – Leeds;
32. Leeds: Clarendon Wing - Leeds
33. Leicester: Leicester Fertility Centre;
34. Liverpool: Hewitt Centre for Reproductive Medicine
35. London: Assisted Conception Unit, King's College Hospital;
36. London: Assisted Reproduction and Gynaecology Centre;

37. London: Barts and The London Centre for Reproductive Medicine;
38. London: Chelsea & Westminster Hospital;
39. London: CRM London;
40. London: Cromwell IVF and Fertility Centre, London (now closed);
41. London: Guys Hospital;
42. London: Homerton University Hospital;
43. London: London Female And Male Fertility Centre;
44. London: London Fertility Centre;
45. London: Reproductive Genetics Institute (now closed);
46. London: The Bridge Centre;
47. London: IVF Hammersmith;
48. London: The Harley Street Fertility Centre;
49. London: The Lister Fertility Clinic;
50. London: The Centre for Reproductive and Genetic Health
51. Manchester: CARE Manchester;
52. Manchester: Manchester Fertility Services LTD;
53. Manchester: St Mary's Hospital
54. Liddlesbrough: The James Cook University Hospital
55. Newcastle Upon Tyne: Newcastle Fertility Centre at Life
56. Northampton: CARE Northampton
57. Nottingham: CARE Nottingham;
58. Nottingham: NURTURE;
59. Orpington: BMI Chelsfield Park ACU
60. Oxford: Oxford Fertility Unit
61. Plymouth: South West Centre for Reproductive Medicine
62. Salisbury: Salisbury Fertility Centre
63. Sheffield: CARE Sheffield;
64. Shefield: Centre for Reproductive Medicine and Fertility, Sheffield
65. Shrewsbury: Shropshire and Mid-Wales Fertility Centre
66. Southampton: Wessex Fertility Limited
67. Swansea: London Women’s Clinic, Swansea
68. Tunbridge Wells: South East Fertility Clinic
69. Woking: The Woking Nuffield Hospital
70. Wolverhampton: St Jude's Women’s Hospital

Annex 6a: Cross border reproductive care in six European countries

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Abstract

BACKGROUND: The quantity and the reasons for seeking cross border reproductive care are unknown. The present paper provides a picture of this activity in 6 selected European countries receiving patients.

METHODS: Data were collected from 46 ART centres, voluntarily participating in 6 European countries receiving cross border patients. All treated patients treated in these centres during one calendar month filled an individual questionnaire containing their major socio-demographic characteristics, the sought treatment and the reason to cross their borders.

RESULTS: In total, 1230 forms were obtained from the 6 countries: 29.7% from Belgium, 20.5% from Czech republic, 12.5% from Denmark, 5.3% from Slovenia, 15.7% from Spain, and 16.3% from Switzerland. Patients originated from 49 different countries. Among the cross border patients participating, almost two-thirds came from 4 countries Italy (31.8%), Germany (14.4%), The Netherlands (12.1%) and France (8.7%). Women' mean age was 37.3 years for all countries (range 21 - 51 years), 69.9% were married, and 90% were heterosexual. Their reasons for crossing borders for treatment varied between countries of origin: legal reasons were predominant for patients travelling from Italy (70.6%), Germany (80.2%), France (64.5%), Norway (71.6%), and Sweden (56.6%). Better

access was more often noted for UK patients (34.0%) than for the other countries of origin. Quality was an important factor for patients from most countries.

CONCLUSIONS: The cross border phenomenon is now well entrenched. The data show that many patients travel to evade restrictive legislation in their own country, and that support from their home health providers is variable. There may be a need for professional societies to establish standards for cross border reproductive care.

Key words: access, cross border reproductive care, ethics, public health

Introduction

An unknown, but probably substantial, number of couples travel to another country in order to obtain fertility treatments with assisted reproductive technology (ART) as well as intrauterine inseminations (IUI). This phenomenon has had several names over the last few years, and we have settled for the neutral descriptive term of "cross border reproductive care" (ESHRE Taskforce on Ethics and law, 2008). The semantic arguments have been well rehearsed, and the terminology ranges from the derogatory "tourism" to our pragmatic choice, via the politically charged "exile" (Pennings 2002, 2004, 2005 and 2006; Matorras, 2005; Inhorn and Patrizio, 2009).

Cross border health care, and more specifically reproductive care, is of concern to patients, practitioners and policy makers (Commission of the European Communities, 2008) alike, but only limited data on such movements or their reasons have yet been published. There are several reasons to explain such movements, among which the most frequent are law evasion, difficulty of access and expected quality of care (ESHRE Taskforce on Ethics and law, 2008).

This practice of going to another country may be viewed as a local limitation of rights to access reproductive care or as the exercise of patients' autonomy (Pennings, 2006). Indeed, cross border medical care is encouraged by European Union policy plans (European Commission, 2008), ~~(new r~~although there is no certainty as yet when and whether fertility treatment will be part of this planned package. It raises many questions, amongst which the differences in national laws and their practical effect on clinical practice and especially safety of the patients. This topic is often discussed with spectacular press titles (Dawar, 2009). However, no data exist to date, apart from one study representing Belgium incoming flow of foreign patients over 5 years (Pennings et al., 2009). There was thus clearly a need for quantitative and qualitative information. ESHRE, as the main European professional and scientific organisation in infertility, felt very concerned by this public health problem and decided to start a Taskforce on this topic. The Taskforce initiated a large multinational prospective study.

The initial purpose of the study was to get an estimate of the number of women/couples who cross borders, and of the reasons for them to make such a choice. It was not the intention to analyse the results of the treatments. In practice, it is almost impossible to obtain an estimate of the proportion of patients exiting their own country, as no data are kept in countries of origin. There is one Italian estimate of this phenomenon (Ossevatorio Turismo procreativo, 2006), prompted by the restrictive change of legislation in 2004, which started an exodus of patients to less restrictive climes (Ferraretti et al., 2009). We therefore chose to study recipient countries, and the reasons patients had to cross borders. Additionally the help / support from their own country was investigated.

Methods

A collaboration between two ESHRE groups, the European IVF Monitoring (EIM) and the Taskforce on Ethics and Law was started in 2008, with 3 members of each group planning the study, and designing 2 questionnaires.

Based on the knowledge of the two ESHRE groups and their national contacts, it was found feasible to conduct this study in the following 6 countries: Belgium, the Czech Republic, Denmark, Switzerland, Slovenia and Spain. In each country the contact and information to ART centres were performed by a local national coordinator, as listed in the acknowledgement. Those centres that accepted to participate received the summarized protocol, the forms and instructions. They were asked to enrol all women coming from abroad for an ART or IUI cycle during one calendar month. The patient form consisted in a simple, one page questionnaire, containing the main socio-demographic characteristics (age, marital status, sexual orientation, patient's and partner's education), the main reasons for crossing borders (law evasion, inaccessibility, quality of care), the type of treatments sought, the information received by the patients, and the degree of support/help from their doctor. We also enrolled the help of several colleagues (acknowledgement), who translated the instructions to participating collaborators and the questionnaires in all languages of the recipient countries and of the expected cross border patients

More specifically, we asked whether the type of treatment sought was illegal in their home country, or illegal because of their specific socio demographic characteristics, inaccessible because of waiting list, distance or cost, or whether they expected better quality of care or had previous treatment failure. In the case of gamete/embryo donation, we also asked specifically whether the reason for crossing borders included a wish for anonymous, identifiable, or known donation. Whenever appropriate, patients could tick more than one answer. Almost all questions were closed questions (the questionnaire is shown in the appendix). In addition each clinic was asked to fill a short questionnaire, recording the total number of treatment cycles performed during the same month. The survey was conducted between October 2008 and March 2009.

The patients forms contained no patient or centre identification. The study was approved by ethics committees, according to the rules of each specific collaborating country. Patient participation was anonymous.

Data were entered at ESHRE Central office, and analysed at INSERM with the SAS software system, version 9.1 (SAS institute inc. Cary , NC, USA). In this paper, results are presented by country of

origin and by country of destination. Statistical methods include variance analysis and chi square according to the nature of the variables.

Results

1. General description

In total, 1230 forms were received by ESHRE Central office, from 46 clinics participating in the 6 countries (Table I): Belgium 29.7%, 20.5% from the Czech republic, 12.5% from Denmark, 16.3% from Switzerland, 15.7% from Spain, and 5.3% from Slovenia. In Slovenia all clinics collaborated (3/3) and in Denmark 21/24, in Belgium 50% of clinics, and only a few self-selected centres participated in the 3 other countries. Patients came from 49 countries (see addendum), among which four countries were particularly represented, with more than 100 forms returned to ESHRE's Central Office each (Table I): Italy (31.8%), Germany (14.8%), the Netherlands (12.1%) and France (8.7%). The following countries returned more than 50 forms each: Norway (5.5%), the UK (4.3%) and Sweden (4.3%). The remaining 42 countries of origin represented less than 19% of forms (n=233). Table I provides an overview of all 1230 women. It also shows that most Italians went to Switzerland and Spain, most Germans to the Czech Republic, most Dutch and French patients to Belgium and a few to Spain and most Norwegians and Swedish to Denmark. Other tables focus on the seven main contributors.

2. Socio-demographic characteristics

The mean age (Table II) was 37.3 years (range 21 to 51 years). The proportion of women aged 40 or more was 34.9% for the whole sample, and reached 51.1% for Germany and 63.5% for the UK, compared to 32.2% for Italy and 30.2% for France.

Civil status was also very different according to the countries of residence (Table III). In total, 69.9% of women were married, 24.0% cohabiting and 6.1% single. Most Italian women were married (82.0%), whilst 50% of French women, and 34.9% of Dutch women were cohabiting. In Sweden 43.4% were single. Many same sex couples travelled from France, Sweden and Norway.

Furthermore, 57.9% of the women and 53.3 % of the partners had a university degree and 29.3% (31.7% partners) had secondary education.

3. Reasons for crossing borders

Reasons varied from one “outgoing” country to another. Legal reasons were predominant for patients coming from Italy (70.6%), Germany (80.2%), France (64.5%) and Norway (71.6%). Access difficulties were more often noted by UK patients (34.0%) than by patients from other countries, and expected quality was an important factor for most patients (Table IV).

Furthermore, on average 17.9% patients ticked the “wish for anonymous donation” box, in particular the French (42.1%), British (26.4%), Germans (25.4 %), Swedes (18.9%) and Norwegians (16.4%).

4. Distribution of treatments sought

Among the responders (98.7%), 22.2% of patients were seeking IUI only (Table V), 73.0% ART only whereas 4.9% were seeking both. The figures varied between countries, with a majority requesting IUI for French (61.7%) and Swedish (62.3%) patients, and a majority ART for most other countries.

With regards to gametes and embryo donation, 18.3% of patients were looking for semen donation, 22.8% for egg donation and 3.4% for embryo donation. There were also huge differences according to the country of origin. French, Norwegian and Swedish women looked for semen donation more often than others, whereas German and British women were seeking oocyte donation more frequently. In several cases, patients were considering more than one option.

5. Information, costs and reimbursement

For 91.4% of all patients the formation was obtained in their language, and considered satisfactory. Most patients declared having received information on cost (93.7%). However the percentage was slightly lower in Belgium (88.0%) and Switzerland (88.2%).

Cost itself could not be quantified because of a large amount of missing information and inconstancies, but

cross border patients were poorly reimbursed (Table VI). Only 13.4% received partial reimbursement, and 3.8% total reimbursement. The most generous country was the Netherlands, with a partial or total reimbursement of 44.4% and 22.1% of patients, respectively.

6. Selection of centres/destinations by patients

The two main sources of information to select their centre (Table VII) were the internet (41.1%) and patients’ doctors (41.1%). Friends and relatives were also frequently consulted (24.2%). By contrast, patients’ organizations were far less used (5.0%). There were huge differences between the countries: internet was a frequent source in Sweden (73.6%), Germany (65.0%), and the UK (58.5%) whereas patients’ doctors were more often cited in Italy (55.2%).

7. Patients' doctors help

Among the patients who answered this question (92.3% of total), a majority (59.0%) received some help from their own doctor, for drug prescription (16.7%), for cycle monitoring (16.7 %) or both (25.6%). This varied across the countries, with high level of medical support in Germany (81.7%), France (79.0%), Switzerland (86.4%), and low level in the Netherlands (35.0%), the UK (45.3%), and Sweden (31.4%).

8. Treatments sought in the recipient countries

Patients sought mostly IUI (Table VIII) in Denmark (56.5%) and Switzerland (54.1%), whereas they requested ART in Slovenia (100%), the Czech Republic (98.4%) and Spain (98.4%). Oocyte and embryo donation were mainly provided by Spain (62%), and the Czech Republic (52%). Denmark (40.9%), Switzerland (27.4%) and Belgium (20.5%) received many patients seeking sperm donation.

Discussion

This prospective study is the first to present a set of hard data concerning cross border reproductive care at a European level and includes several countries known to be recipients of foreign patients.

We collected 1230 cycles over one month from 44 clinics in 6 countries, which may represent around 12 000 to 15 000 cycles annually in those clinics taking into account seasonal variability and annual closures. As the selected countries were chosen because they are assumed to be popular countries of destination, simple extrapolation of our findings to estimate the whole European activity is inappropriate. However, a multiplication by a factor of two seems to be a minimum estimate, or 24 000 to 30 000 cycles. If we then apply the treatment distribution of cycles observed in this study (75% ART, 25% IUI) and make the reasonable hypothesis that on average 3 cycles per patient are performed for IUI and 2 cycles per patient for ART, this leads to a minimum estimated number of patients of 11000-14000 per year. This number confirms the importance of the cross border phenomenon, and also calls for the necessity of studying it more accurately. One possibility could be to incorporate patients' "country of origin" in the national registers so that the data might be summarised in the EIM database.

This study has some limitations, mainly due to the limited number of centres participating in some countries like Spain. One of the main strengths of this study, however, was the collection of

information from individual patients seeking treatment and this is the first study on a relatively large scale using this method.

The mean female age of patients crossing borders was 37.3 ± 5.1 years, which is older on average than European patients treated with ART (EIM, 2009). For example, 33.2% of Italian women were aged 40 or more in our study, whilst this age group of Italian patients represented 20.7% in the latest EIM report ($p<0.05$). The same was true for German women (51.1% vs. 11.1%, $p<0.05$) and French women (30.2% vs. 12.7%, $p<0.05$). However, this belies some of the misgivings expressed by the public, puzzled if not outraged when women over the age of 60 go for treatment abroad (Anil, 2009) as no one was older than 51 years in our sample.

There may be several explanations for the increased age, according to the patients' country of residence. For example, in Germany, oocyte donation (OD), a treatment generally required by older women, is forbidden by law (Beier and Beckman, 1991) and was sought by almost half the German women (Table V). In France, the law restricts ART access to women of "reproductive age", which in practice means 43 and, in the UK, access to free NHS treatment is limited to women below 40. Furthermore, when patients look for " better quality" abroad, it is mostly after previous failure at home, which results in them being older. Finally, they have on average a level of education higher than the general population, which is usually related to an older reproductive age (Eurostat, 2009).

Before reviewing the different reasons for crossing borders, we note that many patients (about one in three in our sample) stated more than one reason to travel abroad. An average of 29.1 % of patients had previous failure of treatment (Table IV), with German and UK residents above the average (respectively 43.5% and 37.7%). In the case of Germany, this higher percentage may be due to recent decrease in the funding of cycles through insurance regulations (Connelly et al., 2009), as it may be cheaper to cross the border to the Czech Republic than to have a cycle in the private sector at home. In the case of the UK, regions have autonomy in prioritising (or not) the funding of ART, resulting in vastly different waiting lists and inequity of access, particularly in the number of cycles reimbursed (Shenfield, 1997; Shapps, 2009). Interestingly, the Swedish, Norwegian and French residents only mention this specific reason (previous failure) in respectively 5.7%, 16.4%, and 18.4 %, well below the average. Indeed, we know that reimbursement is generous in the Nordic countries, and good in France: the Swedish, Norwegian and French residents mention "difficulty of access" in respectively 13.2%, 0.0 % and 12.1%, whilst the UK residents quote 34%.

Vicinity is also a common factor between all patients. Ease of access via common borders explains why so many French women go to Belgium, mainly for sperm donation (Pennings et al., 2009). It is, however, surprising to note the relatively small number of French women going to Spain for OD, which is probably due to the low proportion of participating centres in Spain: we had 6 participating centres, whilst 131 report to EIM (EIM, 2009) (see limitations of study at the beginning of discussion). Swedes and Norwegians go to Denmark (>90%), again within a short distance, and Germans go mostly (67.2%) to the Czech Republic. Furthermore 50% Italian women go to Switzerland for sperm donation.

Our findings show that the majority of patients cross borders for legal reasons (Table IV), apart from the Dutch or UK citizens. Thus legal barriers are a major factor, either because of a specific ban on some techniques like gametes donation or Preimplantation Genetic Diagnosis (PGD), or because of a prohibition on treatment of patients with specific characteristics like sexual preference or age. Italian law banned all donor gametes and PGD techniques in 2004 (Italian Law 40-2004), sending a wave of patients to neighbouring countries: Switzerland received 51% of the Italian patients, mostly for sperm donation and Spain received 31.7%, mostly for OD. The German law bans oocyte donation and 44.6 % of our German patients requested OD (Table V), whilst French law bans "private" advertising for recruiting, leading to a dearth of donors, and 20.6% of our French patients requested OD.

Another legal barrier, which increases the number of movements across border for donor insemination (DI) is the regulation regarding donor anonymity. Scandinavian patients often go to Denmark for DI where anonymity is compulsory in the medical setting. In this study 18.9 % of Swedish and 16.4% of Norwegian patients stated they did not merely want donor insemination, but that they sought "*anonymous*" donation. Thus, for Sweden and Norway, this flow is most likely related to the legislation requiring non anonymous donation (Swedish Insemination Act, 1985). Another important legal reason is related to the civil status and sexual orientation of the patient .

In Sweden only couples have access, whether homosexual or heterosexual, which explains the high proportion of single Swedish women (43.4%) seeking treatment abroad. Also, till recently, DI was forbidden for lesbian couple in Norway (Norwegian Law 1987), where the reversal of this ban thanks to legislation on non discrimination on the grounds of sexual orientation in early 2009 has not yet been followed by improved access, explaining why 20% of Norwegian women were lesbians. In France, assisted conception for single women or same sex couples is illegal (Law no. 94-654,1994 and Law no. 2004- 800 2004). Thus in our sample, almost 39.2% of the French women were lesbians and 16.4% were single. By contrast, none travelled from the UK for these reasons, as access to treatment for single or homosexual women has never been forbidden (HFE Act 1990) and the legislation is one of the most open and tolerant to differences in Europe (HFE Act 2008). Indeed, for the patients originating from the UK, legal reason were the lowest of our sample, with only 9.4%,. Furthermore, lesbian couples going through ART have recently have been given equal parenting rights and responsibilities to heterosexual couples (HFE Act 2008).

Thus, statutory limits concerning access to ART vary widely between European countries, and this may partially explain some of the movements. Additionally some countries have regulations that limit reimbursement of ART to a maximum age. For instance, in France the "social security" does not reimburse if women are aged 43 years or more and in the Netherlands treatment is forbidden after 41 years (Pennings et al., 2009).

The lack of access to donor gametes may also be linked to the regulatory limits of compensation to donors. Examples of this are the UK allowing a very limited compensation and France where compensation is forbidden whereas in Spain (about 900 euros) and the Czech Republic (approximately 500 euros) more compensation is allowed (Garcia Vasco, 2007). The significance of this is supported by the observation that in our study 62.2 % of foreign patients treated in Spain and 62.4 % in Czech Republic had OD. However, the degree of the compensation may not be the only cause of the high number of gamete donors in these countries, since in Spain there is a strong tradition of donation reflected in the high rate of organ donation.

For the Dutch patients the main reason was the search for “quality” (53%) which may relate to ICSI with testicular sperm being only accessible in a research setting in the Netherlands, and in fact be also a kind of legal barrier.

Finally, from the ethical, political and public health points of view, one needs to consider justice and safety. Even if local access if preferable on the grounds that patients are nearer their usual support system, like friends and family, the evidence that they cross border in large numbers may have little effect on national policy. Indeed “at present, the movements by patients to other countries can be seen as a form of civil disobedience, which intends to change the existing legislation” but which also ”may have the opposite effect: politicians may accept the movements of some citizens to clinics abroad as a safety valve which decreases the pressure for law reform internally” (Ethics and law Taskforce 15, 2008). Many may have to wait a long time before they see improved access at the national level.

Clearly there is inequality of access to fertility treatments in Europe, and whilst cross border movements can increase the autonomy of our patients, it must be stressed that in many instances it is only available to those with the financial means of travelling (ESHRE Ethics and law Taskforce 14, 2008), apart from the cases where patients state that a private cycle (including travel) abroad is cheaper than at home. This may be particularly so when they go to some Eastern European countries not included in our study, or further a field, like India. Nevertheless, this also raises further ethical issues specific to low income countries, with the danger of this cross border influx may ”aggravate the already existing brain drain of health care professionals to private hospitals” (Ethics and Law Taskforce 16, 2009).

Conclusion

This study is the first analysing cross border reproductive care movements between several European countries. The study documents a considerable flow of patients crossing borders between European countries. In relation to quantity, 1230 cycles were recorded during a single month in the participating centres, implying that the annual number of cycles reached a minimum of 24 to 30 000 Cycles (X).

The main reasons for travelling were legal restrictions based on prohibition of the technique per se, or because of inaccessibility due to the characteristics of the patients (like age, sexual orientation or civil status).

This phenomenon raises a lot of broad social, ethical and political problems, which require a coordinate effort from various stake- holders like patients organisations, professional societies, and policy makers both at the national and European levels.

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Table I: Percentage of patients crossing borders to the six treating countries

	Received forms		Forms per treating country (%)					
Country of residence	n	%	Belgium	Czech republic	Denmark	Slovenia	Spain	Switzerland
Italy	**391**	31.8	13.0	2.6	0.3	1.0	31.7	51.4
Germany	177	14.4	10.2	67.2	11.9	0.0	10.7	0.0
Netherlands	149	12.1	96.6	0.0	0.0	0.0	3.4	0.0
France	107	8.7	85.0	7.5	0.0	0.0	7.5	0.0
Norway	67	5.5	0.0	1.5	98.5	0.0	0.0	0.0
UK	53	4.3	7.55	52.8	11.3	0.0	28.3	0.0
Sweden	53	4.3	0.0	5.7	92.4	0.0	1.9	0.0
Other Europe	173	14.0	12.1	38.1	5.2	34.7	9.8	0.0
Outside Europe	46	3.7	54.3	35.2	4.3	0.0	6.5	0.0
Not specified	14	1.1	78.6	7.1	0.0	7.1	7.1	0.0
Total clinics :			9	6	21	3	5	2
Total forms: n	**1230**		365	252	154	65	193	201
%	100		29.7	20.5	12.5	5.3	15.7	16.3

*

Table II: Age of the women crossing borders from the 7 most represented countries

		Women's age (%)				
	Mean ± SD years	<35 (%)	35–39 (%)	40-44 (%)	≥ 45 (%)	Range
Italy	37.4 ± 5.0	27.3	40.5	24.7	7.5	21-50
Germany	38.8 ± 5.0	21.0	27.8	40.3	10.8	23-49
Netherlands	35.4 ± 5.1	44.3	34.9	17.4	3.4	23-51
France	36.6 ± 5.8	32.1	37.7	20.8	9.4	21-49
Norway	35.8 ± 4.6	38.8	43.3	16.4	1.5	21-47
UK	40.8 ± 5.4	11.5	25.0	32.7	30.8	21-49
Sweden	37.4 ± 5.5	26.4	32.1	37.7	3.8	24-45
Total	37.3 ± 5.1	29.5	35.6	26.8	8.1	21-51

Table III: civil status and sexual orientation according to patients' residence

	Civil status (%)			Sexual orientation (%)
Country of residence	Married	Cohabiting	Single	Homo/ Bisexual
Italy	82.0	17.2	0.8	1.5
Germany	72.0	25.7	2.3	11.2
Netherlands	62.3	34.9	2.7	8,5
France	33.6	50.0	16.4	39.2
Norway	47.6	28.6	23.8	21.3
UK	62.0	30.0	8.0	0.0
Sweden	32.1	24.5	43.4	32.7
Total (%)	69.9	24.0	6.1	9.7

Table IV. General reasons for travelling according to the country of patients' residence

	Legal reason	Access difficulty	Better quality	Previous failure
Italy	70.6	2.6	46.3	26.1
Germany	80.2	6.8	32.8	43.5
France	64.5	12.1	20.6	18.7
Netherlands	32.2	7.4	53.0	25.5
Norway	71.6	0.0	22.4	16.4
UK	9.4	34.0	28.3	37.7
Sweden	56.6	13.2	24.5	5.7
Total %	54.8	7.0	43.2	29.1

Table V. Sought treatment according to the country of patients' residence

	Infertility treatment*		Specific treatments			
			PGD-PGS	Donation**		
	ART	IUI		Semen	Oocyte	Embryo
Italy	76.5	32.6	2.1	17.4	17.9	2.3
Germany	90.5	10.3	8.5	10.2	44.6	6.2
Netherlands	78.1	27.4	3.4	11.4	9.4	0.7
France	46.7	61.7	2.8	43.0	20.6	5.6
Norway	62.7	41.8	1.5	38.8	1.5	1.5
UK	90.6	9.4	3.8	15.1	62.3	11.3
Sweden	37.7	62.3	0.0	43.4	5.7	1.9
Total	77.9	27.1	3.2	18.3	22.8	3.4

Percentages are computed among the total number of women coming from each country

* The sum of ART and IUI is over 100% because some patients (4.9%) sought both

** Some patients sought more than one type donation

Table VI. Reimbursement according to the country of patient's residence

	No	Partial	Total	Unspecified
Italy	74.9	10.7	0.3	14,1
Germany	81.9	8.5	2.3	7,3
Netherlands	16.8	44.3	22.1	16.8
France	77.6	12.2	3.7	6,5
Norway	79.1	10.4	1.5	9.0
UK	92.6	1.9	1.9	0.0
Sweden	73.6	3.8	0.0	22.6
Total	71.7	13.4	3.8	11.1

Table VII. Selection mode of the centre according to the country of patients' residence

	Internet	Patients organization	Friends	Doctor	Unspecified
Italy	25.3	1.5	25.8	55.2	2.6
Germany	65.0	4.0	11.9	35.6	2.8
Netherlands	42.3	6.0	20.8	39.6	6.0
France	44.9	10.3	29.0	27.1	5.6
Norway	49.3	6.0	22.4	31.3	4.5
UK	58.5	18.9	15.1	28.3	3.8
Sweden	73.6	9.4	24.5	13.2	5.7
Total	41.1	5.0	24.2	41.1	3.7

Table VIII. Treatment sought according to the recipient country

Recipient Country	Forms (n)	Infertility treatment*		PGD/ PGS	Donation*		
		ART	IUI		Semen	Oocyte	Embryo
Belgium	359	71.9	33.4	5.2	20.5	6.8	0.3
Czech Republic	251	98.4	1.6	5.6	9.5	52.4	11.9
Denmark	154	46.8	55.5	0.6	40.9	1.3	0.6
Slovenia	64	100	0.0	0.0	0.0	0.0	0.0
Spain	190	98.4	5.8	2.1	4.1	62.2	4.7
Switzerland	196	59.7	54.1	0.5	27.4	1.0	0.5
Total	1204	73.0	22.2	3.2	18.3	22.8	3.4

Annex 6b: Cross-border reproductive care
in Belgium, Annex 7: Definitions Assisted Reproductive Technology, Annex 9: ESHRE Position Paper and Annex 10: Cross Border questionnaire are provided in other pdf files.

Annex 8 Abbreviation List

EUTCD	European Tissues and Cells Directive
MAR	Medically Assisted Reproduction
WP	Work Package
ESHRE	European Society of Human Reproduction and Embryology
EACC	European Assisted Conception Consortium
CNR	Committee of National Representatives
PGD	Pre Implantation Genetic Diagnosis
PGS	Pre Implantation Genetic Screening
AID	Artificial insemination Donor sperm
AIH	Artificial Insemination Husband sperm
ART	Artificial (Assisted) Reproductive Technology (Treatment)
ED	Embryo Donation
FET	Frozen Embryo Transfer
ICSI	IntraCytoplasmatic Sperm Injection
IUI	Intrauterine Insemination
IVF	In Vitro Fertilisation
IVM	In Vitro Maturation
MAR	Medically Assisted Reproduction
MESA	Microsurgical Epididymal Sperm Aspiration
NIVF	Natural Cycle In Vitro fertilization
OD	Oocyte Donation
PGD	Preimplantation Genetic Diagnosis
PGS	Preimplantation Genetic Screening
SET	Single Embryo Transfer
SD	Sperm Donation
TESE	Testicular Sperm Extraction
ICE	Association of Irish Clinical Embryologists
AER	Embryology Association of Romania
AGES	Austrian Agency for Health and Food Safety
BELRAP	Belgian Register for Assisted Procreation
FAMHP	Federal Agency for Medicines and Health Products
EIM	European IVF Monitoring Consortium
HFEA	Human Fertilisation and Embryology Authority
SEF	Spanish Fertility Society
ASRM	American Society for Reproductive Medicine
KELA	Social Insurance Institute of Finland - Kansaneläkelaitos

european society of human reproduction & embryology

ESHRE position paper on the EU Tissues and Cells Directive EC/ 2004/23

November 2007

Introduction

The European Union Tissues and Cells Directive (EUTCD) is a legal document originating from the European Union's public health programme. The EUTCD covers donation of all tissues and cells within EU (except blood and blood-products). It aims at preventing threats to human health related to the application of cells and tissues to the human body. Within this background the EUTCD foresees common standards of safety and quality for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications. The requirements were laid down in a single "mother" Directive 2004/23/EC and two subsequent Technical Directives 2006/17/EC and 2006/86/EC. Assisted Reproduction Technologies (ART) is considered as covered by this directive. This applies to all ART units in all European Union (EU) and European Economic Area (EEA) member states (Iceland, Liechtenstein and Norway).
The directive is basically concerned with increasing quality and safety in application of human tissues and cells to the human body.

In an ART perspective this involves basically minimizing the risk of two severe adverse events, namely transmission of infections and prevention of gamete/zygote/embryo exchange (mix-up). The directive is not concerned with pointing at specific ways of increasing "performance" such as success rates. Instead, the directive aims at increasing quality through mandatory implementation of a quality management system. This involves the presence of adequately trained and certified staff, full documentation and formulation of standard operating procedures, quality control and quality assurance at all units performing assisted reproduction.

Based on this ESHRE considers initiatives aiming at improving performance must be covered outside the framework of the directive. As a consequence ESHRE has initiated a number of initiatives including a revision of the "ESHRE Guidelines for good practice in IVF laboratories" which should be seen as a complement to the requirements issued by the Tissues and Cells Directive.

ESHRE, as the European representative society in the area of reproductive medicine, considers it to be important to work for harmonization of implementation, inspection and certification throughout EU member states. One ESHRE initiative was therefore to install the European Assisted Conception Consortium (EACC). The primary aims of the Consortium were to understand all implications of the EU Tissues and Cells Directives, to identify areas problematic to the ART community, and to provide interpretations to be used locally in all the European countries. ESHRE considers it pivotal to a successful implementation that a good dialog be established between EU, the profession and the national regulative authorities. During this process the EACC has had a key role in bringing together ART professionals and competent authorities of the EU member states. In EACC each EU member state is represented by one clinician, one embryologist and one representative of the competent authority. Non - EU member states are allowed to join for information.

Implementation of the directive:

As implementation of EUTCD is coming close by in several EU member states, ESHRE wants to clarify its position on EUTCD. The aim is to assist ART professionals and representatives of competent authorities in their dialogue on the EUTCD. Further, suggestions for minimal requirements in selected areas will be provided.

It is important to realize that the EUTCD will have to be interpreted and implemented through national authorities in each individual country. Depending on the national interpretation of the text, the directive may be implemented differently in the different European member states. This is also reflected in the initial approaches already taken by the profession in the different countries in preparing for the directive. Further, the national implementation is subject to national regulations that may be already in place in each member state.

As a consequence, this ESHRE position paper and interpretation cannot ensure equal regulation in all countries. However, it will be a useful document to be used by the professionals when working together with the authorities towards implementation of the directive in each member state.

ESHRE strongly encourages its members and the national societies to identify the relevant national bodies responsible for translating the EUTCD into national legislation and the bodies involved in the practical implementation of the directive in order to establish a constructive collaboration.

Impact of the directive:

The EUTCD will have a profound impact on all units conducting assisted reproduction. All units will have to be licensed or accredited as decided by the national authorities. Further, all units must implement a quality management system with written standard operating procedures and ensure full documentation of all activities in the clinic/unit - including full traceability for all materials used in each treatment. This documentation must be kept for 30 years.

ESHRE acknowledges that non-partner gamete donation is an area with specific requirements. However, assisted reproduction involving the usage of husband/partner sperm in combination with the woman's own eggs represent more than 95 % of all ART in Europe.

Further, with the implementation of screening of all patients seeking assisted reproduction it is possible to make a clear distinction between infected and non-infected patients. It is clearly stated in the EUTCD that testing positive for HIV or Hepatitis does not automatically exclude patients from treatments. However, ESHRE estimates that an overwhelming majority of all patients will be non-infected. On this background ESHRE recommends that the national authorities clearly define how and where viral positive patients should be treated as this could minimize the organizational and financial negative impact of the EUTCD on many clinics/units.

EUTCD areas that are clearly defined

- The directive applies to fresh and cryopreserved reproductive tissues and cells for application to the human body. This covers gametes, zygotes, embryos and ovarian and testicular tissues.
- The directive is concerned with issues of safety and quality in ART such as prevention of transmission of infectious disease and prevention of misidentification or mix-up of gametes, zygotes or embryos. Each tissue establishment has to put in place and update a quality management system based on the principles of good practice.
- The directive applies to all ART procedures where reproductive cells and tissues are being processed, cultured, banked or stored. This means that intra-uterine insemination falls under the EUTCD. The terminology "direct use" is not applicable on reproductive tissues and cells that will be processed, cultured, banked or stored.
- "Donor" means every human source, whether living or deceased, of human cells and tissues. Partner donation means the donation of reproductive cells between a man and a woman who declare to have an intimate physical relationship. In a couple, man and woman are considered donors to each other.

- Biological testing of the donor is necessary whenever the donated cells will be processed, cultured, banked or stored. Biological testing for HIV 1, 2, for Hepatitis B surface Antigen, Hepatitis B Core antibodies and Hepatitis C antibodies is requested.
- For non-partner donation, additional screening for syphilis and in case of sperm donation for Chlamydia is required.
- Genetic screening for recessive diseases known to be prevalent in a non- partner donors' ethnic background is requested.
- Cells and tissues have to be traceable from donor to acceptor and vice versa. Traceability is also mandatory to all products and materials coming into contact with tissues and cells. This includes for instance all culture media, all culture media supplements and all disposables,
- A unique European coding system is not applicable to reproductive tissues and cells for partner donation. A unique code guaranteeing traceability remains however required.
- The EU has ordered a workshop at CEN, the European Committee of Standardization, to propose a unique European coding system which will apply in case of non -partner donation.
- In assisted reproduction every misidentification or mix-up of gametes, zygotes or embryos is to be considered a serious adverse event.

Identification of problematic areas for ART with respect to the EUTCD:
ESHRE has identified sensitive and possible problematic areas for ART with respect to the EUTCD and is providing interpretations and possible solutions to be discussed with the local authorities implementing the directive.

Problematic areas
ESHRE considers a number of areas in the directive to be particularly problematic for the ART community. This is a consequence of the wide coverage of the directive in comparison to the very specific nature of ART including numerous repeated procedures on the same patient and the usually long duration of treatments at the clinics/units.

Frequency of screening for HIV and Hepatitis: (Commission Directive 2006/17/EC, Annex III.4.2.)
It is specified in the directive that all donors (patients) shall be tested for HIV and Hepatitis B and C at the "time of donation". It is however not specified if it is required to re-test the patient prior to each treatment or whether a specified interval will be acceptable. This will have a profound impact on the financial consequences of the directive.
For example, the EUTCD has been fully implemented in Denmark. The position of the Danish authorities is that screening for HIV and Hepatitis must be done "prior" egg-recovery and the test is valid for 24 month if the patients are tested negative. For egg donors the Danish authorities have specified that the test must be done no more than 30 days prior to donation. Based on the fact that assisted reproduction often is comprised of a "series of treatments" and that treatment is initiated based on a known status of infection of the couples ESHRE suggests a system were the patients in case of partner donation must be tested no more than 30 days prior to starting the initial treatment and if the test is negative the result should be valid for at least 24 months. If the test is definitely positive the couples are considered positive in all future treatments. All additional testing should only be done as a requirement for treating viral positive couples with ART.

Personnel: (Commission Directive 2006/86/EC Annex I. B .Personnel)
It is stated in the directive that a) staff should be available in sufficient numbers, b) a training program should be available and c) that work descriptions must be clearly documented.
While recognizing these needs ESHRE wishes to specify that the number and the complexity of the treatments can vary profoundly between clinics/units. On this background ESHRE considers it impossible to define a general statement covering all type of clinics/units; staff requirements should be specified at each individual clinic/unit and the number and type of treatments offered. As a consequence of the EUTCD a new ESHRE initiative is the establishment of a certification system for

clinical and senior clinical embryologists. The system aims at certifying both practical and theoretical competence of the laboratory staff.

Termination of activities: (Commission Directive 2004/23/EC, Article 21.5)
"Member states shall ensure that tissue establishments have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored tissues and cells shall be transferred, according to the consent pertaining to them, to other tissue establishment or establishments accredited, designated, authorized or licensed…"

This paragraph specifies what is to be done if a clinic/unit closes. ESHRE considers this the responsibility of the local authorities.
The background for this position is based on the fact that it is the responsibility of the authority to issue or withdraw a clinic/unit's license. Consequently, it must also be the responsibility of the authorities to ensure the transferral of stored gametes, zygotes, embryos and ovarian and testicular tissues to a licensed clinic/unit.
Further, in the EUTCD it is required that clinics/units prior to obtaining a license from the authorities must have an acceptance from another clinic/unit accepting to take over their stored biomaterials in case of closure or termination of activities
ESHRE considers it inappropriate if existing clinics/units can prevent or block the establishment of new clinics/units by refusing an agreement to accept their stored biomaterials in case of closure or termination of activities.

Air quality: (Commission Directive 2006/86/EC, Annex I.D. Facilities/Premises)

It is stated that the air quality should be a GMP defined Grade A on a background air quality of Grade D unless a less stringent air quality may be justified according to one or more of the provisions set out under section 4. After having performed Assisted Reproduction in Europe for more than 20 years there is no documented evidence of a single case of transmission of infective diseases (hepatitis/HIV etc) that can be attributed to air quality in the laboratory. Further, with the introduction of screening of the patients prior to start of treatment as specified in the EUTCD, we will know the viral status of the patients we treat, enabling us to handle infectious patients in a separate environment from non-infectious patients.
On this background ESHRE considers assisted reproduction to be covered by section 4 and - with reference to historical documentation - that it has been both demonstrated and documented that the chosen environment achieves the quality and safety required for the intended purpose.

Coverage
ESHRE interprets the directive to cover ART "from needle to catheter". This means that procedures outside of this are not covered by the directive. Consequently, it is our opinion that well known side effects to the treatment such as OHSS are considered outside of the scope of the directive. However, although the EUTCD is mainly concerned with the laboratory it also covers clinical procedures involving procurement of reproductive cells such as oocyte aspiration.

Intra uterine insemination:
IUI is included in the directive as it involves processing of gametes and this may have a profound impact on insemination performed outside of regular fertility clinics/units.

Cost
There is no doubt that the implementation of the directive will be extremely expensive for the involved clinics/units and that increased financial support will be mandatory both in the public system and private clinics. Without such a financial support, an increase in cost to patients is to be expected, particularly at private clinics/units.

Link to the directives: http://europa.eu.int/comm/health/ph_threats/human_substance/tissues_en.htm
Link to EACC: http://www.eshre.com/emc.asp?pageId=678

Cross border reproductive care study

Patient's data

Not to be filled by the patient

What is your age (years) ?.....

What is your country of residence?.....

For the next questions, tick the appropriate answer

Are you ? ☐ Married ☐ Cohabiting ☐ Single; ☐ Not applicable / No answer

Are you ? ☐ Heterosexual ☐ Homosexual ☐ Bisexual ☐ No answer

What is your school degree? ☐ Primary ☐ Secondary ☐ University /similar ☐ Other (professional) ☐ Unspecified

What is your partner's school degree? ☐ Primary ☐ Secondary ☐ University /similar ☐ Other (professional) ☐ Unspecified

Please indicate your reason(s) for travelling (you may tick more than one)

☐ The treatment you want is not legal in your home country

☐ You cannot obtain treatment because of: age, unmarried, single, sexual orientation, etc. Specify: :……

☐ Treatment is not easily accessible: long waiting list, distance to the centre, cost, etc. Specify:……

☐ You expect a better quality and/or outcome in this centre than in your home country

☐ You want anonymous donation of sperm / egg / embryo. Specify: ……

☐ You want donation from a known donor (relative, friend): sperm / egg / embryo. Specify: ……

☐ You want the donor's name to be released to the child at some stage

☐ You had previous treatment failures in your home country

☐ Other. Specify

☐ Unspecified, unknown

For which treatment do you attend this centre? You can tick more than one

☐ Artificial insemination

☐ IVF or ICSI

☐ PGD / PGS

☐ Other (IVM, freezing, TESE / MESA, etc.)

☐ Semen donation

☐ Oocyte donation

☐ Embryo donation

Did you receive information in your language? ☐ No ☐ Not satisfactory ☐ Yes, satisfactory

second box needed

Did you receive information about the cost of this treatment? ☐ Yes ☐ No

Amount: Currency: ……

Does this include drugs? ☐ No ☐ Yes ☐ Unspecified

Will you receive any reimbursement for this cycle in your country of origin?

☐ No ☐ Partial ☐ Total ☐ Unspecified, unknown

How did you select this centre? ☐ Internet ☐ Patients organisation ☐ Friends/relative ☐ Doctor from country of residence ☐ Unspecified

Did you receive help from your doctor at home for this cycle? ☐ No ☐ Prescription ☐ Cycle monitoring ☐ Both