



**Europe regulation : Access to treatments (IUI or IVF) with Donor Sperm**



Not allowed in : Tunisia, Morocco, Egypt, Turkey

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**Europe Regulation on Donors**

- Ethical Standard adopted by many countries : prohibition of payment ( only reimbursement )  
.... but is possible to buy donor semen from cryo-banks



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**Europe regulation : access to "infertility" treatments for single women and lesbian couples**



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## Europe



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### Sperm donation : register and cross border today

- Difficult to collect data on this topic from the registers :
- National Registers ( and also EIM ) do not indicate the *origin* of the treated patients
- In ART , *semen donation* procedure is sometime included in IVF/ICSI cycles *without* specific *distinction* from husband/partner' s semen .
- In EIM the distinction is only made for *inseminations*

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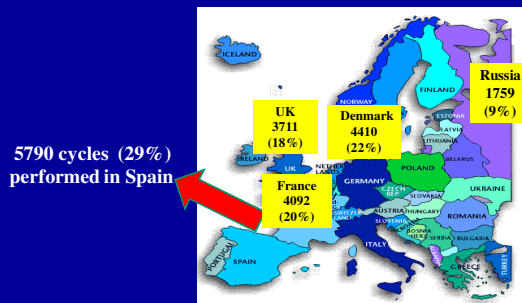
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### EIM Report 2006: 459.170 total cycles from 32 countries

Donor Insemination: 20.247 cycles reported by 22 countries



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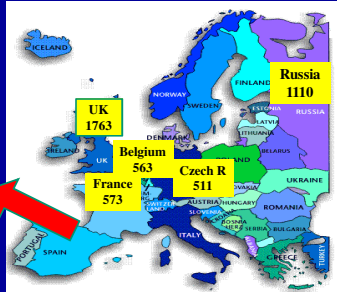
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**EIM Report 2006:**  
**459.170 total cycles from 32 countries**

**Egg donation:** 12.685 cycles reported by 24 countries

6547 cycles (52%)  
performed in Spain



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**EIM Report 2006**

Country	% centres reporting
Spain	60%
Russia	90%
UK	100%
Belgium	100%
Czech Rep	100%
Sweden	100%
France	100%
Denmark	100%

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**Sperm ( and oocyte ) donation :**  
**register and cross border in the future**

- **EIM** collection will ask on the number of foreign patients for each technique
- The **European directives** on cell and tissue will require full record on donations

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## Sperm donation and cross border

### Data from the pilot study of the Task Force on Cross Border Reproductive Care

*In name of the ESHRE Committee:*

*F. Shenfield, G. DeWert, AP Ferrarretti, J. de Mouzon,  
A. Nyboe-Andersen, G. Pennings*

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## Protocol

**Study design:** open, European, multicentric, transversal  
pilot study

### Six countries

- ♦ Known as receiving many patients
- ♦ With voluntary investigators

**All foreign patients** in one calendar month received a  
**questionnaire**

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## Questionnaire

### ♦ Main socio- demographic characteristics

- ♦ Age, country of residence, education
- ♦ Marital status, sexual orientation

### ♦ Reasons for travelling (more than one allowed)

- ♦ Law evasion (treatment illegal or restricted),
- ♦ Access limitations at home,
- ♦ Quality of care, previous failure,
- ♦ Specific wish for donation (anonymous, direct,...)

### ♦ Treatment sought: IVF, IUI, donation, etc.

### ♦ Organisational questions

- ♦ Information received, selection means, reimbursement  
in country of residence

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### Countries selected for the study and Clinics participating to the study

Country	Total clinics in the country	Clinics participating to the study	N of forms collected
Belgium	18	8 (44%)	375
Czech Rep	21	6 (29%)	253
Switzerland	24	2 (8%)	201
Spain	182	4 (2%)	183
Denmark	22	21 (100%)	153
Slovenia	3	3 (100%)	65
<b>TOTAL</b>	<b>278</b>	<b>44</b>	<b>1230</b>

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### Patients origin

Country	Forms
Italy	391 (32%)
Germany	177 (15%)
Netherlands	149 (12%)
France	107 (9%)
Norway	67 (5%)
UK	53 (4%)
Sweden	53 (4%)

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### Treatment sought according to the country of origin

Country	Infertility treatment			Donation		
	ART only	IUI only	ART/IUI	Semen	Oocyte	Embryo
Italy	67.4	23.5	9.1	17.4	17.9	2.3
Germany	89.7	0.7	0.6	10.2	44.8	6.2
Netherlands	72.6	21.9	5.5	11.4	9.4	0.7
France	38.3	53.3	8.4	43.0	20.6	5.6
Norway	58.2	37.3	4.5	38.8	1.5	1.5
UK	90.6	9.4	0.0	15.1	62.3	11.1
Sweden	37.7	62.3	0.0	43.4	5.7	1.9
Total	73.0	22.2	4.9	18.3	22.8	3.4

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### Patients from Italy -Treatment sought

<b>Total treatments</b>	<b>391</b>
ART	76%
IUI	32%
PGD/PGS	2%
<b>Only donation</b>	<b>144 (37%)</b>
eggs	49%
semen	45%
embryos	6%

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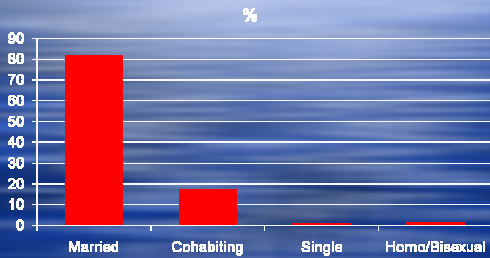
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### Patients from Italy Civil Status and sexual orientation




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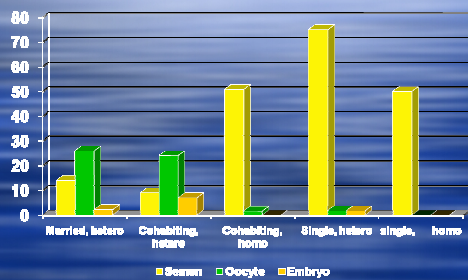
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### Donation sought according to women's civil status and sexual orientation together




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Treatment sought according to the regulation in country of origin				
Country	Regulation		Donation (%)	
	Donors	Access to single/homo	Semen	Oocyte
Netherlands	known	yes	11.4	9.4
France	anonymous	no	43.0	20.6
Norway	known	no	38.8	1.5
UK	known	yes	15.1	62.3
Sweden	known	no	43.4	5.7

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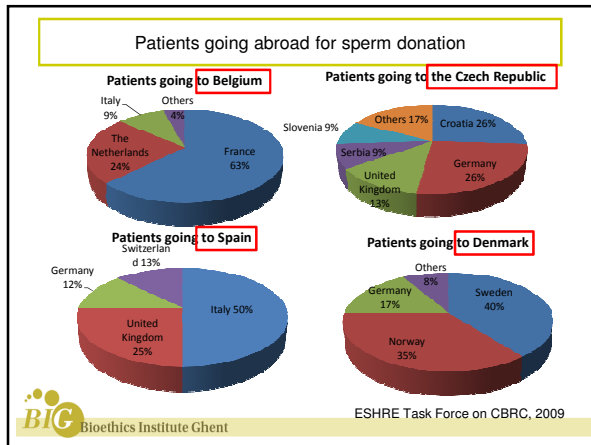
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### Sperm donation and cross-border

- There is a **strong correlation** between restrictive laws or guidelines on sperm donation and the number of patients leaving a country. These restrictions may be focused on :
  - **the donors** (altruistic, identifiable etc.) frequently resulting in scarcity and long waiting lists
  - **the recipients** (single, lesbian etc.)
  - **law prohibition.**
- Restrictions on **import of sperm** will lead to more travelling by patients.
- Greater efforts to recruit donors** in each country could reduce the need to look for sperm abroad either by patients going there or by clinics importing sperm

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## Semen donor recruitment in a oocyte donation programme

A.P.Ferraretti, G.Pennings et al  
*Human Reprod* 10,2006

A mirror exchange system based on the principle of fairness : people who voluntarily accept to benefit from a system can make a contribution to that system

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## Cross Border Reproductive Care



Way to study the phenomenon ?

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## Cross border - Ethical perspective

*Cross border is a "safety valve" for patients , reduce moral conflict and contributes to a peaceful coexistence of different views ( Pennings,2006)*

Position of the ESHRE Task Force on ethics and Law: **reproductive autonomy justifies law evasion.**



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## Cross-Border Reproductive Care

- Part of the global “ **healthcare across EU borders** ”
- **The right of patients** from EU Member States to travel to another Member State to receive healthcare is a principle that has been confirmed on a number of occasions over the last ten years by the European Court of Justice

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## Healthcare across EU borders

**Reproductive care across EU borders has specific aspects** because different ethical, religious and legal attitudes exist in our society regarding reproductive health

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## Patient mobility for medical problems

Outside  
Reproduction



**Positively** evaluated as a patient's right to have access to the highest quality health care

In the field  
of Reproduction



**Negative** perception focused on the idea of law evasion or patient looking for something strange or trivial

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## Cross-Border reproductive care

- Is a *benefit* for patient' autonomy
- It hold **high risk to generate** dangers, frustration and disparities **for patients**

*The price the patients pay for their autonomy should be balanced by the protection against dangers*

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### Dangers

#### **Danger: choosing the wrong clinic**

- Problem: **no** reliable **information** available
- Problem: exaggerated success rates, **lack of transparency**
- Solution: information should be actively collected by the local fertility specialist and by the professional organisations



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### Dangers

#### **Danger: violation of safety standards**

- Multiple pregnancy rates
- Donor screening

#### **Danger: social isolation and lack of psychological support from friends and family**

#### **Danger: violation of moral principles**

No or insufficient counselling: no informed consent



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## ESHRE's aims

- Promote **transparency**
- Promote awareness and **information** at all levels (government, patients and professional), warn citizens re: possible dangers
- Promote **means** (guidelines, certification of clinics by national and international organisations) to guarantee **safe and effective** treatment for patients travelling abroad



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## Cross-Border

### To analyse , monitor and discuss :

- to better clarify the causes
- to find possible solutions to the existing problems
- to prevent further dangers and risks for patients
- to have an impact on policy formulations

"Although RT offers benefits to patients, its dangers should not be underestimated or ignored" ( Pennings )

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## Healthcare across EU borders

The European Parliament recognized the need of **framework** for provision of **save, high quality and efficient** healthcare cross border.

### Key points

- *Cooperation and sharing of responsibility between home and host member States*
- *Continuity of care and clarity about the responsibility*
- *Prior Authorisation for reimbursement*
- *Information in the home State*

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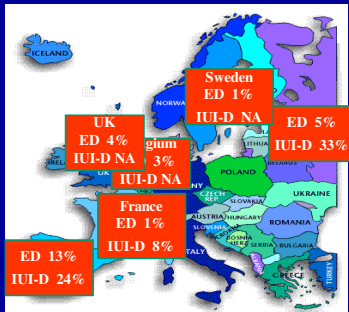


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**Europe** : percentage of gametes donation cycles on the total of cycles reported from the country (EIM Report 2006)




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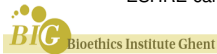


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The Rough Guide to insemination:  
reproductive tourism for insemination due  
to different regulations.

Guido Pennings

ESHRE campus Genk, 13-15 December 2009




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Cross-border movements

Three parts should be distinguished:

**1. Recipients cross borders**

French lesbians

**2. Sperm cross borders**

Cryos exports 80% of its 20.000 donations to 400 clinics  
in 60 countries

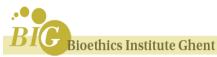
**3. Donors cross borders**

Canadians go to Australia (gives a new meaning to travel expenses!)

Caucasians go to India

Swedes go to Denmark

almost 20% of the UK sperm donors are from overseas




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Canada - United States

In 2008, Canada had 33 donors. Total population: 33.5 million

Number of sperm banks has diminished

- before 2004 because of more stringent requirements for donor  
screening and semen processing

- after 2004 because the Assisted Human Reproduction Act forbade  
payment of donors above expenses

Now transition period: import sperm from paid donors in the US and  
Europe!

Patients going to US	Canada	Europe	India	Latin America	Australia / New Zealand
Donor insemination	88	44	3	73	7

Hughes, 2009




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Number of foreign patients per type of treatment between 2003 and 2007 in Belgium

Type of treatment	Mean number of cycles per patient	Number of patients				
		2003	2004	2005	2006	2007
Sperm donation	4,0	518	491	572	726	764
Oocyte donation	1,6	185	152	153	136	120
Embryo donation	1,9	11	15	18	13	17
IUI partner	3,3	34	46	45	48	58
IVF own gametes	2,4	94	131	237	264	251
ICSI ejaculated sperm	2,3	385	426	550	645	640
ICSI non-ejaculated sperm	2,1	131	126	146	122	125
PGD	1,9	99	104	131	166	141
All treatments		1456	1491	1853	2119	2117

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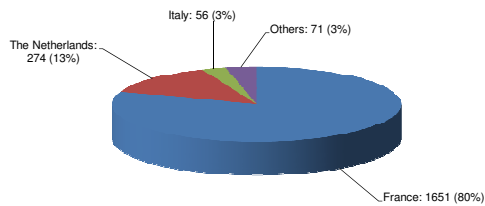
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Foreign patients coming to Belgium from 2005 to 2007 for sperm donation




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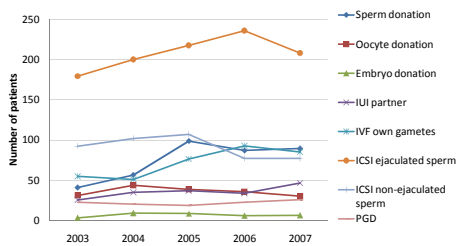
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Evolution in time of Dutch patients coming to Belgium per treatment type



June 2004: Law 'Donor data': abolishment of donor anonymity

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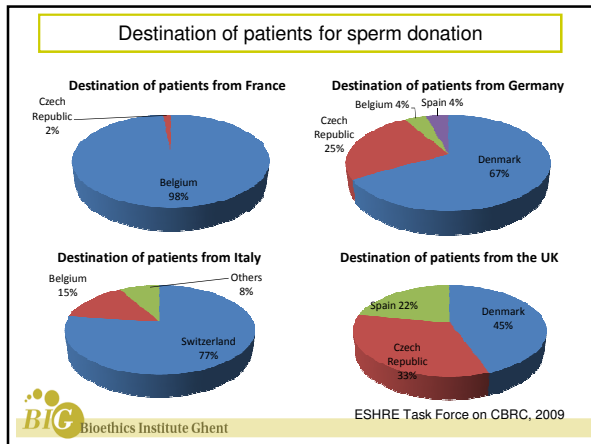
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**Directive 2004/23/EC**

- 2004/23/EC      **Mother Directive**  
into force on 7 April 2006
- 2006/17/EC      **Technical directive 1**  
**on donation, procurement, testing**  
into force on 1 November 2006
- 2006/86/EC      **Technical directive 2**  
**coding, processing, preservation,**  
**storage and distribution**  
into force on 1 September 2007

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**Technical Directive 1 2006/17/EC**

- Full donor documentation on donation, procurement, testing
  - voluntary
  - unpaid
  - informed consent
  - unique donor identification
  - medical history
  - laboratory testing results
- All records entered into registry
- Clear and readable
- Protected
- Accessible for authority
- to be kept for at least 30 years.

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