

**ERA-NET SCHEME**

**COORDINATION ACTION**

**ALLIANCE-O**



**European Group for Coordination of National Research Programmes on Organ Donation and Transplantation**

Project/Contract Number: 0011853

**Work Package 2: Expanding donor pool**

**Deliverable 2.1: State of the art in expanding donor pool**

**Work Package Leader:** CENATMER Spain

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## Table of contents

<b>1. STATE OF THE ART</b> .....	<b>4</b>
1.1. Background .....	4
1.2. Organ transplantation and waiting lists .....	5
1.4. Expanding donor pool: a common problem to face .....	7
1.5. Proposal for a preliminary study .....	9
1.6. Efficiency and benefits of the donation-transplantation process .....	9
1.7. European framework: an added value .....	10
<b>2. DATA COLLECTION AND ANALYSIS</b> .....	<b>11</b>
<b>3. RESULTS</b> .....	<b>13</b>
<b>3.1 Donation and transplantation activity</b> .....	<b>13</b>
3.2. Waiting lists and transplant centres .....	21
3.3. Comparative data among the partners: Donation and transplantation activities, Transplant centres and patients admitted to the waiting lists. Year 2004.....	28
3.4. Data on Expanded donors.....	35
3.4. Data on Expanded donors.....	36
3.5. Initiatives and programmes aimed to promote organ donation and transplantation and to increase the number of organs available for transplantation .....	39
3.5.1. CADAVERIC HEARTBEATING DONORS.....	63
3.5.2. LIVING DONORS.....	71
3.5.3. CADAVERIC NON-HEARTBEATING DONORS .....	73
<b>4. DESCRIPTIVE STUDY AND CONCLUSIONS</b> .....	<b>75</b>
4.1. Donation and transplantation activity. General European Data .....	78
4.2. Waiting lists. General European Data .....	78
4.3. Countries involved in ALLIANCE-O .....	78
4.4. Expanded donors.....	79
4.5. Initiatives and Programs .....	80
<b>5. CONCLUSIONS</b> .....	<b>82</b>

## 1. STATE OF THE ART

### 1.1. Background

Organ transplantation is the therapeutic use of human organs that involves the substitution of a non-functional organ form another coming from a donor. After five decades of experience the progress in the field of transplantation medicine has been impressive. Advances in techniques and the development of new immunosuppressive drugs and strategies have made it possible to transplant organs in a large number of patients. Nearly 1 million people worldwide have benefited from successful organ transplantation, and significant proportion of patients can now expect to achieve a long-term survival with a high quality of live (Charles D., Carpentier B., Improving the success of organ transplantation. N.Eng.J.Med. 2000; 342:647-648). (Human Transplantation 2004; 78:493).

Conditions that can be treated or cured by transplantation usually carry a significant burden of morbidity and mortality having a significant ongoing impact on Health Care National budgets. It is estimated that, at present, more than 3% of health care budgets of European Member Sates are dedicated to patients who are waiting for a transplant.

Mean expected half-life for a deceased kidney grafted in the USA has increased by 75% from 1988 to 1996, rising from 7.9 to 13.8 years. When adjusted to exclude dead patients with functioning graft, these data are 11 and 19.5 years respectively (Hariraran S. Johnson CP., Bresnatian BA., Taranto SE., McIntosh MJ., Stabilein D. Improved graft survival after transplantation in the USA. 1988-1996. N.Eng.J.Med. 2000; 342:605-612).

Ten years survival rate for liver transplantation was 31% before 1988 and it has been improved to nearly 60% in most European countries (European Liver Transplant Registry Report. [www.eltr.org](http://www.eltr.org)., Spanish Liver Transplant Registry Report.[www.msc.es/ont](http://www.msc.es/ont). Updated Sept. 2003).

According to the Registry of International Society for Heart and Lung Transplantation and the UNOS Registry, lung survival has increased from 70.9% to 76% between 1990 and 1997 (UNOS Registry Data. [www.unos.org](http://www.unos.org). Updated daily).

Not only does organ transplantation provide the possibility of saving lives but it also has the best cost/benefit ration in terms of both, economics' and the quality of life. The different types of organ transplantation have better quality indexes than other replacement therapies as compared with controls (Keown P. Improving the quality of life. The New Target for Transplantation. 2001; 72:567-574).

Currently more than 80,000 patients per year worldwide are receiving a grafted solid organ and the demand is increasing continuously owing to greater experience and better results.

## **1.2. Organ transplantation and waiting lists**

Despite all these advantages conferred by organ transplantation many people cannot benefit from such opportunity.

More than 40,000 patients are currently waiting for a kidney in Western Europe, while the number of deceased donors remain stable (International Figures on organ donation and transplantation – 2003. Newsletter Transplant. Sept. 2004; Vol.9.Nº1) mortality rates while waiting range from 5 to 30% depending on the country and the type of organ that is needed.

Tables 1 and 2 show the evolution of the figures for patients admitted to the waiting list and grafted for both kidney and liver transplants, in some selected European countries from which there are data received by the Council of Europe since 1989. It can be easily seen that the number of indications increased much more than the grafts performed.

**Table 1. Kidney Transplants and Waiting List Patients**

	1989		2004			
	WL	Tx	WL	Δ %	Tx	Δ %
France	4.603	1957	5.380	16,8	2.127	8,6
Eurotransplant	9.445	3.172	12.251	29,7	3.948	24,4
Skandiatransplant	926	854	1.235	33,3	927	8,3
U.K. /Ireland	3.704	1.960	6.829	84	1.924	-1,8
Spain	5.024	1.039	4.026	-19,8	2.133	105

**Table 2. Liver Transplants and Waiting List Patients**

	1989		2004			
	WL	Tx	WL	Δ %	Tx	Δ %
France	183	585	460	151	833	42
Eurotransplant	180	499	2.035	1000	1.391	178
Skandiatransplant	21	65	58	176	248	281
U.K. /Ireland	51	298	271	431	665	123
Spain	90	170	631	600	1037	501

Data are presented as Waiting List Patients (absolute number on December 31<sup>st</sup>) and transplant patients (absolute annual number).

Eurotransplant: Austria, Belgium, Germany, Luxembourg, Slovenia and The Netherlands. Population: 119 million inhabitants.

France: Population: 61,2 million inhabitants.

Skandiatransplant: Denmark, Finland, Norway and Sweden. Population: 24.1 million inhabitants.

United of Kingdom + Ireland: Population: 62.8 million inhabitants.

Spain: Population: 42,8 million inhabitants.

However, this is only the top of the iceberg and that the unmet need for organs is probable much higher. Due to the scarcity of organs, transplant clinicians are extremely selective about the patients they include in the waiting list.

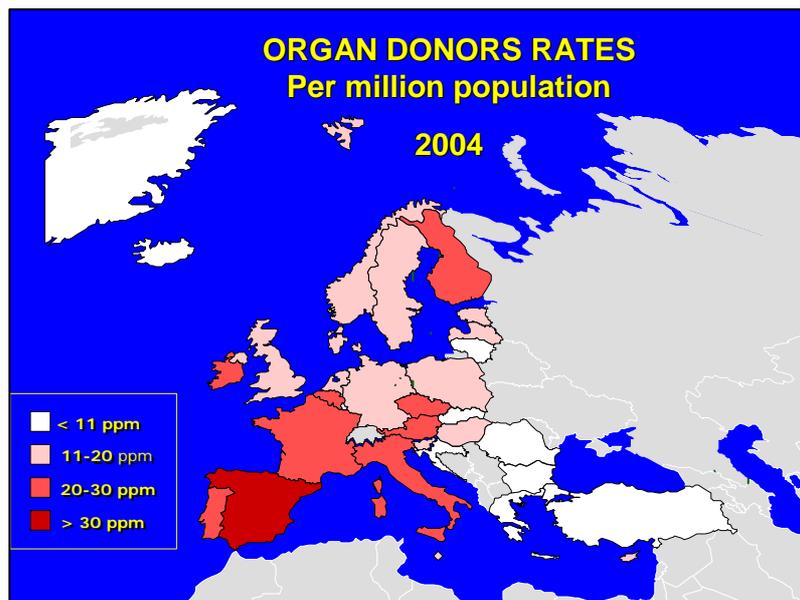
Even in cases of sustained increases in the number of donors', waiting list patients and times are very difficult to reduce. Demand of transplant increases more and faster than organ donor rates. However, the increase in the number of available donors will help to reduce the gap between supply and demand if not getting an absolute reduction of the waiting list.

Average prevalence rate of end stage renal failure in Europe is around 1,000 patients p.m.p. Among those, between 20 and 30% are accepted to the waiting list for a kidney transplant. Annual incidence is around 140-150 new patients p.m.p., giving an average need of kidney transplants of 50 grafts p.m.p. per year, to cover the yearly needs. This rate will stabilize the waiting list but not decrease it, since the historical will always remain. Mean waiting time for a kidney transplant is very often over 2 or 2.5 years. However, it is well known that kidney survival after transplantation is highly correlated with the time that the patient has been under replacement therapy with dialysis. There is an absolute need to decrease mean waiting times if not the absolute number of patients on the waiting list. Kidney transplant rates over 60 p.m.p. are necessary to reduce both renal waiting patients and waiting times. An increase in the organ donation rate up to 25 donors p.m.p. which is feasible and achievable will not be enough, but more easily complemented with other alternatives such as living donation

#### **1.4. Expanding donor pool: a common problem to face**

Severe organ shortage remains main challenge for Member states in the European Union face with regard to organ transplantation. Every day nearly ten patients will die waiting for an organ in our western European societies.

Fig. 1 Shows differences in the organ donor rate in the European Union.



**Fig. 1** Organ Donors Rate 2004 (pmp)

There are different reasons to explain this shortage of organs. The majority of organ donors are patients who died in a hospital after a severe brain damage and can be diagnosed as having brain death. It has to be outlined that not more than 1% of death people and not more than 3% of the people who die in a hospital hits this situation. Therefore, in any case, the number of potential donors is very low. Besides, the process of organ donation and procurement is a very delicate and complex one that implies the cooperation of many actors and can be broken at any time. Moreover it is subject to time pressure and should be done within few hours what enhances the weakness of the process itself.

The use of living donors is an increasing alternative but not widely and extensively implemented and presenting with an important ethical dilemma; the physician must risk the life of a healthy person to save or improve the life of a patient. The use of living donation varies widely within Europe with an average activity of 16% of all kidney transplant procedures.

Organizational structure is a cornerstone in the organ donation/transplantation systems. It has an important role in the establishment of levels of quality and safety, in the allocation procedures in ensuring accountability for performance

hence, having an important role, or even being determinant in defining studies and, strategies to entrance organ availability.

Even among European Countries with well developed health services there are considerable differences in the organ donation and transplantation and it seems that some organizational models are better performing than others several studies have shown that investing in organ procurement is a good health investment. It is highly likely that obtaining additional donors will be cost effective, even at much higher average cost per donor.

### **1.5. Proposal for a preliminary study**

The scarcity of available grafts will have severe consequences that can reach ever greater dimension in the wider European context with an increasing need for organ transplantation and circulation of patients. Aspects such as ethics, organization or safety need to be addressed also. Efforts should be stressed to optimize existing strategies and techniques and to increase the availability of transplant material. Several European countries have developed models and strategies aimed to organize and improve procurement and transplantation activities. The analysis of such programs is mandatory to explore what ever it can be applicable to other areas or regions. Organ donation acceptance rates vary widely among the European Countries and the analysis of legislative aspects, communication or teaching programmes or publicity measures can be of outmost interest to determine what kind of actions can be more efficient to reduce refusals to donation.

Aim of this first and preliminary analysis is to go through the different actions and programs in place to better understand the difference and try to propose common or specific strategies.

### **1.6. Efficiency and benefits of the donation-transplantation process**

It has been calculated that 10,000 renal patients living with a functioning kidney graft are saving to health systems over 200 million € annually (in terms of differences of the economical costs of the different replacement therapies for end stage kidney patients, when comparing cost of transplantation versus costs of

dialysis treatments). This is just taking into account daily dialysis costs and not including structural costs. Cost-saving and cost benefits referred to Quality's gains can be increased with a transplant. It has been defined that an increase of 6 donors p.m.p. in a country like Germany will lead to 29 Quality's gains of patients with end-stage renal disease (calculation was made over a 20 years period). (Leo Roels, Bernard Cohen, Caroline Gachet and Blanca Miranda. *Joining Efforts in Tackling the Organ Shortage: The Donor Action Experience*. *Clinical Transplants* 2002;Chap. 8:111-120).

However, being this very important, the most important benefit for the grafted patients is measured in terms of both, survival and the improvement of the perceived quality of life. Quality analysis and cost/benefit studies programmed for large samples and in different countries will definitely establish the need of a minimal invest in the organ donor promotion activities. With the saved money with a larger pool of kidney transplant patients in a given country, the total expenditures for a donation and transplantation system for all types of organs can, for sure, be covered.

### **1.7. European framework: an added value**

One of the most important aim of European Union policies is that all inhabitants should have same duties and rights. This obviously applies to health care provision and hence transplantation medicine. The provisions of harmonized health standards and guidelines are of almost interest Newsletters. It is not less important to study the different problems that can affect the country system and try to harmonize common ways to face and solve these problems.

Alliance-O provides the best framework to exchange experiences and harmonize common position to face problems that are affecting all of us in transplantation medicine. Besides, the addition of the experience of all of us will give the only opportunity to gain enough knowledge in areas where the problem is anecdotic or very rare in each country. It is always better to add than to divide but in this field it is specially true.

Transnational cooperation is not always well organized: duplicate work is often taking place. The work done in different countries is some times difficult to compare due to unnecessary methodological variations. Harmonization of analysis and implementation practices is hence of great interest. The development of a uniform and comprehensive set of standards or suggestion programs will be the basis for a better care in this field within the scope of the European countries.

## **2. DATA COLLECTION AND ANALYSIS**

Questionnaires included in the annex have been sent to all participants to obtain the data that is presented. Activity data on donation and transplantation has been checked with the official data published by the Council of European (Transplant Newsletter, Vol. 10 n° 1, 2005).

Questionnaires included data about general health care items as well as transplant topics and initiatives and also the data concerning the expanded donor pool.

Donation areas have been analyzed separately depending on the source of the donated organs, being living, encephalic death or non heart beating donation.

First part of the results is concerned with activity in organ donation and transplantation in all European Countries. Data comes from the official data collection action of the select Committee of Experts of the Council of Europe and corresponds to 2004 figures. Data presented includes all indicators of donation and transplantation in absolute numbers as well as population referred indicators. Waiting list data were applicable is also included. Transplantation activity is recorded and shown taking into account the different and possible subtypes that is living or deceased (encephalic death or non heart beating), paediatric or adult single or double, split or full sized, etc. Second set of data records figures only for participant countries, referred to number of transplant centres, transplant activity or waiting list. Third set of data corresponds to the use of extended donors were data could be collected. Finally data corresponding to initiatives to entrance organ

availability, that were collected as open questions, have been aggregated in the most common items addressed by participant countries

Data has been introduced into a specific database and corresponding correlation and general descriptive statistical analysis has been undertaken.

Comparative graphics are presented.

Data corresponding to initiatives and implementation of programmes concerning transplantation and donation topics has been collected and analysed in two phases. In the first part we made open questions addressed to partners asking about activities and initiatives aimed to promote organ donation and improve the number of available organs either from cadaveric or living donors, and referred to both types encephalic deaths and non heart beating donors.

The open answer were classified and stratified and resent to the partners for evaluation and review. Besides, in that way they could answer only with a yes or a no, and this is the final way in which data is presented in the printed tables. So far, we could get more accessible data on the activities, initiatives and programmes that are described.

### 3. RESULTS

#### 3.1 Donation and transplantation activity

COUNTRIES	AUSTRIA	BELGIUM	BULGARIA	CROATIA	CYPRUS	CZECH R.	DENMARK	ESTONIA	FINLAND	FRANCE	GEORGIA	GERMANY	GREECE
<b>Population (million inhab.)</b>	8'2	10'4	7.8	4.4	0.7	10'3	5'4	1'4	5'2	61'5	5	82'4	11
<b>DONATION</b>													
Cadaveric D. - included NHBD - (Rate - pmp -)	185 (22'56)	227 (21'83)	7 (0.9)	59 (13.4)	8 (11.4)	211 (20'5)	64 (11'9)	19 (13'6)	109 (20'9)	1291 (21)		1075 (13'05)	66 (6)
NHB Donors (pmp)	3 (0,37)	5 (0'48)				2 (0'19)							
% Multiorgan donors	76'8	83'7	57	83		54	65'6	10	56	96		76'7	
<b>TRANSPLANTATION</b>													
<b>KIDNEY</b>													
TX – included all the combinations - (pmp) % (Living TX/ Total TX)	386 (47'07) 9.8	372 (35'77) 5.1	24 (3) 41.6	113 (25.7) 6.1	44 (62.8) 65.9	442 (43) 8.6	187 (34'6) 27.8	40 (28'6) 12.5	197 (37'4) 2.5	2423 (39'4) 6.7	8 (1'6) 100	2478 (30'07) 19.7	192 (17'4) 39.5
Paediatric <15 years	14	16		2	1	8	10		8	68		78	
Cadaveric TX (pmp)	348 (42'44)	353 (33'94)	14 (1.8)	106 (24)	15 (21.4)	404 (39'3)	135 (25)	35 (25)	192 (36'8)	2259 (36'7)		1989 (24'14)	116 (10'5)
-Single TX (pmp)				95 (21.59)	1 (1.4)	404 (39'3)		35 (25)		2226 (36'2)			114 (10'4)
-Double TX (pmp)					7 (10)					33 (0'5)			2 (0'18)
Living TX (pmp)	38 (4'6)	19 (1'8)	10 (1.3)	7 (1.59)	29 (41.4)	38 (3'7)	52 (9'6)	5 (3'6)	5 (1)	164 (2'7)	8 (1'6)	489 (5'9)	76 (6'9)
NHB kidney TX (pmp)	13 (1'59)	7 (0'67)				2 (0'2)							
<b>LIVER</b>													
TX – included all the combinations - (pmp)	132 (16'10)	229 (22'02)	1 (0.13)	43 (9.7)		83 (8'1)	42 (7'8)		50 (9'6)	931 (15'1)		881 (10'69)	29 (2'6)
Paediatric <15 years	8	31	1 (0.13)			3	11		4	51		91	
-Split Liver TX (pmp)	8 (0'98)	20 (1'92)								56 (0'9)		117 (1'42)	
-Domino Liver TX(pmp)		1 (0'10)								12 (0'2)		7 (0'08)	
Living Liver TX (pmp)	6 (0'73)	25 (2'40)	1 (0.13)			1 (0'1)	1 (0'2)			48 (0'8)		64 (0'78)	
NHB Liver TX (pmp)		5 (0'48)											

COUNTRIES	AUSTRIA	BELGIUM	BULGARIA	CROATIA	CYPRUS	CZECH R.	DENMARK	ESTONIA	FINLAND	FRANCE	GEORGIA	GERMANY	GREECE
<b>HEART</b>													
TX-included Heart-lung transplant- (pmp)	64 (7'8)	77 (7'4)	1 (0.13)	8 (1.8)		48 (4'7)	24(4'5)		21 (4)	339 (5'6)		412 (5)	6 (0'54)
Paediatric <15 years		2							3	8		31	
<b>HEART-LUNG</b>													
Transplants (pmp)	1 (0'12)	3 (0'29)					1 (0'2)		2 (0'4)	22 (0'4)		14 (0'17)	
Paediatric <15 years												1	
<b>LUNG</b>													
TX – included all the combinations - (pmp)	78 (9'51)	63 (6'06)				7 (0'7)	28 (5'2)		10 (1'9)	167 (2'8)		240 (2'91)	
Paediatric <15 years	1									2		3	
-Single (pmp)	20 (2'4)	28 (2'7)				3 (0'3)	22 (4'1)		3 (0'6)	47 (0'7)		44 (0'5)	
-Double - included Heart/ Lung TX - (pmp)	58 (7'1)	35 (3'4)				4 (0'4)	6 (1'1)		7 (1'3)	120 (2)		196 (2'4)	
NHB – double + single - Lung TX (pmp)													
<b>PANCREAS</b>													
TX – included all the combinations - (pmp)	41 (5)	42 (4'04)	11 (2.5)			25 (2'4)				103 (1'7)		192 (2'33)	
Paediatric <15 years													
-Kidney - Pancreas TX (pmp)	30 (3'66)	18 (1'73)	11 (2.5)			17 (1'6)				86 (1'4)		163b (1'98)	
-Pancreas TX Alone (pmp)	5 (0'61)	5 (0'48)				8 (0'8)				17 (0'3)		20 (0'24)	
<b>SMALL BOWEL</b>													
TX – included all the combinations - (pmp)										7 (0'1)			
Paediatric <15 years										7			
-Liver + Small Bowel (pmp)										1 (0'02)			
-S. B. TX Alone (pmp)										6 (0'1)			
<b>MULTIVISCERAL</b> (pmp)										49 (0'8)			

COUNTRIES	HUNGARY	ICELAND	IRELAND	ISRAEL	ITALY	LATVIA	LITHUANIA	LUXEMBURG	MALTA	NORWAY	POLAND	POR TUGAL	ROMANIA
<b>Population (million inhabitants)</b>	10	0'3	3'9	6'8	56.9	2'3	3.4	0'5	0.4	4'6	38'2	10	21
<b>DONATION</b>													
Cadaveric D. - included NHB D. - (Rate - pmp -)	160 (16)	5 8 (16'7)	86 (22'1)	60 (8'82)	1203 (21'1)	41 (17'83)	35 (10.2)	1 (2)	4 (10)	90 (19'6)	562 (14'7)	222 (22'2)	10 (0'48)
NHB Donors (pmp)				1 (0'14)		15 (6'53)							
% Multiorgan donors	45	80		75	83'7	2'44	17.1	100	100	90	39	79'7	80
<b>TRANSPLANTATION</b>													
<b>KIDNEY</b>													
TX – included all the combinations - (pmp) % (Living TX/ Total TX)	295 (29'5) 3.7	3 (10'2) 100	146 (37'4) 2	81 (11'9) 85.1	1881 (33) 7.1	72 (31'31) 1.3	61 (17.7) 6.55	10 (20) 0	11 (27.5) 36.4	265 (57'6) 35.8	1067 (27'9) 2	436 (43'6) 6.6	189 (9) 88.8
Paediatric <15 years	13		10	14	40	1			1	9	31	10	7
Cadaveric TX (pmp)	284 (28'4)		143 (36'7)	81 (11'9)	1746 (30'6)	71 (30'87)	57 (16.5)	10 (20)	8 (20)	170 (37)	1045 (27'3)	392 (39'2)	19 (0'9)
-Single TX (pmp)	284 (28'4)		138 (35'4)	70 (10'29)	1564 (27'4)	71 (30'87)	57 (16.5)		8 (20)		1045 (27'3)	391 (39'1)	
-Double TX (pmp)			5 (1'3)		101 (1'8)							1 (0'1)	
Living TX (pmp)	11 (1'1)	3 (10'2)	3 (0'8)	69 (10)	135 (2'4)	1 (0'44)	4 (1.2)		4 (10)	95 (20'7)	22 (0'6)	29 (2'9)	168 (8)
NHB kidney TX (pmp)				2 (0'29)		24 (10'44)							
<b>LIVER</b>													
TX – included all the combinations - (pmp)	43 (4'3)		45 (11'5)	45 (6'61)	1035 (18'2)					45 (9'8)	199 (5'2)	205 (20'5)	16 (0'76)
Paediatric <15 years	6			6	61					5	33	11	2
-Split Liver TX (pmp)				2 (0'29)	94 (1'6)					1 (0'2)		3 (0'3)	
-Domino Liver TX(pmp)												46 (4'6)	
Living Liver TX (pmp)				6 (0'88)	19 (0'3)						18 (0'5)	5 (0'5)	9 (0'43)
NHB Liver TX (pmp)													
<b>HEART</b>													
TX-included Heart-lung transplant- (pmp)	10 (1'0)			17 (2'5)	353 (6'2)	1 (0'44)				34 (7'4)	105 (2'7)	45 (4'5)	4 (0'19)
Paediatric <15 years				2	14					1	2	1	
<b>HEART-LUNG</b>													
Transplants (pmp)					3 (0'1)						1 (0'03)		
Paediatric <15 years					1								

COUNTRIES	HUNGARY	ICELAND	IRELAND	ISRAEL	ITALY	LATVIA	LITHUANIA	LUXEMBURG	MALTA	NORWAY	POLAND	PORTUGAL	ROMANIA
<b>LUNG</b>													
TX – included all the combinations - (pmp)	4 (0'4)			29 (4'26)	85 (1'5)					11 (2'4)	1 (0'03)	10 (0'1)	
Paediatric <15 years				1	4								
-Single (pmp)				23 (3'38)	40 (0'7)						1 (0'03)	10 (0'1)	
-Double - included Heart/ Lung TX - (pmp)	4 (0'4)			6 (0'88)	45 (0'8)					11 (2'4)			
NHB – double + single - Lung TX (pmp)													
<b>PANCREAS</b>													
TX – included all the combinations - (pmp)	12 (1'2)		4 (1)	9 (1'32)	94 (1'6)					10 (2'2)	16 (0'4)	12 (1'2)	2 (0'1)
Paediatric <15 years					1								
-Kidney - Pancreas TX (pmp)	12 (1'2)		4 (1)	9 (1'32)	55 (1)					8 (1'7)	15 (0'4)	12 (1'2)	2 (0'1)
-Pancreas TX Alone (pmp)					39 (0'6)					2 (0'4)	1 (0'03)		
<b>SMALL BOWEL</b>													
TX – included all the combinations - (pmp)					7 (0'1)								
Paediatric <15 years													
-Liver + Small Bowel (pmp)													
-S. B. TX Alone (pmp)					6 (0'1)								
<b>MULTIVISCERAL (pmp)</b>													
					1 (0'02)								

COUNTRIES	SERBIA	SLOVAK R.	SLOVENI A	SPAIN	SWEDEN	SWITZER LAND	T. NETHERL ANDS	TURKEY	U. K.	AUSTRA LIA	CANADA	N. ZEALAND	USA
<b>Population (million inhabitants)</b>	7.5	5'4	2	43'2	9	7'2	16'3	67'8	59	20'1	31'9	4'1	297
<b>DONATION</b>													
Cadaveric D. - included NHBD - (Rate - pmp -)		55 (10'22)	36 (18)	1495 (34'6)	123 (13'7)	91 (12'6)	247 (15'5)	136 (2)	813 (13'8)	218 (10'8)	414 (13)	40 (9'8)	7150 (24'1)
NHB Donors (pmp)				71 (1.6)		6 (0'8)	111 (6'81)	1 (0'01)	87 (1'5)	4 (0'2)			
% Multiorgan donors		32'73	64	83.5	88'6	80	53	17	84	84	85	80	
<b>TRANSPLANTATION</b>													
<b>KIDNEY</b>													
TX – included all the combinations - (pmp) % (Living TX/ Total TX)	71 (9.5) 86	99 (18'4) 0	55 (27'50) 0	2125 (49'2) 2.8	372 (41'3) 38.1	256 (35'5) 31.6	673 (41'29) 37.1	775 (11'4) 68.2	1905 (32'3) 24.3	651 (32'3) 37.8	1061 (33'2) 38.9	106 (26'1) 45.2	16001 (54) 41.5
Paediatric <15 years	4	1		68	14	6	38		86	8			764
Cadaveric TX (pmp)	10 (1.4)	99 (18'4)	55 (27'50)	2064 (47'8)	230 (25'5)	163 (22'6)	423 (25'95)	246 (3'6)	1442 (24'4)	405 (20'1)	603 (18'9)	58 (14'2)	9354 (31'5)
-Single TX (pmp)			55 (27'50)	2025 (46'9)		160 (22'2)		243 (3'5)	1358 (23)	402 (19'9)	589 (18'4)	54 (13'2)	
-Double TX (pmp)				39 (0'9)		3 (0'4)		3 (0'04)	8 (0'1)	3 (0'1)	14 (0'4)	4 (0'9)	
Living TX (pmp)	61 (8.2)			61 (1'4)	142 (15'8)	81 (11'3)	250 (15'3)	529 (7'8)	463 (7'8)	246 (12'2)	413 (12'9)	48 (11'8)	6647 (22'4)
NHB kidney TX (pmp)				92 (2'1)		12 (1'6)	171 (10'49)	1 (0'01)	147 (2'5)	8 (0'4)			
<b>LIVER</b>													
TX – included all the combinations - (pmp)			15 (7'50)	1040 (24'1)	133 (14'8)	84 (11'7)	109 (6'69)	245 (3'6)	731 (12'4)	177 (8'8)	420 (13'2)	36 (8'8)	6168 (20'8)
Paediatric <15 years				58	13	5	11		83	6	10	1	580
-Split Liver TX (pmp)				14 (0'3)		2 (0'3)	6 (0'37)	2 (0'02)	60 (1)	28 (1'3)	10 (0'3)	2 (0'4)	
-Domino Liver TX (pmp)				7 (0'2)	6 (0'7)	2 (0'3)			2 (0'03)				
Living Liver TX (pmp)		2 (0'4)		18 (0'4)	9 (1)	4 (0'6)	3 (0'18)	133 (1'9)	10 (0'2)	1 (0'04)	53 (1'7)		323 (1'1)
NHB Liver TX (pmp)				5 (0'1)			8 (0'49)		28 (0'5)				
<b>HEART</b>													
TX-included Heart-lung transplant- (pmp)		11 (2'04)	3 (1'50)	294 (6'8)	31 (3'4)	29 (4)	32 (1'96)	33 (0'4)	180 (3'1)	78 (3'8)	146 (4'6)	6 (1'4)	2055 (6'9)
Paediatric <15 years				20	2			1	24	1	32		297
<b>HEART-LUNG</b>													
Transplants (pmp)				7 (0'2)					15 (0'3)	6 (0'2)	3 (0'09)		39 (0'1)
Paediatric <15 years									4				6

COUNTRIES	SERBIA	SLOVAK R.	SLOVENIA	SPAIN	SWEDEN	SWITZER LAND	T. NETHERLANDS	TURKEY	U. K.	AUSTRALIA	CANADA	N. ZEALAND	USA
<b>LUNG</b>													
TX – included all the combinations - (pmp)				143 (3'3)	26 (2'9)	36 (5)	54 (3'31)	2 (0'02)	134 (2'3)	98 (4'8)	135 (4'2)	12 (2'9)	1173 (3'9)
Paediatric <15 years				7		1	1		5	4	6		54
-Single (pmp)				41 (0'9)	19 (2'1)	2 (0'3)	7 (0'4)	2 (0'02)	37 (0'6)	11 (0'5)	29 (0'9)	2 (0'4)	
-Double - included Heart/ Lung TX - (pmp)				102 (2'4)	7 (0'8)	34 (4'7)	47 (2'9)		97 (1'6)	87 (4'3)	106 (3'3)	10 (2'4)	
NHB – double + single - Lung TX (pmp)				7 (0'2)					2 (0'03)				
<b>PANCREAS</b>													
TX – included all the combinations - (pmp)				74 (1'7)	8 (0'9)	11 (1'5)	22 (1'35)	37 (0'5)	79 (1'3)	31 (1'5)	61 (1'9)	2 (0'4)	1484 (5)
Paediatric <15 years										1			
-Kidney - Pancreas TX (pmp)				61 (1'4)	5 (0'6)	10 (1'4)	18 (1'10)	21 (0'3)	69 (1'2)	23 (1'1)	45 (1'4)	2 (0'4)	880 (3)
-Pancreas TX Alone (pmp)				12 (0'3)	3 (0'3)	1 (0'1)	4 (0'25)	16 (0'2)	10 (80'2)	5 (0'2)	16 (0'5)		604 (2)
<b>SMALL BOWEL</b>													
TX – included all the combinations - (pmp)				7 (0'2)				1 (0'01)	7 (80'1)		1 (0'03)		152 (0'5)
Paediatric <15 years				5					7				92
-Liver + Small Bowel (pmp)				4 (0'1)					6 (0'1)				
-S. B. TX Alone (pmp)				3 (0'1)				1 (0'01)	1 (0'02)				152 (0'5)
<b>MULTIVISCERAL</b> (pmp)					2 (0'2)						1 (0'03)		

Data from 35 countries is shown (including Israel and Turkey). Data from countries abroad: Australia, USA, Canada and N. Zealand is also shown as a matter for comparison. A population of nearly 600 million people is covered. However, there is a very high diversity both in geographic extension and population. Six countries are over 40 million inhabitants and accounted for 60% of the population (370 million people) and 23 countries are below 10 million inhabitants. Although activity is shown as referred to the population, to try to make it comparable, probably data cannot be compared as easily. All countries recorded donation and kidney transplantation activities. But not every country got all transplantation programmes and possibilities, as shown in the summary table.

	<b>Number of Countries</b>	<b>Range (pmp)</b>	<b>Median</b>
<b>Deceased Donation Rate</b>	33	0.5-34.6	14.25
<b>NHBD</b>	10	0.01-6.8	0.42
<b>Kidney Tx</b>	35	1.6-57.6	30.69
<b>Living donation (%)</b>	32	1%-100%	29.70
<b>Cad. Kidney Tx</b>	33	0.9-48	25.90
<b>Paediatric Kidney Tx</b>	27	-	1.43
<b>Double Kidney Tx</b>	8	-	0.40
<b>NHBD Kidney Tx</b>	9		1.60
<b>Liver Tx</b>	25	0.8-24	10.20
<b>Paediatric Liver Tx</b>	20	1-58*	0.60
<b>Split Liver Tx</b>	13	1-117*	0.90
<b>Domino Liver Tx</b>	8	1-46*	0.20
<b>NHBD Liver Tx</b>	4	5-28*	0.48
<b>Living Liver Tx</b>	19	1-133*	0.50
<b>Heart Tx</b>	26	0.13-6.8	3.40
<b>Lung Tx</b>	19	0.1-4.6	1.60
<b>Pancreas</b>	20	0.1-5	1.20
<b>Small Bowel</b>	5	1-7*	0.10

(\*) Absolute numbers.

As can be observed there is a great variability among European Countries both in activities, size and characteristics.

There are 2 countries that did not report any living kidney transplant activity and 3 that did not registered any deceased activity. Among those reporting living kidney

transplantations, in many of them it represented less than 10% of the overall kidney transplants.

Non heart beating donation is presented in only 10 countries and in all cases with a very low activity (median of 0.42 donors pmp/year). Kidney transplants from NHBD are reported from 9 countries only, liver transplants from 4 countries and ....

25 Countries reported some liver activity but in 15 it was less than 10 grafts per million population. Living liver transplants were reported in 19 countries, but in 12 less than 10 grafts were registered and 4 countries did only one.

### 3.2. Waiting lists and transplant centres

COUNTRIES	AUSTRIA	BELGIUM	CZECH R.	CYPRUS	DENMARK	ESTONIA	FINLAND	FRANCE	GEORGIA	GERMANY	GREECE	HUNGARY
<b>Population (million inhabitants)</b>	8.2	10.4	10.29	0.7	5.4	1.4	5.2	61.53	5	82.4	11	4
<b>WAITING LIST</b>												
<b>KIDNEY</b>												
<b>N°TX CENTRES:</b>			7	1	4	1	1	45	2		4	4
Patients admitted WL during 2004	402	452	440	20	257	40	224	3032		2833		371
Patients awaiting for a TX 2004, 31 <sup>st</sup> Dec	805	936	608	100	403	23	244	5626		9270	847	1021
Patients dead on the WL during 2004	44	31	44	5	3	3	5	115		482		43
ESRD on dialysis treatment during 2004			4504	240					408			4600
<b>LIVER</b>												
<b>N°TX CENTRES:</b>			2		1		1	24			1	1
Patients admitted WL during 2004	183	308	93		52		50	1160		1427		81
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec	108	243	46		16		2	474		1525		47
Patients dead on the WL during 2004	52	26	7		2			103		288		15
<b>HEART</b>												
<b>N°TX CENTRES:</b>			2		2		1	26			1	1
Patients admitted WL during 2004	95	93	75		33		23	429		756	9	21
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec	75	34	74		18		4	277		613	18	22
Patients dead WL during 2004	19	12	16		2		4	87		172	2	13
<b>HEART-LUNG</b>												
<b>N°TX CENTRES:</b>								9				
Patients admitted WL during 2004								29				
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec								39				
Patients dead WL 2004								18				

COUNTRIES	AUSTRIA	BELGIUM	CZECH R.	CYPRUS	DENMARK	ESTONIA	FINLAND	FRANCE	GEORGIA	GERMANY	GREECE	HUNGARY
<b>LUNG</b>												
<b>N°TX CENTRES:</b>			1		1		1	12			1	
Patients admitted WL during 2004	100	66	16		45		9	176		405		9
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec	57	46	22		41		4	144		457	2	4
Patients dead the WL during 2004	13	11	3		8		1	44		108		
<b>PANCREAS</b>												
<b>N°TX CENTRES:</b>			1					8				2
Patients admitted WL during 2004	38	37	5				5	111		213		13
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec	36	53	6				13	181		158		14
Patients dead WL during 2004	1	5						8		14		1
<b>SMALL BOWEL</b>												
<b>N°TX CENTRES:</b>								1				
Patients admitted WL during 2004								3				
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec								4				
Patients dead WL during 2004												

COUNTRIES	ICELAN D	IRELAN D	ISRAEL	ITALY	LATVIA	LITHUA NIA	LUXEMB URG	MALTA	NORWA Y	POLAND	PORTUG AL	ROMANI A
<b>Population (million inhabitants)</b>	0.3	3.9	6.8	56.99	2.3	3.4	0.5	0.4	4.6	38.23	10	21
<b>WAITING LIST</b>												
<b>KIDNEY</b>												
<b>N°TX CENTRES:</b>	1	1	6	39	1	2		1	1	18		5
Patients admitted WL during 2004			220	2604	52	61	3	25	192	1190		432
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec		171	497	6561	375	434	14	85	169	1201		1626
Patients dead WL during 2004			29	188	12	4			13	38		73
ESRD on dialysis treatment during 2004								190		15340		
<b>LIVER</b>												
<b>N°TX CENTRES:</b>		1	3	20					1	6		1
Patients admitted WL during 2004			118	1359					53	290		234
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec		21	130	1457					4	105		290
Patients dead WL during 2004			27	137					5	25		36
<b>HEART</b>												
<b>N°TX CENTRES:</b>			3	18	6				1	4		2
Patients admitted WL during 2004			68	498	6				35	213		35
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec			121	640	6				4	178		72
Patients dead WL during 2004			24	93	1				1	42		8
<b>HEART-LUNG</b>												
<b>N°TX CENTRES:</b>										2		
Patients admitted WL during 2004										18		
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec										14		
Patients dead WL during 2004										7		
<b>LUNG</b>												
<b>N°TX CENTRES:</b>			2	14					1	1		

COUNTRIES	ICELAND	IRELAND	ISRAEL	ITALY	LATVIA	LITHUANIA	LUXEMBURG	MALTA	NORWAY	POLAND	PORTUGAL	ROMANIA
Patients admitted WL during 2004			41	186					32	7		
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec			44	238					45	8		
Patients dead WL during 2004			10	66					9			
<b>PANCREAS</b>												
<b>N°TX CENTRES:</b>		1	3	17					1	4		1
Patients admitted WL during 2004				126					14	30		
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec		7		205					14	25		
Patients dead the WL during 2004				7						2		
<b>SMALL BOWEL</b>												
<b>N°TX CENTRES:</b>				1								
Patients admitted WL during 2004				8								
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec				22								
Patients dead WL during 2004												

COUNTRIES	SLOVAK R.	SLOVENIA	SPAIN	SWEDEN	SWITZERLAND	T. NETHERLANDS	TURKEY	U. K.	AUSTRALIA	CANADA	NEW ZEALAND	USA
<b>Population (million inhabitants)</b>	5.38	2	43.2	9	7.2	16.3	67.8	59	20.11	31.94	4.06	297
<b>WAITING LIST</b>												
<b>KIDNEY</b>												
<b>N°TX CENTRES:</b>	4	1	42	4	6		25	25	20	24	3	250
Patients admitted WL during 2004	224	38		357	282	832	1403	2808				27298
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec	759	108	4231	350	488	116	7904	5299	1399	2975	301	61924
Patients dead WL during 2004	70	1		6	18	111		273		58		21548
ESRD on dialysis treatment during 2004		1225	21031				34262					
<b>LIVER</b>												
<b>N°TX CENTRES:</b>	1	1	24	3	3		17	7	8	9	1	117
Patients admitted WL during 2004	3	12	1460	130	115	154	631	875				10180
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec	7	6	701	17	86	155	737	253	104	667	12	17336
Patients dead WL during 2004	1	1	163	6	15	21		62		96		9573
<b>HEART</b>												
<b>N°TX CENTRES:</b>	2	1	17	3	4		12	7	4	12	1	131
Patients admitted WL during 2004	9	9	394	36	45	59	24	206				2908
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec	3	16	113	16	18	45	182	111	45	129	10	3309
Patients dead the WL during 2004	1	5	36	2	6	16		17		26		3150
<b>HEART-LUNG</b>												
<b>N°TX CENTRES:</b>												
Patients admitted WL during 2004												
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec												
Patients dead WL during 2004												

COUNTRIES	SLOVAK R.	SLOVENIA	SPAIN	SWEDEN	SWITZERLAND	T. NETHERLANDS	TURKEY	U. K.	AUSTRALIA	CANADA	NEW ZEALAND	USA
<b>LUNG</b>												
<b>N°TX CENTRES:</b>		1	8	2	2		12	6	4	5	1	67
Patients admitted WL during 2004		1	209	38	41	88	1	205				1964
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec			145	31	17	86	1	272	87	181	7	3659
Patients dead WL during 2004		1	26	6	3	14		46		43		1882
<b>PANCREAS</b>												
<b>N°TX CENTRES:</b>	1		10	3	2		25	9	2	7	1	141
Patients admitted WL during 2004			98		12	39	5	26				2788
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec			79		6	34	35	36	30	154	4	4159
Patients dead WL during 2004			3		1	2		1		3		2604
<b>SMALL BOWEL</b>												
<b>N°TX CENTRES:</b>			2	1	1			3		3		18
Patients admitted WL during 2004			8		2			14				244
Patients awaiting for a TX by 2004, 31 <sup>st</sup> Dec			6		1			6		1		195
Patients dead WL during 2004								2		1		219

Waiting list collection of data is quite difficult. Not all countries did register the number of patients admitted every year to the waiting list or the number of patient that died while waiting. On the other hand, there are no data about patients crossing borders and being admitted on waiting list of foreign countries. Data on waiting list seems not to be very accurate. Nevertheless it can be summarized that at the end of 2004 more than 39.100 patients were waiting for a kidney. This represents a prevalence of 67.5 kidney patients on waiting list per million population. If figures from Italy, Germany, France the UK and Spain (the biggest European countries) are taken this prevalence goes to 102. This has to be compared with 208 patients pmp in the USA, 69 in Australia or 93 in Canada.

Liver or heart values are much more difficult to compare since May that European Countries did not register liver or heart waiting list data. In the following summary table we try to offer some comparative data that can be non accurate between the biggest European Countries and the USA.

		France	Germany	Italy	Spain	UK	European Countries	USA
Population		1.5	82.4	56.9	43.2	59	303	297
Liver	Liver patients admitted during 2004	1,160	1,427	2,604	1,460	875	7,526 (24.8)	10,180 (33.6)
	Patients at the end of the year	474	1,525	6,561	701	253	9,514 (31.4)	17,336 (58.3)
	Dead patients	103	288	188	163	62	804 (2.65)	9,573 (31.6)
Heart	Heart patients admitted during 2004	429	756	1,359	394	206	3,144 (10.3)	2,908 (9.8)
	Patients at the end of the year	277	613	1,457	113	111	2,571 (8.48)	3,309 (11.1)
	Dead patients	87	172	137	36	17	449 (1.48)	3,150 (10.6)

As can be seen no big differences can be observed among the compared European Countries globally taken and the USA in terms of incidence of new patients admitted yearly to the waiting list. Differences start when cumulative patients or deaths on the waiting lists are compared.

Even among European countries difficulties are evident (i.e. 875 patients admitted in the UK for the liver waiting list, compared with 1460 in Spain or 2604 in Italy).

And those differences cannot be explained with different rates of morbidity and mortality due to liver or heart disease.

### **3.3. Comparative data among the partners: Donation and transplantation activities, Transplant centres and patients admitted to the waiting lists. Year 2004**

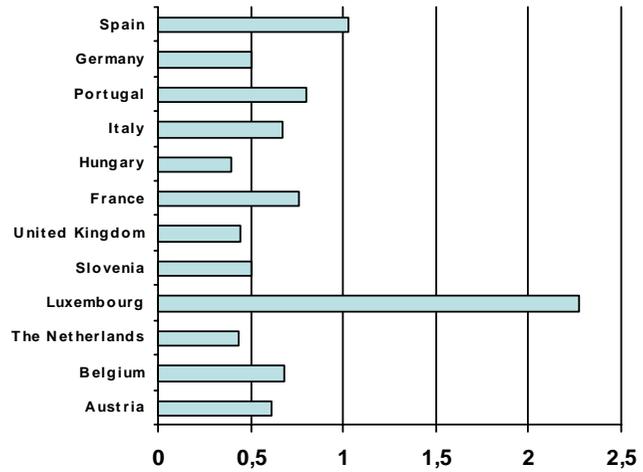
Just as a matter of better studying what is going on the participant's countries we've blocked the data collected for the group of partners: Transplant centres, transplant activity and waiting lists. If we analyzed the number of transplant centres related to the population covered we found that there are countries with concentrated activities in few centres such as Hungary or the UK: less than 0.5 kidney transplant centres per million population, less than 0.2 liver or heart transplant centres pmp and less than 0.1 lung transplant centres pmp. On the other side, there are countries with decentralized activity such as Spain or Belgium: more than 1 kidney transplant centres pmp, or nearly 0.6 liver transplant pmp.

It does not seem to be a correlation between the global activity and the type of organization of the activity, concentrated or decentralized. However, too few countries are analyzed at the point.

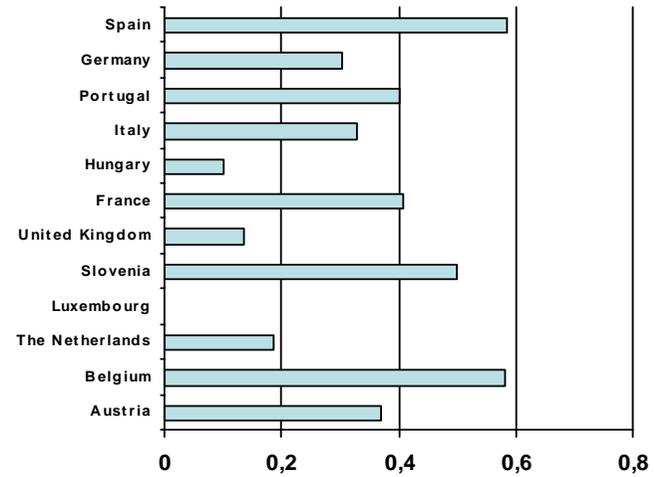
Big differences are also registered among participants in what is related with global activity of transplantation, living donation vs deceased donation and the admittance of the patients in the waiting list.

Kidney and liver transplantation is much higher in Austria, Belgium and Spain than in the countries. However, living transplantation does not account for significant percentage in those countries. It seems that living donation correlates negatively with deceased donation, but, again too few data is analysed. Besides, lung and heart transplant activity is much higher in Belgium and Austria than in the other countries and this data correlates with the number of patients admitted to the waiting list. Due to the allocation system of Eurotransplant, as larger is the waiting list as higher is the possibility for matching heart or lung donors with recipients. However it remains unclear why those small countries account for higher

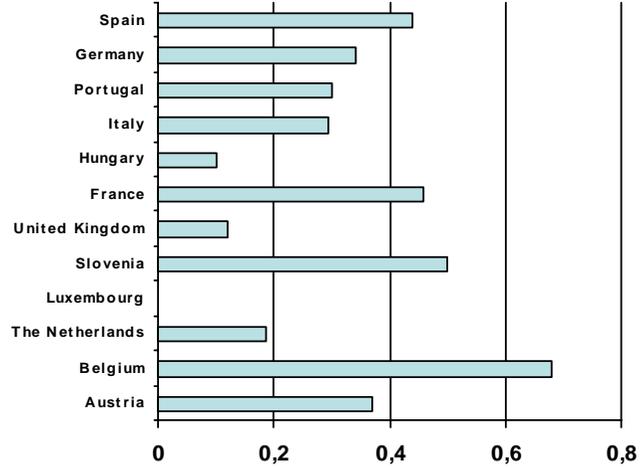
registrations rates on the waiting list. Probably they are accepting patients across borders for lung, heart and pancreas transplantations. On the other side, there are countries such as France or the UK with very low rates of registrations. The reason for these differences remains unclear. However it does not seem to lie on differences on mortality rates due to heart or diabetes or respiratory diseases.



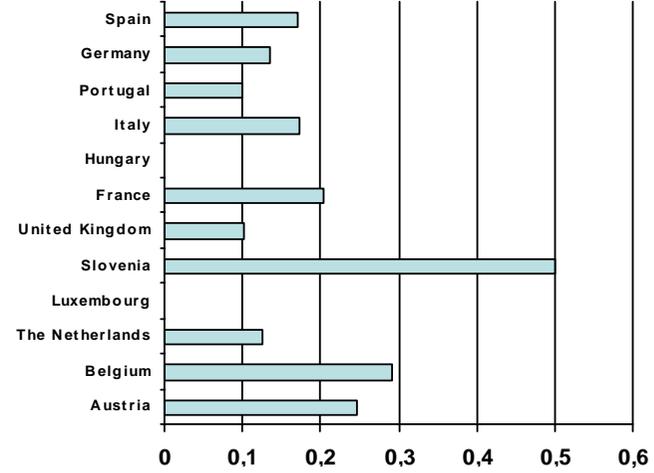
Kidney Transplant Centers pmp



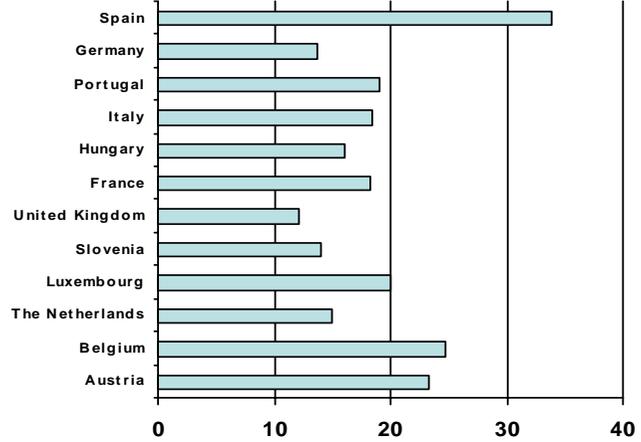
Liver Transplant Centers pmp



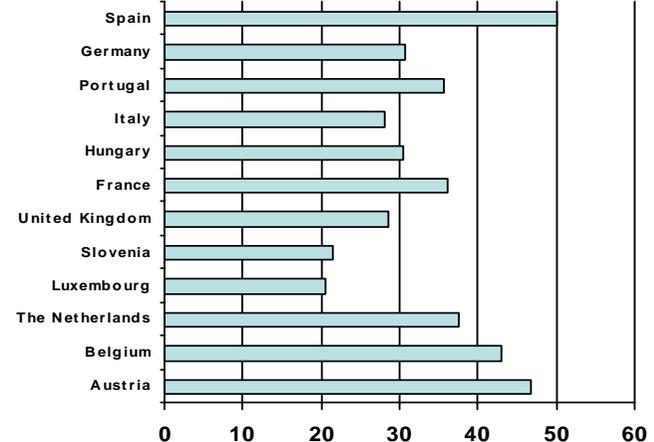
Heart Transplant Centers pmp



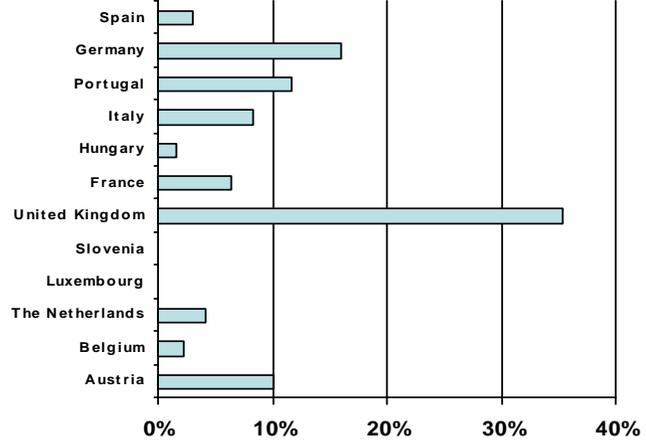
Lung Transplant Centers pmp



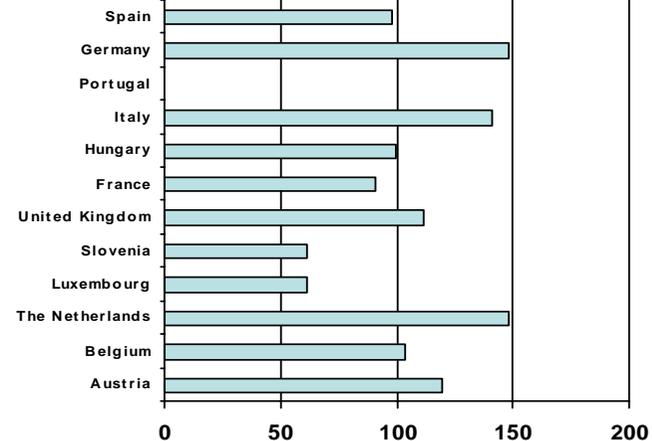
Donors pmp



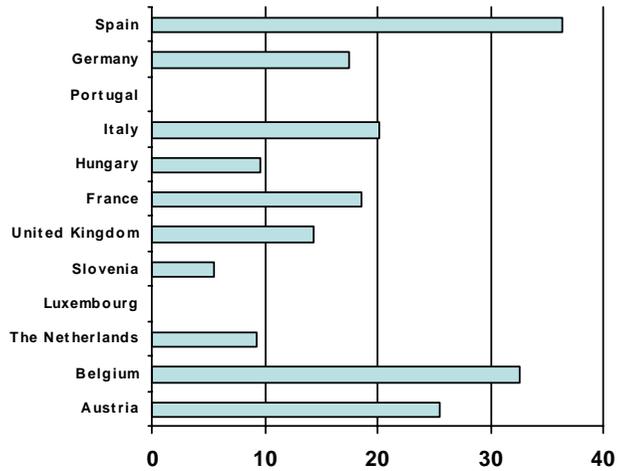
Kidney Transplants pmp



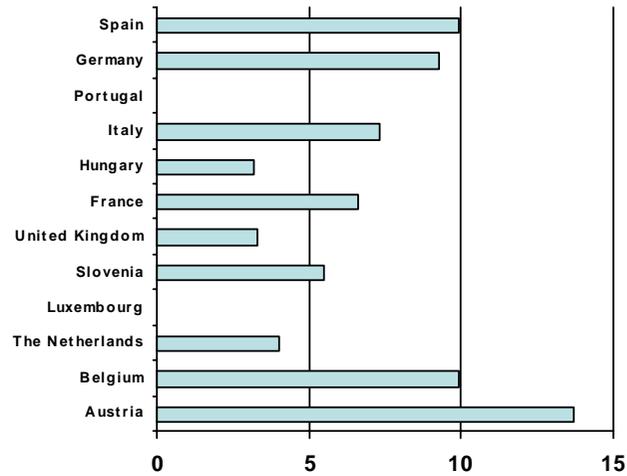
% of Living Kidney Transplants



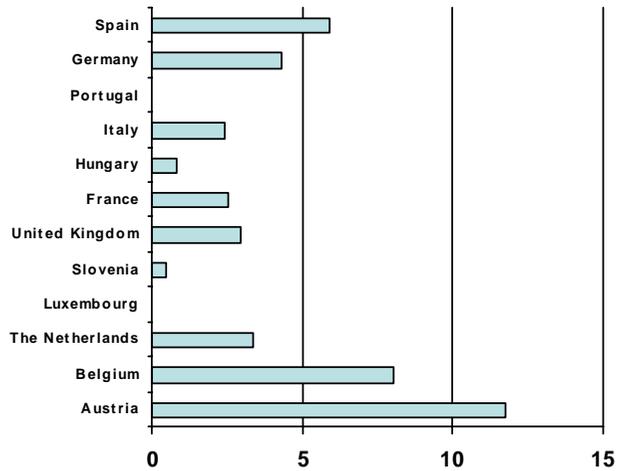
Patients on the Kidney WL pmp



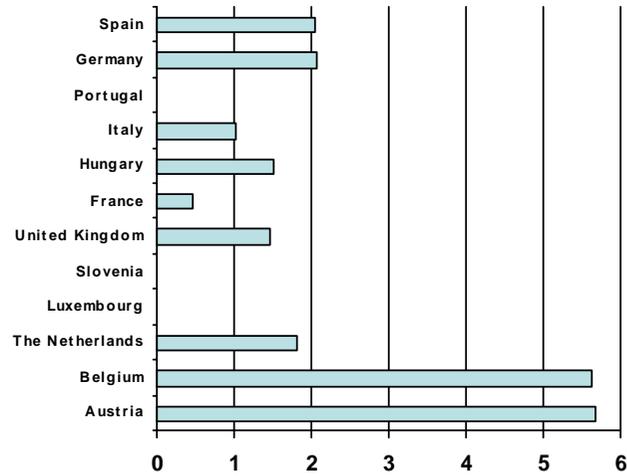
Liver patients admitted to the WL pmp



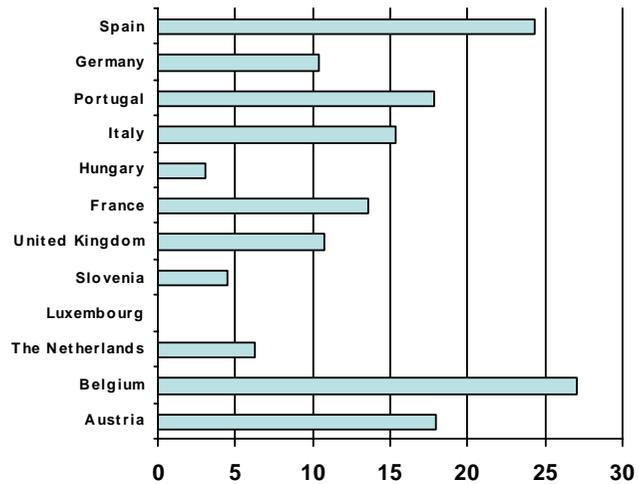
Heart patients admitted to the WL pmp



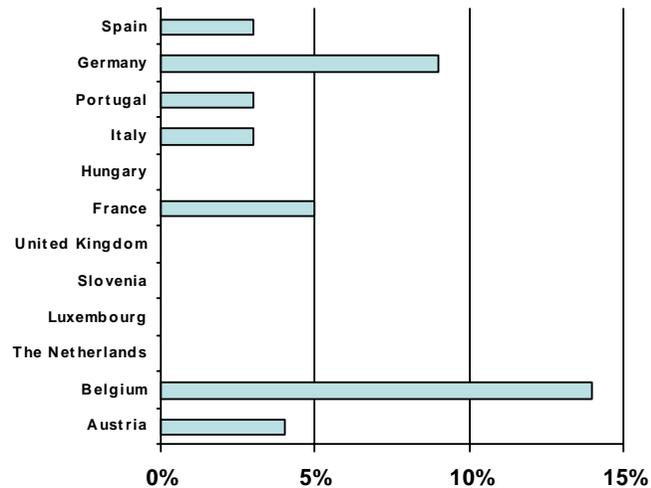
Lung patients admitted to the WL pmp



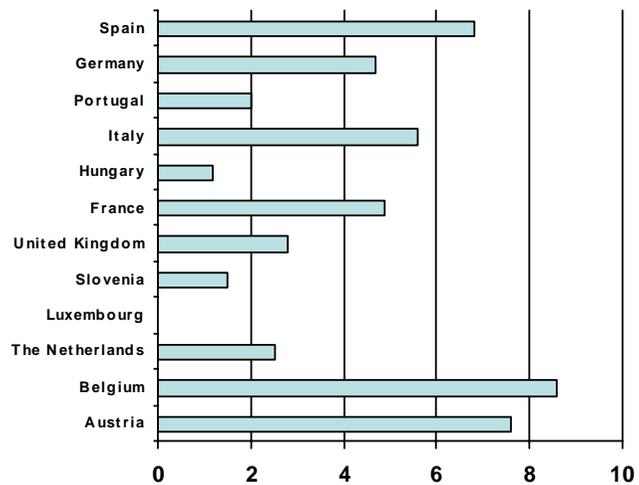
Pancreas patients admitted to the WL pmp



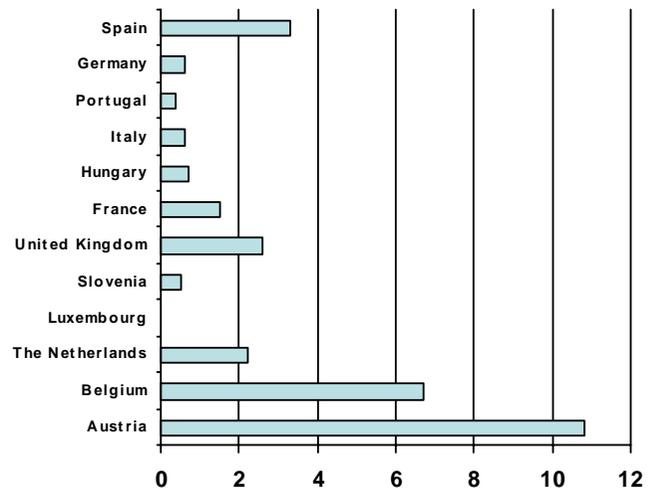
Liver Transplants pmp



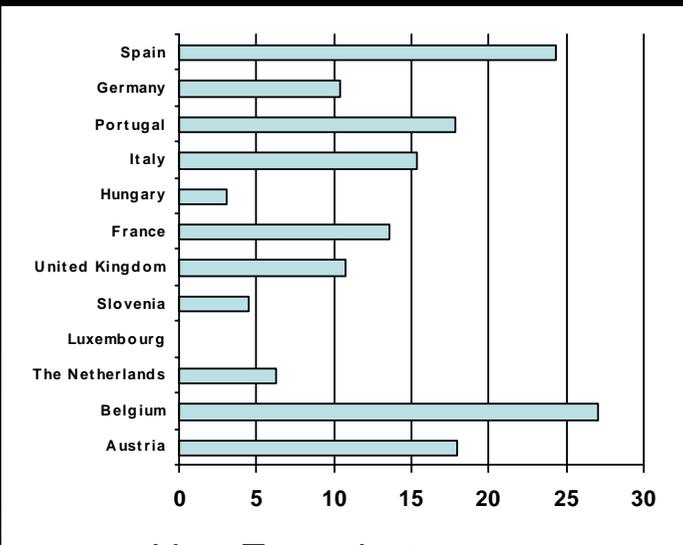
Liver Transplants: % living donors



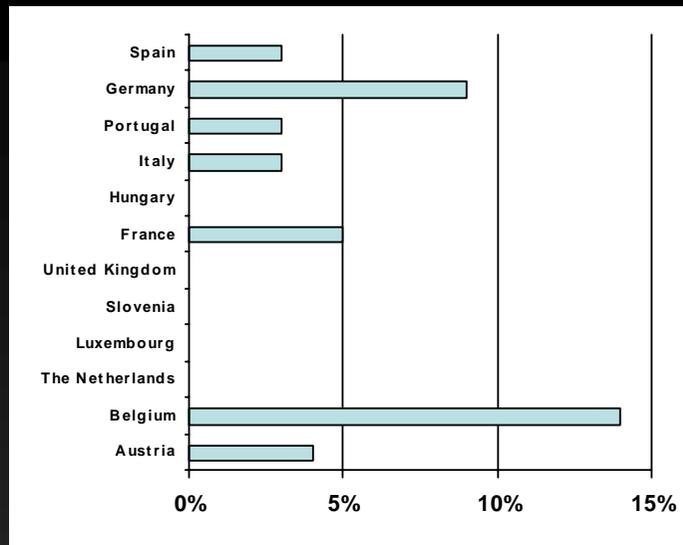
Heart Transplants pmp



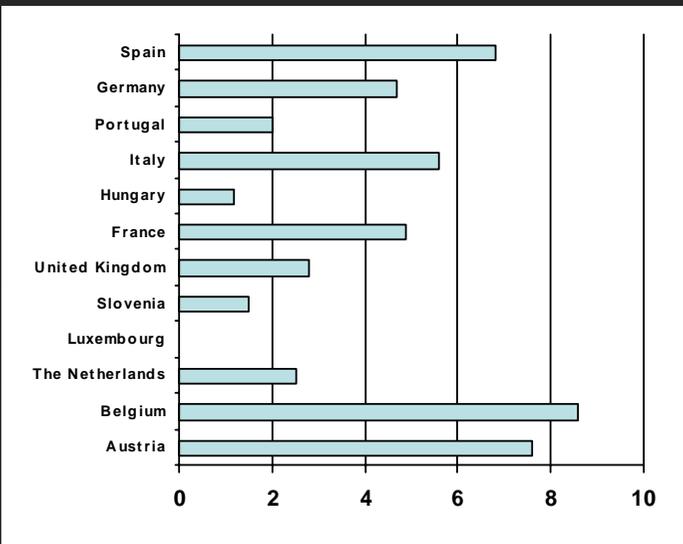
Lung Transplants pmp



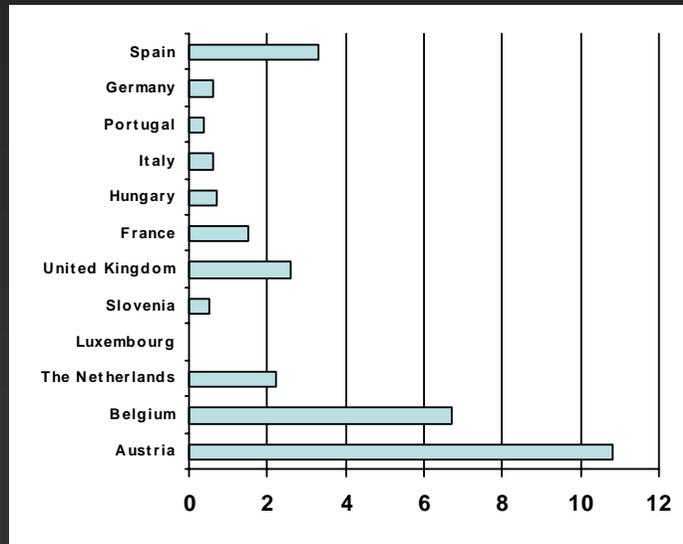
Liver Transplants pmp



Liver Transplants: % living donors



Heart Transplants pmp



Lung Transplants pmp

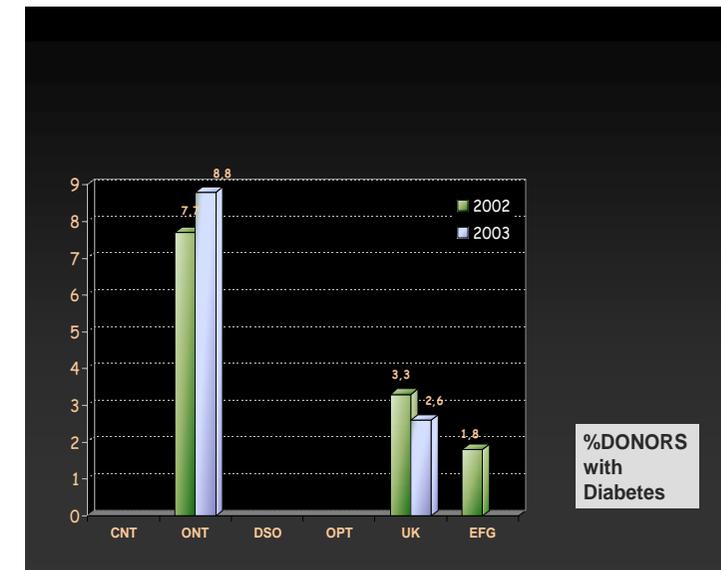
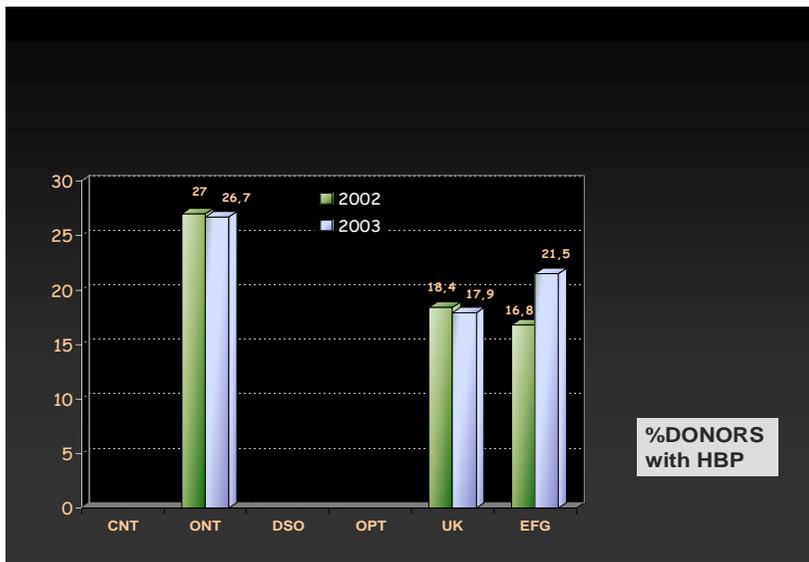
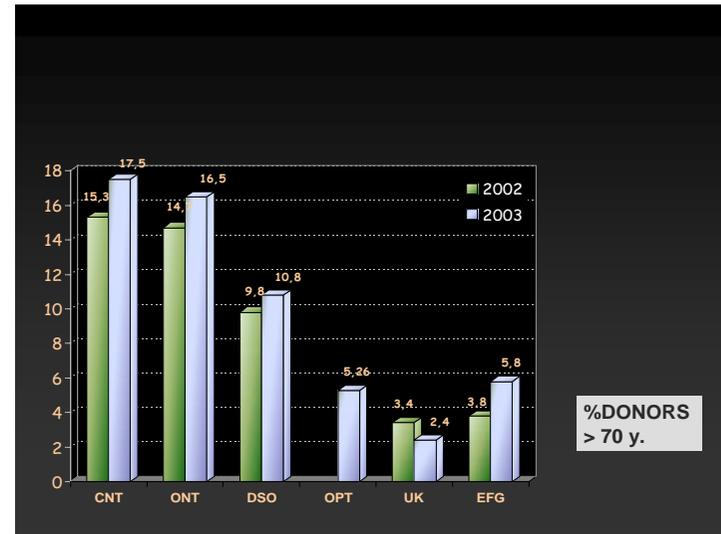
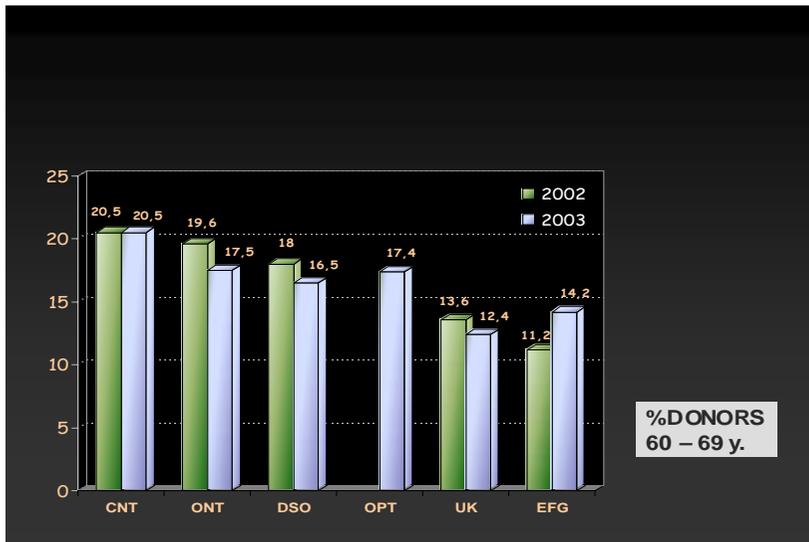
### **3.4. Data on Expanded donors**

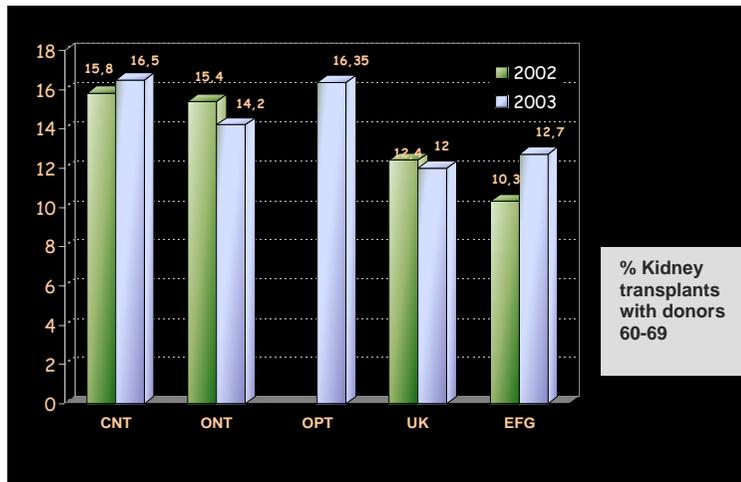
Although there are no widely accepted definitions for the concept of expanded donor, we have asked the participants to come back with data on the use of organs from donors that could be called expanded donors: elderly donors, hypertensive or diabetic donors. There are no accurate aggregated figures in all countries related to these items. All countries can provide data on the use of organs from elderly donors but not with hypertensive or diabetic conditions.

Italy and Spain accounted with the higher percentage of elderly donors, and the higher proportion for liver and kidney transplants done with those organs. Only Spain, the UK and France got data about diabetic or hypertensive antecedents among organ donors.

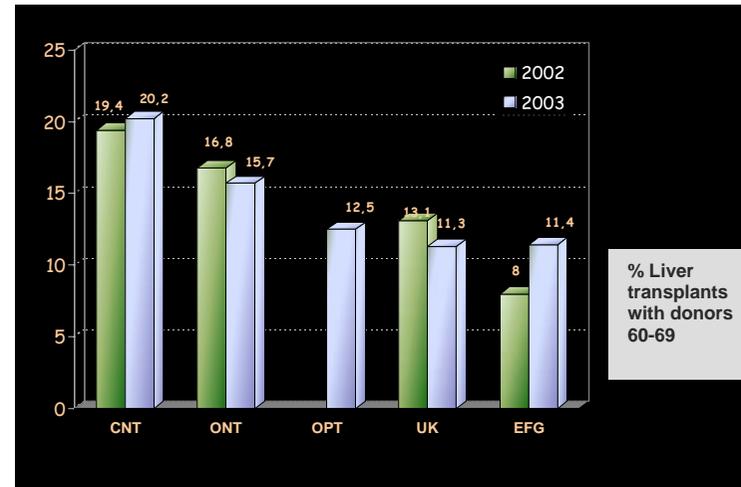
As a matter of discussion it must be underlined that more than 30% of donors are over 60, nearly 20% are hypertensive and 5% are diabetic.

### 3.4. Data on Expanded donors

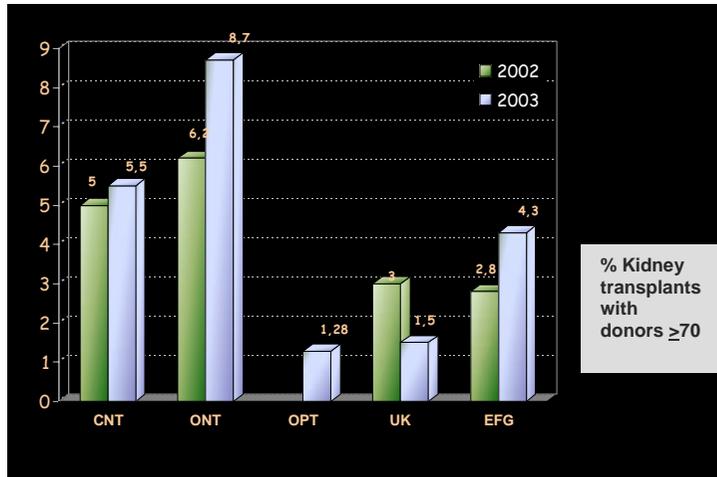




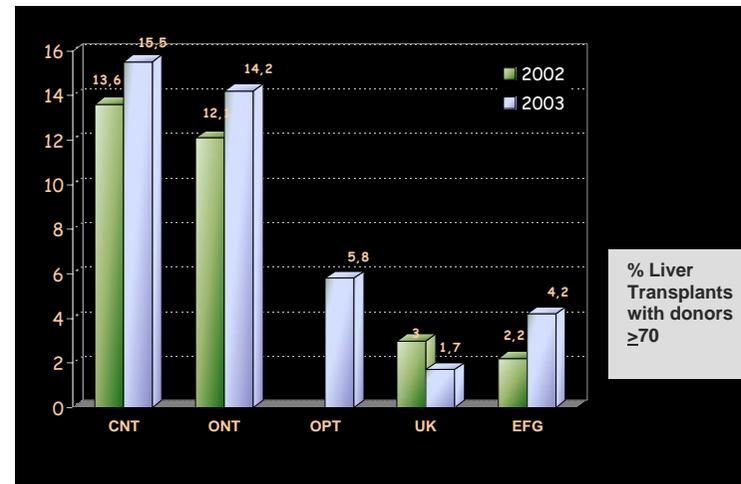
DSO:  
 2002: 49 out of 991 (4.9%)  
 2003: 38 out of 1,100 (3.45%)



DSO:  
 2002: 98 out of 660 (14.8%)  
 2003: 85 out of 795 (10.7%)

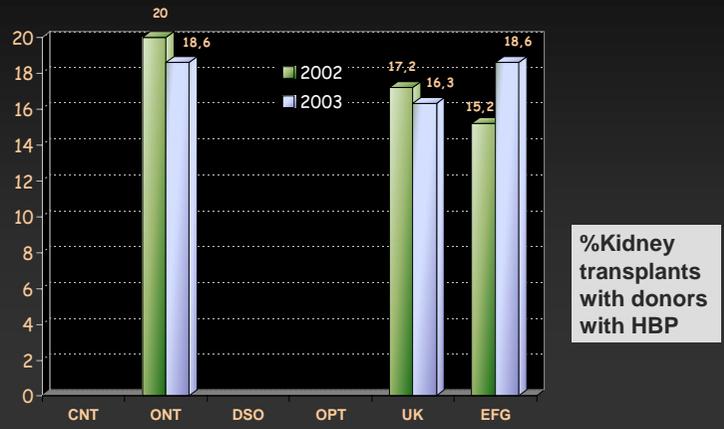


DSO:  
 2002: 44 out of 991 (4.4%)  
 2003: 46 out of 1,100 (4.2%)



DSO:  
 5 out of 660 (3.8%)  
 2003: 55 out of 795 (6.9%)

DSO: The figures refer to kidney donors (that donated one or two kidneys) in this age group/ out of a total of kidney donors (that donated one or two kidneys). They include all the donors from whom the organs were explanted and allocated- but some of them might finally not have been used. / The figures refer to liver donors (that donated a liver that however theoretically could be a split liver) in this age group/ out of a total of liver donors. They include all the donors from whom the organs were allocated- but some of them might finally no have been used. This is why the figure of livers procured and transplanted is lower than the number of donors of liver. It is not possible to know the exact figures of the transplantations performed in Germany with kidneys/livers from donors of this age group since some donations go to other ET member states and vice versa.



%Kidney transplants with donors with HBP



%Kidney transplants with donors with Diabetes

### **3.5. Initiatives and programmes aimed to promote organ donation and transplantation and to increase the number of organs available for transplantation**

Before presenting the collected data about the initiatives for the promotion of organ donation and transplantation, a very brief description of the legal and organizational structure of each country is summarized.

#### **FRANCE**

##### **A. France. Legal aspects**

###### A.1. Protection of the donor

The French Organ transplant law regulates the anonymity of the donor, the confidentiality and the non-remuneration for the donations as general principles.

The law includes Organs retrieved for therapeutic purposes and Organs for clinical research.

###### A.2. Living Donor

Living Donation is only permitted for genetic relation or other close relative. The consent for living donor is regulated by law. Informed written consent with witnessed court is required for these donations. The donor consent withdrawal is not included in the legislation.

The Donation from living donors unable to consent is forbidden by law.

The suitability for a living donor is indicated in technical Guidelines, these guidelines take into account clinical examination.

###### A.3. Deceased Donor

The consent for cadaver donor is regulated by law. The law required a presumed consent but the confirmation of the family is needed.

There is a national register of non-donors established by law.

The law defines the concept of death. The law establishes that the test for determining brain death have to be carried out and confirmed by at least two doctors, independent of the transplant team and the procedure has to comply with defined criteria.

The law also establish that these criteria shall include a clinical examination plus two ECG or angiography. There are guidelines for donors with specific circumstances (temperature, toxics)

The brain death certificate has to be signed for at least two doctors, any doctor with current license to practice could sign.

#### A.4 Authorization for transplantation procedures

Organ procurement centres require specific authorization by law. The law establishes standards for organ procurement. There are technical guidelines for quality control.

Transplantation centres and teams do require specific authorization by law.

The transport of organs is regulated by law, specifically the documentation and the requirements to ensure traceability.

Authorization is required by law for organ exchange and import/export of organs.

The law establishes a National register containing data on the origin and destination of the organs, with a serum from each donor banked.. The confidentiality of all these activities is regulated by law.

There is a mechanism for the notification of adverse events established by law.

#### **B. France. Organizational aspects**

The Organ Transplant/Exchange activities are carried out by national public organization: The Etablissement francais des Greffes (EfG).

The scope of the activities includes Organs, tissues and haematopoietic progenitors.

The functions of the EfG include:

- Coordination of organ donation, organ allocation, oversight/regulation of transplantation procedures, organ distribution, statistics/analysis and audit of organ donation and transplantation, promotion of donation, elaboration of protocols and ethical guidelines, training programmes and information to the public or professionals, biovigilancy, promotion of research and international relations.

There are a number of national advisory groups coordinated by the EfG on ethics, quality and safety, organ allocation development of regulation, xenotransplantation, accreditation of centres and communication, information and educational programmes.

There are legally binding criteria for Organ allocation, these criteria are clinical and geographical. The government is responsible for establish the criteria.

The Allocation criteria are public.

The Transplant organization is responsible of monitoring the application of the allocation criteria. These criteria could change on the basis of the probability of transplant for the different groups (age, blood type group, place of residency..etc) and o the basis of the global evaluation of the results.

The criteria for Inclusion/exclusion in the waiting list are regulated by law.

### **C. France. Technical aspects**

The standards and the risk assessment for the eligibility of cadaveric and living donors are governed by law.

No absolute contraindication: rejection of organs is made on the basis of risk/benefit analysis.

The authorization of Laboratories and tests is regulated by law.

Routine serological test carried out in donors included: Anti HIV1 and HIV2, Ag HIV, Anti-HCV, Ag-HBs, Anti-HBc, CMV, HTLV 1 and 2 and EBV. Treponema Pallidum is required depending on the characteristics of the donor. All tests are regulated by law.

No tumour markers are carried out on a routine basis, depending on the donor characteristics. Pregnancy test; BHCG, PSA, Carcinoembryonic antigen and alphafetoprotein are available. The indications are regulated by Guidelines

Organs retrieval procedures, labelling, documentation, audit of accidents and organ preservation are regulated by law.

There are Guidelines in place for packaging and quality systems, but they are not regulated by law.

## **ITALY**

### **A. Italy. Legal aspects**

#### A.1. Protection of the donor

The Organ transplant law regulates the anonymity of the donor, the confidentiality and the non-remuneration for the donations as general principles.

The law includes Organs retrieved for therapeutic purposes but not Organs for clinical research.

#### A.2. Living Donor

The consent for living donor is regulated by law. Informed consent and with the witnessed of a court is required for these donations.

The donation of organs from living donors unable to consent is forbidden by the law.

Guidelines indicate that the donor is able to withdraw the consent at any time.

The evaluation of the living donor (medical or psychological examination) is not regulated.

### A.3. Deceased Donor

The consent for cadaver donor is regulated by law. The law required agreement of those close to the deceased.

There is a national register of donors established by law.

The law defines the concept of death. The law establishes that the test for determining brain death have to be carried out and confirmed by at least three doctors, independent of the transplant team and the procedure has to complied with defined criteria.

The law also establish that these criteria shall include a clinical examination. If the doctors are not able to make a definitive diagnosis of brain death by clinical means then they use all available diagnostic tools and facilities in order to make a definitive diagnosis.

The brain death certificate has to be signed for at least three doctors (the attending doctor, an anaesthesiologist and a neurologist or neurosurgeon).

### A.4 Authorization for transplantation procedures

Organ procurement teams require specific authorization by law. There are technical guidelines for organ procurement and quality control.

Transplantation centres and teams do require specific authorization by law. Technical guidelines are in place including standards for organ transplantation and quality control systems.

The transport of organs is regulated by law.

Organ exchange between organizations and import/export of organs are not specifically regulated.

The law establishes a National register containing data on the origin and destination of the organs. The confidentiality of all these activities is regulated by law.

There is not a mechanism for the notification of adverse events established by law.

## **B. Italy. Organizational aspects**

The Organ Transplant/Exchange activities are carried out by national public organization: the Hellenic Transplant Organization.

The scope of the activities includes Organs, tissues and haematopoietic progenitors.

The functions of this body include:

- Coordination of organ donation, organ allocation, oversight/regulation of transplantation procedures, organ distribution, statistics/analysis and audit of organ donation and transplantation, promotion of donation, elaboration of protocols and ethical guidelines, training programmes and information to the public or professionals and financing.

There are a number of national advisory groups on ethics, quality and safety (this group gives a second opinion in case of doubtful cases), development of regulation (national Technical transplant Council), Xenotransplantation (High Health Council Group on Xenotransplantation), accreditation of centres and communication (regional administrative districts), information and educational programmes (Health Ministry)

There are legally binding criteria for Organ allocation, these criteria are clinical and geographical. The medical and other professionals are responsible for establish the clinical criteria, the government establishes the geographical criteria.

These Allocation criteria are public and the Transplant organization is responsible of monitoring the application of the allocation criteria. These criteria could change on the basis of the probability of transplant for different groups (age, blood group, place of residency ...etc).

The criteria for Inclusion/exclusion in the waiting list are regulated by technical guidelines.

### **C. Italy. Technical aspects**

The standards and the risk assessment for the eligibility of cadaveric are governed by guidelines. But the clinical history, clinical evidence or confirmed positive result of HIV/AIDS is a contraindication by law. The Criteria for the evaluation of living donors are regulated by law.

The absolute contraindications are systemic infections that not respond to therapy, HIV+, concurrent positivity for AgHBs and HDV, malignant diseases (with a number of exceptions), prion disease.

The authorization of Laboratories and test is regulated by law.

Routine serological test carried out in donors included: Anti HIV1 and HIV2, Anti-HCV, Ag-HBs, , HTLV 1 and 2, CMV, Toxoplasma, Treponema Pallidum, EBV and HZ. Ag-HIV, Anti HBs and, Anti-HBc are required depending on the characteristics of the donor.

No tumour markets are carried out on a routine basis, depending on the donor characteristics Pregnancy test; BHCG, PSA, Carcinoembryonic antigen and alphafetoprotein are available.

Organs retrieval procedures, labelling, documentation, packaging and organ transport, audit of accidents, organ preservation and quality systems are not specifically regulated.

All countries have legislation in place for basic aspects related with donation and transplantation. Consent for deceased and living donation is included in the legal texts and all but Portugal and Hungary got informed consent or presumed consent but with the agreement or confirmation of the family. Most countries have a register in place. All have binding legislation establishing definitions and/or diagnostic procedures for brain death.

Official Authorization for donation and transplantation activities is necessary in most countries. However there are no regulations in place for biovigilance and the notification of adverse effects or the traceability systems in all countries.

All countries got an organization in charge of coordination of donation and transplantation and in most instances also responsible for promotion of organ donation.

## **GERMANY**

### **A. Germany. Legal aspects**

#### A.1. Protection of the donor

The law regulates the anonymity of the donor, the confidentiality and the non-remuneration for the donations as general principles.

The scope of the German Transplantation Act so far covers only organs and tissues retrieved for transplantation purposes.

#### A.2. Living Donor

Living donation is regulated by the German Transplantation act.. Informed written consent is required for these donations plus an authorization of an ethical committee. The donor is able to withdraw the consent at any time.

Living donation is limited to persons over 18, the recipient must be a relative of the first or second degree, spouse, fiancés or a person with whom the donor obviously entertains a close personal relationship. Furthermore the principle of Subsidiarity applies; hence every recipient of a living donation must be registered on the waiting list.

#### A.3. Deceased Donor

According to the Transplantation Act informed consent is needed for cadaveric donation. If no written consent or objection is available the relatives are asked whether they know the deceased persons will. Only if the deceased persons will is unknown the relatives are asked for their consent to organ donation.

A national donor-register is not in place.

Apart from the necessity of an informed consent the diagnosis of brain death is the second mandatory prerequisite for organ donation. The brain death diagnosis has to be performed by two independent physicians not involved in the donation or transplantation process. Further details on the requirements and the procedures for brain death diagnosis are laid down in guidelines from the German Medical Association.

A confirmation test is an optional requirement (ECG, transcranial Doppler or Cerebral angiography)

#### A.4. Authorization for transplantation procedures

Transplantation centers do require a specific authorization by law.

Organ allocation is carried out by Eurotransplant. Rules for allocation are laid down in the German Transplantation Act and Guidelines from the German Medical Association. Rules on organ exchange and import /export within the ET-Region are laid down in the Eurotransplant manual.

There is a National register containing data on the origin and destination of the organs. There are registers in place in the procurement establishments, a serum from each donor is banked, and however this is not a legal requirement. The confidentiality of all these activities is regulated by law. Technical Guidelines establish a mechanism for the notification of adverse events (not binding).

## **B. Germany. Organizational aspects**

The Organ procurement is organized by the DSO, the national coordination agency.

The scope of the activities so far only includes organs. Tissues are to some extent the responsibility of the DSO-G a hundred percent affiliate of the DSO.

The functions are divided:

By law organ procurement is a common task of hospitals and transplant centres, organized by an organ procurement organization, while allocation, distribution and organ exchange is the responsibility of Eurotransplant.

Access to the waiting list is regulated by law and guidelines from the German Medical Association.

There exist no national advisory groups on Organ transplantation; however the national medical association has a permanent commission for organ transplantation under the supervision of the Federal ministry of health, which is responsible for the national transplantation policy and is entitled to pass guidelines on various issues regarding organ transplantation.

## **C. Germany. Technical aspects**

The standards and the risk assessment for the eligibility of donors are binding.

In the guidelines there are four causes for absolute contraindication: prion disease, presence or (previous history of) malignant disease, not controlled systemic infection and HIV +.

The use of authorised Laboratories is not regulated. The use of authorised tests is regulated by law.

Routine serological test carried out in donors included: Anti HIV1 and HIV2, Anti-HCV, Ag-HBs, Anti-HBc, Anti HBs, CMV, Treponema Pallidum. Ag HIV, Toxoplasmosis and HTLV 1 and 2 are available depending on donor's characteristics.

No tumor markers are carried out on a routine basis, depending on the donor characteristics. BHCG, PSA, Carcinoembryonic antigen and alpha-fetoprotein are available.

There are Guidelines in place for organs retrieval procedures, labeling, packaging, documentation, transport, preservation, and quality systems.

Audit of accident is not regulated neither by guidelines or binding measures. However there is a legally defined commission for auditing and surveillance of the OPO.

## **PORTUGAL**

### **A. Portugal. Legal aspects**

#### A.1. Protection of the donor

The law regulates the anonymity of the donor, the confidentiality and the non-remuneration for the donations as general principles.

The law includes Organs retrieved for therapeutic purposes and Organs for clinical research.

#### A.2. Living Donor

The consent for living donor is regulated by law. Written Informed consent is required for these donations. Only donors with genetic or other close relative relation are permitted.

The donation of organs from living donors unable to consent is prohibited by law..

The law indicates that the donor is able to withdraw the consent at any time.

Medical and psychological examination is required by law for the evaluation of the living donor. The law also requires the agreement of a representative of the Hospital Medical Director.

#### A.3. Deceased Donor

The consent for cadaver donor is regulated by law. Presumed consent is requested (not need for family consent).

There is a national register of not-donors in place.

The law defines the concept of brain death. The law establishes that the test for determining brain death have to be carried out by at least two doctors, independent of the transplant team and the procedure has to comply with defined criteria.

The law also establish that these criteria be based in a clinical examination.

The brain death certificate has to be signed for two doctors. The following specialities can certify the death: neurosurgery, neurology or specialist in intensive care units.

#### A.4 Authorization for transplantation procedures

Organ procurement centres and teams require specific authorization by law. The law requires standards for organ procurement and quality control.

Specific authorization of Transplant centres and teams is required by law. The law requires standards for organ transplantation and quality control.

The transport of organs is regulated by technical guidelines.

Organ exchange between organizations is regulated by law, import/export of organs are governed by technical guidelines.

The law establishes a National register containing data on the origin and destination of the organs. Technical Guidelines indicate that a serum sample for each donor should be banked. The law establishes registers at procurement and transplantation centres. The confidentiality of all these activities is included in the law.

There is not a mechanism for the notification of adverse events specifically regulated.

### **B. Portugal. Organizational aspects**

The Organ Transplant/Exchange activities are carried out by national public organization.

The scope of the activities includes Organs, tissues and cells.

The functions of this body are:

- The national level has the responsibility of Coordination of organ donation, organ allocation, organ distribution, statistics and audit of organ donation and transplantation, elaboration of protocols and ethical guidelines, training programmes, information to the public or professionals, promotion of donation and financing.
- It collaborates with international bodies in coordination of organ donation, organ allocation, organ distribution and elaboration of protocols, recommendations or consensus documents.

There is a national advisory groups on organ allocation (Lusotrasnplante).

There are legally binding criteria for Organ allocation, these criteria are clinical and geographical. The medical and other professionals are responsible for establishing the criteria. The government is also responsible of establishing the geographical criteria.

These Allocation criteria are public. The Transplant organization is responsible of monitoring the application of the allocation criteria. These criteria could change on the basis of the probability of transplant for different groups (age, blood group, place of residency ...etc) or the tissue typing.

The criteria for Inclusion/exclusion in the waiting list are regulated by technical guidelines.

### **C. Portugal. Technical aspects**

The standards and the risk assessment for the eligibility of donors are governed by guidelines.

The absolute contraindications for organ donation are: positive result for HIV, HBs, HCV, HTLV and Syphilis. Sepsis. Malignant diseases, except those brain tumours without evidence of disease outside the brain.

The authorization of Laboratories and tests are regulated by law.

Routine serological test carried out in donors included: Anti HIV1 and HIV2, Ag-HIV, Anti-HCV, Ag-HBs, Anti-HBs, Anti HBc , CMV, HTLV 1 and 2 and. Treponema Pallidum.

No tumour markets are carried out on a routine basis.

Organs retrieval procedures are regulated by law.

Labelling, documentation, packaging, organ preservation, organ transport, audit of accidents and quality systems are regulated by technical guidelines.

## **HUNGARY**

### **A. Hungary. Legal aspects**

#### A.1. Protection of the donor

The law regulates the anonymity of the donor and the non-remuneration for the donations as general principles. Act XLVII of 1997.

Remuneration: Act CLIV of 1997 on Health, Section 207: "1. Donation of organs and tissues shall only take place without consideration given in return. 2. The donors shall be eligible for recompense of loss of income related to the donation, and of his justified costs incurred in connection with making his statement of donation and with travelling, which are not reimbursed under his social insurance coverage. Such costs shall be borne by the state."

The law includes Organs retrieved for therapeutic purposes and Organs for clinical research. (Act CLIV of 1997 on Health, Section 220)

#### A.2. Living Donor

The consent for living donor is regulated by law (Act CLIV of 1997 on Health, Section 209).

Written and informed consent is required for living donors with genetic relation. A witnessed court authorization after a written informed consent is required for donations of other close relatives or emotional relationship.

The donation of organs from living donors unable to consent is prohibited. Bone marrow, hematopoietic primordial cells or other renewable tissues might be taken for transplantation into a kin even from the body of a person under legal age. In this case the consent of the legal representative will become valid after it has been endorsed by the hospital ethics committee.

The law indicates that the donor is free to withdraw his consent any time until the removal of the organ or tissue without any formal restrictions. Even in case of a valid consent the physician must terminate the organ or tissue donation procedure if during the course of such procedure a situation has arisen that will endanger the donor's life or impair his health.

Medical examination is required by law for the evaluation of the living donor. The Law also requires before a transplant procedure to the physician to document that the donor meets the conditions for organ or tissue transplant, that there is no medical contraindication of the transplant, that the transplant is justified for the recipient and that the conditions for the procedure are met and that the organ is suitable for transplantation."

### A.3. Deceased Donor

The consent for cadaver donor is regulated by law. Presumed consent is requested, Organs or tissues may only be removed from cadaver donors if the deceased did not make a declaration opposing donation during his lifetime

Since 1999 a non-donor register exists. It is available around the clock for those health workers who are registered in advance. All the hospitals are requested to register some of their physicians in order to be able to check in the registry if a brain dead person is among the objectors or not.

The law defines the concept of brain death. The law establishes that the test for determining brain death have to be carried out by at least two doctors, independent of the transplant team and the procedure has to complied with defined criteria.

The law also establish that these criteria be based in a clinical examination.

The brain death certificate has to be signed for three doctors. The doctors must be assigned by the director of the hospital, they have to be trained and experienced on the field. They must have specialty, but any kind.

#### A.4 Authorization for transplantation procedures

Specific authorization for procurement centres is required by law There are technical guidelines for organ procurement and quality control systems.

Specific authorization for Transplant centres is required by law. There are technical guidelines for organ transplantation and quality control systems.

The transport of organs is regulated by law.

Organ exchange between organizations and import/export of organs are regulated by law.

Guidelines indicate that a register/database should be in place in Procurement and transplantation centres, with restrict access and confidential.

Notification of adverse events is not regulated.

### **B. Hungary. Organizational aspects**

The Organ Transplant/Exchange activities are carried out by a public national body: Hungarotransplant that has been established by the Ministry of Health in 2001. The goal for the corporation is to contribute to increasing the number and improving the outcomes of organ transplantations.

The scope of the activities is limited to organs.

The functions are coordination of organ donation, promotion of donation, training, and information to the public and professionals.

There are three national advisory groups: organ allocation (Waiting list committees for each organ except kidney), accreditation of transplant centers and programmes (Ministry of Health) and communication, information and educational programmes (Hungarotransplant)

There are legally binding criteria for Organ allocation. These criteria are clinical and geographical. The medical and other professionals are responsible for establishing the criteria.

These Allocation criteria are public. The Transplant organization is not responsible of monitoring the application of the allocation criteria. There is not responsible body to analyze the outcomes and the need for changes in allocation criteria.

Since 1998 a Ministerial Decree regulates the rules of waiting list management, but in practice the regulations are not fulfilled. E.g. the waiting list committee for kidney has never been established. The allocation of organs is regulated by guidelines that are not approved by all centers.

### **C. Hungary. Technical aspects**

The criteria for the eligibility of donors are governed by law and guidelines.

The absolute contraindications for organ donation are:

- Age > 75 years
- Active TB
- Human Immunodeficiency Virus (HIV) – infection or positive serological findings
- Creutzfeldt-Jakob Disease
- Extra cerebral Malignancy (except basalioma and in situ portio carcinoma)
  
- Anti- Hepatitis C positive

- Hepatitis B Surface Antigen positive
- Connective Tissue Disease
- Agranulocytosis
- Aplastic Anaemia
- Haemophilia

The use of authorized laboratories and tests are regulated by law.

Routine serological test carried out in donors included: Anti HIV1 and HIV2, Anti-HCV, Ag-HBs, CMV, Treponema Pallidum.

No tumour markers are screened

Organ labelling, packaging, organ transport are regulated by law

Organs retrieval procedures, organ preservation, documentation, audit of accidents and quality systems procedures are regulated by technical guidelines.

## **SPAIN**

### **A. Spain. Legal aspects**

#### A.1. Protection of the donor

The law regulates the anonymity of the donor, the confidentiality and the non-remuneration for the donations as general principles.

The law includes Organs retrieved for therapeutic purposes but not Organs for clinical research.

#### A.2. Living Donor

The consent for living donor is regulated by law. A witnessed court authorization after a written Informed consent is required for these donations. The law also require the agreement of the Hospital Ethical Committee.

The donation of organs from living donors unable to consent is prohibited by law.

The law indicates that the donor is able to withdraw the consent at any time.

Medical and psychological examination is required by law for the evaluation of the living donor.

### A.3. Deceased Donor

The consent for cadaver donor is regulated by law. Presumed consent is requested, but the confirmation of the family is needed.

There is not a national register of donors in place.

The law defines the concept of brain death. The law establishes that the test for determining brain death have to be carried out by at least two doctors, independent of the transplant team and the procedure has to complied with defined criteria.

The law also establish that these criteria be based in a clinical examination plus a confirmation test under specific circumstances. In situations like hypothermia, presence of neuro-depressor drugs, children that less of one year of age or circumstances that impede a clinical examination, a supplementary test is required: electroencephalogram, evoked potentials or a test to evaluate the cerebral flow (arteriography, transcranial Doppler or isotope perfusion studies).

The brain death certificate has to be signed for three doctors. The following specialities can certify the death: neurosurgery, neurology and the chief of the department of the correspondent Unit.

### A.4 Authorization for transplantation procedures

Organ procurement centres require specific authorization by law. There are technical guidelines establishing standards for organ procurement and quality control.

Specific authorization of Transplant centres is required by law. The law requires standards for organ transplantation and quality control.

The transport of organs is regulated by law.

Organ exchange between organizations and import/export of organs are regulated by law.

The law establishes a National register containing data on the origin and destination of the organs. It indicates that a serum sample for each donor should be banked. The law establishes registers at procurement and transplantation centres. The confidentiality of all these activities is included in the law.

There are guidelines for the notification of adverse events, but these are not binding.

## **B. Spain. Organizational aspects**

The Organ Transplant/Exchange activities are carried out by national public organization: in collaboration with regional bodies.

The scope of the activities includes Organs, tissues and cells.

The functions are:

- The national level has the responsibility of coordination of organ donation.
- The national in collaboration with the regional bodies is in charge of: organ allocation, organ distribution, statistics and audit of organ donation and transplantation, elaboration of protocols and ethical guidelines, training programmes, information to the public or professionals, promotion of donation, elaboration of protocols, recommendations or consensus documents.
- The regional bodies have the financing competences.

There are a number of national advisory groups on quality and safety of organs, organ allocation, development of regulation, xeno-transplantation, Accreditation of transplant centres and communication, information and educational programmes

There are legally binding criteria for Organ allocation, these criteria are clinical and geographical. The medical and other professionals are responsible for establishing the clinical criteria. The government is responsible for establishing the geographical criteria.

These Allocation criteria are public. The Transplant organization is responsible of monitoring the application of the allocation criteria. These criteria could change on the basis of the probability of transplant for different groups (age, blood group, place of residency ...etc)

The criteria for Inclusion/exclusion in the waiting list are regulated by technical guidelines.

### **C. Spain. Technical aspects**

The standards and the risk assessment for the eligibility of donors are governed by guidelines.

The absolute contraindications for organ donation are: positive result for HIV; Prion disease; malignant diseases with the exception of skin cancer, carcinoma in situ of cervix or brain tumours without high grade of malignancy; not controlled infection and defect in the organ to be procured.

The authorization of Laboratories and tests (only in the case of HIV) are regulated by law.

Routine serological test carried out in donors included: Anti HIV1 and HIV2, Anti-HCV, Ag-HBs and CMV.

Ag-HIV, Anti-HBs, Anti HBc, Toxoplasmosis, Treponema Pallidum and HTLV 1 and 2 are available depending on the donors characteristics.

Pregnancy test is carried out on a routine basis. BHCG and PSA are available depending on the donor characteristics.

Organ Labelling, documentation, packaging and organ transport procedures are regulated by law.

Organs retrieval procedures, organ preservation, audit of accidents and quality systems are regulated by technical guidelines.

## **UNITED KINGDOM**

### **A. United Kingdom. Legal aspects**

#### A.1. Protection of the donor

The law regulates the anonymity of the donor and the non-remuneration for the donations as general principles.

The law includes Organs retrieved for therapeutic purposes and Organs for clinical research.

#### A.2. Living Donor

The consent for living donor is regulated by law. A witnessed court authorization after a written informed consent is required for these donations.

The donation of organs from living donors unable to consent is only permitted with authorization of the court.

The law indicates that the donor is able to withdraw the consent at any time.

Medical and psychological examination is required by technical guidelines for the evaluation of the living donor. The Law requires an independent report.

#### A.3. Deceased Donor

The consent for cadaver donor is regulated by law. The wishes of the deceased are paramount, but the consent of relatives will be sought. In practical terms, if a relative denies consent, organ donation would not.

There is a national register of donors, the Organ Donor Register.

The law defines the concept of brain death. The law establishes that the test for determining brain death have to be carried out by at least two doctors, independent of the transplant team and the procedure has to comply with defined criteria.

The law also establish that these criteria be based in a clinical examination.

The brain death certificate has to be signed for one doctor with a current license to practice.

#### A.4 Authorization for transplantation procedures

There are technical guidelines for organ procurement centres and teams and establishing standards for organ procurement and quality control..

There are technical guidelines for organ transplantation centres and teams and establishing standards for organ procurement and quality control.

In the National Health Services are commissioned specifically from hospital to Units by Primary Care trusts and the national specialists Commissioning Advisory group. Units not specifically paid for the service cannot provide it. This provide indirect accreditation of transplant units

The transport of organs is regulated by technical guidelines.

Organ exchange between organizations and import/export of organs are regulated by law.

The law establishes a National register containing data on the origin and destination of the organs. Guidelines indicate that a serum sample for each donor should be banked. The confidentiality of all these activities is included in the law.

There are guidelines for the notification of adverse events, but these are not binding.

#### **B. United Kingdom. Organizational aspects**

The Organ Transplant/Exchange activities are carried out by UK transplant, which is an international body in the sense that it acts for all four home countries: England, Wales, Scotland and Northern Ireland. It also provides service on contract for the republic of Ireland. Thus the one organization provides both international and national services.

The scope of the activities includes Organs and tissues.

The functions are:

- To coordinate all aspects of organ transplantation in the UK, and to maximize the number of donors.
- UK Transplant is responsible for: coordination of organ donation organ allocation, organ distribution, statistics and audit of organ donation and transplantation, elaboration of protocols and ethical guidelines, training programmes, information to the public or professionals, promotion of donation, elaboration of protocols, recommendations or consensus documents and financing.

There are a number of national advisory groups on ethics of organ transplantation (UK Transplant Advisory Group), quality and safety of organs (Committee on Microbiological Safety for Blood and Tissues and Organs for transplantation), organ allocation (UK Transplant {Organ} Advisory Committees), xeno-transplantation (UK Xenotransplant Interim Regulatory Authority), and communication, information and educational programmes (UK Transplant).

There are not legally binding criteria for Organ allocation. Although not legally based, Units are required to follow the UK Transplant allocation rules by the secretary of State. Compliance with the agreed allocation schemes is continuously monitored.

These criteria are clinical and geographical and based on technical guidelines. The medical and other professionals are responsible for establishing the criteria.

These Allocation criteria are public. The Transplant organization is responsible for monitoring the application of the allocation criteria. The organ allocation criteria are audited on a regular basis, and changed in the light of evidence that they are not working in the intended manner.

The criteria for Inclusion/exclusion in the waiting list are regulated by technical guidelines.

### **C. United Kingdom. Technical aspects**

The standards and the risk assessment for the eligibility of donors are governed by guidelines.

The absolute contraindications for organ donation are: positive result for HIV or Prion disease.

The use of authorized laboratories and tests are regulated by Technical guidelines.

Routine serological test carried out in donors included: Anti HIV1 and HIV2, Anti-HCV, Ag-HBs, CMV, Treponema Pallidum and HTLV 1 and 2. Anti HBc and Toxoplasmosis are available depending on the donors characteristics.

Tumour markers: Pregnancy test is available depending on the donor characteristics.

Organs retrieval procedures, organ preservation, organ labelling, documentation, packaging organ transport, audit of accidents and quality systems procedures are regulated by technical guidelines.

### **3.5.1. CADAVERIC HEARTBEATING DONORS**

There are several technical initiatives that can be addressed to get either more information to promote possible strategies or directly to get more available organs. Monitoring to all brain damage or brain death people in the ICU's is not in place everywhere the use of Donor Action tolls is not extended. In what's related with specific programmes aimed to get more organs it must be underlined that split transplantation or guidelines for NSK evaluation are in place every where. From the organizations point of view, there are no coordinating networks at the there levels everywhere, no national training programmes strategies neither national programmes aimed to reduce refusals to donation.

It has been stressed that organ donation deserves investment, both in human and infrastructure resources. Not everywhere a true support for the donation process is in place and the need of allocating specific budget to donation and procurement activities in the hospitals is not fully understood.

Educational programmes and programmes aimed to improve relationships with other implicated social groups, such a coroners, judges or journalists are not in place.

Probably the area where countries have less developed initiatives or programmes is the communication one. There are no strategies developed for training or information to professionals. Public campaigns are present everywhere but specific strategies directed towards specific groups (teenagers, students, health care workers, etc.,) are not in place. The use of new technologies for dissemination places is not widely implanted. Besides, relation with media is not based on a regular or professional strategy of communication.

Finally, it must be underlined that some local programmes such as Quality Control Programmes, external audits on donation units, pilot in house transplant coordinators post or registries for severe brain damage need further analysis to explore whether they can be adapted to other countries and how cost/effective its implantation was.

LEGAL INICIATIVES	UKINGDOM UKT	FRANCE EFG	GERMANY DSO	HUNGARY HT	PORTUGAL OPT	ITALY CNT	SPAIN ONT
Regulation for brain death diagnosis	YES	YES	YES *1	YES	YES	YES	YES
Regulation for organ donation and transplantation procedure	YES *6	YES	YES *2	NO	YES	YES	YES
Regulation for donation consent	YES *6	YES	YES *3	YES	YES	YES	ES
Regulation for organ registry	NO	YES	YES *4	NO	YES	YES	YES
Regulation for transplantation organs infected by HBC or HCB	YES*6	YES	YES *5		YES	YES	YES

\*1: Richtlinien zur Feststellung des Hirntodes“

Guidelines from the German Medical Association based on section. 16 of the German Transplantation Act for brain death diagnosis

\*2: The German Transplantation Act contains regulations on the removal of organs from deceased donors and for the removal, allocation and transplanting of solid organs.

This is supplemented by following the guidelines of the German Medical Association

1) brain death diagnosis

2) Allocation and Access to waiting lists

3) Quality management (implementation is pending)

Further there exist handbooks for coordinators, and also hospital staff about how to proceed in case of potential donors

\*3: in section 3, 4 of the German Transplantation Act

\*4: the German Transplantation act contains a provision for the installation of an organ donor registry – so far such a registry does not exist and is not planned for the near future due to various reasons

\*5: it is part of the extended donor criteria regulations that are part of the guidelines for the allocation of solid organs from the German Medical Association. (I attached the excerpt from the guidelines)

\*6: The above depends on the meaning of 'Regulation'. In the UK there is Department policy and guidance, and Codes of Practice for organ donation and transplantation procedures, consent for donation, and transplantation of organs infected by hepatitis B virus (HBV) and hepatitis C virus (HCV), but these are not legal. The only legal initiative is brain death diagnosis

<b>TECHNICAL INITIATIVES</b>	<b>UKINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Monitoring of ALL deaths in Intensive Care Units	YES	IMPROVING	NO	IMPROVING	YES	YES	YES
Monitoring of ALL brain damaged dead patients	NO	IMPROVING	NO	IMPROVING	YES	YES	YES
Guideline for expanded donor criteria	YES	YES	YES *1	YES	YES Only kidneys	YES	YES
Split liver transplantation	YES	YES	YES *1	IMPROVING	S	YES	YES
Domino transplantation	YES	YES	YES *1	NO	YES	YES	YES
Protocol for increasing availability of kidneys by procuring and grafting 2 kidneys from expanded donors	YES	YES	NO *2	NO	IMPROVING	NO	YES
Diagnostic tools of Donor Action Program	NO	IMPROVING	NO	YES	NO	YES SOME REGS	NO
Accepted Maastricht Category IV	YES	YES	YES	YES	NO	YES	YES
Technical Assistance by Transplant Organization	YES	YES	YES	YES	YES	YES	YES
Extended donor criteria	YES	YES	YES	YES	YES	YES	YES
Guideline for national donor management	YES	YES	YES	YES	NO	YES	YES
Guidelines for the evaluation of neoplasias in the donor and subsequent use of organs	YES	IMPROVING	IMPROVING	YES	YES	YES	YES
Guidelines for the evaluation of infectious diseases in the donor and subsequent use of organs	YES	YES	IMPROVING	YES	YES	YES	YES

\*1: regulated in the guidelines concerning the allocation of solid organs from the German Medical Association based on § 16 of the German Transplantation Act

\*2: there was a single centre protocol at the university of Münster that was terminated 2 years ago.

<b>ORGANIZATIONAL INITIATIVES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>**GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Implementation in coordinating local offices of dedicated medical and nursing staff to procurement activity	YES	YES	YES	YES	YES	YES	YES
Organization and support of the transplantation process by national organization coordinators	YES	NO	YES	YES	YES	YES	YES
Procurement network among hospitals authorised for procurement activities and referring hospitals	YES	YES	NO	YES	YES	YES	YES
Developing of Donor Action Program	NO	IMPROVING	NO	YES	NO	YES SOME REGIONS	NO
Implementation of quality management training for hospital coordinators	YES	YES	NO	YES	YES	YES	YES
EDHEP training	NO	YES	YES	NO	NO	NO	YES
Creation of three levels coordination network	NO	NO	NO	YES	NO	YES	YES
Hospital visiting programs	YES	YES IMPROVING	YES	YES	NO	YES	YES
Implementation at National level of the donor detection programme	YES	YES	NO	YES	YES	NO	YES
A new national professional leadership of donor transplant coordination	YES	IMPROVING	YES	YES	NO	YES	YES
Coordination network	YES	YES	YES	YES	YES	YES	YES
National programme for improving the family refusal rate	YES	IMPROVING	NO	YES	NO	YES	YES

<b>HUMAN RESOURCES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>**GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Use of Intensive Care Unit physicians, laboratory technicians, immunologists and anatomo-pathologists medical and nurse staff in H24 service	YES	NO	YES	YES	YES	YES	YES
Transplant agents in hospitals: coordinators and responsible people for information of public, press releases, education	YES	YES	YES	NO	YES	YES	YES
Implementation full time positions allocated to increase personnel devoted to procurement coordination	YES	YES	NO	YES	YES	YES	YES
Nomination of helpful personnel in the donation process	NO		NO	YES	NO	NO	NO
Creation of bureaus for the harvesting and transplanting of organs	NO		NO	YES	YES	YES	NO
Foundation of whole time equivalent donor transplant coordinators	NO	YES	YES	YES	YES	NO	NO
Hospital based transplant-coordinating teams. 24h functioning	YES	YES	NO	YES	YES	YES	YES
Specific and trained staff "on call" for the donation and transplantation activities	YES	YES	YES	YES	YES	YES	YES

<b>FINANCIAL INITIATIVES</b>	<b>U.KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>**GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Funds allocated by law to Regional Administrative Districts	NO	YES	NO	YES	NO	YES	YES
Financial subsidies to harvesting institutions, transplant centres, HLA typing labs and coordination labs and coordination bureaux	NO	YES	YES	YES	YES	YES	YES
Funds from insurance companies	NO	NO	NO	YES	NO	NO	NO
Special funds for donation and transplantation topics related	NO	NO	YES	YES	YES	YES	YES
Specific hospital budget for the donation and coordination activities	NO	YES	NO	YES	NO	YES	YES

\*\* According to the German Transplant act the removal, allocation and transplantation of solid organs is the joint responsibility of transplantation centers, donor hospitals and coordination agency.

<b>EDUCATIONAL RESOURCES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
National Transplant Procurement Management Courses	YES	IMPROVING	YES	YES	NO	YES	YES
National Courses for Brain Death Diagnosis	NO	YES	NO	YES	NO	YES	YES
National Courses on communication with mass media	YES	NO	NO	NO	NO	YES	YES
Training Regional Courses for health personnel and information regional course citizens	YES	NO	NO	NO	NO	YES	YES
Educational courses/activities to population in general	YES Only activities	NO	YES	IMPROVING	NO	NO	NO
Educational courses / activities to schools	YES	NO	YES	YES	IMPROVING	YES	IMPROVING
Educational courses/activities to qualified personnel.	YES	YES	YES	YES	IMPROVING	YES	YES
Implementation of Donor Action Programme	NO	IMPROVING	NO	YES	NO	YES SOME REGS	NO
Regular training courses for anaesthesiologists and neurologists	NO	NO	YES	YES	NO	YES	NO
Guides, protocols and promotion material for ICU personnel	YES	YES	YES	YES	IMPROVING	YES	YES
Teaching courses on transplantation already implemented in medical and nursing schools	YES	IMPROVING	NO	IMPROVING	IMPROVING	YES	NO/IMPROV
Educational programmes for senior healthcare professionals	YES	NO	NO	NO	NO	YES	YES
EDHEP	NO	YES	YES	NO	NO	NO	YES
Training course: "Donor family's relationship"	NO	YES	YES	NO	NO	YES	YES
Meetings with judges and coroners	YES Only coroners	YES	NO	NO	NO	YES	YES

<b>COMMUNICATION INITIATIVES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
National Information Campaign on Organ and Tissue donation and transplantation	YES	YES	YES	YES	NO	YES	YES
An informative web presence	YES	YES	YES	YES	YES	YES	YES
Free informative brochures	YES	YES	YES	YES	NO	YES	YES
National day of donation	YES	YES	YES	NO	NO	YES	YES
Campaigns of information and promotion	YES	YES	YES	YES	NO	YES	YES
Public relations together with civil organizations	YES	YES	YES	YES	NO	YES	YES
Telephone 24 hours for general information	YES	YES	NO	NO	NO	YES	YES
National programme for promotion of organ donation working with general population, specific leading groups, health care workers and donation interview	NO	YES	YES	YES	NO	YES	YES
Questions/answers on the web page	YES	IMPROVING	YES	NO	NO	NO	NO/IMPROVING
Forums	YES			YES	NO	NO	NO
Public Relation Department			YES				NO
Press releases about successes on a regular basis			YES				YES
Professional Conferences			YES				YES

<b>SPECIFIC PROGRAMMES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
National Registry for Brain Damaged patients	NO	NO	NO	NO	YES	YES	ES
Pilot in-house donor transplant coordinator posts in Intensive Care Units	YES	NO	NO	YES	NO	NO	NO
Quality control programme on donation process: internal and external audits	YES	YES IMPROVING	BUILT UP PHASE	YES	NO	YES	YES

### 3.5.2. LIVING DONORS

LEGAL INICIATIVES	UNITED KINGDOM UKT	FRANCE EFG	GERMANY DSO	HUNGARY HT	PORTUGAL OPT	ITALY CNT	SPAIN ONT
Regulated BY LAW. Allowed only for donors, genetically related	NO	NO	NO	NO	YES	NO	NO
Regulated BY LAW. Allowed for donors, genetically and non genetically related	YES	YES	YES	YES	NO	YES	YES
Only admissible for the purpose of transplanting to relatives of the first or second degree, spouses, fiancés or other persons with whom the donor obviously entertains an especially intimate personal relationship after an informed consent and the authorization of an "Ethical Commission"	YES	NO	YES	NO	NO	YES	YES
National Guidelines for transplant from living donor	YES	NO	YES ALSO FEDERAL REGULATIONS	YES	YES	YES	YES
Forbidden for minors and unable to decide	YES	YES	YES	NO	YES	YES	YES

TECHNICAL INICIATIVES	UNITED KINGDOM UKT	FRANCE EFG	GERMANY DSO	HUNGARY HT	PORTUGAL OPT	ITALY CNT	SPAIN ONT
Living kidney transplant programmes	YES	YES	YES	YES	YES	YES	YES
Living liver transplant programmes	YES	YES	YES	IMPROVING	NO	YES	YES
Living liver paediatric transplant programmes	YES	YES	YES	IMPROVING	YES	YES	YES
Guideline for living donor for kidney transplantation	YES	YES	NO	YES	IMPROVING	YES	YES
National transplant Database for living kidney donors	YES	YES	YES	YES	NO	YES	NO
Surveys on living donation directed towards kidney tx units, kidney patients and nephrology staff	NO	YES	NO ONLY TX CENTRES	NO	IMPROVING	YES	YES

ORGANIZATIONAL INICIATIVES	UNITED KINGDOM UKT	FRANCE EFG	GERMANY DSO	HUNGARY HT	PORTUGAL OPT	ITALY CNT	SPAIN ONT
Evaluation Committees	YES	YES	NO	NO	IMPROVING	YES	YES
Ethical Committees	YES	YES	YES	YES	NO	YES	YES
Specific professional leader for living donors	YES		NO	NO	NO	NO	NO
Same organization and budgetary coverage as for cadaveric donation	YES	NO	NO	YES	YES	YES	YES

<b>HUMAN RESOURCES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Living donor coordinators	YES	NO	NO	NO	NO	NO	NO
New Committees	NO	YES	NO	NO	NO	NO	NO
More surgical teams	NO	NO	NO	NO	IMPROVING	NO	NO
Ethical committee of the hospital	YES	NO	YES	YES	YES	YES	YES
Same staff as for cadaveric donation, procurement and transplantation	YES	YES	YES	YES	YES	YES	YES

<b>FINANCIAL INITIATIVES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Financial subsidies for living programmes	YES	YES	NO	NO	YES	NO	NO

<b>EDUCATIONAL RESOURCES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
National courses on surgical techniques for transplantation from living donors	NO	NO	NO	NO	NO	YES	NO
New materials for information and education are developed to inform patients and living donors	YES	YES	NO	NO	IMPROVING	NO	NO
Inputs to the mass media	YES	YES	NO	NO	NO	NO	YES
Living donor forum	YES	NO	NO	NO	NO	NO	NO

<b>SPECIFIC PROGRAMMES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Audits in hospitals to obtain authorization to perform transplants from living donors in order to monitor follow-ups in donors and recipients	NO		NO	NO	IMPROVING	YES	NO

Living donation can be an alternative to improve the availability of organs. However, as it has been stated before there is a need for drawing up living programs in a complementary way with deceased programmes and not in competition. There should

be no negative correlation between living transplantation activity and deceased one. As it has been analyzed most countries got legal statements to regulate living donation, and most of them except Portugal, allowed donation between genetically unrelated people, in most of them, donation from minors is forbidden. In four countries there is need for an external advisory board (ethical committee) evaluation of each case.

In most countries there are technical initiatives to promote living donation, but in practice, living donation activity is almost anecdotal. The UK living kidney transplant program has increased living transplant activity but overall activity did not increase in the same way. In Germany some cross over donations have taken place during the last year however they are still legally not undisputed. Additionally more than 30 successful ABO incompatible transplantations based on living donation have been performed. Surveys have been conducted and it will be helpful to evaluate and analyze and if possible compress the results.

Most countries do not deserve specific organizational or specific budget to living transplant activity. Same organization developed for deceased donation and transplantation activity is used. In the same way no financial subsidies for living programmes or specific training or communication activities are in place.

### 3.5.3. CADAVERIC NON-HEARTBEATING DONORS

LEGAL INICIATIVES	UNITED KINGDOM UKT	FRANCE EFG	GERMANY DSO	HUNGARY HT	PORTUGAL OPT	ITALY CNT	SPAIN ONT
Legally approved	YES	YES	NO	NO	NOT IMPLEMENTED	YES	YES
Not allowed	NO	NO	YES	YES		NO	-
Legislation under revision	YES	NO	NON EXPECTED	NO		NO	-

TECHNICAL INICIATIVES	UNITED KINGDOM UKT	FRANCE EFG	GERMANY DSO	HUNGARY HT	PORTUGAL OPT	ITALY CNT	SPAIN ONT
Guideline for national donor management	YES	YES		NO		YES IMPROVING	YES
Programmes providing kidneys, livers and lungs	YES	YES ONLY KIDNEYS		NO		NO	YES
Research with perfusion devices	YES			NO		YES	YES
Guidelines for the evaluation of NHBD and the consequent use of organs	YES	YES IMPROVING		NO		YES IMPROVING	YES

<b>ORGANIZATIONAL INICIATIVES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Pilot protocols	YES	YES		NO		YES	YES
New programmes	YES	YES		NO		NO	YES
A new national professional leadership of donor transplant coordination	YES	YES		NO		NO	NO
Cooperation organized with extra hospital emergency services	NO	YES IMPROVING		NO		NO	YES

<b>HUMAN RESOURCES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
More persons in emergency, trauma coordinators and surgical teams	YES	NO		NO		NO	NO
New NHBD teams	YES	NO		NO		NO	NO
Coordinators involved	YES	YES		NO		YES	YES

<b>FINANTIAL INICIATIVES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Special funds for NHB donation and transplantation topics related	YES	NO		NO		NO	NO
Financial subsidies to harvesting institutions, transplant centres, HLA typing labs and coordination labs and coordination bureaux	NO			NO		NO	NOT SPECIFIC
Same resources that are available for ED donation programmes	NO	YES		YES		NO	YES

<b>EDUCATIONAL RESOURCES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Educational programmes for senior healthcare professionals	YES	YES		NO		NO IMPROVING	NO
Specific national course on NHBD for transplant coordinators	YES	NO		NO		NO IMPROVING	YES
Training for extra hospital emergency service staff	NO	NO		NO		YES	YES

<b>COMMUNICATION INICIATIVES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Specific communications to health professionals	YES	YES		NO		NO	YES

<b>SPECIFIC PROGRAMMES</b>	<b>UNITED KINGDOM UKT</b>	<b>FRANCE EFG</b>	<b>GERMANY DSO</b>	<b>HUNGARY HT</b>	<b>PORTUGAL OPT</b>	<b>ITALY CNT</b>	<b>SPAIN ONT</b>
Lung programme from NHBD	YES	NO		NO		NO	YES

In two countries, Germany and Hungary, non heart beating donation is not legally possible. Only one country, Spain, developed an organized cooperation with extrahospital emergency services and in one more, France, they are preparing such a cooperation programme. None of the evaluated countries is developing any initiative in allocating more human or budget resources to NHBD Donation programmes. Specific communication and training programmes have been developed in two countries. These programmes should be evaluated in order to analyze whether they could be applicable elsewhere.

#### **4. DESCRIPTIVE STUDY AND CONCLUSIONS**

The use of organs for transplantation poses common problems that need to be faced. Legal and ethical items are a matter of concern for many professionals and international bodies. Technical problems, such as the risk of transmission for diseases, such as infections or cancer. The need of improving survival rates and of reducing medium and long term rates of complications such as chronic failure, cardiovascular diseases, immunological responses, immunosuppression side effects, etc. is evident. However, all this points that need study, entrancement research, investment to be able to improve transplant results can not be started or developed if we do not improve the rate of organ donation for transplantation. The severe shortage of organ donors remains the main challenge for Member States in the European Union. First part of this study was devoted to the collection for donation and transplantation activity as well as data of waiting lists.

Mean activity in organ donation and transplantation in Europe is below USA figures and that is true for both, deceased and living donation and transplantation. Even if we analyze data from the biggest and better developed western European countries, all indicators remains below the American ones. It is true that waiting lists and mortality rates while waiting are large in the USA, but this can be explained by a lower rate of patients' admittance to the waiting list.

Among the analyzed European countries it has to be showed that there are wide differences in all collected indicators: donation rates, transplantation rates & patients' admittance to the waiting list.

These differences between Europe and the USA and between the European Countries cannot be explained by differences in the mortality rates or geographic or socioeconomic indicators differences. Nevertheless this is something that needs further analysis. Differences observed in the waiting list are probably the lack of transplant indication reflect. Due to the scarcity of organs or the lack of available transplant programmes, transplant clinicians are extremely selective about the patients they include in the waiting lists only those patients with clear lifeblood of benefit from an organ are being considered for transplantation.

Living donation is anecdotal in some countries while in others it goes to 30% or 40% of the activity. However it is necessary to stress the idea of keeping the deceased activity while promoting living donation and to avoid the opposite situation. Living donation needs to be promoted in several countries, but being sure that deceased donation does not decrease at the same time.

The use of elderly donors or donors with known antecedents of diabetes or hypertension is being increase everywhere. However, even the use of older donors has been considered as safe provided the appropriate histological study is performed and the appropriate matching with the recipient is done, there are big differences among the European countries in the use of such donors. While more than 30% of the kidney or liver transplant activity corresponds to elderly (>60) donation in Italy or Spain, this percentage is much lower in other countries. Same comments can be made for hypertensive or diabetic donors. In many countries this data is even unknown. Effects should be made to collect such data. Besides, it would be highly advisable to organize pilot programmes or set up guidelines to ensure that all available organs are safety used and only those organs that necessary gave to be discarded are so.

Several initiatives have been put in place to entrance organ availability. Most countries have legislation covering organ donation and transplantation activities deferens in terms of required consent, binding rules for the diagnosis of brain death, control over living donation or the establishment of donation registries does not seem to correlate with higher donation rates.

Monitorization of brain damaged or brain death people in the ICUs' have resulted in different countries in an increased knowledge about what are the weakest links in the donation process in donors hospitals and where and how to put the efforts on improving organ donation.

One of the main obstacles to improve organ donation rate is the level of acceptance to donate among citizens. Refusal rates are as higher as 40-50% in some countries or areas. This lead to an important cut down on the potential for organ donation. Willingness to donation on the trust of citizens on there donation and transplantation system and this implies the need of keeping the society informed about the donation and transplantation processes. We can find publicity campaigns almost every where, but there is a lack of a true national strategy to reduce refusal rates or programmes aimed to improve relationships with implicated specific social groups, such as coroners, journalist, judges, minority leaders, etc. Besides communication programmes for selected social statements, like teenagers, students or the elderly are not developed. At the same time, we can observe that tern is a lack of a true strategy in developing training programmes for health care professionals or transplant coordinators everywhere.

The use of new technologies such as form of questions and answers in internet is not fully developed.

Living donation can be a complementary activity to improve the availability of organs. However, there is a need for promotion of such activities after the adequate analysis and definition for such programmes including technical, organizational and communication actions. Of course, the competition between living and deceased programmes should be avoided, and complementarily should be promoted.

NHB donation is unacceptable for two countries in the consortium and only one got specific legal statements and organizative actions supporting such activities. Nevertheless, non heart beating donation should be contemplated as a possible way to increase organ availability.

#### **4.1. Donation and transplantation activity. General European Data**

There is a wide range of activity in terms of donation and transplantation rates among the different European countries; same can be said in reference to the use of alternatives such as living donation or split transplantation.

As an average 14.3 donors p.m.p. are recorded in Europe while North is 21.2 p.m.p., south America 7.2 p.m.p. and Australia 9 p.m.p.

Nearly 16,500 kidney transplants are performed in Europe every year, among those only 17% are done with living donation. In the USA 42.3% of all kidney transplants (50.1 p.m.p.) are from living donors.

Among the 6,000 liver transplants done in Europe every year, 8% are split transplants, 5% are living transplants and 1.5% domino transplants. In the USA also around 6,000 liver transplants are done every year and also 5% of them are from living donors.

#### **4.2. Waiting lists. General European Data**

Also wide range is observed in all figures corresponding to the people admitted to the waiting lists is seen. Same can be said in reference to the variability of the referred death while waiting.

#### **4.3. Countries involved in ALLIANCE-O**

If we analyze only those countries involved in the Alliance-O study we can underestimate some facts:

- The number of transplant centers is variable but maintained between 0.5 and 1 p.m.p. in most countries. Only Luxemburg shows different figures but this is explained by the small population.
- Liver transplant centers varies between 0.1 p.m.p. in Hungary or the UK and 0,6 p.m.p. in Spain or Belgium. Most countries refer 0.3-0.4 heart transplant centers p.m.p. except Belgium (0.6) or the UK and Hungary (0.1 p.m.p.).

- Lung transplant centers are kept between 0.1 and 0.2 p.m.p. in most countries. It seems to be that in the biggest countries activity seems to be very concentrated in few centers in the case of UK or distributed in more centers, such as the case of Spain, Italy, France or Germany.

- Kidney transplant activity is kept in most countries between 30 and 50 cases p.m.p. but the percentage of living donation in the case of the kidney programs shows a big difference between the UK (35%) or Germany (20%) and Italy, France or Spain (less than 10%). Countries with large kidney waiting lists are Germany, Italy and the Netherlands. In the other countries this figure remains close or under 100 patients p.m.p.

Observed differences are bigger in relation to liver, heart and lung transplants, both in terms of activity, percentage of living transplant, liver activity and the number of patients admitted on the waiting lists.

Probably the high number of patients on heart, lung or pancreas waiting lists that there are in Belgium or Austria do not correspond with higher disease's incidences or prevalences but with the inclusion of non residents on their waiting lists.

#### **4.4. Expanded donors**

Nearly 35% of donors in Italy or Spain are over 60 years old and 16 or 17% are over 70. In other countries these figures are lower but with a progressive increase year after year. 6% of French donors and 11% of German donors are over 70, while same figure three or four years ago were anecdotic.

Consequently between 15 and 20% of all kidney transplants are done with the organs obtained from those donors over 60 years old.

At the same time an increasing number of liver transplants are done as well with same kind of organs.

Data about other subjects like the prevalence of high blood pressure or diabetes among organ donors are not recorded in most countries. When this data is available nearly 20% of all donors are hypertensive and 5% are diabetic.

#### **4.5. Initiatives and Programs**

Legal coverage is quite similar in the different countries reviewed in reference to encephalic death or living donation. But we can see differences in the regulation of non heart beating donation, which is not accepted in Hungary and Germany. Legal texts are under revision in the UK in reference to non heart beating donation.

Differences can also be observed in the technical and organizational aspects but those differences are quite small in reference to encephalic deaths donors. To be underlined that international programs such a Donor Acton or EDEP are not being used every where, although other alternatives have been put in place.

Again observed differences are higher in reference to non heart beating programs.

Human resources and financial initiatives are areas where differences can also be observed. Specific budgets for donation programs in hospitals are not available in the UK, Germany or Portugal.

Living programs or non-heart beating programs are not specifically supported in most countries, except the UK that got specific resources for both programs in the rest of the countries there is either no budget or the same as is contemplated for cadaveric ED donation programs.

Again we can observe differences in the programmed training courses in the different countries analyzed. No specific or programmed training is deserved for coordinators or health care personnel in social or communication tools neither covering technical aspects such as brain death, donor management or quality management.

Also in the area bigger differences are observed when living or non heart beating donation is contemplated.

Communication plans are present in all countries but electronic tools such as forms or questions answered on the web site are areas that can clearly be improved everywhere. Again a lack of structured or programmed activity can be noticed and is more evident when living or non heart beating donation is analyzed.

## 5. CONCLUSIONS

- 1.- Wide differences in terms of donation and transplantation activities and size of the waiting lists are seen between Europe and the USA and between European countries.  
Further analyses of mortality rates, socio-economic and demographic indicators are needed. However, these observed variations probably cannot be explained solely by those possible differences.
- 2.- Initiatives on the study of the potential for organ donation have been started in several European countries. It would be of outmost interest to contrast these expediences in order to check their cost/effectiveness and what they can be extrapolated and/or implanted in other European countries.
- 3.- Some local programmes aimed to analyze the potential and the outcome of the organ donors and the final use or discard rate of retrieved organs should be put in place. Strategies aimed to analyze the cost/benefit ratio for such programmes should be developed.
- 4.- Differences in the waiting list admittance rates and mortalities need further analysis. Probably they cannot be only the consequence of differences in the rates of incidence or prevalence of diseases that can be treated or ameliorated with transplantation.
- 5.- Wide differences in the number of transplant centres per million in habitants are seen among the European countries. These differences did not correlate with differences in terms of overall transplant activity in the countries. It remains to be analyzed if these differences are impacting in the outcome of grafted patients.

- 6.- Living donation in Europe represents 17% of kidney transplant activity and 5% of liver transplantation. While living donation is very frequent in some countries (30-40%) like in the USA, it remains anecdotal in others.  
Living donation does not receive specific attention; however living donation should be promoted as complementary activity for deceased transplantation activity.
- 7.- The use of expanded donors is not uniformly extended in all European countries. Efforts should enable a safe utilization of such organs without any impact on the outcome rates. Pilot studies should be deeply analyzed and where applicable extended to other areas.
- 8.- Refusals to donation is a major obstacle to the full development of the donation programmes. There is a lack of strategic national plan to reduce refusal rates. Besides training programmes for professionals, communication plan for special social groups or interactive actions such as seminars or meetings with selected social groups such as judges, coroners, journalists, minority leaders, etc. should be explored.
- 9.- Training programmes are organized without preexisting specific plans in most countries. Actions aimed to promote such activities but with defined aims and in the appropriate areas should be promoted.
- 10.- Adequate financing and allocation of human resources to donation and procurement process does not seem to be widely accepted. In most cases it does not follow the appropriate analysis or national strategic plan.  
It should be advisable to make the most adequate scenario study before deciding where and when to allocate both human and economic resources.