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2010

INTERNATIONAL FIGURES ON
DONATION AND TRANSPLANTATION - 2009

NEWSLETTER TRANSPLANT

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MINISTERIO DE SANIDAD Y POLÍTICA SOCIAL
ONT ORGANIZACIÓN NACIONAL DE TRASPLANTES

INTERNATIONAL FIGURES ON ORGAN, TISSUE & HEMATOPOIETIC STEM CELL DONATION & TRANSPLANTATION ACTIVITIES. DOCUMENTS PRODUCED BY THE COMMITTEE OF EXPERTS ON THE ORGANISATIONAL ASPECTS OF CO-OPERATION IN ORGAN TRANSPLANTATION (2009)

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Foot Note - For the purposes of this Newsletter the following definitions were used:
Organ donor: Every potential donor transferred to the operating theatre from whom, at least, one solid organ has been retrieved
Multiorgan donor: Every donor from whom, at least, two different solid organs have been retrieved
Absolute number: Include all figures corresponding to all donors/patients adults and children
Paediatric: Includes only paediatric activity (patients under 15 years old)
N.° TX Centres: One centre can include adult and pediatric program for each organ - type transplant

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International Figures on Donation and Transplantation Activity. Year 2009

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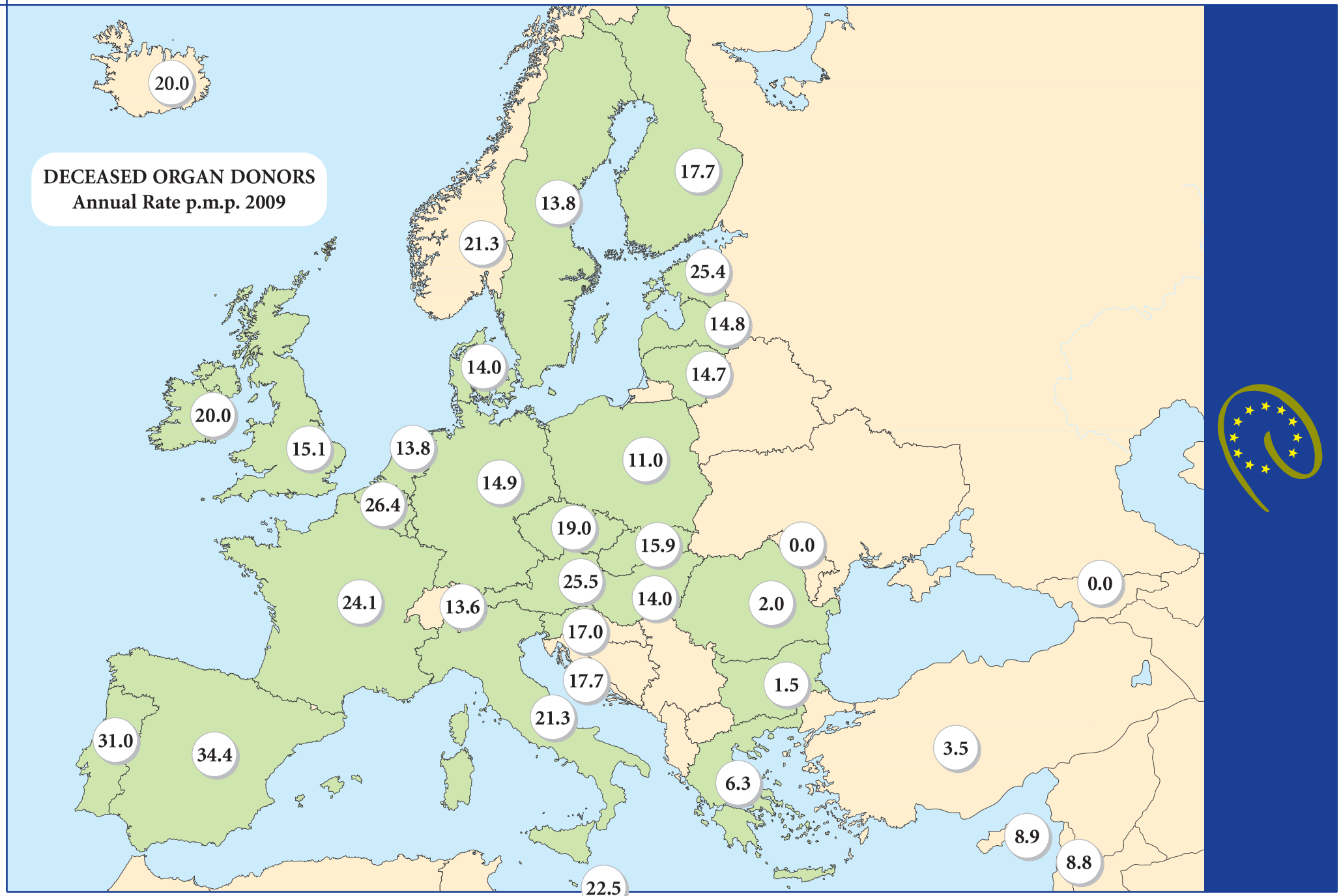
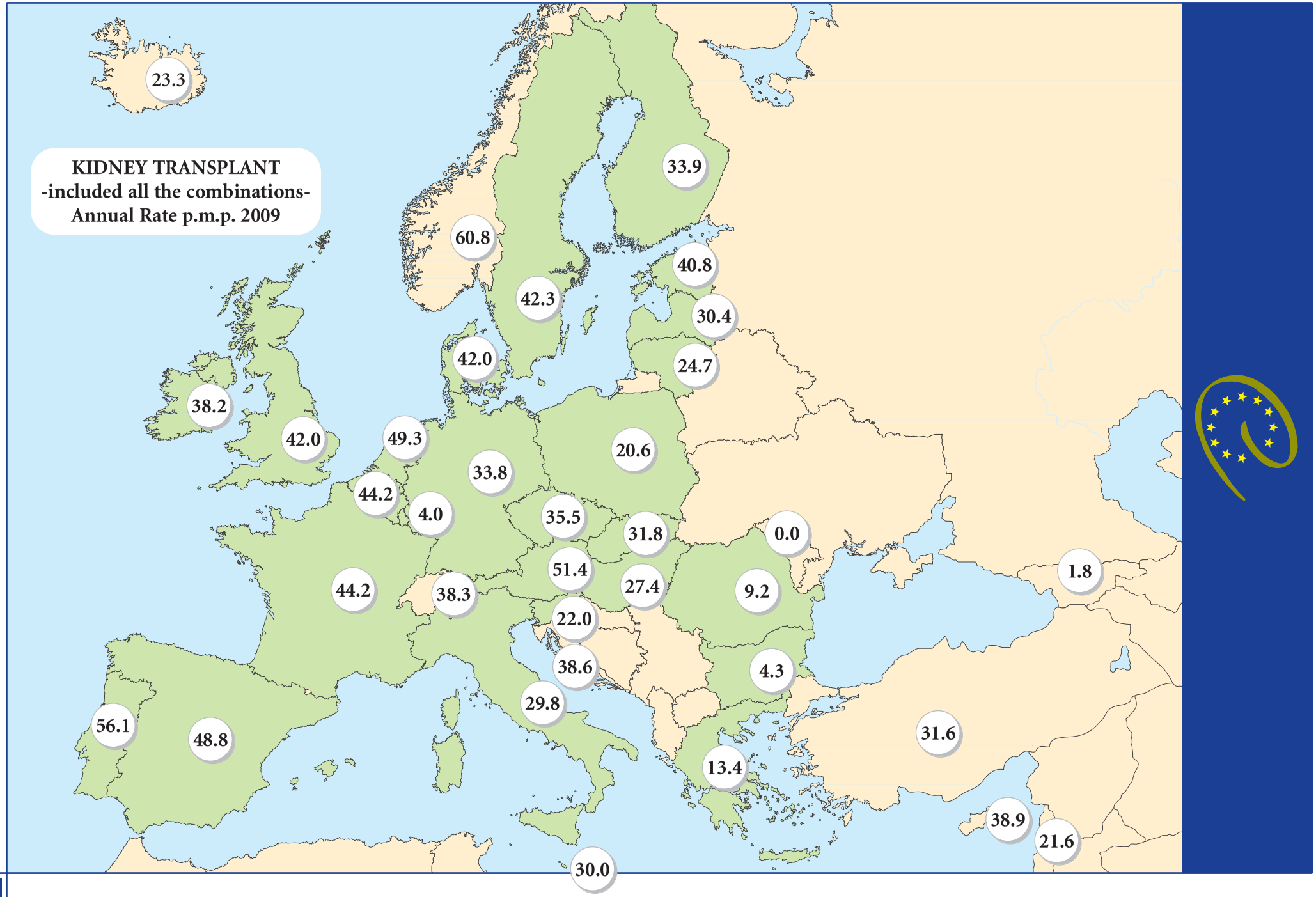
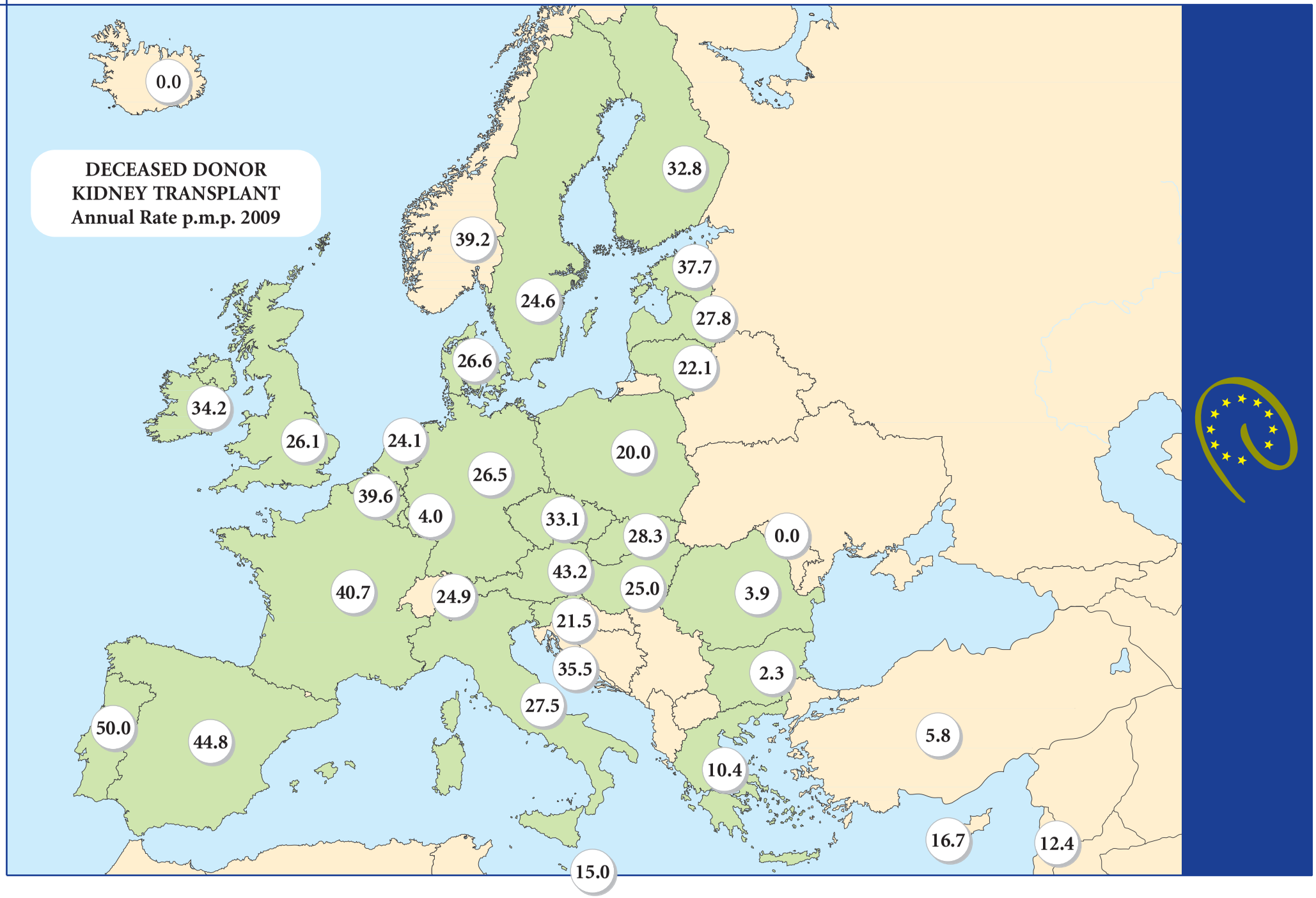
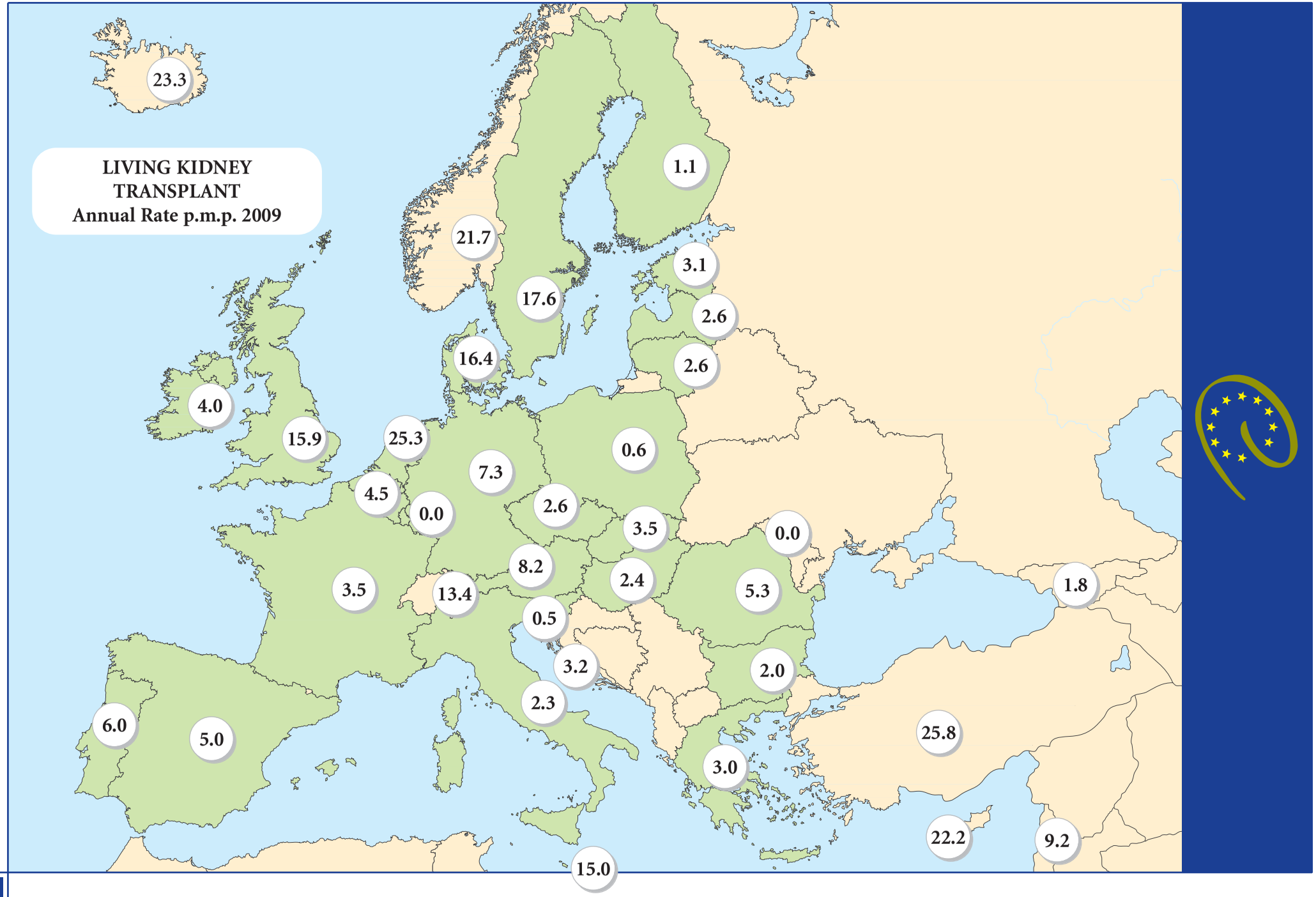
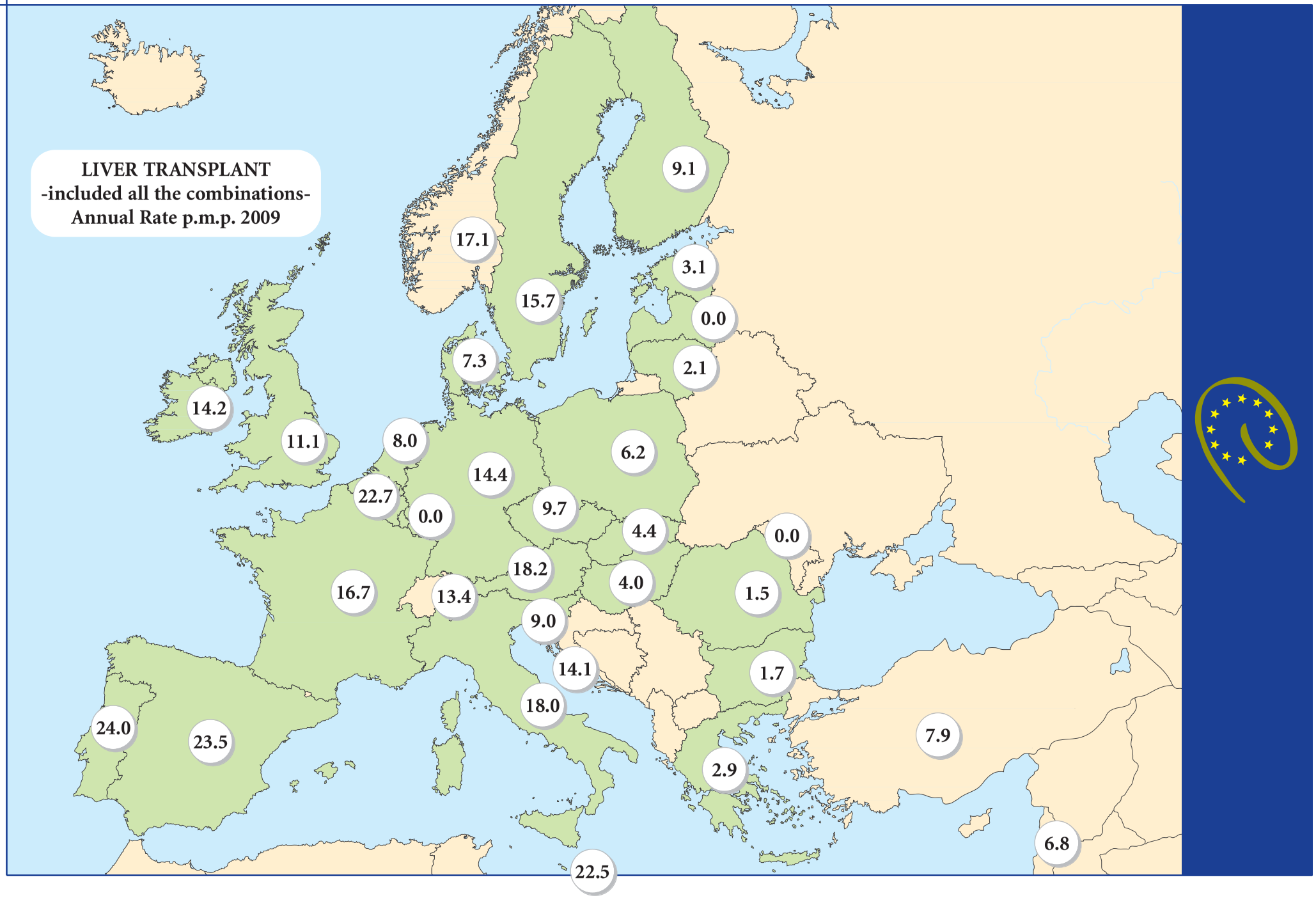
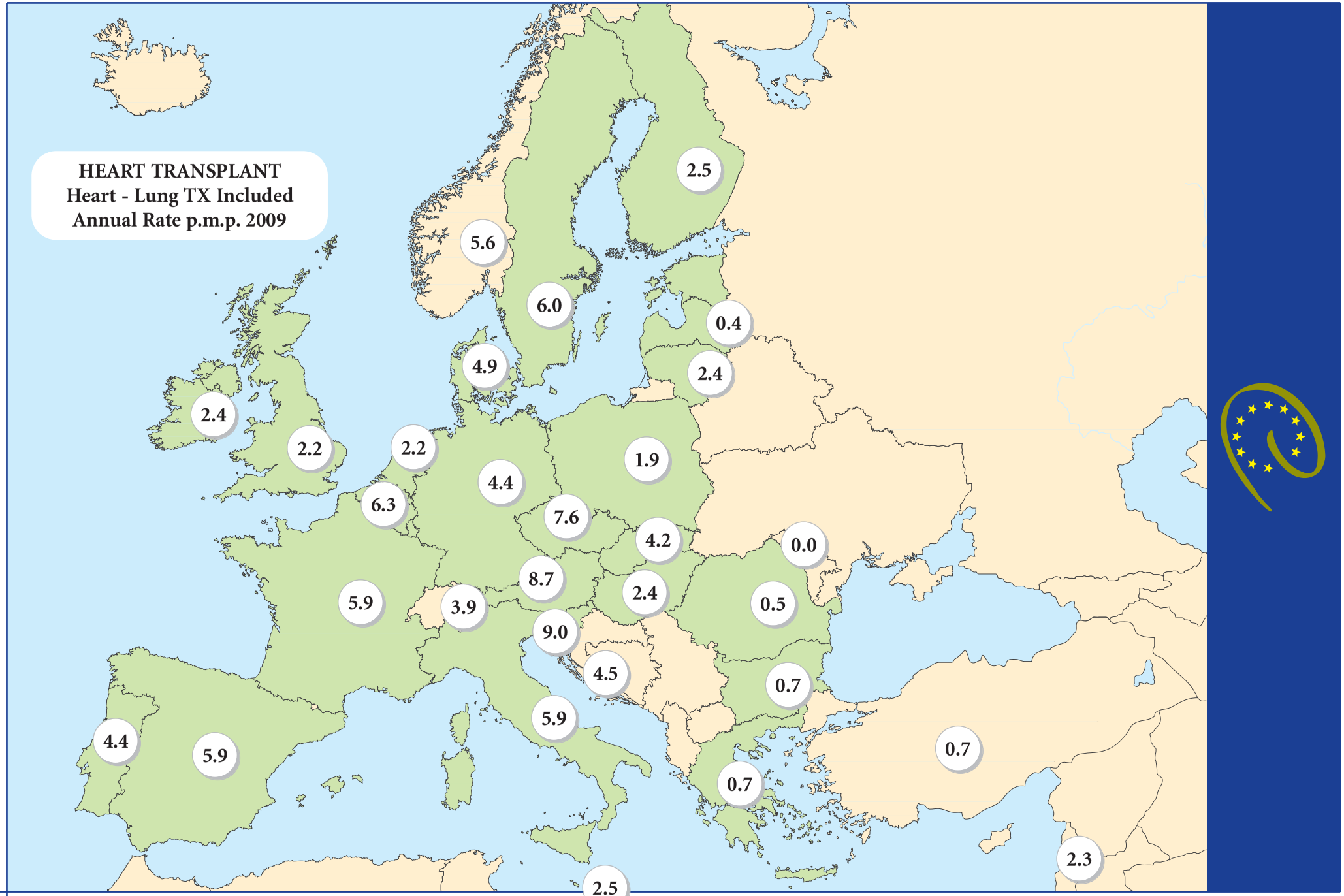

DECEASED ORGAN DONORS
Annual Rate p.m.p. 2009
20.0
17.7
13.8
21.3
25.4
14.8
14.0
14.7
20.0
15.1
13.8
11.0
14.9
26.4
19.0
15.9
0.0
25.5
0.0
24.1
13.6
14.0
2.0
17.0
17.7
1.5
21.3
31.0
34.4
3.5
6.3
8.9
8.8
22.5

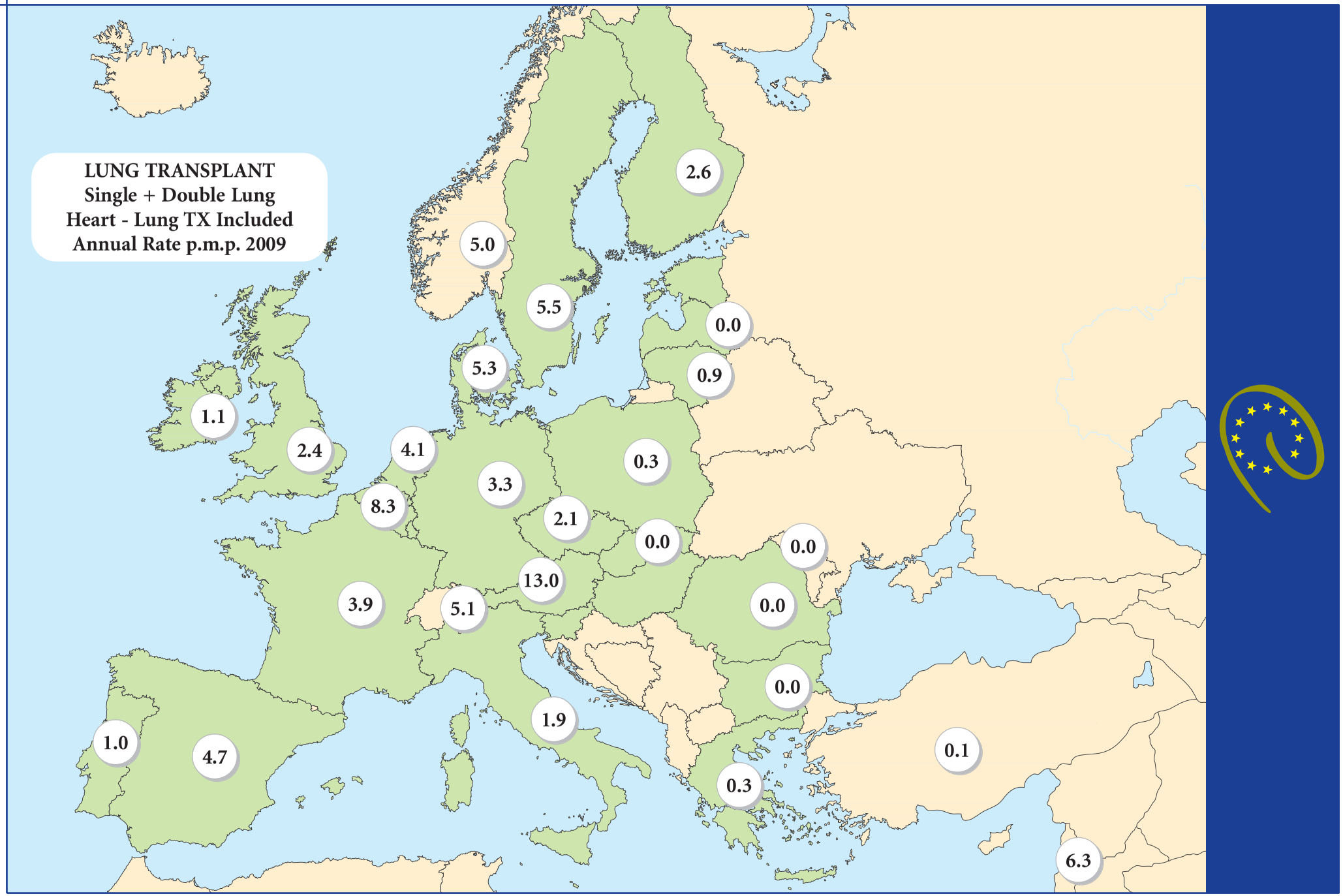

KIDNEY TRANSPLANT
-included all the combinations-
Annual Rate p.m.p. 2009
23.3
33.9
60.8
40.8
42.3
30.4
42.0
24.7
38.2
42.0
49.3
20.6
33.8
44.2
4.0
35.5
31.8
0.0
51.4
1.8
44.2
38.3
27.4
9.2
22.0
38.6
4.3
29.8
56.1
48.8
31.6
13.4
38.9
21.6
30.0

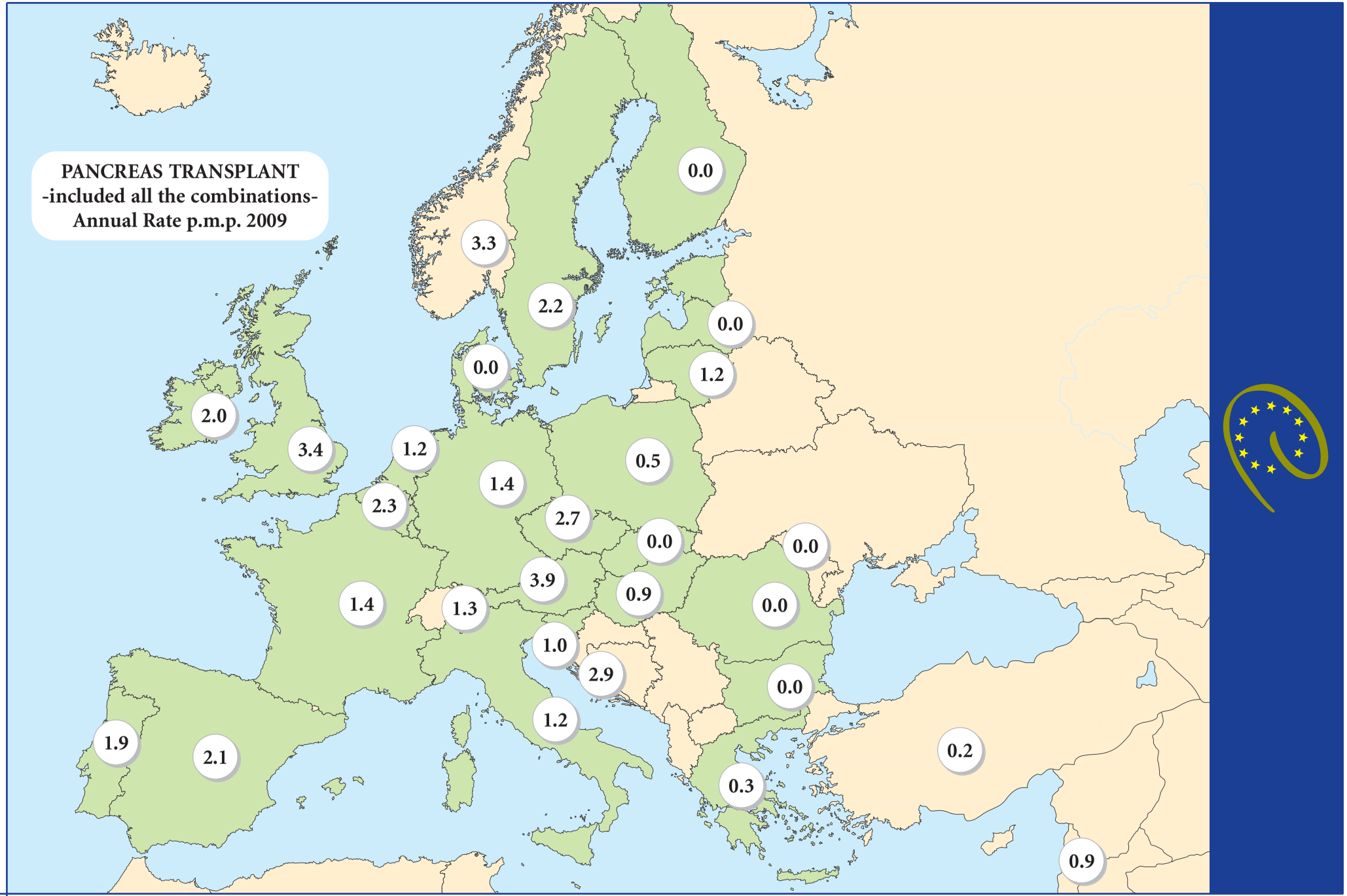

DECEASED DONOR
KIDNEY TRANSPLANT
Annual Rate p.m.p. 2009
0.0
32.8
39.2
37.7
24.6
27.8
26.6
22.1
34.2
26.1
24.1
20.0
26.5
39.6
4.0
33.1
28.3
0.0
43.2
40.7
24.9
25.0
3.9
21.5
35.5
2.3
27.5
50.0
44.8
5.8
10.4
16.7
12.4
15.0

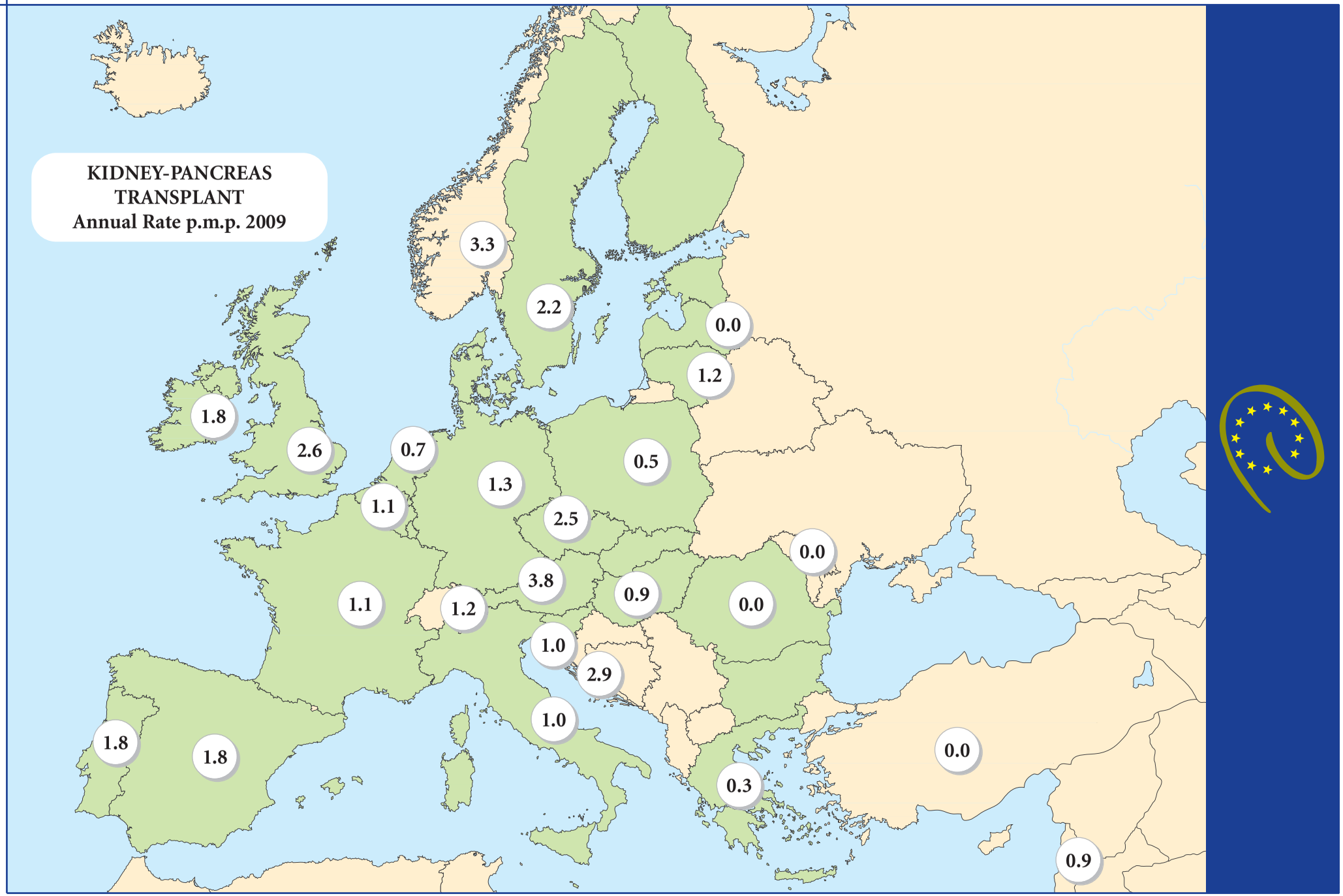

LIVING KIDNEY
TRANSPLANT
Annual Rate p.m.p. 2009
23.3
1.1
21.7
3.1
17.6
2.6
16.4
2.6
4.0
15.9
25.3
0.6
7.3
4.5
0.0
2.6
3.5
0.0
8.2
2.4
5.3
1.8
3.5
13.4
0.5
3.2
2.0
2.3
6.0
5.0
25.8
3.0
22.2
9.2
15.0


LIVER TRANSPLANT
-included all the combinations-
Annual Rate p.m.p. 2009
9.1
17.1
3.1
15.7
0.0
7.3
2.1
14.2
11.1
8.0
6.2
14.4
22.7
0.0
9.7
4.4
0.0
18.2
4.0
1.5
16.7
13.4
9.0
14.1
1.7
18.0
24.0
23.5
7.9
2.9
6.8
22.5

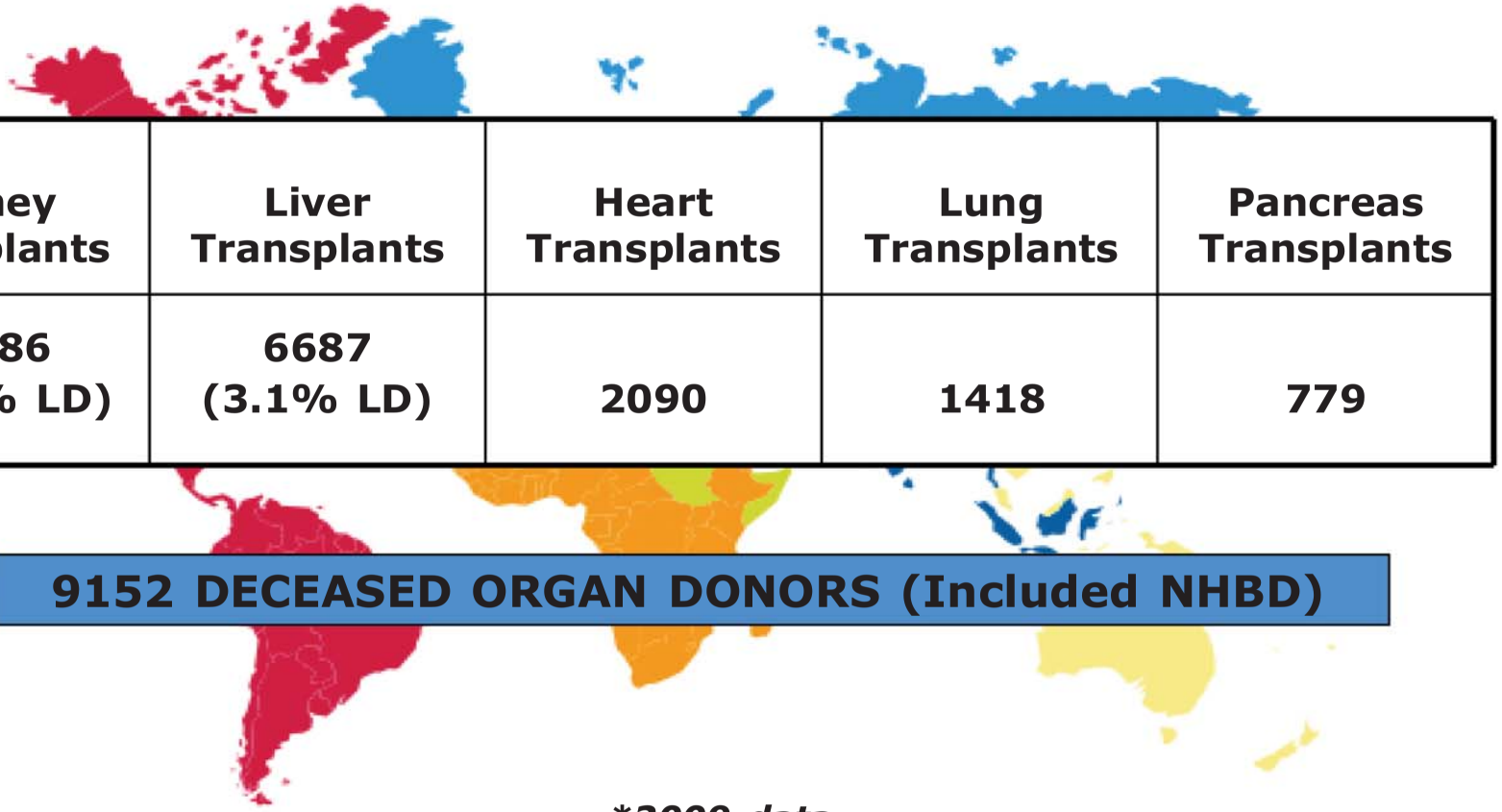

HEART TRANSPLANT
Heart - Lung TX Included
Annual Rate p.m.p. 2009
2.5
5.6
6.0
0.4
4.9
2.4
2.4
2.2
2.2
1.9
4.4
6.3
7.6
4.2
0.0
8.7
2.4
0.5
5.9
3.9
9.0
4.5
0.7
5.9
4.4
5.9
0.7
0.7
2.3
2.5


LUNG TRANSPLANT
Single + Double Lung
Heart - Lung TX Included
Annual Rate p.m.p. 2009
2.6
5.0
5.5
0.0
5.3
0.9
1.1
2.4
4.1
0.3
3.3
8.3
2.1
0.0
0.0
13.0
3.9
5.1
0.0
0.0
1.9
1.0
4.7
0.1
0.3
6.3


PANCREAS TRANSPLANT
-included all the combinations-
Annual Rate p.m.p. 2009
0.0
3.3
2.2
0.0
0.0
1.2
2.0
3.4
1.2
0.5
1.4
2.3
2.7
0.0
0.0
3.9
0.9
0.0
1.4
1.3
1.0
2.9
0.0
1.2
1.9
2.1
0.2
0.3
0.9


KIDNEY-PANCREAS
TRANSPLANT
Annual Rate p.m.p. 2009
3.3
2.2
0.0
1.2
1.8
2.6
0.7
0.5
1.3
1.1
2.5
0.0
3.8
0.9
0.0
1.1
1.2
1.0
2.9
1.0
1.8
1.8
0.0
0.3
0.9

EUROPEAN UNION DATA

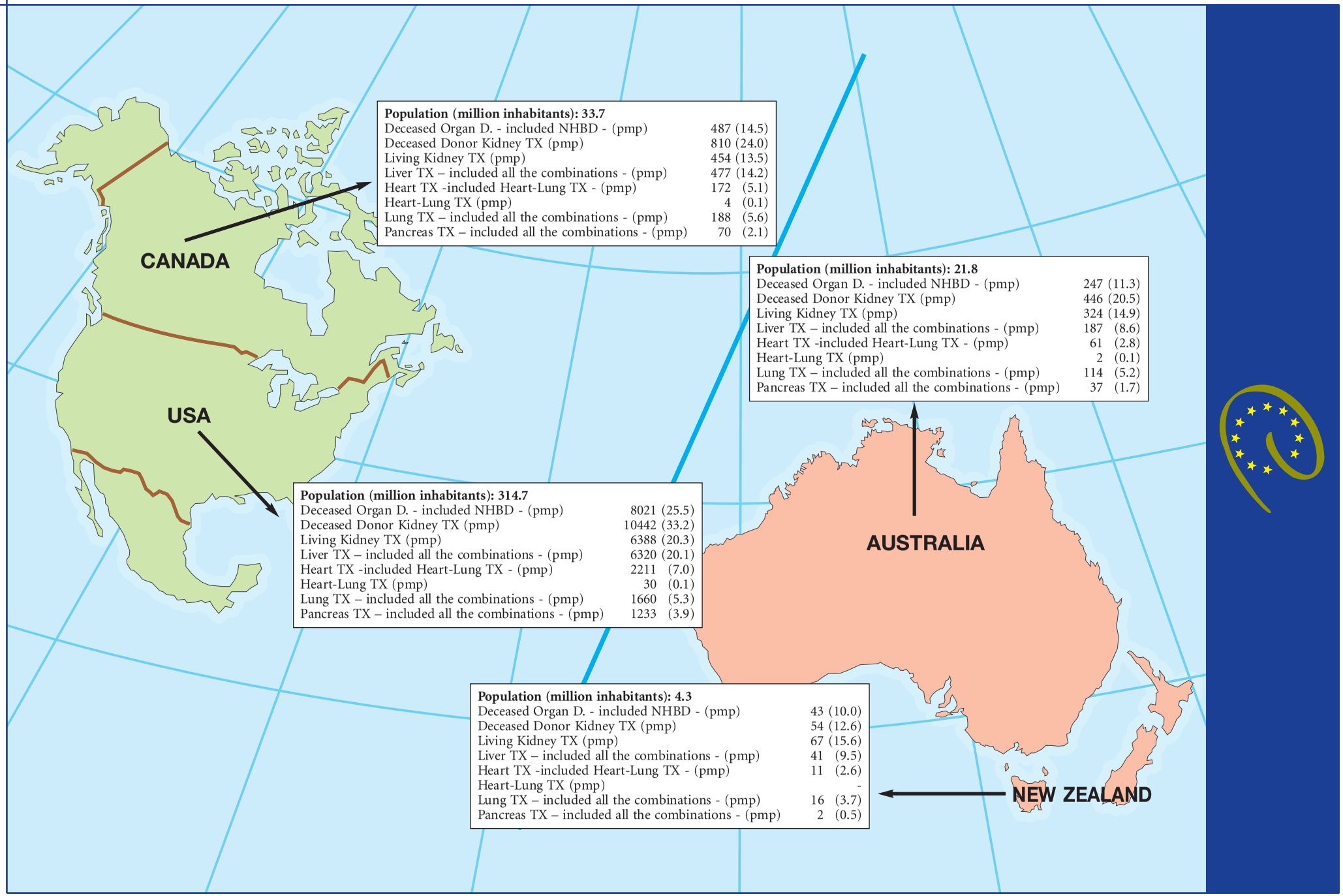


Kidney Transplants	Liver Transplants	Heart Transplants	Lung Transplants	Pancreas Transplants
17886 (18.7% LD)	6687 (3.1% LD)	2090	1418	779

9152 DECEASED ORGAN DONORS (Included NHBD)

2009 data

N= 27 COUNTRIES (500 million inhabitants)



Population (million inhabitants): 33.7	
Deceased Organ D. - included NHBD - (pmp)	487 (14.5)
Deceased Donor Kidney TX (pmp)	810 (24.0)
Living Kidney TX (pmp)	454 (13.5)
Liver TX – included all the combinations - (pmp)	477 (14.2)
Heart TX -included Heart-Lung TX - (pmp)	172 (5.1)
Heart-Lung TX (pmp)	4 (0.1)
Lung TX – included all the combinations - (pmp)	188 (5.6)
Pancreas TX – included all the combinations - (pmp)	70 (2.1)

Population (million inhabitants): 21.8	
Deceased Organ D. - included NHBD - (pmp)	247 (11.3)
Deceased Donor Kidney TX (pmp)	446 (20.5)
Living Kidney TX (pmp)	324 (14.9)
Liver TX – included all the combinations - (pmp)	187 (8.6)
Heart TX -included Heart-Lung TX - (pmp)	61 (2.8)
Heart-Lung TX (pmp)	2 (0.1)
Lung TX – included all the combinations - (pmp)	114 (5.2)
Pancreas TX – included all the combinations - (pmp)	37 (1.7)

Population (million inhabitants): 314.7	
Deceased Organ D. - included NHBD - (pmp)	8021 (25.5)
Deceased Donor Kidney TX (pmp)	10442 (33.2)
Living Kidney TX (pmp)	6388 (20.3)
Liver TX – included all the combinations - (pmp)	6320 (20.1)
Heart TX -included Heart-Lung TX - (pmp)	2211 (7.0)
Heart-Lung TX (pmp)	30 (0.1)
Lung TX – included all the combinations - (pmp)	1660 (5.3)
Pancreas TX – included all the combinations - (pmp)	1233 (3.9)

Population (million inhabitants): 4.3	
Deceased Organ D. - included NHBD - (pmp)	43 (10.0)
Deceased Donor Kidney TX (pmp)	54 (12.6)
Living Kidney TX (pmp)	67 (15.6)
Liver TX – included all the combinations - (pmp)	41 (9.5)
Heart TX -included Heart-Lung TX - (pmp)	11 (2.6)
Heart-Lung TX (pmp)	-
Lung TX – included all the combinations - (pmp)	16 (3.7)
Pancreas TX – included all the combinations - (pmp)	2 (0.5)


DECEASED ORGAN DONORS
Annual Rate p.m.p. 2009
2.8
12.1
0.9
0.4
5.3
3.7
12.1
3.2
1.2
8.0
3.0
6.5
12.5
19.1


KIDNEY TRANSPLANT
-included all the combinations-
Annual Rate p.m.p. 2009
20.8
11.9
5.9
4.9
29.0
12.3
18.5
9.0
4.1
21.9
5.4
4.5
8.9
11.7
26.2
38.2


DECEASED DONORS KIDNEY TRANSPLANT / LIVING KIDNEY TRANSPLANT
Annual Rate p.m.p. 2009
4.5 / 16.3
11.6 / 0.4
1.7 / 4.3
0.9 / 4.1
10.2 / 18.7
7.4 / 4.9
6.0 / 3.1
17.0 / 1.5
2.4 / 1.8
13.0 / 8.9
- / 1.6
3.0 / 5.9
11.7 / -
20.9 / 5.3
36.2 / 2.1


LIVER TRANSPLANT
-included all the combinations-
Annual Rate p.m.p. 2009
0.7
2.2
0.2
3.6
0.4
5.4
0.1
6.2
0.4
4.1
6.6
2.9


HEART TRANSPLANT
Heart - Lung TX Included
Annual Rate p.m.p. 2009
0.2
0.3
0.7
1.3
0.1
1.0
0.2
1.1
2.3
2.1


LUNG TRANSPLANT
Single + Double Lung
Heart - Lung TX Included
Annual Rate p.m.p. 2009
0.0
0.1
0.1
0.0
0.7
0.0


KIDNEY - PANCREAS
TRANSPLANT
Annual Rate p.m.p. 2009
0.0
0.0
0.2
0.0
0.0
0.1
1.7
1.5

LATINAMERICAN COUNTRIES

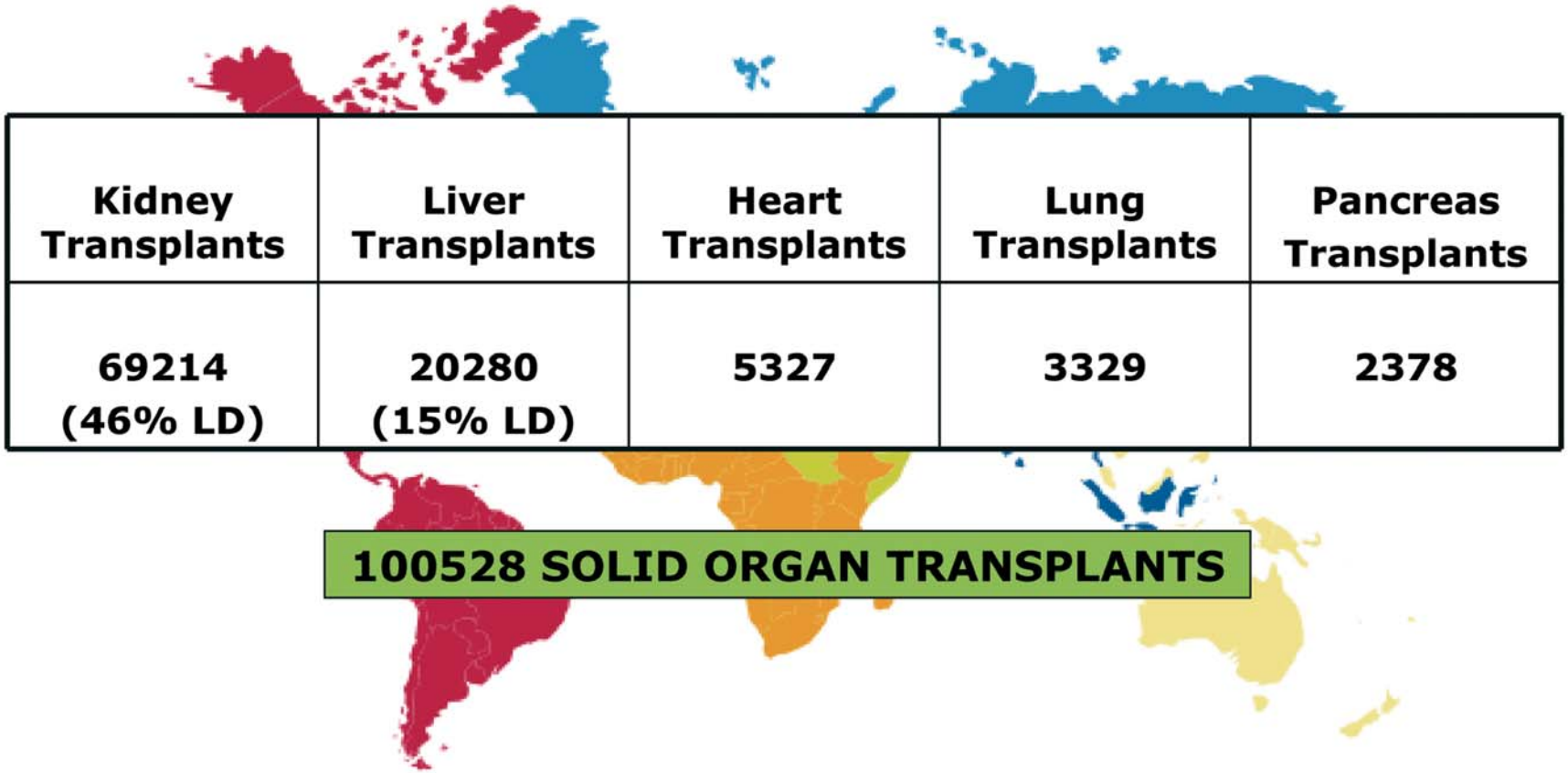
Kidney Transplants	Liver Transplants	Heart Transplants	Lung Transplants	Pancreas Transplants
9759 (42.6% LD)	1934 (2.7% LD)	401	65	90

3410 DECEASED ORGAN DONORS (Included NHBD)

**2009 data*

N= 16 COUNTRIES (540.9 million inhabitants)

GLOBAL DATA



Kidney Transplants	Liver Transplants	Heart Transplants	Lung Transplants	Pancreas Transplants
69214 (46% LD)	20280 (15% LD)	5327	3329	2378

100528 SOLID ORGAN TRANSPLANTS

***2008 data**

In collaboration with World Health Organization

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Wednesday, 21 July 2010

Events´Announcement

Events

Title	Initial Date
13th ASIA PACIFIC ASSOCIATION OF SURGERY TISSUE BANK 2010	26/10/2010
12th Congress of the Middle East Society for Organ Transplantation (MESOT).	18/10/2010
22nd ETCO Congress	24/09/2010
XXIII Internacional Congress of The Transplantation Society	15/08/2010
IX Meeting of Iberoamerican Council/Network on Donation and Transplantation	15/06/2010
MESOT Fellowship Program.	14/05/2010

Last global news

New

Prince of Asturias Award for International Cooperation
In conjunction with The Transplantation Society (TTS), the Spanish "Organización Nacional de Trasplantes" (ONT), has been recognized by the award of the highly prestigious Premio Principe de Asturias for International Cooperation. The previous winners of this award include Nelson Mandela, Al Gore, the Bill and Melinda Gates Foundation, Helmut Kohl, Lula da Silva, the WHO and other equally prestigious contributors to the goal of international cooperation. The Prize will be received by these two organizations from Prince Felipe of Spain in the city of Oviedo on October 22nd, 2010.

PHILIPPINES. Health dep't directive setting up registry seeks to curb illegal organ trade.
The Philippine Network for Organ Sharing (PHILNOS) has been established under Administrative Order 2010-0019 that set rules on "organ donation and organ transplantation involving deceased donors in the country."

MEPs back European rules on organ donations and transplants.
People needing organ transplants should face shorter waiting times after Parliament approved on Wednesday a draft directive on quality and safety standards for human organs used for transplants. The directive covers all stages of the chain from donation to transplantation and provides for cooperation between Member States. MEPs also adopted a resolution on an Action Plan for organ donation.

Highlights


World Health Organization

WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION

PREAMBLE

www.transplant-observatory.org

International Data on Organ Donation and Transplantation, Waiting List and Family Refusals. Year 2009

DONATION AND TRANSPLANTATION ACTIVITY

EUROPEAN UNION COUNTRIES

COUNTRIES	AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH. R.	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY
Population (million inhabitants)	8.4	10.8	7.5	0.9	10.5	5.5	1.3	5.3	63.9	81.9
DONATION										
Deceased Organ D. -included NHBD- (pmp)	214 (25.5)	285 (26.4)	11 (1.5)	8 (8.9)	200 (19.0)	77 (14.0)	33 (25.4)	94 (17.7)	1543 (24.1)	1217 (14.9)
NHB Donors (pmp)	1 (0.1)	61 (5.6)	0	-	0	0	-	0	62 (1.0)	0
% Multiorgan donors	82.7	78.6	100	-	58.5	60	24	65	-	86.2
TRANSPLANTATION										
KIDNEY										
TX. –included all the combinations- (pmp)	432 (51.4)	477 (44.2)	32 (4.3)	35 (38.9)	373 (35.5)	231 (42.0)	53 (40.8)	180 (33.9)	2826 (44.2)	2772 (33.8)
% (Living TX. / Total TX.)	16	10.3	46.9	57.1	7.2	39	7.5	3.3	7.9	21.6
Paediatric <15 years	9	7	1	2	5	15	-	5	80	-
Deceased Donor TX. (pmp)	363 (43.2)	428 (39.6)	17 (2.3)	15 (16.7)	346 (33.1)	141 (26.6)	49 (37.7)	174 (32.8)	2603 (40.7)	2172 (26.5)
-Single TX. (pmp)	363 (43.2)	421 (39.0)	17 (2.3)	15 (16.7)	318 (30.4)	141 (26.6)	49 (37.7)	174 (32.8)	2540 (39.7)	2152 (26.3)
-Double TX. (pmp)	0	7 (0.6)	0	-	2 (0.2)	0	-	0	63 (1.0)	20 (0.2)
Living TX. (pmp)	69 (8.2)	49 (4.5)	15 (2.0)	20 (22.2)	27 (2.6)	90 (16.4)	4 (3.1)	6 (1.1)	223 (3.5)	600 (7.3)
NHB Kidney TX. (pmp)	15 (1.8)	71 (6.6)	0	-	0	0	-	0	70 (1.1)	0
LIVER										
TX. –included all the combinations- (pmp)	153 (18.2)	245 (22.7)	13 (1.7)	-	102 (9.7)	40 (7.3)	4 (3.1)	48 (9.1)	1047 (16.4)	1179 (14.4)
Paediatric <15 years	8	26	4	-	4	1	-	6	64	-
Split Liver TX. (pmp)	0	12 (1.1)	0	-	1 (0.1)	1 (0.2)	-	0	74 (1.2)	100 (1.2)
Domino Liver TX. (pmp)	0	2 (0.2)	0	-	0	1 (0.2)	-	0	12 (0.2)	1 (0.0)
Living Liver TX. (pmp)	7 (0.8)	23 (2.1)	4 (0.5)	-	0	0	-	0	12 (0.2)	60 (0.7)
NHB Liver TX. (pmp)	0	41 (3.8)	0	-	0	0	-	0	0	0
HEART										
TX. -included Heart/ Lung TX.- (pmp)	73 (8.7)	68 (6.3)	5 (0.7)	-	80 (7.6)	27 (4.9)	-	13 (2.5)	380 (5.9)	363 (4.4)
Paediatric <15 years	6	2	1	-	3	2	-	1	17	-
HEART-LUNG										
Transplants (pmp)	1 (0.1)	1 (0.1)	0	-	0	0	-	0	21 (0.3)	16 (0.2)
Paediatric <15 years	-	-		-	0	0	-	0	0	-
LUNG										
TX. –included all the combinations- (pmp)	109 (13.0)	90 (8.3)	0	-	22 (2.1)	29 (5.3)	-	14 (2.6)	252 (3.9)	272 (3.3)
Paediatric <15 years	2	1		-	-	-	-	-	2	-
Single (pmp)	9 (1.1)	11 (1.0)		-	10 (1.0)	7 (1.3)	-	0	56 (0.9)	39 (0.5)
Double -included Heart/ Lung TX.- (pmp)	100 (12.0)	79 (7.3)		-	12 (1.1)	22 (4.0)	-	14 (2.6)	196 (3.1)	233 (2.8)
NHB –double + single- Lung TX. (pmp)	-	15 (1.4)		-	0	0	-	0	0	0
PANCREAS										
TX. –included all the combinations- (pmp)	33 (3.9)	25 (2.3)	0	-	28 (2.7)	0	-	0	89 (1.4)	115 (1.4)
Paediatric <15 years	-	-		-	-	-	-	-	1	-
Kidney - Pancreas TX. (pmp)	32 (3.8)	12 (1.1)		-	26 (2.5)	-	-	-	69 (1.1)	103 (1.3)
Pancreas TX. Alone (pmp)	1 (0.1)	-		-	2 (0.2)	-	-	-	16 (0.3)	8 (0.1)
SMALL BOWEL										
TX. –included all the combinations- (pmp)	-	-	0	-	0	-	-	-	7 (0.1)	8 (0.1)
Paediatric <15 years	-	-		-	-	-	-	-	4	-
Liver + Small Bowel (pmp)	-	-		-	0	-	-	-	1 (0.0)	5 (0.1)
Small Bowel TX. Alone (pmp)	-	-		-	0	-	-	-	3 (0.0)	3 (0.0)
MULTIVISCERAL (pmp)	-	-	0	-	-	-	-	-	3 (0.0)	5 (0.1)

DONATION AND TRANSPLANTATION ACTIVITY

EUROPEAN UNION COUNTRIES

COUNTRIES	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND
Population (million inhabitants)	11.2	10.0	4.5	59.9	2.3	3.4	0.5	0.4	16.5	38.15
DONATION										
Deceased Organ D. -included NHBD- (pmp)	71 (6.3)	140 (14.0)	90 (20.0)	1273 (21.3)	34 (14.8)	50 (14.7)	-	9 (22.5)	227 (13.8)	420 (11.0)
NHB Donors (pmp)	-	0	0	2 (0.0)	13 (5.7)	-	-	-	96 (5.8)	0
% Multiorgan donors	71.8	42.8	80	81.1	3	30	-	100	73.6	56
TRANSPLANTATION										
KIDNEY										
TX. –included all the combinations- (pmp)	150 (13.4)	274 (27.4)	172 (38.2)	1786 (29.8)	70 (30.4)	84 (24.7)	2 (4.0)	12 (30.0)	814 (49.3)	785 (20.6)
% (Living TX. / Total TX.)	22.7	8.8	10.5	7.6	8.6	10.7	0	50	51.2	2.9
Paediatric <15 years	6	6	3	56	0	2	0	1	22	32
Deceased Donor TX. (pmp)	116 (10.4)	250 (25.0)	154 (34.2)	1650 (27.5)	64 (27.8)	75 (22.1)	2 (4.0)	6 (15.0)	397 (24.1)	762 (20.0)
-Single TX. (pmp)	116 (10.4)	250 (25.0)	148 (32.9)	1391 (23.2)	64 (27.8)	75 (22.1)	2 (4.0)	6 (15.0)	396 (24.0)	758 (19.9)
-Double TX. (pmp)	0	0	6 (1.3)	128 (2.1)	0	-	0	-	1 (0.1)	4 (0.1)
Living TX. (pmp)	34 (3.0)	24 (2.4)	18 (4.0)	136 (2.3)	6 (2.6)	9 (2.6)	0	6 (15.0)	417 (25.3)	23 (0.6)
NHB Kidney TX. (pmp)	-	0	0	2 (0.0)	26 (11.3)	-	0	-	160 (9.7)	0
LIVER										
TX. –included all the combinations- (pmp)	33 (2.9)	40 (4.0)	64 (14.2)	1076 (18.0)	0	7 (2.1)	0	9 (22.5)	132 (8.0)	236 (6.2)
Paediatric <15 years	0	1	-	67	0	-	0	-	13	43
Split Liver TX. (pmp)	-	0	-	78 (1.3)	0	-	0	-	9 (0.5)	0
Domino Liver TX. (pmp)	-	0	-	1 (0.0)	0	-	0	-	0	0
Living Liver TX. (pmp)	-	0	-	15 (0.3)	0	-	0	-	3 (0.2)	22 (0.6)
NHB Liver TX. (pmp)	-	0	-	0	0	-	0	-	28 (1.7)	0
HEART										
TX. -included Heart/ Lung TX.- (pmp)	8 (0.7)	24 (2.4)	11 (2.4)	355 (5.9)	1 (0.4)	8 (2.4)	-	1 (2.5)	36 (2.2)	71 (1.9)
Paediatric <15 years	0	3	-	25	0	-	-	-	1	4
HEART-LUNG										
Transplants (pmp)	0	-	0	1 (0.0)	0	1 (0.3)	-	0	2 (0.1)	0
Paediatric <15 years	0	-	-	0	0	-	-	-	-	0
LUNG										
TX. –included all the combinations- (pmp)	3 (0.3)	-	5 (1.1)	112 (1.9)	0	3 (0.9)	-	0	67 (4.1)	10 (0.3)
Paediatric <15 years	0	-	-	4	0	-	-	-	1	0
Single (pmp)	3 (0.3)	-	4 (0.9)	45 (0.8)	0	-	-	-	20 (1.2)	9 (0.2)
Double -included Heart/ Lung TX.- (pmp)	0	-	1 (0.2)	67 (1.1)	0	3 (0.9)	-	-	47 (2.8)	1 (0.0)
NHB –double + single- Lung TX. (pmp)	-	-	0	0	0	-	-	-	18 (1.1)	0
PANCREAS										
TX. –included all the combinations- (pmp)	3 (0.3)	9 (0.9)	9 (2.0)	72 (1.2)	0	4 (1.2)	-	0	20 (1.2)	20 (0.5)
Paediatric <15 years	0	0	-	2	0	-	-	-	-	0
Kidney - Pancreas TX. (pmp)	3 (0.3)	9 (0.9)	8 (1.8)	58 (1.0)	0	4 (1.2)	-	-	11 (0.7)	20 (0.5)
Pancreas TX. Alone (pmp)	0	0	1 (0.2)	12 (0.2)	0	-	-	-	9 (0.5)	0
SMALL BOWEL										
TX. –included all the combinations- (pmp)	-	-	0	4 (0.7)	0	-	-	0	1 (0.1)	0
Paediatric <15 years	-	-	0	3	0	-	-	-	1 (0.1)	0
Liver + Small Bowel (pmp)	-	-	0	3 (0.6)	0	-	-	-	0	0
Small Bowel TX. Alone (pmp)	-	-	0	1 (0.0)	0	-	-	-	1 (0.1)	0
MULTIVISCERAL (pmp)	-	-	0	2 (0.0)	0	-	-	0	16 (1.0)	0

DONATION AND TRANSPLANTATION ACTIVITY

	EUROPEAN UNION COUNTRIES							OTHER COUNTRIES		
COUNTRIES	**PORTUGAL**	**ROMANIA**	**SLOVAKIA**	**SLOVENIA**	**SPAIN**	**SWEDEN**	**U. K.**	**AUSTRALIA**	**CANADA**	**CROACIA**
Population (million inhabitants)	10.6	21.3	5.4	2.0	46.75	9.3	61.8	21.8	33.7	4.4
DONATION										
Deceased Organ D. -included NHBD- (pmp)	329 (31.0)	42 (2.0)	86 (15.9)	34 (17.0)	1606 (34.4)	128 (13.8)	931 (15.1)	247 (11.3)	487 (14.5)	78 (17.7)
NHB Donors (pmp)	0	0	0	-	107	0	318 (5.1)	42 (1.9)	43 (1.3)	-
% Multiorgan donors	68.1	75	47	79.4	80.1	82	74.9	80	-	82.1
TRANSPLANTATION										
KIDNEY										
TX. –included all the combinations- (pmp)	595 (56.1)	196 (9.2)	172 (31.8)	44 (22.0)	2328 (48.8)	393 (42.3)	2598 (42.0)	770 (35.3)	1264 (37.5)	170 (38.6)
% (Living TX. / Total TX.)	10.8	57.7	11	2.3	10.1	41.7	37.8	42.1	35.9	8.2
Paediatric <15 years	16	7	1	0	62	11	86	10	-	2
Deceased Donor TX. (pmp)	531 (50.0)	83 (3.9)	153 (28.3)	43 (21.5)	2093 (44.8)	229 (24.6)	1616 (26.1)	446 (20.5)	810 (24.0)	156 (35.5)
-Single TX. (pmp)	522 (49.2)	82 (3.8)	151 (28.0)	43 (21.5)	2072 (44.3)	229 (24.6)	1606 (26.0)	440 (20.2)	784 (23.3)	155 (35.2)
-Double TX. (pmp)	9 (0.9)	1 (0.0)	2 (0.4)	0	21 (0.4)	0	10 (0.2)	6 (0.3)	26 (0.8)	1 (0.2)
Living TX. (pmp)	64 (6.0)	113 (5.3)	19 (3.5)	1 (0.5)	235 (5.0)	164 (17.6)	982 (15.9)	324 (14.9)	454 (13.5)	14 (3.2)
NHB Kidney TX. (pmp)	0	0	-	0	148 (3.2)	0	515 (8.3)	75 (3.4)	80 (2.4)	0
LIVER										
TX. –included all the combinations- (pmp)	255 (24.0)	32 (1.5)	24 (4.4)	18 (9.0)	1099 (23.5)	146 (15.7)	685 (11.1)	187 (8.6)	477 (14.2)	62 (14.1)
Paediatric <15 years	8	1	-	0	67	9	83	6	-	2
Split Liver TX. (pmp)	2 (0.2)	1 (0.0)	-	0	7 (0.1)	11 (1.2)	104 (1.7)	30 (1.4)	13 (0.4)	1 (0.2)
Domino Liver TX. (pmp)	52 (4.9)	0	-	0	11 (0.2)	7 (0.8)	3 (0.0)	-	-	0
Living Liver TX. (pmp)	1 (0.1)	3 (0.1)	-	0	29 (0.6)	2 (0.2)	25 (0.4)	2 (0.1)	64 (1.9)	2 (0.5)
NHB Liver TX. (pmp)	0	0	-	0	20 (0.4)	0	83 (1.3)	4 (0.2)	10 (0.3)	0
HEART										
TX. -included Heart/ Lung TX.- (pmp)	47 (4.4)	10 (0.5)	23 (4.2)	18 (9.0)	274 (5.9)	56 (6.0)	138 (2.2)	61 (2.8)	172 (5.1)	20 (4.5)
Paediatric <15 years	3	0	1	-	25	11	37	3	-	-
HEART-LUNG										
Transplants (pmp)	0	0	-	-	1 (0.0)	1 (0.1)	3 (0.0)	2 (0.1)	4 (0.1)	-
Paediatric <15 years	0	0	-	-	-	-	0	-	-	-
LUNG										
TX. –included all the combinations- (pmp)	11 (1.0)	0	0	-	219 (4.7)	51 (5.5)	149 (2.4)	114 (5.2)	188 (5.6)	-
Paediatric <15 years	0	0	-	-	9	2	4	2	-	-
Single (pmp)	5 (0.5)	0	-	-	93 (2.0)	16 (1.7)	39 (0.6)	11 (0.5)	29 (0.9)	-
Double -included Heart/ Lung TX.- (pmp)	6 (0.6)	0	-	-	126 (2.7)	35 (3.8)	110 (1.8)	103 (4.7)	159 (4.7)	-
NHB –double + single- Lung TX. (pmp)	0	0	-	-	-	0	10 (0.2)	16 (0.7)	9 (0.3)	-
PANCREAS										
TX. –included all the combinations- (pmp)	20 (1.9)	0	0	2 (1.0)	97 (2.1)	20 (2.2)	213 (3.4)	37 (1.7)	70 (2.1)	13 (2.9)
Paediatric <15 years	0	0	-	-	5	-	7	-	-	0
Kidney - Pancreas TX. (pmp)	19 (1.8)	0	-	2 (1.0)	82 (1.8)	20 (2.2)	159 (2.6)	36 (1.6)	48 (1.4)	13 (2.9)
Pancreas TX. Alone (pmp)	1 (0.1)	0	-	-	15 (0.3)	0	48 (0.8)	1 (0.1)	22 (0.7)	-
SMALL BOWEL										
TX. –included all the combinations- (pmp)	0	0	0	-	11 (0.2)	-	22 (0.4)	-	1 (0.0)	-
Paediatric <15 years	0	0	-	-	-	-	11	-	-	-
Liver + Small Bowel (pmp)	0	0	-	-	-	-	4 (0.1)	-	0	-
Small Bowel TX. Alone (pmp)	0	0	-	-	-	-	7 (0.1)	-	1 (0.0)	-
MULTIVISCERAL (pmp)	0	0	0	-	5 (0.1)	2 (0.2)	11 (0.2)	-	0	-

DONATION AND TRANSPLANTATION ACTIVITY

OTHER COUNTRIES

COUNTRIES	GEORGIA	ICELAND	ISRAEL	MOLDOVA	NEW ZEALAND	NORWAY	SWITZERLAND	TURKEY	USA
Population (million inhabitants)	4.5	0.3	7.5	3.8	4.3	4.8	7.6	74.8	314.7
DONATION									
Deceased Organ D. -included NHBD- (pmp)	0	6 (20.0)	66 (8.8)	0	43 (10.0)	102 (21.3)	103 (13.6)	262 (3.5)	8021 (25.5)
NHB Donors (pmp)	0	0	1 (0.1)	0	2 (0.5)	0	0	0	-
% Multiorgan donors	0	50	71.2	0	79	81	84.5	90	-
TRANSPLANTATION									
KIDNEY									
TX. –included all the combinations- (pmp)	8 (1.8)	7 (23.3)	162 (21.6)	0	121 (28.1)	292 (60.8)	291 (38.3)	2362 (31.6)	16830 (53.5)
% (Living TX. / Total TX.)	100	100	42.6	0	55.4	35.6	35.1	81.8	38
Paediatric <15 years	0	-	9	0	4	6	6	91	866
Deceased Donor TX. (pmp)	-	0	93 (12.4)	0	54 (12.6)	188 (39.2)	189 (24.9)	431 (5.8)	10442 (33.2)
-Single TX. (pmp)	-	0	93 (12.4)	0	2 (0.5)	188 (39.2)	172 (22.6)	425 (5.7)	-
-Double TX. (pmp)	-	0	-	0	52 (12.1)	0	16 (2.1)	6 (0.1)	-
Living TX. (pmp)	8 (1.8)	7 (23.3)	69 (9.2)	0	67 (15.6)	104 (21.7)	102 (13.4)	1931 (25.8)	6388 (20.3)
NHB Kidney TX. (pmp)	-	0	-	0	4 (0.9)	0	0	0	-
LIVER									
TX. –included all the combinations- (pmp)	-	-	51 (6.8)	0	41 (9.5)	82 (17.1)	102 (13.4)	593 (7.9)	6320 (20.1)
Paediatric <15 years	-	-	5	0	3	14	6	64	572
Split Liver TX. (pmp)	-	-	3 (0.4)	0	-	5 (1.0)	5 (0.7)	3 (0.0)	-
Domino Liver TX. (pmp)	-	-	-	0	-	0	1 (0.1)	0	-
Living Liver TX. (pmp)	-	-	4 (0.5)	0	8 (1.9)	0	7 (0.9)	364 (4.9)	219 (0.7)
NHB Liver TX. (pmp)	-	-	-	0	1 (0.2)	0	0	0	
HEART									
TX. -included Heart/ Lung TX.- (pmp)	-	-	17 (2.3)	0	11 (2.6)	27 (5.6)	30 (3.9)	55 (0.7)	2211 (7.0)
Paediatric <15 years	-	-	-	0	-	2	4	8	358
HEART-LUNG									
Transplants (pmp)	-	-	2 (0.3)	0	-	0	0	0	30 (0.1)
Paediatric <15 years	-	-	1	0	-	-	0	-	4
LUNG									
TX. –included all the combinations- (pmp)	-	-	47 (6.3)	0	16 (3.7)	24 (5.0)	39 (5.1)	7 (0.1)	1660 (5.3)
Paediatric <15 years	-	-	-	0	1	-	1	1	61
Single (pmp)	-	-	33 (4.4)	0	1 (0.2)	0	38 (5.0)	7 (0.1)	-
Double -included Heart/ Lung TX.- (pmp)	-	-	14 (1.9)	0	15 (3.5)	24 (5.0)	1 (0.1)	0	-
NHB –double + single- Lung TX. (pmp)	-	-	-	0	-	0	0	0	-
PANCREAS									
TX. –included all the combinations- (pmp)	-	-	7 (0.9)	0	2 (0.5)	16 (3.3)	10 (1.3)	18 (0.2)	1233 (3.9)
Paediatric <15 years	-	-	-	0	1	-	0	0	63
Kidney - Pancreas TX. (pmp)	-	-	7 (0.9)	0	2 (0.5)	16 (3.3)	9 (1.2)	0	854 (2.7)
Pancreas TX. Alone (pmp)	-	-	-	0	-	0	1 (0.1)	18 (0.2)	379 (1.2)
SMALL BOWEL									
TX. –included all the combinations- (pmp)	-	-	-	0	-	-	0	1	180 (0.6)
Paediatric <15 years	-	-	-	0	-	-	0	0	94
Liver + Small Bowel (pmp)	-	-	-	0	-	-	0	0	-
Small Bowel TX. Alone (pmp)	-	-	-	0	-	-	0	0	180 (0.6)
MULTIVISCERAL (pmp)	-	-	-	0	-	-	0	0	-

DONATION AND TRANSPLANTATION ACTIVITY

LATINAMERICAN COUNTRIES

COUNTRIES Population (million inhabitants)	ARGENTINA 40.1	BOLIVIA 10.2	BRASIL 193.7	CHILE 17.0	COLOMBIA 45.7	COSTA RICA 4.5	CUBA 11.2	DOMINICANA 10.1	ECUADOR 14.0	EL SALVADOR 6.2
DONATION										
Deceased Organ D. -included NHBD- (pmp)	500 (12.5)	-	1553 (8.0)	111 (6.5)	554 (12.1)	24 (5.3)	136 (12.1)	9 (0.9)	17 (1.2)	-
NHB Donors (pmp)	0	-	-	-	0	0	0	0	-	-
% Multiorgan donors	50.8	-	-	-	20	-	21.3	66.7	-	-
TRANSPLANTATION										
KIDNEY										
TX. –included all the combinations- (pmp)	1051 (26.2)	47 (4.5)	4241 (21.9)	199 (11.7)	847 (18.5)	130 (29.0)	134 (11.9)	60 (5.9)	58 (4.1)	-
% (Living TX. / Total TX.)	20.2	34	40.5	0	8.3	64.6	3	71.7	43.1	-
Paediatric <15 years	70	-	-	-	82	6	3	0	-	-
Deceased Donor TX. (pmp)	839 (20.9)	-	2524 (13.0)	199 (11.7)	777 (17.0)	46 (10.2)	130 (11.6)	17 (1.7)	33 (2.4)	-
-Single TX. (pmp)	758 (18.9)	-	-	-	775 (17.0)	46 (10.2)	128 (11.4)	17 (1.7)	-	-
-Double TX. (pmp)	81 (2.0)	-	-	-	2 (0.0)	0	2 (0.2)	0	-	-
Living TX. (pmp)	212 (5.3)	16 (1.6)	1717 (8.9)	-	70 (1.5)	84 (18.7)	4 (0.4)	43 (4.3)	25 (1.8)	-
NHB Kidney TX. (pmp)	-	-	-	-	0	0	-	0	-	-
LIVER										
TX. –included all the combinations- (pmp)	265 (6.6)	-	1197 (6.2)	69 (4.1)	245 (5.4)	16 (3.6)	25 (2.2)	2 (0.2)	1 (0.1)	-
Paediatric <15 years	45	-	-	-	31	6	8	0	-	-
Split Liver TX. (pmp)	17 (0.4)	-	-	-	4 (0.1)	-	-	-	-	-
Domino Liver TX. (pmp)	2 (0.1)	-	-	-	0	-	-	-	-	-
Living Liver TX. (pmp)	20 (0.5)	-	-	-	8 (0.2)	1 (0.2)	2 (0.2)	-	-	-
NHB Liver TX. (pmp)	-	-	-	-	0	-	-	-	-	-
HEART										
TX. -included Heart/ Lung TX.- (pmp)	93 (2.3)	-	200 (1.0)	18 (1.1)	58 (1.3)	3 (0.7)	3 (0.3)	-	1 (0.1)	-
Paediatric <15 years	5	-	-	-	10	0	-	-	-	-
HEART-LUNG										
Transplants (pmp)	4 (0.1)	-	-	-	1 (0.0)	0	-	-	-	-
Paediatric <15 years	-	-	-	-	1	0	-	-	-	-
LUNG										
TX. –included all the combinations- (pmp)	30 (0.7)	-	28 (0.1)	-	6 (0.1)	0	-	-	-	-
Paediatric <15 years	-	-	-	-	1	0	-	-	-	-
Single (pmp)	16 (0.4)	-	-	-	0	0	-	-	-	-
Double -included Heart/ Lung TX.- (pmp)	14 (0.4)	-	-	-	6 (0.1)	0	-	-	-	-
NHB –double + single- Lung TX. (pmp)	-	-	-	-	0	0	-	-	-	-
PANCREAS										
TX. –included all the combinations- (pmp)	70 (1.7)	-	-	1 (0.1)	10 (0.2)	0	-	-	-	-
Paediatric <15 years	-	-	-	-	0	0	-	-	-	-
Kidney - Pancreas TX. (pmp)	67 (1.7)	-	-	1 (0.1)	8 (0.2)	0	-	-	-	-
Pancreas TX. Alone (pmp)	3 (0.1)	-	-	-	2 (0.0)	0	-	-	-	-
SMALL BOWEL										
TX. –included all the combinations- (pmp)	3 (0.1)	-	-	-	0	0	-	-	-	-
Paediatric <15 years	2	-	-	-	0	0	-	-	-	-
Liver + Small Bowel (pmp)	1 (0.0)	-	-	-	0	0	-	-	-	-
Small Bowel TX. Alone (pmp)	2 (0.1)	-	-	-	0	0	-	-	-	-
MULTIVISCERAL (pmp)	-	-	-	-	1 (0.0)	0	-	-	-	-

DONATION AND TRANSPLANTATION ACTIVITY

LATINAMERICAN COUNTRIES

COUNTRIES Population (million inhabitants)	GUATEMALA 14.0	HONDURAS 7.5	MEXICO 109.6	NICARAGUA 5.7	PANAMA 3.5	PARAGUAY 6.3	PERU 29.2	URUGUAY 3.4	VENEZUELA 28.4
DONATION									
Deceased Organ D. -included NHBD- (pmp)	6 (0.4)	-	312 (2.8)	0	13 (3.7)	19 (3.0)	-	65 (19.1)	91 (3.2)
NHB Donors (pmp)	-	-	0	0	-	-	-	0	0
% Multiorgan donors	-	-	-	0	-	-	-	93	0
TRANSPLANTATION									
KIDNEY									
TX. –included all the combinations- (pmp)	69 (4.9)	-	2280 (20.8)	0	43 (12.3)	56 (8.9)	158 (5.4)	130 (38.2)	256 (9.0)
% (Living TX. / Total TX.)	82.6	-	78.3	0	39.5	66.1	-	5.4	34
Paediatric <15 years	6	-	-	0	-	3	-	0	17
Deceased Donor TX. (pmp)	12 (0.9)	-	495 (4.5)	0	26 (7.4)	19 (3.0)	-	123 (36.2)	169 (6.0)
-Single TX. (pmp)	12 (0.9)	-	-	0	-	19 (3.0)	-	123 (36.2)	169 (6.0)
-Double TX. (pmp)	-	-	-	0	-	-	-	0	0
Living TX. (pmp)	57 (4.1)	-	1785 (16.3)	0	17 (4.9)	37 (5.9)	-	7 (2.1)	87 (3.1)
NHB Kidney TX. (pmp)	-	-	0	0	-	-	-	0	0
LIVER									
TX. –included all the combinations- (pmp)	-	-	79 (0.7)	0	-	-	13 (0.4)	10 (2.9)	12 (0.4)
Paediatric <15 years	-	-	-	0	-	-	-	0	0
Split Liver TX. (pmp)	-	-	-	0	-	-	-	0	0
Domino Liver TX. (pmp)	-	-	-	0	-	-	-	0	0
Living Liver TX. (pmp)	-	-	6 (0.1)	0	-	-	4 (0.1)	0	12 (0.4)
NHB Liver TX. (pmp)	-	-	0	0	-	-	-	0	0
HEART									
TX. -included Heart/ Lung TX.- (pmp)	-	-	17 (0.2)	0	-	1 (0.2)	-	7 (2.1)	0
Paediatric <15 years	-	-	-	0	-	-	-	0	0
HEART-LUNG									
Transplants (pmp)	-	-	0	0	-	-	-	0	0
Paediatric <15 years	-	-	0	0	-	-	-	0	0
LUNG									
TX. –included all the combinations- (pmp)	-	-	1 (0.0)	0	-	-	-	0	0
Paediatric <15 years	-	-	0	0	-	-	-	0	0
Single (pmp)	-	-	1 (0.0)	0	-	-	-	0	0
Double -included Heart/ Lung TX.- (pmp)	-	-	0	0	-	-	-	0	0
NHB –double + single- Lung TX. (pmp)	-	-	0	0	-	-	-	0	0
PANCREAS									
TX. –included all the combinations- (pmp)	-	-	3 (0.0)	0	-	-	1 (0.0)	5 (1.5)	0
Paediatric <15 years	-	-	0	0	-	-	-	0	0
Kidney - Pancreas TX. (pmp)	-	-	3 (0.0)	0	-	-	1 (0.0)	5 (1.5)	0
Pancreas TX. Alone (pmp)	-	-	0	0	-	-	-	0	0
SMALL BOWEL									
TX. –included all the combinations- (pmp)	-	-	0	0	-	-	-	0	0
Paediatric <15 years	-	-	0	0	-	-	-	0	0
Liver + Small Bowel (pmp)	-	-	0	0	-	-	-	0	0
Small Bowel TX. Alone (pmp)	-	-	0	0	-	-	-	0	0
MULTIVISCERAL (pmp)	-	-	0	0	-	-	-	0	0

WAITING LIST

EUROPEAN UNION COUNTRIES

COUNTRIES	AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH. R.	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY
Population (million inhabitants)	8.4	10.8	7.5	0.9	10.5	5.5	1.3	5.3	63.9	81.9
KIDNEY										
Nº TX CENTRES	-	-	4	1	-	4	1	1	44	40
Patients admitted to the WL during 2009	369	540	127	30	413	242	53	203	3782	3409
Patients awaiting for a TX by 2009, 31st Dec	827	866	551	120	590	455	39	383	7511	8014
Patients dead while on the WL during 2009	28	27	57	20	17	44	-	15	187	319
Patients on dialysis by 2009, 31st Dec	-	-	2930	280	-	-	270	-	-	-
LIVER										
Nº TX CENTRES	-	-	2	-	-	1	1	1	24	22
Patients admitted to the WL during 2009	184	306	6	-	143	23	5	44	1465	2098
Patients awaiting for a TX by 2009, 31st Dec	106	191	15	-	72	33	3	5	805	2163
Patients dead while on the WL during 2009	41	51	5	-	17	4	-	3	135	383
HEART										
Nº TX CENTRES	-	-	2	-	-	2	-	1	25	25
Patients admitted to the WL during 2009	100	102	5	-	94	27	-	28	485	791
Patients awaiting for a TX by 2009, 31st Dec	66	58	20	-	79	12	-	17	310	974
Patients dead while on the WL during 2009	6	18	5	-	8	6	-	6	68	169
LUNG										
Nº TX CENTRES	-	-	0	-	-	1	-	1	14	14
Patients admitted to the WL during 2009	122	120	0	-	37	35	-	14	273	477
Patients awaiting for a TX by 2009, 31st Dec	73	95	0	-	41	53	-	3	176	657
Patients dead while on the WL during 2009	8	9	0	-	25	9	-	1	28	95
PANCREAS										
Nº TX CENTRES	-	-	0	-	-	0	-	0	15	21
Patients admitted to the WL during 2009	27	37	0	-	30	-	-	-	121	209
Patients awaiting for a TX by 2009, 31st Dec	32	46	0	-	36	-	-	-	151	314
Patients dead while on the WL during 2009	2	1	0	-	1	-	-	-	7	20
SMALL BOWEL										
Nº TX CENTRES	-	-	0	-	-	0	-	0	6	5
Patients admitted to the WL during 2009	-	-	0	-	0	-	-	-	7	-
Patients awaiting for a TX by 2009, 31st Dec	-	-	0	-	0	-	-	-	20	-
Patients dead while on the WL during 2009	-	-	0	-	0	-	-	-	2	-

WAITING LIST

EUROPEAN UNION COUNTRIES

COUNTRIES	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND
Population (million inhabitants)	11.2	10.0	4.5	59.9	2.3	3.4	0.5	0.4	16.5	38.15
KIDNEY										
Nº TX CENTRES	4	4	1	43	1	2	-	1	10	17
Patients admitted to the WL during 2009	270	295	202	2799	26	82	-	32	1123	1124
Patients awaiting for a TX by 2009, 31st Dec	983	667	515	7000	267	223	-	112	926	1241
Patients dead while on the WL during 2009	46	40	17	169	17	22	-	10	88	41
Patients on dialysis by 2009, 31st Dec	-	5613	1660	-	-	-	-	220	826	-
LIVER										
Nº TX CENTRES	2	1	1	22	0	2	-	-	3	6
Patients admitted to the WL during 2009	-	153	33	1394	0	24	-	6	164	318
Patients awaiting for a TX by 2009, 31st Dec	-	78	12	1435	0	35	-	6	110	170
Patients dead while on the WL during 2009	-	21	4	177	0	7	-	0	24	15
HEART										
Nº TX CENTRES	1	2	1	19	1	2	-	1	3	4
Patients admitted to the WL during 2009	22	28	14	507	3	20	-	2	60	171
Patients awaiting for a TX by 2009, 31st Dec	21	18	18	700	5	37	-	4	60	241
Patients dead while on the WL during 2009	2	2	3	125	1	8	-	1	4	21
LUNG										
Nº TX CENTRES	1	0	1	13	0	2	-	0	3	2
Patients admitted to the WL during 2009	11	14	24	213	0	2	-	-	104	17
Patients awaiting for a TX by 2009, 31st Dec	6	5	28	309	0	3	-	-	186	20
Patients dead while on the WL during 2009	4	1	7	78	0	-	-	-	19	1
PANCREAS										
Nº TX CENTRES	0	2	1	13	0	1	-	0	2	3
Patients admitted to the WL during 2009	-	19	10	115	0	2	-	-	30	35
Patients awaiting for a TX by 2009, 31st Dec	-	19	13	233	0	23	-	-	33	29
Patients dead while on the WL during 2009	-	0	0	4	0	2	-	-	3	3
SMALL BOWEL										
Nº TX CENTRES	0	0	0	3	0	-	-	0	1	0
Patients admitted to the WL during 2009	-	-	0	5	0	-	-	-	4	0
Patients awaiting for a TX by 2009, 31st Dec	-	-	0	20	0	-	-	-	3	0
Patients dead while on the WL during 2009	-	-	0	2	0	-	-	-	1	0

WAITING LIST

	EUROPEAN UNION COUNTRIES							OTHER COUNTRIES		
COUNTRIES	**PORTUGAL**	**ROMANIA**	**SLOVAKIA**	**SLOVENIA**	**SPAIN**	**SWEDEN**	**U. K.**	**AUSTRALIA**	**CANADA**	**CROACIA**
Population (million inhabitants)	10.6	21.3	5.4	2.0	46.75	9.3	61.8	21.8	33.7	4.4
KIDNEY										
Nº TX CENTRES	8	5	4	-	38	4	27	21	25	-
Patients admitted to the WL during 2009	579	438	202	33	-	288	2860	-	-	182
Patients awaiting for a TX by 2009, 31st Dec	2111	2194	448	53	4552	480	9726	1310	2788	324
Patients dead while on the WL during 2009	53	24	42	4	-	19	324	-	82	8
Patients on dialysis by 2009, 31st Dec	9000	2039	-	-	23391	-	-	-	-	-
LIVER										
Nº TX CENTRES	3	1	2	-	24	3	7	8	9	-
Patients admitted to the WL during 2009	56	108	41	26	1460	185	942	-	-	84
Patients awaiting for a TX by 2009, 31st Dec	133	338	21	15	722	70	392	182	551	56
Patients dead while on the WL during 2009	3	22	3	8	127	8	123	-	91	15
HEART										
Nº TX CENTRES	4	2	1	-	18	3	8	5	10	-
Patients admitted to the WL during 2009	66	31	34	27	344	60	219	-	-	33
Patients awaiting for a TX by 2009, 31st Dec	19	158	21	19	77	29	139	101	140	14
Patients dead while on the WL during 2009	8	15	3	9	24	2	29	-	30	11
LUNG										
Nº TX CENTRES	1	0	0	-	8	2	6	5	6	-
Patients admitted to the WL during 2009	22	0	0	-	275	59	269	-	-	-
Patients awaiting for a TX by 2009, 31st Dec	16	0	0	-	164	19	271	141	245	-
Patients dead while on the WL during 2009	0	0	0	-	28	3	70	-	44	-
PANCREAS										
Nº TX CENTRES	1	1	0	-	11	3	10	2	7	-
Patients admitted to the WL during 2009	25	9	0	1	150	16	290	-	-	10
Patients awaiting for a TX by 2009, 31st Dec	14	70	0	-	127	19	493	32	98	1
Patients dead while on the WL during 2009	1	4	0	-	1	0	23	-	6	-
SMALL BOWEL										
Nº TX CENTRES	0	0	0	-	3	1	4	1	4	-
Patients admitted to the WL during 2009	0	0	0	-	-	-	29	-	-	-
Patients awaiting for a TX by 2009, 31st Dec	0	0	0	-	5	-	15	4	5	-
Patients dead while on the WL during 2009	0	0	0	-	-	-	2	-	0	-

WAITING LIST

OTHER COUNTRIES

COUNTRIES	GEORGIA	ICELAND	ISRAEL	MOLDOVA	NEW ZEALAND	NORWAY	SWITZERLAND	TURKEY	USA
Population (million inhabitants)	4.5	0.5	7.5	3.8	4.3	4.8	7.6	74.8	314.7
KIDNEY									
Nº TX CENTRES	2	1	6	1	3	1	6	53	250
Patients admitted to the WL during 2009	-	-	343	30	-	192	1132	2000	35112
Patients awaiting for a TX by 2009, 31st Dec	-	-	690	130	449	240	789	16589	91164
Patients dead while on the WL during 2009	-	-	36	20	-	11	22	-	4777
Patients on dialysis by 2009, 31st Dec	800	61	-	370	-	-	-	54135	-
LIVER									
Nº TX CENTRES	0	0	3	0	1	1	3	26	117
Patients admitted to the WL during 2009	-	-	59	0	-	77	250	310	11255
Patients awaiting for a TX by 2009, 31st Dec	-	-	151	0	16	13	107	1750	16785
Patients dead while on the WL during 2009	-	-	24	0	-	6	26	-	1504
HEART									
Nº TX CENTRES	0	0	3	0	1	1	3	14	131
Patients admitted to the WL during 2009	-	-	43	0	-	36	60	-	3515
Patients awaiting for a TX by 2009, 31st Dec	-	-	133	0	7	12	20	-	3153
Patients dead while on the WL during 2009	-	-	22	0	-	3	10	-	356
LUNG									
Nº TX CENTRES	0	0	2	0	1	1	2	1	67
Patients admitted to the WL during 2009	-	-	41	0	-	52	102	-	2279
Patients awaiting for a TX by 2009, 31st Dec	-	-	66	0	6	60	52	-	1784
Patients dead while on the WL during 2009	-	-	10	0	-	6	9	-	237
PANCREAS									
Nº TX CENTRES	0	0	3	0	1	1	2	5	141
Patients admitted to the WL during 2009	-	-	3	0	-	6	61	-	2370
Patients awaiting for a TX by 2009, 31st Dec	-	-	23	0	4	9	16	-	3730
Patients dead while on the WL during 2009	-	-	-	0	-	1	0	-	229
SMALL BOWEL									
Nº TX CENTRES	0	0	-	0	-	0	1	2	18
Patients admitted to the WL during 2009	-	-	-	0	-	-	1	-	260
Patients awaiting for a TX by 2009, 31st Dec	-	-	-	0	-	-	1	-	253
Patients dead while on the WL during 2009	-	-	-	0	-	-	0	-	25

WAITING LIST

LATINAMERICAN COUNTRIES

COUNTRIES	ARGENTINA	BOLIVIA	BRASIL	CHILE	COLOMBIA	COSTA RICA	CUBA	DOMINICANA	ECUADOR	EL SALVADOR
Population (million inhabitants)	40.1	10.2	193.7	17.0	45.7	4.5	11.2	10.1	14.0	6.2
KIDNEY										
Nº TX CENTRES	49	-	-	-	19	4	9	9	-	-
Patients admitted to the WL during 2009	1571	0	-	-	-	110	300	127	-	-
Patients awaiting for a TX by 2009, 31st Dec	4949	0	-	-	743	62	1300	127	-	-
Patients dead while on the WL during 2009	269	324	-	-	14	13	260	45	-	-
Patients on dialysis by 2009, 31st Dec	25228	1800	-	-	-	277	3000	1289	-	-
LIVER										
Nº TX CENTRES	18	-	-	-	5	3	3	1	-	-
Patients admitted to the WL during 2009	345	-	-	-	-	48	30	5	-	-
Patients awaiting for a TX by 2009, 31st Dec	583	-	-	-	74	25	15	6	-	-
Patients dead while on the WL during 2009	100	-	-	-	11	7	2	2	-	-
HEART										
Nº TX CENTRES	23	-	-	-	6	1	1	0	-	-
Patients admitted to the WL during 2009	77	-	-	-	-	3	9	0	-	-
Patients awaiting for a TX by 2009, 31st Dec	94	-	-	-	5	0	1	0	-	-
Patients dead while on the WL during 2009	31	-	-	-	7	0	0	0	-	-
LUNG										
Nº TX CENTRES	10	-	-	-	1	1	1	0	-	-
Patients admitted to the WL during 2009	59	-	-	-	-	0	-	0	-	-
Patients awaiting for a TX by 2009, 31st Dec	95	-	-	-	4	0	-	0	-	-
Patients dead while on the WL during 2009	23	-	-	-	1	0	-	0	-	-
PANCREAS										
Nº TX CENTRES	10	-	-	-	3	0	2	0	-	-
Patients admitted to the WL during 2009	86	-	-	-	-	0	-	0	-	-
Patients awaiting for a TX by 2009, 31st Dec	89	-	-	-	4	0	-	0	-	-
Patients dead while on the WL during 2009	8	-	-	-	0	0	-	0	-	-
SMALL BOWEL										
Nº TX CENTRES	3	-	-	-	2	0	0	0	-	-
Patients admitted to the WL during 2009	3	-	-	-	-	0	-	0	-	-
Patients awaiting for a TX by 2009, 31st Dec	5	-	-	-	2	0	-	0	-	-
Patients dead while on the WL during 2009	2	-	-	-	0	0	-	0	-	-

WAITING LIST

LATINAMERICAN COUNTRIES

COUNTRIES	GUATEMALA	HONDURAS	MEXICO	NICARAGUA	PANAMA	PARAGUAY	PERU	URUGUAY	VENEZUELA
Population (million inhabitants)	14.0	7.5	109.6	5.7	3.5	6.3	29.2	3.4	28.4
KIDNEY									
Nº TX CENTRES	-	-	203	0	1	4	8	4	11
Patients admitted to the WL during 2009	-	-	-	0	49	-	-	137	392
Patients awaiting for a TX by 2009, 31st Dec	-	-	6173	0	148	127	-	418	1058
Patients dead while on the WL during 2009	-	-	-	0	2	-	-	14	19
Patients on dialysis by 2009, 31st Dec	-	-	-	0	1500	700	-	2501	12000
LIVER									
Nº TX CENTRES	-	-	-	0	-	0	3	1	2
Patients admitted to the WL during 2009	-	-	-	0	-	-	-	31	7
Patients awaiting for a TX by 2009, 31st Dec	-	-	336	0	-	-	-	17	6
Patients dead while on the WL during 2009	-	-	-	0	-	-	-	5	3
HEART									
Nº TX CENTRES	-	-	-	0	-	2	1	2	0
Patients admitted to the WL during 2009	-	-	-	0	-	3	-	15	0
Patients awaiting for a TX by 2009, 31st Dec	-	-	46	0	-	2	-	16	0
Patients dead while on the WL during 2009	-	-	-	0	-	2	-	4	0
LUNG									
Nº TX CENTRES	-	-	-	0	-	0	1	0	0
Patients admitted to the WL during 2009	-	-	-	0	-	-	-	0	0
Patients awaiting for a TX by 2009, 31st Dec	-	-	4	0	-	-	-	0	0
Patients dead while on the WL during 2009	-	-	-	0	-	-	-	0	0
PANCREAS									
Nº TX CENTRES	-	-	-	0	-	0	-	1	0
Patients admitted to the WL during 2009	-	-	-	0	-	-	-	10	0
Patients awaiting for a TX by 2009, 31st Dec	-	-	-	0	-	-	-	16	0
Patients dead while on the WL during 2009	-	-	-	0	-	-	-	0	0
SMALL BOWEL									
Nº TX CENTRES	-	-	-	0	-	0	-	0	0
Patients admitted to the WL during 2009	-	-	-	0	-	-	-	0	0
Patients awaiting for a TX by 2009, 31st Dec	-	-	-	0	-	-	-	0	0
Patients dead while on the WL during 2009	-	-	-	0	-	-	-	0	0

FAMILY REFUSALS

EUROPEAN UNION COUNTRIES

COUNTRIES	AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH. R.	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY
Population (million inhabitants)	8.4	10.8	7.5	0.9	10.5	5.5	1.3	5.3	63.9	81.9
Number of interviews, asking for consent to donation	-	-	-	8	-	-	63	-	-	-
Number of family refusals (%)	-	-	(50)	0	-	-	30 (47.6)	-	526	-

COUNTRIES	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND
Population (million inhabitants)	11.2	10.0	4.5	59.9	2.3	3.4	0.5	0.4	16.5	38.15
Number of interviews, asking for consent to donation	110	222	127	2328	24	79	-	10	518	500
Number of family refusals (%)	18 (16.4)	11 (50)	22 (17.3)	707 (30.4)	11 (45.8)	24 (30.4)	-	1 (10)	274 (52.9)	56 (11.2)

EUROPEAN UNION COUNTRIES / OTHER COUNTRIES

COUNTRIES	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	U. K.	AUSTRALIA	CANADA	CROACIA
Population (million inhabitants)	10.6	21.3	5.4	2.0	46.75	9.3	61.8	21.8	33.7	4.4
Number of interviews, asking for consent to donation	-	112	105	-	1922	-	1265	-	-	-
Number of family refusals (%)	-	70 (62.5)	-	-	316 (16.4)	-	510 (40.3)	-	-	-

OTHER COUNTRIES

COUNTRIES	GEORGIA	ICELAND	ISRAEL	MOLDOVA	NEW ZEALAND	NORWAY	SWITZERLAND	TURKEY	USA
Population (million inhabitants)	4.5	0.5	7.5	3.8	4.3	4.8	7.6	74.8	314.7
Number of interviews, asking for consent to donation	0	8	122	0	-	-	-	952	-
Number of family refusals (%)	-	2 (25)	56 (45.9)	0	-	-	-	654 (68.7)	-

LATINAMERICAN COUNTRIES

COUNTRIES	ARGENTINA	BOLIVIA	BRASIL	CHILE	COLOMBIA	COSTA RICA	CUBA	DOMINICANA	ECUADOR	EL SALVADOR
Population (million inhabitants)	40.1	10.2	193.7	17.0	45.7	4.5	11.2	10.1	14.0	6.2
Number of interviews, asking for consent to donation	1027	-	-	-	749	-	159	29	-	-
Number of family refusals (%)	523 (50.9)	-	-	-	198 (26.4)	-	23 (14.5)	15 (51.7)	-	-

COUNTRIES	GUATEMALA	HONDURAS	MEXICO	NICARAGUA	PANAMA	PARAGUAY	PERU	URUGUAY	VENEZUELA
Population (million inhabitants)	14.0	7.5	109.6	5.7	3.5	6.3	29.2	3.4	28.4
Number of interviews, asking for consent to donation	-	-	-	-	20	0	127	72	182
Number of family refusals (%)	-	-	-	-	7 (35)	-	74 (58.3)	18 (25)	48 (26.4)

International Data on Tissue and Hematopoeitic Stem Cell Donation and Transplantation Activity. Year 2009

TISSUE & HEMATOPOIETIC STEM CELL NATIONAL DATA PROVIDED BY:

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EUROCET

Data recorded & prepared by: EUROCET - European Network of Competent Authorities for Tissues and Cells -Team (www.eurocet.org)

PRELIMINARY SUMMARY OF TISSUE DATA

EUROPEAN UNION COUNTRIES

Country		AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH R.	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE
Population (Font: eurostat 1.1.2008)		8.355.260	10.754.528	7.606.551	793.963	10.467.542	5.511.451	1.340.415	5.326.314	64.351.000	82.002.356	11.257.285
Data related to year		2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
TYPE OF TISSUE	**TYPE OF DATA**											
CORNEA	N. of tissue donations			196		359		32		4430	5816	
	Tissue donation PMP			25,8		34,3		23,9		68,8	70,9	
	N° of tissue retrieved			175		718		58		8880	0	
	N° tissue processed			177		1181		58		8880	0	
	N° tissue distributed			158		859		57		3541	0	
	N° tissue imported			0		0		0		0	732	
	N° tissue exported			0		402		0		200	216	
	N° of tissues transplanted			158		529		57		3541	3904	
	N° of patients transplanted			158		529		57		3402	0	
	N° of transplants			158		529		57		3402	0	
SKIN	N. of tissue donations			0		47		0		158	30	
	Tissue donation PMP			0,0		4,5		0,0		2,5	0,4	
	N° of tissue retrieved (cm^2)			0		0		0		345506	0	
	N° tissue processed (cm^2)			0		152448		0		345506	0	
	N° tissue distributed (cm^2)			0		128188		0		298258	0	
	N° tissue imported (cm^2)			0		0		0		95500	92629	
	N° tissue exported (cm^2)			0		128188		0		0	11378	
	N° of tissues transplanted (cm^2)			0		0		0		0	80751	
	N° of patients transplanted			0		0		0		0	0	
	N° of transplants			0		0		0		0	0	
CARDIAC TISSUE	N. of tissue donations			0		56		0		192	183	
	Tissue donation PMP			0,0		5,3		0,0		3,0	2,2	
	N° of tissue retrieved			0		101		0		659	0	
	N° tissue processed			0		113		0		659	0	
	N° tissue distributed			0		98		0		170	0	
	N° tissue imported			0		0		0		39	561	
	N° tissue exported			0		40		0		0	1704	
	N° of tissues transplanted			0		68		0		0	57	
	N° of patients transplanted			0		68		0		0	0	
	N° of transplants			0		68		0		0	0	
BLOOD VESSEL	N. of tissue donations			0		3		0		264	141	
	Tissue donation PMP			0,0		0,3		0,0		4,1	1,7	
	N° of tissue retrieved			0		3		0		3442	0	
	N° tissue processed			0		3		0		3442	0	
	N° tissue distributed			0		3		0		1011	0	
	N° tissue imported			0		0		0		46	1	
	N° tissue exported			0		0		0		9	0	
	N° of tissues transplanted			0		3		0		0	121	
	N° of patients transplanted			0		3		0		0	0	
	N° of transplants			0		3		0		0	0	
MUSCULOS-KELETAL	N. of tissue donations			342		843		190		77	9979	
	Tissue donation PMP			45,0		80,5		141,7		1,2	121,7	
	N° of tissue retrieved			315		1842		190		2227	0	
	N° tissue processed (units or *grams)			4749		2584		267		2227	0	
	N° tissue distributed (units or *grams)			4631		2483		177		3871	0	
	N° tissue imported (units or *grams)			0		0		0		343	0	
	N° tissue exported (units or *grams)			4631		55		0		10	0	
	N° of tissues transplanted			16		2114		108		0	22204	
	N° of patients transplanted			15		2114		132		0	0	
	N° of transplants			15		2114		279		0	0	
PLACENTA/ AMNIOTIC MEMBRANE	N. of tissue donations			0		7		27		0	57	
	Tissue donation PMP			0,0		0,7		20,1		0,0	0,7	
	N° of tissue retrieved			0		7		27		77	0	
	N° tissue processed (units or *cm^2)			0		415		*150		2463	0	
	N° tissue distributed (units or *cm^2)			8		282		*100		1932	0	
	N° tissue imported (units or *cm^2)			0		0		0		0	0	
	N° tissue exported (units or *cm^2)			0		91		0		0	156	
	N° of tissues transplanted (units or *cm^2)			0		260		55		0	2329	
	N° of patients transplanted			8		260		55		0	0	
	N° of transplants			8		260		55		0	0	
OTHERS	N. of tissue donations			0		277		0		0	699	
	Tissue donation PMP			0,0		26,5		0,0		0,0	8,5	
	N° of tissue retrieved			0		301		0		150	0	
	N° tissue processed			630		0		0		150	0	
	N° tissue distributed			599		0		0		33	0	
	N° tissue imported			0		0		0		0	26563	
	N° tissue exported			413		1		0		0	100166	
	N° of tissues transplanted			0		0		0		0	0	
	N° of patients transplanted			0		0		0		0	0	
	N° of transplants			0		0		0		0	0	

PRELIMINARY SUMMARY OF TISSUE DATA

EUROPEAN UNION COUNTRIES

Country		HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA
Population (Font: eurostat 1.1.2008)		10.031.208	4.465.540	60.053.442	2.261.294	3.349.872	493.500	413.627	16.486.587	38.135.876	10.627.250	21.498.616
Data related to year		2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
TYPE OF TISSUE	**TYPE OF DATA**											
CORNEA	N. of tissue donations	179		5995	27	34		21		601	486	14
	Tissue donation PMP	17,8		99,8	11,9	10,1		50,8		15,8	45,7	0,7
	N° of tissue retrieved	162		11990	27	68		21		1006	874	28
	N° tissue processed	811		11514	27	72		21		703	0	0
	N° tissue distributed	548		5270	27	66		21		676	40	0
	N° tissue imported	0		31		4		0		0	18	0
	N° tissue exported	0		192		0		0		0	0	0
	N° of tissues transplanted	438		0	27	66		21		0	755	25
	N° of patients transplanted	448		0	27	63		21		0	755	25
	N° of transplants	473		4993	27	66		21		0	755	25
SKIN	N. of tissue donations	1		368	0	0		0		24	2	25
	Tissue donation PMP	0,1		6,1	0,0	0,0		0,0		0,6	0,2	1,2
	N° of tissue retrieved (cm^2)	2500		1189002	0	0		0		5040	743	21505
	N° tissue processed (cm^2)	2500		1163852	0	0		0		6837	1468	0
	N° tissue distributed (cm^2)	18161		729400	0	0		0		0	2025	0
	N° tissue imported (cm^2)	0		0	0	0		1115		0	817	0
	N° tissue exported (cm^2)	0		0	0	0		0		0	0	0
	N° of tissues transplanted cm^2)	0		0	0	0		0		0	2025	23
	N° of patients transplanted	0		0	0	0		0		0	2	23
	N° of transplants	0		1506	0	0		0		0	2	23
CARDIAC TISSUE	N. of tissue donations	0		183	0	6		0		164	29	0
	Tissue donation PMP	0,0		3,0	0,0	1,8		0,0		4,3	2,7	0,0
	N° of tissue retrieved	7		334	0	6		0		328	70	0
	N° tissue processed	14		317	0	6		0		150	52	0
	N° tissue distributed	7		176	0	2		0		121	8	0
	N° tissue imported	0		0		0		0		0	0	0
	N° tissue exported	0		0		0		0		16	0	0
	N° of tissues transplanted	7		0	0	2		0		0	8	0
	N° of patients transplanted	7		0	0	2		0		0	8	0
	N° of transplants	7		152	0	2		0		0	8	0
BLOOD VESSEL	N. of tissue donations	0		809	0	0		0		2	47	0
	Tissue donation PMP	0,0		13,5	0,0	0,0		0,0		0,1	4,4	0,0
	N° of tissue retrieved	39		1078	0	0		0		3	47	0
	N° tissue processed	39		1240	0	0		0		2	0	0
	N° tissue distributed	29		538	0	0		0		2	0	0
	N° tissue imported	0		7		0		0		0	0	0
	N° tissue exported	0		0		0		0		0	0	0
	N° of tissues transplanted	44		0	0	0		0		0	0	0
	N° of patients transplanted	41		0	0	0		0		0	0	0
	N° of transplants	42		267	0	0		0		0	0	0
MUSCULOS-KELETAL	N. of tissue donations	728		2791	27	113		0		477	135	97
	Tissue donation PMP	72,6		46,5	11,9	33,7		0,0		12,5	12,7	4,5
	N° of tissue retrieved	569		6339	27	133		0		4363	0	118
	N° tissue processed (units or *grams)	542		0	226	132		0		587 - *9629	0	53
	N° tissue distributed (units or *grams)	516		9.025 - *56.438	226	82		0		445 - *9591	0	14
	N° tissue imported (units or *grams)	0		797 - *16085		0		0		9	0	48
	N° tissue exported (units or *grams)	0		2190		0		0		9	0	0
	N° of tissues transplanted	15		0	226	83		0		0	0	14
	N° of patients transplanted	15		0	179	76		0		0	0	14
	N° of transplants	0		6795	179	83		0		0	0	14
PLACENTA/ AMNIOTIC MEMBRANE	N. of tissue donations	0		271	0	5		0		65	60	0
	Tissue donation PMP	0,0		4,5	0,0	1,5		0,0		1,7	5,6	0,0
	N° of tissue retrieved	0		254	0	5		0		65	60	0
	N° tissue processed (units or *cm^2)	189		226	0	8		0		847	*27423	0
	N° tissue distributed (units or *cm^2)	100		*12.437	0	56		0		802	*9748	0
	N° tissue imported (units or *cm^2)	0		0		0		0		0	0	0
	N° tissue exported (units or *cm^2)	0		0		0		0		0	0	0
	N° of tissues transplanted (units or *cm^2)	101		0	0	56		0		0	9748	0
	N° of patients transplanted	97		0	0	51		0		0	82	0
	N° of transplants	97		939	0	56		0		0	82	0
OTHERS	N. of tissue donations	3		0	0	0		0		112	0	0
	Tissue donation PMP	0,3		0,0	0,0	0,0		0,0		2,9	0,0	0,0
	N° of tissue retrieved	0		0	0	0		0		158	0	0
	N° tissue processed	382		0	0	0		0		191	0	0
	N° tissue distributed	4		0	0	0		0		65	0	0
	N° tissue imported	0		0		0		0		0	0	0
	N° tissue exported	379		0		0		0		0	0	0
	N° of tissues transplanted	4		0	0	0		0		0	0	0
	N° of patients transplanted	3		0	0	0		0		0	0	0
	N° of transplants	4		0	0	0		0		0	0	0

PRELIMINARY SUMMARY OF TISSUE DATA

EUROPEAN UNION COUNTRIES

OTHER COUNTRIES

Country		SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	U. K.	CROATIA	ICELAND	MACEDONIA	NORWAY	SWITZERLAND	TURKEY
Population (Font: eurostat 1.1.2008)		5.412.254	2.032.362	45.828.172	9.256.347	61.634.599	4.435.056	319.368	2.048.620	4.799.252	7.700.202	71.517.100
Data related to year		2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
TYPE OF TISSUE	**TYPE OF DATA**											
CORNEA	N. of tissue donations	142	58	2665		0	91			10		875
	Tissue donation PMP	26,2	28,5	58,2		0,0	20,5			2,1		12,2
	N° of tissue retrieved	268	113	5185		5460	175			10		1750
	N° tissue processed	268	113	3076		5042	169			179		1529
	N° tissue distributed	149	88	2209		294	76			174		404
	N° tissue imported	0	0			638	81			270		0
	N° tissue exported	0	0			294	81			0		0
	N° of tissues transplanted	0	88	0		0	157			0		1529
	N° of patients transplanted	149	88	2837		0	152			275		1529
	N° of transplants	0	88	0		0	157			280		1529
SKIN	N. of tissue donations	5	4	229		0	9			0		-
	Tissue donation PMP	0,9	2,0	5,0		0,0	2,0			0,0		-
	N° of tissue retrieved (cm^2)	18232	0	648155		1134	92			0		-
	N° tissue processed (cm^2)	18232	0	421806		927	12000			0		-
	N° tissue distributed (cm^2)	18823	0	303753		10	8925			0		-
	N° tissue imported (cm^2)	0	0			1047	0			0		-
	N° tissue exported (cm^2)	0	0			10	0			0		-
	N° of tissues transplanted (cm^2)	0	25	0		0	8925			0		-
	N° of patients transplanted	2	0	49		0	6			0		-
	N° of transplants	0	0	0		0	10			0		-
CARDIAC TISSUE	N. of tissue donations	13	0	204		0	0			0		298
	Tissue donation PMP	2,4	0,0	4,5		0,0	0,0			0,0		4,2
	N° of tissue retrieved	21	0	303		1257	0			0		-
	N° tissue processed	21	0	219		1155	0			0		-
	N° tissue distributed	13	0	161		748	0			0		-
	N° tissue imported	0	0			460	0			0		0
	N° tissue exported	0	0			764	0			0		0
	N° of tissues transplanted	0	0	0		0	0			0		38
	N° of patients transplanted	19	0	72		0	0			0		38
	N° of transplants	0	0	0		0	0			0		38
BLOOD VESSEL	N. of tissue donations	1	0	307		0	0			0		-
	Tissue donation PMP	0,2	0,0	6,7		0,0	0,0			0,0		-
	N° of tissue retrieved	2	0	407		381	0			0		-
	N° tissue processed	2	0	336		173	0			0		-
	N° tissue distributed	2	0	217		3	0			0		-
	N° tissue imported	0	0			495	0			0		-
	N° tissue exported	0	0			3	0			0		-
	N° of tissues transplanted	0	0	0		0	0			0		-
	N° of patients transplanted	2	0	147		0	0			0		-
	N° of transplants	0	0	0		0	0			0		-
MUSCULOS-KELETAL	N. of tissue donations	289	10	1962		0	370			0		-
	Tissue donation PMP	53,4	4,9	42,8		0,0	83,4			0,0		-
	N° of tissue retrieved	1533	10	10897		9187	496			0		-
	N° tissue processed (units or *grams)	1433	0	10298		1916	496			0		-
	N° tissue distributed (units or *grams)	316	4	18751		13679	323			0		-
	N° tissue imported (units or *grams)	0	0			23997	0			0		-
	N° tissue exported (units or *grams)	0	0			14568	0			0		-
	N° of tissues transplanted	0	2	0		0	277			0		-
	N° of patients transplanted	316	0	7947		0	274			0		-
	N° of transplants	0	0	0		0	274			0		-
PLACENTA/ AMNIOTIC MEMBRANE	N. of tissue donations	16	0	0		0	0			0		-
	Tissue donation PMP	3,0	0,0	0,0		0,0	0,0			0,0		-
	N° of tissue retrieved	6638	0	0		0	0			0		-
	N° tissue processed (units or *cm^2)	*6638	0	1616		76	0			0		-
	N° tissue distributed (units or *cm^2)	*1568	0	0		0	0			0		-
	N° tissue imported (units or *cm^2)	0	0			134	19			0		-
	N° tissue exported (units or *cm^2)	0	0			0	19			0		-
	N° of tissues transplanted (units or *cm^2)	0	0	0		0	19			0		-
	N° of patients transplanted	98	0	1064		0	18			0		-
	N° of transplants	0	0	0		0	18			0		-
OTHERS	N. of tissue donations	3	20	0		0	0			0		-
	Tissue donation PMP	0,6	9,8	0,0		0,0	0,0			0,0		-
	N° of tissue retrieved	4	20	0		5292	0			0		-
	N° tissue processed	4	0	0		4516	0			0		-
	N° tissue distributed	0	27	0		273	0			0		-
	N° tissue imported	0	0			321	0			0		-
	N° tissue exported	0	0			311	0			0		-
	N° of tissues transplanted	0	0	0		0	0			0		-
	N° of patients transplanted	0	0	0		0	0			0		-
	N° of transplants	0	0	0		0	0			0		-

PRELIMINARY SUMMARY OF TISSUE DATA

LATINAMERICAN COUNTRIES

Country Population (million inhabitants) Data related to year		ARGENTINA 40.1 2009	COLOMBIA 45.7 2009	COSTA RICA 4.5 2009	CUBA 11.2 2009	DOMINICANA 10.1 2009	MEXICO 109.6 2009	PANAMA 3.5 2009	PARAGUAY 6.3 2009	PERU 29.2 2009	URUGUAY 3.4 2009	VENEZUELA 28.4 2009
TYPE OF TISSUE	**TYPE OF DATA**											
CORNEA	N. of tissue donations	649	1581	12	709	12			25	80	80	63
	Tissue donation PMP	16,2	34,6	2,7	63,3	1,2			4,0	2,7	23,5	2,2
	N° of tissue retrieved	1298	3035	24	491						161	126
	N° tissue processed											
	N° tissue distributed											
	N° tissue imported											
	N° tissue exported											
	N° of tissues transplanted											
	N° of patients transplanted	920	2823	21	382				57	133	140	110
	N° of transplants											
SKIN	N. of tissue donations	28									25	
	Tissue donation PMP	0,7									7,4	
	N° of tissue retrieved (cm^2)	23890									34100	
	N° tissue processed (cm^2)											
	N° tissue distributed (cm^2)											
	N° tissue imported (cm^2)											
	N° tissue exported (cm^2)											
	N° of tissues transplanted (cm^2)											
	N° of patients transplanted	39	4								15	
	N° of transplants											
CARDIAC TISSUE	N. of tissue donations	278	10								6	
	Tissue donation PMP	6,9	0,2								1,8	
	N° of tissue retrieved	550	92								9	
	N° tissue processed											
	N° tissue distributed											
	N° tissue imported											
	N° tissue exported											
	N° of tissues transplanted											
	N° of patients transplanted	294	37								3	
	N° of transplants											
BLOOD VESSEL	N. of tissue donations	3									16	
	Tissue donation PMP	0,1									4,7	
	N° of tissue retrieved	3									25	
	N° tissue processed											
	N° tissue distributed											
	N° tissue imported											
	N° tissue exported											
	N° of tissues transplanted											
	N° of patients transplanted	3									25	
	N° of transplants											
MUSCULOS-KELETAL	N. of tissue donations	754	238		130						51	
	Tissue donation PMP	18,8	5,2		11,6						15,0	
	N° of tissue retrieved	1027	3494		301						57	
	N° tissue processed (units or *grams)											
	N° tissue distributed (units or *grams)											
	N° tissue imported (units or *grams)											
	N° tissue exported (units or *grams)											
	N° of tissues transplanted											
	N° of patients transplanted	5894	15080		229						126	
	N° of transplants											
PLACENTA/ AMNIOTIC MEMBRANE	N. of tissue donations											
	Tissue donation PMP											
	N° of tissue retrieved											
	N° tissue processed (units or *cm^2)											
	N° tissue distributed (units or *cm^2)											
	N° tissue imported (units or *cm^2)											
	N° tissue exported (units or *cm^2)											
	N° of tissues transplanted (units or *cm^2)											
	N° of patients transplanted											
	N° of transplants											
OTHERS	N. of tissue donations											
	Tissue donation PMP											
	N° of tissue retrieved											
	N° tissue processed											
	N° tissue distributed											
	N° tissue imported											
	N° tissue exported											
	N° of tissues transplanted											
	N° of patients transplanted											
	N° of transplants											

PRELIMINARY SUMMARY OF HPC DATA

EUROPEAN UNION COUNTRIES

Country		AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH R.	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE
Population (Font: eurostat 1.1.2008)		8.355.260	10.754.528	7.606.551	793.963	10.467.542	5.511.451	1.340.415	5.326.314	64.351.000	82.002.356	11.257.285
Data related to year		2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
CATEGORY OF DATA	TYPE OF DATA											
POTENTIAL DONATION AND SEARCHING IN THE NATIONAL REGISTRIES	N° of potential donors at 31.12			44		20.015		0		176.364	0	
	N° of coord blood unit at 31.12			0		3.317		0		8.501	0	
	N° of searches requested			0		0		0		16.655	0	
	N° of unrelated donation			0		91		0		1.185	0	
DONATION	N° of donation - Autologous			19		189		56		5.785	15.763	
	N° of donation - Allogenic			5		98		8		1.208	12.267	
	N° of donation - Allogenic, related			5		7		8		803	1.031	
	N° of donation - Allogenic, unrelated			0		91		0		405	11.236	
BANKING of CORD BLOOD	N° of unrelated cord blood units collected			1.126		1.369		0		1.629	5.874	
	N° of unrelated cord blood units distributed			0		40		0		164	147	
	N° of unrelated cord blood units at 31.12			1.126		449		0		8.501	0	
	N° of related cord blood units collected			0		0		0		0	17	
	N° of related cord blood units distributed			0		2		0		0	3	
	N° of related cord blood units at 31.12			0		0		0		0	0	
TRANSPLANT	N° of transplants - Autologous			48		0		24		2.675	3.004	
	N° of patients transplanted - Autologous			46		270		33		2.528	2.556	
	N° of transplants - Allogenic			0		0		0		1.538	2.195	
	N° of patients transplanted - Allogenic			0		202		16		1.513	2.019	
	N° of transplants - Allogenic, related			0		0		0		637	755	
	N° of patients transplanted - Allogenic, related			0		43		8		612	685	
	N° of transplants - Allogenic, unrelated			0		0		0		901	1.440	
	N° of patients transplanted - Allogenic, unrelated			0		159		8		901	1.334	

PRELIMINARY SUMMARY OF HPC DATA

EUROPEAN UNION COUNTRIES

Country		HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA
Population (Font: eurostat 1.1.2008)		10.031.208	4.465.540	60.053.442	2.261.294	3.349.872	493.500	413.627	16.486.587	38.135.876	10.627.250	21.498.616
Data related to year		2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
CATEGORY OF DATA	TYPE OF DATA											
POTENTIAL DONATION AND SEARCHING IN THE NATIONAL REGISTRIES	N° of potential donors at 31.12	4.813		329.847		3.976				24.871	181.661	0
	N° of coord blood unit at 31.12	11.475		19.631		371				35.634	951	0
	N° of searches requested	87		3.584		93				780	2.459	0
	N° of unrelated donation	47		603		28				193	92	0
DONATION	N° of donation - Autologous	242		0		331				1.998	413	98
	N° of donation - Allogenic	89		287		43				227	156	104
	N° of donation - Allogenic, related	42		0		15				170	89	54
	N° of donation - Allogenic, unrelated	47		287		28				57	67	50
BANKING of CORD BLOOD	N° of unrelated cord blood units collected	0		16.207		0				4	951	25
	N° of unrelated cord blood units distributed	0		116		0				0	0	0
	N° of unrelated cord blood units at 31.12	0		33.115		0				493	951	24
	N° of related cord blood units collected	4.095		252		233				9.475	19.478	8
	N° of related cord blood units distributed	0		116		0				1	3	1
	N° of related cord blood units at 31.12	11.538		1.821		352				35.141	48.920	11
TRANSPLANT	N° of transplants - Autologous	242		2.712	29	98				0	287	112
	N° of patients transplanted - Autologous	242		2.412	29	89				0	259	100
	N° of transplants - Allogenic	81		1.463	0	43				363	136	27
	N° of patients transplanted - Allogenic	81		1.436	0	42				323	132	22
	N° of transplants - Allogenic, related	42		805	0	15				170	80	25
	N° of patients transplanted - Allogenic, related	42		785	0	14				143	77	20
	N° of transplants - Allogenic, unrelated	39		658	0	28				193	56	2
	N° of patients transplanted - Allogenic, unrelated	39		651	0	28				180	55	2

PRELIMINARY SUMMARY OF HPC DATA

		EUROPEAN UNION COUNTRIES					OTHER COUNTRIES					
Country		**SLOVAKIA**	**SLOVENIA**	**SPAIN**	**SWEDEN**	**U. K.**	**CROATIA**	**ICELAND**	**MACEDONIA**	**NORWAY**	**SWITZERLAND**	**TURKEY**
Population (Font: eurostat 1.1.2008)		5.412.254	2.032.362	45.828.172	9.256.347	61.634.599	4.435.056	319.368	2.048.620	4.799.252	7.700.202	71.517.100
Data related to year		2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
CATEGORY OF DATA	**TYPE OF DATA**											
POTENTIAL DONATION AND SEARCHING IN THE NATIONAL REGISTRIES	N° of potential donors at 31.12		14.029	80.314	0		12.096			28.323		39.264
	N° of coord blood unit at 31.12		0	41.771	0		571			0		25.758
	N° of searches requested		270	686	0		127			6.235		901
	N° of unrelated donation		11	0	0		12			32		-
DONATION	N° of donation - Autologous		62	0	13.051		144			260		1.786
	N° of donation - Allogenic		23	0	6.427		19			108		162
	N° of donation - Allogenic, related		12	0	995		17			44		162
	N° of donation - Allogenic, unrelated		11	0	5.432		2			64		0
BANKING of CORD BLOOD	N° of unrelated cord blood units collected		0	0	0		977			0		0
	N° of unrelated cord blood units distributed		0	0	0		0			0		0
	N° of unrelated cord blood units at 31.12		0	0	0		508			0		0
	N° of related cord blood units collected		1.382	0	0		15			0		1.948
	N° of related cord blood units distributed		0	0	0		0			0		11
	N° of related cord blood units at 31.12		854	0	0		102			0		8.302
TRANSPLANT	N° of transplants - Autologous		73	0	4.720		132			0		663
	N° of patients transplanted - Autologous		62	1.457	0		123			160		663
	N° of transplants - Allogenic		25	0	2.645		23			0		540
	N° of patients transplanted - Allogenic		22	818	0		23			127		540
	N° of transplants - Allogenic, related		12	0	735		15			0		492
	N° of patients transplanted - Allogenic, related		9	466	0		15			56		492
	N° of transplants - Allogenic, unrelated		13	0	1.910		8			0		48
	N° of patients transplanted - Allogenic, unrelated		13	352	0		8			71		48

PRELIMINARY SUMMARY OF HPC DATA

LATINAMERICAN COUNTRIES

Country		ARGENTINA	COLOMBIA	COSTA RICA	CUBA	DOMINICANA	MEXICO	PANAMA	PARAGUAY	PERU	URUGUAY	VENEZUELA
Population (million inhabitants)		40.1	45.7	4.5	11.2	10.1	109.6	3.5	6.3	29.2	3.4	28.4
Data related to year		2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
CATEGORY OF DATA	**TYPE OF DATA**											
POTENTIAL DONATION AND SEARCHING IN THE NATIONAL REGISTRIES	N° of potential donors at 31.12											
	N° of coord blood unit at 31.12											
	N° of searches requested											
	N° of unrelated donation											
DONATION	N° of donation - Autologous											
	N° of donation - Allogenic											
	N° of donation - Allogenic, related											
	N° of donation - Allogenic, unrelated											
BANKING of CORD BLOOD	N° of unrelated cord blood units collected											
	N° of unrelated cord blood units distributed											
	N° of unrelated cord blood units at 31.12											
	N° of related cord blood units collected											
	N° of related cord blood units distributed											
	N° of related cord blood units at 31.12											
TRANSPLANT	N° of transplants - Autologous	430		21	16		143	11	3		82	48
	N° of patients transplanted - Autologous											
	N° of transplants - Allogenic	220		12	3		174	7			22	21
	N° of patients transplanted - Allogenic											
	N° of transplants - Allogenic, related	168		12	3		125	7			19	21
	N° of patients transplanted - Allogenic, related											
	N° of transplants - Allogenic, unrelated	52		0	0		49	0			3	0
	N° of patients transplanted - Allogenic, unrelated											

“Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation”

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168 (4) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee[1],

After consulting the Committee of the Regions,

Having regard to the opinion of the European Data Protection Supervisor[2],

Acting in accordance with the ordinary legislative procedure[3],

WHEREAS:

1 Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs (hereinafter "organs") for transplantation has steadily increased during the last two decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment.

2 Risks are, however, associated with the use of organs in transplantation. The extensive therapeutic use of organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases. Well organised national and international transplantation systems and use of the best available expertise, technology and innovative medical treatment can significantly reduce the associated risks of transplanted organs for recipients.

3 In addition the availability of organs used for therapeutic purposes is dependent on citizens of the Union being prepared to donate them. In order to safeguard public health and to prevent the transmission of diseases by these organs, precautionary measures should be taken during their procurement, transport and use.

4 Every year organs are exchanged between Member States. The exchange of organs is an important way of increasing the number of organs available and ensuring a better match between donor and recipient and therefore improving the quality of the transplantation. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatment, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.

5 However, transplantation is carried out by hospitals or professionals falling under different jurisdictions and there are significant differences in quality and safety requirements between Member States.

6 There is therefore a need for common quality and safety standards for the procurement, transport and use of organs at Union level. Such standards would facilitate exchanges of organs to the benefit of thousands of European patients in need of this type of therapy each year. Union legislation should ensure that organs comply with recognised standards of quality and safety. Such standards would help to reassure the public that organs procured in another Member State carry the same basic quality and safety guarantees as those obtained in their own country.

7 Unacceptable practices in organ donation and transplantation include trafficking in organs, sometimes linked to trafficking in persons for the purpose of the removal of organs, which constitutes a serious violation of fundamental rights and, in particular, of human dignity and physical integrity. This Directive, although having as its first objective the safety and quality of organs, contributes indirectly to combating organ trafficking through the establishment of competent authorities, the authorisation of transplantation centres, the establishment of conditions of procurement and systems of traceability.

8 According to Article 168 (7) of the Treaty on the Functioning of the European Union (TFEU), the measures adopted under Article 168 (4) (a) thereof shall not affect national provisions on the medical use of organs, nor therefore the surgical act of transplantation itself. However, in view of the objective of reducing the associated risks of the transplanted organs, it is necessary to include in the scope of this Directive certain provisions concerning transplantation and, in particular, provisions aimed at addressing those unintended and unexpected situations occurring during the transplantation that might affect the quality and safety of organs.

9 In order to reduce the risks and maximise the benefits of transplantation, Member States need to operate an effective framework for quality and safety. That framework should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the healthcare personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The framework for quality and safety should include auditing where necessary. Member States should be able to delegate the performance of activities provided for under the framework for quality and safety to specific bodies deemed appropriate under national provisions, including European organ exchange organisations.

[1] OJ C 306, 16.12.2009, p. 64.

[2] OJ C 192, 15.8.2009, p. 6.

[3] Position of the European Parliament of 19 May 2010 (not yet published in the Official Journal) and decision of the Council of…

10 Competent authorities should supervise compliance with the conditions of procurement through the authorisation of procurement organisations. Such organisations should have in place proper organisation, suitably qualified or trained and competent personnel and adequate facilities and material.

11 The risk-benefit ratio is a fundamental aspect of organ transplantation. Owing to the shortage of organs and the inherent life-threatening nature of diseases leading to the need for organs for transplantation, the overall benefits of organ transplantation are high and more risks are accepted than with blood or most tissues and cell-based treatments. The clinician plays an important role in this context by deciding whether or not organs are suitable for transplantation. This Directive sets out the information required to make that assessment.

12 Pre-transplant evaluation of potential donors is an essential part of organ transplantation. That evaluation has to provide enough information for the transplantation centre to undertake a proper risk-benefit analysis. It is necessary to identify and document the risks and characteristics of the organ in order to allow its allocation to a suitable recipient. Information from a potential donor's medical history, physical examination and complementary tests should be collected for the adequate characterisation of the organ and the donor. To obtain an accurate, reliable and objective history, the medical team should perform an interview with the living donor or, where necessary and appropriate, with the relatives of the deceased donor, during which the team should properly inform them about the potential risks and consequences of donation and transplantation. Such an interview is particularly important due to the time constraints in the process of deceased donation which reduce the ability to rule out potentially serious transmissible diseases.

13 The shortage of organs available for transplantation and the time constraints in the process of organ donation and transplantation make it necessary to take into account those situations in which the transplantation team lacks some of the information required for organ and donor characterisation as set out in Part A of the Annex, which specifies a mandatory minimum data set. In those particular cases, the medical team should assess the particular risk posed to the potential recipient by the lack of information and by not proceeding with transplantation of the organ in question. Where a complete characterisation of an organ, according to Part A of the Annex, is not possible in time or due to particular circumstances, the organ may be considered for transplantation where non-transplantation might pose a greater risk to the potential recipient. Part B of the Annex, referring to a complementary data set, should allow a more detailed organ and donor characterisation to be made.

14 Effective rules for the transportation of organs should be provided that optimise ischaemic times and reduce organ damage. While maintaining medical confidentiality, the organ container should be clearly labelled and accompanied by the necessary documentation.

15 The transplantation system should ensure traceability of organs from donation to reception and should have the capacity to raise the alert if there is any unexpected complication. A system should therefore be put in place to detect and investigate serious adverse events and reactions for the protection of vital interest of the individuals concerned.

16 An organ donor is also very often a tissue donor. Quality and safety requirements for organs should complement and be linked with the existing Union system for tissues and cells laid down in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[4]. This does not mean that systems for organs and for tissues and cells should necessarily be electronically linked. An unexpected adverse reaction in an organ donor or recipient should be traced by the competent authority and reported through the notification system for serious adverse events and reactions for tissues and cells as provided for in that Directive.

17 Healthcare personnel directly involved in the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs should be suitably qualified or trained and competent. The importance of donor coordinators, appointed at hospital level, has been acknowledged by the Council of Europe. The role of the donor coordinator or coordination team should be recognised as key to improving not only the effectiveness of the process of donation and transplantation, but also the quality and safety of the organs to be transplanted.

18 As a general principle, organ exchange with third countries should be supervised by the competent authority. Organ exchange with third countries should be allowed only where standards equivalent to those provided for in this Directive are met. However, the important role played by existing European organ exchange organisations in the exchange of organs between the Member States and third countries participating in such organisations should be taken into account.

19 Altruism is an important factor in organ donations. To ensure the quality and safety of organs, organ transplantation programmes should be founded on the principles of voluntary and unpaid donation. This is essential because the violation of these principles might be associated with unacceptable risks. Where donation is not voluntary

[4] OJ L 102, 7.4.2004, p. 48.

and/or is undertaken with a view to financial gain, the quality of the process of donation could be jeopardised because improving the quality of life or saving the life of a person is not the main and/or the unique objective. Even if the process is developed in accordance with appropriate quality standards, a clinical history obtained from either a potential living donor or the relatives of a potential deceased donor who are seeking financial gain or are subjected to any kind of coercion might not be sufficiently accurate in terms of conditions and/or diseases potentially transmissible from donor to recipient. This could give rise to a safety problem for potential recipients since the medical team would have a limited capability for performing an appropriate risk assessment. The Charter of Fundamental Rights of the European Union should be recalled, notably the principle set out in Article 3 (2) (c) thereof. That principle is also enshrined in Article 21 of the Convention on Human Rights and Biomedicine of the Council of Europe, which many Member States have ratified. It is also reflected in the World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation, whereby the human body and its parts may not be the subject of commercial transactions.

20 Other internationally recognised principles guiding practices in organ donation and transplantation include, inter alia, the certification or the confirmation of death in accordance with national provisions before the procurement of organs from deceased persons and the allocation of organs based on transparent, non-discriminatory and scientific criteria. They should be recalled and be taken into account in the context of the Commission's Action Plan on Organ Donation and Transplantation.

21 Several models of consent to donation coexist in the Union, including opting-in systems in which consent to organ donation has to be explicitly obtained, and opting-out systems in which donation can take place unless there is evidence of any objection to donation. In order to enable individuals to express their wishes in this regard, some Member States have developed specific registries where citizens record them. This Directive is without prejudice to the broad diversity of the systems of consent already in place in the Member States. In addition, by means of its Action plan on Organ Donation and Transplantation the Commission aims to increase public awareness of organ donation and in particular to develop mechanisms to facilitate the identification of organ donors across Europe.

22 Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[5] prohibits in principle the processing of data concerning health, while laying down limited exemptions. Directive 95/46/EC also requires the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing. It should be ensured that strict confidentiality rules and security measures are in place for the protection of donors' and recipients' personal data, in accordance with Directive 95/46/EC. Moreover, the competent authority may also consult the national data protection supervisory authority in relation to developing a framework for the transfer of data on organs to and from third countries. As a general principle, the identity of the recipient(s) should not be disclosed to the donor or the donor's family or vice versa, without prejudice to legislation in force in Member States which, under specific conditions, might allow such information to be made available to donors or donors' families and organ recipients.

23 Living donation coexists with deceased donation in most Member States. Living donation has evolved over the years in such a way that good results can be obtained even where there is no genetic relationship between donor and recipient. Living donors should be adequately evaluated to determine their suitability for donation in order to minimise the risk of transmission of diseases to the recipients. In addition, living donors face risks linked both to testing to ascertain their suitability as a donor and to the procedure to obtain the organ. Complications may be medical, surgical, social, financial or psychological. The level of risk depends, in particular, on the type of organ to be donated. Therefore, living donations need to be performed in a manner that minimises the physical, psychological and social risk to the individual donor and the recipient and does not jeopardise the public's trust in the healthcare community. The potential living donor has to be able to take an independent decision on the basis of all the relevant information and should be informed in advance as to the purpose and nature of the donation, the consequences and risks. In this context, and to guarantee respect for the principles governing donation, the highest possible protection of living donors should be ensured. It should also be noted that some Member States are signatories to the Convention on Human Rights and Biomedicine of the Council of Europe, and its additional protocol on Transplantation of Organs and Tissues of Human Origin. Complete information, a proper evaluation and an adequate follow-up are internationally recognised measures aimed at protecting the living donors and also contribute to ensuring the quality and safety of organs.

24 The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation and in evaluating their quality and safety throughout patients' recovery and during the subsequent follow-up. For that purpose, besides the system for reporting serious adverse events and reactions, the collection of relevant post transplantation data is needed for a more comprehensive evaluation of the quality and safety of organs intended for

[5] OJ L 281, 23.11.1995, p. 31.

transplantation. Sharing such information between Member States would facilitate further improvement of donation and transplantation across the Union. As emphasised by the Recommendation Rec (2006) 15 of the Committee of Ministers of the Council of Europe to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO), it is preferable to have a single non-profit making body which is officially recognised with overall responsibility for donation, allocation, traceability and accountability. However, depending especially on the division of competences within the Member States, a combination of local, regional, national and/or international bodies may work together to coordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, cooperation and efficiency.

25 Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that these penalties are implemented. Those penalties should be effective, proportionate and dissuasive.

26 The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to adapt the Annex. The Commission should supplement or amend the minimum data set specified in Part A of the Annex only in exceptional situations where it is justified by a serious risk to human health, and supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

27 The exchange of organs between Member States requires that uniform rules on the procedures for the transmission of information on organs and donor characterisation, as well as for ensuring the traceability of organs and for reporting serious adverse events and reactions, should be adopted by the Commission, in order to ensure the highest standards of quality and safety of the organs exchanged. According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[6] continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

28 Since the objectives of this Directive, namely laying down quality and safety standards for organs intended for transplantation to the human body, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I
SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1
Subject Matter

This Directive lays down rules to ensure standards of quality and safety for human organs (hereinafter "organs") intended for transplantation to the human body, in order to ensure a high level of human health protection.

Article 2
Scope

1. This Directive applies to the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation.
2. Where such organs are used for research purposes, this Directive only applies where they are intended for transplantation into the human body.

Article 3
Definitions

For the purposes of this Directive, the following definitions apply:

a) "authorisation" means authorisation, accreditation, designation, licensing or registration, depending on the concepts used and the practices in place in each Member State;

b) "competent authority" means an authority, body, organisation and/or institution responsible for implementing the requirements of this Directive;

c) "disposal" means the final placement of an organ where it is not used for transplantation;

d) "donor" means a person who donates one or several organs, whether donation occurs during lifetime or after death;

e) "donation" means donating organs for transplantation;

f) "donor characterisation" means the collection of the relevant information on the characteristics of the donor

[6] OJ L 184, 17.7.1999, p. 23.

needed to evaluate his/her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

g) "European organ exchange organisation" means a non-profit organisation, whether public or private, dedicated to national and cross-border organ exchange, in which the majority of its member countries are Member States;

h) "organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;

i) "organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

j) "procurement" means a process by which the donated organs become available;

k) "procurement organisation" means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the competent authority under the regulatory framework in the Member State concerned;

l) "preservation" means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation;

m) "recipient" means a person who receives a transplant of an organ;

n) "serious adverse event" means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

o) "serious adverse reaction" means an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

p) "operating procedures" means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

q) "transplantation" means a process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient;

r) "transplantation centre" means a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs and is authorised to do so by the competent authority under the regulatory framework in the Member State concerned;

s) "traceability" means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to:

– identify the donor and the procurement organisation,
– identify the recipient(s) at the transplantation centre(s), and
– locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ.

CHAPTER II
THE QUALITY AND SAFETY OF ORGANS

Article 4
Framework for quality and safety

1. Member States shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation or disposal, in compliance with the rules laid down in this Directive.

2. The framework for quality and safety shall provide for the adoption and implementation of operating procedures for:

   a) the verification of donor identity;

   b) the verification of the details of the donor's or the donor's family's consent, authorisation or absence of any objection, in accordance with the national rules that apply where donation and procurement take place;

   c) the verification of the completion of the organ and donor characterisation in accordance with Article 7 and the Annex;

   d) the procurement, preservation, packaging and labelling of organs in accordance with Articles 5, 6 and 8;

   e) the transportation of organs in accordance with Article 8;

   f) ensuring traceability, in accordance with Article 10, guaranteeing compliance with the Union and national provisions on the protection of personal data and confidentiality;

   g) the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11 (1);

   h) the management of serious adverse events and reactions in accordance with Article 11 (2).

   The operating procedures referred to in points (f), (g) and (h) shall specify inter alia the responsibilities of procurement organisations, European organ exchange organisations and transplantation centres.

3. In addition, the framework for quality and safety shall ensure that the healthcare personnel involved at all stages

of the chain from donation to transplantation or disposal are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.

Article 5
Procurement organisations

1. Member States shall ensure that the procurement takes place in, or is carried out by, procurement organisations that comply with the rules laid down in this Directive.
2. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of procurement organisations.

Article 6
Organ procurement

1. Member States shall ensure that medical activities in procurement organisations, such as donor selection and evaluation, are performed under the advice and the guidance of a doctor of medicine as referred to in Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications[7].
2. Member States shall ensure that procurement takes place in operating theatres, which are designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured.
3. Member States shall ensure that procurement material and equipment are managed in accordance with relevant Union, international and national legislation, standards and guidelines on the sterilisation of medical devices.

Article 7
Organ and donor characterisation

1. Member States shall ensure that all procured organs and donors thereof are characterised before transplantation through the collection of the information set out in the Annex.
   The information specified in Part A of the Annex contains a set of minimum data which has to be collected for each donation. Information specified in Part B of the Annex contains a set of complementary data to be collected in addition, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.
2. Notwithstanding paragraph 1, if according to a risk-benefit analysis in a particular case, including in life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all of the minimum data specified in Part A of the Annex are available.
3. In order to meet the quality and safety requirements laid down in this Directive, the medical team shall endeavour to obtain all necessary information from living donors and for that purpose shall provide them with the information they need to understand the consequences of donation. In the case of deceased donation, where possible and appropriate, the medical team shall endeavour to obtain such information from relatives of the deceased donor or other persons. The medical team shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of that information.
4. The tests required for organ and donor characterisation shall be carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.
5. Member States shall ensure that organisations, bodies and laboratories involved in organ and donor characterisation have appropriate operating procedures in place to ensure that the information on organ and donor characterisation reaches the transplantation centre in due time.
6. Where organs are exchanged between Member States, those Member States shall ensure that the information on organ and donor characterisation, as specified in the Annex, is transmitted to the other Member State with which the organ is exchanged, in conformity with the procedures established by the Commission pursuant to Article 29.

Article 8
Transport of organs

1. Member States shall ensure that the following requirements are met:
   a) the organisations, bodies or companies involved in the transportation of organs have appropriate operating procedures in place to ensure the integrity of the organs during transport and a suitable transport time;
   b) the shipping containers used for transporting organs are labelled with the following information:
      i) identification of the procurement organisation and the establishment where the procurement took place, including their addresses and telephone numbers,
      ii) identification of the transplantation centre of destination, including its address and telephone number,
      iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked "HANDLE WITH CARE",
      iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position;

[7] OJ L 255, 30.9.2005, p. 22.

c) the organs transported are accompanied by a report on the organ and donor characterisation.

2. The requirements laid down in point (b) of paragraph 1 need not be met where the transportation is carried out within the same establishment.

Article 9
Transplantation centres

1. Member States shall ensure that transplantation takes place in, or is carried out by, transplantation centres that comply with the rules laid down in this Directive.
2. The competent authority shall indicate in the authorisation which activities the transplantation centre concerned may undertake.
3. The transplantation centre shall verify before proceeding to transplantation that:
   a) the organ and donor characterisation are completed and recorded in accordance with Article 7 and the Annex;
   b) the conditions of preservation and transport of shipped organs have been maintained.
4. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of transplantation centres.

Article 10
Traceability

1. Member States shall ensure that all organs procured, allocated and transplanted on their territory can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients.
2. Member States shall ensure the implementation of a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it. With regard to such a system, Member States shall ensure that confidentiality and data security measures are in place in compliance with Union and national provisions, as referred to in Article 16.
3. Member States shall ensure that:
   a) the competent authority or other bodies involved in the chain from donation to transplantation or disposal keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal and the information on organ and donor characterisation as specified in the Annex, in accordance with the framework for quality and safety;
   b) data required for full traceability is kept for a minimum of 30 years after donation. Such data may be stored in electronic form.
4. Where organs are exchanged between Member States, those Member States shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the Commission pursuant to Article 29.

Article 11
Reporting system and management concerning serious adverse events and reactions

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.
2. Member States shall ensure that an operating procedure is in place for the management of serious adverse events and reactions as provided for in the framework for quality and safety.
3. In particular, and with regard to paragraphs 1 and 2, Member States shall ensure that operating procedures are in place for the notification, in due time, of:
   a) any serious adverse event and reaction to the competent authority and to the concerned procurement organisation or transplantation centre;
   b) the management measures with regard to serious adverse events and reactions to the competent authority.
4. Where organs are exchanged between Member States, those Member States shall ensure the reporting of serious adverse events and reactions in conformity with the procedures established by the Commission pursuant to Article 29.
5. Member States shall ensure the interconnection between the reporting system referred to in paragraph 1 of this Article and the notification system established in accordance with Article 11 (1) of Directive 2004/23/EC.

Article 12
Healthcare personnel

Member States shall ensure that healthcare personnel directly involved in the chain from donation to the transplantation or disposal of organs are suitably qualified or trained and competent to perform their tasks and are provided with the relevant training, as referred to in Article 4 (3).

CHAPTER III
DONOR AND RECIPIENT PROTECTION AND DONOR SELECTION AND EVALUATION

Article 13
Principles governing organ donation

1. Member States shall ensure that donations of organs from deceased and living donors are voluntary and unpaid.

2. The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of income related to the donation. Member States shall define the conditions under which such compensation may be granted, while avoiding there being any financial incentives or benefit for a potential donor.

3. Member States shall prohibit advertising the need for, or availability of, organs where such advertising is with a view to offering or seeking financial gain or comparable advantage.

4. Member States shall ensure that the procurement of organs is carried out on a non-profit basis.

Article 14
Consent requirements

The procurement of organs shall be carried out only after all requirements relating to consent, authorisation or absence of any objection in force in the Member State concerned have been met.

Article 15
Quality and safety aspects of living donation

1. Member States shall take all necessary measures to ensure the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation.

2. Member States shall ensure that living donors are selected on the basis of their health and medical history, by suitably qualified or trained and competent professionals. Such assessments may provide for the exclusion of persons whose donation could present unacceptable health risks.

3. Member States shall ensure that a register or record of the living donors is kept, in accordance with Union and national provisions on the protection of the personal data and statistical confidentiality.

4. Member States shall endeavour to carry out the follow-up of living donors and shall have a system in place in accordance with national provisions, in order to identify, report and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.

Article 16
Protection of personal data, confidentiality and security of processing

Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in conformity with Union provisions on the protection of personal data, such as Directive 95/46/EC, and in particular Articles 8 (3), 16, 17 and 28 (2) thereof. Pursuant to Directive 95/46/EC, Member States shall take all necessary measures to ensure that:

a) the data processed are kept confidential and secure in accordance with Articles 16 and 17 of Directive 95/46/EC. Any unauthorised accessing of data or systems that makes identification of donor or recipients possible shall be penalised in accordance with Article 23 of this Directive;

b) donors and recipients whose data are processed within the scope of this Directive are not identifiable, except as permitted by Article 8 (2) and (3) of Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for the purposes permitted by Article 8 (2) and (3) of Directive 95/46/EC, including medical purposes, and by national provisions implementing that Directive shall be penalised in accordance with Article 23 of this Directive;

c) the principles relating to data quality, as set out in Article 6 of Directive 95/46/EC, are met.

CHAPTER IV
OBLIGATIONS OF COMPETENT AUTHORITIES AND EXCHANGE OF INFORMATION

Article 17
Designation and tasks of competent authorities

1. Member States shall designate one or more competent authorities.

   Member States may delegate, or may allow a competent authority to delegate, part or all of the tasks assigned to it under this Directive to another body which is deemed suitable under national provisions. Such a body may also assist the competent authority in carrying out its functions.

2. The competent authority shall, in particular, take the following measures:

a) establish and keep updated a framework for quality and safety in accordance with Article 4;

b) ensure that procurement organisations and transplantations centres are controlled or audited on a regular basis to ascertain compliance with the requirements of this Directive;

c) grant, suspend, or withdraw, as appropriate, the authorisations of procurement organisations or transplantation centres or prohibit procurement organisations or transplantation centres from carrying out their activities where control measures demonstrate that such organisations or centres are not complying with the requirements of this Directive;

d) put in place a reporting system and management procedure for serious adverse events and reactions as provided for in Article 11 (1) and (2);

e) issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantion information to evaluate the quality and safety of the organs transplanted;

f) participate, whenever possible, in the network of competent authorities referred to in Article 19 and coordinate at national level input to the activities of that network;

g) supervise organ exchange with other Member States and with third countries as provided for in Article 20 (1);

h) ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with Union provisions on the protection of personal data, in particular Directive 95/46/EC.

Article 18
Records and reports concerning procurement organisations and transplantation centres

1. Member States shall ensure that the competent authority:

   a) keeps a record of the activities of procurement organisations and transplantation centres, including aggregated numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in accordance with Union and national provisions on the protection of personal data and statistical confidentiality;

   b) draws up and makes publicly accessible an annual report on activities referred to in point (a);

   c) establishes and maintains an updated record of procurement organisations and transplantation centres.

2. Member States shall, upon the request of the Commission or another Member State, provide information on the record of procurement organisations and transplantation centres.

Article 19
Exchange of information

1. The Commission shall set up a network of the competent authorities with a view to exchanging information on the experience acquired with regard to the implementation of this Directive.

2. Where appropriate, experts on organ transplantation, representatives from European organ exchange organisations, as well as data protection supervisory authorities and other relevant parties may be associated with this network.

CHAPTER V
ORGAN EXCHANGE WITH THIRD COUNTRIES AND EUROPEAN ORGAN EXCHANGE ORGANISATIONS

Article 20
Organ exchange with third countries

1. Member States shall ensure that organ exchange with third countries is supervised by the competent authority. For this purpose, the competent authority and European organ exchange organisations may conclude agreements with counterparts in third countries.

2. The supervision of organ exchange with third countries may be delegated by the Member States to European organ exchange organisations.

3. Organ exchange, as referred to in paragraph 1, shall be allowed only where the organs:

   a) can be traced from the donor to the recipient and vice versa;

   b) meet quality and safety requirements equivalent to those laid down in this Directive.

Article 21
European organ exchange organisations

Member States may conclude or allow a competent authority to conclude agreements with European organ exchange organisations, provided that such organisations ensure compliance with the requirements laid down in this Directive, delegating to those organisations, inter alia:

a) the performance of activities provided for under the framework for quality and safety;

b) specific tasks in relation to the exchanges of organs to and from Member States and third countries.

CHAPTER VI
GENERAL PROVISIONS

Article 22
Reports concerning this Directive

1. Member States shall report to the Commission before…[8] and every three years thereafter on the activities undertaken in relation to the provisions of this Directive, and on the experience gained in implementing it.

2. Before…[9] and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, a report on the implementation of this Directive.

[8] OJ: Please insert deadline: Three years after the entry into force of this Directive.

[9] OJ: Please insert deadline: Four years after the entry into force of this Directive.

Article 23
Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by…[10] and shall notify it without delay of any subsequent amendments affecting them.

Article 24
Adaptation of the Annex

The Commission may adopt delegated acts in accordance with Article 25 and subject to the conditions of Articles 26, 27 and 28 in order to:

a) supplement or amend the minimum data set specified in Part A of the Annex only in exceptional situations where it is justified by a serious risk to human health considered as such on the basis of the scientific progress;

b) supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation.

Article 25
Exercise of the delegation

1. The power to adopt the delegated acts referred to in Article 24 shall be conferred on the Commission for a period of five years following…[11] The Commission shall make a report in respect of the delegated powers not later than six months before the end of the five-year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 26.
2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 26 and 27.
4. Where, in the case of the emergence of new serious risk to human health, imperative grounds of urgency so require, the procedure provided for in Article 28 shall apply to delegated acts adopted pursuant to point (a) of Article 24.

Article 26
Revocation of the delegation

1. The delegation of powers referred to in Article 24 may be revoked at any time by the European Parliament or by the Council.
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.
3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 27
Objection to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification.

   At the initiative of the European Parliament or the Council this period shall be extended by two months.
2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

   The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.
3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 28
Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act adopted under this Article to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. The European Parliament or the Council may object to a delegated act adopted under this Article in accordance with the procedure referred to in Article 27 (1). In such a case, the act shall cease to apply. The institution which objects to such a delegated act shall state its reasons therefor.

[10] OJ: Please insert deadline: Two years after the entry into force of this Directive.

[11] OJ: Please insert deadline: The date of entry into force of this Directive.

Article 29
Implementing measures

The Commission shall adopt, where organs are exchanged between Member States, detailed rules for the uniform implementation of this Directive in accordance with the procedure referred to in Article 30 (2), on the following:

a) procedures for the transmission of information on organ and donor characterisation as specified in the Annex in accordance with Article 7 (6);

b) procedures for the transmission of the necessary information to ensure the traceability of organs in accordance with Article 10 (4);

c) procedures for ensuring the reporting of serious adverse events and reactions in accordance with Article 11 (4).

Article 30
Committee

1. The Commission shall be assisted by the Committee on organ transplantation, hereinafter referred to as "the Committee."
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down to in Article 5 (6) of Decision 1999/468/EC shall be set at three months.

Article 31
Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by…[12] They shall forthwith inform the Commission thereof.

   When they are adopted by Member States, those measures shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.
2. This Directive shall not prevent any Member State from maintaining or introducing more stringent rules, provided that they comply with the provisions of the Treaty on the Functioning of the European Union.
3. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

CHAPTER VII
FINAL PROVISIONS

Article 32
Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

[12] OJ: Please insert deadline: Two years after the entry into force of this Directive.

Article 33
Addressees

This Directive is addressed to the Member States.

Done at

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

ORGAN AND DONOR CHARACTERISATION

PART A
MINIMUM DATA SET

Minimum data - information for the characterisation of organs and donors, which has to be collected for each donation in accordance with second subparagraph of Article 7 (1) and without prejudice to Article 7 (2).

MINIMUM DATA SET

The establishment where the procurement takes place and other general data

Type of donor

Blood group

Gender

Cause of death

Date of death

Date of birth or estimated age

Weight

Height

Past or present history of IV drug abuse

Past or present history of malignant neoplasia

Present history of other transmissible disease

HIV; HCV; HBV tests

Basic information to evaluate the function of the donated organ

PART B
COMPLEMENTARY DATA SET

Complementary data - information for the characterisation of organs and donors to be collected in addition to minimum data specified in Part A, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case, in accordance with the second subparagraph of Article 7 (1).

COMPLEMENTARY DATA SET

GENERAL DATA

Contact details of the procurement organisation/the establishment where the procurement takes place necessary

for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

DONOR DATA

Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor/organ and the recipient.

DONOR MEDICAL HISTORY

Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

PHYSICAL AND CLINICAL DATA

Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of organs for transplantation or might imply the risk of disease transmission.

LABORATORY PARAMETERS

Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

IMAGE TESTS

Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

THERAPY

Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.

Sixty-Third World Health Assembly. Human Organ and Tissue Transplantation: WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.

Human organ and tissue transplantation

The Sixty-third World Health Assembly,

Having considered the report on human organ and tissue transplantation;[1]

Recalling resolutions WHA40.13, WHA42.5 and WHA44.25 on organ procurement and transplantation and WHA57.18 requesting an update of the Guiding Principles on Human Organ Transplantation;

Aware of the growing magnitude and utility of human cell, tissue and organ transplantation for a wide range of conditions in low-resource as well as high-resource countries;

Committed to the principles of human dignity and solidarity which condemn the buying of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations and the human trafficking that result from such practices;

Determined to prevent harm caused by the seeking of financial gain or comparable advantage in transactions involving human body parts, including organ trafficking and transplant tourism;

Convinced that the voluntary, non-remunerated donation of organs, cells and tissues from deceased and living donors helps to ensure a vital community resource;

Conscious of the extensive cross-boundary circulation of cells and tissues for transplantation;

Sensitive to the need for post-transplantation surveillance of adverse events and reactions associated with the donation, including long-term follow up of the living donor, processing and transplantation of human cells, tissues and organs as such and for international exchange of such data to optimize the safety and efficacy of transplantation,

1 ENDORSES the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation;

2 URGES Member States:[2]

1. to implement the Guiding Principles on Human Cell, Tissue and Organ Transplantation in the formulation and enforcement of their own policies, laws and legislation regarding human cell, tissue and organ donation and transplantation where appropriate;
2. to promote the development of systems for the altruistic voluntary non-remunerated donation of cells, tissues and organs as such, and increase public awareness and understanding of the benefits as a result of the voluntary non-remunerated provision of cells, tissues and organs as such from deceased and living donors, in contrast to the physical, psychological and social risks to individuals and communities caused by trafficking in material of human origin and transplant tourism;
3. to oppose the seeking of financial gain or comparable advantage in transactions involving human body parts, organ trafficking and transplant tourism, including by encouraging healthcare professionals to notify relevant authorities when they become aware of such practices in accordance with national capacities and legislation;
4. to promote a system of transparent, equitable allocation of organs, cells and tissues, guided by clinical criteria and ethical norms, as well as equitable access to transplantation services in accordance with national capacities, which provides the foundation for public support of voluntary donation;
5. to improve the safety and efficacy of donation and transplantation by promoting international best practices;
6. to strengthen national and multinational authorities and/or capacities to provide oversight, organization and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased donors and to protecting the health and welfare of living donors with appropriate health-care services and long-term follow up;
7. to collaborate in collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation;
8. to encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation;

3 REQUESTS the Director-General:

1. to disseminate the updated Guiding Principles on Human Cell, Tissue and Organ Transplantation as widely as possible to all interested parties;
2. to provide support to Member States and nongovernmental organizations in order to ban trafficking in material of human origin and transplant tourism;

[1] Document A63/24.

[2] And regional economic international organizations where appropriate.

3. to continue collecting and analysing global data on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation of human cells, tissues and organs;
4. to facilitate Member States' access to appropriate information on the donation, processing and transplantation of human cells, tissues and organs, including data on severe adverse events and reactions;
5. to provide, in response to requests from Member States, technical support for developing national legislation and regulation on, and suitable and traceable coding systems for, donation and transplantation of human cells, tissues or organs, in particular by facilitating international cooperation;
6. to review the Guiding Principles on Human Cell, Tissue and Organ Transplantation periodically in the light of national experience with their implementation and of developments in the field of transplantation of human cells, tissues and organs;
7. to report to the Health Assembly, through the Executive Board, at least every four years on actions taken by the Secretariat, as well as by Member States, to implement this resolution.

Eighth plenary meeting, 21 May 2010
A63/VR/8

Who Guiding Principles On Human Cell, Tissue And Organ Transplantation[1]

PREAMBLE

1 As the Director-General's report to the Executive Board at its Seventy-ninth session pointed out, human organ transplantation began with a series of experimental studies at the beginning of the twentieth century. The report drew attention to some of the major clinical and scientific advances in the field since Alexis Carrel was awarded the Nobel Prize in 1912 for his pioneering work. Surgical transplantation of human organs from deceased, as well as living, donors to sick and dying patients began after the Second World War. Over the past 50 years, the transplantation of human organs, tissues and cells has become a worldwide practice which has extended, and greatly enhanced the quality of, hundreds of thousands of lives. Continuous improvements in medical technology, particularly in relation to organ and tissue rejection, have led to an increase in the demand for organs and tissues, which has always exceeded supply despite substantial expansion in deceased organ donation as well as greater reliance on donation from living persons in recent years.

2 The shortage of available organs has not only prompted many countries to develop procedures and systems to increase supply but has also stimulated commercial traffic in human organs, particularly from living donors who are unrelated to recipients. The evidence of such commerce, along with the related traffic in human beings, has become clearer in recent decades. Moreover, the growing ease of international communication and travel has led many patients to travel abroad to medical centres that advertise their ability to perform transplants and to supply donor organs for a single, inclusive charge.

3 Resolutions WHA40.13 and WHA42.5 first expressed the Health Assembly's concern over commercial trade in organs and the need for global standards for transplantation. Based on a process of consultation undertaken by the Secretariat, the Health Assembly then endorsed the WHO Guiding Principles on Human Organ Transplantation in resolution WHA44.25. Over the past 17 years the Guiding Principles have greatly influenced professional codes and practices as well as legislation around the world. In the light of changes in practices and attitudes regarding organ and tissue transplantation, the Fifty-seventh World Health Assembly in resolution WHA57.18 requested the Director-General, inter alia, "to continue examining and collecting global data on the practices, safety, quality, efficacy and epidemiology of allogeneic transplantation and on ethical issues, including living donation, in order to update the Guiding Principles on Human Organ Transplantation".

4 The following Guiding Principles are intended to provide an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes. Each jurisdiction will determine the means of implementing the Guiding Principles. They preserve the essential points of the 1991 version while incorporating new provisions in response to current trends in transplantation, particularly organ transplants from living donors and the increasing use of human cells and tissues. The Guiding Principles do not apply to transplantation of gametes, ovarian or testicular tissue, or embryos for reproductive purposes, or to blood or blood constituents collected for transfusion purposes.

Cells, tissues and organs may be removed from deceased and living persons for the purpose of transplantation, only in accordance with the following Guiding Principles.

GUIDING PRINCIPLE 1

Cells, tissues and organs may be removed from the bodies of deceased persons for the purpose of transplantation if:

a) any consent required by law is obtained, and

b) there is no reason to believe that the deceased person objected to such removal.

Commentary on Guiding Principle 1

Consent is the ethical cornerstone of all medical interventions. National authorities are responsible for defining the process of obtaining and recording consent for cell, tissue and organ donation in the light of international ethical standards, the manner in which organ procurement is organized in their country, and the practical role of consent as a safeguard against abuses and safety breaches.

[1] As endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22

Whether consent to procure organs and tissues from deceased persons is "explicit" or "presumed" depends upon each country's social, medical and cultural traditions, including the manner in which families are involved in decision-making about health care generally. Under both systems any valid indication of deceased persons' opposition to posthumous removal of their cells, tissues or organs will prevent such removal.

Under a regime of explicit consent – sometimes referred to as "opting in" – cells, tissues or organs may be removed from a deceased person if the person had expressly consented to such removal during his or her lifetime; depending upon domestic law, such consent may be made orally or recorded on a donor card, driver's license or identity card or in the medical record or a donor registry. When the deceased has neither consented nor clearly expressed opposition to organ removal, permission should be obtained from a legally specified surrogate, usually a family member.

The alternative, presumed consent system – termed "opting (or contracting) out" – permits material to be removed from the body of a deceased person for transplantation and, in some countries, for anatomical study or research, unless the person had expressed his or her opposition before death by filing an objection with an identified office, or an informed party reports that the deceased definitely voiced an objection to donation. Given the ethical importance of consent, such a system should ensure that people are fully informed about the policy and are provided with an easy means to opt out.

Although expressed consent is not required in an opting-out system before removal of the cells, tissues or organs of a deceased person who had not objected while still alive, procurement programmes may be reluctant to proceed if the relatives personally oppose the donation; likewise, in opting-in systems, programmes typically seek permission from the family even when the deceased gave pre-mortem consent. Programmes are more able to rely on the deceased's explicit or presumed consent, without seeking further permission from family members, when the public's understanding and acceptance of the process of donating cells, tissues and organs is deep-seated and unambiguous. Even when permission is not sought from relatives, donor programmes need to review the deceased's medical and behavioural history with family members who knew him or her well, since accurate information about donors helps to increase the safety of transplantation.

For tissue donation, which entails slightly less challenging time constraints, it is recommended always to seek the approval of the next of kin. An important point to be addressed is the manner in which the appearance of the deceased's body will be restored after the tissues are removed.

GUIDING PRINCIPLE 2

Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues and organs.

Commentary on Guiding Principle 2

This Principle is designed to avoid the conflict of interest that would arise were the physician or physicians determining the death of a potential donor to be responsible in addition for the care of other patients whose welfare depended on cells, tissues or organs transplanted from that donor.

National authorities will set out the legal standards for determining that death has occurred and specify how the criteria and process for determining death will be formulated and applied.

GUIDING PRINCIPLE 3

Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients.

Live donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion.

Commentary on Guiding Principle 3

The Principle emphasizes the importance both of taking the legal and logistical steps needed to develop deceased donor programmes where these do not exist and of making existing programmes as effective and efficient as possible.

While favouring the maximal development of transplant programmes that avoid the inherent risks to live donors, the Principle also sets forth basic conditions for live donation. A genetic relationship between donor and recipient may be therapeutically advantageous and can provide reassurance that the donor is motivated by genuine concern for the recipient, as can a legal relationship (such as that between spouses). Many altruistic donations also originate from emotionally related donors, though the strength of a claimed connection may be difficult to evaluate. Donations by unrelated donors have been a source of concern, though some such cases are unexceptionable, such as in hematopoietic stem cell transplantation (where a wide donor pool is therapeutically advisable) or when an exchange of kidneys is made because the donors are not immunologically well matched with the recipients to whom they are related.

With live donation, particularly by unrelated donors, psychosocial evaluation is needed to guard against coercion of the donor or the commercialism banned by Principle 5. The national health authority should ensure that the evaluation is carried out by an appropriately qualified, independent party. By assessing the donor's motivation and the donor's and recipient's expectations regarding outcomes, such evaluations may help identify – and avert – donations that are forced or are actually paid transactions.

The Principle underscores the necessity of genuine and well-informed choice, which requires full, objective, and locally relevant information and excludes vulnerable persons who are incapable of fulfilling the requirements for voluntary and knowledgeable consent. Voluntary consent also implies that adequate provisions exist for withdrawal of consent up until medical interventions on the recipient have reached the point where the recipient would be in acute danger if the transplant did not proceed. This should be communicated at the time of consent.

Finally, this Principle stresses the importance of protecting the health of living donors during the process of selection, donation, and necessary aftercare to ensure that the potential untoward consequences of the donation are unlikely to disadvantage the remainder of the donor's life. Care for the donor should match care for the recipient, and health authorities have the same responsibility for the welfare of both.

GUIDING PRINCIPLE 4

No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.

Commentary on Guiding Principle 4

This Principle states a general prohibition on the removal of cells, tissues or organs from legal minors for transplantation. The major exceptions that may be authorized are familial donation of regenerative cells (when a therapeutically comparable adult donor is not available) and kidney transplants between identical twins (where avoiding immunosuppression represents a benefit to the recipient adequate to justify the exception, in the absence of a genetic disorder that could adversely affect the donor in the future).

While the permission of the parent(s) or the legal guardian for organ removal is usually sufficient, they may have a conflict of interest if they are responsible for the welfare of the intended recipient. In such cases, review and approval by an independent body, such as a court or other competent authority, should be required. In any event, a minor's objection to making a donation should prevail over the permission provided by any other party. The professional counselling provided to potential living donors in order to assess, and when needed, address any pressure in the decision to donate, is especially important for minor donors.

GUIDING PRINCIPLE 5

Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

Commentary on Guiding Principle 5

Payment for cells, tissues and organs is likely to take unfair advantage of the poorest and most vulnerable groups, undermines altruistic donation, and leads to profiteering and human trafficking. Such payment conveys the idea that some persons lack dignity, that they are mere objects to be used by others.

Besides preventing trafficking in human materials, this Principle aims to affirm the special merit of donating human materials to save and enhance life. However, it allows for circumstances where it is customary to provide donors with tokens of gratitude that cannot be assigned a value in monetary terms. National law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs. Incentives in the form of "rewards" with monetary value that can be transferred to third parties are not different from monetary payments.

While the worst abuses involve living organ donors, dangers also arise when payments for cells, tissues and organs are made to next of kin of deceased persons, to vendors or brokers, or to institutions (such as mortuaries) having charge of dead bodies. Financial returns to such parties should be forbidden.

This Principle permits compensation for the costs of making donations (including medical expenses and lost earnings for live donors), lest they operate as a disincentive to donation. The need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation is also accepted as long as the human body and its parts as such are not a source of financial gain.

Incentives that encompass essential items which donors would otherwise be unable to afford, such as medical care or health insurance coverage, raise concerns. Access to the highest attainable standard of health is a fundamental right, not something to be purchased in exchange for body parts. However, free periodic medical assessments related to the donation and insurance for death or complications that arise from the donation may legitimately be provided to living donors.

Health authorities should promote donation motivated by the need of the recipient and the benefit for the community. Any measures to encourage donation should respect the dignity of the donor and foster societal recognition of the altruistic nature of cell, tissue and organ donation. In any event, all practices to encourage the procurement of cells, tissues and organs for transplantation should be defined explicitly by health authorities in a transparent fashion.

National legal frameworks should address each country's particular circumstances because the risks to donors and recipients vary. Each jurisdiction will determine the details and method of the prohibitions it will use, including sanctions which may encompass joint action with other countries in the region. The ban on paying for cells, tissues and organs should apply to all individuals, including transplant recipients who attempt to circumvent domestic regulations by travelling to locales where prohibitions on commercialization are not enforced.

GUIDING PRINCIPLE 6

Promotion of altruistic donation of human cells, tissues or organs by means of advertisement or public appeal may be undertaken in accordance with domestic regulation.

Advertising the need for or availability of cells, tissues or organs, with a view to offering or seeking payment to individuals for their cells, tissues or organs, or, to the next of kin, where the individual is deceased, should be prohibited. Brokering that involves payment to such individuals or to third parties should also be prohibited.

Commentary on Guiding Principle 6

This Principle does not affect general advertisements or public appeals to encourage altruistic donation of human cells, tissues or organs, provided that they do not subvert legally established systems of organ allocation. Instead, it aims to prohibit commercial solicitations, which include offering to pay individuals, the next of kin of deceased persons, or other parties in possession (such as undertakers), for cells, tissues or organs; it targets brokers and other intermediaries as well as direct purchasers.

GUIDING PRINCIPLE 7

Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such procedures, if the cells, tissues or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor.

Commentary on Guiding Principle 7

Health care professionals should only proceed with the removal, intermediate management or implantation of cells, tissues or organs when donations are unpaid and truly voluntary. (In the case of live donors, a psychosocial evaluation of the donor is usually indicated, as described in Guiding Principle 3). Failing to ensure that the person consenting to the donation has not been paid, coerced or exploited breaches professional obligations and should be sanctioned by the relevant professional organizations and government licensing or regulatory authorities.

Physicians and health care facilities should also not refer patients to transplant facilities in their own or other countries that make use of cells, tissues or organs obtained through payments to donors, their families or other vendors or brokers; nor may they seek or accept payment for doing so. Post-transplant care may be provided to patients who have undergone transplantation at such facilities, but physicians who decline to provide such care should not face professional sanctions for such refusals, provided that they refer such patients elsewhere.

Health insurers and other payers should reinforce adherence to high ethical standards by refusing to pay for transplants that violate the Guiding Principles.

GUIDING PRINCIPLE 8

All health care facilities and professionals involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.

Commentary on Guiding Principle 8

This provision reinforces Guiding Principles 5 and 7 by forbidding profiteering in cell, tissue and organ recovery and implantation. Health authorities should monitor the fees charged for transplantation services to ensure that they are not disguised charges for the cells, tissues or organs themselves. All persons and facilities involved should be accountable for all payments for transplantation services. A medical or other

health care practitioner uncertain whether a fee is justifiable should seek the opinion of an appropriate licensing or disciplinary authority before proposing or levying the fee. Fees charged for similar services may be used as a reference.

GUIDING PRINCIPLE 9

The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent.

Commentary on Guiding Principle 9

Where donation rates do not meet clinical demand, allocation criteria should be defined at national or subregional level by a committee that includes experts in the relevant medical specialties, bioethics and public health. Such multidisciplinarity is important to ensure that allocation takes into account not only medical factors but also community values and general ethical rules. The criteria for distributing cells, tissues and organs should accord with human rights and, in particular, should not be based on a recipient's gender, race, religion, or economic condition.

This principle implies that the cost of transplantation and follow-up, including immunosuppressive treatment where applicable, should be affordable to all patients concerned – that is, no recipient should be excluded solely for financial reasons.

The concept of transparency is not exclusive to the allocation process but is central to all aspects of transplantation (as is discussed in the commentary on Guiding Principle 11, below).

GUIDING PRINCIPLE 10

High-quality, safe and efficacious procedures are essential for donors and recipients alike. The longterm outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.

The level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health products of an exceptional nature, must be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products.

Commentary on Guiding Principle 10

Optimizing the outcome of cell, tissue and organ transplantation entails a rules-based process that encompasses clinical interventions and *ex vivo* procedures from donor selection through long-term follow-up. Under the oversight of national health authorities, transplant programmes should monitor both donors and recipients to ensure that they receive appropriate care, including information regarding the transplantation team responsible for their care.

Evaluation of information regarding the long-term risks and benefits is essential to the consent process and for adequately balancing the interests of donors as well as recipients. The benefits to both must outweigh the risks associated with the donation and transplantation. Donors should not be permitted to donate in clinically hopeless situations.

Donation and transplant programmes are encouraged to participate in national and/or international transplant registries. All deviations from accepted processes that could elevate the risk to recipients or donors, as well as any untoward consequences of donation or transplantation, should be reported to and analysed by responsible health authorities.

Transplantation of human material which does not involve maintenance treatment may not require active, long-term follow-up, though traceability should be ensured for the anticipated lifetime of the donor and the recipient. Internationally agreed means of coding to identify tissues and cells used in transplantation are essential for full traceability.

GUIDING PRINCIPLE 11

The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

Commentary on Guiding Principle 11

Transparency can be summarized as maintaining public access to regularly updated comprehensive data on processes, in particular allocation, transplant activities and outcomes for both recipients and living donors, as well as data on organization, budgets and funding. Such transparency is not inconsistent with shielding from public access information that could identify individual donors or recipients while still respecting the necessity of traceability recognized in Principle 10. The objective of the system should be not only to maximize the availability of data for scholarly study and governmental oversight but also to identify risks – and facilitate their correction – in order to minimize harm to donors or recipients.

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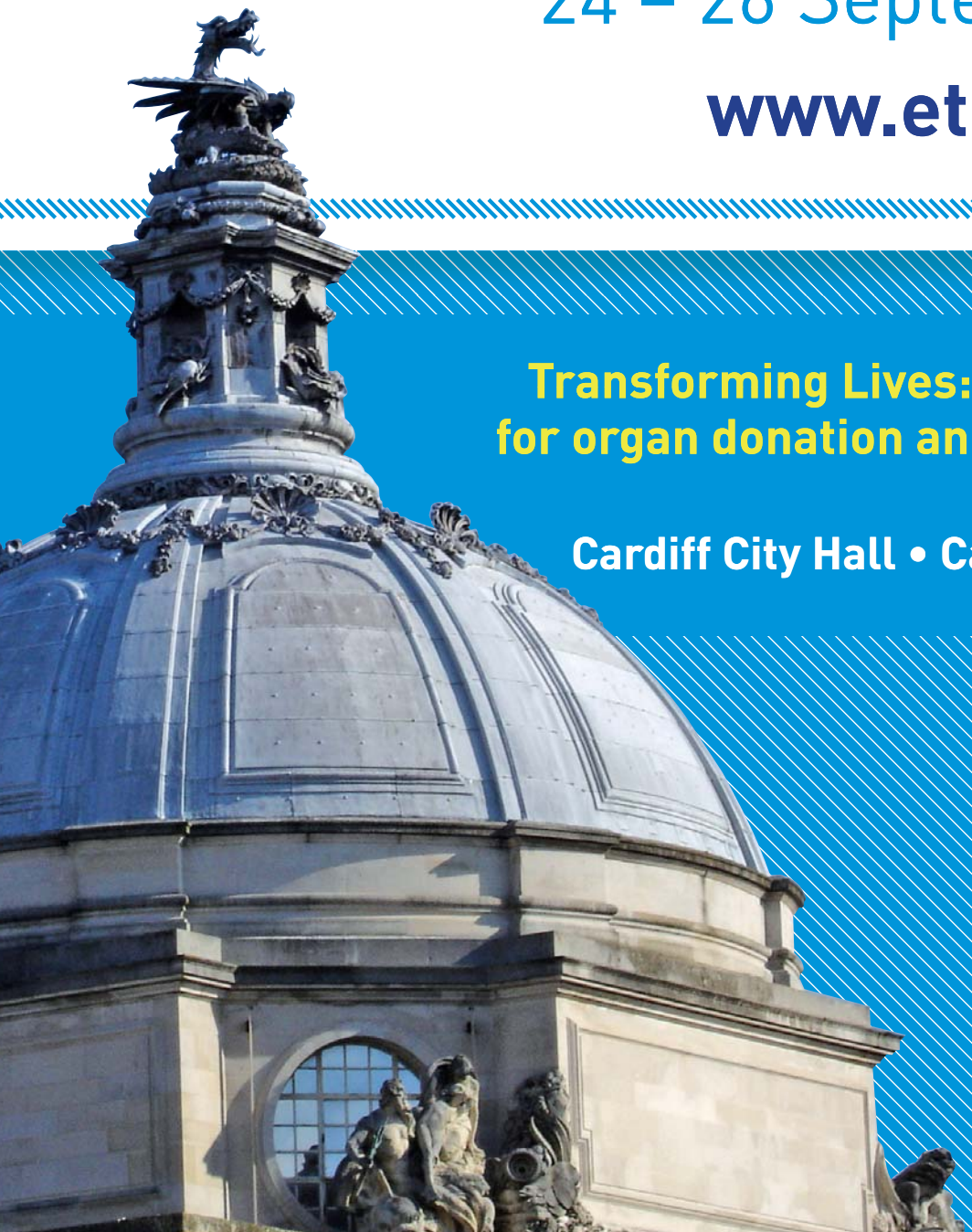

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