

NEWSLETTER

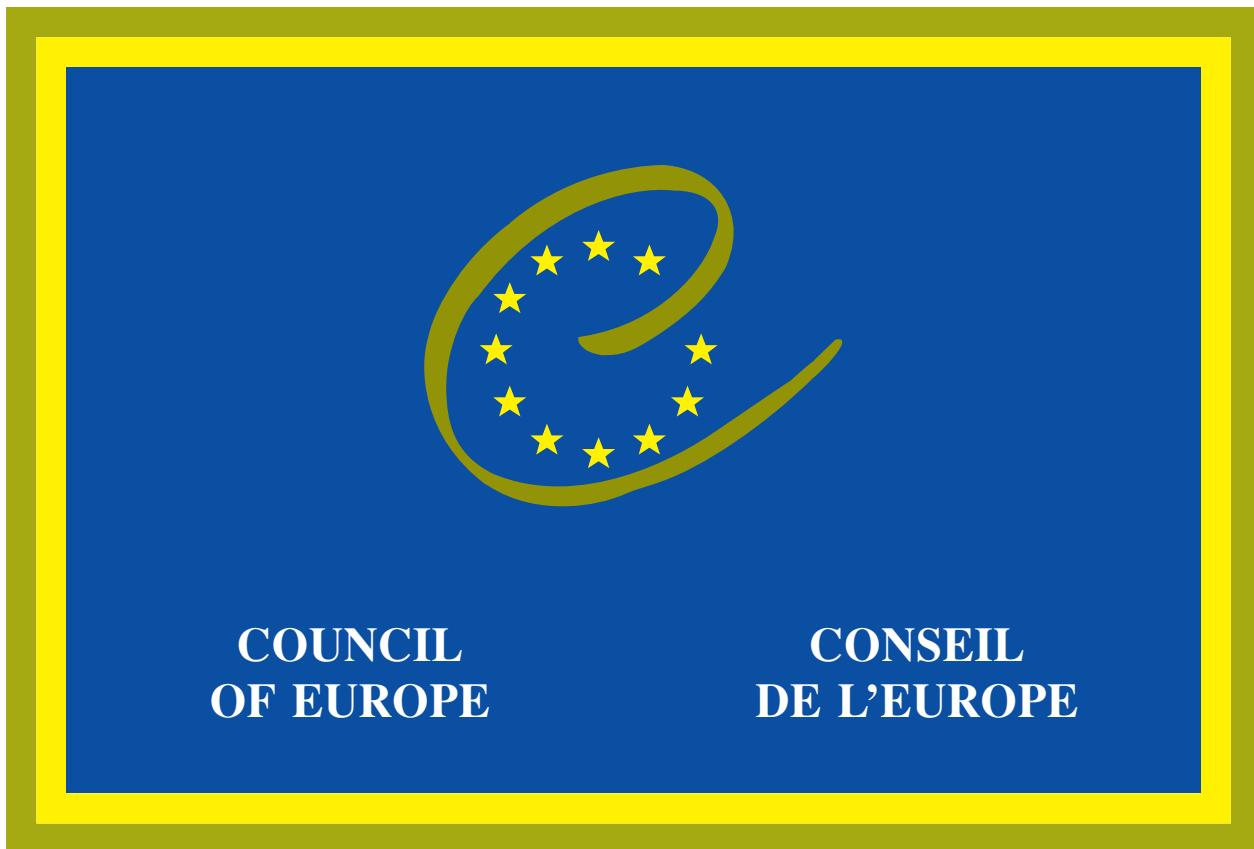
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TRANSPLANT



Vol. 10. Nº 1

INTERNATIONAL FIGURES ON ORGAN DONATION AND TRANSPLANTATION - 2004



2005



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 (2004)

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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)



NEWSLETTER TRANSPLANT 2005

INTRODUCTION

• • • • •

FROM EUROPE TO OTHER PARTS OF THE WORLD

The outstanding work of the Transplant Committee of the Council of Europe in the field of organ, tissue and cells donation and transplantation for many years is now serving as a model for other International bodies in other parts of the world for setting standards, obtaining accurate data of activity, and implementing new forms of organization.

UE has widely used the documents elaborated by this Committee for the tissue and cell directive. WHO is now in the phase of development of the 57th World Health Assembly Resolution about Human Organ and Tissue Transplantation and certainly our experience will serve as a basis for the future work in Latin America or Asia.

TRANSPLANT NEWSLETTER is now the only official publication which provides data of organ donation and transplantation of everyday more and more countries all over the world. A wonderful example has been Latino America. Thanks to the cooperation of professionals and authorities of these countries and the coordinators of the GRUPO PUNTACANA, we started to publish their data and now we are the more accurate source of data for this continent. The recent approval of the project of IBEROAMERICAN COUNCIL OF ORGAN DONATION AND TRANSPLANTATION which will serve to harmonize these activities in Spanish and Portuguese speaking countries can be considered as a reflex of this Committee at the other side of Atlantic ocean.

Information is an absolute need for taking decisions. It is a simple question of justice thank to all the people who provides these data every year from more and more countries. We all are contributing to provide these therapies everyday to more and more people all over the world.

Rafael Matesanz

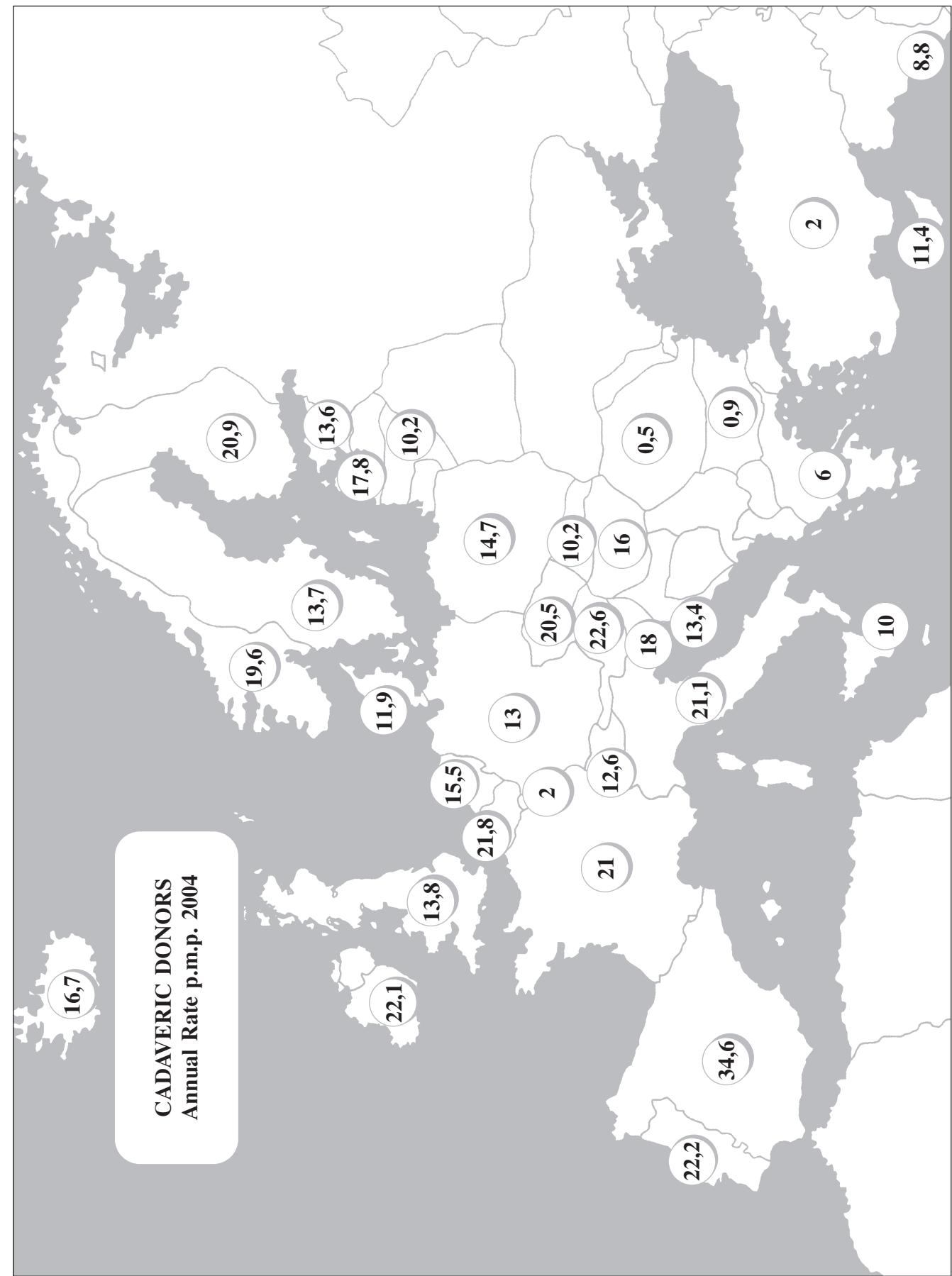
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COUNCIL CONSEIL
OF EUROPE DE L'EUROPE

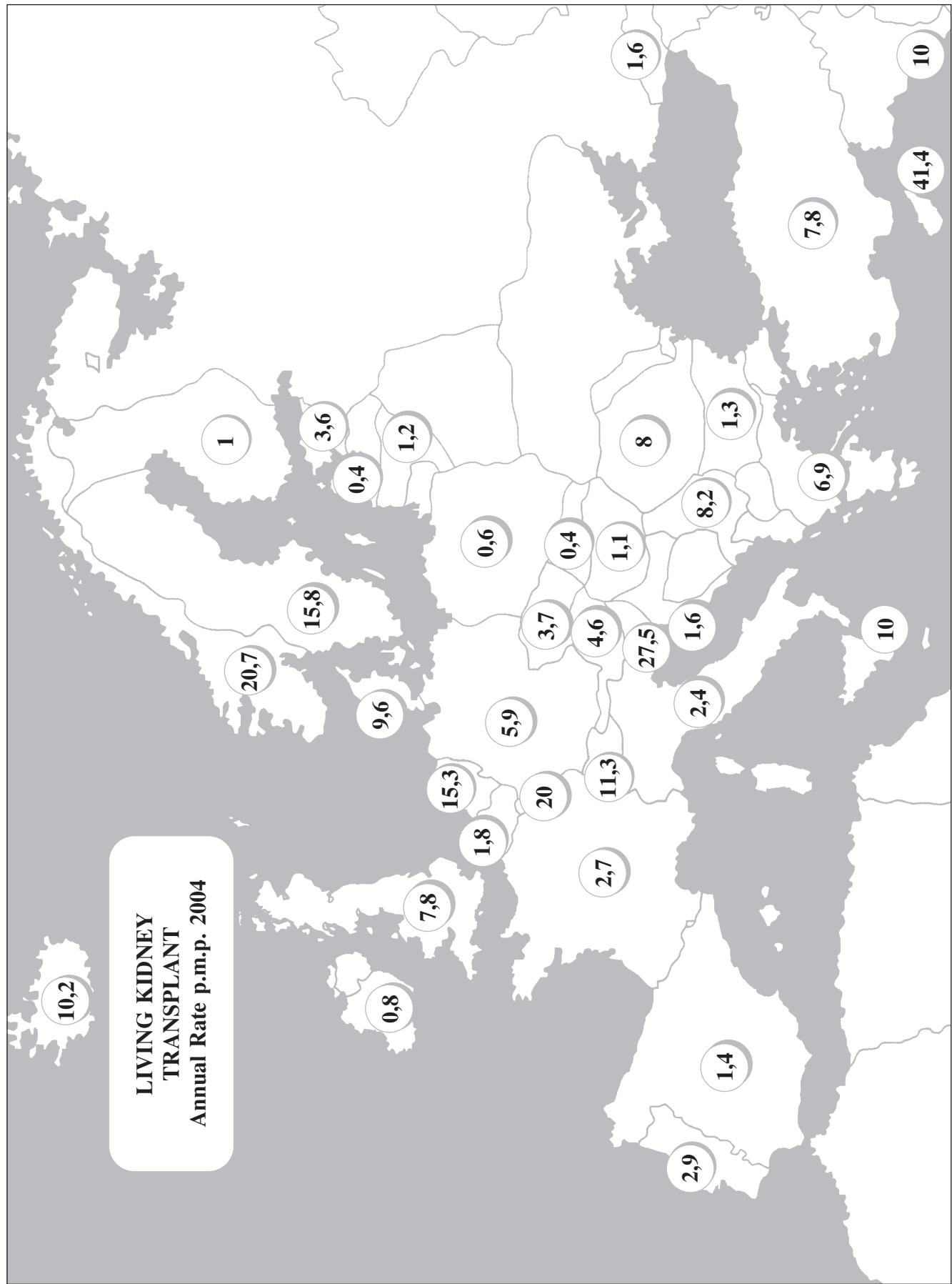
**International figures on
organ donation and
transplantation activity
Year 2004**

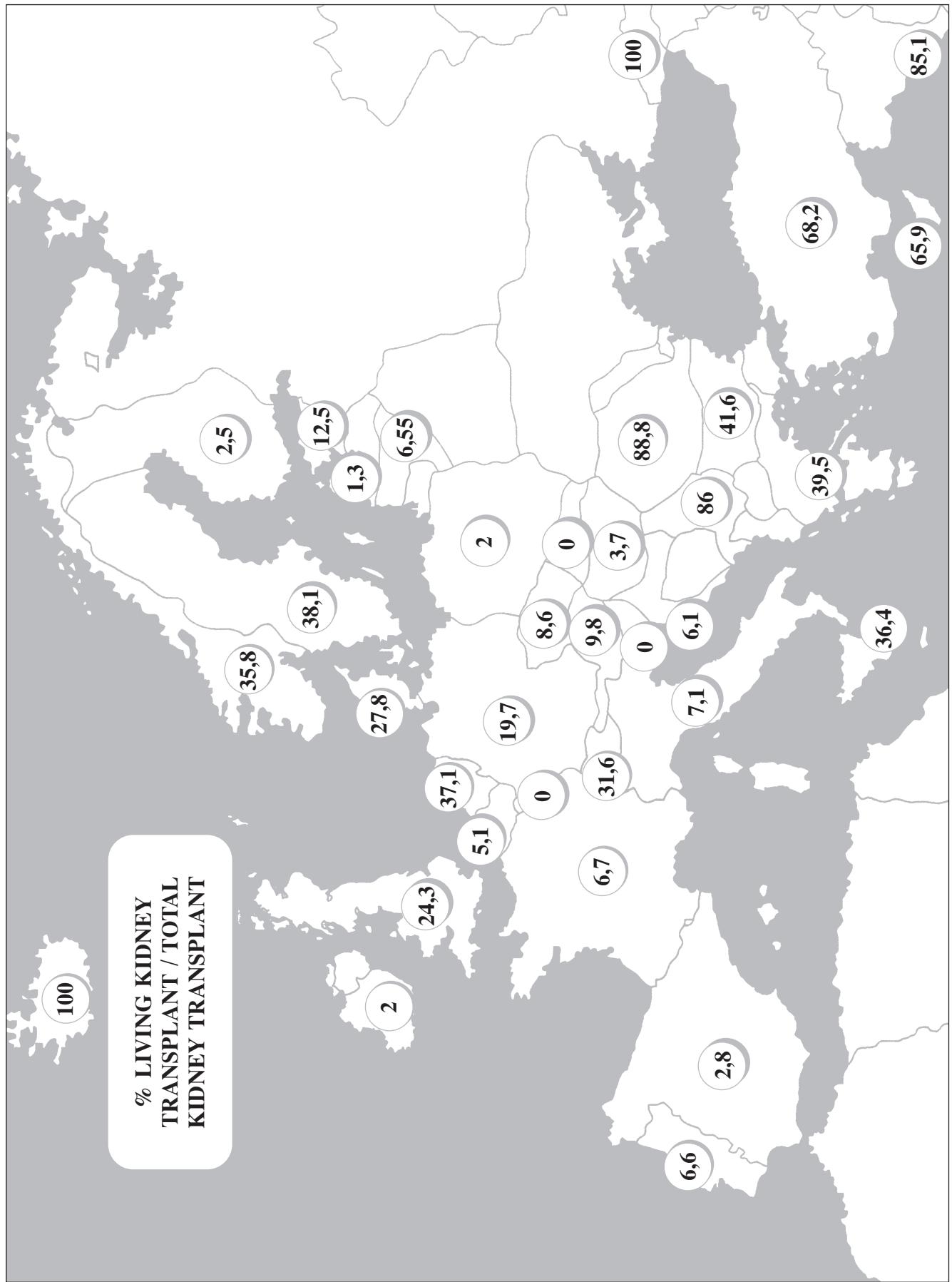




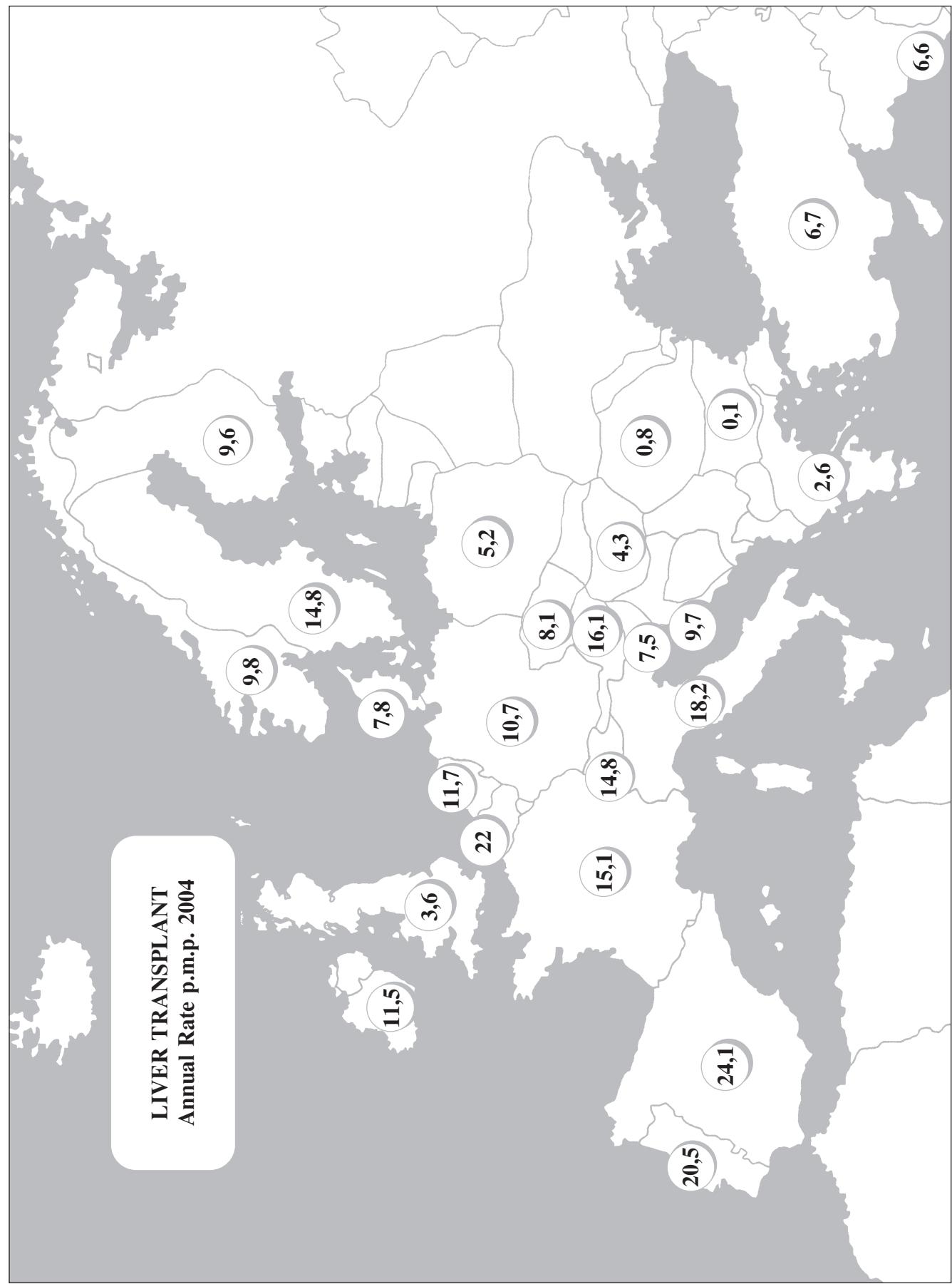
**CADAVERIC KIDNEY
TRANSPLANT**
Annual Rate p.m.p. 2004





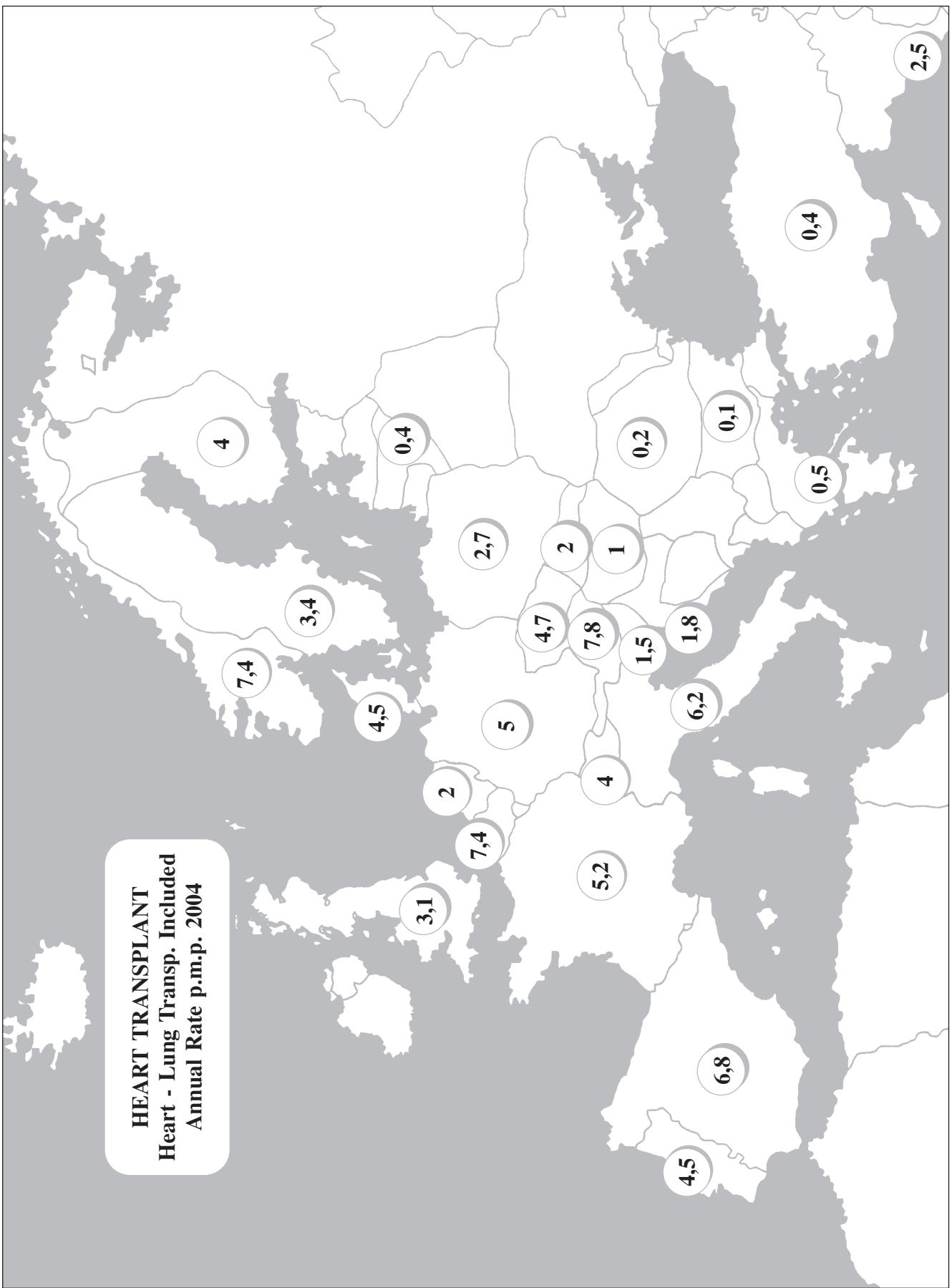


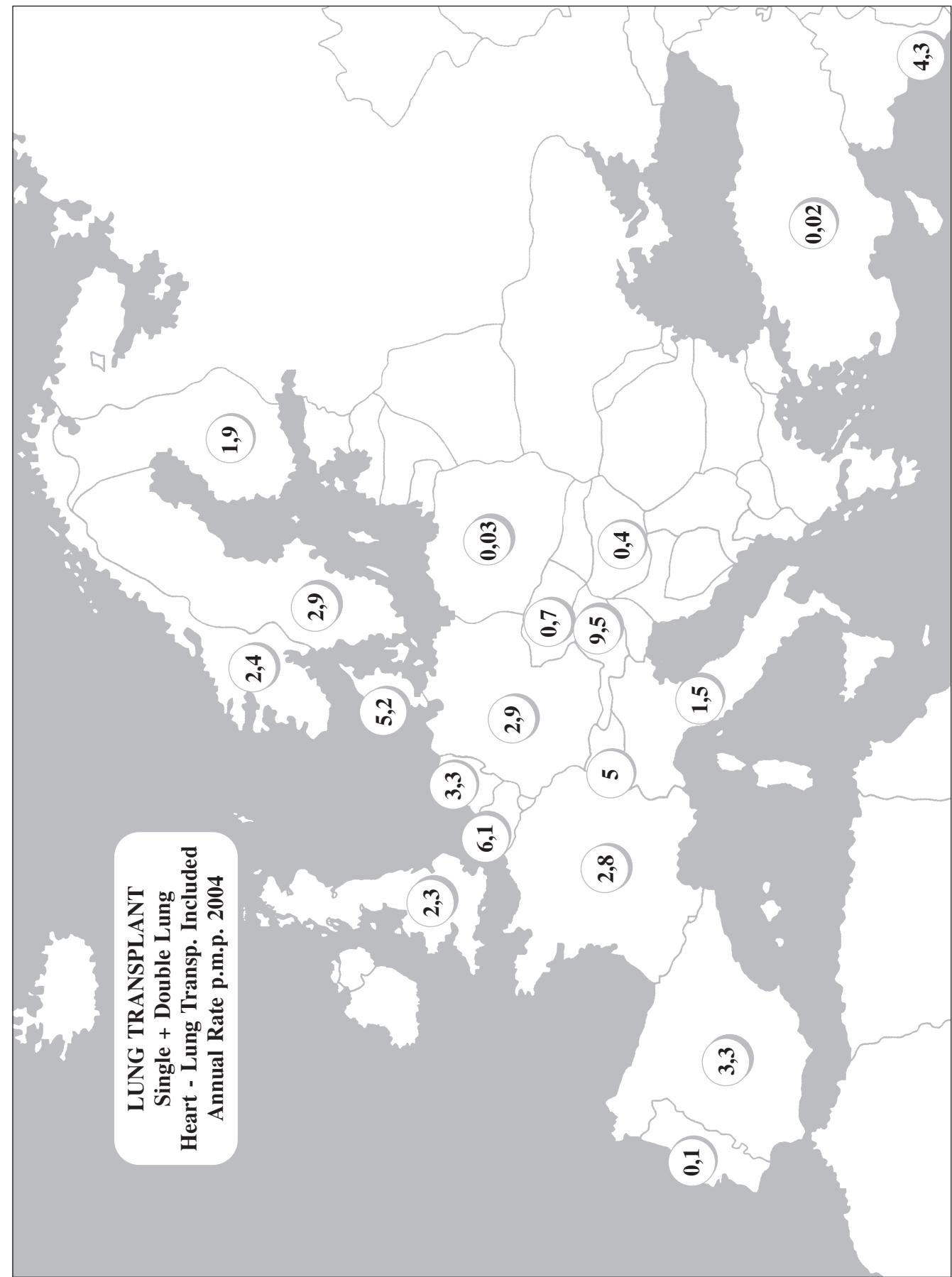
% LIVING KIDNEY
TRANSPLANT / TOTAL
KIDNEY TRANSPLANT





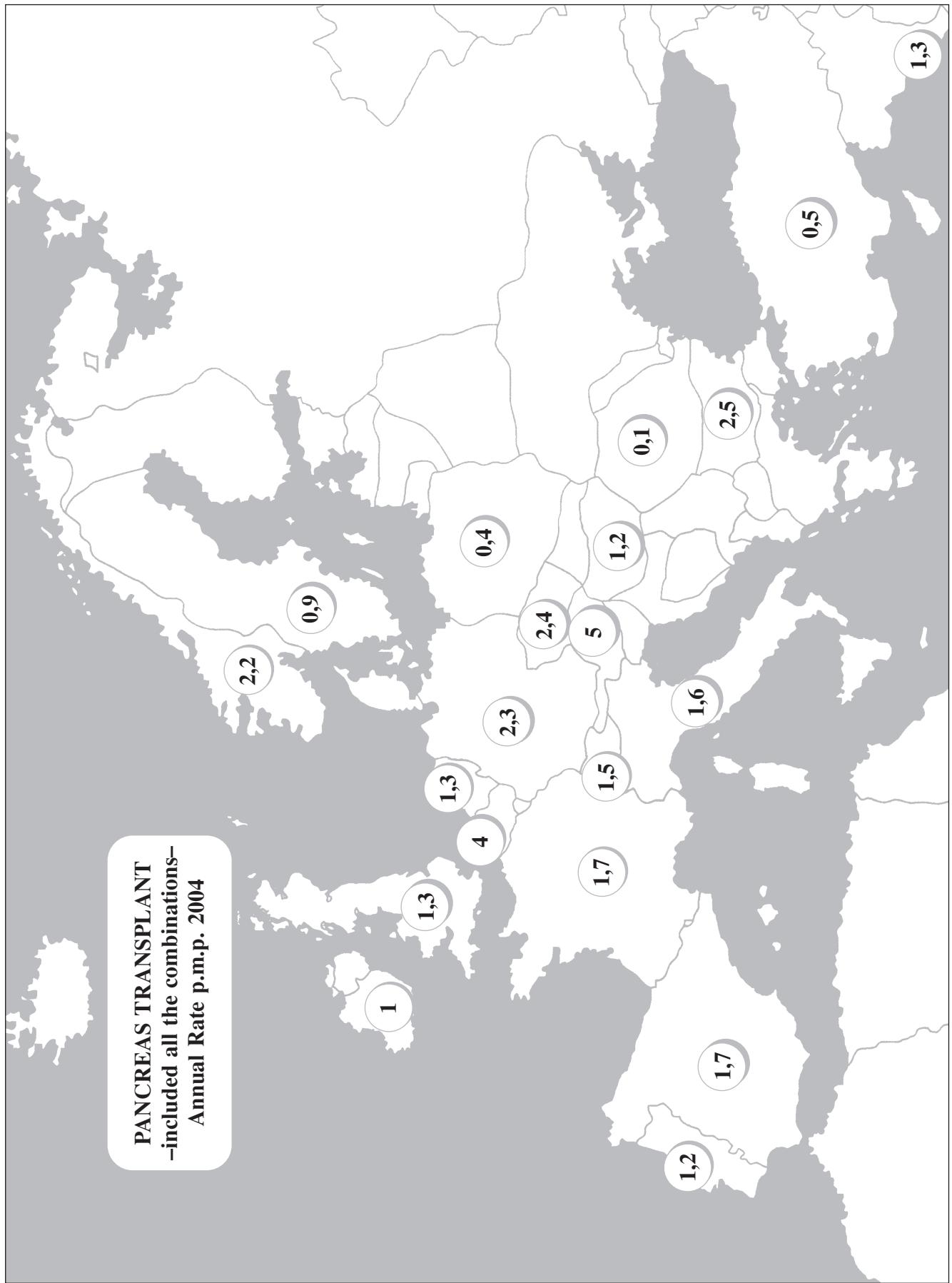
HEART TRANSPLANT
Heart - Lung Transp. Included
Annual Rate p.m.p. 2004

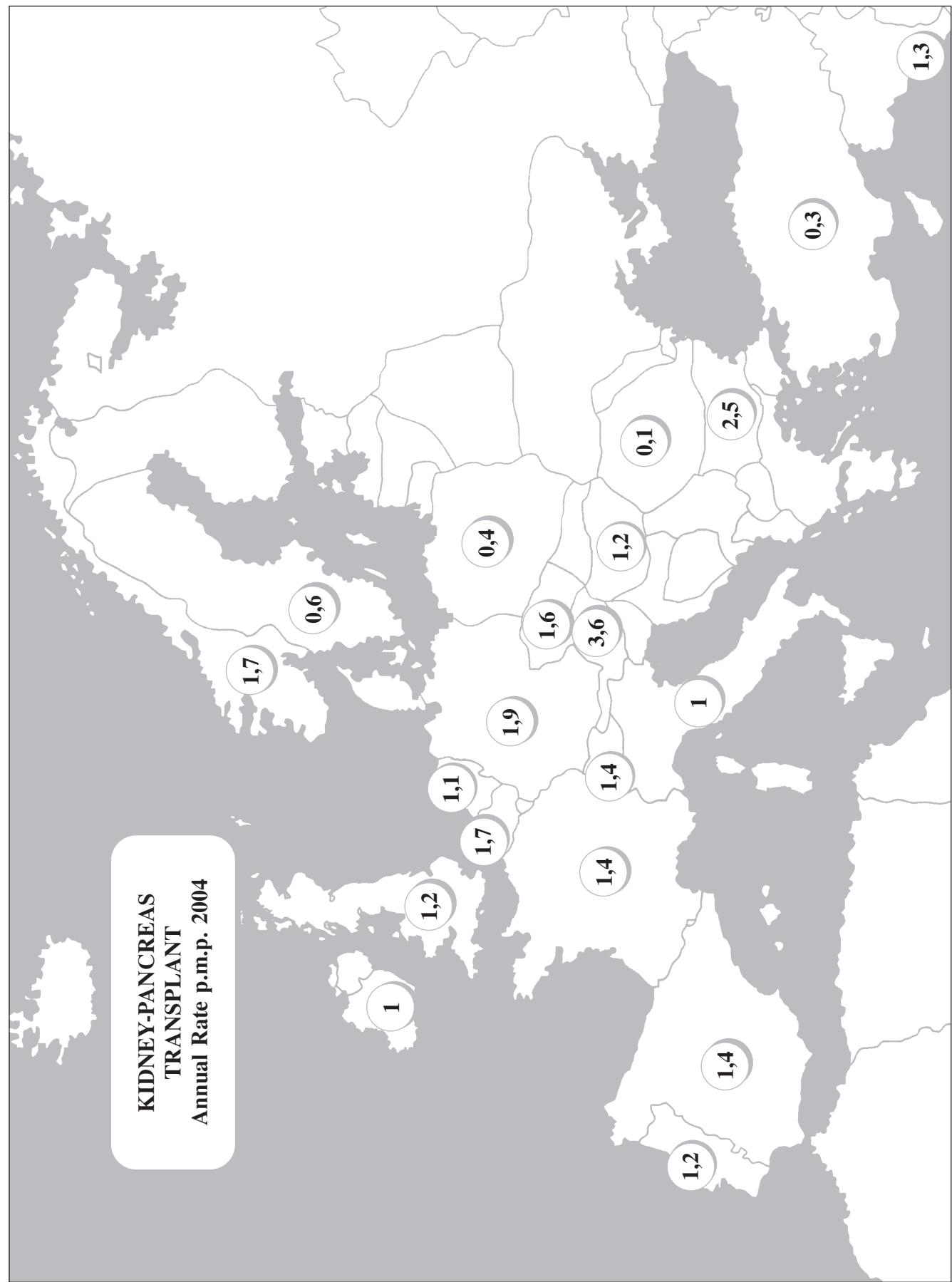


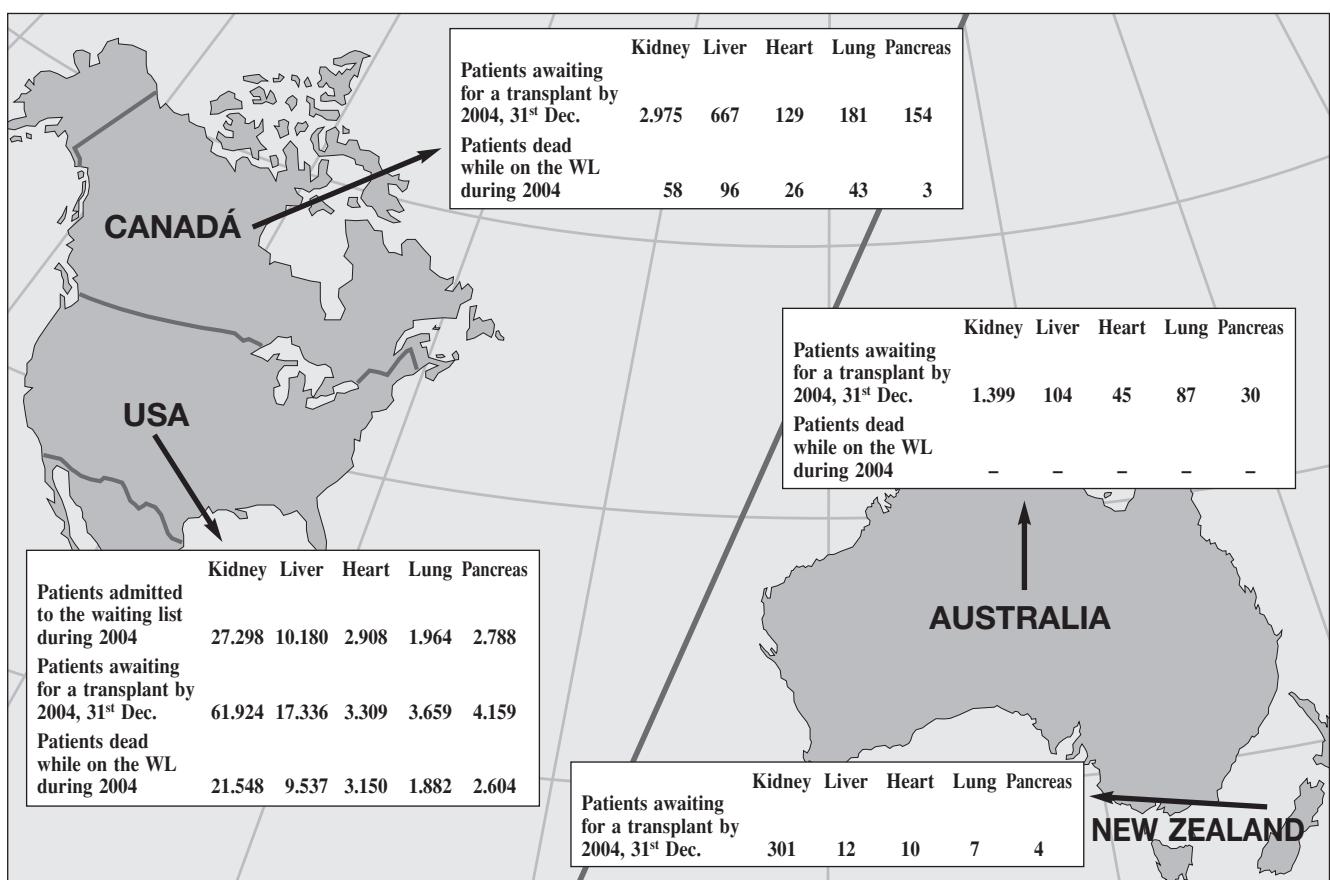
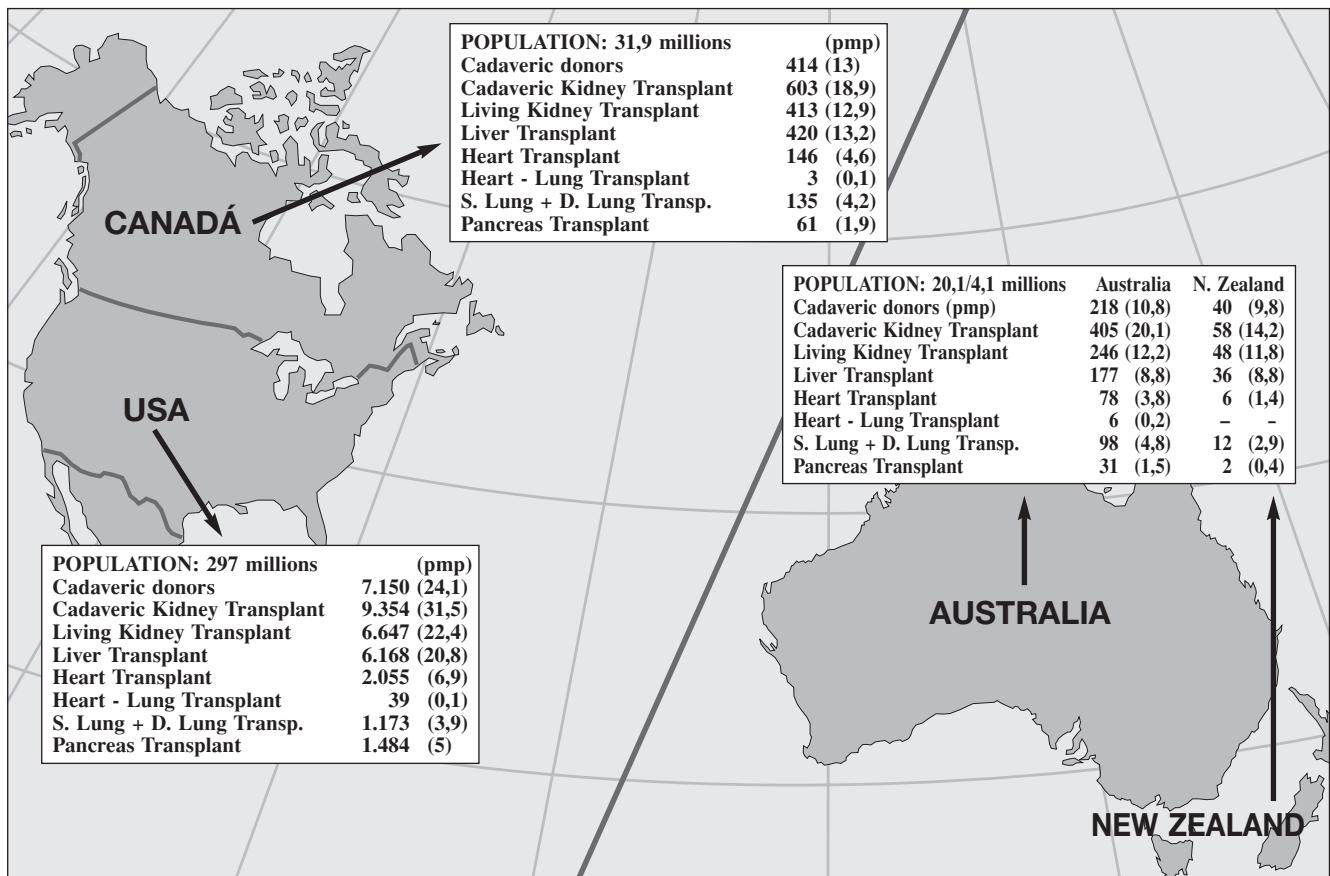




PANCREAS TRANSPLANT
-included all the combinations-
Annual Rate p.m.p. 2004











**CADAVERIC KIDNEY
TRANSPLANT & / LIVING
KIDNEY TRANSPLANT**
Annual Rate p.m.p. 2004

$\frac{16,5}{0}$

$\frac{1,5}{1,4}$

$\frac{0}{2,8}$

$\frac{16}{6,1}$

$\frac{0,5}{5,5}$

$\frac{10}{2,1}$

$\frac{8,9}{1,9}$

$\frac{3,6}{4,21}$

$\frac{3,2}{2,6}$

$\frac{1,6}{0,9}$

$\frac{0}{1,2}$

$\frac{10,2}{7,3}$

$\frac{15,6}{2,2}$

$\frac{15,3}{5}$

$\frac{26,3}{0}$





LIVER TRANSPLANT
Annual Rate p.m.p. 2004

1

2,3

17,9

2

3

0,2

5,3

0,4

4,7

6,6





LUNG TRANSPLANT
Single + Double Lung
Heart - Lung Transp. Included
Annual Rate p.m.p. 2004

0,3

1,8

0,1

0,2

0,4

0,8

0,3



PANCREAS TRANSPLANT
–included all the combinations–
Annual Rate p.m.p. 2004

2,8

0,4

0,1

0,2

1,6



International data on organ donation and transplantation activity, waiting list and family refusals

Year 2004





COUNTRIES Population (million inhabitants)	ARGENTINA	BOLIVIA	BRASIL	CHILI	COLOMBIA	CUBA	DOMINICAN R.	ECUADOR	EL SALVADOR
37.4	9.2	181.6	15	43	112	8.9	12.5	6.6	
DONATION									
Cadaveric D. - included NHBD - (Rate - pmp -)	403 (10.8)	3 (0.3)	1408 (7.75)	134 (8.9)	258 (6)	159 (14.1)			40 (3.2)
NHB Donors (pmp)									
% Multorgan donors	50.62			55	85				
TRANSPLANTATION									
KIDNEY									
TX - included all the combinations - (pmp)	761 (20.3)	11 (1.2)	3168 (17.45)	267 (17.8)	466 (10.8)	85 (16.5)	25 (2.8)	72 (5.8)	
% (Living TX/ Total TX)	24.7	100	41.7	12.3	17.51	8.6	100	44.4	
Paediatric <15 years									
Cadaveric TX (pmp)	111 (<18)		1846 (10.17)	234 (15.6)	384 (8.9)	169 (15.1)		40 (3.2)	
-Single TX (pmp)	573 (15.3)			234 (15.6)				40 (3.2)	
-Double TX (pmp)	563 (15)								
-Split Liver TX (pmp)	10 (0.3)								
Living TX (pmp)	108 (5)		11 (1.2)	1322 (7.28)	33 (2.2)	82 (1.9)	16 (1.4)	25 (2.8)	32 (2.6)
NHB Kidney/TX (pmp)									
LIVER									
TX - included all the combinations - (pmp)	247 (6.6)		960 (5.29)	70 (4.66)	131 (3)	26 (2.3)			
Paediatric <15 years	76 (<18)								
-Split Liver TX (pmp)				2 (0.13)					
-Dominio Liver TX (pmp)									
Living Liver TX (pmp)									
NHB Liver TX (pmp)									
HEART									
TX-included Heart-lung transplant- (pmp)	73 (1.95)		195 (1.07)	21 (1.4)			27 (0.62)		
Paediatric <15 years	14 (<18)								
HEART-LUNG									
Transplants (pmp)									
Paediatric <15 years	5 (0.1)								
LUNG									
TX - included all the combinations - (pmp)	31 (0.83)		43 (0.24)	6 (0.4)	4 (0.09)				
Paediatric <15 years	2 (<18)								
-Single (pmp)	26 (0.7)								
-Double - included Heart/ Lung TX - (pmp)	5 (0.1)								
NHB - double + single - Lung TX (pmp)									
PANCREAS									
TX - included all the combinations - (pmp)	9 (0.2)		100 (0.37)	1 (0.066)					
Paediatric <15 years									
-Kidney - Pancreas TX (pmp)									
-Pancreas TX Alone (pmp)	9 (0.2)								
SMALL BOWEL									
TX - included all the combinations - (pmp)									
Paediatric <15 years									
-Liver + Small Bowel (pmp)									
-S. B. TX Alone (pmp)									
MULTIVISCERAL (pmp)									
	5								





COUNTRIES	AUSTRIA	BELGIUM	CZECH R.	CYPRUS	DENMARK	ESTONIA	FINLAND	FRANCIA	GEORGIA	GERMANY	GREECE	HUNGARY
Population (million inhabitants)	8.2	10.4	10.29	0.7	5.4	1.4	5.2	61.53	5	82.4	11	4
WAITING LIST												
KIDNEY												
N^oTX CENTRES:												
Patients admitted to the WL during 2004	402	452	440	7	1	4	1	45	2	4	4	4
Patients awaiting for a TX by 2004, 31 st Dec	805	936	608	20	257	40	224	3032	2833	371		
Patients dead while on the WL during 2004	44	31	44	100	403	23	244	5626	9270	847	1021	
ESRD on dialysis treatment during 2004				5	3	3	5	115	482		43	
				4504	240							4600
LIVER												
N^oTX CENTRES:												
Patients admitted to the WL during 2004	183	308	93	2	1	1	24		1	1	1	1
Patients awaiting for a TX by 2004, 31 st Dec	108	243	46	52	52	50	1160		1427		81	
Patients dead while on the WL during 2004	52	26	7	16	16	2	474		1525		47	
				2	2	2	103		288		15	
HEART												
N^oTX CENTRES:												
Patients admitted to the WL during 2004	95	93	75	2	33	23	429		756	9	21	
Patients awaiting for a TX by 2004, 31 st Dec	75	34	74	16	18	4	277		613	18	22	
Patients dead while on the WL during 2004	19	12	16	2	2	4	87		172	2	13	
HEART-LUNG												
N^oTX CENTRES:												
Patients admitted to the WL during 2004								9		1	1	
Patients awaiting for a TX by 2004, 31 st Dec								29				
Patients dead while on the WL during 2004								39				
								18				
LUNG												
N^oTX CENTRES:												
Patients admitted to the WL during 2004												
Patients awaiting for a TX by 2004, 31 st Dec	100	66	16	1	45	9	176		405	9	13	
Patients dead while on the WL during 2004	57	46	22	11	41	4	144		457	2	4	
				3	8	1	44		108			
PANCREAS												
N^oTX CENTRES:												
Patients admitted to the WL during 2004												
Patients awaiting for a TX by 2004, 31 st Dec												
Patients dead while on the WL during 2004	13	11	3									
SMALL BOWEL												
N^oTX CENTRES:												
Patients admitted to the WL during 2004	38	37	5	1	5	111		8		2		
Patients awaiting for a TX by 2004, 31 st Dec	36	53	6	6	13	181		13		13		
Patients dead while on the WL during 2004	1	5			8			8		14		



COUNTRIES	ICELAND	IRELAND	ISRAEL	ITALY	LATVIA	LITHUANIA	LUXEMBURGO	MALTA	NORWAY	POLAND	PORTUGAL	ROMANIA
Population (million inhabitants)	0.3	3.9	6.8	56.99	2.3	3.4	0.5	0.4	4.6	38.23	10	21
KIDNEY												
N°TX CENTRES:	1	1	6	39	1	2			1	18		5
Patients admitted to the WL during 2004		220	2604	52	61	3	25	192		1190		432
Patients awaiting for a TX by 2004, 31 st Dec	171	497	6561	375	434	14	85	169		1201		1626
Patients dead while on the WL during 2004		29	188	12	4			13		38		73
ESRD on dialysis treatment during 2004							190			15340		
LIVER												
N°TX CENTRES:	1	3	20						1	6		1
Patients admitted to the WL during 2004		118	1359						53	290		234
Patients awaiting for a TX by 2004, 31 st Dec	21	130	1457						4	105		290
Patients dead while on the WL during 2004		27	137						5	25		36
HEART												
N°TX CENTRES:	3	18	6						1	4		2
Patients admitted to the WL during 2004	68	498	6						35	213		35
Patients awaiting for a TX by 2004, 31 st Dec	121	640	6						4	178		72
Patients dead while on the WL during 2004	24	93	1						1	42		8
HEART-LUNG												
N°TX CENTRES:										2		
Patients admitted to the WL during 2004										18		
Patients awaiting for a TX by 2004, 31 st Dec										14		
Patients dead while on the WL during 2004										7		
LUNG												
N°TX CENTRES:	2	14							1	1		
Patients admitted to the WL during 2004	41	186							32	7		
Patients awaiting for a TX by 2004, 31 st Dec	44	238							45	8		
Patients dead while on the WL during 2004	10	66							9			
PANCREAS												
N°TX CENTRES:	1	3	17						1	4		1
Patients admitted to the WL during 2004			126						14	30		
Patients awaiting for a TX by 2004, 31 st Dec	7		205						14	25		
Patients dead while on the WL during 2004			7						2			
SMALL BOWEL												
N°TX CENTRES:	1	8							1			
Patients admitted to the WL during 2004									14	30		
Patients awaiting for a TX by 2004, 31 st Dec									14	25		
Patients dead while on the WL during 2004									2			



COUNTRIES	SLOVAK R.	SLOVENIA	SPAIN	SWEDEN	SWITZERLAND	T. NETHERLANDS	TURKEY	U. K.	AUSTRALIA	CANADA	NEW ZEALAND	USA
Population (million inhabitants)	5.38	2	43.2	9	7.2	16.3	67.8	59	20.11	31.94	4.06	297
WAITING LIST												
KIDNEY												
N^oTX CENTRES:	4	1	42	4	6		25	25	20	24	3	250
Patients admitted to the WL during 2004	224	38	357	282	832	1403	2808					27298
Patients awaiting for a TX by 2004, 31 st Dec	759	108	4231	350	488	116	7904	5299	1399	2975	301	61924
Patients dead while on the WL during 2004	70	1	6	18	111	111		273		58		21548
ESRD on dialysis treatment during 2004		1225	21031				34262					
LIVER												
N^oTX CENTRES:	1	1	24	3	3		17	7	8	9	1	117
Patients admitted to the WL during 2004	3	12	1460	130	115	154	631	875				10180
Patients awaiting for a TX by 2004, 31 st Dec	7	6	701	17	86	155	737	253	104	667	12	17336
Patients dead while on the WL during 2004	1	1	163	6	15	21		62		96		9573
HEART												
N^oTX CENTRES:	2	1	17	3	4		12	7	4	12	1	131
Patients admitted to the WL during 2004	9	9	394	36	45	59	24	206				2908
Patients awaiting for a TX by 2004, 31 st Dec	3	16	113	16	18	45	182	111	45	129	10	3309
Patients dead while on the WL during 2004	1	5	36	2	6	16		17		26		3150
HEART-LUNG												
N^oTX CENTRES:												
Patients admitted to the WL during 2004												
Patients awaiting for a TX by 2004, 31 st Dec												
Patients dead while on the WL during 2004												
LUNG												
N^oTX CENTRES:	1	8	2	2			12	6	4	5	1	67
Patients admitted to the WL during 2004	1	209	38	41	88	1		205				1964
Patients awaiting for a TX by 2004, 31 st Dec	145	31	17	86	1		272	87		181	7	3659
Patients dead while on the WL during 2004	1	26	6	3	14		46		43			1882
PANCREAS												
N^oTX CENTRES:	1											
Patients admitted to the WL during 2004												
Patients awaiting for a TX by 2004, 31 st Dec												
Patients dead while on the WL during 2004												
SMALL BOWEL												
N^oTX CENTRES:	2	1	1									
Patients admitted to the WL during 2004												
Patients awaiting for a TX by 2004, 31 st Dec												
Patients dead while on the WL during 2004												





FAMILY REFUSALS										
COUNTRIES	CZECH R.	ESTONIA	FRANCE	HUNGARY	ICELAND	ISRAEL	ITALY	LATVIA	NORWAY	
Population (million inhabitants)	10.29	1.4	61.53	10	0.3	6.8	56.99	2.3	4.6	
Number of interviews, asking for consent to donation	36	229	7	154	2027	38	122	696		
Number of family refusals (%)	13	17 (47)	488	16 (7)	87 (56)	594 (29)	11 (29)	31 (25)	73 (10)	
COUNTRIES	ROMANIA	SLOVENIA	SPAIN	TURKEY	U.K.	ARGENTINA	CHILI	CUBA	URUGUAY	VENEZUELA
Population (million inhabitants)	21	2	43.2	67.8	59	37.4	15	11.2	3.2	26
Number of interviews, asking for consent to donation	12	47	1974	220	1183	933	212	221	62	103
Number of family refusals (%)	2 (17)	36 (77)	351 (18)	76 (34)	442 (37)	515 (55)	78 (37)	22 (10)	17 (27)	52 (50)



DATA ON ORGAN EXCHANGE IN EUROPE
LIVER (WHOLE) / RIGHT LIVER LOBE (RL) (IMPORTED AND GRAFTED)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	TOTAL IMPORTED
IMPORTED																										34	
1. Austria	6										23	1					2			1	1					75	
2. Belgium	7									1	49	2					12			3	1						75
3. Croatia																											0
4. Cyprus																											0
5. Denmark																											0
6. ET																											0
7. Finland																											0
8. France																											0
9. Germany	31	52								1		1					36	1	1	12	4	2	1			143	
10. Greece										1																	1
11. Hungary																											0
12. Italy																4				1							16
13. Latvia																											0
14. Luxembourg																											0
15. SKT																											0
16. Malta																											0
17. Netherlands	4	3																		1							38
18. Norway																											0
19. Poland																											0
20. Portugal																											0
21. Slovenia		1																		1							8
22. Slovak R.																											0
23. Spain																				3							6
24. Sweden																											0
25. Switzerland	1																										10
26. U.K.																											5



DATA ON ORGAN EXCHANGE IN EUROPE
KIDNEY (IMPORTED AND GRAFTED)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	TOTAL IMPORTED
IMPORTED																												
1. Austria	17																										92	
2. Belgium	11																										103	
3. Croatia																											0	
4. Cyprus																											0	
5. Denmark																											0	
6. Estonia																											0	
7. ET																											0	
8. Finland																											0	
9. France																											0	
10. Germany	65	79																									234	
11. Greece																											0	
12. Hungary																											0	
13. Italy																											1	
14. Latvia																											1	
15. Luxembourg																											10	
16. SKT																											0	
17. Malta																											0	
18. Netherlands	8	18																									50	
19. Norway																											0	
20. Poland																											0	
21. Portugal																											0	
22. Slovenia	4	3																									28	
23. Slovak R.																											0	
24. Spain																											1	
25. Sweden																											0	
26. Switzerland																											0	
27. U.K.																											0	



DATA ON ORGAN EXCHANGE IN EUROPE
HEART (IMPORTED AND GRAFTED)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	TOTAL IMPORTED
IMPORTED																											
1. Austria																										6	
2. Belgium	2																									4	
3. Croatia																										0	
4. Cyprus																										0	
5. Denmark																										0	
6. ET																										0	
7. Finland																										0	
8. France																										0	
9. Germany	10	14																								51	
10. Greece																										1	
11. Hungary																										0	
12. Italy																6										11	
13. Latvia																										0	
14. Luxembourg																										0	
15. SKT																										0	
16. Malta																										0	
17. Netherlands																										2	
18. Norway																										0	
19. Poland																										0	
20. Portugal																										0	
21. Slovenia																										0	
22. Slovak R.																										0	
23. Spain																										2	
24. Sweden																										0	
25. Switzerland																										2	
26. U.K.																										3	

DATA ON ORGAN EXCHANGE IN EUROPE
LUNG / SMALL BOWEL (SB) (IMPORTED AND GRAFTED)

IMPORTED	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	TOTAL IMPORTED
1. Austria																										53	
2. Belgium																										3	
3. Croatia																										0	
4. Cyprus																										0	
5. Denmark																										0	
6. ET																										0	
7. Finland																										0	
8. France																										0	
9. Germany																										0	
10. Greece																										1	
11. Hungary																										0	
12. Italy																										5	
13. Latvia																										0	
14. Luxembourg																										0	
15. SKT																										0	
16. Malta																										1	
17. Netherlands																										0	
18. Norway																										0	
19. Poland																										0	
20. Portugal																										0	
21. Slovenia																										0	
22. Slovak R.																										0	
23. Spain																										0	
24. Sweden																										2	
25. Switzerland																										1	
26. U.K.																										0	





DATA ON ORGAN EXCHANGE IN EUROPE
PANCREAS (IMPORTED AND GRAFTED)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	TOTAL IMPORTED
IMPORTED																										14	
1. Austria	2																										41
2. Belgium																											0
3. Croatia																											0
4. Cyprus																											0
5. Denmark																											0
6. ET																											0
7. Finland																											0
8. France																											0
9. Germany	8	5																									18
10. Greece																											0
11. Hungary																											0
12. Italy																											0
13. Latvia																											0
14. Luxembourg																											0
15. SKT																											0
16. Malta																											0
17. Netherlands	1	5																									28
18. Norway																											0
19. Poland																											0
20. Portugal																											0
21. Slovenia																											0
22. Slovak R.																											0
23. Spain																											0
24. Sweden																											0
25. Switzerland																											0
26. U.K.																											0



COUNCIL CONSEIL
OF EUROPE DE L'EUROPE

International data on tissue and hematopoietic stem cell transplant activity Year 2004





COUNTRIES	BULGARIA	GREECE	ISRAEL	ITALY	LITHUANIA	POLAND	PORTUGAL	ROMANIA	SLOVENIA	SPAIN	SWITZERLAND	T. NETHERLANDS	TURKEY	U. K.
Population (million inhabitants)	7.8	11	6.8	56.9	3.4	38.23	21	2	43.2	7.2	16	67.8	59	
TISSUE ACTIVITY INDICATORS														
Vascular Tissue														
Nº Cadaveric donors (pmp)					168	10 (2.9)					176 (4.07)			
Nº Grafted Patients (pmp)					166	7 (2.1)	11 (0.3)				99 (2.3)			
Nº Bank Processed Pieces (pmp)					972 (17.1)						147 (3.4)			
Percentage of Desestimation												20.9		
Types of Tissues Distributed:														
Artery														
Vein														
Nº Living Donors (pmp)					41.05						4.8			
Valves														
Nº Cadaveric Donors (pmp)					47 (7)	265 (4.6)	10 (2.9)				175 (4.05)	17 (2.36)	342 (21.4)	7 (0.1)
Nº Living Donors (pmp)												12 (0.75)		
Nº Grafted Patients (pmp)													7 (0.1)	
Nº Bank Processed Pieces (pmp)														
Percentage of Desestimation														
Types of Tissues Distributed:														
Aortic/ Pulmonary %														
Types of Tissues Distributed:														
Tricuspid/ Mitral %														
41.1/ 58.9														
40/ 60														



COUNTRIES Population (million inhabitants)	BULGARIA	GREECE	ISRAEL	ITALY	LITHUANIA	POLAND	PORTUGAL	ROMANIA	SLOVENIA	SPAIN	SWITZERLAND	T. NETHERLANDS	TURKEY	U. K.	
TISSUE ACTIVITY INDICATORS															
Skin															
Nº Cadaveric donors (pmp)															
Nº Cadaveric donors (pmp)	352 (45.1)			151 (22.5)	217 (3.8)				6 (0.28)	68 (1.5)			346 (21.6)		
Nº living donors (pmp)				28 (0.5)					8 (0.38)						
Nº grafted patients (pmp)	296 (38)			1122 (19.7)		52 (1.4)		14 (0.66)					55 (1.2)		
Nº Bank Processed Pieces (pmp)	308 (39.5)			413939 (6916.8)									159210 (3365.3)		
Percentage of Desestimation	81								2						
Cell Cultures															
Nº Cadaveric donors (pmp)															
Nº Living Donors (pmp)													29 (4.03)		
Nº Grafted Patients (pmp)															
Nº bank Processed Pieces (pmp)													12 (1.66)		
Percentage of Desestimation													83 (1.92)		
Types of Tissues Distributed: Chondrocytes													147 (3.4)		
Types of Tissues Distributed: Keratinocytes %													58.6		
Types of Tissues Distributed: Other %													36		
													64		
													14		
COUNTRIES Population (million inhabitants)	BULGARIA	CROATIA	FRANCE	GREECE	HUNGARY	ITALY	LITHUANIA	POLAND	PORTUGAL	ROMANIA	SLOVENIA	SPAIN	SWITZERLAND TURKEY		
HEMATOPOIETIC STEM CELL TRANSPLANTS															
Autologous	12	115	3176	120	147	3209	26	465	178	10	50	1429	309	264	
Allogeneic related	3	17	671	44	36	886	12	169	74	7	12	413	122	-	
Allogeneic unrelated	-	4	311	22	21	387	-	134	27	-	8	131	41	-	
Total	15	136	4158	186	204	4482	38	768	279	17	70	1973	472	460	



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OF EUROPE DE L'EUROPE

**Documents produced by the
Transplant Committee of the
Council of Europe
Year 2004**



GUIDE TO SAFETY AND QUALITY ASSURANCE FOR ORGANS, TISSUES AND CELLS - 2nd Edition (2004)



This Guide includes standards for procurements, preservation, processing and distribution of organs, tissues and cells. It is the first international text on this topic adopted by Health Authorities.

ISBN: 92-871-5518-6

Format: 16 x 24 cm

No. of pages: 95

SYNOPSIS

The purpose of this guide is to provide guidance for all those involved in the transplantation to maximise the quality, and thereby the success rate, of transplants, and to minimise the risks to all involved in this complex procedure. It includes safety and quality standards for procurement, preservation, processing, and distribution of organs, tissues and cells of human origin (allogeneic and autologous) used for transplantation purposes.

As the European Union Directive on Tissues and Cells (2004/23/EC) was recently adopted, the European Commission will build on the Council of Europe's guide when establishing technical standards under the directive. This co-operation will ensure that the same standards are applied throughout Europe.

CONTENTS

1. Introduction.
 2. Quality management: principles for ensuring the quality of organs, tissues and cells.
 3. Selection of donors.
 4. Organ procurement and preservation.
 5. Tissue and cell procurement.
 6. Tissue establishments.
 7. Transplantation practices.
- Appendices.

http://www.coe.int/T/E/Social_Cohesion/Health/Activities/Organ_transplantation/



RECOMMENDATION REC(2004)19 OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON CRITERIA FOR THE AUTHORISATION OF ORGAN TRANSPLANTATION FACILITIES

*Adopted by the Committee of Ministers on 15 December 2004
at the 909th meeting of the Ministers' Deputies*



The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued *inter alia* by the adoption of common action in the health field;

Taking into account Resolution No. R (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances, the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987); Articles 19 and 20 of the Convention of Human Rights and Biomedicine, and Articles 3 and 4 of the Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin;

Considering that:

- organ transplantation is a well-established, life-saving, and effective treatment: a successful organ transplantation may be the only treatment available for some forms of end stage organ failure and is the most clinically and cost effective treatment for chronic renal failure;
- organ exchange and circulation of recipients among member states is becoming a more frequent phenomenon, and that a minimum common standard should be guaranteed to the citizens;

- member states should therefore provide high-quality transplant services for the benefit of their citizens. Considering the limited organ supply, all necessary steps should be taken to make sure all available organs are properly safeguarded and used so as to maximise the benefit to patients;
- the highest professional standards are to be maintained in the area of organ transplantation,

Recommends that the governments of member states take all necessary measures to ensure the following:

1. An appropriate mechanism for the authorisation¹ of health care facilities carrying out organ transplantsations² should be set up. In order to obtain authorisation these facilities should meet the following criteria:

- feasibility of programme, based on clinical need assessment and a documented estimate of organ supply, to ensure that projected activity levels are sufficient to maintain clinical expertise and programme quality;

¹ For the purpose of this Recommendation, the term «authorisation» refers to any appropriate mechanism for designating, authorising, accrediting or licensing health care facilities carrying out organ transplantsations.

² This Recommendation refers to the facilities where organs are being «implanted».



- standards of vocational training of team members, and infrastructural conditions relating to availability of beds, intensive care facilities, and diagnostic and therapeutic back-up services (radiology, microbiology, immunology services, etc.), and to care provided by nursing, physiotherapy, social services and related medical professionals.
2. Medical professionals forming part of an organ transplant team should be properly qualified and their previous training in the field of transplantation should be documented and personalised.
 3. A quality-management system should be put in place to evaluate performance against established national and/or international standards as applicable, and to ensure the quality of the process of organ procurement and transplantation, following the principles described in the Council of Europe's *Guide to safety and quality assurance for organs, tissues and cells*.
 4. Authorisations should be regularly reviewed against agreed quality criteria and standards, as well as against audit results.
 5. Outcome results for each type of transplant should be within the margins of internatio-
- nal registers, at an equivalent degree of complexity of patients. In order to guarantee clinical results and cost-effective performance, minimal yearly activity standards shall be established in order to maintain an active programme.
6. These minimal activity standards, required to keep active each kind of transplant programme, should be related to the mean number of cadaveric organs available to the transplant team in recent years.
 7. Any transplant centre which, after several warnings, continues to fail to meet activity or outcome criteria may have its authorisation withdrawn.
 8. No new transplant centre may be authorised if there are not enough organs available to enable a new centre to reach the required standards.
 9. Any new transplant centre should be authorised, accredited or licensed on the basis of agreed criteria and initially should be limited in time. If, within an agreed timescale, the new centre does not achieve the required standards, authorisation shall be withdrawn.



RECOMMENDATION REC(2005)11 OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON THE ROLE AND TRAINING OF PROFESSIONALS RESPONSIBLE FOR ORGAN DONATION (TRANSPLANT «DONOR CO-ORDINATORS»)

*Adopted by the Committee of Ministers on 15 June 2005
at the 930th meeting of the Ministers' Deputies*



The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Taking into account Resolution (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances, the final text of the 3rd Conference of European Health Ministers (Paris, 16 and 17 November 1987); Articles 19 and 20 of the Convention on Human Rights and Biomedicine, and Articles 3 and 4 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, and principles established in the 1998 Council of Europe consensus document entitled «Meeting the organ shortage»;

Considering that organ transplantation is a well-established, life-saving, and effective treatment: a successful organ transplant may be the only treatment available for some forms of end stage organ failure and is the most clinically effective and cost-effective treatment for chronic renal failure;

Considering the universal shortage of organs for transplantation;

Considering that the transplant process is complex, involves various services and therefore requires effective organisation and co-ordination of health care professionals;

Bearing in mind that in many member states the training and employment of health care professionals responsible for detecting potential deceased organ donors and organising the donation process has increased the efficiency of the procurement of organs and improved the functioning of local and national transplant systems; and that such professionals can also increase the rate of donation of tissues for transplantation,

Recommends that the governments of member states take the measures contained in the appendix to this recommendation as regards the role and training of professionals responsible for organ donation (transplant «donor co-ordinators»).

APPENDIX TO RECOMMENDATION REC(2005)11

1. A professional responsible for the identification of potential deceased organ and/or tissue donors should be appointed in every hospital with an intensive care unit. This professional should have appropriate training and experience, be independent of any transplant teams, and have



- clearly defined responsibilities for the establishment, management and audit of a hospital-based system for potential deceased donor identification and organ/tissue procurement. The person should also be responsible for monitoring the donation and procurement process and for identifying and implementing improvements. For the purposes of this recommendation, the professional will be termed a transplant «donor coordinator».
2. Donor co-ordinators should be properly accountable to senior management of the relevant health institution and to any regional or national

transplant organisations. Donor co-ordinators may be complemented by, or responsible to, other transplant co-ordinators at regional or national level.

3. Donor co-ordinators, and any other transplant co-ordinators should have a high standard of professional training consistent with internationally recognised standards, to ensure the highest possible professional and ethical standards in organ donation and procurement. Member states should establish formal national or international accreditation for donor co-ordination activities/donor co-ordinators.



A GIFT FOR LIFE

14 October 2005
Palexpo, Geneva, Switzerland

**Council of Europe 7th European Day for Organ Donation
and Transplantation**

1st World Day for Organ Donation and Transplantation
With the participation of the World Health Organization

Preliminary Program

Morning: **Council of Europe's 7th European day
for organ donation and transplantation**
with participation of the Council of Europe Committee of Experts
on Transplantation (SP-CTO)

10:00-10:55 Welcome from local, national and international representatives
Council of Europe Role in Transplantation and Organ Donation

11:00 – 11:45 **Round table I:**
Quality of life after organ transplantation

11:55-12:40 **Round Table II:**
Organ Donation: Ethical and religious aspects
Handing the vase over to Turkey, which will host the 8th European Day in Istanbul

12:40-14:00 Lunch

Afternoon: **1st World day for organ donation and transplantation**
With the participation of the World Health Organisation (WHO)

14:00-14:45 Resolution WHA 57.18 of the 57th World Health Assembly (organ and tissue transplantation)
will be brought by a transplanted sport-person from the WHO headquarters to Palexpo. The
content of the resolution will be presented

14:50-15:35 **Round Table III:**
Economical aspects of organ donation and transplantation

15:45-16:30 **Round table IV:**
Access to organ transplantation worldwide

16:40-18:00 **Closing ceremony:**
Launch of an international donor card
Passage of the baton to the organizers of the 2nd World day for organ donation
and transplantation (Argentina)
Human chain of solidarity

18:00 Onwards: Festive evening (concert, films)



A GIFT FOR LIFE

14 October 2005
Palexpo, Geneva, Switzerland

Council of Europe
7th European Day for Organ Donation
and Transplantation

1st World Day for Organ Donation
and Transplantation
With the participation of the World Health Organization

