NEWSLETTER TRANSPLANT

International figures on donation and transplantation 2018

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COUNCIL OF EUROPE
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INTERNATIONAL FIGURES ON ORGAN, TISSUE & HAEMATOPOIETIC STEM CELL DONATION & TRANSPLANTATION ACTIVITIES. DOCUMENTS PRODUCED BY THE COUNCIL OF EUROPE EUROPEAN COMMITTEE (PARTIAL AGREEMENT) ON ORGAN TRANSPLANTATION (CD-P-TO). YEAR 2018.

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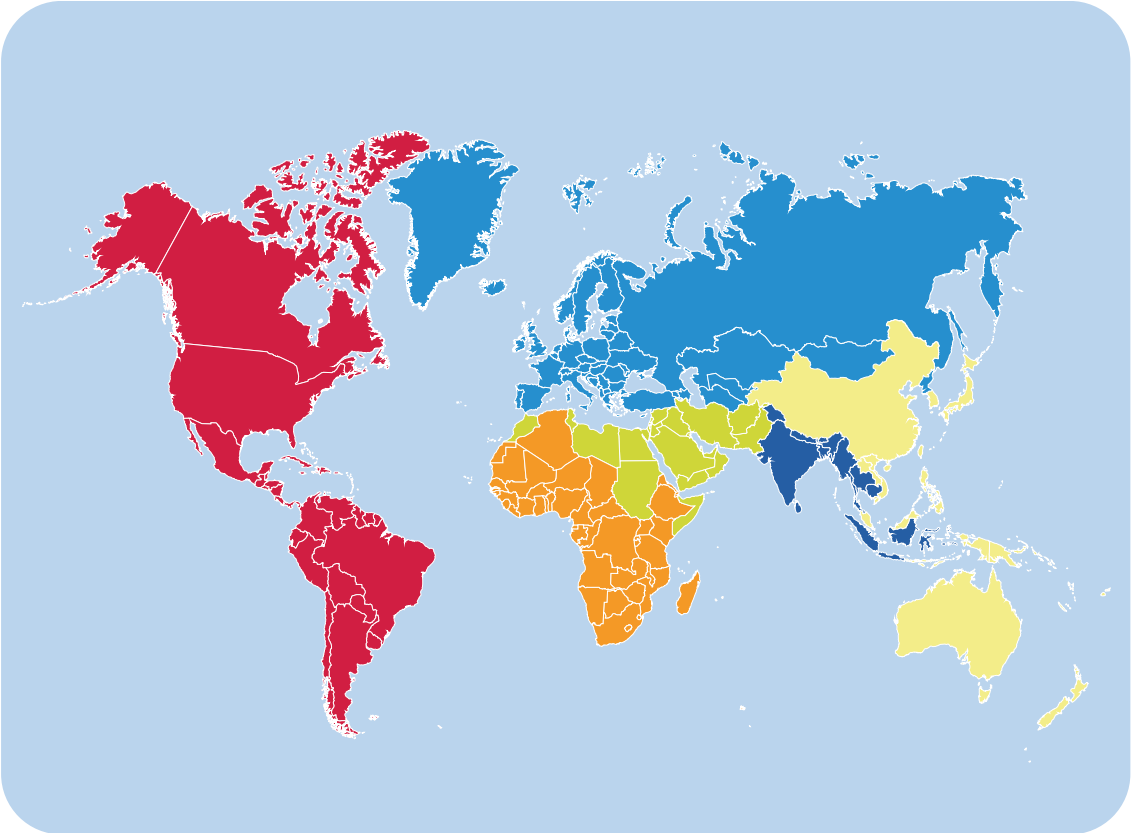


CONTENTS

FOR THE PURPOSES OF THIS NEWSLETTER THE FOLLOWING DEFINITIONS WERE USED:

Actual deceased organ donor
An actual deceased organ donor is a person from whom at least one organ has been recovered for the purpose of transplantation, in contrast to a utilised donor, who is an actual donor from whom at least one organ has been transplanted. The number of utilised donors is therefore lower or equal than the number of actual donors.

Donor after brain death
A donor after brain death (DBD) is a deceased organ donor in whom death has been determined by neurologic criteria.

Donor after circulatory death
A donor after circulatory death (DCD) is a deceased organ donor in whom death has been determined by circulatory and respiratory criteria.

Total Tx (all combinations included)
Includes the transplantation of the corresponding organ with or without the simultaneous transplant of a different type of organ (s).

Double-kidney Tx
One double-kidney Tx is counted as 1 Tx.

Tx from living donors
A living donor is a living human being from whom organs have been recovered for the purpose of transplantation. A living Donor has one of the following relationships with the recipient:

A/ Related: The donor is genetically and/or emotionally related to the recipient.

A1/ Genetically Related: A genetic relation exists between donor and recipient (e.g. brother/sister, parent/offspring).
A2/ Emotionally Related: The donor is a genetically unrelated family member (e.g. spouse) of the recipient or a friend.

B/ Unrelated = Non Related: The donor has no genetic or emotional relationship with the recipient. The relation between donor and recipient must be outlined further by a sub-specification.

B1/ Paired exchange or cross-over: By a controlled programme, unrelated donor and recipient pairs exchange grafts beyond any emotional or genetic relation, with the aim of overcoming immunological restrictions.

B2/ Non-directed altruistic or anonymous: By a controlled programme, the donor can provide a graft to society which allocates this to a previously unknown recipient by defined rules.

B3/ Directed altruistic: By a controlled programme, the donor provides a graft to a recipient of the donor's choice.

Heart-lung Tx
One heart-lung Tx is counted as 1 lung Tx, 1 heart Tx and 1 heart-lung Tx.

Double-lung Tx
One double-lung Tx is counted as 1 Tx.

Total number of patients transplanted
When more than one organ is transplanted into the same recipient, only one recipient is counted (e.g. kidney-liver-heart Tx = counted as one recipient).

Paediatric
Includes only paediatric activity (patients aged < 18 years).

Waiting List (WL)
Example: At 1/1/201X there were 200 patients active on the WL. Along the year, 100 patients are newly included on the WL (first row). In total, 300 patients have been ever active on the WL during the year (second row). Along the year, 200 patients were transplanted (number recorded in a different questionnaire), 50 patients remain active at the end of the year (third row), 25 patients died (fourth row) and 25 patients were excluded (number not to be reported, but derived from previous figures).

Patients included on the WL for the first time in the course of 201X	100
Total number of patients ever active on the WL during 201X	300
Patients awaiting for a transplant (only active candidates) on 31/12/201X	50
Patients who died while on the WL during 201X	25

*(*The United Nations Fund report (UNFPA: http://www.unfpa.org/public/) is used as the data source for estimates of population size)*

Letter from the Editor

Letter from the Editor

Beatriz Domínguez-Gil, MD, PhD
Director Organización Nacional de Trasplantes, Spain
Editor of Newsletter Transplant

Dear friends

It is with pleasure that I introduce a new issue of the *Newsletter Transplant*, one of the most valuable tools produced by the Committee of Transplantation of the Council of Europe (CD-P-TO) in conjunction with the Spanish Organización Nacional de Trasplantes (ONT). Since 1996, this publication has allowed the CD-P-TO to share information on donation and transplantation activities in member states of the Council of Europe (CoE) – and beyond – and to present some of the projects developed by this committee and documents of relevance to the field. The *Newsletter Transplant* is in itself an opportunity to demonstrate the active contribution of the CD-P-TO to secure fundamental human rights, as well as to increase organ availability, improve the effectiveness of transplantation systems and enhance the quality and safety of organs, tissues and cells for clinical use.

Without doubt, monitoring of practices in donation and transplantation of substances of human origin in member states is essential for the sake of transparency and international benchmarking. This is the main aim of the *Newsletter Transplant*, and the reason it has become an international reference. In this new issue, the *Newsletter Transplant* reports data from almost 70 countries throughout the world for the year 2018 (global data refer to 2017). The information presented relates to organ donation and transplantation activities, management of the waiting lists, rate of refusals to organ donation and transplant centres. Data are displayed by age group and gender for both organ donors and recipients. Let me take this opportunity to remind you that the underlying data collection is also hosted by the Global Observatory on Organ Donation and Transplantation (http://www.transplant-observatory.org/) developed and maintained by the ONT on behalf of the World Health Organization. The Observatory allows users to download data and create figures online. For obvious reasons, not all information that is collected from countries is displayed in the *Newsletter Transplant* and the *Observatory*, but additional data can be provided to final users on an ad hoc basis and upon request.

Information presented in the *Newsletter Transplant* is not limited to the organ field, but also covers tissues and cells. Provided by the Centro Nazionale di Trapianti (CNT) in Italy, which conducts the corresponding annual data collection, the *Newsletter Transplant* also presents data on the donation, procurement, processing, distribution and clinical use of tissues and cells from a significant number of countries.

This issue of the *Newsletter Transplant* also presents an important document produced by the CD-P-TO addressing illicit and unethical practices in the field of tissues and cells. In this document, the CD-P-TO analyses the international legal framework that regulates the process of donation and clinical use of tissues and cells of human origin. It concludes that an international agreement is needed to prohibit and criminalise certain unethical practices of particular severity, in terms of violation of the fundamental principles of human dignity and integrity. This work is intended to support decision-making bodies at the Council of Europe to decide on the need to elaborate an Additional Protocol to the Council of Europe *Convention against Trafficking in Human Organs* to address the trafficking of human tissues and cells.

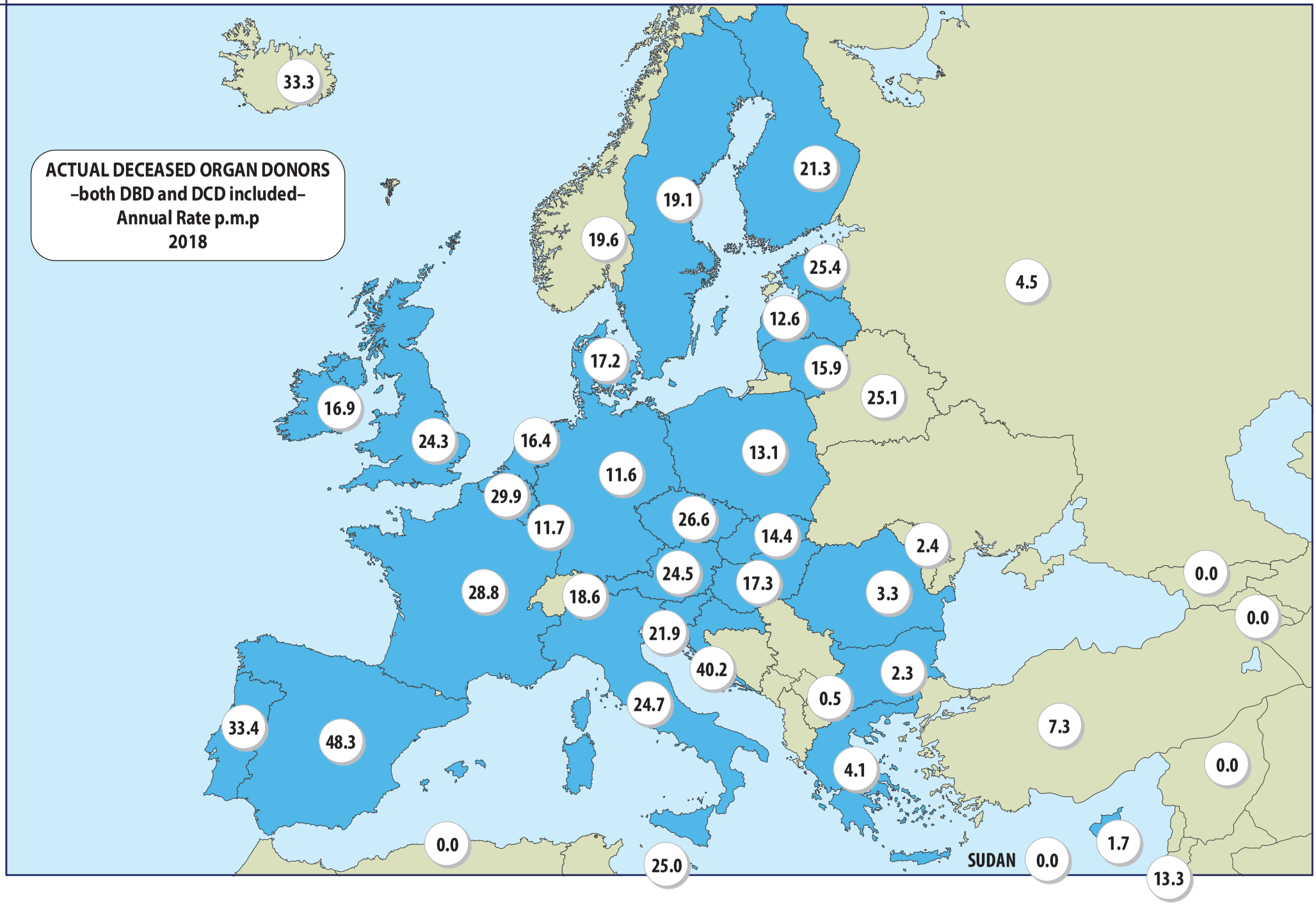
The CD-P-TO has also contributed to the elaboration and dissemination of this Convention, which provides clarity on the practices in the field of organ donation and transplantation that must be criminalised and mechanisms to be strengthened for cooperation and victim protection. This issue of the *Newsletter Transplant* includes the current status of signatures and ratifications and invites countries that have not already done so to move forward in their accession to this important legal instrument.

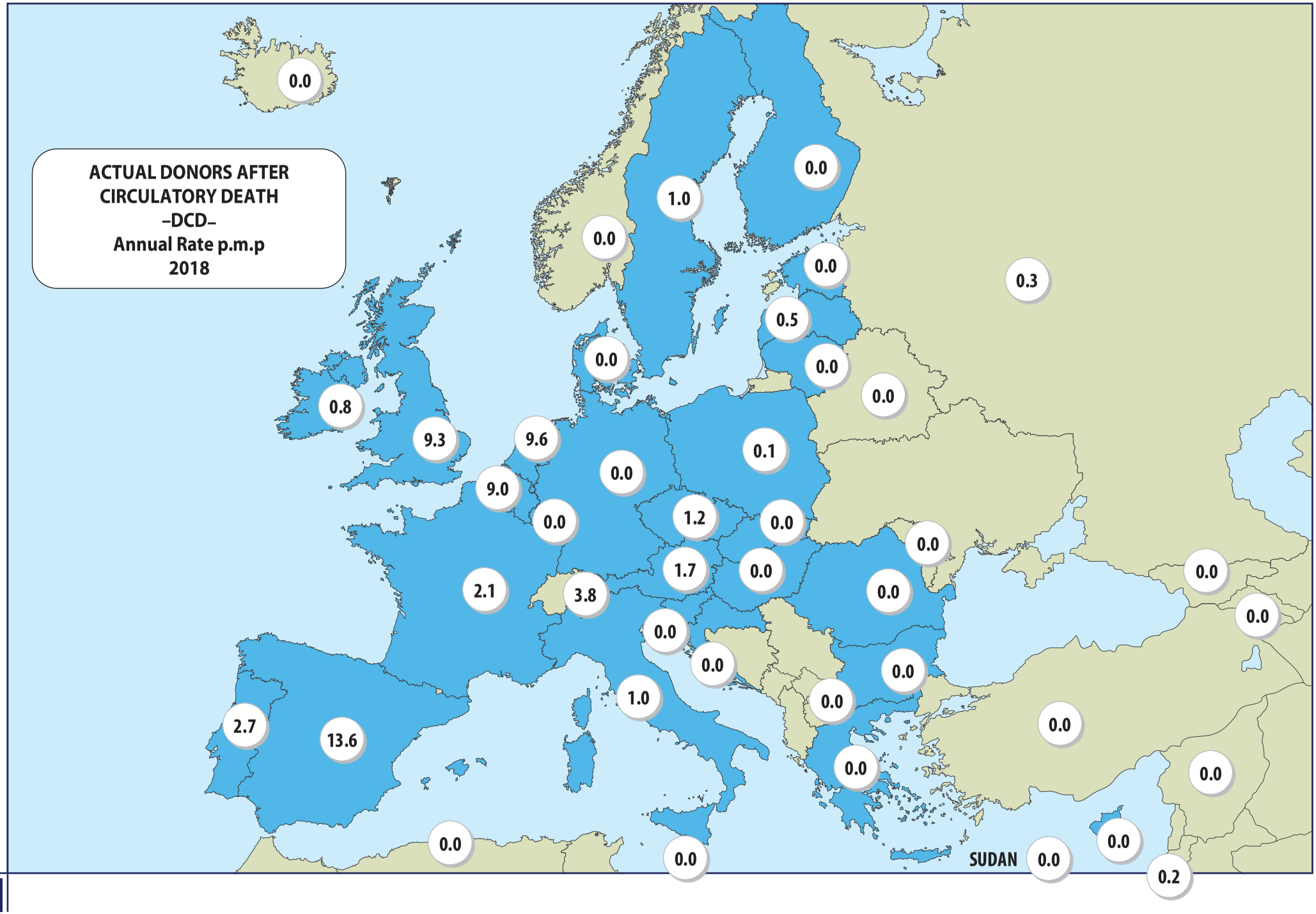
I take this opportunity to remind you of the importance and usefulness of the technical guides in the fields of organs, tissues and cells that are regularly up-

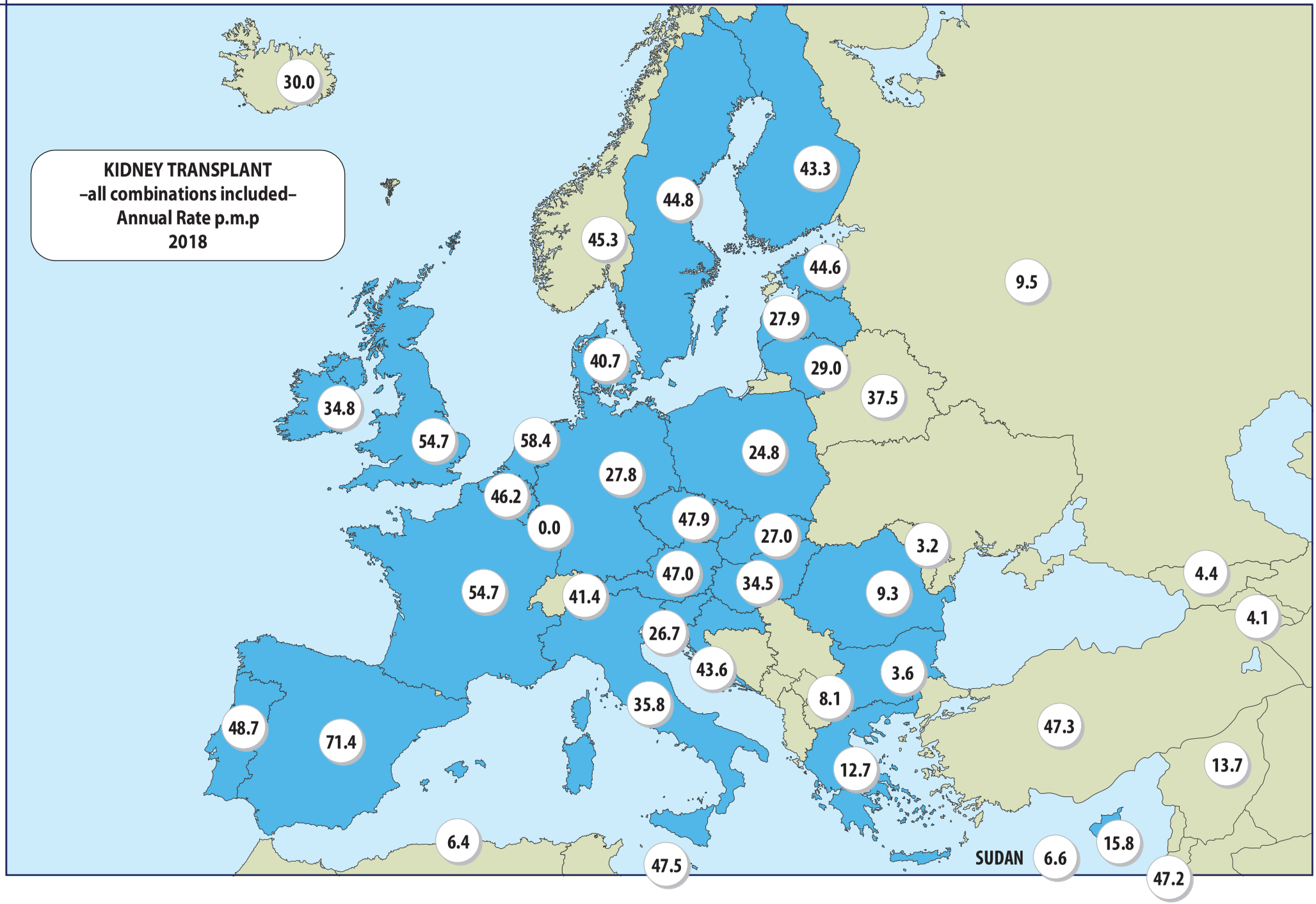
dated by the CD-P-TO. These are invaluable tools for regulators and health professionals throughout Europe and beyond.

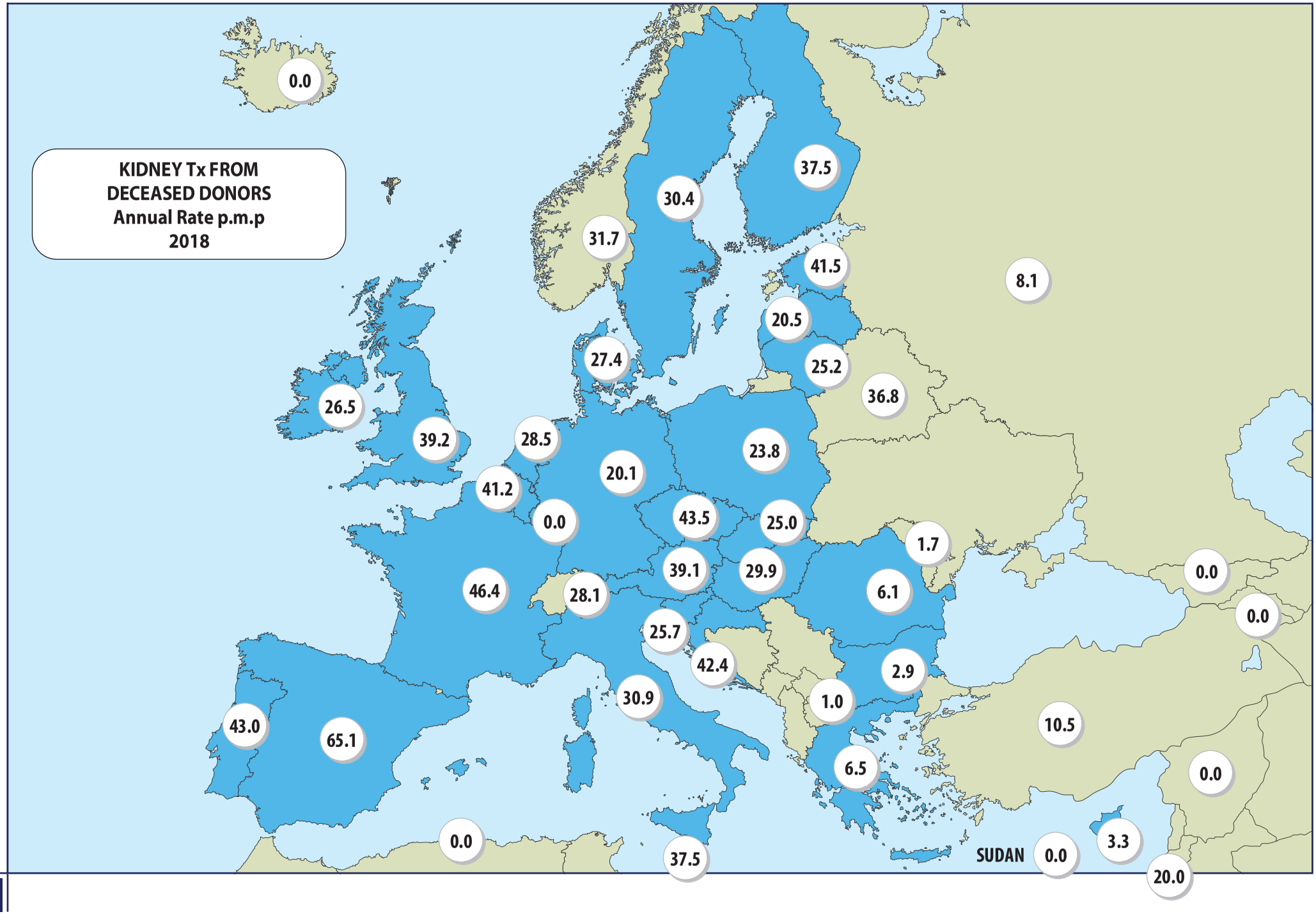
Please allow me to finish this letter by thanking all those who make the *Newsletter Transplant* possible - members of the CD-P-TO, national focal points providing data on a regular basis and the EDQM secretariat. But, most importantly, let me thank the members of the ONT whose continuous work, commitment and enthusiasm are essential for an exercise that every year showcases the European progress in the fascinating field of transplantation.

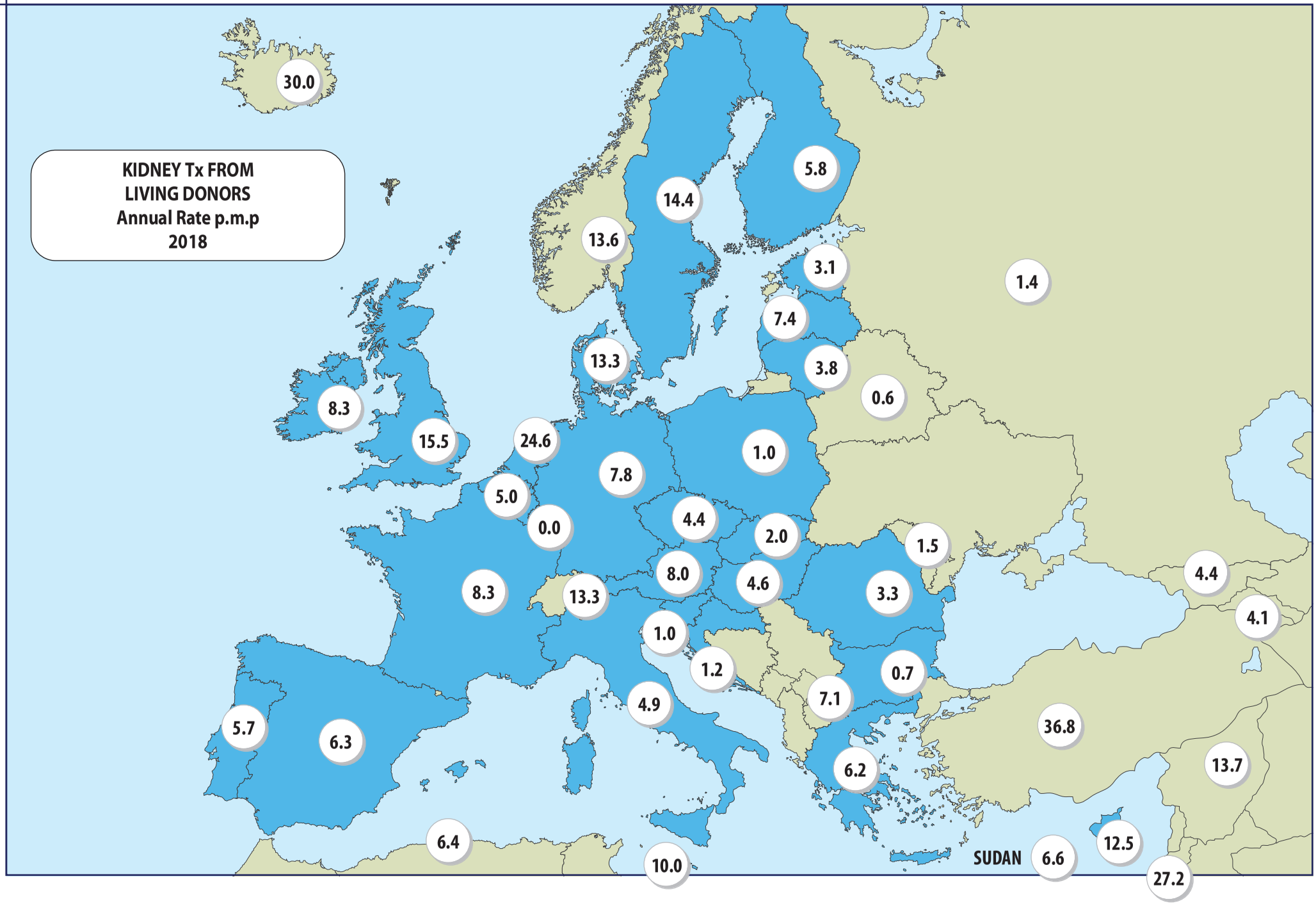
International Figures on Organ Donation and Transplantation Activity. Year 2018

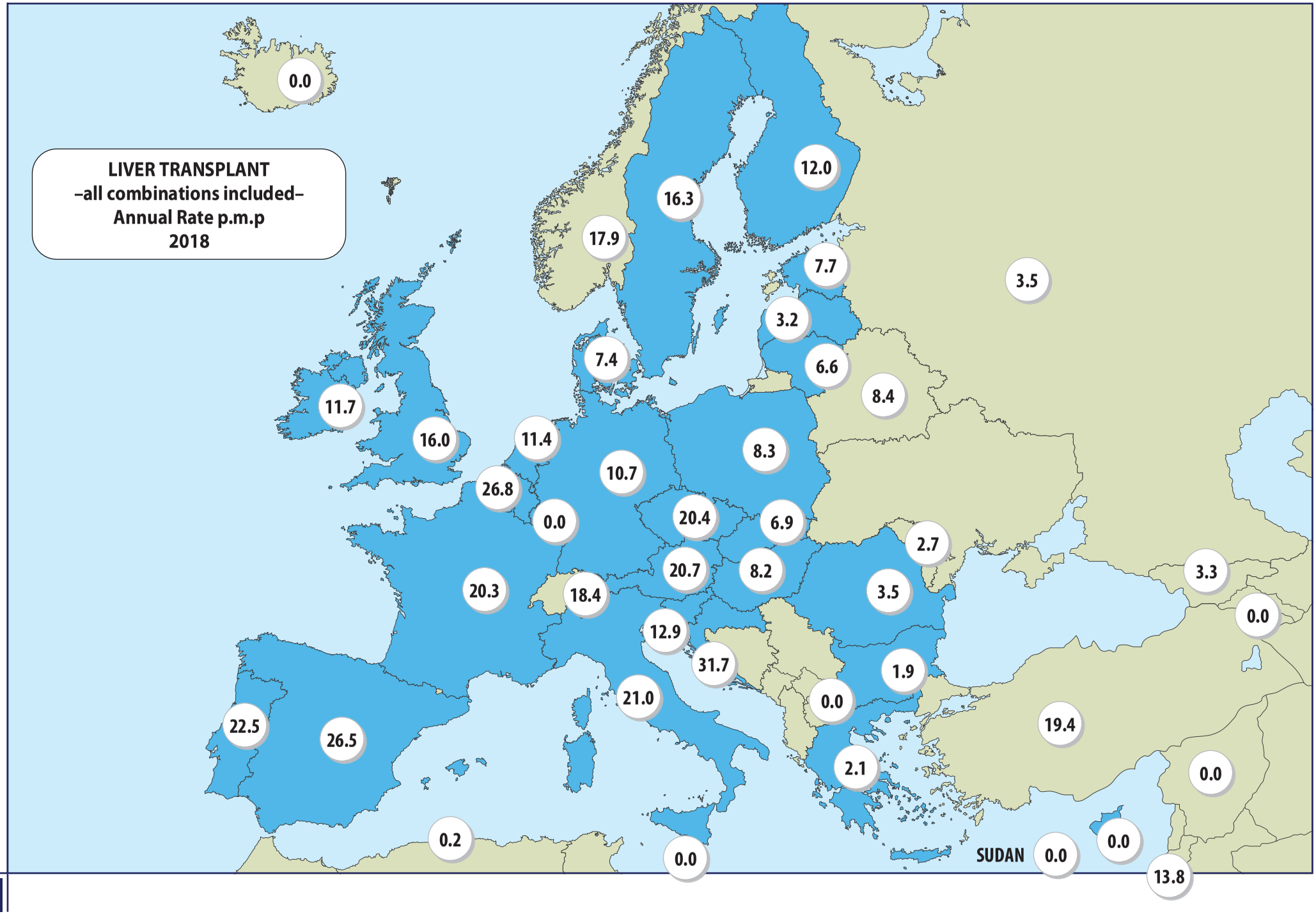

ACTUAL DECEASED ORGAN DONORS
–both DBD and DCD included–
Annual Rate p.m.p
2018
33.3
19.1
21.3
19.6
25.4
4.5
12.6
17.2
15.9
25.1
16.9
24.3
16.4
13.1
11.6
29.9
26.6
11.7
14.4
2.4
24.5
17.3
0.0
28.8
18.6
3.3
0.0
21.9
40.2
2.3
0.5
24.7
33.4
48.3
7.3
4.1
0.0
0.0
1.7
SUDAN
0.0
13.3
25.0

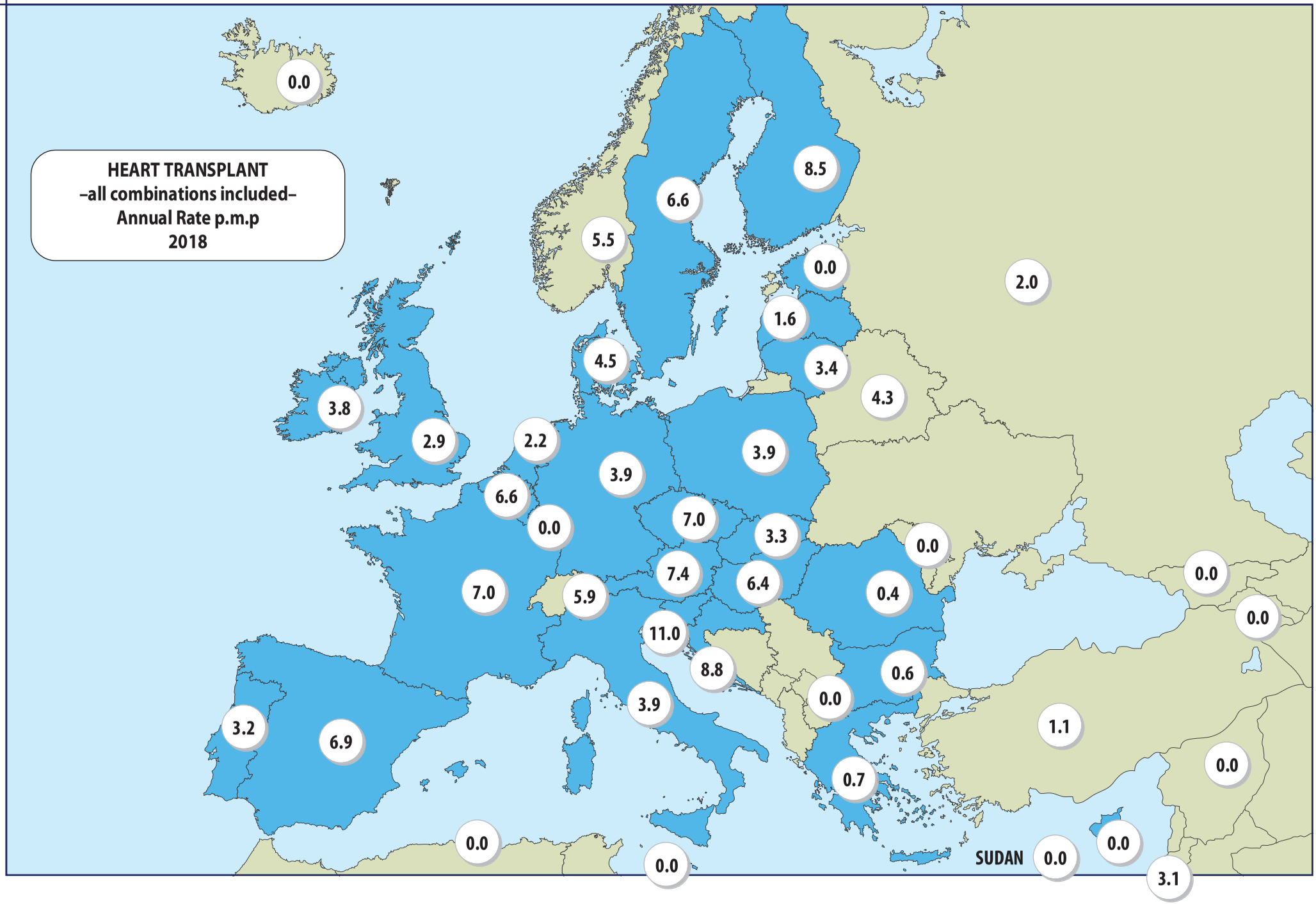

ACTUAL DONORS AFTER
CIRCULATORY DEATH
–DCD–
Annual Rate p.m.p
2018
0.0
0.0
1.0
0.0
0.0
0.3
0.5
0.0
0.0
0.0
0.8
9.3
9.6
0.0
0.1
9.0
0.0
1.2
0.0
0.0
1.7
0.0
0.0
2.1
3.8
0.0
0.0
0.0
0.0
0.0
1.0
0.0
2.7
13.6
0.0
0.0
0.0
0.0
0.0
0.0
0.0
SUDAN
0.0
0.0
0.2

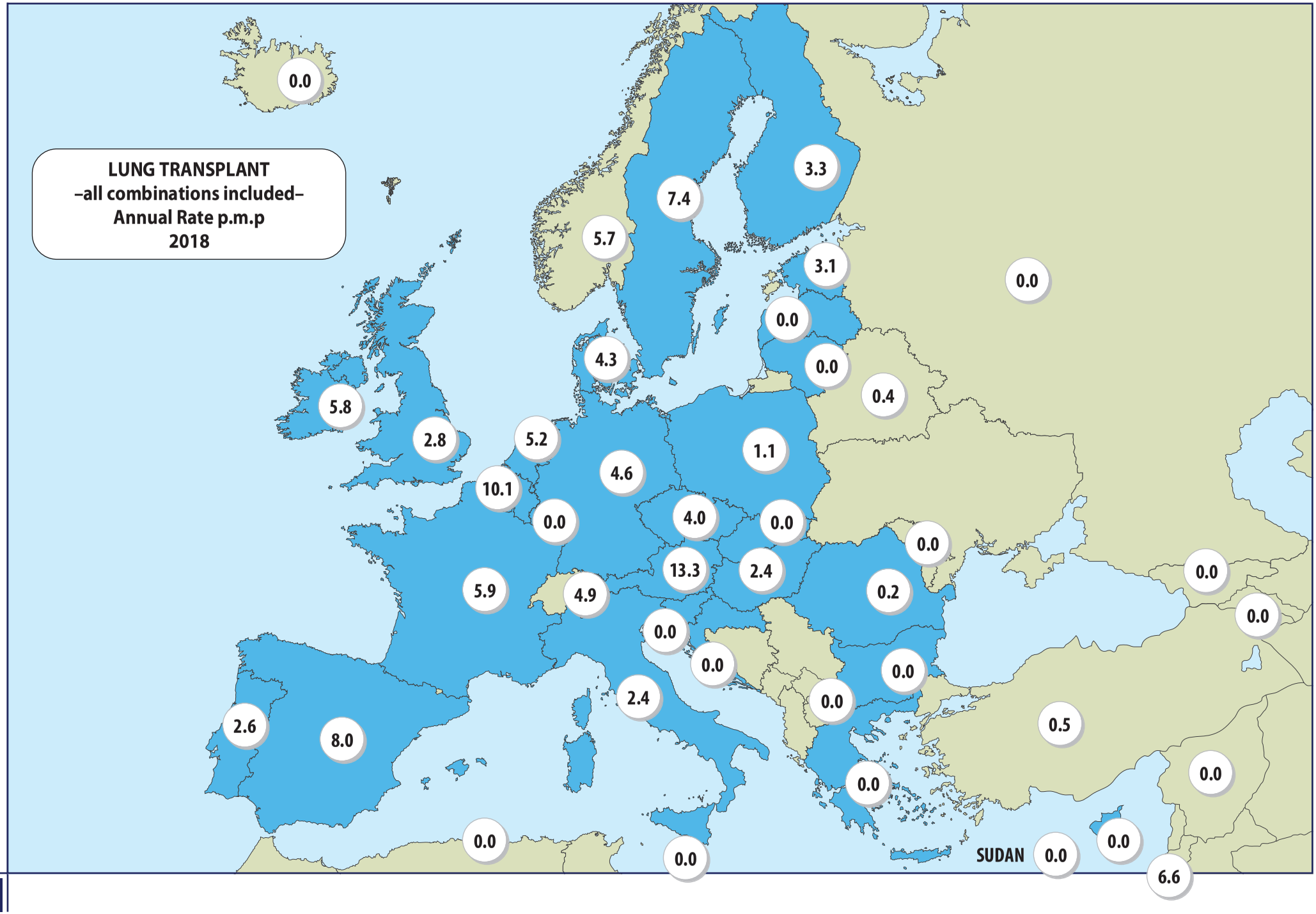

KIDNEY TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
30.0
43.3
44.8
45.3
44.6
9.5
27.9
40.7
29.0
37.5
34.8
54.7
58.4
24.8
27.8
46.2
0.0
47.9
27.0
3.2
47.0
34.5
4.4
54.7
41.4
9.3
4.1
26.7
43.6
3.6
35.8
8.1
48.7
71.4
47.3
12.7
13.7
6.4
47.5
SUDAN
6.6
15.8
47.2

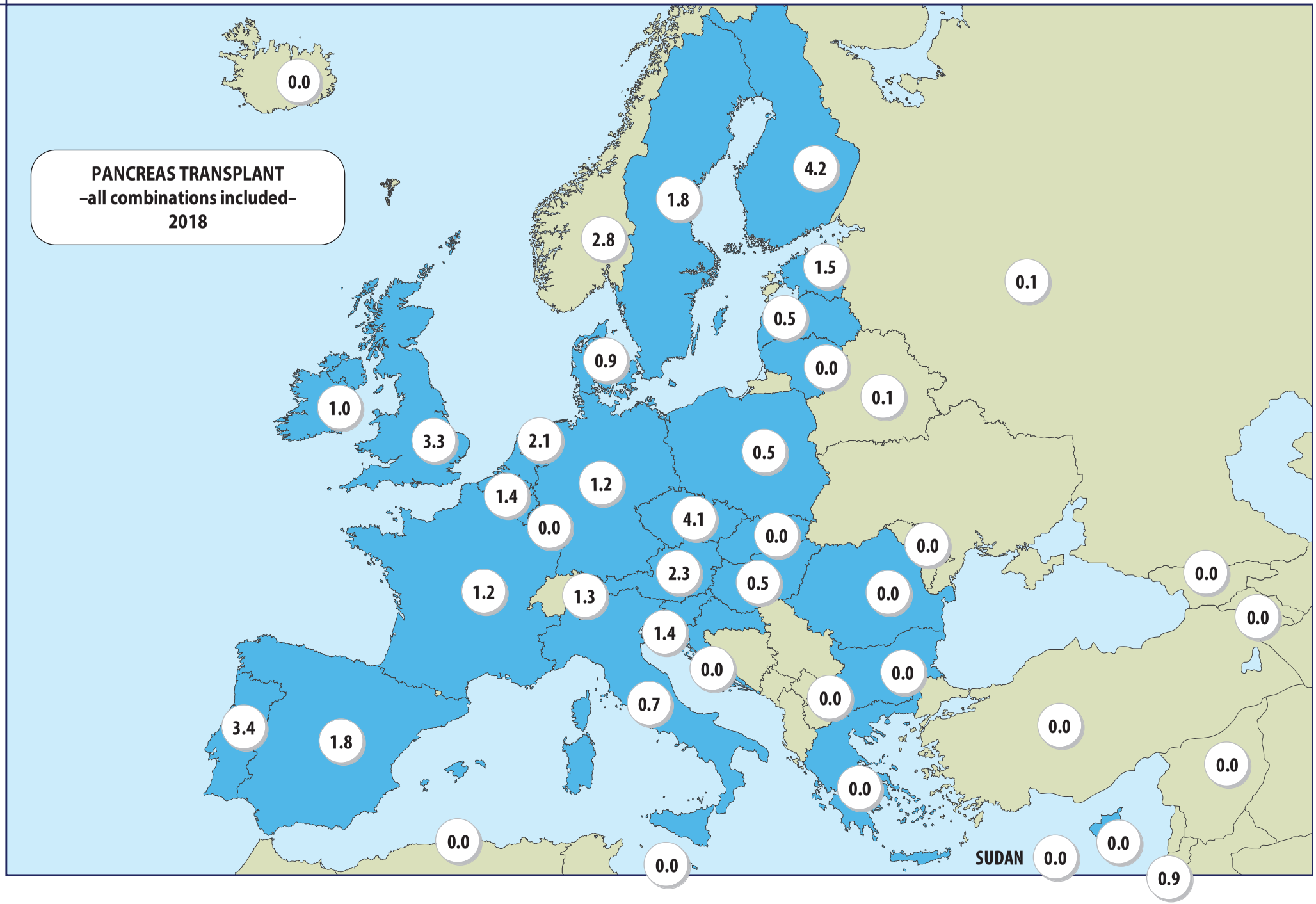

KIDNEY Tx FROM
DECEASED DONORS
Annual Rate p.m.p
2018
0.0
37.5
30.4
31.7
41.5
8.1
20.5
27.4
25.2
36.8
26.5
39.2
28.5
23.8
20.1
41.2
0.0
43.5
25.0
1.7
39.1
29.9
0.0
46.4
28.1
6.1
0.0
25.7
42.4
2.9
30.9
1.0
43.0
65.1
10.5
6.5
0.0
0.0
37.5
SUDAN
0.0
3.3
20.0

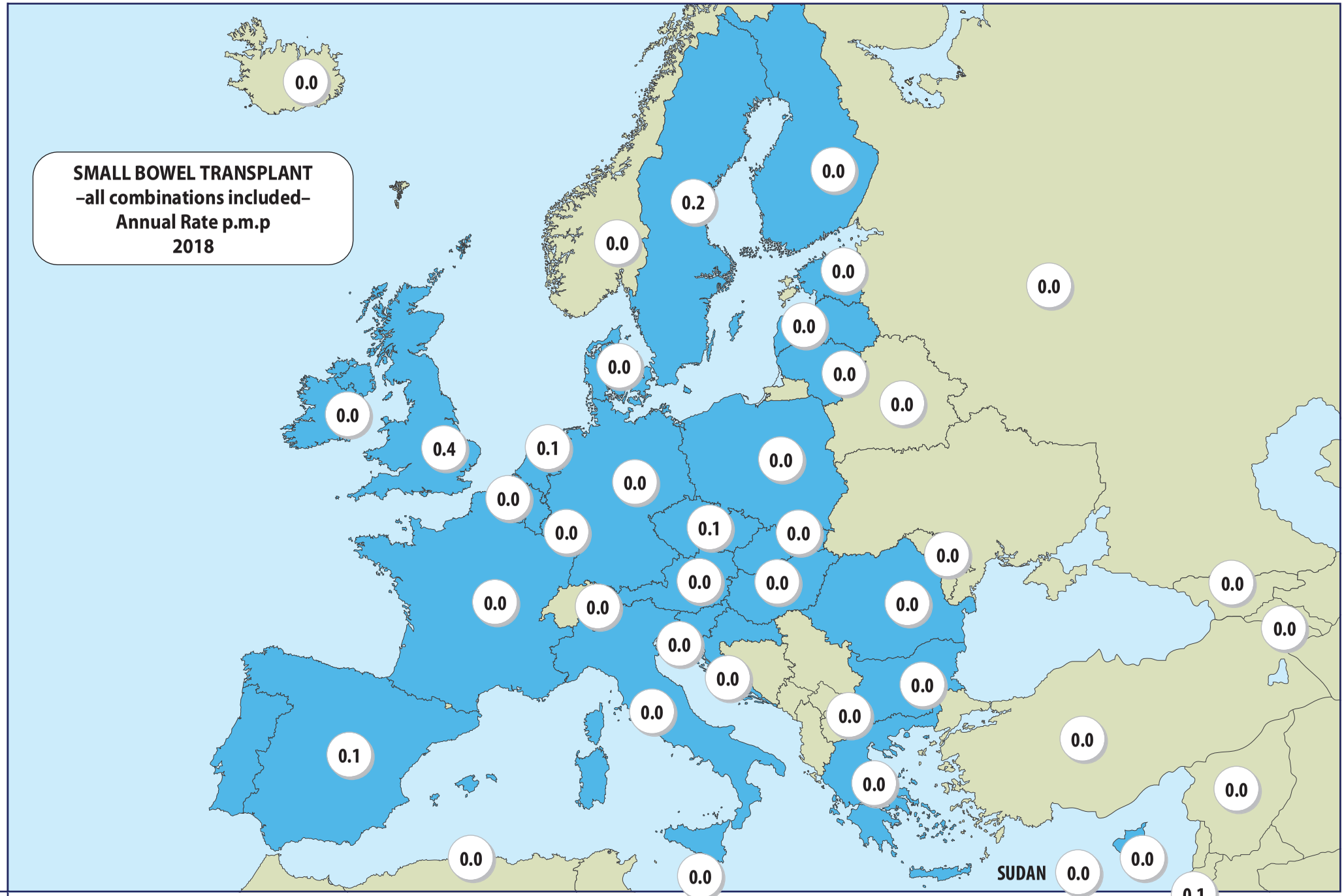

KIDNEY Tx FROM
LIVING DONORS
Annual Rate p.m.p
2018
30.0
14.4
5.8
13.6
3.1
1.4
7.4
13.3
3.8
8.3
0.6
15.5
24.6
1.0
7.8
5.0
4.4
0.0
2.0
1.5
8.0
4.6
4.4
8.3
13.3
3.3
4.1
1.0
1.2
0.7
7.1
4.9
5.7
6.3
36.8
6.2
13.7
6.4
10.0
SUDAN
6.6
12.5
27.2

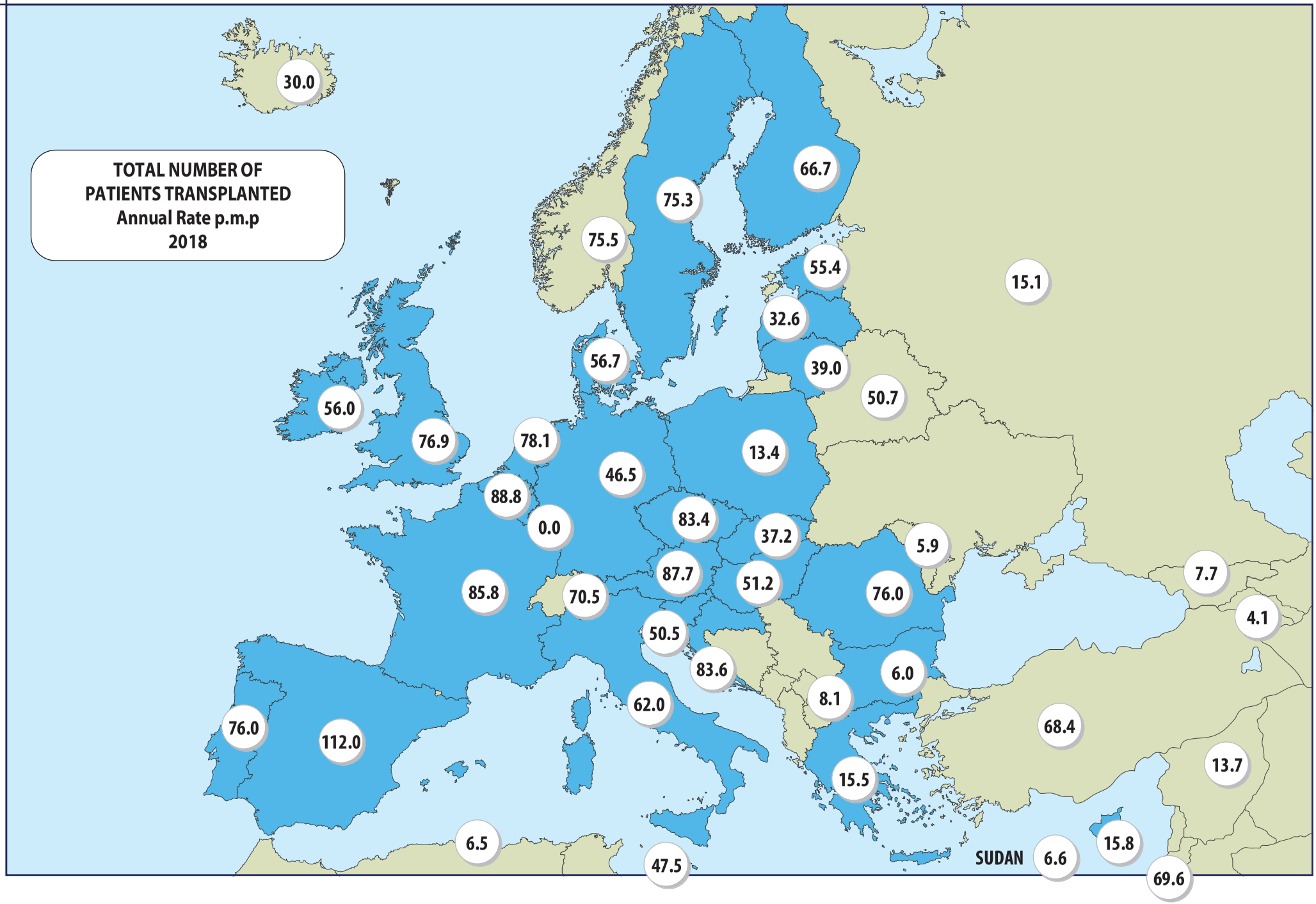

LIVER TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
0.0
12.0
16.3
17.9
7.7
3.5
3.2
7.4
6.6
8.4
11.7
16.0
11.4
8.3
10.7
26.8
0.0
20.4
6.9
2.7
20.7
8.2
3.3
20.3
18.4
3.5
0.0
12.9
31.7
1.9
21.0
0.0
22.5
26.5
19.4
2.1
0.0
0.2
0.0
SUDAN
0.0
0.0
13.8


HEART TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
0.0
8.5
6.6
5.5
0.0
2.0
1.6
4.5
3.4
4.3
3.8
2.9
2.2
3.9
3.9
6.6
0.0
7.0
3.3
0.0
7.4
6.4
0.4
7.0
5.9
0.0
0.0
11.0
8.8
0.6
0.0
3.9
3.2
6.9
1.1
0.0
0.7
0.0
0.0
SUDAN
0.0
0.0
3.1

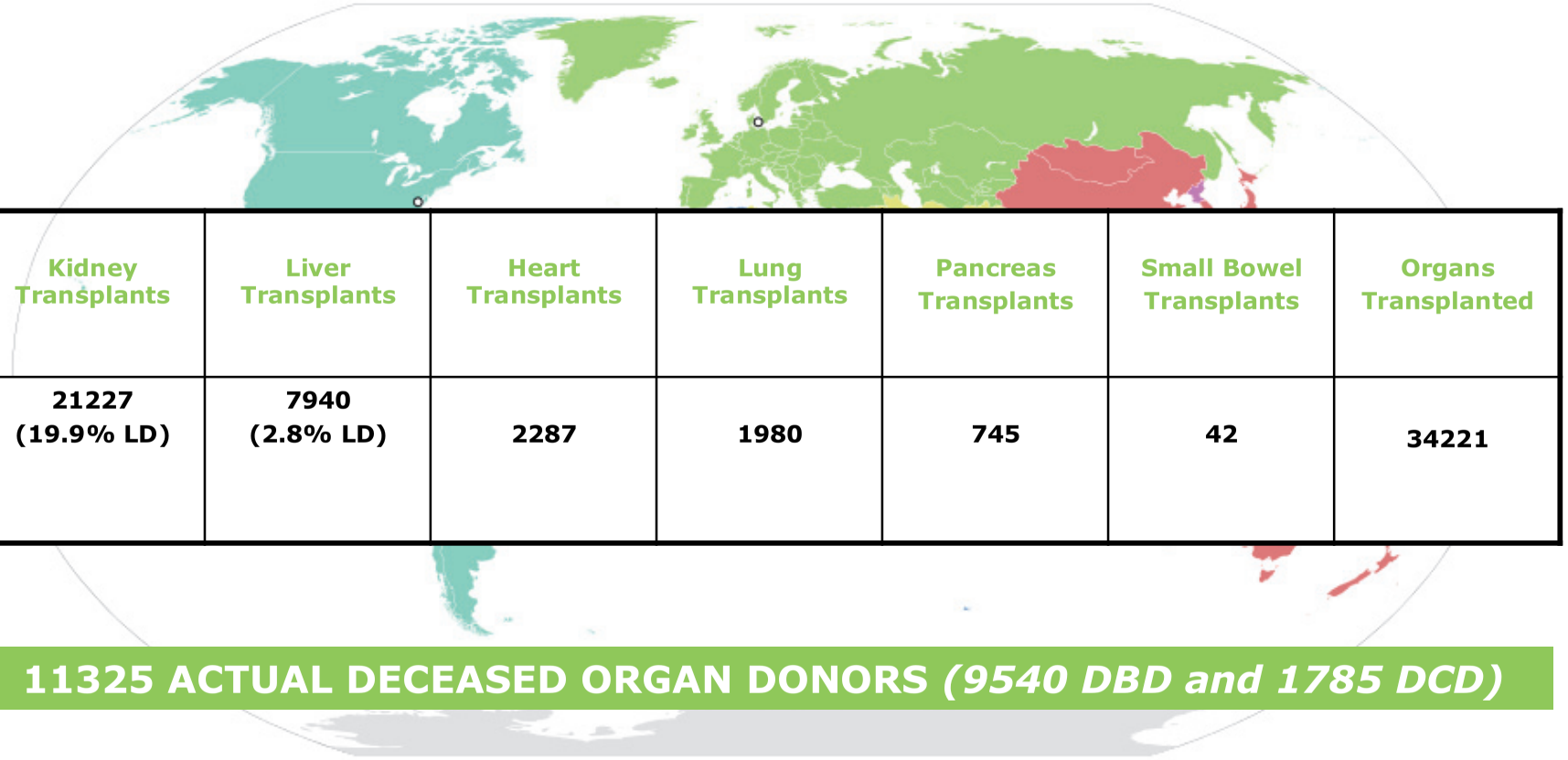

LUNG TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
0.0
3.3
7.4
5.7
3.1
0.0
0.0
0.0
4.3
0.4
5.8
2.8
5.2
1.1
4.6
10.1
0.0
4.0
0.0
0.0
13.3
2.4
0.2
0.0
0.0
5.9
4.9
0.0
0.0
0.0
0.0
2.4
0.0
0.5
2.6
8.0
0.0
0.0
0.0
0.0
SUDAN
0.0
0.0
6.6


PANCREAS TRANSPLANT
–all combinations included–
2018
0.0
4.2
1.8
2.8
1.5
0.1
0.5
0.9
0.0
1.0
0.1
3.3
2.1
0.5
1.2
1.4
4.1
0.0
0.0
0.0
2.3
0.0
0.5
1.2
1.3
0.0
0.0
1.4
0.0
0.0
0.7
3.4
1.8
0.0
0.0
SUDAN
0.0
0.0
0.9


SMALL BOWEL TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
0.0
0.2
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.4
0.1
0.0
0.0
0.0
0.0
0.1
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.1
0.0
0.0
0.0
SUDAN
0.0
0.0
0.1


TOTAL NUMBER OF
PATIENTS TRANSPLANTED
Annual Rate p.m.p
2018
30.0
66.7
75.3
75.5
55.4
15.1
32.6
56.7
39.0
50.7
56.0
76.9
78.1
13.4
46.5
88.8
83.4
0.0
37.2
5.9
87.7
51.2
76.0
7.7
85.8
70.5
4.1
50.5
83.6
6.0
8.1
62.0
76.0
112.0
68.4
13.7
15.5
6.5
47.5
SUDAN
6.6
15.8
69.6

EUROPEAN UNION DATA

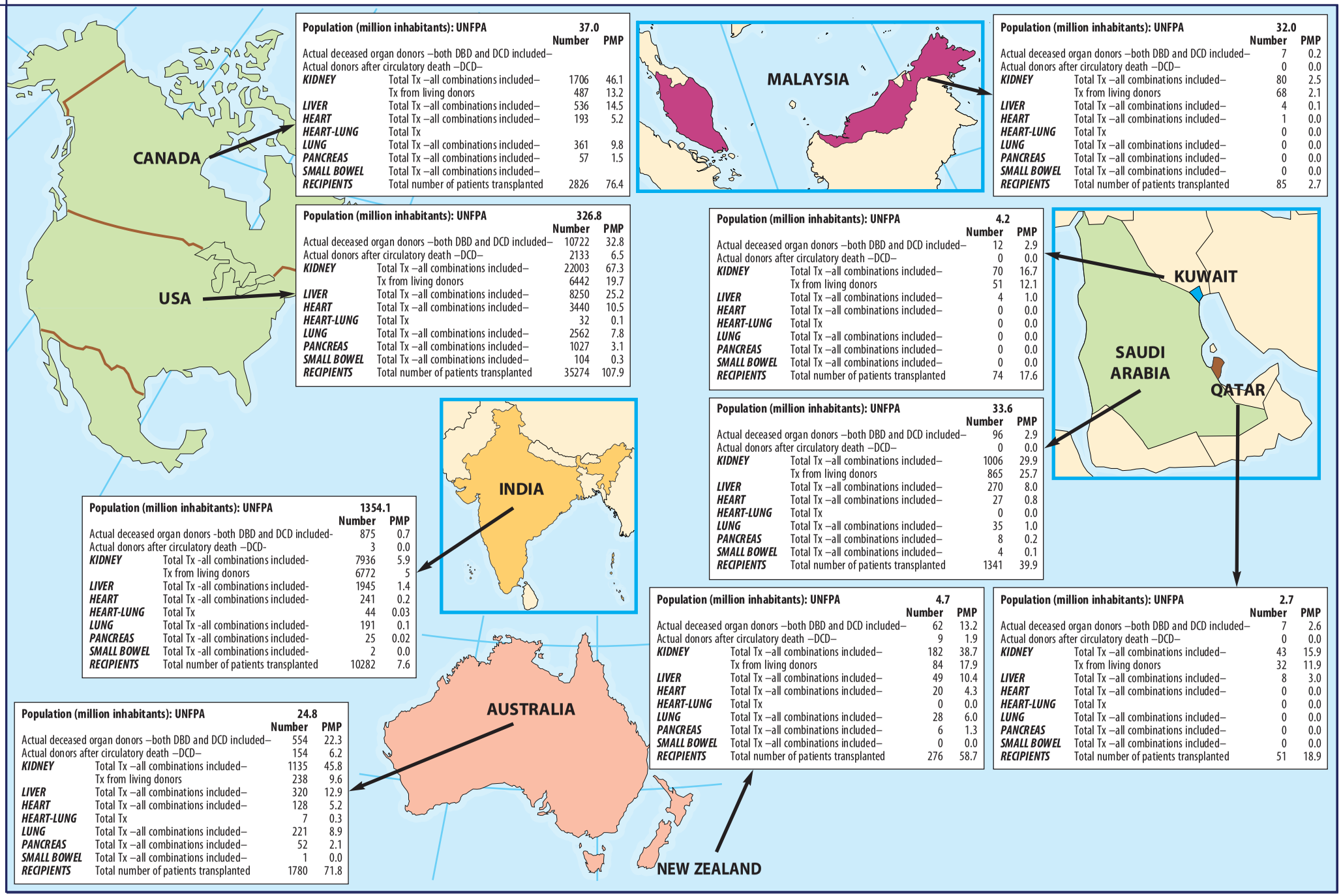


Kidney Transplants	Liver Transplants	Heart Transplants	Lung Transplants	Pancreas Transplants	Small Bowel Transplants	Organs Transplanted
21227 (19.9% LD)	7940 (2.8% LD)	2287	1980	745	42	34221

11325 ACTUAL DECEASED ORGAN DONORS *(9540 DBD and 1785 DCD)*

2018 data

N= 28 COUNTRIES (509.7 million inhabitants)



Population (million inhabitants): UNFPA 37.0

		Number	PMP
Actual deceased organ donors –both DBD and DCD included–			
Actual donors after circulatory death –DCD–			
KIDNEY	Total Tx –all combinations included–	1706	46.1
	Tx from living donors	487	13.2
LIVER	Total Tx –all combinations included–	536	14.5
HEART	Total Tx –all combinations included–	193	5.2
HEART-LUNG	Total Tx		
LUNG	Total Tx –all combinations included–	361	9.8
PANCREAS	Total Tx –all combinations included–	57	1.5
SMALL BOWEL	Total Tx –all combinations included–		
RECIPIENTS	Total number of patients transplanted	2826	76.4

Population (million inhabitants): UNFPA 326.8

		Number	PMP
Actual deceased organ donors –both DBD and DCD included–		10722	32.8
Actual donors after circulatory death –DCD–		2133	6.5
KIDNEY	Total Tx –all combinations included–	22003	67.3
	Tx from living donors	6442	19.7
LIVER	Total Tx –all combinations included–	8250	25.2
HEART	Total Tx –all combinations included–	3440	10.5
HEART-LUNG	Total Tx	32	0.1
LUNG	Total Tx –all combinations included–	2562	7.8
PANCREAS	Total Tx –all combinations included–	1027	3.1
SMALL BOWEL	Total Tx –all combinations included–	104	0.3
RECIPIENTS	Total number of patients transplanted	35274	107.9

Population (million inhabitants): UNFPA 1354.1

		Number	PMP
Actual deceased organ donors -both DBD and DCD included-		875	0.7
Actual donors after circulatory death –DCD-		3	0.0
KIDNEY	Total Tx -all combinations included-	7936	5.9
	Tx from living donors	6772	5
LIVER	Total Tx -all combinations included-	1945	1.4
HEART	Total Tx -all combinations included-	241	0.2
HEART-LUNG	Total Tx	44	0.03
LUNG	Total Tx -all combinations included-	191	0.1
PANCREAS	Total Tx -all combinations included-	25	0.02
SMALL BOWEL	Total Tx -all combinations included-	2	0.0
RECIPIENTS	Total number of patients transplanted	10282	7.6

Population (million inhabitants): UNFPA 24.8

		Number	PMP
Actual deceased organ donors –both DBD and DCD included–		554	22.3
Actual donors after circulatory death –DCD–		154	6.2
KIDNEY	Total Tx –all combinations included–	1135	45.8
	Tx from living donors	238	9.6
LIVER	Total Tx –all combinations included–	320	12.9
HEART	Total Tx –all combinations included–	128	5.2
HEART-LUNG	Total Tx	7	0.3
LUNG	Total Tx –all combinations included–	221	8.9
PANCREAS	Total Tx –all combinations included–	52	2.1
SMALL BOWEL	Total Tx –all combinations included–	1	0.0
RECIPIENTS	Total number of patients transplanted	1780	71.8

Population (million inhabitants): UNFPA 32.0

		Number	PMP
Actual deceased organ donors –both DBD and DCD included–		7	0.2
Actual donors after circulatory death –DCD–		0	0.0
KIDNEY	Total Tx –all combinations included–	80	2.5
	Tx from living donors	68	2.1
LIVER	Total Tx –all combinations included–	4	0.1
HEART	Total Tx –all combinations included–	1	0.0
HEART-LUNG	Total Tx	0	0.0
LUNG	Total Tx –all combinations included–	0	0.0
PANCREAS	Total Tx –all combinations included–	0	0.0
SMALL BOWEL	Total Tx –all combinations included–	0	0.0
RECIPIENTS	Total number of patients transplanted	85	2.7

Population (million inhabitants): UNFPA 4.2

		Number	PMP
Actual deceased organ donors –both DBD and DCD included–		12	2.9
Actual donors after circulatory death –DCD–		0	0.0
KIDNEY	Total Tx –all combinations included–	70	16.7
	Tx from living donors	51	12.1
LIVER	Total Tx –all combinations included–	4	1.0
HEART	Total Tx –all combinations included–	0	0.0
HEART-LUNG	Total Tx	0	0.0
LUNG	Total Tx –all combinations included–	0	0.0
PANCREAS	Total Tx –all combinations included–	0	0.0
SMALL BOWEL	Total Tx –all combinations included–	0	0.0
RECIPIENTS	Total number of patients transplanted	74	17.6

Population (million inhabitants): UNFPA 33.6

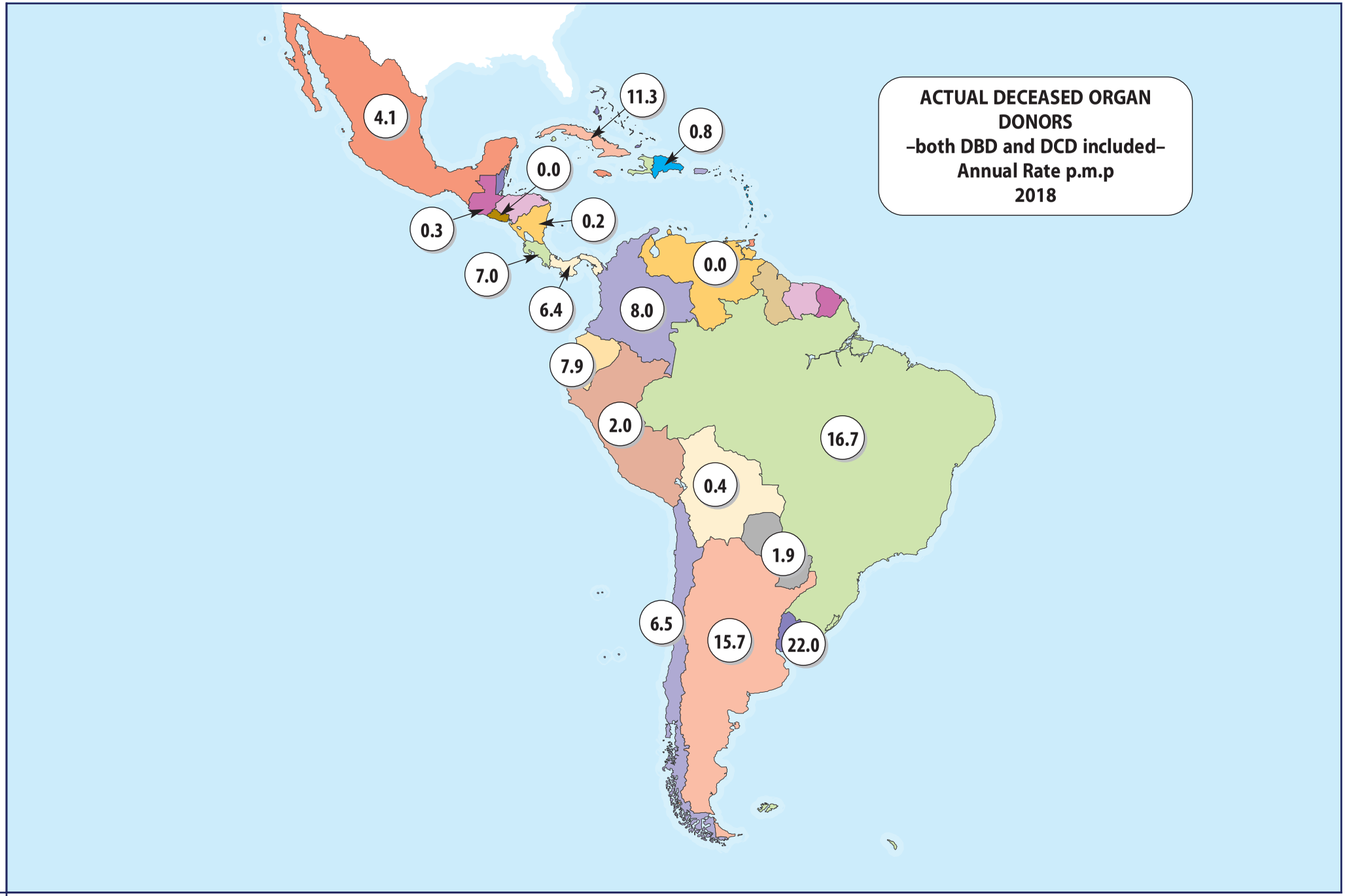
		Number	PMP
Actual deceased organ donors –both DBD and DCD included–		96	2.9
Actual donors after circulatory death –DCD–		0	0.0
KIDNEY	Total Tx –all combinations included–	1006	29.9
	Tx from living donors	865	25.7
LIVER	Total Tx –all combinations included–	270	8.0
HEART	Total Tx –all combinations included–	27	0.8
HEART-LUNG	Total Tx	0	0.0
LUNG	Total Tx –all combinations included–	35	1.0
PANCREAS	Total Tx –all combinations included–	8	0.2
SMALL BOWEL	Total Tx –all combinations included–	4	0.1
RECIPIENTS	Total number of patients transplanted	1341	39.9

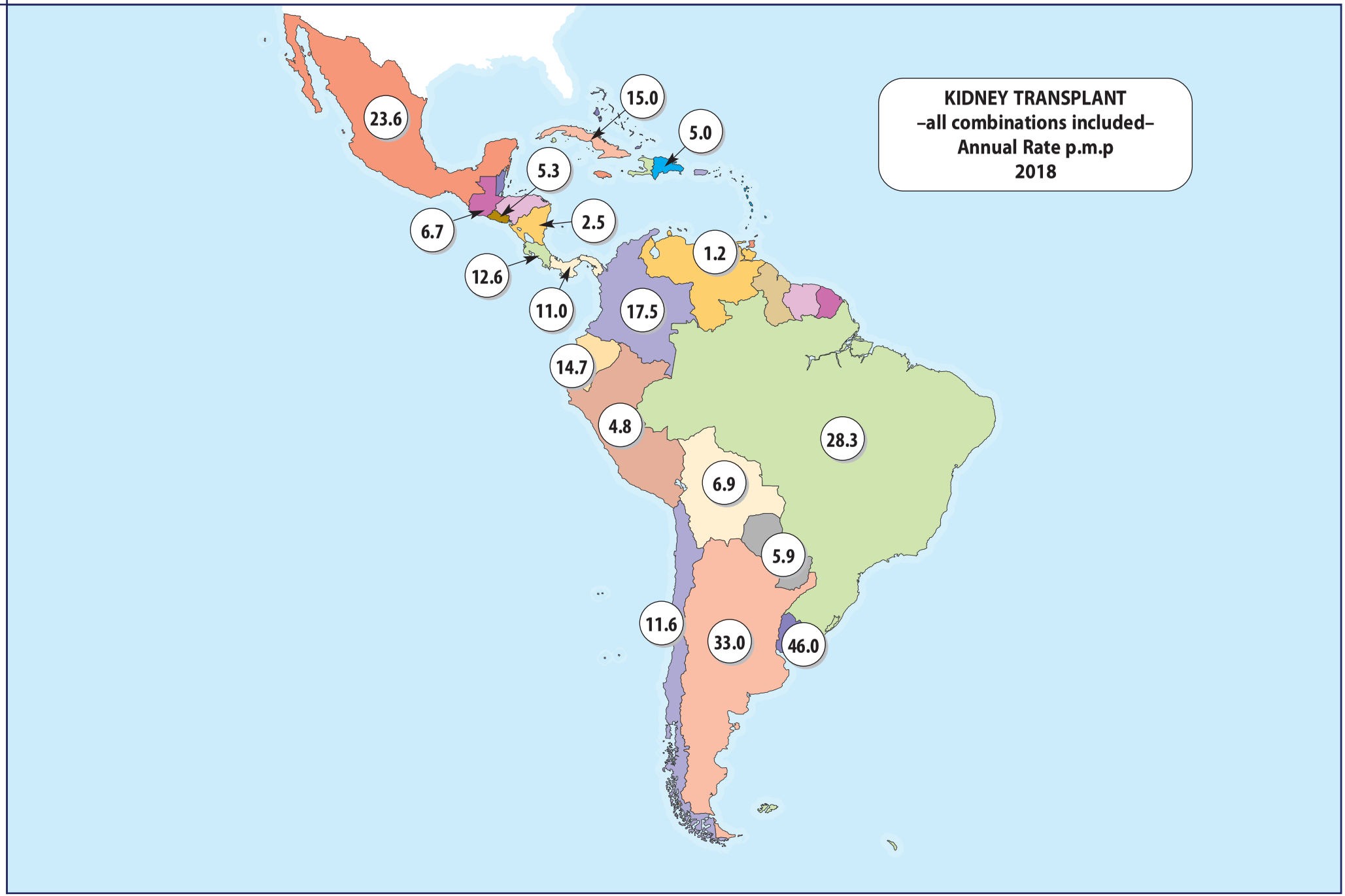
Population (million inhabitants): UNFPA 4.7

		Number	PMP
Actual deceased organ donors –both DBD and DCD included–		62	13.2
Actual donors after circulatory death –DCD–		9	1.9
KIDNEY	Total Tx –all combinations included–	182	38.7
	Tx from living donors	84	17.9
LIVER	Total Tx –all combinations included–	49	10.4
HEART	Total Tx –all combinations included–	20	4.3
HEART-LUNG	Total Tx	0	0.0
LUNG	Total Tx –all combinations included–	28	6.0
PANCREAS	Total Tx –all combinations included–	6	1.3
SMALL BOWEL	Total Tx –all combinations included–	0	0.0
RECIPIENTS	Total number of patients transplanted	276	58.7

Population (million inhabitants): UNFPA 2.7

		Number	PMP
Actual deceased organ donors –both DBD and DCD included–		7	2.6
Actual donors after circulatory death –DCD–		0	0.0
KIDNEY	Total Tx –all combinations included–	43	15.9
	Tx from living donors	32	11.9
LIVER	Total Tx –all combinations included–	8	3.0
HEART	Total Tx –all combinations included–	0	0.0
HEART-LUNG	Total Tx	0	0.0
LUNG	Total Tx –all combinations included–	0	0.0
PANCREAS	Total Tx –all combinations included–	0	0.0
SMALL BOWEL	Total Tx –all combinations included–	0	0.0
RECIPIENTS	Total number of patients transplanted	51	18.9


ACTUAL DECEASED ORGAN DONORS
–both DBD and DCD included–
Annual Rate p.m.p
2018
4.1
11.3
0.8
0.0
0.3
0.2
7.0
6.4
0.0
8.0
7.9
2.0
16.7
0.4
1.9
6.5
15.7
22.0


KIDNEY TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
23.6
15.0
5.0
5.3
2.5
6.7
12.6
11.0
1.2
17.5
14.7
4.8
28.3
6.9
5.9
11.6
33.0
46.0


KIDNEY Tx FROM DECEASED DONORS
Annual Rate p.m.p
2018
7.5
13.9
1.2
0.0
0.6
0.2
8.4
0.0
9.0
14.6
13.4
3.5
23.4
0.7
3.6
24.6
42.3


KIDNEY Tx FROM
LIVING DONORS
Annual Rate p.m.p
2018
16.1
1.1
3.8
5.3
6.1
2.4
4.2
1.9
1.2
2.8
1.3
1.3
4.9
6.8
2.3
8.4
3.7

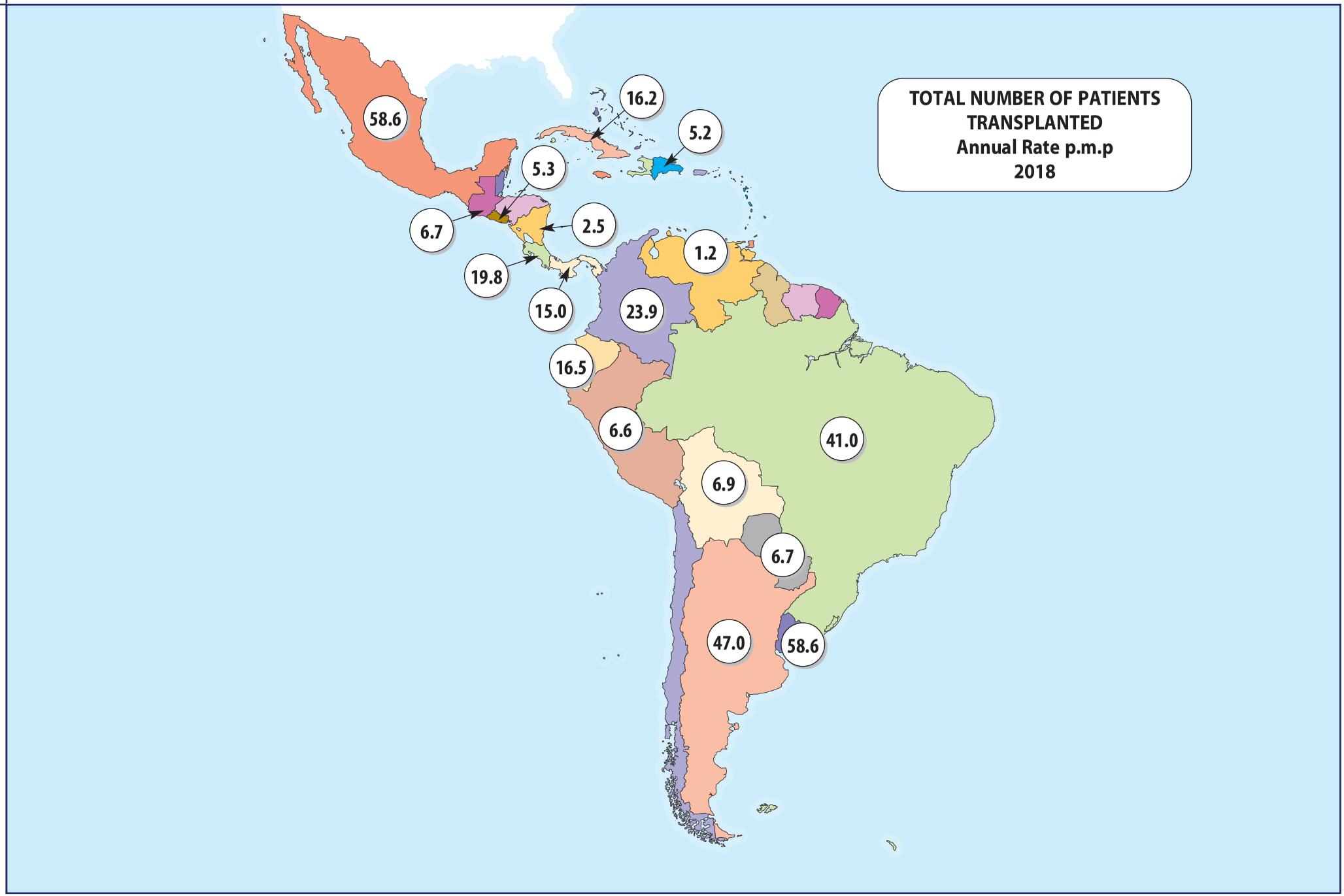

LIVER TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
1.8
1.1
0.3
0.0
0.0
0.0
0.0
5.4
3.8
5.1
1.7
1.4
10.5
0.1
0.4
4.8
10.6
7.1


HEART TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
0.2
0.0
0.0
0.0
0.0
0.0
1.6
0.2
0.0
1.2
0.0
0.4
1.7
0.0
0.3
1.6
3.0
4.0

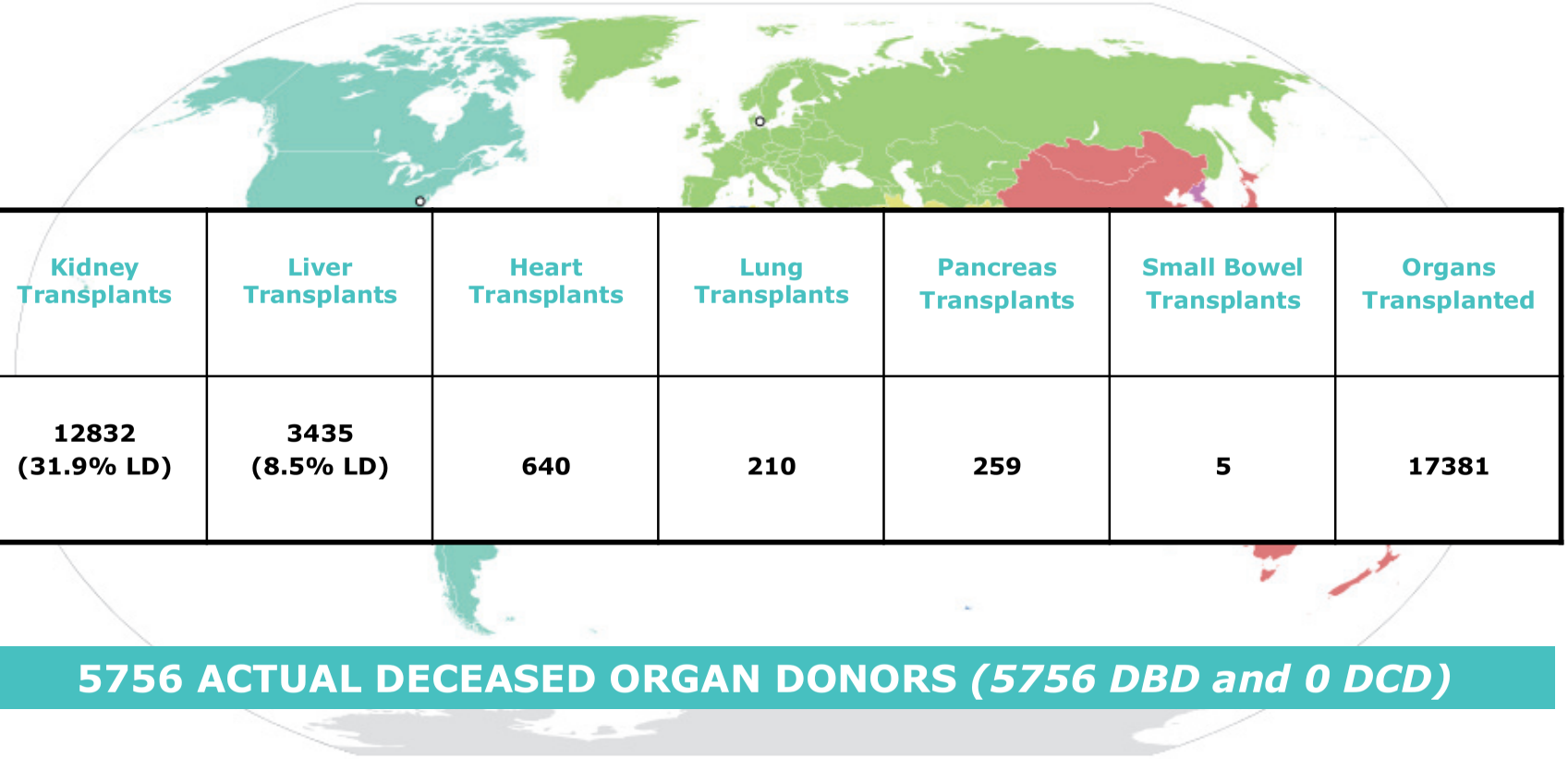

LUNG TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
0.0
0.0
0.0
0.0
0.0
0.0
0.4
0.0
0.3
0.1
0.1
0.6
0.0
0.0
0.7
1.0
1.4


PANCREAS TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.2
0.0
0.1
0.7
0.0
0.0
0.4
2.0
0.0


SMALL BOWEL TRANSPLANT
–all combinations included–
Annual Rate p.m.p
2018
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0
0.0


TOTAL NUMBER OF PATIENTS
TRANSPLANTED
Annual Rate p.m.p
2018
58.6
16.2
5.2
5.3
6.7
2.5
1.2
19.8
15.0
23.9
16.5
6.6
41.0
6.9
6.7
47.0
58.6

LATIN AMERICAN COUNTRIES



Kidney Transplants	Liver Transplants	Heart Transplants	Lung Transplants	Pancreas Transplants	Small Bowel Transplants	Organs Transplanted
12832 (31.9% LD)	3435 (8.5% LD)	640	210	259	5	17381

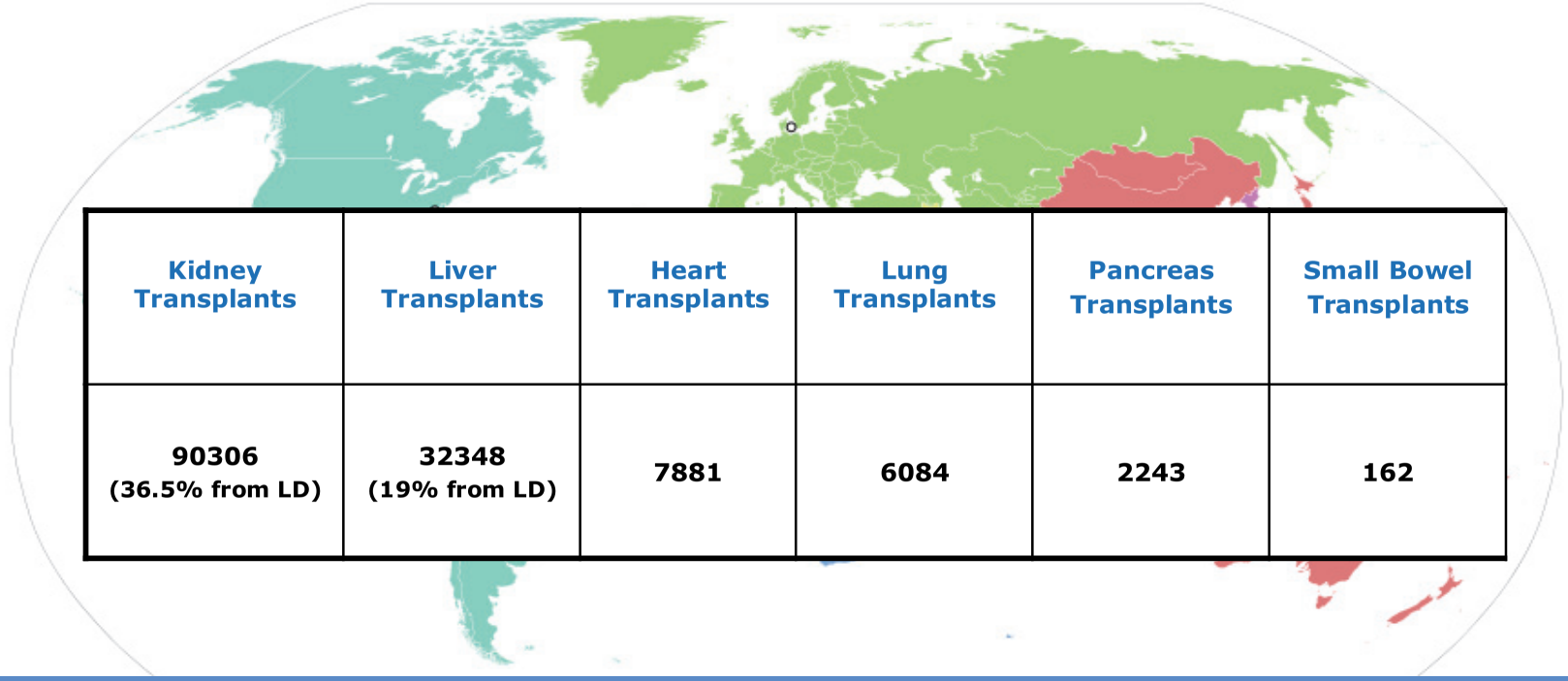
5756 ACTUAL DECEASED ORGAN DONORS *(5756 DBD and 0 DCD)*

2018 data

N= 18 COUNTRIES (619.1 million inhabitants)

Global Observatory on Donation and Transplantation

INTERNATIONAL ACTIVITIES IN ORGAN TRANSPLANTATION 2017 ESTIMATES



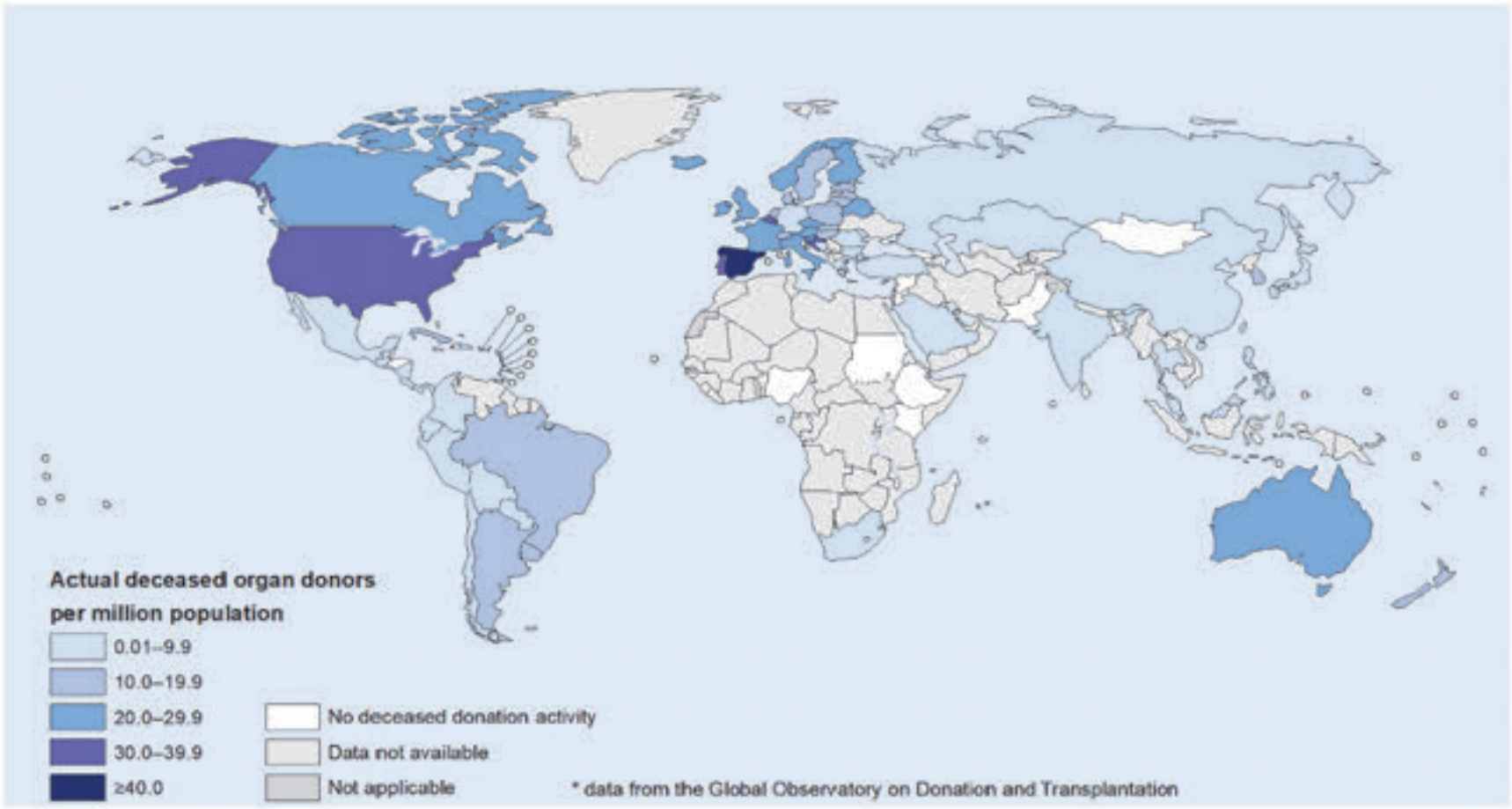
Kidney Transplants	Liver Transplants	Heart Transplants	Lung Transplants	Pancreas Transplants	Small Bowel Transplants
90306 (36.5% from LD)	32348 (19% from LD)	7881	6084	2243	162

37447 ACTUAL DECEASED ORGAN DONORS *(29462 DBD and 7985 DCD)*

- ***Information of 82 Member States on organ transplantation activities is included in the GODT***
- ***139024 organ transplants were reported for 2017***

GODT
Global Observatory on Donation and Transplantation

Actual donors from deceased persons, 2017*



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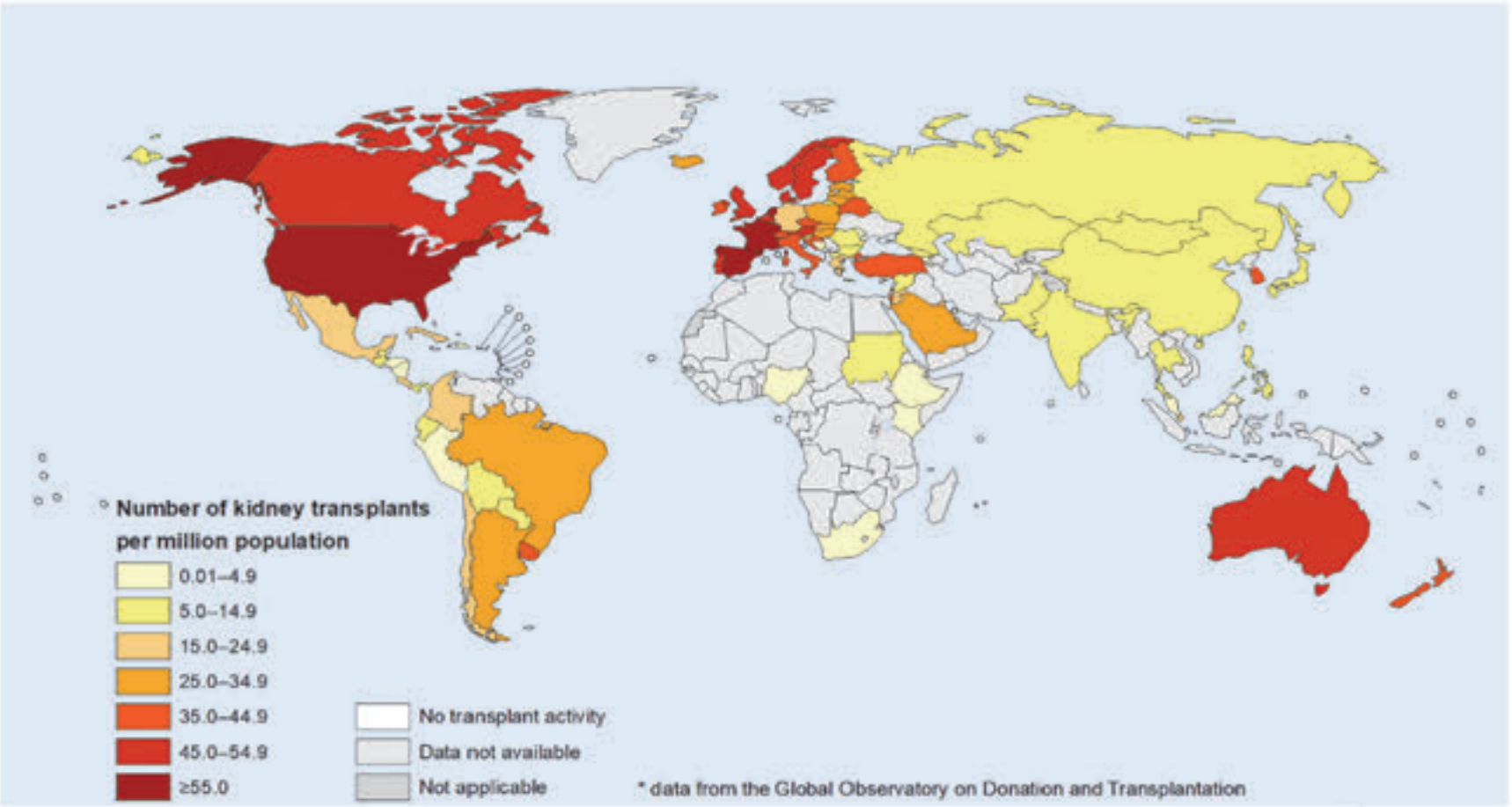
Data Source: Global Observatory on Donation & Transplantation, Map Production: Information Evidence and Research (IER)
World Health Organization

World Health Organization

GODT
Global Observatory on Donation and Transplantation

Kidney transplantation activities, 2017*



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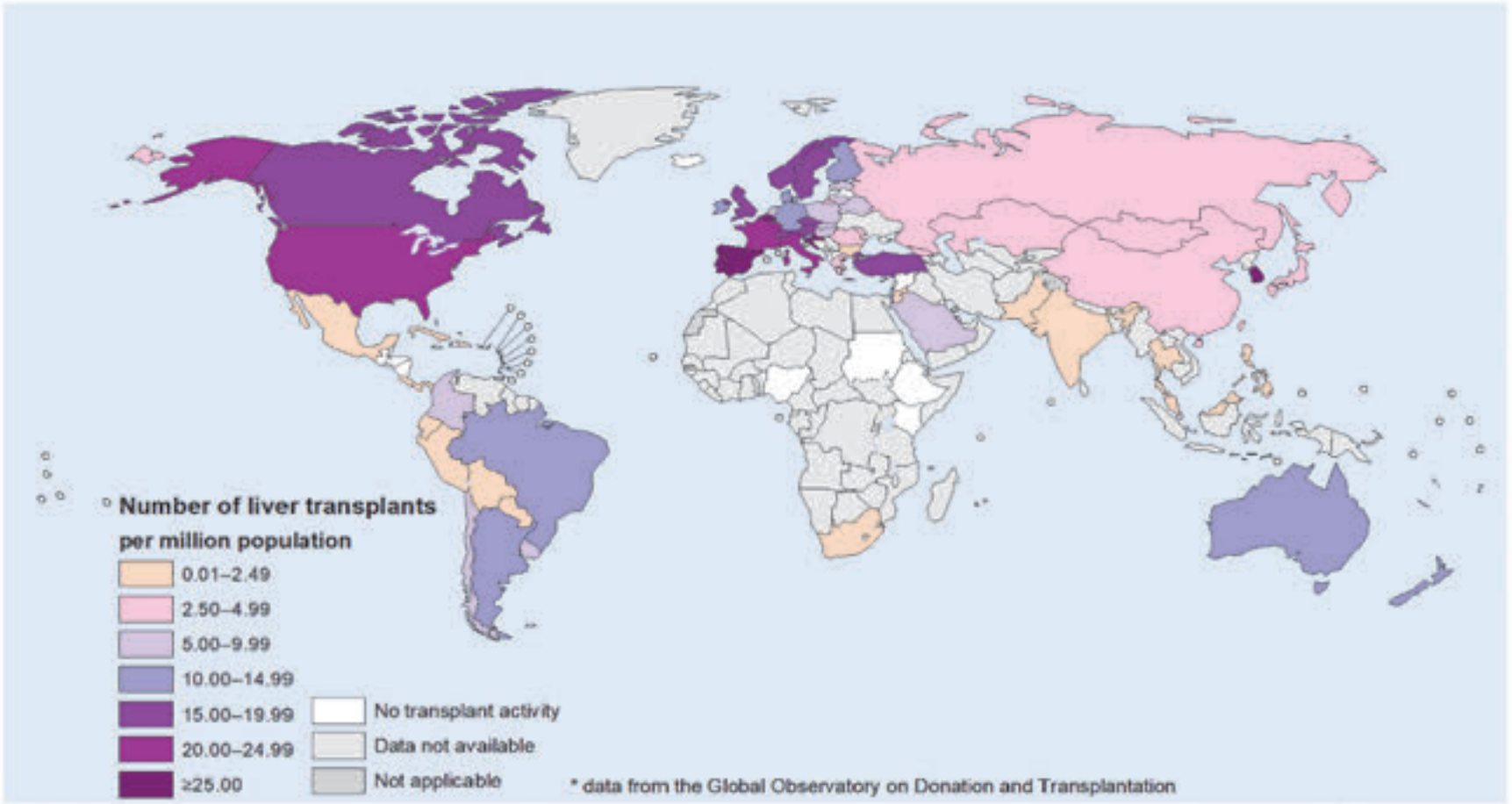
Data Source: Global Observatory on Donation & Transplantation. Map Production: Information Evidence and Research (IER) World Health Organization

World Health Organization

GODT
Global Observatory on Donation and Transplantation

Liver transplantation activities, 2017*



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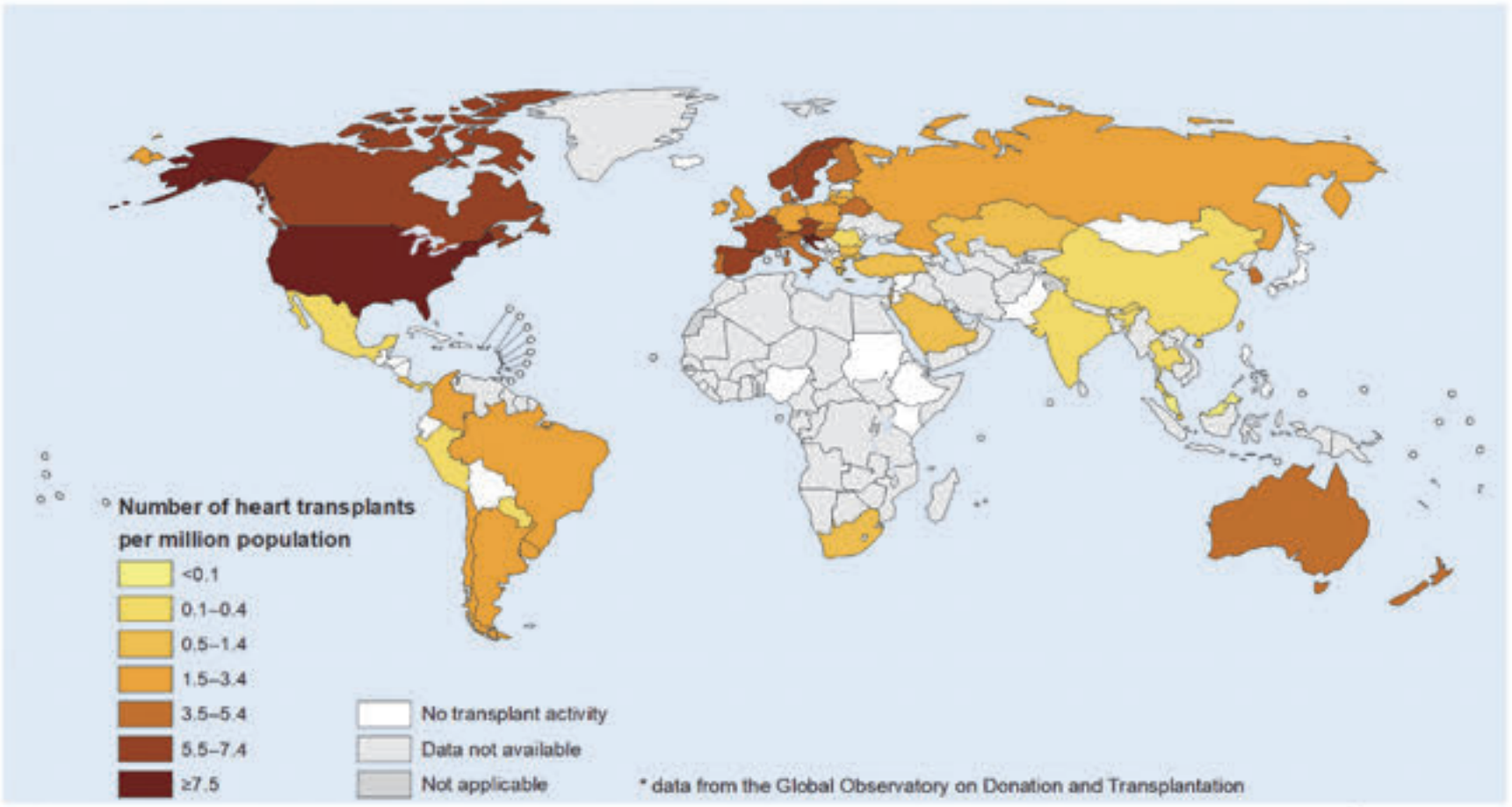
World Health Organization

GODT
Global Observatory on Donation and Transplantation

Heart transplantation activities, 2017*



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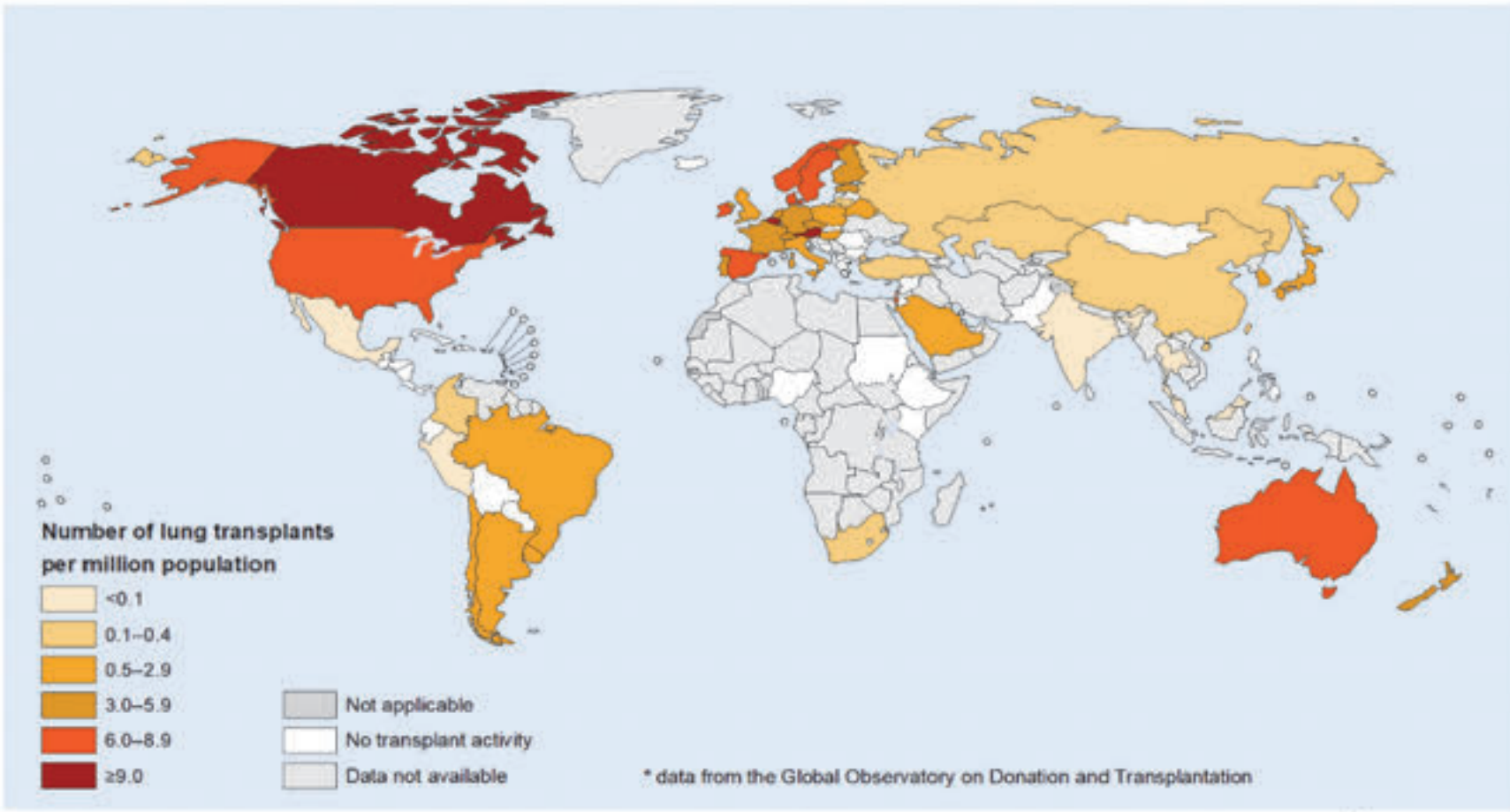
Data Source: Global Observatory on Donation & Transplantation. Map Production: Information Evidence and Research (IER) World Health Organization

World Health Organization

GODT
Global Observatory on Donation and Transplantation

Lung transplantation activities, 2017*



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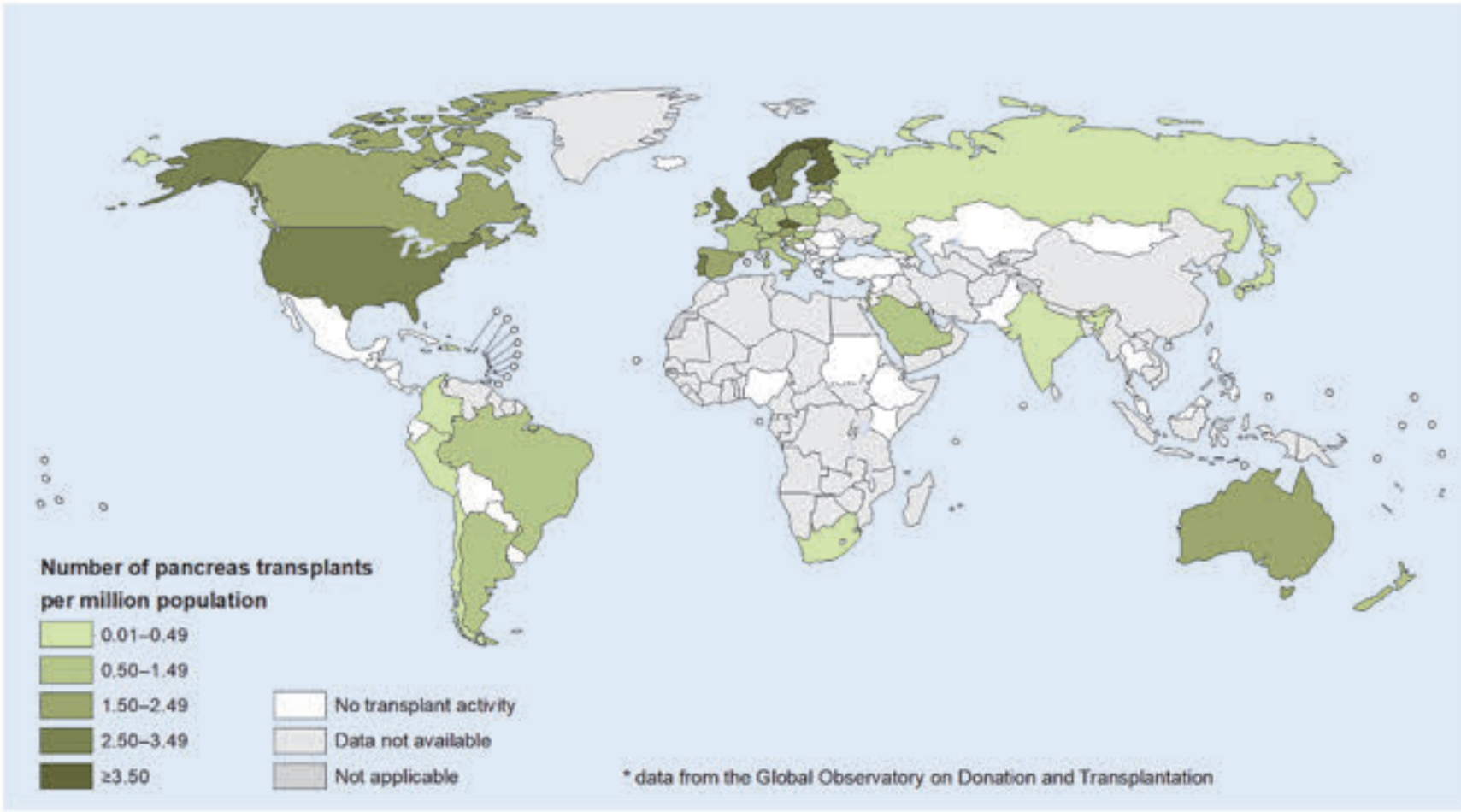
Data Source: Global Observatory on Donation & Transplantation. Map Production: Information Evidence and Research (IER) World Health Organization

World Health Organization

GODT
Global Observatory on Donation and Transplantation

Pancreas transplantation activities, 2017*



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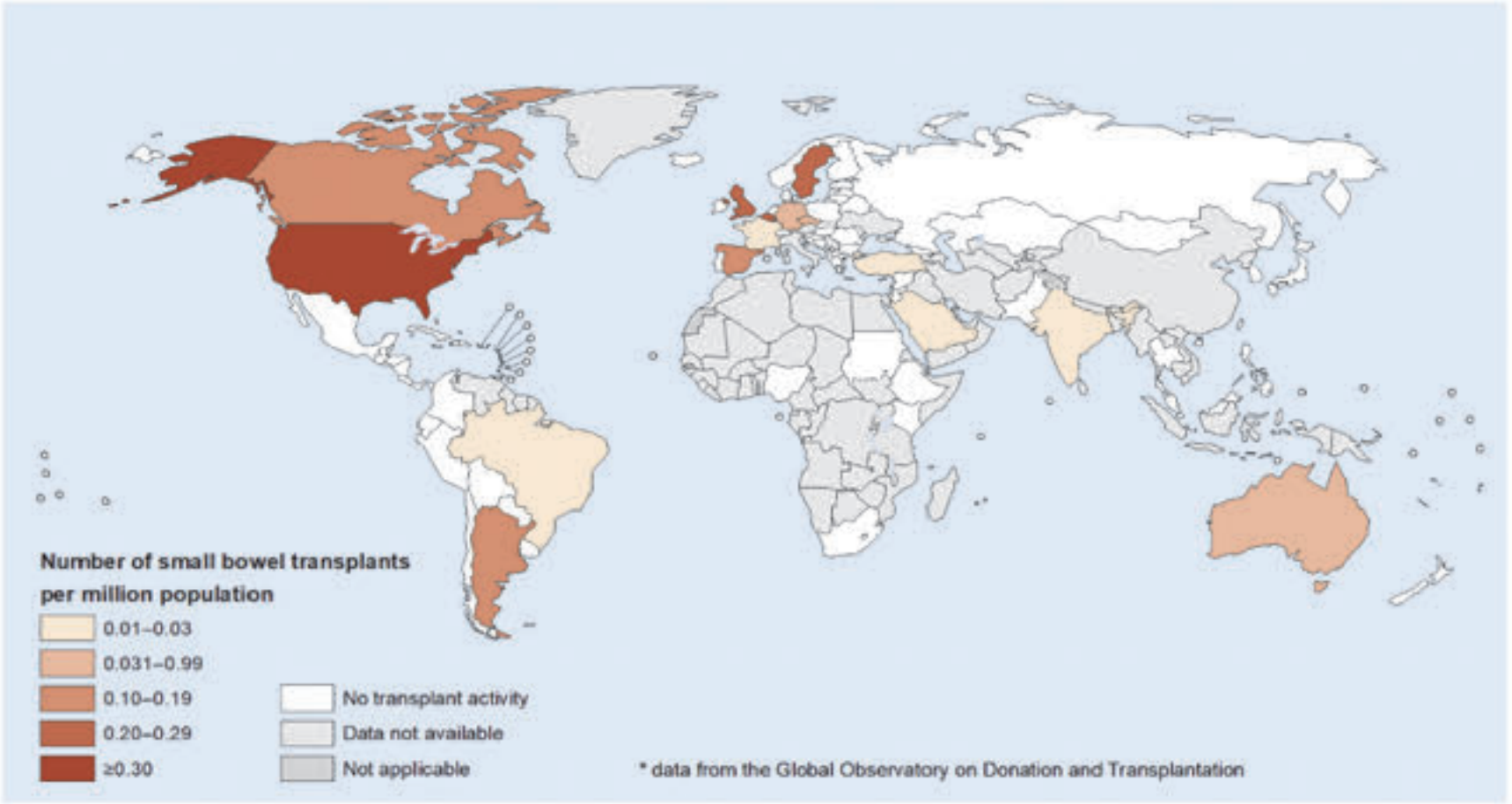
Data Source: Global Observatory on Donation & Transplantation. Map Production: Information Evidence and Research (IER)

World Health Organization

GODT
Global Observatory on Donation and Transplantation

Small bowel transplantation activities, 2017*



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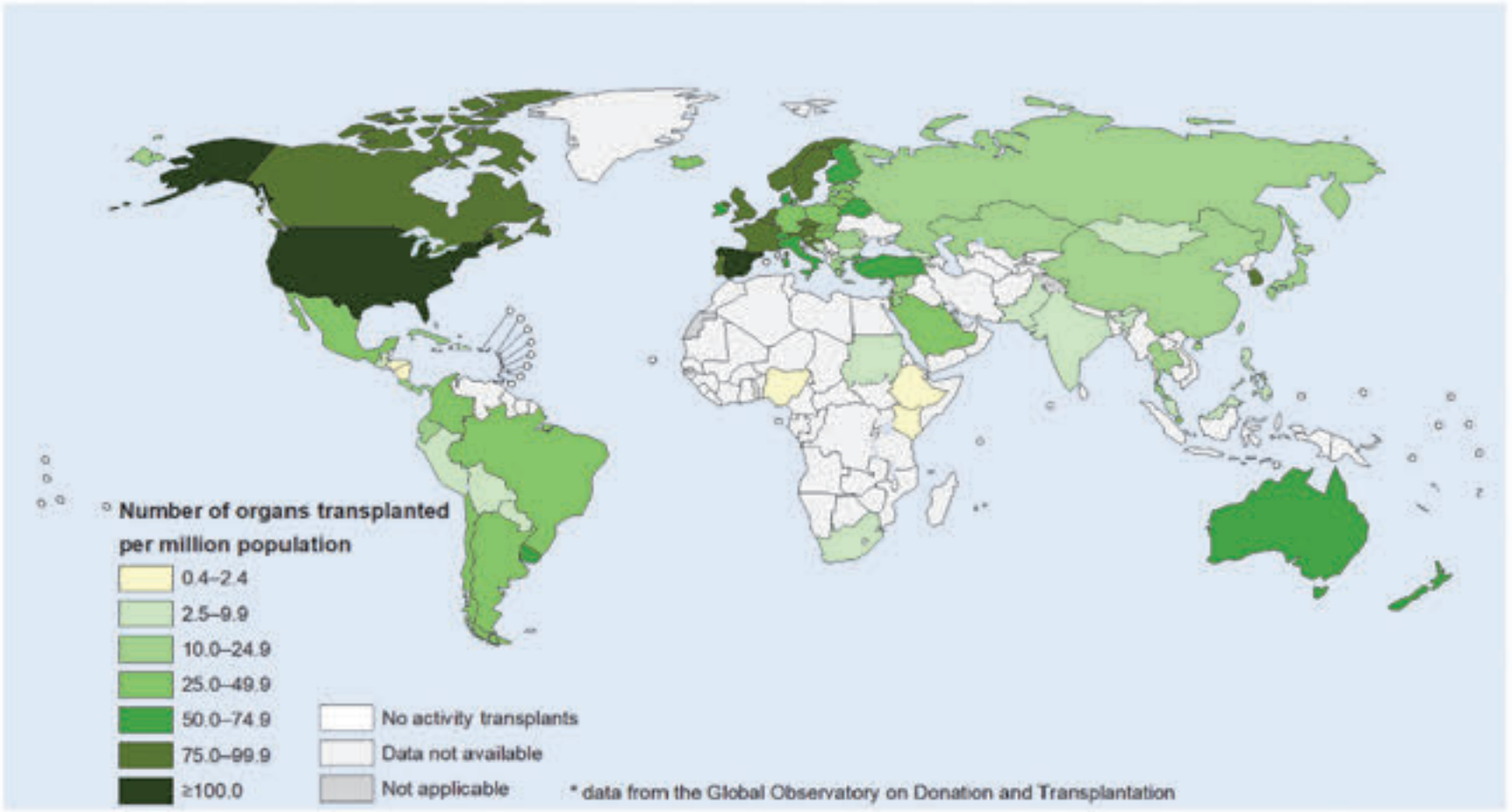
Data Source: Global Observatory on Donation & Transplantation. Map Production: Information Evidence and Research (IER) World Health Organization

World Health Organization

GODT
Global Observatory on Donation and Transplantation

Global transplantation activities of solid organs, 2017*



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Data Source: Global Observatory on Donation & Transplantation. Map Production: Information Evidence and Research (IER) World Health Organization

World Health Organization

International Data on Organ Donation and Transplantation Activity and Waiting List. Year 2018

DONATION ACTIVITY

EUROPEAN UNION COUNTRIES

Country	Austria		Belgium		Bulgaria		Croatia		Cyprus		Czech Republic		Denmark		Estonia		Finland		France	
Population (million inhabitants): UNFPA	**8.8**		**11.5**		**7.0**		**4.2**		**1.2**		**10.6**		**5.8**		**1.3**		**5.5**		**65.2**	
DONATION																				
Actual deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Actual deceased organ donor –both DBD and DCD included–	216	24.5	344	29.9	16	2.3	169	40.2	2	1.7	282	26.6	100	17.2	33	25.4	117	21.3	1881	28.8
Actual deceased donors: Number of men	125	14.2	209	18.2	9	1.3					174	16.4	50	8.6	24	18.5	58	10.5	1045	16.0
Actual deceased donors: Number of DD > 60 years	69	7.8	124	10.8	1	0.1			0	0.0	110	10.4	50	8.6	5	3.8	58	10.5	912	14.0
Actual donors after circulatory death –DCD–	15	1.7	103	9.0	0	0.0			0	0.0	13	1.2	0	0.0	0	0.0	0	0.0	138	2.1
II/ Witnessed cardiac arrest (uncontrolled)											0	0.0							17	0.3
III/ Withdrawal of life–sustaining therapy (controlled)											13	1.2							121	1.9
IV/ Cardiac arrest while brain dead											0	0.0							0	0.0
Utilised deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Utilised deceased organ donors –both DBD and DCD included–	202	23.0	335	29.1	16	2.3	151	36.0	2	1.7	259	24.4	85	14.7	33	25.4	108	19.6	1823	28.0
Utilised deceased donors: Number of men	117	13.3	204	17.7	9	1.3					154	14.5	43	7.4	24	18.5	54	9.8	1015	15.6
Utilised deceased donors: Number of DD > 60 years	59	6.7	117	10.2	1	0.1			0	0.0	83	7.8	41	7.1	5	3.8	50	9.1	866	13.3
Utilised donors after circulatory death –DCD–	14	1.6	98	8.5	0	0.0	0	0.0	0	0.0	11	1.0	0	0.0	0	0.0	0	0.0	132	2.0
II/ Witnessed cardiac arrest (uncontrolled)											0	0.0							16	0.2
III/ Withdrawal of life–sustaining therapy (controlled)											11	1.0							116	1.8
IV/ Cardiac arrest while brain dead											0	0.0							0	0.0
Living organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Living Kidney donors: Number of men					0	0.0			4	3.3	14	1.3	29	5.0	1	0.8	14	2.5	173	2.7
Living Liver donors: Number of men					0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	10	0.2
Living Lung donors: Number of men					0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

DONATION ACTIVITY

EUROPEAN UNION COUNTRIES

Country	Germany		Greece		Hungary		Ireland		Italy		Latvia		Lithuania		Luxembourg		Malta	
Population (million inhabitants): UNFPA	**82.3**		**11.1**		**9.7**		**4.8**		**59.3**		**1.9**		**2.9**		**0.6**		**0.4**	
DONATION																		
Actual deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Actual deceased organ donors –both DBD and DCD included–	955	11.6	45	4.1	168	17.3	81	16.9	1466	24.7	24	12.6	46	15.9	7	11.7	10	25.0
Actual deceased donors: Number of men	505	6.1	20	1.8	102	10.5	39	8.1	802	13.5	10	5.3	27	9.3	6	10.0	5	12.5
Actual deceased donors: Number of DD > 60 years	402	4.9	13	1.2	55	5.7	20	4.2	866	14.6	8	4.2	20	6.9	3	5.0	4	10.0
Actual donors after circulatory death –DCD–	0	0.0	0	0.0	0	0.0	4	0.8	57	1.0	1	0.5	0	0.0	0	0.0	0	0.0
II/ Witnessed cardiac arrest (uncontrolled)							0	0.0	24	0.4	0	0.0						
III/ Withdrawal of life–sustaining therapy (controlled)							4	0.8	32	0.5	0	0.0						
IV/ Cardiac arrest while brain dead							0	0.0	1	0.0	1	0.5						
Utilised deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PM**
Utilised deceased organ donors –both DBD and DCD included–	933	11.3	43	3.9	167	17.2	73	15.2	1371	23.1	22	11.6	45	15.5	7	11.7	10	25.0
Utilised deceased donors: Number of men	492	6.0	19	1.7	101	10.4	35	7.3	742	12.5	10	5.3	26	9.0	6	10.0	5	12.5
Utilised deceased donors: Number of DD > 60 years	387	4.7	13	1.2	55	5.7	16	3.3	785	13.2	6	3.2	19	6.6	3	5.0	4	10.0
Utilised donors after circulatory death –DCD–	0	0.0	0	0.0	0	0.0	3	0.6	47	0.8	1	0.5	0	0.0	0	0.0	0	0.0
II/ Witnessed cardiac arrest (uncontrolled)							0	0.0	18	0.3	0	0.0						
III/ Withdrawal of life–sustaining therapy (controlled)							3	0.6	28	0.5	0	0.0						
IV/ Cardiac arrest while brain dead							0	0.0	1	0.0	1	0.5						
Living organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PM**
Living Kidney donors: Number of men			18	1.6	8	0.8	16	3.3	81	1.4	6	3.2	5	1.7			2	5.0
Living Liver donors: Number of men			0	0.0	0	0.0	0	0.0	10	0.2	0	0.0	0	0.0			0	0.0
Living Lung donors: Number of men			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0			0	0.0

DONATION ACTIVITY

EUROPEAN UNION COUNTRIES

Country	Netherlands		Poland		Portugal		Romania		Slovakia		Slovenia		Spain		Sweden		United Kingdom	
Population (million inhabitants): UNFPA	**17.1**		**38.1**		**10.3**		**19.6**		**5.4**		**2.1**		**46.4**		**10.0**		**66.6**	
DONATION																		
Actual deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Actual deceased organ donors –both DBD and DCD included–	281	16.4	498	13.1	344	33.4	65	3.3	78	14.4	46	21.9	2241	48.3	191	19.1	1619	24.3
Actual deceased donors: Number of men	165	9.6	329	8.6	208	20.2	43	2.2	49	9.1	33	15.7	1344	29.0	107	10.7	879	13.2
Actual deceased donors: Number of DD > 60 years	125	7.3	113	3.0	187	18.2	20	1.0	19	3.5	26	12.4	1278	27.5	113	11.3	592	8.9
Actual donors after circulatory death –DCD–	164	9.6	4	0.1	28	2.7	0	0.0	0	0.0	0	0.0	629	13.6	10	1.0	619	9.3
II/ Witnessed cardiac arrest (uncontrolled)			4	0.1	28	2.7							72	1.6	0	0.0	0	0.0
III/ Withdrawal of life–sustaining therapy (controlled)			0	0.0	0	0.0							556	12.0	10	1.0	619	9.3
IV/ Cardiac arrest while brain dead			0	0.0	0	0.0							1	0.0	0	0.0	0	0.0
Utilised deceased organ donors																		
Utilised deceased organ donors –both DBD and DCD included–	273	16.0	475	12.5	309	30.0	65	3.3	74	13.7	40	19.0	1925	41.5	182	18.2	1542	23.2
Utilised deceased donors: Number of men	159	9.3	311	8.2	186	18.1	43	2.2	48	8.9	30	14.3	1139	24.5	103	10.3	835	12.5
Utilised deceased donors: Number of DD > 60 years	118	6.9	97	2.5	161	15.6	20	1.0	16	3.0	21	10.0	1041	22.4	105	10.5	541	8.1
Utilised donors after circulatory death –DCD–	157	9.2	4	0.1	23	2.2	0	0.0	0	0.0	0	0.0	527	11.4	10	1.0	565	8.5
II/ Witnessed cardiac arrest (uncontrolled)			4	0.1	23	2.2							41	0.9	0	0.0	0	0.0
III/ Withdrawal of life–sustaining therapy (controlled)			0	0.0	0	0.0							485	10.5	10	1.0	565	8.5
IV/ Cardiac arrest while brain dead			0	0.0	0	0.0							1	0.0	0	0.0	0	0.0
Living organ donors																		
Living Kidney donors: Number of men			14	0.4	16	1.6			1	0.2			94	2.0	66	6.6	479	7.2
Living Liver donors: Number of men			8	0.2	1	0.1			0	0.0			8	0.2	1	0.1	10	0.2
Living Lung donors: Number of men			0	0.0	0	0.0	0	0.0	0	0.0			0	0.0	0	0.0	0	0.0

DONATION ACTIVITY

OTHER COUNTRIES

Country	Algeria		Armenia		Australia		Belarus		Bosnia and Herzegovina		Canada		Georgia		Iceland		India		Israel		Kuwait		Malaysia	
Population (million inhabitants): UNFPA	**42.0**		**2.9**		**24.8**		**9.5**		**3.5**		**37.0**		**3.9**		**0.3**		**1354.1**		**8.5**		**4.2**		**32.0**	
DONATION																								
Actual deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Actual deceased organ donors –both DBD and DCD included–	0	0.0	0	0.0	554	22.3	238	25.1					0	0.0	10	33.3	875	0.7	113	13.3	12	2.9	7	0.2
Actual deceased donors: Number of men					325	13.1	90	9.5							7	23.3			67	7.9	10	2.4	4	0.1
Actual deceased donors: Number of DD > 60 years					167	6.7	20	2.1							3	10.0	143	0.1	45	5.3	1	0.2	0	0.0
Actual donors after circulatory death –DCD–					154	6.2	0	0.0							0	0.0	3	0.0	2	0.2	0	0.0	0	0.0
II/ Witnessed cardiac arrest (uncontrolled)																			2	0.2				
III/ Withdrawal of life–sustaining therapy (controlled)																			0	0.0				
IV/ Cardiac arrest while brain dead																			0	0.0				
Utilised deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Utilised deceased organ donors –both DBD and DCD included–	0	0.0	0	0.0	531	21.4	238	25.1			763	20.6	0	0.0	10	33.3	712	0.5	110	12.9	10	2.4	7	0.2
Utilised deceased donors: Number of men					312	12.6	90	9.5							7	23.3			65	7.6	8	1.9	4	0.1
Utilised deceased donors: Number of DD > 60 years					150	6.0	20	2.1							3	10.0	115	0.1	42	4.9	1	0.2	0	0.0
Utilised donors after circulatory death –DCD–					145	5.8	0	0.0			227	6.1			0	0.0	3	0.0	2	0.2	0	0.0	0	0.0
II/ Witnessed cardiac arrest (uncontrolled)																			2	0.2				
III/ Withdrawal of life–sustaining therapy (controlled)																			0	0.0				
IV/ Cardiac arrest while brain dead																			0	0.0				
Living organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Living Kidney donors: Number of men	94	2.2	4	1.4	99	4.0	2	0.2					10	2.6	4	13.3			127	14.9	40	9.5	25	0.8
Living Liver donors: Number of men	4	0.1	0	0.0	0	0.0	0	0.0					9	2.3	0	0.0			11	1.3	0	0.0	1	0.0
Living Lung donors: Number of men	0	0.0	0	0.0	0	0.0	0	0.0					0	0.0	0	0.0			0	0.0	0	0.0	0	0.0

DONATION ACTIVITY

OTHER COUNTRIES

Country	New Zealand		Norway		Qatar		Republic of Moldova		Russian Federation		Saudi Arabia		Sudan		Switzerland		Syrian Arab Republic		The Rep. of North Macedonia		Turkey		United States of America	
Population (million inhabitants): UNFPA	**4.7**		**5.4**		**2.7**		**4.0**		**144.0**		**33.6**		**41.5**		**8.5**		**18.3**		**2.1**		**81.9**		**326.8**	

DONATION

Actual deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Actual deceased organ donors –both DBD and DCD included–	62	13.2	104	19.6	7	2.6	10	2.4	646	4.5	96	2.9	0	0.0	158	18.6	0	0.0	1	0.5	598	7.3	10722	32.8
Actual deceased donors: Number of men	32	6.8	59	11.1	6	2.2	6	1.5	423	2.9	85	2.5			94	11.1					377	4.6	6497	19.9
Actual deceased donors: Number of DD > 60 years	20	4.3	54	10.2	0	0.0	4	1.0	68	0.5	6	0.2			80	9.4			0	0.0	203	2.5	1544	4.7
Actual donors after circulatory death –DCD–	9	1.9	0	0.0	0	0.0	0	0.0	37	0.3	0	0.0			32	3.8			0	0.0	0	0.0	2133	6.5
II/ Witnessed cardiac arrest (uncontrolled)									26	0.2					0	0.0							29	0.1
III/ Withdrawal of life–sustaining therapy (controlled)									0	0.0					32	3.8							2104	6.4
IV/ Cardiac arrest while brain dead									9	0.1					0	0.0							0	0.0

Utilised deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Utilised deceased organ donors –both DBD and DCD included–	58	12.3	100	18.9	6	2.2	8	2.0	639	4.4	94	2.8	0	0.0	154	18.1	0	0.0	1	0.5	560	6.8	10106	30.9
Utilised deceased donors: Number of men	30	6.4	56	10.6	5	1.9	4	1.0	417	2.9	83	2.5			91	10.7					356	4.3	6158	18.8
Utilised deceased donors: Number of DD > 60 years	17	3.6	50	9.4	0	0.0	3	0.7	68	0.5	6	0.2			77	9.1			0	0.0	184	2.2	1335	4.1
Utilised donors after circulatory death –DCD–	8	1.7	0	0.0	0	0.0	0	0.0	35	0.2	0	0.0			31	3.6			0	0.0	0	0.0	1862	5.7
II/ Witnessed cardiac arrest (uncontrolled)									26	0.2					0	0.0							22	0.1
III/ Withdrawal of life–sustaining therapy (controlled)									0	0.0					31	3.6							1840	5.6
IV/ Cardiac arrest while brain dead									9	0.1					0	0.0							0	0.0

Living organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Living Kidney donors: Number of men	30	8.1	31	5.8	13	4.8	2	0.5	65	0.5			135	3.3							1981	24.2	2358	7.2
Living Liver donors: Number of men	0	0.0	0	0.0	3	1.1	3	0.7	77	0.5			0	0.0			0	0.0	0	0.0	724	8.8	180	0.6
Living Lung donors: Number of men	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

DONATION ACTIVITY

LATIN AMERICAN COUNTRIES

Country	Argentina		Bolivia		Brazil		Chile		Colombia		Costa Rica		Cuba		Dominican Republic		Ecuador		El Salvador	
Population (million inhabitants): UNFPA	**44.7**		**11.2**		**210.9**		**18.2**		**49.5**		**5.0**		**11.5**		**10.9**		**16.9**		**6.4**	
DONATION																				
Actual deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Actual deceased organ donors –both DBD and DCD included–	701	15.7	4	0.4	3529	16.7	119	6.5	398	8.0	35	7.0	130	11.3	9	0.8	133	7.9	0	0.0
Actual deceased donors: Number of men	279	6.2	2	0.2	2074	9.8			262	5.3	23	4.6	88	7.7	7	0.6	87	5.1		
Actual deceased donors: Number of DD > 60 years	131	2.9	0	0.0	415	2.0			36	0.7	6	1.2	16	1.4	2	0.2	12	0.7		
Actual donors after circulatory death –DCD–	0	0.0	0	0.0	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
II/ Witnessed cardiac arrest (uncontrolled)																				
III/ Withdrawal of life–sustaining therapy (controlled)																				
IV/ Cardiac arrest while brain dead																				
Utilised deceased organ donors																				
Utilised deceased organ donor –both DBD and DCD included–	643	14.4	4	0.4	3022	14.3	119	6.5	394	8.0	35	7.0	80	7.0	7	0.6	128	7.6	0	0.0
Utilised deceased donors: Number of men	386	8.6	2	0.2	1852	8.8			260	5.3	23	4.6	46	4.0	2	0.2	84	5.0		
Utilised deceased donors: Number of DD > 60 years	103	2.3	0	0.0	225	1.1			34	0.7	6	1.2	7	0.6	1	0.1	12	0.7		
Utilised donors after circulatory death –DCD–	0	0.0	0	0.0	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
II/ Witnessed cardiac arrest (uncontrolled)																				
III/ Withdrawal of life–sustaining therapy (controlled)																				
IV/ Cardiac arrest while brain dead																				
Living organ donors																				
Living Kidney donors: Number of men	207	4.6	35	3.1					60	1.2	13	2.6	9	0.8	24	2.2	11	0.7	22	3.4
Living Liver donors: Number of men	16	0.4	1	0.1					25	0.5	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0
Living Lung donors: Number of men	0	0.0	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

DONATION ACTIVITY

LATIN AMERICAN COUNTRIES

Country	Guatemala		Honduras		Mexico		Nicaragua		Panama		Paraguay		Peru		Uruguay		Venezuela	
Population (million inhabitants): UNFPA	**17.2**		**9.4**		**130.8**		**6.3**		**4.2**		**6.9**		**32.6**		**3.5**		**32.4**	
DONATION																		
Actual deceased organ donors	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
Actual deceased organ donors –both DBD and DCD included–	5	0.3			534	4.1	1	0.2	27	6.4	13	1.9	65	2.0	77	22.0	0	0.0
Actual deceased donors: Number of men	3	0.2			354	2.7	1	0.2	16	3.8	5	0.7	40	1.2	44	12.6		
Actual deceased donors: Number of DD > 60 years	0	0.0			47	0.4	0	0.0	1	0.2	0	0.0	4	0.1	10	2.9		
Actual donors after circulatory death –DCD–	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
II/ Witnessed cardiac arrest (uncontrolled)																		
III/ Withdrawal of life–sustaining therapy (controlled)																		
IV/ Cardiac arrest while brain dead																		
Utilised deceased organ donors																		
Utilised deceased organ donors –both DBD and DCD included–	5	0.3			518	4.0	1	0.2	27	6.4	13	1.9	62	1.9	76	21.7	0	0.0
Utilised deceased donors: Number of men	3	0.2			347	2.7	1	0.2	16	3.8	5	0.7	37	1.1	44	12.6		
Utilised deceased donors: Number of DD > 60 years	0	0.0			39	0.3	0	0.0	1	0.2	0	0.0	4	0.1	9	2.6		
Utilised donors after circulatory death –DCD–	5	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
II/ Witnessed cardiac arrest (uncontrolled)																		
III/ Withdrawal of life–sustaining therapy (controlled)																		
IV/ Cardiac arrest while brain dead																		
Living organ donors																		
Living Kidney donors: Number of men	61	3.5			1034	7.9	6	1.0	5	1.2	9	1.3	15	0.5	5	1.4		
Living Liver donors: Number of men	0	0.0			12	0.1	0	0.0	0	0.0	0	0.0	0	0.0				
Living Lung donors: Number of men	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		

TRANSPLANTATION ACTIVITY

EUROPEAN UNION COUNTRIES

TRANSPLANTATION

Country Population (million inhabitants): UNFPA	Austria 8.8		Belgium 11.5		Bulgaria 7.0		Croatia 4.2		Cyprus 1.2		Czech Republic 10.6		Denmark 5.8		Estonia 1.3		Finland 5.5		France 65.2	
	Number	PMP	Number	PMP	Number	PMP	Number	PMP	Number	PMP	Number	PMP	Number	PMP	Number	PMP	Number	PMP	Number	PMP
KIDNEY																				
Total Tx –all combinations included–	414	47.0	531	46.2	25	3.6	183	43.6	19	15.8	508	47.9	236	40.7	58	44.6	238	43.3	3567	54.7
Kidney tx: Number of men	294	33.4	341	29.7	20	2.9	0	0.0	14	11.7	348	32.8	153	26.4	34	26.2	145	26.4	2240	34.4
Paediatric <18 years	14	1.6	14	1.2	0	0.0			0	0.0	15	1.4	8	1.4	2	1.5	15	2.7	95	1.5
Tx from DD	344	39.1	474	41.2	20	2.9	178	42.4	4	3.3	461	43.5	159	27.4	54	41.5	206	37.5	3026	46.4
– Tx from DCD	35	4.0	98	8.5	0	0.0	0	0.0			22	2.1	0	0.0	0	0.0	0	0.0	244	3.7
– Single Tx	334	38.0	474	41.2	20	2.9	178	42.4			454	42.8	158	27.2	54	41.5	206	37.5	2988	45.8
– Double Tx	10	1.1	0	0.0	0	0.0	0	0.0			7	0.7	1	0.2	0	0.0	0	0.0	38	0.6
Tx from living donors	70	8.0	57	5.0	5	0.7	5	1.2	15	12.5	47	4.4	77	13.3	4	3.1	32	5.8	541	8.3
– Tx from related living donors	68	7.7	56	4.9	5	0.7	5	1.2	15	12.5	40	3.8	76	13.1	4	3.1	32	5.8	541	8.3
– Tx from unrelated living donors	2	0.2	1	0.1	0	0.0	0	0.0	0	0.0	7	0.7	1	0.2	0	0.0	0	0.0	0	0.0
Paired exchange or cross–over													0	0.0						
Non–directed altruistic or anonymous													1	0.2						
Directed altruistic													0	0.0						
LIVER																				
Total Tx –all combinations included–	182	20.7	308	26.8	13	1.9	133	31.7	0	0.0	216	20.4	43	7.4	10	7.7	66	12.0	1325	20.3
Liver tx: Number of men	134	15.2	217	18.9	0	0.0					125	11.8	12	2.1	7	5.4	28	5.1	934	14.3
Paediatric <18 years	12	1.4	42	3.7	4	0.6					13	1.2	5	0.9	0	0.0	8	1.5	82	1.3
Split Tx	4	0.5	9	0.8	0	0.0	0	0.0			11	1.0	0	0.0	0	0.0	0	0.0	75	1.2
Domino Tx	0	0.0	0	0.0	0	0.0	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	6	0.1
Tx from living donors	7	0.8	33	2.9	2	0.3	1	0.2			0	0.0	0	0.0	0	0.0	0	0.0	14	0.2
Tx from DCD	8	0.9	73	6.3	0	0.0	0	0.0			1	0.1	0	0.0	0	0.0	0	0.0	48	0.7
HEART																				
Total Tx –all combinations included–	65	7.4	76	6.6	4	0.6	37	8.8	0	0.0	74	7.0	26	4.5	0	0.0	47	8.5	459	7.0
Heart tx: Number of men	52	5.9			4	0.6					53	5.0	21	3.6			31	5.6	309	4.7
Paediatric <18 years	7	0.8	2	0.2	0	0.0					2	0.2	1	0.2			9	1.6	34	0.5
HEART–LUNG																				
Total Tx	0	0.0	2	0.2	0	0.0	0	0.0	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	9	0.1
Paediatric <18 years			0	0.0							0	0.0							1	0.0
LUNG																				
Total Tx –all combinations included–	117	13.3	116	10.1	0	0.0	0	0.0	0	0.0	42	4.0	25	4.3	4	3.1	18	3.3	382	5.9
Lung Tx: Number of men	72	8.2	0	0.0							24	2.3	14	2.4	2	1.5	11	2.0	213	3.3
Paediatric <18 years	2	0.2	0	0.0							1	0.1	0	0.0	0	0.0	0	0.0	11	0.2
Single Tx	5	0.6	4	0.3							3	0.3	1	0.2	1	0.8	0	0.0	35	0.5
Double Tx (heart–lung Tx included)	112	12.7	112	9.7							39	3.7	24	4.1	3	2.3	18	3.3	347	5.3
Tx from DCD (double + single)	9	1.0	30	2.6							0	0.0	0	0.0	0	0.0	0	0.0	10	0.2
PANCREAS																				
Total Tx –all combinations included–	20	2.3	16	1.4	0	0.0	0	0.0	0	0.0	43	4.1	5	0.9	2	1.5	23	4.2	78	1.2
Pancreas Tx: Number of men	16	1.8	57	5.0							24	2.3	5	0.9	0	0.0	13	2.4	44	0.7
Paediatric <18 years	0	0.0	0	0.0							0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pancreas Tx Alone	1	0.1	2	0.2							7	0.7	1	0.2	0	0.0	0	0.0	13	0.2
Kidney – Pancreas Tx	19	2.2	14	1.2							36	3.4	4	0.7	2	1.5	23	4.2	65	1.0
Tx from DCD	1	0.1	2	0.2							0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
SMALL BOWEL																				
Total Tx –all combinations included–	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	3	0.0
Small bowel Tx: Number of men											0	0.0							1	0.0
Paediatric <18 years											0	0.0							1	0.0
Small bowel Tx Alone											0	0.0							1	0.0
RECIPIENTS																				
Total number of patients transplanted	772	87.7	1021	88.8	42	6.0	351	83.6	19	15.8	884	83.4	329	56.7	72	55.4	367	66.7	5591	85.8
Patients transplanted: Number of men	548	62.3	665	57.8	34	4.9			14	11.7	574	54.2	200	34.5	43	33.1	231	42.0		
Paediatric <18 years	29	3.3	54	4.7	4	0.6			0	0.0	0	0.0	13	2.2	2	1.5	32	5.8	213	3.3
Patients transplanted from living donors	77	8.8	90	7.8	7	1.0	6	1.4	15	12.5	47	4.4	77	13.3	4	3.1	32	5.8	555	8.5

TRANSPLANTATION ACTIVITY

EUROPEAN UNION COUNTRIES

Country Population (million inhabitants): UNFPA	Germany 82.3		Greece 11.1		Hungary 9.7		Ireland 4.8		Italy 59.3		Latvia 1.9		Lithuania 2.9		Luxembourg 0.6		Malta 0.4	
TRANSPLANTATION																		
	Number	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
KIDNEY																		
Total Tx –all combinations included–	2291	27.8	141	12.7	335	34.5	167	34.8	2124	35.8	53	27.9	84	29.0	0	0.0	19	47.5
Kidney tx: Number of men	1436	17.4	100	9.0	209	21.5	116	24.2	1383	23.3	34	17.9	47	16.2			16	40.0
Paediatric <18 years	107	1.3	2	0.2	15	1.5	7	1.5	75	1.3	0	0.0	2	0.7			0	0.0
Tx from DD	1653	20.1	72	6.5	290	29.9	127	26.5	1831	30.9	39	20.5	73	25.2			15	37.5
– Tx from DCD	0	0.0	0	0.0	0	0.0	6	1.3	63	1.1	1	0.5	0	0.0			0	0.0
– Single Tx	1635	19.9	72	6.5	290	29.9	120	25.0	1705	28.8	39	20.5	72	24.8			15	37.5
– Double Tx	18	0.2	0	0.0	0	0.0	1	0.2	126	2.1	0	0.0	1	0.3			0	0.0
Tx from living donors	638	7.8	69	6.2	45	4.6	40	8.3	293	4.9	14	7.4	11	3.8			4	10.0
– Tx from related living donors	629	7.6	69	6.2	45	4.6			275	4.6	11	5.8					4	10.0
– Tx from unrelated living donors	9	0.1	0	0.0	0	0.0			18	0.3	3	1.6					0	0.0
Paired exchange or cross–over									15	0.3	2	1.1						
Non–directed altruistic or anonymous									3	0.1	1	0.5						
Directed altruistic									0	0.0	0	0.0						
LIVER																		
Total Tx –all combinations included–	877	10.7	23	2.1	80	8.2	56	11.7	1246	21.0	6	3.2	19	6.6	0	0.0	0	0.0
Liver tx: Number of men	575	7.0	16	1.4	49	5.1	32	6.7	931	15.7	6	3.2	14	4.8				
Paediatric <18 years	102	1.2	0	0.0	5	0.5	1	0.2	91	1.5	0	0.0	0	0.0				
Split Tx	74	0.9	0	0.0	0	0.0	0	0.0	64	1.1	0	0.0	0	0.0				
Domino Tx	5	0.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0				
Tx from living donors	52	0.6	0	0.0	0	0.0	0	0.0	25	0.4	6	3.2	0	0.0				
Tx from DCD	0	0.0	0	0.0	0	0.0	0	0.0	34	0.6	0	0.0	0	0.0				
HEART																		
Total Tx –all combinations included–	318	3.9	8	0.7	62	6.4	18	3.8	233	3.9	3	1.6	10	3.4	0	0.0	0	0.0
Heart tx: Number of men	232	2.8	3	0.3	44	4.5	15	3.1	172	2.9	2	1.1	9	3.1				
Paediatric <18 years	42	0.5	1	0.1	4	0.4	0	0.0	20	0.3	0	0.0	2	0.7				
HEART–LUNG																		
Total Tx	2	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Paediatric <18 years	0	0.0																
LUNG																		
Total Tx –all combinations included–	375	4.6	0	0.0	23	2.4	28	5.8	144	2.4	0	0.0	0	0.0	0	0.0	0	0.0
Lung Tx: Number of men	199	2.4			9	0.9	21	4.4	98	1.7								
Paediatric <18 years	14	0.2			1	0.1	0	0.0	10	0.2								
Single Tx	54	0.7			0	0.0	16	3.3	19	0.3								
Double Tx (heart–lung Tx included)	321	3.9			23	2.4	12	2.5	125	2.1								
Tx from DCD (double + single)	0	0.0			0	0.0	0	0.0	3	0.1								
PANCREAS																		
Total Tx –all combinations included–	95	1.2	0	0.0	5	0.5	5	1.0	41	0.7	1	0.5	0	0.0	0	0.0	0	0.0
Pancreas Tx: Number of men	47	0.6			4	0.4	2	0.4	23	0.4	0	0.0						
Paediatric <18 years	1	0.0			0	0.0	0	0.0	0	0.0	0	0.0						
Pancreas Tx Alone	6	0.1			0	0.0	0	0.0	9	0.2	0	0.0						
Kidney – Pancreas Tx	84	1.0			5	0.5	5	1.0	32	0.5	1	0.5						
Tx from DCD	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0						
SMALL BOWEL																		
Total Tx –all combinations included–	3	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Small bowel Tx: Number of men																		
Paediatric <18 years	1	0.0																
Small bowel Tx Alone	0	0.0																
RECIPIENTS																		
Total number of patients transplanted	3830	46.5	172	15.5	497	51.2	269	56.0	3675	62.0	62	32.6	113	39.0	0	0.0	19	47.5
Patients transplanted: Number of men	2429	29.5	119	10.7	310	32.0	186	38.8	2539	42.8	42	22.1	70	24.1	0	0.0	16	40.0
Paediatric <18 years	260	3.2	3	0.3	25	2.6	8	1.7	186	3.1	0	0.0			0	0.0	0	0.0
Patients transplanted from living donors	690	8.4	69	6.2	45	4.6	40	8.3	318	5.4	14	7.4	11	3.8	0	0.0	4	10.0

TRANSPLANTATION ACTIVITY

EUROPEAN UNION COUNTRIES

Country Population (million inhabitants): UNFPA	Netherlands 17.1		Poland 38.1		Portugal 10.3		Romania 19.6		Slovakia 5.4		Slovenia 2.1		Spain 46.4		Sweden 10.0		United Kingdom 66.6	
TRANSPLANTATION																		
	Number	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
KIDNEY																		
Total Tx –all combinations included–	998	58.4	946	24.8	502	48.7	183	9.3	146	27.0	56	26.7	3313	71.4	448	44.8	3642	54.7
Kidney tx: Number of men	648	37.9	606	15.9	321	31.2			88	16.3	35	16.7	2130	45.9	289	28.9	2286	34.3
Paediatric <18 years	28	1.6	41	1.1	9	0.9	5	0.3	2	0.4	0	0.0	79	1.7	18	1.8	139	2.1
Tx from DD	488	28.5	906	23.8	443	43.0	119	6.1	135	25.0	54	25.7	3020	65.1	304	30.4	2608	39.2
– Tx from DCD	296	17.3	7	0.2	46	4.5	0	0.0	0	0.0	0	0.0	856	18.4	17	1.7	989	14.8
– Single Tx	480	28.1	906	23.8	409	39.7	119	6.1	135	25.0	54	25.7	3013	64.9	302	30.2	2579	38.7
– Double Tx	8	0.5	0	0.0	34	3.3	0	0.0	0	0.0	0	0.0	7	0.2	2	0.2	29	0.4
Tx from living donors	510	29.8	40	1.0	59	5.7	64	3.3	11	2.0	2	1.0	293	6.3	144	14.4	1034	15.5
– Tx from related living donors	421	24.6	40	1.0	53	5.1	64	3.3	11	2.0	2	1.0	275	5.9	139	13.9	820	12.3
– Tx from unrelated living donors	89	5.2	0	0.0	6	0.6	0	0.0	0	0.0	0	0.0	18	0.4	5	0.5	214	3.2
Paired exchange or cross–over					6	0.6							13	0.3	3	0.3	146	2.2
Non–directed altruistic or anonymous					0	0.0							5	0.1	2	0.2	68	1.0
Directed altruistic					0	0.0							0	0.0	0	0.0	0	0.0
LIVER																		
Total Tx –all combinations included–	195	11.4	316	8.3	232	22.5	69	3.5	37	6.9	27	12.9	1230	26.5	163	16.3	1068	16.0
Liver tx: Number of men	127	7.4	182	4.8	163	15.8			22	4.1	16	7.6	914	19.7	108	10.8	662	9.9
Paediatric <18 years	27	1.6	32	0.8	9	0.9	2	0.1	0	0.0	0	0.0	66	1.4	11	1.1	105	1.6
Split Tx	7	0.4	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	12	0.3	6	0.6	96	1.4
Domino Tx	0	0.0	0	0.0	12	1.2	0	0.0	0	0.0	0	0.0	1	0.0	0	0.0	1	0.0
Tx from living donors	12	0.7	22	0.6	1	0.1	11	0.6	0	0.0	0	0.0	23	0.5	1	0.1	19	0.3
Tx from DCD	69	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	196	4.2	0	0.0	194	2.9
HEART																		
Total Tx –all combinations included–	38	2.2	147	3.9	33	3.2	7	0.4	18	3.3	23	11.0	321	6.9	66	6.6	194	2.9
Heart tx: Number of men	25	1.5	105	2.8	21	2.0			14	2.6	18	8.6	228	4.9	48	4.8	123	1.8
Paediatric <18 years	9	0.5	7	0.2	3	0.3	2	0.1	1	0.2	1	0.5	36	0.8	6	0.6	38	0.6
HEART–LUNG																		
Total Tx	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.0	0	0.0	6	0.1
Paediatric <18 years													0	0.0			2	0.0
LUNG																		
Total Tx –all combinations included–	89	5.2	43	1.1	27	2.6	4	0.2	0	0.0	0	0.0	369	8.0	74	7.4	189	2.8
Lung Tx: Number of men	59	3.5	29	0.8	16	1.6							222	4.8	38	3.8	102	1.5
Paediatric <18 years			2	0.1	1	0.1	0	0.0					7	0.2	2	0.2	6	0.1
Single Tx	9	0.5	8	0.2	4	0.4	0	0.0					106	2.3	11	1.1	15	0.2
Double Tx (heart–lung Tx included)	80	4.7	35	0.9	23	2.2	4	0.2					263	5.7	63	6.3	174	2.6
Tx from DCD (double + single)	30	1.8	0	0.0	0	0.0	0	0.0					64	1.4	1	0.1	38	0.6
PANCREAS																		
Total Tx –all combinations included–	36	2.1	20	0.5	35	3.4	0	0.0	0	0.0	3	1.4	82	1.8	18	1.8	217	3.3
Pancreas Tx: Number of men	23	1.3	12	0.3	21	2.0					0	0.0	39	0.8	12	1.2	124	1.9
Paediatric <18 years	1	0.1	0	0.0	0	0.0					0	0.0	2	0.0	1	0.1	4	0.1
Pancreas Tx Alone	14	0.8	1	0.0	2	0.2					0	0.0	10	0.2	6	0.6	20	0.3
Kidney – Pancreas Tx	20	1.2	19	0.5	33	3.2					3	1.4	68	1.5	12	1.2	174	2.6
Tx from DCD	19	1.1	0	0.0	0	0.0					0	0.0	4	0.1	0	0.0	58	0.9
SMALL BOWEL																		
Total Tx –all combinations included–	2	0.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	0.1	2	0.2	25	0.4
Small bowel Tx: Number of men													2	0.0	2	0.2	16	0.2
Paediatric <18 years													2	0.0	1	0.1	5	0.1
Small bowel Tx Alone													2	0.0	0	0.0	2	0.0
RECIPIENTS																		
Total number of patients transplanted	1336	78.1	1447	38.0	783	76.0	263	13.4	201	37.2	106	50.5	5196	112.0	753	75.3	5122	76.9
Patients transplanted: Number of men	868	50.8	917	24.1	512	49.7			124	23.0	69	32.9	3462	74.6	483	48.3	3190	47.9
Paediatric <18 years	50	2.9	82	2.2	22	2.1	9	0.5	3	0.6	1	0.5	188	4.1	36	3.6	283	4.2
Patients transplanted from living donors	522	30.5	62	1.6	60	5.8	75	3.8	11	2.0	2	1.0	316	6.8	145	14.5	1053	15.8

TRANSPLANTATION ACTIVITY

OTHER COUNTRIES

Country	Algeria		Armenia		Australia		Belarus		Bosnia and Herzegovina		Canada		Georgia		Iceland		India		Israel		Kuwait		Malaysia	
Population (million inhabitants): UNFPA	**42.0**		**2.9**		**24.8**		**9.5**		**3.5**		**37.0**		**3.9**		**0.3**		**1354.1**		**8.5**		**4.2**		**32.0**	
TRANSPLANTATION	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
KIDNEY																								
Total Tx –all combinations included–	268	6.4	12	4.1	1135	45.8	356	37.5			1706	46.1	17	4.4	9	30.0	7936	5.9	401	47.2	70	16.7	80	2.5
Kidney tx: Number of men	153	3.6	5	1.7	715	28.8	170	17.9					10	2.6	8	26.7			273	32.1	49	11.7	41	1.3
Paediatric <18 years	11	0.3	1	0.3	45	1.8	21	2.2			50	1.4	1	0.3	1	3.3	50	0.0	27	3.2	3	0.7	5	0.2
Tx from DD	0	0.0	0	0.0	897	36.2	350	36.8			1219	32.9	0	0.0	0	0.0	1164	0.9	170	20.0	19	4.5	12	0.4
– Tx from DCD	0	0.0			249	10.0	0	0.0			357	9.6	0	0.0			5	0.0	4	0.5	0	0.0	0	0.0
– Single Tx	0	0.0			872	35.2	350	36.8			1204	32.5	0	0.0			1111	0.8	165	19.4	19	4.5	12	0.4
– Double Tx	0	0.0			25	1.0	0	0.0			15	0.4	0	0.0			53	0.0	5	0.6	0	0.0	0	0.0
Tx from living donors	268	6.4	12	4.1	238	9.6	6	0.6			487	13.2	17	4.4	9	30.0	6772	5.0	231	27.2	51	12.1	68	2.1
– Tx from related living donors	268	6.4	12	4.1	192	7.7	6	0.6			250	6.8			9	30.0	5205	3.8	105	12.4	27	6.4	68	2.1
– Tx from unrelated living donors	0	0.0	0	0.0	46	1.9	0	0.0			237	6.4			0	0.0	1567	1.2	126	14.8	24	5.7	0	0.0
Paired exchange or cross–over					40	1.6													25	2.9	0	0.0		
Non–directed altruistic or anonymous					6	0.2													17	2.0	0	0.0		
Directed altruistic																			84	9.9	24	5.7		
LIVER																								
Total Tx –all combinations included–	7	0.2	0	0.0	320	12.9	80	8.4			536	14.5	13	3.3	0	0.0	1945	1.4	117	13.8	4	1.0	4	0.1
Liver tx: Number of men	4	0.1			203	8.2	47	4.9					9	2.3					73	8.6	3	0.7	1	0.0
Paediatric <18 years	0	0.0					7	0.7			42	1.1	0	0.0			99	0.1	20	2.4	0	0.0	0	0.0
Split Tx	0	0.0			43	1.7	0	0.0			8	0.2					5	0.0	4	0.5	0	0.0	0	0.0
Domino Tx	0	0.0			0	0.0	0	0.0					0	0.0			1	0.0	0	0.0	0	0.0	0	0.0
Tx from living donors	7	0.2			0	0.0	6	0.6			69	1.9	13	3.3			1313	1.0	17	2.0	0	0.0	1	0.0
Tx from DCD	0	0.0			21	0.8	0	0.0			41	1.1					0	0.0	0	0.0	0	0.0	0	0.0
HEART																								
Total Tx –all combinations included–	0	0.0	0	0.0	128	5.2	41	4.3			193	5.2	0	0.0	0	0.0	241	0.2	26	3.1	0	0.0	1	0.0
Heart tx: Number of men					87	3.5	32	3.4											14	1.6			0	0.0
Paediatric <18 years					11	0.4	0	0.0			22	0.6					17	0.0	2	0.2			0	0.0
HEART–LUNG																								
Total Tx	0	0.0			7	0.3	0	0.0					0	0.0			44	0.0	0	0.0	0	0.0	0	0.0
Paediatric <18 years					1	0.0											0	0.0						
LUNG																								
Total Tx –all combinations included–	0	0.0	0	0.0	221	8.9	4	0.4			361	9.8	0	0.0	0	0.0	191	0.1	56	6.6	0	0.0	0	0.0
Lung Tx: Number of men					133	5.4	2	0.2											43	5.1				
Paediatric <18 years					5	0.2	0	0.0			5	0.1					4	0.0	1	0.1				
Single Tx					22	0.9	0	0.0			37	1.0					5	0.0	12	1.4				
Double Tx (heart–lung Tx included)					199	8.0	4	0.4			324	8.8					186	0.1	44	5.2				
Tx from DCD (double + single)					56	2.3	0	0.0			83	2.2					0	0.0	0	0.0				
PANCREAS																								
Total Tx –all combinations included–	0	0.0	0	0.0	52	2.1	1	0.1			57	1.5	0	0.0	0	0.0	25	0.0	8	0.9	0	0.0	0	0.0
Pancreas Tx: Number of men					30	1.2	1	0.1											4	0.5				
Paediatric <18 years					0	0.0	0	0.0			0	0.0					0	0.0	0	0.0				
Pancreas Tx Alone					4	0.2	0	0.0			9	0.2					11	0.0	1	0.1				
Kidney – Pancreas Tx					47	1.9	1	0.1			48	1.3					14	0.0	7	0.8				
Tx from DCD					2	0.1	0	0.0			5	0.1					0	0.0	0	0.0				
SMALL BOWEL																								
Total Tx –all combinations included–	0	0.0	0	0.0	1	0.0	0	0.0					0	0.0	0	0.0	2	0.0	1	0.1	0	0.0	0	0.0
Small bowel Tx: Number of men					1	0.0													0	0.0				
Paediatric <18 years					1	0.0											0	0.0	0	0.0				
Small bowel Tx Alone					0	0.0											0	0.0	1	0.1				
RECIPIENTS																								
Total number of patients transplanted	275	6.5	12	4.1	1780	71.8	482	50.7			2826	76.4	30	7.7	9	30.0	10282	7.6	592	69.6	74	17.6	85	2.7
Patients transplanted: Number of men	157	3.7	5	1.7	454	18.3	252	26.5					19	4.9	8	26.7			398	46.8	52	12.4	42	1.3
Paediatric <18 years	11	0.3	1	0.3	62	2.5	28	2.9			127	3.4	1	0.3	1	3.3	170	0.1	50	5.9	3	0.7	5	0.2
Patients transplanted from living donors	275	6.5	12	4.1	236	9.5	12	1.3			556	15.0	30	7.7	9	30.0	8085	6.0	248	29.2	51	12.1	69	2.2

TRANSPLANTATION ACTIVITY

OTHER COUNTRIES

Country	New Zealand		Norway		Qatar		Republic of Moldova		Russian Federation		Saudi Arabia		Sudan		Switzerland		Syrian Arab Republic		The Rep. of North of Macedonia		Turkey		United States of America	
Population (million inhabitants): UNFPA	**4.7**		**5.4**		**2.7**		**4.0**		**144.0**		**33.6**		**41.5**		**8.5**		**18.3**		**2.1**		**81.9**		**326.8**	
TRANSPLANTATION																								
	Number	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
KIDNEY																								
Total Tx -all combinations included-	182	38.7	240	45.3	43	15.9	13	3.2	1361	9.5	1006	29.9	273	6.6	352	41.4	251	13.7	17	8.1	3874	47.3	22003	67.3
Kidney tx: Number of men	114	24.3	137	25.8	29	10.7	7	1.7	754	5.2			198	4.8	227	26.7					2485	30.3	1382	4.2
Paediatric <18 years	6	1.3	5	0.9	1	0.4	0	0.0	86	0.6	87	2.6	29	0.7	15	1.8	27	1.5			224	2.7	756	2.3
Tx from DD	98	20.9	168	31.7	11	4.1	7	1.7	1161	8.1	141	4.2	0	0.0	239	28.1	0	0.0	2	1.0	859	10.5	15561	47.6
- Tx from DCD	15	3.2	0	0.0	0	0.0	0	0.0	65	0.5	0	0.0	0	0.0	37	4.4	0	0.0	0	0.0	0	0.0	3302	10.1
- Single Tx	97	20.6	166	31.3	10	3.7			1161	8.1	136	4.0	0	0.0	228	26.8	0	0.0			819	10.0	15245	46.6
- Double Tx	1	0.2	2	0.4	1	0.4			0	0.0	5	0.1	0	0.0	11	1.3	0	0.0			40	0.5	316	1.0
Tx from living donors	84	17.9	72	13.6	32	11.9	6	1.5	200	1.4	865	25.7	273	6.6	113	13.3	251	13.7	15	7.1	3015	36.8	6442	19.7
- Tx from related living donors	69	14.7	72	13.6	32	11.9	6	1.5	200	1.4	701	20.9	269	6.5			123	6.7	15	7.1	2550	31.1	5121	15.7
- Tx from unrelated living donors	15	3.2	0	0.0	0	0.0	0	0.0	0	0.0	164	4.9	4	0.1			128	7.0	0	0.0	465	5.7	1321	4.0
Paired exchange or cross-over											52	1.5	4	0.1			0	0.0			181	2.2	933	2.9
Non-directed altruistic or anonymous											5	0.1	0	0.0			0	0.0			0	0.0	382	1.2
Directed altruistic											107	3.2	0	0.0			128	7.0			0	0.0	6	0.0
LIVER																								
Total Tx -all combinations included-	49	10.4	95	17.9	8	3.0	11	2.7	505	3.5	270	8.0	0	0.0	156	18.4	0	0.0	0	0.0	1587	19.4	8250	25.2
Liver tx: Number of men	27	5.7	57	10.8	5	1.9	8	2.0	247	1.7					112	13.2					1041	12.7	5278	16.2
Paediatric <18 years	8	1.7	13	2.5	0	0.0	5	1.2	133	0.9	102	3.0			12	1.4					265	3.2	563	1.7
Split Tx	9	1.9	6	1.1	0	0.0	0	0.0	22	0.2	12	0.4			10	1.2					22	0.3	199	0.6
Domino Tx	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.0			0	0.0					6	0.1	9	0.0
Tx from living donors	2	0.4	1	0.2	3	1.1	5	1.2	163	1.1	207	6.2			7	0.8					1143	14.0	392	1.2
Tx from DCD	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0			21	2.5					0	0.0	535	1.6
HEART																								
Total Tx -all combinations included-	20	4.3	29	5.5	0	0.0	0	0.0	285	2.0	27	0.8	0	0.0	50	5.9	0	0.0	0	0.0	91	1.1	3440	10.5
Heart tx: Number of men	14	3.0	15	2.8					248	1.7	20	0.6			36	4.2					66	0.8	2397	7.3
Paediatric <18 years	2	0.4	5	0.9					9	0.1	4	0.1			6	0.7					17	0.2	473	1.4
HEART-LUNG																								
Total Tx	0	0.0	0	0.0	0	0.0	0	0.0	3	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	32	0.1
Paediatric <18 years									0	0.0													5	0.0
LUNG																								
Total Tx -all combinations included-	28	6.0	30	5.7	0	0.0	0	0.0	28	0.2	35	1.0	0	0.0	42	4.9	0	0.0	0	0.0	43	0.5	2562	7.8
Lung Tx: Number of men	16	3.4	17	3.2					19	0.1	21	0.6			29	3.4					31	0.4	1531	4.7
Paediatric <18 years	0	0.0	1	0.2					2	0.0	3	0.1			1	0.1					0	0.0	40	0.1
Single Tx	1	0.2	0	0.0					3	0.0	2	0.1			2	0.2					0	0.0	640	2.0
Double Tx (heart-lung Tx included)	27	5.7	30	5.7					25	0.2	33	1.0			40	4.7					43	0.5	1922	5.9
Tx from DCD (double + single)	2	0.4	0	0.0					0	0.0	0	0.0			4	0.5					0	0.0	121	0.4
PANCREAS																								
Total Tx -all combinations included-	6	1.3	15	2.8	0	0.0	0	0.0	17	0.1	8	0.2	0	0.0	11	1.3	0	0.0	0	0.0	4	0.0	1027	3.1
Pancreas Tx: Number of men	2	0.4	3	0.6					8	0.1	3	0.1			8	0.9					1	0.0	614	1.9
Paediatric <18 years	0	0.0	0	0.0					0	0.0	0	0.0			0	0.0					0	0.0	32	0.1
Pancreas Tx Alone	0	0.0	8	1.5					1	0.0	0	0.0			3	0.4					4	0.0	191	0.6
Kidney – Pancreas Tx	6	1.3	7	1.3					16	0.1	8	0.2			8	0.9					0	0.0	836	2.6
Tx from DCD	0	0.0	0	0.0					0	0.0	0	0.0			0	0.0					0	0.0	25	0.1
SMALL BOWEL																								
Total Tx -all combinations included-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	0.1			0	0.0	0	0.0	0	0.0	0	0.0	104	0.3
Small bowel Tx: Number of men											2	0.1											60	0.2
Paediatric <18 years											0	0.0											37	0.1
Small bowel Tx Alone											4	0.1											37	0.1
RECIPIENTS																								
Total number of patients transplanted	276	58.7	400	75.5	51	18.9	24	5.9	2177	15.1	1341	39.9	273	6.6	599	70.5	251	13.7	17	8.1	5599	68.4	35274	107.9
Patients transplanted: Number of men			226	42.6	34	12.6	15	3.7	1262	8.8			198	4.8	402	47.3					3624	44.2	21825	66.8
Paediatric <18 years	16	3.4	24	4.5	1	0.4	1	0.2	230	1.6	195	5.8	29	0.7	34	4.0	27	1.5			506	6.2	1796	5.5
Patients transplanted from living donors	86	18.3	73.0	13.8	35	13.0	11	2.7	363	2.5	1072	31.9	273	6.6	120	14.1	251	13.7	15	7.1	4164	50.8	6842	20.9

TRANSPLANTATION ACTIVITY

LATIN AMERICAN COUNTRIES

Country	Argentina		Bolivia		Brazil		Chile		Colombia		Costa Rica		Cuba		Dominican Republic		Ecuador		El Salvador	
Population (million inhabitants): UNFPA	**44.7**		**11.2**		**210.9**		**18.2**		**49.5**		**5.0**		**11.5**		**10.9**		**16.9**		**6.4**	
TRANSPLANTATION																				
	Number	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
KIDNEY																				
Total Tx –all combinations included–	1475	33.0	76	6.8	5975	28.3	212	11.6	864	17.5	63	12.6	173	15.0	54	5.0	249	14.7	34	5.3
Kidney tx: Number of men	850	19.0	36	3.0	3621	17.2			502	10.1	38	7.6			34	3.1	145	8.6	22	3.4
Paediatric <18 years	155	3.5	4	0.4	337	1.6			55	1.1	2	0.4	4	0.3	0	0.0	22	1.3	1	0.2
Tx from DD	1099	24.6	8	0.7	4942	23.4			724	14.6	42	8.4	160	13.9	13	1.2	227	13.4	0	0.0
– Tx from DCD	0	0.0	0	0.0	0	0.0			0	0.0			0	0.0	0	0.0	0	0.0		
– Single Tx	1099	24.6	8	0.7	4932	23.4			709	14.3			160	13.9	0	0.0	227	13.4		
– Double Tx	0	0.0	0	0.0	10	0.0			15	0.3			0	0.0	13	1.2	0	0.0		
Tx from living donors	376	8.4	68	6.1	1033	4.9			140	2.8	21	4.2	13	1.1	41	3.8	22	1.3	34	5.3
– Tx from related living donors	376	8.4	68	6.1	981	4.7			140	2.8			13	1.1	28	2.6	22	1.3		
– Tx from unrelated living donors	0	0.0	0	0.0	52	0.2			0	0.0			0	0.0	13	1.2	0	0.0		
Paired exchange or cross–over																				
Non–directed altruistic or anonymous																				
Directed altruistic																				
LIVER																				
Total Tx –all combinations included–	473	10.6	1	0.1	2221	10.5	87	4.8	251	5.1	27	5.4	13	1.1	3	0.3	29	1.7	0	0.0
Liver tx: Number of men	276	6.2	0	0.0	1491	7.1			132	2.7	14	2.8			3	0.3	20	1.2		
Paediatric <18 years	97	2.2	0	0.0	239	1.1			71	1.4	6	1.2	1	0.1	0	0.0	2	0.1		
Split Tx	55	1.2	0	0.0	6	0.0			0	0.0	1	0.2	0	0.0			0	0.0		
Domino Tx	0	0.0	0	0.0	6	0.0					0	0.0	0	0.0	0	0.0				
Tx from living donors	41	0.9	1	0.1	175	0.8			50	1.0	2	0.4	1	0.1	0	0.0				
Tx from DCD	0	0.0	0	0.0	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0				
HEART																				
Total Tx –all combinations included–	132	3.0	0	0.0	358	1.7	30	1.6	57	1.2	8	1.6	0	0.0	0	0.0	0	0.0	0	0.0
Heart tx: Number of men	86	1.9			234	1.1			47	0.9	6	1.2								
Paediatric <18 years	15	0.3			39	0.2			3	0.1	0	0.0								
HEART–LUNG																				
Total Tx	1	0.0	0	0.0	0	0.0			0	0.0	2	0.4	0	0.0	0	0.0	0	0.0	0	0.0
Paediatric <18 years	0	0.0									0	0.0								
LUNG																				
Total Tx –all combinations included–	44	1.0	0	0.0	121	0.6	13	0.7	17	0.3	2	0.4	0	0.0	0	0.0	1	0.1	0	0.0
Lung Tx: Number of men	26	0.6			65	0.3			5	0.1	0	0.0					0	0.0		
Paediatric <18 years	4	0.1			12	0.1			1	0.0	0	0.0					0	0.0		
Single Tx	19	0.4			46	0.2			7	0.1	0	0.0					0	0.0		
Double Tx (heart–lung Tx included)	25	0.6			73	0.3			10	0.2	2	0.4					1	0.1		
Tx from DCD (double + single)	0	0.0			0	0.0			0	0.0	0	0.0					0	0.0		
PANCREAS																				
Total Tx –all combinations included–	89	2.0	0	0.0	150	0.7	7	0.4	10	0.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pancreas Tx: Number of men	32	0.7			62	0.3			4	0.1										
Paediatric <18 years	0	0.0			0	0.0			0	0.0										
Pancreas Tx Alone	5	0.1			44	0.2			2	0.0										
Kidney – Pancreas Tx	84	1.9			106	0.5			8	0.2										
Tx from DCD	0	0.0			0	0.0			0	0.0										
SMALL BOWEL																				
Total Tx –all combinations included–	1	0.0	0	0.0	4	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Small bowel Tx: Number of men	0	0.0			4	0.0														
Paediatric <18 years	1	0.0			1	0.0														
Small bowel Tx Alone	0	0.0			0	0.0														
RECIPIENTS																				
Total number of patients transplanted	2102	47.0	77	6.9	8642	41.0			1184	23.9	99	19.8	186	16.2	57	5.2	279	16.5	34	5.3
Patients transplanted: Number of men	1224	27.3	36	3.2	3502	16.6			686	13.9	58	11.6			34	3.1	165	9.8	22	3.4
Paediatric <18 years	265	5.9	4	0.4	616	2.9			130	2.6	8	1.6	5	0.4	0	0.0	24	1.4	1	0.2
Patients transplanted from living donors	417	9.3	69	6.2	1192	5.7			190	3.8	23	4.6	14	1.2	41	3.8	22	1.3	34	5.3

TRANSPLANTATION ACTIVITY

LATIN AMERICAN COUNTRIES

Country Population (million inhabitants): UNFPA	Guatemala 17.2		Honduras 9.4		Mexico 130.8		Nicaragua 6.3		Panama 4.2		Paraguay 6.9		Peru 32.6		Uruguay 3.5		Venezuela 32.4	
TRANSPLANTATION																		
	Number	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**	**Number**	**PMP**
KIDNEY																		
Total Tx –all combinations included–	115	6.7			3081	23.6	16	2.5	46	11.0	41	5.9	157	4.8	161	46.0	40	1.2
Kidney tx: Number of men	67	3.9			1958	15.0			31	7.4	33	4.8	91	2.8	100	28.6		
Paediatric <18 years	10	0.6			224	1.7	1	0.2	0	0.0	4	0.6	27	0.8	7	2.0	0	0.0
Tx from DD	10	0.6			976	7.5	1	0.2	38	9.0	25	3.6	115	3.5	148	42.3	0	0.0
– Tx from DCD	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
– Single Tx	10	0.6			966	7.4	1	0.2	38	9.0			115	3.5			0	0.0
– Double Tx	0	0.0			10	0.1	0	0.0	0	0.0			0	0.0			0	0.0
Tx from living donors	105	6.1			2105	16.1	15	2.4	8	1.9	16	2.3	42	1.3	13	3.7	40	1.2
– Tx from related living donors	103	6.0			1719	13.1	15	2.4	8	1.9	16	2.3	41	1.3	13	3.7		
– Tx from unrelated living donors	2	0.1			386	3.0	0	0.0	0	0.0	0	0.0	1	0.0	0	0.0		
Paired exchange or cross–over																		
Non–directed altruistic or anonymous																		
Directed altruistic																		
LIVER																		
Total Tx –all combinations included–	0	0.0			241	1.8	0	0.0	16	3.8	3	0.4	45	1.4	25	7.1	0	0.0
Liver tx: Number of men					138	1.1			11	2.6	0	0.0	26	0.8	13	3.7		
Paediatric <18 years					37	0.3			0	0.0	0	0.0	13	0.4	3	0.9		
Split Tx									0	0.0	0	0.0	3	0.1	0	0.0		
Domino Tx					0	0.0			0	0.0	0	0.0	0	0.0	0	0.0		
Tx from living donors					17	0.1			0	0.0	0	0.0	5	0.2	2	0.6		
Tx from DCD					0	0.0			0	0.0	0	0.0	0	0.0	0	0.0		
HEART																		
Total Tx –all combinations included–	0	0.0			26	0.2	0	0.0	1	0.2	2	0.3	12	0.4	14	4.0	0	0.0
Heart tx: Number of men					20	0.2			1	0.2	2	0.3	10	0.3	9	2.6		
Paediatric <18 years					0	0.0			0	0.0	0	0.0	3	0.1	1	0.3		
HEART–LUNG																		
Total Tx	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Paediatric <18 years																		
LUNG																		
Total Tx –all combinations included–	0	0.0			3	0.0	0	0.0	0	0.0	0	0.0	4	0.1	5	1.4	0	0.0
Lung Tx: Number of men					3	0.0							2	0.1	2	0.6		
Paediatric <18 years					0	0.0							0	0.0	0	0.0		
Single Tx					2	0.0												
Double Tx (heart–lung Tx included)					1	0.0												
Tx from DCD (double + single)					0	0.0							0	0.0	0	0.0		
PANCREAS																		
Total Tx –all combinations included–	0	0.0			1	0.0	0	0.0	0	0.0	0	0.0	2	0.1	0	0.0	0	0.0
Pancreas Tx: Number of men					1	0.0							2	0.1				
Paediatric <18 years					0	0.0							0	0.0				
Pancreas Tx Alone					0	0.0							0	0.0				
Kidney – Pancreas Tx					0	0.0							2	0.1				
Tx from DCD					0	0.0							0	0.0				
SMALL BOWEL																		
Total Tx –all combinations included–	0	0.0			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Small bowel Tx: Number of men																		
Paediatric <18 years																		
Small bowel Tx Alone																		
RECIPIENTS																		
Total number of patients transplanted	115	6.7					16	2.5	63	15.0	46	6.7	216	6.6	205	58.6	40	1.2
Patients transplanted: Number of men	67	3.9							43	10.2	35	5.1	130	4.0	124	35.4		
Paediatric <18 years	10	0.6					1	0.2	0	0.0	4	0.6	42	1.3	11	3.1	0	0.0
Patients transplanted from living donors	105	6.1					15	2.4	8	1.9	16	2.3	47	1.4	15	4.3	40	1.2

WAITING LIST

EUROPEAN UNION COUNTRIES

Country Population (million inhabitants): UNFPA	Austria 8.8	Belgium 11.5	Bulgaria 7.0	Croatia 4.2	Cyprus 1.2	Czech Republic 10.6	Denmark 5.2	Estonia 1.3	Finland 5.5	France 65.2
KIDNEY										
N Tx CENTRES	5	8	3	4	1	7	3	1	1	44
Patients included on the WL for the first time in the course of 2018	508	607	148	171	12	480	276	46	273	5269
Total number of patients ever active on the WL during 2018	1036	1456	1052		62	799	881	111	787	19625
Patients awaiting for a transplant (only active candidates) on 31/12/2018	597	824	924	168	58	523	414	33	380	8065
Patients who died while on the WL during 2018	27	33	77	15	0	43	33	2	10	396
Patients on dialysis on 31/12/2018			877	2500				410		
LIVER										
N Tx CENTRES	3	7	3	3	0	2	1	1	1	21
Patients included on the WL for the first time in the course of 2018	231	375	22	161	0	242	48	11	64	1883
Total number of patients ever active on the WL during 2018	299	576	68		0	105	80	15	77	3306
Patients awaiting for a transplant (only active candidates) on 31/12/2018	87	189	24	114	0	76	25	4	7	737
Patients who died while on the WL during 2018	20	35	13	30	0	10	3	1	0	193
HEART										
N Tx CENTRES	3	7	2	2	0	2	2	0	1	24
Patients included on the WL for the first time in the course of 2018	68	99	31	62	0	87	31		42	626
Total number of patients ever active on the WL during 2018	137	202	60		0	138	52		85	941
Patients awaiting for a transplant (only active candidates) on 31/12/2018	60	111	28	38	0	82	14		27	256
Patients who died while on the WL during 2018	10	8	17	6	0	26	2		5	67
LUNG										
N Tx CENTRES	2	3	2	0	0	1	1	1	1	12
Patients included on the WL for the first time in the course of 2018	126	141	13	0	0	60	29	6	26	419
Total number of patients ever active on the WL during 2018	231	284	22	0	0	65	59	11	47	545
Patients awaiting for a transplant (only active candidates) on 31/12/2018	72	143	13	0	0	58	26	5	20	119
Patients who died while on the WL during 2018	9	6	7	0	0	15	3	0	6	14
PANCREAS										
N Tx CENTRES	3	8	1	1	0	1	1	1	1	12
Patients included on the WL for the first time in the course of 2018	21	34	0	7	0	50	8	4	28	103
Total number of patients ever active on the WL during 2018	31	95	11		0	49	15	6	43	339
Patients awaiting for a transplant (only active candidates) on 31/12/2018	10	57	11	11	0	33	7	2	15	106
Patients who died while on the WL during 2018	2	2	0	4	0	1	2	0	0	6
SMALL BOWEL										
N Tx CENTRES		10	1	1	0	1	0	0	1	5
Patients included on the WL for the first time in the course of 2018			0	0	0	3	0		0	2
Total number of patients ever active on the WL during 2018			0	0	0	2	0		0	6
Patients awaiting for a transplant (only active candidates) on 31/12/2018		6	0	0	0	1	0		0	2
Patients who died while on the WL during 2018			0	0	0	0	0		0	

WAITING LIST

EUROPEAN UNION COUNTRIES

Country Population (million inhabitants): UNFPA	Germany 82.3	Greece 11.1	Hungary 9.7	Ireland 4.8	Italy 59.3	Latvia 1.9	Lithuania 2.9	Luxembourg 0.6	Malta 0.4
KIDNEY									
N Tx CENTRES	38	5	4	1	40	1	2	0	1
Patients included on the WL for the first time in the course of 2018	2348	220	393	178	2330	59	99	0	10
Total number of patients ever active on the WL during 2018	10616	1354	1230	660	9059	82	201	0	92
Patients awaiting for a transplant (only active candidates) on 31/12/2018	7526	1246	818	429	6770	28	100	0	
Patients who died while on the WL during 2018	453	35	53	17	167	1	7	0	6
Patients on dialysis on 31/12/2018		11843	6915	2124		650	1340	0	292
LIVER									
N Tx CENTRES	21	2	1	1	22	1	2	0	0
Patients included on the WL for the first time in the course of 2018	1177	70	81	63	1461	17	51	0	0
Total number of patients ever active on the WL during 2018	2387	218	181	98	2434	9	97	0	0
Patients awaiting for a transplant (only active candidates) on 31/12/2018	851	159	72	32	961	6	38	0	0
Patients who died while on the WL during 2018	289	21	12	6	129	3	22	0	0
HEART									
N Tx CENTRES	23	1	2	1	16	1	2	0	1
Patients included on the WL for the first time in the course of 2018	493	15	84	23	324	8	27	0	
Total number of patients ever active on the WL during 2018	1223	57	144	37	1047	8	70	0	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	719	38	60	10	711	5	38	0	
Patients who died while on the WL during 2018	86	9	10	2	53	0	16	0	
LUNG									
N Tx CENTRES	15	0	1	1	11	0	1	0	0
Patients included on the WL for the first time in the course of 2018	391		30	43	214	0	4	0	0
Total number of patients ever active on the WL during 2018	799		42	85	562	0	14	0	0
Patients awaiting for a transplant (only active candidates) on 31/12/2018	314		10	32	362	0	6	0	0
Patients who died while on the WL during 2018	71		4	16	39	0	6	0	0
PANCREAS									
N Tx CENTRES	28	0	2	1	16	1	1	0	0
Patients included on the WL for the first time in the course of 2018	144		17	10	62		4	0	0
Total number of patients ever active on the WL during 2018	458		48	24	311	0	7	0	0
Patients awaiting for a transplant (only active candidates) on 31/12/2018	287		40	19	253	0	0	0	0
Patients who died while on the WL during 2018	36		0	1	0	0	0	0	0
SMALL BOWEL									
N Tx CENTRES	9	0	0		2	0	0	0	0
Patients included on the WL for the first time in the course of 2018			0	0	0	0		0	0
Total number of patients ever active on the WL during 2018			0	0	12	0		0	0
Patients awaiting for a transplant (only active candidates) on 31/12/2018	12		0	0	11	0		0	0
Patients who died while on the WL during 2018			0	0	0	0		0	0

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EUROPEAN UNION COUNTRIES

Country	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	United Kingdom
Population (million inhabitants): UNFPA	**17.1**	**38.1**	**10.3**	**19.6**	**5.4**	**2.1**	**46.4**	**10.0**	**66.6**
KIDNEY									
N Tx CENTRES	10	21	8	5	4	1	40	4	24
Patients included on the WL for the first time in the course of 2018	1521	1178	323	523	154	79		408	2552
Total number of patients ever active on the WL during 2018	2194	2745	2342	5582	432	132	7246	1173	9072
Patients awaiting for a transplant (only active candidates) on 31/12/2018	741	1196	1968	5255	296	73	3933	423	5000
Patients who died while on the WL during 2018	66	73	41	13	29			31	283
Patients on dialysis on 31/12/2018		20000	13014	9900	3560		27629		2841
LIVER									
N Tx CENTRES	3	9	3	4	1	1	25	2	7
Patients included on the WL for the first time in the course of 2018	239	393	238	138	38	36	1374	168	334
Total number of patients ever active on the WL during 2018	372	626	323	610	64	54	1829	222	1692
Patients awaiting for a transplant (only active candidates) on 31/12/2018	127	158	113	573	22	19	386	42	407
Patients who died while on the WL during 2018	26	27	18	32	4	5	51	4	39
HEART									
N Tx CENTRES	3	6	4	3	1	1	16	2	7
Patients included on the WL for the first time in the course of 2018	57	326	47	29	24	39	363	75	159
Total number of patients ever active on the WL during 2018	164	946	71	214	51	81	475	113	603
Patients awaiting for a transplant (only active candidates) on 31/12/2018	121	453	27	15	33	48	126	31	309
Patients who died while on the WL during 2018	9	99	12	9	4	5	11	3	23
LUNG									
N Tx CENTRES	3	5	1	1	0		8	2	6
Patients included on the WL for the first time in the course of 2018	133	145	39	6	0		411	60	175
Total number of patients ever active on the WL during 2018	311	228	97	10	0		671	95	633
Patients awaiting for a transplant (only active candidates) on 31/12/2018	186	113	57	2	0		241	15	354
Patients who died while on the WL during 2018	12	22	6	0	0		25	0	63
PANCREAS									
N Tx CENTRES	2	1	2	0	1	1	13	4	10
Patients included on the WL for the first time in the course of 2018	42	44	33	0	0	3	107	26	163
Total number of patients ever active on the WL during 2018	89	107	77	0	0	5	210	38	478
Patients awaiting for a transplant (only active candidates) on 31/12/2018	41	47	28	0	0	1	98	16	185
Patients who died while on the WL during 2018	1	2	1	0	0		3	1	19
SMALL BOWEL									
N Tx CENTRES				0	0		3	1	4
Patients included on the WL for the first time in the course of 2018		1		0	0		4	2	0
Total number of patients ever active on the WL during 2018		2		0	0		16	3	41
Patients awaiting for a transplant (only active candidates) on 31/12/2018		1		0	0		9	1	10
Patients who died while on the WL during 2018		0		0	0		1	0	2

WAITING LIST

OTHER COUNTRIES

Country	Algeria	Armenia	Australia	Belarus	Bosnia and Herzegovina	Canada	Georgia	Iceland	India	Israel	Kuwait	Malaysia
Population (million inhabitants): UNFPA	**42.0**	**2.9**	**24.8**	**9.5**		**37.0**	**3.9**	**0.3**	**1354.1**	**8.5**	**4.2**	**32.0**
KIDNEY												
N Tx CENTRES	12	1	20	7		25	3	1	443	6	1	6
Patients included on the WL for the first time in the course of 2018			1014	395					6094	419	104	
Total number of patients ever active on the WL during 2018			1979	721					12758		389	
Patients awaiting for a transplant (only active candidates) on 31/12/2018			982	334		2016			8158	813	131	5147
Patients who died while on the WL during 2018			6	31		94			192	47	6	459
Patients on dialysls on 31/12/2018	23798		13412	3741			2645		11222	6687	2000	42350
LIVER												
N Tx CENTRES	3	0	8	1		9	2	0	147	3	1	2
Patients included on the WL for the first time in the course of 2018			361	109					3017	171	8	6
Total number of patients ever active on the WL during 2018			508	216					4173		8	9
Patients awaiting for a transplant (only active candidates) on 31/12/2018			136	124		377			1700	101	3	4
Patients who died while on the WL during 2018			6	12		81			456	32	1	1
HEART												
N Tx CENTRES	0	0	5	1		11	0	0	115	2	0	1
Patients included on the WL for the first time in the course of 2018			159	52					302	63	0	2
Total number of patients ever active on the WL during 2018			223	116					425		0	9
Patients awaiting for a transplant (only active candidates) on 31/12/2018			74	67		109			155	85	0	7
Patients who died while on the WL during 2018			8	8		9			22	14	0	1
LUNG												
N Tx CENTRES	0	0	5	2		6	0	0	59	1	0	1
Patients included on the WL for the first time in the course of 2018			258	5					57	106	0	4
Total number of patients ever active on the WL during 2018			345	41					75		0	7
Patients awaiting for a transplant (only active candidates) on 31/12/2018			97	35		221			16	109	0	3
Patients who died while on the WL during 2018			14	2		28			3	30	0	4
PANCREAS												
N Tx CENTRES	0	0	2	1		8	0	0	40	2	1	0
Patients included on the WL for the first time in the course of 2018			32	14					36		8	
Total number of patients ever active on the WL during 2018			103	77					48		5	
Patients awaiting for a transplant (only active candidates) on 31/12/2018			39	74		81			18	10	5	
Patients who died while on the WL during 2018			3	2					11		0	
SMALL BOWEL												
N Tx CENTRES	0	0	1	1		3	0	0	18	1	0	0
Patients included on the WL for the first time in the course of 2018			0	0					1		0	
Total number of patients ever active on the WL during 2018			3	0					6		0	
Patients awaiting for a transplant (only active candidates) on 31/12/2018			1	0		0			0		0	
Patients who died while on the WL during 2018			0	0		0			0		0	

WAITING LIST

OTHER COUNTRIES

Country	New Zealand	Norway	Qatar	Republic of Moldova	Russian Federation	Saudi Arabia	Sudan	Switzerland	Syrian Arab Republic	The Rep. of North Macedonia	Turkey	United States of America
Population (million inhabitants): UNFPA	**4.7**	**5.4**	**2.7**	**4.0**		**33.6**	**41.5**	**8.5**	**18.3**	**2.1**	**81.9**	**326.8**
KIDNEY												
N Tx CENTRES	4	1	1	1	49	18	7	6	6	1	78	237
Patients included on the WL for the first time in the course of 2018		258	42	13	1728	2650		394			6308	30726
Total number of patients ever active on the WL during 2018		771	108	51	6219	6750	216				28145	88595
Patients awaiting for a transplant (only active candidates) on 31/12/2018		343	54	32	4815	4850	30	478			20877	60901
Patients who died while on the WL during 2018		16	1	1	57			25			1939	3934
Patients on dialysis on 31/12/2018	2949		905	660	45000	19214	9525	400			63349	726331
LIVER												
N Tx CENTRES		1	1	1	28	6		3	1	0	49	147
Patients included on the WL for the first time in the course of 2018		97	12	22	579	285		209			2182	11766
Total number of patients ever active on the WL during 2018		142	16	110	1830	570					3424	23695
Patients awaiting for a transplant (only active candidates) on 31/12/2018		32	6	91	1171	300		88			1774	10666
Patients who died while on the WL during 2018		6	2	8	154			29			380	1164
HEART												
N Tx CENTRES		1	0	0	18	2		3	0	0	15	140
Patients included on the WL for the first time in the course of 2018		32		0	397	81		60			475	4293
Total number of patients ever active on the WL during 2018		48		3	823	120					1156	7648
Patients awaiting for a transplant (only active candidates) on 31/12/2018		11		3	490	93		46			946	2891
Patients who died while on the WL during 2018		0		0	48			12			199	316
LUNG												
N Tx CENTRES		1	0	0	3	2		2	0	0	5	71
Patients included on the WL for the first time in the course of 2018		37			35	50		43			81	3016
Total number of patients ever active on the WL during 2018		80			77	75					84	4363
Patients awaiting for a transplant (only active candidates) on 31/12/2018		41			34	37		24			48	1230
Patients who died while on the WL during 2018		7			15			4			36	213
PANCREAS												
N Tx CENTRES		1	0	0	6	2		2	0	0	8	135
Patients included on the WL for the first time in the course of 2018		9			33	18		18			23	1308
Total number of patients ever active on the WL during 2018		37			153	35					170	2432
Patients awaiting for a transplant (only active candidates) on 31/12/2018		13			132	27		19			166	1041
Patients who died while on the WL during 2018		0			4			6			2	112
SMALL BOWEL												
N Tx CENTRES		0	0	0	0	1		2	0	0	5	20
Patients included on the WL for the first time in the course of 2018		0			0	2		0			4	115
Total number of patients ever active on the WL during 2018		0			0	4		0			4	263
Patients awaiting for a transplant (only active candidates) on 31/12/2018		0			0	2		0			1	159
Patients who died while on the WL during 2018		0			0			0			3	14

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LATIN AMERICAN COUNTRIES

Country Population (million inhabitants): UNFPA	Argentina 44.7	Bolivia 11.2	Brazil 210.9	Chile 18.2	Colombia 49.5	Costa Rica 5.0	Cuba 11.5	Dominican Republic 10.9	Ecuador 16.9	El Salvador 6.4
KIDNEY										
N Tx CENTRES	58	10	191		25	7	9	8	8	
Patients included on the WL for the first time in the course of 2018	2177		12631		1484	50	100	53	420	
Total number of patients ever active on the WL during 2018	8310		33201		5166		450	255	592	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	5834		22736		2576	250	382	207	400	
Patients who died while on the WL during 2018	514		1402		93	32		4	14	
Patients on dialysis on 31/12/2018	30053		108468		26952	226	3200	4197	12367	
LIVER										
N Tx CENTRES	37	1	85		11	4	3	1	2	
Patients included on the WL for the first time in the course of 2018	834		3847		307	20	10	13	55	
Total number of patients ever active on the WL during 2018	2101		5112		726		32	42	58	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	1195		1112		138	21	30	33	15	
Patients who died while on the WL during 2018	192		814		24	10		8	11	
HEART										
N Tx CENTRES	25	0	64		7	1	1	2	1	
Patients included on the WL for the first time in the course of 2018	204		566		85	10	3	0	0	
Total number of patients ever active on the WL during 2018	330		843		179		5	0	0	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	120		270		22	0	4	0	0	
Patients who died while on the WL during 2018	40		110		9			0	0	
LUNG										
N Tx CENTRES	8	0	9		4	1	0	0	1	
Patients included on the WL for the first time in the course of 2018	137		177		46	4	0	0	1	
Total number of patients ever active on the WL during 2018	336		366		102	4	0	0	1	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	233		175		32	2	0	0	1	
Patients who died while on the WL during 2018	38		36		7		0	0	0	
PANCREAS										
N Tx CENTRES	16	0	22		5	1	0	1	0	
Patients included on the WL for the first time in the course of 2018	9		312		4		0	0	0	
Total number of patients ever active on the WL during 2018	14		855		5		0	0	0	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	11		438		3		0	0	0	
Patients who died while on the WL during 2018	0		63		0		0	0	0	
SMALL BOWEL										
N Tx CENTRES	2	0	3		4	1	0	0	0	
Patients included on the WL for the first time in the course of 2018	1		7		2		0	0	0	
Total number of patients ever active on the WL during 2018	11		9		2		0	0	0	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	9		7		1		0	0	0	
Patients who died while on the WL during 2018	0		0		0		0	0	0	

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LATIN AMERICAN COUNTRIES

Country Population (million inhabitants): UNFPA	Guatemala 17.2	Honduras	Mexico 130.8	Nicaragua	Panama 4.2	Paraguay 6.9	Peru 326.0	Uruguay 3.5	Venezuela 32.4
KIDNEY									
N Tx CENTRES	4		265		2	6	13	3	11
Patients included on the WL for the first time in the course of 2018			6017		35	84	28	193	
Total number of patients ever active on the WL during 2018			19316		134	175	998	615	
Patients awaiting for a transplant (only active candidates) on 31/12/2018			14912		81	88	841	389	
Patients who died while on the WL during 2018			159		5	0	0	24	
Patients on dialysls on 31/12/2018					2801	1400	12773	3329	
LIVER									
N Tx CENTRES	0		77		1	1	4	1	3
Patients included on the WL for the first time in the course of 2018	0		370		10	5	30	31	
Total number of patients ever active on the WL during 2018	0		694		20	13	70	65	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	0		323		3	7	22	33	
Patients who died while on the WL during 2018	0		60		1	3	3	5	
HEART									
N Tx CENTRES	0		56		1	4	3	3	0
Patients included on the WL for the first time in the course of 2018	0		34		1	8	14	20	
Total number of patients ever active on the WL during 2018	0		72		1	16	20	55	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	0		32		0	8	7	32	
Patients who died while on the WL during 2018	0		4		0	3	1	4	
LUNG									
N Tx CENTRES	0		11		0	0	2	1	0
Patients included on the WL for the first time in the course of 2018	0		7		0	0	4	10	
Total number of patients ever active on the WL during 2018	0		8		0	0	6	27	
Patients awaiting for a transplant (only active candidates) on 31/12/2018	0		2		0	0	2	19	
Patients who died while on the WL during 2018	0		1		0	0	0	0	
PANCREAS									
N Tx CENTRES	0		22		0	0	2	0	0
Patients included on the WL for the first time in the course of 2018	0		2		0	0	2		
Total number of patients ever active on the WL during 2018	0		15		0	0	2		
Patients awaiting for a transplant (only active candidates) on 31/12/2018	0		8		0	0	0		
Patients who died while on the WL during 2018	0		0		0	0	0		
SMALL BOWEL									
N Tx CENTRES	0		3		0	0	0	0	0
Patients included on the WL for the first time in the course of 2018	0		0		0	0	0		
Total number of patients ever active on the WL during 2018	0		0		0	0	0		
Patients awaiting for a transplant (only active candidates) on 31/12/2018	0		0		0	0	0		
Patients who died while on the WL during 2018	0		0		0	0	0		

International Data on Tissues and Haematopoietic Stem Cell Donation and Transplantation Activity. Year 2018

Data provided by National Competent Authorities:

EUROPE

Austria

Belgium

Bulgaria
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Yordan Peev

Cyprus

Czech Republic
Eva Křemenová

Germany
Dagmar Dörmann

Denmark

Estonia
Pille Säälik

Spain
Jorge Gayoso
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Finland
Anne Vaskunlahti

France
Katia Bruneau

Greece

Croatia
Milena Ivanković

Hungary
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Ireland

Italy
Fiorenza Bariani
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Liliam Santilli

Lithuania
Justina Davainytė

Luxembourg
Martine Debacker

Latvia
Ieva Bekere

The Republic of Moldova
Igor Codreanu
Tatiana Timbalari

The Rep. of North Macedonia

Malta
Patricia Galea

Netherlands
Frank van Linden

Norway

Poland

Portugal
Paulo Severino

Romania

Sweden
Nina Lundmark
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Slovakia
Magdaléna Krátka
Daniel Kuba

Switzerland
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Uruguay
Milka Bengochea

Venezuela
Evelyn Alonzo

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

Glossary (Tissues)

A

Adipose tissue: Connective tissue in which fat is stored and which has the cells distended by droplets of fat.

Amniotic membrane: The innermost layer of the placental membrane; it surrounds the foetus during pregnancy.

Autologous: Refers to tissues or cells removed from and applied in the same individual.

B

Blood vessels: A tube in the body carrying blood to (veins) or from (arteries) the heart.

Bone: The hard, rigid, mineralised form of connective tissue constituting most of the skeleton of vertebrates and composed primarily of calcium salts. There are two types of osseous tissue that form bones: cortical bone (the compact bone of the shaft of a bone that surrounds the marrow cavity) and cancellous or trabecular bone (typically occurs at the ends of long bones, proximal to joints and within the interior of vertebrae). Cancellous bone is highly vascular and frequently contains bone marrow.

Bone filling material: Cancellous (spongy type of bone with a very high surface area found at the ends of long bones) or Corticocancellous bone which has been chopped, shaped or ground to chips, cubes, granules or powder.

C

Cancellous bone chips: Spongy (cancellous) bone cut in pieces, chopped or shaped to chips or cubes of various sizes.

Cardiovascular: Relating to the heart or vessels carrying blood.

Competent authority (or health authority/regulatory authority/regulatory agency): the body which has been delegated with the responsibility for ensuring that tissue and cell donation, banking and human application are appropriately promoted, regulated and monitored in the interests of donor and patient safety and public transparency on a national or regional basis by their government.

Cornea: The transparent anterior part of the outer fibrous coat of the eye. A collagenous tissue bounded by an outer stratified epithelium and an inner monolayer of endothelial cells. The major refractive component of the eye.

Cortical strut: A small shaped piece of compact bone mainly from the femur or tibia used in structural grafting, such as rings, pins etc.

Cortico cancellous bone chips: Bone containing both compact and spongy part cut into pieces, chopped or shaped to chips or cubes of varying sizes.

Craniectomy: The surgical removal of a portion of the skull.

D

Deceased donor: A person declared to be dead according to established medical criteria and from whom cells, tissues or organs have been recovered for the purpose of human application.

Deceased heart-beating donor (DBD) (Donor after Brain Death): A donor who is declared dead based on the irreversible loss of neurological functions. Also known as heart-beating donor.

Deceased non-heart beating donor (DCD) (Donor after Cardiac Death): A donor who is declared dead and diagnosed by means of cardiopulmonary criteria.

Distribution: Transportation and delivery of cells or tissues intended for human application.

Donation: Donating human tissues or cells intended for human applications.

Donor: Every human source, whether living or deceased of human cells or tissues.

E

Export: Act of transporting a tissue or cell intended for human application to another country where it is to be processed further or used directly.

F

Fascia: A layer of fibrous connective tissue that surrounds muscles, groups of muscles, blood vessels and nerves, which binds some structures together while permitting others to slide smoothly over each other.

Femoral arteries superficial: The section of femoral artery from the bifurcation of the common femoral artery with the profunda femoris artery to the popliteral artery.

Femoral head: Ball shaped proximal head of the femur (thigh bone) forming ball and socket joint with the os coxae (hip bone)

H

Heart valve: One of the four structures within the heart that prevent backflow of blood by opening and closing with each heartbeat. They include two

semilunar valves (aortic and pulmonary), the mitral (or bicuspid) valve, and the tricuspid valve. They permit blood flow in only one direction.

Human application: The use of tissues or cells on or in a human recipient.

Human tissues and cells for human application: Material containing or consisting of human tissues and/or cells intended for implantation, transplantation, infusion, or transfer into a human recipient.

I

Import: The act of bringing tissues or cells into one country from another for the purpose of human application or further processing.

Importing tissue establishment: A tissue bank or a unit of a hospital or another body established within the EU which is a party to a contractual agreement with a third country supplier for the import into the EU of tissues and cells coming from a third country and intended for human application.

L

Ligament: A tough band of fibrous connective tissue that connects bone to bone.

Living donor: A living person from whom cells or tissues have been removed for the purpose of human application.

M

Menisci: The cartilage cushions found in the knee joint between the femur and tibia.

Musculoskeletal: Tissues that are part of the skeleton and muscular system, including muscles, bones, cartilage, tendons and ligaments, which function in the support and movement of the body.

N

Number of tissues discarded: The number of tissues and/or cells that have been discarded.

Number of tissues distributed: the total number transported or delivered to a clinical unit (as Article 3 (k) of Directive 2004/23/EC defines: Distribution "means transportation and delivery of tissues or cells intended for human applications" (Article 3 (k) Directive 2004/23/EC), whereas 'human application' is defined in the same article as follows: "means the use of tissues or cells on or in a human recipient and extracorporeal applications'.)

Number of tissues processed: Article 3(g) of Directive 2004/23/EC defines processing as 'all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications'. This term refers to tissues and cells processed in TEs but not necessarily distributed.

Number of tissue procured: The number of donated tissue made available through the process of procurement.

Number of recipients for each type of tissue: The total number of patients who had at least one unit of tissues or cells applied during the year concerned in a given country. It is acknowledged that not all Member States currently collect data on the total number of patients treated with each type of tissue or cells.

O

Ocular tissue: Corneas and Scleras.

Other tissue: All human tissues for human application that does not have a dedicated row on the form.

P

Pancreas: A large lobulated gland that in humans lies in front of the upper lumbar vertebrae and behind the stomach and is somewhat hammer-shaped and firmly attached anteriorly to the curve of the duodenum with which it communicates through one or more pancreatic ducts.

Pancreatic islets: Any of the groups of small slightly granular endocrine cells that form anastomosing trabeculae among the tubules and alveoli of the pancreas and secrete insulin and glucagon.

Parathyroid: Any of the usually four small endocrine glands that are adjacent to or embedded in the thyroid gland, are composed of irregularly arranged secretory epithelial cells lying in a stroma rich in capillaries, and produce parathyroid hormone.

Placenta: An organ that connects the developing foetus to the uterine wall to allow nutrient uptake, waste elimination and gas exchange via the mother's blood supply.

Processing: All operations involved in the preparation, manipulation, preservation, storage and packaging of tissues or cells intended for human application.

R

Recipient: Person to whom human tissues, cells or reproductive cells and embryos are applied.

Retrieval or Recovery: See Number of tissue procured.

S

Sclera: Fibrous white outer coat of the eye.

Skin: Thin layer of tissue forming the natural outer covering of the human body. Skin is composed of two primary

layers: the epidermis and dermis. These layers are separated by a thin sheet of fibres, the 'basement membrane'. Keratinocytes constitute 95% of the epidermis. The dermis provides tensile strength and elasticity to the skin through an extracellular matrix composed of collagen fibrils, microfibrils, and elastic fibres, embedded in proteoglycans.

Skin – meshed: Strips of skin graft less than 1mm in depth cut into a lattice structure to increase surface area.

Storage: Means maintaining the product under appropriate controlled conditions until distribution.

T

Tendon: A tough band of fibrous connective tissue that usually connects muscle to bone and which can withstand tension.

Tissue: All constituent parts of the human body formed by cells.

Tissue establishment: A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement and/or testing of tissues and cells.

Tissue donation (effective): When tissue intended for human application is retrieved from a human body.

Transplantation/implantation/grafting: Transfer (engraftment) of human tissues or cells from a donor to a recipient with the aim of restoring function(s) in the body.

U

Unique donation number: The unique number attributed to a specific donation of tissues and cells in line with the system in place in each Member State for allocating such numbers, as further specified in Annex VII to Commission Directive (EU) 2015/565.

W

Whole bone: Whole or pieces of bone which remain as a piece rather than being ground down.

Glossary (Haematopoietic Stem Cells)

A

Allogeneic use: Cells removed from one person and applied to another.

Autologous use: Cells removed from and applied in the same person.

B

Banking: Processing, preservation, storage and distribution of cells for human application or other purposes, including research and training.

Bone marrow: Tissue at the centre of large bones. It is the place where new blood cells are produced. Bone marrow contains two types of stem cell: haematopoietic (which can produce blood cells) and stromal (which can produce fat, cartilage and bone). In this collection: as a source of haematopoietic stem cells or mesenchymal stem cells.

C

Cells: Means individual human cells or a collection of human cells when not bound by any form of connective tissue.

Collection: Any procedure for procuring a cellular therapy product regardless of technique or source (synonym: harvest).

Competent authority (or health authority/regulatory authority/regulatory agency): the body which has been delegated with the responsibility for ensuring that tissue and cell donation, banking and human application are appropriately promoted, regulated and monitored in the interests of donor and patient safety and public transparency on a national or regional basis by their government.

Cord blood: Blood collected from placental vessels and umbilical cord blood vessels after the umbilical cord is clamped and/or severed as a source of haematopoietic progenitor cells.

Cord blood bank: An organisation responsible for donor management and the collection, processing, testing, cryopreservation, storage, listing, reservation, release, and distribution of cord blood units.

Cryopreservation: Preservation and storage of viable tissues and cells (including gametes and embryos) to preserve viability, either by freezing or vitrification, or alternatively (to extend their viable life) by low-temperature storage.

D

Distribution: Transportation and delivery of tissues or cells intended for human applications.

Donation: Donating human tissues or cells intended for human applications.

Donation centre: An organisation responsible for donor recruitment, consenting, testing, management and the collection of donor personal, genetic, medical data.

Donor: Every human source, whether living or deceased of human cells.

Donor registry: An organisation responsible for coordinating the search for haematopoietic stem cells from donors (including cord blood) unrelated to the potential recipient.

H

HPC transplant centre: A medical facility where a patient (recipient) receives a transplant (graft) with HSC from an unrelated donor or from an umbilical cord blood unit. The TC oversees the immediate medical treatment and provides long-term follow-up of the recipient. The search unit undertakes the search for an unrelated donor for specific patients using criteria defined and documented by the TC. This entity may be contained within a TC or may be separate from the TC. If separate, the search unit may coordinate searches for one or several TCs. In the standards, reference to a TC should be interpreted as a TC and/or a search unit as appropriate. Transplant centres/search units seeking an international donor work through the registry in their country.

Haematopoietic progenitor cells (HPC): Primitive haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells, unless otherwise specified and regardless of tissue source. Also referred to as 'haematopoietic stem cells.

Human application: The use of tissues or cells on or in a human recipient.

Human tissues and cells for human application: Material containing or consisting of human tissues and/or cells intended for implantation, transplantation, infusion, or transfer into a human recipient.

N

Number of cells distributed: The total number transported or delivered to a clinical unit (as Article 3 (k) of Directive 2004/23/EC define:. Distribution "means transportation and delivery of tissues or cells intended for human applications" (Article 3 (k) Directive 2004/23/EC), whereas 'human application' is defined in the same article as follows: "means the use of tissues or cells on or in a human recipient and extracorporeal applications'.)

O

Organisation responsible for human application: means a healthcare establishment or a unit of a hospital or another body which carries out human application of human tissues and cells

P

Peripheral blood: In this collection: HSC haematopoietic stem cells collected in peripheral blood by apheresis.

Potential donor: Any person who has no medical contraindications for organ, tissue or cell donation and who meets the definition of a deceased heartbeating donor, deceased non-heartbeating donor or living donor.

Procurement organisation: Means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment.

R

Recipient: Person to whom human tissues, cells or reproductive cells and embryos are applied.

Related: Existence of a genetic relationship between donor and recipient.

S

Search performed: Number of searches for compatibility performed in the marrow registry.

T

Transplantation/implantation/grafting: Transfer (engraftment) of human tissues or cells from a donor to a recipient with the aim of restoring function(s) in the body.

Transplant centre: See Organisation responsible for human application.

U

Unique donation number: The unique number attributed to a specific donation of tissues and cells in line with the system in place in each Member State for allocating such numbers, as further specified in Annex VII to Commission Directive (EU) 2015/565.

Unrelated: Where there exists no genetic relationship between donor and recipient.

PRELIMINARY DATA ON TISSUES - YEAR 2018

EUROPEAN UNION COUNTRIES

Country		Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy
Population (Source: eurostat)		8.822.267	11.398.589	7.050.034	4.105.493	864.236	10.610.055	5.781.190	1.319.133	5.513.130	66.926.166	82.792.351	10.741.165	9.778.371	4.830.392	60.483.973
TYPE OF TISSUE	TYPE OF DATA	NO DATA	NO DATA			NO DATA		NO DATA					NO DATA		NO DATA	
CORNEA	N of tissue donations			68	273		517		23	218	5.599	NA		NA		8.765
	Tissue donation PMP			9,6	66,5		48,7		17,4	39,5	83,7	NA		NA		144,9
	N of tissue retrieved			133	540		1.059		46	340	11.145	11.824		317		17.385
	N tissue processed (units)			0	546		330		56	340	5.897	11.510		317		
	N tissue distributed nationally (units)			119	340		590		54	273	5.448	7.995		255		6.808
	N tissue imported (units)			3	13		0		0	46	24	848		0		
	N tissue exported (units)			0	0		101		0	2	158	64		0		619
	N of tissues transplanted			119	353		724		NA	273	4.812	NA		262		
	N of patients transplanted			111	338		724		58	NA	4.437	NA		249		
	N of transplant procedures			119	353		724		NA	NA	UK	NA		262		5.945
SKIN	N of tissue donations			79	1		91		8	23	323	NA		NA		348
	Tissue donation PMP			11,2	0,2		8,6		6,1	4,2	4,8	0,0		NA		5,8
	N of tissue retrieved (cm^2)			125.425	42		127.960		NE	138.402	640.496	26.009		50		915.311
	N tissue processed (units)			14	15		1.303		43	1.189	1.247	120.255		210		
	N tissue distributed nationally (units)			0	21		136		22	1.230	900	260.456		210		3.814
	N tissue imported (units)			0	13		0		0	NE	0	83.000		0		
	N tissue exported (units)			0	0		0		0	NE	35.735	8.134		0		
	N of tissues transplanted			0	28		1.343		NA	1.230	360.003	NA		210		
	N of patients transplanted			0	5		432		4	17	205	NA		210		
	N of transplant procedures			0	14		1.343		NA	NA	UK	NA		210		1.717
HEART VALVE	N of tissue donations			0	5		103		NE	42	333	NA		NA		230
	Tissue donation PMP			0,0	1,2		9,7		NE	7,6	5,0	0,0		NA		3,8
	N of tissue retrieved			0	8		182		NE	95	762	708		27		494
	N tissue processed (units)			0	8		182		NE	95	174	386		27		
	N tissue distributed nationally (units)			0	8		136		NE	111	230	152		21		208
	N tissue imported (units)			0	0		0		NE	NE	57	1		0		1
	N tissue exported (units)			0	0		0		NE	NE	67	37		0		
	N of tissues transplanted			0	7		127		NA	111	230	NA		21		
	N of patients transplanted			0	8		125		NE	NA	230	NA		21		
	N of transplant procedures			0	8		127		NA	NA	UK	NA		21		
BLOOD VESSEL	N of tissue donations			0	6		12		28	17	11.015	NA		NA		425
	Tissue donation PMP			0,0	1,5		1,1		21,2	3,1	164,6	0,0		NA		7,0
	N of tissue retrieved			0	14		21		39	48	11.688	198		136		691
	N tissue processed (units)			0	14		16		70	43	3.400	218		136		
	N tissue distributed nationally (units)			0	4		13		37	29	3.389	74		107		393
	N tissue imported (units)			0	0		0		0	NE	50	1		0		
	N tissue exported (units)			0	0		0		0	NE	39	0		0		
	N of tissues transplanted			0	5		13		NA	29	3.389	NA		242		
	N of patients transplanted			0	3		12		35	NA	1.994	NA		137		
	N of transplant procedures			0	3		12		NA	NA	UK	NA		137		226
MUSCULOSKELETAL	N of tissue donations			2.788	173		1.520		95	816	27.434	NA		NA		3.597
	Tissue donation PMP			395,5	42,1		143,3		72,0	148,0	409,9	0,0		NA		59,5
	N of tissue retrieved			5.700	251		5.145		105	1.210	27.868	21.688		1.672		7278
	N tissue processed (units)			203	251		3.439		471	1.210	24.002	55.541		6.920		
	N tissue distributed nationally (units)			250	184		1.958		274	NA	66.461	71.235		6.769		116.558
	N tissue imported (units)			0	7		96		51	NE	774	4.599		0		
	N tissue exported (units)			0	0		2.268		51	NE	8.190	17.340		0		38
	N of tissues transplanted			176	181		3.437		NA	NA	66.461	NA		161		
	N of patients transplanted			146	142		3.391		186	NA	47.772	NA		158		
	N of transplant procedures			152	147		3.409		NA	NA	UK	NA		159		7.583

PRELIMINARY DATA ON TISSUES - YEAR 2018

EUROPEAN UNION COUNTRIES

Country		Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy
Population (Source: eurostat)		**8.822.267**	**11.398.589**	**7.050.034**	**4.105.493**	**864.236**	**10.610.055**	**5.781.190**	**1.319.133**	**5.513.130**	**66.926.166**	**82.792.351**	**10.741.165**	**9.778.371**	**4.830.392**	**60.483.973**
TYPE OF TISSUE	TYPE OF DATA	NO DATA	NO DATA			NO DATA		NO DATA					NO DATA		NO DATA	
PLACENTA/AMNIOTIC MEMBRANES	N of tissue donations			16	2		704		4	6	241	NA		NA		317
	Tissue donation PMP			2,3	0,5		66,4		3,0	1,1	3,6	0,0		NA		5,2
	N of tissue retrieved			16	2		704		4	6	241	188		0		317
	N tissue processed (units)			45	106		8.378		157	251	2.834	6.845		155		
	N tissue distributed nationally (units)			39	133		780		65	216	3.182	4.052		126		4.383
	N tissue imported (units)			0	0		0		0	138	0	9		0		
	N tissue exported (units)			0	0		601		0	14	172	114		0		
	N of tissues transplanted			310	134		1.420		NA	NA	3.182	NA		119		
	N of patients transplanted			202	109		224		45	NA	2.744	NA		66		
	N of transplant procedures			307	134		1.420		NA	NA	UK	NA		75		855
PANCREAS/PANCREATIC ISLETS	N of tissue donations			0	0		10		NE	0	51	NA		NA		59
	Tissue donation PMP			0,0	0,0		0,9		NE	0,0	0,8	0,0		NA		1,0
	N of tissue retrieved			0	0		10		3	0	51	0		0		59
	N tissue processed (units)			0	0		10		NE	0	UK	0		0		59
	N tissue distributed nationally (units)			0	0		10		NE	0	UK	0		0		14
	N tissue imported (units)			0	0		0		NE	NE	UK	0		0		
	N tissue exported (units)			0	0		0		NE	NE	UK	0		0		
	N of tissues transplanted			0	0		10		NA	0	UK	NA		0		
	N of patients transplanted			0	0		10		NE	0	UK	NA		0		
	N of transplant procedures			0	0		10		NA	0	UK	NA		0		11
ADIPOSE TISSUE	N of tissue donations			2	0		27		NE	1	NA	NA		NA		NA
	Tissue donation PMP			0,3	0,0		2,5		NE	0,2	NA	0,0		NA		NA
	N of tissue retrieved			2	0		27		NE	1	UK	0		0		NA
	N tissue processed (units)			0	0		21		NE	1	UK	0		0		NA
	N tissue distributed nationally (units)			0	0		21		NE	NA	UK	0		0		NA
	N tissue imported (units)			0	0		0		NE	NE	UK	0		0		
	N tissue exported (units)			0	0		0		NE	NE	UK	0		0		
	N of tissues transplanted			0	0		18		NA	NA	UK	NA		0		
	N of patients transplanted			0	0		18		NE	NA	UK	NA		0		
	N of transplant procedures			0	0		18		NA	NA	UK	NA		0		NA
PARATHYROID	N of tissue donations			0	0		0		NE	NE	NA	NA		NA		13
	Tissue donation PMP			0,0	0,0		0,0		NE	NE	NA	0,0		NA		0,2
	N of tissue retrieved			0	0		0		NE	NE	0	0		0		13
	N tissue processed (units)			0	0		0		NE	NE	0	0		0		13
	N tissue distributed nationally (units)			0	0		0		NE	NE	0	0		0		0
	N tissue imported (units)			0	0		0		NE	NE	0	0		0		
	N tissue exported (units)			0	0		0		NE	NE	0	0		0		
	N of tissues transplanted			0	0		0		NA	0	0	NA		0		
	N of patients transplanted			0	0		0		NE	0	0	NA		0		
	N of transplant procedures			0	0		0		NA	0	UK	NA		0		
AUTOLOGOUS CRANIECTOMY PIECES	N of tissue retrieved			0	0		95		NE	9	338	0		0		664
OTHER TISSUE	N of tissue donations			31	0		410		NE	NE	NA	NA		NA		NA
	Tissue donation PMP			4,4	0,0		38,6		NE	NE	NA	0,0		NA		NA
	N of tissue retrieved			31	0		413		NE	NE	UK	3.735		14		NA
	N tissue processed (units)			0	0		324		NE	NE	UK	4.613		14		NA
	N tissue distributed nationally (units)			0	5		142		NE	NE	UK	2.230		9		NA
	N tissue imported (units)			0	0		128		NE	22	UK	11		0		
	N tissue exported (units)			0	0		0		NE	NE	UK	4		0		
	N of tissues transplanted			0	4		18		NA	NA	UK	NA		26		
	N of patients transplanted			0	2		18		NE	NA	UK	NA		26		
	N of transplant procedures			0	3		18		NA	NA	UK	NA		26		NA

PRELIMINARY DATA ON TISSUES - YEAR 2018

		EUROPEAN UNION COUNTRIES													OTHER COUNTRIES		
Country		Latvia	Lithuania	Luxembourg	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	United Kingdom	Norway	Republic Of Moldova	Switzerland
Population (Source: eurostat)		1.934.379	2.808.901	602.005	475.701	17.181.084	37.976.687	10.291.027	19.530.631	5.443.120	2.066.880	46.658.447	10.120.242	66.273.576	5.295.619	3.547.539	8.484.130
TYPE OF TISSUE	TYPE OF DATA						NO DATA		NO DATA		NO DATA				NO DATA		
CORNEA	N of tissue donations	20	29	NA	6	2.203		546		119		3.574	579	6.212		15	869
	Tissue donation PMP	10,3	10,3	NA	12,6	128,2		53,1		21,9		76,6	57,2	93,7		4,2	102,4
	N of tissue retrieved	40	58	NA	6	4.405		1.035		235		7.240	1.125	6.212		27	869
	N tissue processed (units)	40	50	NA	0	4.405		1.039		236		6.620	1.374	6.798		27	759
	N tissue distributed nationally (units)	54	45	NA	0	1.720		969		169		4.402	1.050	4.752		27	290
	N tissue imported (units)	14	0	NA	0	69		239		14		32	NA	409		NE	481
	N tissue exported (units)	0	0	NA	0	605		0		NA		228	9	0		NE	0
	N of tissues transplanted	NA	43	NA	0	1.410		943		181		4.469	1.059	5.682		27	909
	N of patients transplanted	NA	45	NA	0	1.396		923		181		4.454	978	NA		24	872
	N of transplant procedures	NA	45	NA	0	1.410		943		181		NA	1.006	NA		24	909
SKIN	N of tissue donations	NE	UK	NA	0	367		0		0		257	66	512		6	NE
	Tissue donation PMP	NE	UK	NA	0,0	21,4		0,0		0,0		5,5	6,5	7,7		1,7	0,0
	N of tissue retrieved (cm^2)	NE	UK	NA	0	1.549.474		0		0		566.691	66	512		18.278	NE
	N tissue processed (units)	NE	UK	NA	0	15.495		0		0		437.812	88	467		122	NE
	N tissue distributed nationally (units)	NE	UK	NA	0	1.626		25		60		366.582	177	4.164		129	NE
	N tissue imported (units)	NE	UK	74	0	1		25		NA		25.387	1	3.496		NE	NE
	N tissue exported (units)	NE	UK	74	0	13.678		0		NA		75.470	NA	18.912		NE	NE
	N of tissues transplanted	NE	UK	NA	0	160.095		20		60		247.321	66	4.752		0	NE
	N of patients transplanted	NE	UK	NA	0	87		8		30		43	28	NA		0	NE
	N of transplant procedures	NE	UK	NA	0	160.095		10		43		NA	63	NA		0	NE
HEART VALVE	N of tissue donations	NE	NE	NA	0	217		23		4		228	161	630		0	11
	Tissue donation PMP	NE	NE	NA	0,0	12,6		2,2		0,7		4,9	15,9	9,5		0,0	1,3
	N of tissue retrieved	NE	NE	NA	0	229		46		5		441	245	630		0	11
	N tissue processed (units)	NE	NE	NA	0	434		46		5		441	327	704		0	0
	N tissue distributed nationally (units)	NE	NE	NA	0	89		5		2		197	75	529		0	0
	N tissue imported (units)	NE	NE	NA	0	25		0		NA		1	1	129		NE	26
	N tissue exported (units)	NE	NE	NA	0	25		0		NA		111	70	100		NE	6
	N of tissues transplanted	NE	NE	NA	0	114		5		2		65	207	788		0	25
	N of patients transplanted	NE	NE	NA	0	114		5		2		61	198	NA		0	25
	N of transplant procedures	NE	NE	NA	0	114		5		2		NA	198	NA		0	25
BLOOD VESSEL	N of tissue donations	NE	NE	NA	0	16		0		0		184	93	353		5	7
	Tissue donation PMP	NE	NE	NA	0,0	0,9		0,0		0,0		3,9	9,2	5,3		1,4	0,8
	N of tissue retrieved	NE	NE	NA	0	5		0		0		337	229	353		22	7
	N tissue processed (units)	NE	NE	NA	0	16		0		0		19.855	229	414		0	0
	N tissue distributed nationally (units)	NE	NE	11	0	42		0		0		24.877	12	96		0	0
	N tissue imported (units)	NE	NE	11	0	3		0		NA		140	NA	17		NE	55
	N tissue exported (units)	NE	NE	NA	0	20		0		NA		291	NA	7		NE	7
	N of tissues transplanted	NE	NE	NA	0	43		0		0		180	12	174		0	55
	N of patients transplanted	NE	NE	NA	0	42		0		0		131	10	NA		0	55
	N of transplant procedures	NE	NE	NA	0	43		0		0		NA	10	NA		0	55
MUSCULOSKELETAL	N of tissue donations	20	90	NA	0	167		54		441		2.430	1.575	6.076		32	296
	Tissue donation PMP	10,3	32,0	NA	0,0	9,7		5,2		81,0		52,1	155,6	91,7		9,0	34,9
	N of tissue retrieved	40	40	NA	0	1.967		255		1.783		21.847	1.754	6.044		72	299
	N tissue processed (units)	95	90	NA	0	6.372		446		2.138		2.666	2.029	3.108		355	93
	N tissue distributed nationally (units)	43	30	553	0	10.291		446		582		1.911	1.054	27.599		475	NA
	N tissue imported (units)	0	0	4.912	0	673		31		2		0	166	30.902		NE	43
	N tissue exported (units)	0	0	4.359	0	37.449		0		212		361	0	43.752		NE	0
	N of tissues transplanted	NA	32	NA	0	5.613		400		517		24.761	1.017	28.890		419	245
	N of patients transplanted	NA	30	NA	0	5.288		270		319		19.142	1.021	NA		129	237
	N of transplant procedures	NA	30	NA	0	5.613		365		343		NA	1.002	NA		129	237

PRELIMINARY DATA ON TISSUES - YEAR 2018

EUROPEAN UNION COUNTRIES

Country		Latvia	Lithuania	Luxembourg	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	United Kingdom
Population (Source: eurostat)		1.934.379	2.808.901	602.005	475.701	17.181.084	37.976.687	10.291.027	19.530.631	5.443.120	2.066.880	46.658.447	10.120.242	66.273.576
TYPE OF TISSUE	TYPE OF DATA						NO DATA		NO DATA		NO DATA			
PLACENTA/AMNIOTIC MEMBRANES	N of tissue donations	8	2	NA	0	1		17		64		92	3	0
	Tissue donation PMP	4,1	0,7	NA	0,0	0,1		1,7		11,8		2,0	0,3	0,0
	N of tissue retrieved	8	2	NA	0	1		17		64		2.459	379	0
	N tissue processed (units)	NE	UK	NA	0	1		261		304		NA	424	98
	N tissue distributed nationally (units)	NE	UK	NA	0	200		228		377		NA	312	2.096
	N tissue imported (units)	NE	0	NA	0	0		0		NA		NA	NA	266
	N tissue exported (units)	NE	0	NA	0	702		0		NA		NA	NA	772
	N of tissues transplanted	NE	2	NA	0	118		230		378		NA	317	2.224
	N of patients transplanted	NE	33	NA	0	114		183		261		NA	299	NA
	N of transplant procedures	NE	33	NA	0	118		210		309		NA	304	NA
PANCREAS/PANCREATIC ISLETS	N of tissue donations	NE	NE	NA	0	279		NA		0		NA	46	NA
	Tissue donation PMP	NE	NE	NA	0,0	16,2		NA		0,0		NA	4,5	NE
	N of tissue retrieved	NE	NE	NA	0	47		NA		0		NA	46	NA
	N tissue processed (units)	NE	NE	NA	0	47		NA		0		NA	46	122
	N tissue distributed nationally (units)	NE	NE	NA	0	13		NA		0		NA	21	43
	N tissue imported (units)	NE	NE	NA	0	0		NA		NA		NA	NA	0
	N tissue exported (units)	NE	NE	NA	0	0		NA		NA		NA	2	0
	N of tissues transplanted	NE	NE	NA	0	12		NA		0		NA	23	34
	N of patients transplanted	NE	NE	NA	0	9		NA		0		NA	3	NA
	N of transplant procedures	NE	NE	NA	0	12		NA		0		NA	23	NA
ADIPOSE TISSUE	N of tissue donations	NE	33	NA	0	0		NA		89		NA	NE	529
	Tissue donation PMP	NE	117,5	NA	0,0	0,0		NA		163,5		NA	NE	79,8
	N of tissue retrieved	NE	33	NA	0	0		NA		89		NA	NE	529
	N tissue processed (units)	NE	33	NA	0	0		NA		87		NA	NE	63
	N tissue distributed nationally (units)	NE	32	NA	0	0		NA		84		NA	NE	221
	N tissue imported (units)	NE	0	NA	0	0		NA		NA		NA	NE	2
	N tissue exported (units)	NE	0	NA	0	0		NA		NA		NA	NE	2
	N of tissues transplanted	NA	32	NA	0	0		NA		84		NA	NE	294
	N of patients transplanted	NA	19	NA	0	0		NA		84		NA	NE	NA
	N of transplant procedures	NA	133	NA	0	0		NA		84		NA	NE	NA
PARATHYROID	N of tissue donations	NE	NE	NA	0	0		NA		0		NA	NE	NA
	Tissue donation PMP	NE	NE	NA	0,0	0,0		NA		0,0		NA	NE	NA
	N of tissue retrieved	NE	NE	NA	0	0		NA		0		NA	NE	0
	N tissue processed (units)	NE	NE	NA	0	0		NA		0		NA	NE	NA
	N tissue distributed nationally (units)	NE	NE	NA	0	0		NA		0		NA	NE	NA
	N tissue imported (units)	NE	NE	NA	0	0		NA		NA		NA	NE	NA
	N tissue exported (units)	NE	NE	NA	0	0		NA		NA		NA	NE	NA
	N of tissues transplanted	NE	NE	NA	0	0		NA		0		NA	NE	NA
	N of patients transplanted	NE	NE	NA	0	0		NA		0		NA	NE	NA
	N of transplant procedures	NE	NE	NA	0	0		NA		0		NA	NE	NA
AUTOLOGOUS CRANIECTOMY PIECES	N of tissue retrieved	NE	50	NA	0	82		NA		162		NA	215	32
OTHER TISSUE	N of tissue donations	197	NE	NA	0	5		0		1.644		NA	0	2.749
	Tissue donation PMP	101,8	NE	NA	0,0	0,3		0,0		302,0		NA	0,0	41,5
	N of tissue retrieved	197	NE	NA	0	0		0		1.644		NA	0	2.749
	N tissue processed (units)	8	NE	NA	0	80				1.545		NA	0	13.428
	N tissue distributed nationally (units)	0	NE	NA	0	1.236		0		209		NA	0	15.698
	N tissue imported (units)	0	NE	NA	0	12		0		678		NA	0	13.264
	N tissue exported (units)	0	NE	NA	0	0		0		116		NA	0	34.739
	N of tissues transplanted	NA	NE	NA	0	41		0		214		NA	0	1.124
	N of patients transplanted	NA	NE	NA	0	41		0		148		NA	0	NA
	N of transplant procedures	NA	NE	NA	0	41		0		200		NA	0	NA

OTHER COUNTRIES

Country		Norway	Republic Of Moldova	Switzerland
Population (Source: eurostat)		5.295.619	3.547.539	8.484.130
TYPE OF TISSUE	TYPE OF DATA	NO DATA		
PLACENTA/AMNIOTIC MEMBRANES	N of tissue donations		10	10
	Tissue donation PMP		2,8	1,2
	N of tissue retrieved		10	10
	N tissue processed (units)		102	129
	N tissue distributed nationally (units)		74	22
	N tissue imported (units)		NE	27
	N tissue exported (units)		NE	0
	N of tissues transplanted		74	134
	N of patients transplanted		50	115
	N of transplant procedures		68	115
PANCREAS/PANCREATIC ISLETS	N of tissue donations		NE	5
	Tissue donation PMP		NE	0,6
	N of tissue retrieved		NE	5
	N tissue processed (units)		NE	39
	N tissue distributed nationally (units)		NE	NA
	N tissue imported (units)		NE	29
	N tissue exported (units)		NE	23
	N of tissues transplanted		NE	6
	N of patients transplanted		NE	6
	N of transplant procedures		NE	6
ADIPOSE TISSUE	N of tissue donations		0	NE
	Tissue donation PMP		0,0	0,0
	N of tissue retrieved		0	NE
	N tissue processed (units)		0	NE
	N tissue distributed nationally (units)		0	NE
	N tissue imported (units)		NE	NE
	N tissue exported (units)		NE	NE
	N of tissues transplanted		0	NE
	N of patients transplanted		0	NE
	N of transplant procedures		0	NE
PARATHYROID	N of tissue donations		NE	NE
	Tissue donation PMP		NE	0,0
	N of tissue retrieved		NE	NE
	N tissue processed (units)		NE	NE
	N tissue distributed nationally (units)		NE	NE
	N tissue imported (units)		NE	NE
	N tissue exported (units)		NE	NE
	N of tissues transplanted		NE	NE
	N of patients transplanted		NE	NE
	N of transplant procedures		NE	NE
AUTOLOGOUS CRANIECTOMY PIECES	N of tissue retrieved		4	NE
OTHER TISSUE	N of tissue donations		1	NE
	Tissue donation PMP		0,3	0,0
	N of tissue retrieved		3	NE
	N tissue processed (units)		0	NE
	N tissue distributed nationally (units)		0	NE
	N tissue imported (units)		NE	NE
	N tissue exported (units)		NE	NE
	N of tissues transplanted		0	NE
	N of patients transplanted		0	NE
	N of transplant procedures		0	NE

PRELIMINARY DATA ON TISSUES - YEAR 2018

LATIN AMERICAN COUNTRIES

Country		Argentina	Brazil	Chile	Colombia	Costa Rica	Cuba	Dominican R.	Ecuador	El Salvador	Guatemala	Mexico	Nicaragua	Panama	Paraguay	Peru	Uruguay	Venezuela
Population (Source: UNFPA, state of world population, 2018 - Million)		44,7	210,9	18,2	49,5	5,0	11,5	10,9	16,9	6,4	17,2	130,8	6,3	4,2	6,9	32,6	3,5	32,4
TYPE OF TISSUE	TYPE OF DATA	NO DATA		NO DATA			NO DATA			NO DATA			NO DATA			NO DATA		NO DATA
CORNEA	N of tissue donations		34.447		1.388	149		0	320		208	4.546		2	126		88	
	Tissue donation PMP		163,3		28,0	29,8		0,0	18,9		12,1	34,8		0,5	18,3		25,1	
	N of tissue retrieved		30.735		2.831	206		0	292		208	4.544		2	116		201	
	N of tissues transplanted		14.788		2.672	206		0			183	4.311		2	116			
	N of patients transplanted							0			183	4.311		2	116		187	
	N of transplant procedures		14.788			206		0	286		183	4.311		2	116		201	
BLOOD VESSEL	N of tissue donations		0		8	5		0	7		0	0		0	0		22	
	Tissue donation PMP		0,0		0,2	1,0		0,0	0,4		0,0	0,0		0,0	0,0		6,3	
	N of tissue retrieved		0		10	18		0	6		0	0		0	0		22	
	N of tissues transplanted				37	18		0			0			0	0			
	N of patients transplanted					18		0			0			0	0		17	
	N of transplant procedures							0	0		0			0	0		22	
HEART VALVE	N of tissue donations		239		34	5		0	0		0	0		0	0		0	
	Tissue donation PMP		1,1		0,7	1,0		0,0	0,0		0,0	0,0		0,0	0,0		0,0	
	N of tissue retrieved		429		33	17		0	0		0	32		0	0		0	
	N of tissues transplanted		163		37	17		0			0	4		0	0		0	
	N of patients transplanted							0			0	4		0	0		0	
	N of transplant procedures		163			17		0	0		0	4		0	0		0	
MUSCULOSKELETAL	N of tissue donations		1.105		881	57		0	350		0	459		0	0		36	
	Tissue donation PMP		5,2		17,8	11,4		0,0	20,7		0,0	3,5		0,0	0,0		10,3	
	N of tissue retrieved		17.676		1.297	147		0	326		0	477		0	0		36	
	N of tissues transplanted		12.848		16.020	147		0			0			0	0			
	N of patients transplanted							0			0			0	0		120	
	N of transplant procedures		12.848			147		0	292		0			0	0		412	
PLACENTA/AMNIOTIC MEMBRANE	N of tissue donations		0		84	32		0	7		0			0	0		91	
	Tissue donation PMP		0,0		1,7	6,4		0,0	0,4		0,0	0,0		0,0	0,0		26,0	
	N of tissue retrieved		0		83	54		0	251		0			0	0		91	
	N of tissues transplanted		0		465			0			0			0	0			
	N of patients transplanted		0					0			0			0	0		51	
	N of transplant procedures		0			54		0	263		0			0	0		266	
SKIN	N of tissue donations		627		84	8		0	7		0	0		0	0		17	
	Tissue donation PMP		3,0		1,7	1,6		0,0	0,4		0,0	0,0		0,0	0,0		4,9	
	N of tissue retrieved		121.176		498	0		0	161		0	0		0	0		33.000	
	N of tissues transplanted		83.559		564	31		0			0			0	0			
	N of patients transplanted							0			0			0	0		24	
	N of transplant procedures		83.559			31		0	179		0			0	0		772	
OTHERS	N of tissue donations		0		0	0		0	6		0	0		0	0		0	
	Tissue donation PMP		0,0		0,0	0,0		0,0	0,4		0,0	0,0		0,0	0,0		0,0	
	N of tissue retrieved		0		9	0		0	4		0	0		0	0		0	
	N of tissues transplanted		0		9			0			0			0	0			
	N of patients transplanted		0					0			0			0	0			
	N of transplant procedures		0			NA		0	7		0			0	0			

PRELIMINARY DATA ON HPC CELLS - YEAR 2018

EUROPEAN UNION COUNTRIES

Country		Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy
Population (Source: eurostat)		**8.822.267**	**11.398.589**	**7.050.034**	**4.105.493**	**864.236**	**10.610.055**	**5.781.190**	**1.319.133**	**5.513.130**	**66.926.166**	**82.792.351**	**10.741.165**	**9.778.371**	**4.830.392**	**60.483.973**
CATEGORY OF <DATA	TYPE OF DATA	NO DATA	NO DATA			NO DATA		NO DATA					NO DATA		NO DATA	
POTENTIAL DONATIONS AND SEARCHING IN THE NATIONAL REGISTRIES	N of potential donors at 31.12			NA	56.201		115.997		NA	48.141	290.342	UK		NA		416.852
	N of cord blood units at 31.12			NA	3.502		6.707		0	NA	36.651	UK		NA		36.370
	N of searches requested			NA	505		48.991		NA	NA	28.472	UK		NA		3.055
	N of unrelated donations			NA	50		201		NA	NA	1.145	NA		NA		897
DONATIONS	N of donations - Autologous			2.519	570		1.100		57	NA	3.576	4.530		539		4.618
	N of donations - Allogenic			122	1.086		290		3	505	1.266	8.418		123		12.590
	N of donations - Allogenic, related			42	49		103		3	NA	988	1.037		122		1.328
	N of donations - Allogenic, unrelated			80	1.037		187		0	NA	278	7.381		1		11.262
BANKING OF CORD BLOOD	N of unrelated cord blood unitss collected			80	1.014		15		0	0	615	733		0		10.661
	N of unrelated cord blood unitss distributed			0	0		4		0	4	119	0		0		38
	N of related cord blood unitss collected			2.421	11		585		0	NE	NA	25		4.373		150
	N of related cord blood unitss distributed			0	0		0		0	NE	NA	0		2		4
TRANSPLANT	N of transplants - Autologous			98	190		463		55	NA	3.316	4.540		307		3.310
	N of patients transplanted - Autologous			93	131		364		NA	245	3.183	3.757		232		2.628
	N of transplants - Allogenic			64	80		266		23	NA	1.946	3.450		172		1.881
	N of patients transplanted - Allogenic			64	74		248		NA	131	1.905	3.267		158		1.796
	N of transplants - Allogenic, related			42	34		90		3	NA	991	1.017		80		1.020
	N of patients transplanted - Allogenic, related			42	31		83		NA	NA	NA	943		73		948
	N of transplants - Allogenic, unrelated			22	46		176		20	NA	955	2.433		92		861
	N of patients transplanted - Allogenic, unrelated			22	43		165		NA	NA	NA	2.324		85		848

PRELIMINARY DATA ON HPC CELLS - YEAR 2018

		EUROPEAN UNION COUNTRIES													OTHER COUNTRIES		
Country		**Latvia**	**Lithuania**	**Luxembourg**	**Malta**	**Netherlands**	**Poland**	**Portugal**	**Romania**	**Slovakia**	**Slovenia**	**Spain**	**Sweden**	**Unitsed Kingdom**	**Norway**	**Republic of Moldova**	**Switzerland**
Population (Font: Eurostat)		**1.934.379**	**2.808.901**	**602.005**	**475.701**	**17.181.084**	**37.976.687**	**10.291.027**	**19.530.631**	**5.443.120**	**2.066.880**	**46.658.447**	**10.120.242**	**66.273.576**	**5.295.619**	**3.547.539**	**8.484.130**
CATEGORY OF DATA	TYPE OF DATA			NO DATA			NO DATA		NO DATA		NO DATA				NO DATA		
POTENTIAL DONATIONS AND SEARCHING IN THE NATIONAL REGISTRIES	N of potential donors at 31.12	UK	12.159		NE	273.426		403.832		17.549		373.196	NA	NA		NE	129.472
	N of cord blood units at 31.12	UK	1.664		NE	4.663		9.376		1.798		64.526	NA	NA		NE	4.771
	N of searches requested	UK	NA		NE	648		2.526		25.294		909	301	NA		NE	425
	N of unrelated donations	UK	NA		NE	449		136		51		731	NA	NA		NE	NA
DONATIONS	N of donations - Autologous	UK	NA		NE	3.548		495		3.371		2.084	664	7.622		NE	533
	N of donations - Allogenic	263	NA		NE	339		1.200		196		919	691	25.653		NE	171
	N of donations - Allogenic, related	263	NA		NE	202		77		64		795	178	12.315		NE	107
	N of donations - Allogenic, unrelated	0	NA		NE	137		1.123		132		124	513	13.338		NE	64
BANKING OF CORD BLOOD	N of unrelated cord blood unitss collected	0	NE		NE	111		1.041		117		954	317	11.008		NE	109
	N of unrelated cord blood unitss distributed	0	NE		NE	74		0		6		178	3	NA		NE	3
	N of related cord blood unitss collected	265	95		125	1		3		16		NA	63	11.357		NE	NA
	N of related cord blood unitss distributed	0	0		NE	1		0		0		0	0	NA		NE	NA
TRANSPLANT	N of transplants - Autologous	UK	138		NE	3.756		378		166		2.084	528	NA		33	526
	N of patients transplanted - Autologous	UK	NA		NE	1.094		361		135		0	505	NA		32	404
	N of transplants - Allogenic	UK	74		NE	827		159		77		1.294	301	NA		NE	256
	N of patients transplanted - Allogenic	UK	NA		NE	758		154		66		0	294	NA		NE	212
	N of transplants - Allogenic, related	UK	21		NE	253		68		30		795	110	NA		NE	114
	N of patients transplanted - Allogenic, related	UK	NA		NE	230		68		24		0	104	NA		NE	142
	N of transplants - Allogenic, unrelated	UK	53		NE	574		91		47		499	191	NA		NE	91
	N of patients transplanted - Allogenic, unrelated	UK	NA		NE	528		86		42		0	190	NA		NE	121

PRELIMINARY DATA ON HPC CELLS - YEAR 2018

LATIN AMERICAN COUNTRIES

Country		Argentina	Brazil	Chile	Colombia	Costa Rica	Cuba	Dominicana	Ecuador	Guatemala	Mexico	Nicaragua	Panama	Paraguay	Peru	Uruguay	Venezuela
Population (Source: UNFPA, state of world population, 2018 - Million)		**44,7**	**210,9**	**18,2**	**49,5**	**5,0**	**11,5**	**10,9**	**16,9**	**17,2**	**130,8**	**6,3**	**4,2**	**6,9**	**32,6**	**3,5**	**32,4**
CATEGORY OF DATA	TYPE OF DATA	NO DATA		NO DATA			NO DATA					NO DATA			NO DATA		NO DATA
POTENTIAL DONATION AND SEARCHING IN THE NATIONAL REGISTRIES	N of potential donors at 31.12		4.783.465		0	NA		0	35	0	0		0	0		1.230	
	N of cord blood units at 31.12		15.373		0	NA		0	0	0	0		0	0		0	
	N of searches requested		14.477		0	NA		0	0	0	0		0	0		26	
BANKING OF CORD BLOOD	N of unrelated cord blood unitss at 31.12		15.030		0	0		0	1.186	0	0		0	0		0	
	N of related cord blood unitss at 31.12		0		0	0		0	0	0	0		0	0		0	
TRANSPLANT	N of transplants - Autologous		1.294		471	15		0	25	0	0		31	17		89	
	N of patients transplanted - Autologous		0		471			0	0	0	0		31	17		0	
	N of transplants - Allogenic		1.000		423	64		0	10	0	0		0	1		32	
	N of patients transplanted - Allogenic		367		423	0		0	0	0	0		0	1		32	
	N of transplants - Allogenic, related		621		201	64		0	10	0	0		0	1		28	
	N of patients transplanted - Allogenic, related		0		201	0		0	0	0	0		0	1		4	
	N of transplants - Allogenic, unrelated		379		222			0	0	0	0		0	0		28	
	N of patients transplanted - Allogenic, unrelated		367		222	0		0	0	0	0		0	0		4	

Council of Europe Reference Documents. Year 2018

Illicit and Unethical Activities with Human Tissues and Cells: Addressing the Need for the Elaboration of an International Legal Instrument to Protect Donors and Recipients

as adopted following the 22nd meeting of the European Committee on Organ Transplantation (CD-P-TO) on 12 October 2018

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1. Introduction

Biomedical innovation has led in recent years to an increase in the use of human cells, tissues and cellor tissue-based products. Today these human substances, including musculoskeletal, cardiovascular and ocular tissues, haematopoietic progenitor cells, gametes and embryos, are routinely used for medical purposes, therapy and research. A consequence of this growth is that the processing and distribution of tissues and cells of human origin has progressively become an "industry" in some settings and donated human material treated as a commodity [1].

Despite considerable efforts by the European Commission, the number of human tissues and cells that are used for human application in the European Union (EU) healthcare setting can only be estimated. In a survey of EU competent authorities, more than 2.1 million human tissue and cell products were reported to have been distributed for medical use in 2015 [2]. It is unclear from these data whether these are only allogeneic products, or if tissues and cells for autologous use are also included in the reports from the member states (MS). Furthermore, information on the volume of tissue products imported into the EU from third countries or exported outside of the EU is not systematically collected.

From surveys of relevant professional societies in the field and estimates by the European Commission, the total number of tissues and cells used for human application can be broken down into the rough annual figures described in **Table 1**.

This burgeoning field is in some cases highly profitable. In some countries, a progressive transformation of initially not-for-profit activities into for-profit activities in the tissues and cells field (e.g. cornea [3], bone, gametes [4]) has been described, with the potential risk of not complying with the essential principle that *"the human body and its parts shall not give rise, as such, to financial*

Table 1. Estimated annual volume of clinical use of human tissues in the European Union[2].

Human substance	Estimated volume*
Corneas	35 000
Heart valves/cardiovascular tissue	5 000
Haematopoietic stem cells (including cord blood)	57 000
Musculoskeletal tissue	190 000–250 000
Skin	14 000
Medically assisted reproduction (including partner donation)	700 000–800 000

** In products/transplants/implants*

gain". Thus, profit rather than medical need may be the motivating factor for the procurement of tissues and cells. Furthermore, the availability of donors (both living and deceased) is often a limiting factor for the procurement of tissue and cells, thus source materials are often scarce. Due to this scarcity and the potential financial profits, the risk of illicit and unethical activities involving human tissues and cells can be considered a realistic threat.

Much has been written about trafficking in human organs and human trafficking for the purpose of organ removal [5]. Reports of human exploitation for organ removal and its consequences have been widely reported in the literature [6]. Resolutions, Conventions and professional declarations and statements against these crimes have been adopted by the international community and national laws have been enacted or reinforced in many countries to not only prohibit, but also criminalise the trade in human organs. In contrast, limited attention has been paid to illicit and unethical activities associated with the procurement and clinical use of other substances of human origin, such as tissues and cells. This is perhaps because society is less familiar with tissue and cell transplantation compared with organ transplantation, although the latter happens far less frequently. Moreover, there is no international agreement on what represents illicit and unethical activities with human tissues and cells, and there is no consensus on which of these practices should be criminalised.

Various ethical and safety-related scandals have been reported, such as procurement without consent or authorisation, inadequate testing, inaccurate or false donor files, irresponsible allocation and illegal trade. Hearings, lawsuits, convictions, resignations and closures of tissue establishments have followed. Mediatised cases such as the "France Hypophyse scandal" [7], the "New York body-snatching ring" [8] and the "Alder Hey organ retention scandal" [9] drew public attention and called into question the adequacy of the regulatory framework that governed the human cell, tissue and cellularand tissue-based product industry [10].

Furthermore, there are activities that, in addition to their illicit and unethical component, could seriously jeopardise the quality and safety of tissues and cells and thus the recipient's safety. This is the case when excessive reimbursement for donation is given (e.g. in a third country) that could be an incentive for the donor not to disclose relevant information related to certain health risks, or when cell-based experimental treatments are promoted or performed without any clinically demonstrated safety and efficacy.

Regrettably, knowledge about the true extent of these illicit and unethical activities with tissues and cells remains limited [11]. Little information is available from official sources, with figures and trends mostly the result of estimates and rumours. Unsubstantiated reports often appear in the media, such as those describing the existence of undercover networks of brokers, technicians and physicians in various countries. There are probably more cases, but many may go unreported due to fear on the part of the victims/donors and silence on the part of those directly involved in these illicit but lucrative activities. Furthermore, when detected, there are significant disparities from country to country in the management of suspected activities in this context. Inspectors and enforcement officers lack specific training on how to deal with, identify and handle cases of suspected or confirmed illicit activities related to tissues and cells [12].

In view of this evidence, it becomes clear that a definition of "Trafficking in Human Tissues and Cells" should be agreed upon at international level with the involvement of all the relevant stakeholders. Furthermore, the Council of Europe could play a leading role in elaborating an international legal instrument setting out this definition and the measures to prevent such trafficking and protect the victims, as well as the criminal-law measures to punish the crime. Such initiative would follow the elaboration of the *Convention against trafficking in human organs*, which was adopted by the Committee of Ministers of the Council of Europe in July 2014, and represented the first legal document providing an internationally agreed upon definition of trafficking in human organs, and identifying activities that ratifying states must criminalise [11, 13]. During the preparation of the Convention, ad-hoc Committee of Experts on Trafficking in Human Organs, Tissues and Cells (PC-TO) acknowledged the need to develop an *Additional Protocol on Tissues and Cells* in the future. This need was further stressed by the Committee on Organ Transplantation of the Council of Europe (CD-P-TO) and the Council of Europe Committee on Social Affairs, Health and Sustainable Development of the Parliamentary Assembly [14].

2. Objectives

With this paper, the CD-P-TO aims to raise awareness among Council of Europe decision-making bodies of

the necessity to explore the need for an additional protocol to define, prevent and combat illicit activities in the chain of donation to clinical application of human tissue and cells, and to protect donors and recipients.

The present document outlines the issues related to illicit and unethical activities with tissues and cells. In particular, it is intended to provide: i) a review of the existing international legal framework that regulates practices in the field of tissues and cells; ii) a compilation of the available evidence with regard to the dimension and features of illicit and unethical activities involving tissues and cells; iii) a description of the consequences of such practices from the public health and other perspectives; iv) based on the above, a discussion on the need to develop additional international legal tools against unethical practices in the field of human tissues and cells.

In summary, our intention is to use the conclusions and recommendations reached by the CD-P-TO and summarised in this project as food for thought for the Council of Europe decision-making bodies. We are convinced that this study will make us stronger in our fight against illicit activities involving tissues and cells of human origin.

3. International standards in the field of tissues and cells

3.1 World Health Organization

The World Health Organization (WHO), through its 2010 *Guiding Principles on Human Cell, Tissue and Organ Transplantation*, sets out standards for the donation, procurement, clinical use and equitable distribution of human tissues and cells [15]. Although not legally binding, the WHO Guiding Principles have profoundly impacted upon national legislation and professional codes of practice. The fundamental principles laid down include:

- Consent requirements: the living donor must provide duly informed, specific and free consent to the removal of tissues and cells. The Guiding Principles also call for the prohibition of the removal of tissues and cells from living minors, although exceptions may be permissible under national law in the case of regenerative tissues, provided that the minor is duly protected. In the case of the deceased donor, consent for the removal of tissues and cells must be obtained as required by national law, only where there is no reason to believe that the deceased person objected to such removal. Consent may be explicit ("opt in") or presumed ("opt out") depending on the existing legal requirements within a given jurisdiction. Where explicit consent has been given and recorded, for example in a donor registry, such consent may be withdrawn at any time before the procurement. Procurement on the basis of presumed consent cannot proceed where the donor has recorded or otherwise made known an objection to deceased donation.

- Prohibition of financial gain: the principle of unpaid donation and the prohibition of financial gain from the human body and its parts is established in the WHO principles. Living donors may be reimbursed for reasonable and verifiable expenses and loss of earnings directly related to the donation, but countries should define the conditions under which such compensation is justified, always avoiding financial incentives or benefits in kind to living donors or deceased donor families. Procurement must be carried out on a non-profit basis. Similarly, WHO allows the payment of professional fees for the services rendered in connection with the donation, procurement and clinical use of human tissues and cells. The prohibition of advertising the need for, or the availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage is also set down.

- Allocation: the allocation of tissues and cells 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.

- Self-sufficiency: countries should strive to achieve self-sufficiency in human tissues for patient treatment by endorsing donation of tissues and cells and thus removing the incentive for unethical practices involving tissue and cells of human origin.

- Altruistic donation: solidarity between donors and recipients should be advocated without financial gain.

- Equal access to grafts: allocation of human tissues and access to treatment should be based on clinical need only.

- Efficacy, safety and quality: WHO sets out the need to ensure traceability and vigilance systems and to

assess the outcomes of recipients of these substances of human origin and of living donors.

3.2 Council of Europe

The Council of Europe *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (Oviedo convention) and its *Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin* detail some of the essential principles related to the donation of organs and tissue that have been agreed upon [16, 17]. This Convention has been ratified by 29 Council of Europe MS that are hence bound by this treaty.

The fundamental principles laid down by the Oviedo Convention include:

- Organ and tissue removal from living donors: removal of organs or tissue from living persons for clinical use may only by carried out when there is no other therapeutic alternative or organ/tissue available from deceased persons. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body (Article 19).

- Protection of persons not able to consent: the Convention prohibits the removal of organs or tissues from persons not able to provide valid consent (Article 20).

- Prohibition of financial gain: the human body and its parts shall not, as such, give rise to financial gain (Article 21).

- Disposal of a removed part of the human body: the use of parts of the human body must be restricted to that for which specific information and consent was given (Article 22).

The above principles are complemented by those in *the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin* as follows [17]:

- Professional standards and safety: the Protocol stresses the need to conform to professional obligations and standards (Article 4) and further expands on the need to minimise disease transmission or other harm to recipients (Article 6).

- Consent requirements: an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body (Article 13). As regards deceased donation, it is stipulated that organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained. The removal shall not be carried out if the deceased person had objected to it (Article 17).

- Prohibition of financial gain: it is stated that *"the human body and its parts shall not, as such, give rise to financial gain or comparable advantage"*. The text goes on to say that the prohibition of financial gain does not prevent: (i) compensation of living donors for loss of earnings and reimbursement of any other justifiable expenses caused by the removal or by the related medical examinations; (ii) compensation in the case of undue damage resulting from the removal of organs, tissues or cells; (iii) the payment of a justifiable fee for medical or related technical services rendered in connection with the donation (Article 21).

- Organ and tissue trafficking: organ and tissue trafficking are expressly prohibited (Article 22). It must be noted that, while the Council of Europe has developed an international definition of practices that are consistent with trafficking in human organs [13], it has not performed the same exercise in the field of human tissues and cells.

To provide guidance to MS on the implementation of the principle of the prohibition of financial gain as laid down in Article 21 of the Oviedo Convention, a guide was adopted in 2017 – *Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts, as such, from living or deceased donors* – which provides clarification on key notions relevant to the above-mentioned principles and examples of what are considered as "altruistic focused measures" [18].

3.3 European Union

The *Charter of Fundamental Rights* of the EU should be highlighted, notably the principle set out in Article 3(2)(c), which states that the prohibition on making the human body and its parts as such a source of financial gain must be respected [19]. As mentioned above, this principle is also enshrined in Article 21 of the *Convention on Human Rights and Biomedicine* [16], and in the *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation* [16].

The European Commission has issued the following EU Cell and Tissue Directives: *2004/23/EC* [20]; *2006/17/EC* [21]; *2006/86/EC* [22] and *2015/565/566/EC* [23]. These directives were designed to ensure harmonised and high standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human cells and tissues, to facilitate their cross-border movements and to ensure availability in the EU. If MS cannot achieve self-sufficiency, for example because of the scale of the issue or the effects of the potential measures, this can be done at Union level. This means that the Union is allowed to adopt measures in accordance with the principle of subsidiary as set out in Article 5 of the *Lisbon Treaty*[1].

These Directives apply to tissues and cells, including haematopoietic peripheral blood, umbilicalcord blood and bone marrow stem cells, reproductive cells (oocytes, sperm), foetal tissues and cells and adult and embryonic stem cells.

Under *Directive 2004/23/EC* [20], MS must establish an accreditation system for tissue establishments and ensure that appropriate control measures are in place for the procurement of human tissues and cells. Furthermore, MS must organise inspections and control measures, which have to be carried out by officials representing the competent authority, to ensure that tissue establishments comply with the provisions under the EU Directives. The officials involved in inspections and control measures must be appropriately qualified and receive adequate training.

The EU Directives do not, however, describe the penalties that can be imposed in cases of infringement of the national provisions adopted under the EU Directives. MS are obliged to lay down national rules on penalties with regard to breaches of compliance with the EU Directives, penalties that must be effective, proportionate and dissuasive. There is no general overview available of the penalties that the different MS have adopted to ensure compliance with the EU Directives, because of the freedom given to the MS in choosing a legal framework. However, it is known that not all MS have implemented criminal legislation for cases of infringement of the relevant legislation on the quality and safety of tissues and the protection of donors' rights.

To support MS implement a legal framework to combat illicit activities involving tissues and cells, an Inspection guide for Competent Authorities was published in 2011– *Guidance on the detection and investigation of suspected illegal and/or fraudulent activity (IFA) related to tissues and cells* [24] to provide guidance to European Union (EU) Competent Authorities for detecting / identifying, investigating, managing and communicating such activities.

3.4 Professional societies

The *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, originally adopted in June 1964, is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA). [25] It is widely regarded as the cornerstone document on human research ethics. The Declaration developed the ten principles first stated in the *Nuremberg Code* [26], and tied them to the *Declaration of Geneva* (1948), a statement of physicians' ethical duties [27]. Subsequently, in 2012, the WMA also adopted a *Statement On Organ And Tissue Donation* [28].

The *Barcelona Principles: An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies* is an international consensus document, developed by the eye bank and ophthalmic communities under the leadership of the Global Alliance of Eye Bank Associations (GAEBA), to inform on the management of altruistic and voluntary ocular tissue donations, their subsequent utility within ophthalmology and research, their retention as a public resource for the shared benefit of all, and their accessibility by waiting recipients [29]. This document is the result of global sector engagement over a 12-month period that aims at providing leadership, guidance and recommendations that inform and support sound policy, sector wide strategic planning and implementation at local, national, regional, and international levels.

4. Dimension and characteristics of unethical activities involving human tissues and cells

Little research has been performed to investigate the extent of illicit and unethical activities with human cells and tissues in Europe and worldwide. Most of the information comes from case reports, investigating authorities such as the police or health departments and from articles published in the press.

[1] Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.

When illicit and unethical activities involve donors, they frequently relate to recently deceased persons. Tissues may have been sold for the purpose of research or clinical use without the authorisation required in the corresponding jurisdiction, or with falsified papers. Illicitly obtained tissues from one deceased person can reach up to 90 tissue recipients.

When recipients are victims of such practices, cases involve the use of illicitly and/or unsafely procured grafts, but also unethical medical practices such as unauthorised indications or medical treatments without any evidence of efficacy that may cause harm to patients [30]. The latter, however, are primarily violations of laws on practicing medicine and professional medical standards and cannot be prevented simply by regulating the quality and safety of tissues and cells for clinical use.

For the purpose of this document, we define illicit practices in the field of human tissue and cells as any practice performed in violation of one or more legal requirements or guiding principles, as set down in international legally binding instruments (see **Section 3**) that are related to the donation and/or human application of tissue and cells of human origin (see **Table 2**).

4.1 Results from the SOHO V&S project

In 2011, a report on illicit activities involving tissues and cells was prepared as part of an EUfunded project entitled "Vigilance and Surveillance of Substances of Human Origin (SOHO V&S)"[2] [13]. This report aimed at providing EU MS Competent Authorities responsible for tissues and cells with guidance on detecting/identifying, investigating, managing and communicating such activities.

In order to evaluate the experience with illicit activities related to tissues and cells, a questionnaire was developed as part of this project. The questionnaire was submitted to EU Competent Authorities, as well as to several other third countries, during 2010. The scope of the questionnaire was *Directive 2004/23/EC* on tissues and cells used in transplantation and assisted reproduction.

The questionnaire elicited 26 responses from 22 EU MS, 3 European non-EU countries (at the time Croatia had not yet joined the EU) and 1 non-European country[3].

An analysis of all the responses showed that many questionnaires were incomplete due to the fact that MS had limited insight into the matter. Some findings, however, could be highlighted:

- The majority of countries had legislation in place related to illicit activities, which was applicable to human tissue and cells. Those who did not have any legislation in place indicated that they considered it necessary or were working on it.
- Twelve countries indicated having had actual experience with illicit activities over the previous 5 years. In addition, 15 countries had experienced misleading and unsubstantiated claims related to the beneficial effects of cell and tissue transplants.
- Eighteen countries had reported these incidents to other agencies and/or the general public.
- Seventeen cases of illicit were reported which dealt with gametes (sperm, oocytes, embryos), cord blood/tissue and bones/musculoskeletal tissue. Of these, nine were confirmed as constituting illicit activities and the others were still under investigation at the time the questionnaire was being completed. Most of the illicit activities had occurred during the procurement/donation stage of the process.
- Sanctions were imposed where cases of illicit activities had been identified, but it is notable that criminal and administrative sanctions are under the sovereignty of each MS and not EU institutions. Non-harmonised legislation in this regard means that an activity that is criminalised in one MS might not be so in another jurisdiction.

4.2 Interpol survey

At the request of the French Health Authority, a similar survey was developed by Interpol for Law Enforcement Agencies in 2012. In total, representatives from 43 countries completed this survey, most of them from policy-making agencies. One third of the respondents (14) reported cases of illicit with tissues and cells. These reports were based not only on questionnaires, but also on the Interpol database, scientific literature and other open sources. Only 50% of the respondents found legislation in their country sufficient in these matters.

[2] Grant Agreement Number: 20091110. Funded under the EU Second Programme of Community Action in the Field of Health.

[3] Belgium, Croatia, Cyprus, Czech Republic, Denmark, Germany, Estonia, Iceland, Spain, Finland, France, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Sweden, United Kingdom, United States of America..

The types of tissue and cells subjected to illicit activities in these reports were bone (including demineralised bone), tendons and ligaments, ocular tissues (corneas and sclera), skin, human placenta, cord blood for autologous use and gametes.

4.3 Case reports

One of the most cautionary examples of a large-scale fraud is the case of Biomedical Tissue Services Ltd (BTS), where intentional misconduct with tissue donors turned out to be highly lucrative and led to a risk of harm to

Table 2. Areas of potential unethical activities in the field of tissues and cells.

Violation	Related legislation/principles
Procurement of tissue/cells without free, specific and informed consent (living donor) or without the authorisation required in a given jurisdiction, for the purpose of: • Clinical use • Research • Further processing as innovative therapies (e.g. in the EU, following under the regulatory frameworks of medical devices or advanced therapy medicinal products) Use of surgical residues without free, specific and informed consent	• Directive 2004/23/EC (Article 13) • Council of Europe recommendation (2006)4 • Convention on Human Rights and Biomedicine and additional protocols (CETS 168,186,195,203)
Violation of body integrity beyond the necessity to procure tissue or cells	• Council of Europe recommendation (2016)6 • Convention on Human Rights and Biomedicine and additional protocols (CETS 168,186,195,203)
Unlicensed storage, processing, distribution, testing	• Directive 2004/23/EC (Article 6) • Directive 2006/86/EC (Articles 3 and 4)
Breach of legal requirements for traceability, donor evaluation, testing, processing, storage and distribution	• Directive 2004/23/EC (Article 8) • Directive 2015/565/EC (Article 1, sub paragraph 2)
Excessive reimbursement or compensation of living donors or a third party in return for the donation of human tissues or cells	• Directive 2004/23/EC (Article 12) • Council of Europe Convention on Human Rights and Biomedicine (Article 21) • Additional Protocol on transplantation of organs and tissues of human origin • (Article 21)
Distribution of unauthorised tissue and cell products (e.g. from unlicensed tissue establishments, illegal imports, brokers)	• Directive 2004/23/EC (Articles 6 and 9(3)) • Directive 2015/566/EC (Article 3)
Promotion of tissueand cell-based experimental treatments without evidence of safety and/or efficacy	• WHO Guiding Principle 10 • Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (Articles 4 and 6)

patients. Between 2002 and 2005, BTS distributed tens of thousands of illegally obtained and improperly processed tissues throughout the world. BTS acquired tissues from cooperative funeral homes in the New Jersey area without any authorisation, and produced false death certificates and infectious disease test results. The Food and Drug Administration (FDA) estimated that 13,000 patients had ultimately received tissues processed by BTS. Not all hospitals kept records of which tissues had been implanted and in which patients, so the impact on recipients' health remains largely unknown.

The FDA responded to the BTS scandal by strengthening the regulations governing tissue procurement. However, within a year, another organisation supplying improperly obtained and processed tissues, and using an almost identical *modus operandi*, was discovered to be operating in North Carolina, under the name Donor Referral Services [31].

In Europe, similar practices have been brought to the European Court of Human Rights: the removal of tissue from a deceased man's body without the knowledge or consent of his wife amounted to degrading treatment [32]. The applicant was a Latvian woman whose husband had died in a car accident. After the autopsy had taken place, it emerged that tissue had been removed from the body prior to the funeral without her knowledge or consent. Under a State-approved agreement, the tissue had been sent to a pharmaceutical company in Germany to be modified into bio implants. During the course of the investigation, it was established that in 1999 tissues had been removed from 152 people; in 2000, from 151 people; in 2001, from 127 people; and in 2002, from 65 people. In exchange for the supply of tissue to the company in Germany, the forensic centre involved had organised the purchase of various items of medical equipment, instruments, technology and computers for medical institutions in Latvia.

The Court underlined that, in the special field of organ and tissue transplantation, it had been recognised that the human body had to be treated with respect even after death. Indeed, international treaties, including the *Convention on Human Rights and Biomedicine* and its *Additional Protocol on Transplantation* [16, 17], were drafted to protect the dignity, identity and integrity of "everyone" who had been born, whether at the time living or dead. The Court stressed that respect for human dignity formed part of the very essence of the European Convention.

Between 2009 and 2012, concerns were raised about illegally obtained tissues in forensic institutes in Ukraine; these were intended for the German and US markets and processed by for-profit tissue processors in both countries [33]. Although relatives of the deceased accused the forensic institutes of falsifying consent forms and/or obtaining more tissue than originally agreed upon, the police investigation could not substantiate illegal activities according to Ukrainian law. The processors stopped acquiring human tissue from Ukraine after negative publicity.

Recently, the financial gains made by abortion clinics as a result of selling foetal waste material for research purposes have come under public scrutiny. Although these practices have been going on for decades, ownership of the remains of the foetus and the necessity for consent from the mother has not been regulated in several European countries and therefore these practices continue despite the fact that in other countries they are considered to be a violation of principles and legal requirements.

Practices at some European sperm banks have also come under scrutiny. Among them, the direct sale of sperm samples to women for home insemination. In addition, because several MS prohibit anonymous gamete donation (with the purpose of protecting the right of the child to know its parent), distribution of anonymous sperm to some countries is considered illegal.

Stem cell therapy brings a new challenge to the field because of the fraudulent practice of offering cures for almost every known disease using stem cells from different sources (autologous, embryonic, allogenic), sometimes obtained and implanted without fulfilling any legal or quality requirements, and in all cases without any evidence of efficacy of these treatments [34].

5. Potential and actual consequences of unethical activities from the perspectives of society and public health

5.1 Risks for recipients

The most important risk for recipients of tissues or cells obtained through illicit and unethical activities is the lack of control of the quality and safety of the tissue or cell products. Risk are increased by incorrect donor histories, doubtful procurement circumstances, incomplete documentation and traceability, inadequate processing, storage and labelling and lack of vigilance and recall options. The consequences may be diverse but can potentially seriously jeopardise the clinical outcome of the patient.

As is the case with organ trafficking, and in particular due to less stringent acceptance criteria, there is an enhanced risk of viral, bacterial or fungal infections transmitted via grafts procured in the context of illicit and unethical practices. In the past, several diseases have been transmitted via tissues and human cells: bone allografts have transmitted hepatitis viruses, tuberculosis and human immunodeficiency virus (HIV-1) [35]. Corneas have transmitted rabies, herpes simplex viruses, bacteria and fungi. Heart valves have been implicated in transmitting tuberculosis and hepatitis B. HIV-1 and cytomegalovirus seroconversion have been reported in patients receiving skin from seropositive donors. Creutzfeldt-Jacob disease has been transmitted by dura and pericardium transplants and several bacteria, such as *Treponema*, have been transferred through tissue. There are also potential dangers associated with stem cell therapy, such as malignant transformation of the implanted cells [36].

When illicit and unethical practices occur in the form of financial inducement to donors (or their families), there may be a risk of potential living donors not adequately considering and evaluating the potential risks related to the donation procedure or of donors or their families not disclosing relevant medical or behavioural information that would, under normal circumstances, preclude donation. This can also motivate intermediaries to withhold information for fear of losing fees.

While it cannot be stated that these complications are more frequent or particularly severe in the context of illicit and unethical practices with tissues and cells, inappropriate donor (and recipient) selection and substandard practices applied to the procurement, processing and allocation of human tissues and cells are more likely to result in harm to patients.

Desperation may lead patients to search for alternative treatment options for a substantial number of diseases. In this context, advances in the field of stem cell therapies have been accompanied by the promotion of the clinical use of tissues and cells of human origin with no scientific evidence in terms of efficacy and safety. On occasion, patients travel outside of their country of origin in search of these "miraculous" treatments that violate fundamental ethical principles and quality and safety standards (this is the so-called stem cell tourism).

5.2 Consequences for donors or next of kin

The procurement of tissue and cells without consent, or with consent based on insufficient information, may cause severe psychological stress to the living donor and/or deceased donors' families. In particular, the idea that parts of the body "live on" elsewhere, or that the body of the deceased has been violated, often for financial gain, can cause trauma for donors (e.g. repeated and uncontrolled oocyte donation) and their next of kin.

Excessive damage to the deceased body, in the case of unprofessional procurement of tissue, may cause stress during the funeral and leave a permanent stain on relatives' memories of the donor. Other medical considerations include inadequate care and treatment of living donors after procurement of tissue or cells, including donation-related complications. Linked to the lack of appropriate clinical follow up, there is a possible absence of full traceability from donors to recipients and vice versa, as well as failure to record and report serious adverse events and reactions.

5.3 Consequences for the healthcare system

Successful tissue and cell donation and transplantation programs depend on public trust and support. The confidence of the general public in the donation system for tissue and cell products, in a context where the principle of voluntary unpaid donation is legally endorsed, is already threatened by the fact that certain human products are distributed via commercially used channels for pharmaceuticals and medical devices. Furthermore, the public has been shocked on several occasions by incidences of illicit medical practices where unfounded cures were promised by applying human materials.

Against this background, illicit and unethical practices pose an even bigger threat to public trust and support. Not only will scandals related to such practices cause a drop in confidence in all types of donor-derived products, but it will also result in a reluctance to donate bodily materials at all.

Ultimately this will affect the availability of tissue and cell grafts, and jeopardise the availability of organ and blood donors as well.

It is worth noting that desperate patients (as is the case with organ transplantation) who would like to find a solution for their disease are easy prey for illicit and unethical practices with human tissues and cells.

In the end, when financial gain plays a role, the allocation of human tissues and cells according to clinical needs no longer takes priority and this introduces inequality in access to treatment. Patients who benefit will tend

to be those who can afford to pay. In addition to financial incentives to donate, there may be coercion, fraud and abuse of donors, as well as long-term medical, social and financial harm to living donors.

Finally, the risk of transmitting infections or other diseases with tissue or cells obtained through illicit and unethical practices does not only endanger the recipients, but may also affect others that are in contact with the recipients thus constituting a serious public health threat.

6. Conclusions

- The volume of tissue and cell donation and transplantation activities in Europe is substantial and the sector is developing fast, being subject to technological innovations and increasing commercial interest.

- The scarcity of donor material and the potential for financial gain from human tissues and cells for human application may encourage illicit activities. Although some cases of have come to light, the true dimension of the problem remains unknown in the absence of systematic and coordinated efforts to define and monitor these practices (last inventory in 2015).

- Illicit activities with tissue and cells may pose a risk to the individual health of both the donor and the recipient, by causing harm through unnecessary procurement procedures, facilitating the transmission of diseases (which also poses a risk to public health) or applying therapies that have not been tested in terms of safety and quality for the individual.

- Illicit activities may jeopardise public trust and willingness to altruistically donate tissue and cells and therefore limit the availability of these essential healthcare provisions for patients.

- The confidence of the general public in the donation system may be undermined by unethical but very lucrative medicinal procedures, in which treatments with tissues and cells offer unproven cures.

- The existing international legal framework provides ample provisions to ensure good practices and the quality and safety of tissues and cells, e.g. by specifying consent and authorisation requirements, prohibiting financial gain and creating the obligation of sanctions/penalties in cases of violation of such provisions. These provisions and sanctions, however, have not yet been implemented in all European countries and most of those found to be violating these requirements have not been subject to sanctions.

- Despite the existing legal framework, the interpretation of what constitutes illicit practices differs between countries; this may result in tissueand cell-related activities being acceptable in one country while illegal in a neighbouring one. Moreover, there is no international agreement on which illicit practices are of such severity – because they violate fundamental human rights and freedoms, such as that of self-determination, dignity and integrity and/or because they pose important threats to public health – that they should be subject to criminalisation and made consistent with trafficking in tissues and cells. International agreement and coordinated efforts against trafficking in human tissues and cells are imperative in this field where transnational activity is frequent.

7. Recommendations

1. The principle of the prohibition of making financial gain with the human body or its parts should be the paramount consideration in relation to the donation of tissues and cells of human origin. All national legislations concerning the donation and human application of tissues and cells should conform to this principle.

2. The definition and interpretation of what constitute illicit activities, as well as the need for adequate sanctions against these practices, should be agreed at international level. In particular, international agreement should be reached on which illicit activities involving human tissue and cells are of such severity – because they imply the violation of fundamental principles and/or pose important threats to public health – that they should be criminalised.

3. Collaboration between international organisations, as well as national and international law enforcement agencies, such as Interpol and Europol, are indispensable where illicit practices are detected or suspected at an international level or where is the potential to have international consequences.

4. Cooperation among customs authorities, law enforcement agencies and Health Authorities should be strengthened, particularly during ongoing investigations. To coordinate the identification and management of suspected cases, clearly defined roles, training and education for all involved parties

and adequate resources should be set in place.

5. Donors and recipients of tissues and cells, and the general public, should be informed of donors' rights and the legal context of donating, processing and distributing human materials for medical and research purposes, including (acceptable) commercial involvement.

6. Healthcare professionals should continue to promote standards for ethical practices in the field of tissues and cells. Professional societies should have a leading role in the development and dissemination of such professional codes of ethics.

7. It is essential to start collecting reliable data on illicit activities involving human tissues and cells. There is limited knowledge of the scale of the problem since little and fragmentary information about the number of trafficked tissues and cells and victims of illicit practices is available from official sources. This hinders both the quantification of illicit practices and also their qualitative description. The data should be disaggregated by sex in order to assess whether and to what extent the processes disproportionately affect women and girls. States should make efforts in terms of data collection in relation to illicit practices and commission an international body to systematically monitor and report international data and exchange good practices for the prevention and prosecution of such activities.

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Annex 1. Questionnaire to compile information on experience of illegal and fraudulent activities with tissues and cells.

1.	Please provide the number of suspected IFA cases related to tissues and cells your CA/MS has been involved in the last 5 years	
2.	What, in your opinion, are the strengths and weaknesses of the IFA management system in your MS? Please summarise. **strengths:** **weaknesses:**	☐ **Yes** ☐ **No**
3.	Do you have any experience in dealing with misleading advertising in the use of tissues and cells (i.e. unsubstantiated claims)? If **Yes**, please summarise	☐ **Yes** ☐ **No**
4.	Do you have procedures to communicate suspected IFA cases to other agencies/the public? If **Yes**, please summarise	☐ **Yes** ☐ **No**
5.	Have you had any experience with a "virtual" tissue establishment that is involved in import/export? If **Yes**, please summarise	☐ **Yes** ☐ **No**

Annex 2. Examples of cases related to consent matters.

Case	Year	Reason for case	Decision/settlement
Beleno v. Tex. Dept. of State Health Servs., No. SA-09-CA-188-FB, United States District Court for the Western District of Texas	2009	Parents sued state for use of leftover blood samples that were collected for new-born blood screening and were used in research for which parents had not given consent.	Case settled out of court. State destroyed all existing leftover specimens.
Adams v. King County, 192 P. 3d 891 (Wa. 2008)	2008	Organ donor's organs were sent to medical research institute for research. Family sued, contending that donor's consent was limited to transplantation.	Court held that family had a claim based on their interest in proper treatment of body; not a property interest.
Washington University v. Catalona, 490 F 3d 667 (8th Cir. 2007)	2007	Washington University refused to relinquish custody of tissue obtained for research purposes when one of the investigators (and some of the donors) requested that the samples be transferred to another institution.	Court held that donors made a gift of their samples and did not retain a right to direct that they be transferred elsewhere.
Havasupai Tribe v. Arizona State University, Case No. CV2005013190, Superior Court of Arizona, Maricopa County	2004	Native American tribe filed lawsuit claiming samples given to local universities for diabetes research were used for studies on inbreeding, schizophrenia, metabolic diseases, alcoholism and population migration.	Case settled out of court. The University of Arizona's Board of Regents to pay $700,000 to the tribe members, provide other forms of assistance to the impoverished Havasupai and return the blood samples.
Greenberg v. Miami Children's Hospital Research Institute, 264 F. Suppl. 2d, 1064 (SD Fl. 2003)	2003	Plaintiffs donated samples for research which led to development of new diagnostic test. Plaintiffs sued after learning that research institution was licensing the test.	Patients have no property right in tissue voluntarily donated for medical research.
Application nº 61243/08 by Dzintra ELBERTE v Latvia	2001	After the autopsy had taken place, it emerged that tissue had been removed from the body prior to the funeral without his wife knowledge or consent. More cases were discovered later.	Although relatives of the deceased accused the forensic institutes of falsifying consent forms and/or obtaining more tissue than originally agreed upon, the police investigation could not substantiate IFA according to Ukrainian law
Mansaw v. Midwest Organ Bank, 1998 U.S. Dist. LEXUS 10307 (W.D. Mo. 1998)	1998	Father sued for rights to control the removal of tissue and organs from his deceased son's body.	Court acknowledged father's property interest, but held that it was minimal.

Annex 2. Examples of cases related to consent matters. *(cont.)*			
Case	**Year**	**Reason for case**	**Decision/settlement**
Moore v. Regents of University of California, 793 P.2d 479 (Cal. 1990)	1990	Patient's cells were used for research without his knowledge or consent. Patient sued after learning that research institution had developed cell line and realised economic benefit.	Court held that patient did not have property right in excised tissue, but could pursue a breach of fiduciary duty claim.
York v. Jones, 717 F. Suppl. 421 (E.D. Va. 1989)	1989	Couple signed agreement regarding procedures for freezing their fertilised eggs, and permitting use for research if they no longer desired to initiate a pregnancy. Later the couple sought to have the prezygote transferred to another medical school for implantation.	Court ruled that the relationship was that of bailee/bailor and the couple did have property rights and could repossess the prezygote.

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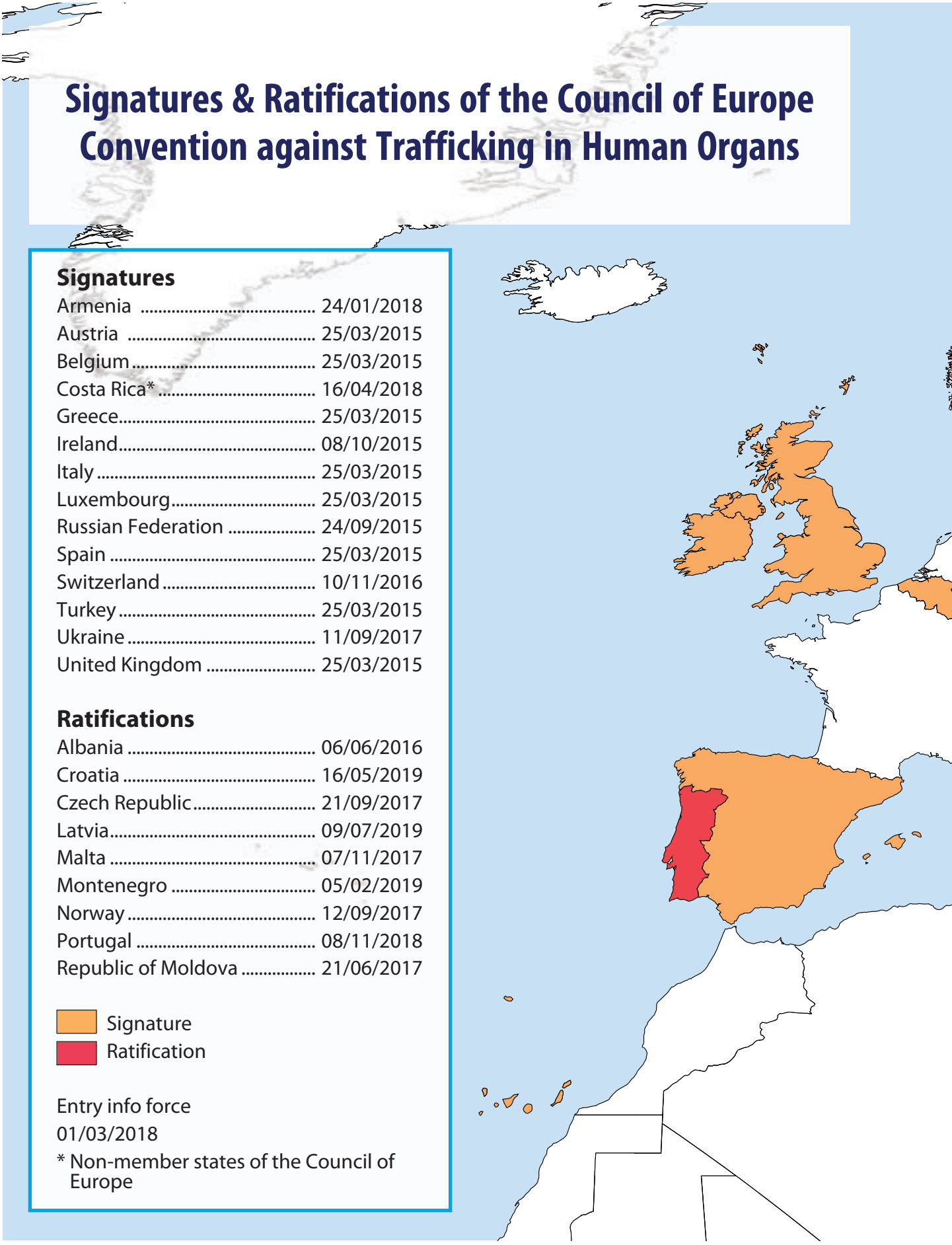

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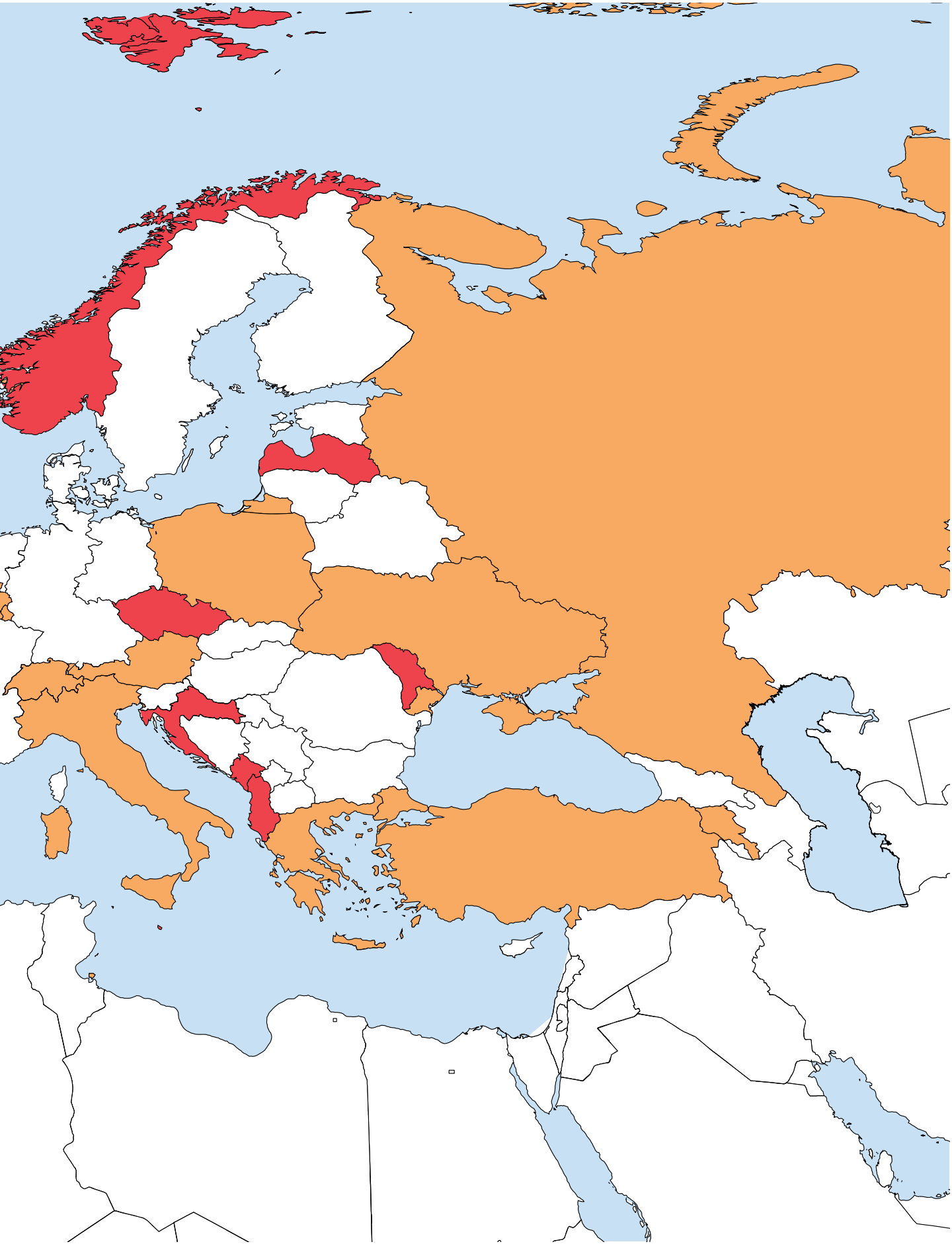

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