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Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on the implementation of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

{COM(2022) 671 final}

1. Designation and Obligations of the Competent Authorities

	1. Have there been any changes to the structures/designations of your competent authorities since the last survey (2014)?	What are these changes? Please provide details (including to which competent authority they relate, if applicable)
AT	No	
BE	No	
BG	Yes	Executive Agency for Transplantation is merged with Executive Agency for Medical Audit. Now we are part of a larger structure, dealing with donation, transplantation and control and audit of the medical establishments. The name of the Directorate, dealing with donation and transplantation activities is 'Management and Control of the Transplantation and the Assisted Reproduction'.
CY	No	
CZ	No	
DE	No	
DK	Yes	The CA has been Danish Patient Safety Authority since 2016 when this body was established.
EE	Yes	New Procurement, Handling and Transplantation of Cells, Tissues and Organs Act came in force in 2015. The National transplantation agency was established and some tasks of it were delegated to Tartu University Hospital, such as organisation of traceability and biovigilance of the procurement, handling and transplantation of organs, maintenance of waiting lists and distribution and international exchange of organs to be transplanted. Estonia joined Scandiatransplant.
EL	No	
ES	No	
FI	No	
FR	No	
HR	No	
HU	Yes	HNBTS developed and manages the Hungarian National Transplant Follow up Registry for which all relevant health care service providers provide data according to the SOP of the HNBTS by law.
IE	No	
IT	No	
LT	No	

LV	No	
NL	No	
PL	No	
PT	No	
SE	No	
SI	Yes	The new law based on the Directive 53/2010 was adopted in 2015.
SK	No	

	2. Do you participate in EOEO activities?	**Do you have an agreement with an EOEO (Article 21 of the Directive)?**
AT	Yes	Yes
BE	No	
BG	Yes	Yes
CY	No	
CZ	Yes	Yes
DE	Yes	Yes
DK	Yes	No
EE	Yes	Yes
EL	Yes	Yes
ES	No	
FI	No	
FR	Yes	Yes
HR	Yes	Yes
HU	Yes	Yes
IE	Yes	Yes
IT	Yes	No
LT	Yes	Yes
LV	Yes	Yes
NL	Yes	Yes
PL	Yes	Yes
PT	Yes	Yes
SE	Yes	Yes
SI	Yes	Yes
SK	Yes	Yes

	2.1 Does your country exchange organs with other EU Member States?	2.2 Does your country exchange organs with third countries?
AT	Yes	Yes
BE	Yes	No
BG	Yes	No
CY	Yes	Yes
CZ	Yes	No
DE	Yes	No
DK	Yes	Yes
EE	Yes	No
EL	Yes	No
ES	Yes	No
FI	Yes	No
FR	Yes	Yes
HR	Yes	No
HU	Yes	No
IE	Yes	Yes
IT	Yes	Yes
LT	Yes	Yes
LV	Yes	No
NL	Yes	No
PL	Yes	No
PT	Yes	Yes
SE	Yes	Yes
SI	Yes	No
SK	Yes	No

	2.3 Would your country be interested in increasing exchanges of organs with other Member States in any of the following cases? Please select all that apply.		Please specify in which cases you would be interested.	Please specify the reasons why you see an interest in exchanging organs with other Member States in this case.
AT	ABO-incompatibility			
	Less transplanted organs			
	Children			
	Other			
	None	x		
BE	ABO-incompatibility			
	Less transplanted organs			
	Children			
	Other			
	None	x		

BG	ABO-incompatibility	x		To be given a chance for treatment of these specific patients that cannot be transplanted in Bulgaria in the particular moment.
	Less transplanted organs	x		
	Children	x		
	Other	x	Lack of transplant program in our country - ABO incompatibility - Children - Urgent cases	
	None			
CY	ABO-incompatibility	x		Increase the donor pool, especially for small countries like our country and increasing the possibility for ABO incompatible and hypersensitized patients to get transplanted
	Less transplanted organs			
	Children			
	Other	x	HLA hypersensitized patients	
	None			
CZ	ABO-incompatibility			Deficit of organs
	Less transplanted organs			
	Children	x		
	Other			
	None			
DE	ABO-incompatibility			
	Less transplanted organs	x		
	Children	x		
	Other			
	None			
DK	ABO-incompatibility			See above - an eventual increase of collaboration would probably and primarily be organised through Scandiatransplant.
	Less transplanted organs			
	Children			
	Other	x	DK is collaborating in all these areas through Scandiatransplant and has done this for more than 50 years. Exchange of organs with other countries happens, but only on rare occasions.	
	None	x		
EE	ABO-incompatibility			To increase the donor pool.
	Less transplanted organs	x		
	Children	x		
	Other			
	None			

EL	ABO-incompatibility			
	Less transplanted organs			
	Children	x		
	Other			
	None			
ES	ABO-incompatibility			The recipients belonging the selected categories have more difficulties in finding the adequate donor and organ, due to size, weight, hyperimmunized status, frailty of the organ itself, or any other reasons. The selection of these two categories is justified because exchanging organs theoretically increases the probability of receiving the necessary organ and getting out from the waiting list (expansion of the donor pool).
	Less transplanted organs	x		
	Children	x		
	Other			
	None			
FI	ABO-incompatibility			
	Less transplanted organs			
	Children			
	Other			
	None	x		
FR	ABO-incompatibility	x		
	Less transplanted organs	x		
	Children	x		
	Other			
	None			
HR	ABO-incompatibility			Due to the lack of expertise of our expert team in transplant treatment for small children
	Less transplanted organs			
	Children	x		
	Other			
	None			
HU	ABO-incompatibility			
	Less transplanted organs			
	Children			
	Other			
	None	x		

IE	ABO-incompatibility	x		Ensure availability of organs is optimised for those on national waiting list for solid organ transplantation
	Less transplanted organs			
	Children	x		
	Other			
	None			
IT	ABO-incompatibility	x		Accessing larger pools of genetically inhomogeneous patients/donors, where difficult-to-transplant patients may find proper compatibility in an easier way
	Less transplanted organs	x		
	Children	x		
	Other	x	A supranational program for hyperimmunized patient for transplant from deceased donor. International kidney-paired donation programs for transplant from living donors	
	None			
LT	ABO-incompatibility	x		
	Less transplanted organs	x		
	Children			
	Other			
	None			
LV	ABO-incompatibility	x		
	Less transplanted organs	x		
	Children	x		
	Other			
	None			
NL	ABO-incompatibility			
	Less transplanted organs			
	Children			
	Other			
	None	x		
PL	ABO-incompatibility			Children: needs related to the small number of paediatric deceased donors. Urgent cases: needs for directly life-saving treatment in the country with average donation rates.
	Less transplanted organs			
	Children	x		
	Other	x	Paediatric and Urgent potential recipients.	
	None			

PT	ABO-incompatibility			
	Less transplanted organs			
	Children			
	Other			
	None	x		
SE	ABO-incompatibility			
	Less transplanted organs			
	Children			
	Other			
	None	x		
SI	ABO-incompatibility			Actually, we are interested in exchanging practices as it is. Namely, in Slovenia we have been already cooperating for more than 20 years with Italy and Austria in the field of liver and kidney transplant program for small children because the number of cases is too low to keep the programs on the highest quality level.
	Less transplanted organs			
	Children	x		
	Other			
	None			
SK	ABO-incompatibility	x		For kidney in the case of ABO incompatibility there are not enough pairs for exchange, and it is better chance to get suitable pairs. In our country is missing program for lung transplantation, now we have agreement with Czech Republic. We have not program for liver transplantation for children and sometimes is a problem with very small children for kidney transplantation.
	Less transplanted organs	x		
	Children	x		
	Other			
	None			

3. In the reporting period, was there collaboration between your competent authority/delegated body and authorities and stakeholders with adjacent areas of expertise in your Member State?

If yes: To what extent does your competent authority/delegated body collaborate with authorities and stakeholders with adjacent areas of expertise in your Member State?

AT:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood					x
Tissues and Cells					x
Medicinal Products					x
Medical Devices					x
Others					x

BG:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood				x	
Tissues and Cells					x
Medicinal Products			x		
Medical Devices				x	
Others		x			
Please specify which other competent authorities you collaborate with:					
National Health Insurance Fund					

CZ:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood			x		
Tissues and Cells			x		
Medicinal Products			x		
Medical Devices					x
Others					x

DE:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood			x		
Tissues and Cells	x				
Medicinal Products				x	
Medical Devices			x		
Others			x		
Please specify which other competent authorities you collaborate with:					
Competent Authorities: - Tissue and Cells: Ministry of Health – extend occasionally - Medical Devices: Ministry of Health – extend occasionally Delegated Bodies: - Tissue and Cells: Paul Ehrlich Institute – to some extent Stakeholders: - Blood: DRK-Blutspendedienst Baden-Württemberg – Hessen; Institut für Transfusionsmedizin und Immunhämatologie Frankfurt am Main gGmbH – To some extent - Tissues and Cells: Individual Tissue banks – great extend					

DK:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood					x
Tissues and Cells					x
Medicinal Products			x		
Medical Devices			x		
Others				x	

EE:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood					x
Tissues and Cells					x
Medicinal Products					x
Medical Devices			x		
Others			x		
Please specify which other competent authorities you collaborate with:					
Occasionally collaboration with Data Protection Agency and Health Board has been required.					

ES:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood		x			
Tissues and Cells					x
Medicinal Products			x		
Medical Devices			x		
Others		x			
Please specify which other competent authorities you collaborate with:					
Competent authority on Assisted Human Reproduction, different from the competent authority on T&C (ONT)					

FR:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood					x
Tissues and Cells		x			
Medicinal Products					x
Medical Devices					x
Others					x

HR:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood	x				
Tissues and Cells	x				
Medicinal Products			x		
Medical Devices				x	
Others					x

HU:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood			x		
Tissues and Cells			x		
Medicinal Products				x	
Medical Devices				x	
Others				x	

IE:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood				x	
Tissues and Cells			x		
Medicinal Products				x	
Medical Devices				x	
Others				x	

IT:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood	x				
Tissues and Cells					x
Medicinal Products			x		
Medical Devices			x		
Others			x		
Please specify which other competent authorities you collaborate with:					
Italian National Blood Centre, AIFA, Italian Health Ministry Office for Medical Devices, Italian Health Ministry Office for Prevention of Infectious Diseases, Italian National Institute of Health					

LV:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood					x
Tissues and Cells					x
Medicinal Products					x
Medical Devices					x
Others	x				
Please specify which other competent authorities you collaborate with:					
P. Stradin's University Hospital which is also delegated body for tasks regarding Article 5,6, 7 of Directive 2012/25/EU					

NL:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood					x
Tissues and Cells	x				
Medicinal Products					x
Medical Devices					x
Others					x

PL:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood			x		
Tissues and Cells	x				
Medicinal Products			x		
Medical Devices				x	
Others				x	

PT:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood		x			
Tissues and Cells		x			
Medicinal Products		x			
Medical Devices			x		
Others					x

SE:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood		x			
Tissues and Cells		x			
Medicinal Products		x			
Medical Devices		x			
Others		x			
Please specify which other competent authorities you collaborate with:					
The Health and Social Care Inspectorate (IVO) and the Medical Products Agency					

SI:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood		x			
Tissues and Cells	x				
Medicinal Products		x			
Medical Devices		x			
Others		x			
Please specify which other competent authorities you collaborate with:					
NIJZ- National institute of public health to exchange and follow epidemiological data					

SK:

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood		x			
Tissues and Cells	x				
Medicinal Products			x		
Medical Devices				x	
Others				x	

	Which of the following topic(s) have been subject to such collaborative interactions? Please select all that apply.		**Please specify which other topics have been subject to collaborative interactions**
AT	Vigilance	x	
	Traceability	x	
	Donor protection	x	
	Other		
	None		
BE			
BG	Vigilance		
	Traceability		
	Donor protection		
	Other		
	None	x	
CY			

CZ	Vigilance		
	Traceability		
	Donor protection	x	
	Other		
	None		
DE	Vigilance	x	
	Traceability	x	
	Donor protection	x	
	Other		
	None		
DK	Vigilance		
	Traceability		
	Donor protection		
	Other		
	None	x	
EE	Vigilance		
	Traceability	x	
	Donor protection	x	
	Other		
	None		
EL			
ES	Vigilance	x	
	Traceability		
	Donor protection		
	Other		
	None		
FI			
FR	Vigilance	x	
	Traceability	x	
	Donor protection	x	
	Other		
	None		
HR	Vigilance	x	
	Traceability	x	
	Donor protection	x	
	Other		
	None		
HU	Vigilance	x	
	Traceability	x	
	Donor protection		
	Other		
	None		
IE	Vigilance	x	
	Traceability	x	
	Donor protection		

	Other		
	None		
IT	Vigilance	x	
	Traceability		
	Donor protection	x	
	Other		
	None		
LT			
LV	Vigilance	x	
	Traceability		
	Donor protection	x	
	Other	x	Collaboration with P. Stradin's University Hospital which is also delegated body for tasks regarding Article 5,6, 7 of Directive 2012/25/EU
	None		
NL	Vigilance	x	
	Traceability	x	
	Donor protection		
	Other		
	None		
PL	Vigilance	x	
	Traceability		
	Donor protection		
	Other	x	Tissue donation and banking. Maintaining national potential bone marrow donor registry. Centres accreditation. Construction of registries related to transplantation medicine.
	None		
PT	Vigilance		
	Traceability		
	Donor protection		
	Other	x	Cells and solid organ exchange.
	None		
SE	Vigilance	x	
	Traceability	x	
	Donor protection	x	
	Other		
	None		
SI	Vigilance	x	
	Traceability	x	
	Donor protection	x	

	Other	x	Besides vigilance, traceability and donor protection is very important promotion of donation based on fundamental ethical principles, altruism, and non-profit approach. Furthermore, cooperation with other Competent authorities is also important to ensure transparency in the field of using parts of human body for the purposes of treatment or research. With NIJZ we are exchanging epidemiological data.
	None		
SK	Vigilance	x	
	Traceability	x	
	Donor protection		
	Other		
	None		

	3.1 Are there (other) areas in which your country would be interested to collaborate (more)?	**Please specify which area/authority you would consider relevant:**
AT	No	
BE	No	
BG	No	
CY	No	
CZ	No	
DE	No	
DK	No	
EE	No	
EL	Yes	Paediatric tx
ES	Yes	Interactions and boundaries between Organs, Tissues & Cells, on one side, and healthcare products and medicines, on the other side. ONT is particularly concerned about Donor protection in the mentioned context. Profit in the context of voluntary unpaid donation is also of interest for the ONT:
FI	No	
FR	Yes	Harmonisation of practices
HR	No	
HU	No	

IE	Yes	Further collaboration in relation to medical devices / tissues for all listed categories
IT	Yes	Educational programs and communication initiatives
LT	No	
LV	Yes	Lung transplantation and paediatric liver transplantation for LV patients
NL	No	
PL	No	
PT	No	
SE	No	
SI	Yes	We are cooperating in the field of tissues and cells with Institute for Transfusion medicine and Public Agency for Drugs and Medical products on an almost daily basis. To our opinion, it should stay as it is until now. Existing legislation is very useful and serves to realize all important requirements in the field. We would like to intensify cooperation with the National institute of public health.
SK	No	

UK(NI):

1. Have there been any changes to the structures/designations of your competent authorities since the last survey (2014)?		**What are these changes? Please provide details (including to which competent authority they relate, if applicable):**	
No			
2. Do you participate in EOEO activities?		**Do you have an agreement with an EOEO (Article 21 of the Directive)?**	
Yes		Yes	
2.1 Does your country exchange organs with other EU Member States?		**2.2 Does your country exchange organs with third countries?**	
Yes		Yes	
2.3 Would your country be interested in increasing exchanges of organs with other Member States in any of the following cases? Please select all that apply.		**Please specify in which cases you would be interested:**	**Please specify the reasons why you see an interest in exchanging organs with other Member States in this case:**
ABO-incompatibility			
Less transplanted organs			

Children			
Other	x		NI already exchanges organs at this level. There is potential to increase living donation and the UK Living Kidney Sharing Scheme. NI is part of that and there has been interest from Republic of Ireland although discussions are in early stages.
None			

3. In the reporting period, was there collaboration between your competent authority/delegated body and authorities and stakeholders with adjacent areas of expertise in your Member State?
If yes: To what extent does your competent authority/delegated body collaborate with authorities and stakeholders with adjacent areas of expertise in your Member State?

	To a great extent	To some extent	Occasionally	Never	Not applicable (e.g., same CA)
Blood		x			
Tissues and Cells	x				
Medicinal Products	x				
Medical Devices		x			
Others					x

Which of the following topic(s) have been subject to such collaborative interactions? Please select all that apply.		**Please specify which other topics have been subject to collaborative interactions**
Vigilance	x	
Traceability	x	
Donor protection	x	
Other		
None		

3.1 Are there (other) areas in which your country would be interested to collaborate (more)?	**Please specify which area/authority you would consider relevant:**
No	

2. Donor and recipient follow-up

	4. Is a register or record of living donors kept in your country?	When was this register or record established? Please provide the year of establishment and, if possible, the month:
AT	Yes	12/2017 Data may be retrospectively from 01/2017
BE	Yes	July 2012
BG	Yes	Year - 2010
CY	Yes	1/2011
CZ	Yes	Since 2004 - the establishment of our organization
DE	Yes	Registry on QA 2006, Transplantation Registry 2019
DK	Yes	1995, January
EE	Yes	We use Scandiatransplant YASWA database since 2017
EL	Yes	2011
ES	Yes	January 2010.
FI	Yes	since 1964, new register platform 2015 ->
FR	Yes	2004
HR	Yes	register is kept by transplant centres
HU	Yes	2018
IE	Yes	July 1972
IT	Yes	2001
LT	No	
LV	Yes	1973
NL	Yes	2002
PL	Yes	Jan 1st 2007
PT	Yes	July 1969
SE	No	
SI	Yes	Since the first kidney transplantation -1970.
SK	Yes	2007

	Please describe how this register or record works and by which authority it is hosted (for example: is it kept at hospital/national/international level? Is it an IT tool, or shared excel sheets, or any other system? …)
AT	After a living donation has been made, certain parameters (before donation, shortly after donation, etc.) are entered in pseudonymised form in a central database hosted by the Austrian Public Health by the procurement centre. After 3 months respectively a year, an automated reminder is sent to the procurement centre with a request to carry out the next follow-up check on the living donor in question and to enter the data. The same process then takes place every 2 years for the kidneys, so that a long-term follow-up of all living donors in Austria is guaranteed.
BE	We are working with Eurotransplant, every transplantation centre gives the follow-up data to the register

BG	Shared excel sheets
CY	Hosted by the Transplant Clinic in Nicosia General Hospital, it is on an excel sheet
CZ	It is kept in our organization generally for CZ, also in TC for their own. IT tool + excel sheets
DE	On the national level the register on liver and kidney living donation as part of the mandatory quality assurance measures covered by Section 137a of the Fifth Book of the Social Code is presently hosted by the Institut für Qualitätssicherung und Transparenz im Gesundheitswesen (IQTIG) under the responsibility of the Federal Joint Committee. In addition, the national Transplantation Registry was established in 2019. The Gesundheitsforen Leipzig GmbH have been assigned by the Central Federal Association of the Health Insurance Funds, the German Medical Association, and the German Hospital Federation to host the national Transplantation Registry under Section 5b of the Transplant Act. The registry is presently being built up. On the hospital level all transplant centres are obliged under para. 10 subsection 2 of the Transplant Act to record all living donations performed in their centre.
DK	The register is hosted and managed by Scandiatransplant (in Aarhus, Denmark) in a dedicated IT-tool. This system is used by all transplant centres in Denmark, Sweden, Norway, Finland, Iceland, and Estonia. Regarding follow up information - there is a delay in data entry of follow up information (see below)
EE	Data is collected and entered by Transplantation centre and the register belongs to Scandiatransplant.
EL	It is kept at a national and hospital level
ES	The staff of the hospitals that make living donations upload the information in a database that may be the ONT's or a regional one which loads in a second step in the ONT's database. The ONT make the data management, the record linkage, the statistical analyses, and the periodical reports.
FI	Transplant surgery is centralized nationally in the Helsinki University Hospital. Register is kept by this hospital (organ transplantation centre, at national level).
FR	Hosted by Agence de la Biomédecine. The data is provided by hospitals.
HR	IT tool
HU	It managed centrally and nationally by the HNBTS It is a dedicated module of the national organ donor registry
IE	It is kept at National kidney Transplantation unit Beaumont Hospital. It is an IT database.
IT	The register is held at national level, it is a part of the national transplant info system, hosted by the Italian Ministry of Health, the information gathered include data about follow-up of living donor and the reporting of serious adverse events if linked to donation (e.g.: infection, death of donor)

LT	
LV	There is only one transplantation centre in Latvia (P. Stradin's University Hospital). The register contains information about all cases of donation/transplantation (date, relation between donor and recipient) since the beginning in 1973. The register currently is in electronic format (Excel) and is kept by the Latvian Transplantation centre. Medical follow-up records are kept in electronic hospital system. Follow-up is organised according to Latvian Transplantation centre's quality and safety procedures.
NL	It is a section of the follow up registry of the Dutch Transplant Foundation: the National Organ Transplantation Registry (NOTR)
PL	Concept of organ donor registry is achieved with the use of a tele-informatic tool (www.rejestrytx.gov.pl). Donation centres are obligated to collect donors' data (demographic and medical) peri-, and post-donation and long-term every year follow-up). The administrators of the register are Ministry of Health and Poltransplant. The database consists of sections containing information on the living kidney donor, the recipient, and the relationship between the donor and the recipient. Donor and recipient data include: name, surname, personal identification number (PESEL), date of birth, age, sex, place of residence, and date of death if applicable. Information on the date and centre of procurement and transplantation were also included in the database. The registry currently handles completed data from 2008 (records and follow up) and all historical procurements
PT	Electronic health records
SE	
SI	It is stored at the University Medical centre at Department for nephrology, where kidney transplants are performed. Documents are kept as paper folders.
SK	Regional (transplant centres) full medical documentation National Transplant organization record and follow up

	Among all living donors who donated an organ during the last year for which you have complete data (2021, otherwise 2020) in your country, which percentage: are included in your register/record? Report percentage	**Among all living donors who donated an organ during the last year for which you have complete data (2021, otherwise 2020) in your country, which percentage: have a correct set of completed follow-up data? Report percentage**	**The data reported for living donors relate to the year:**
AT	100	the completeness of follow up data will be calculated for the first time in 2022 - data can be submitted in May 2022	2020
BE	see Eurotransplant	see Eurotransplant	2020
BG	No	No	2021
CY	100	100	2021
CZ	100	100	2021
DE	No Data presently available	No Data presently available	2020
DK	100%	70%	2020
EL	100%	100%	2021
EE	100	100	2021
ES	100	72	2020
FI	100	100	2021
FR	100%	n/a	2021
HR	100	100	2020
HU	100	Few	2021
IE	100	100	2021
IT	94%	71%	2020
LT			
LV	100	100	2021
NL	67%	67%	2020
PL	100%	98%	2020
PT	100%	50%	2021
SE			
SI	100	100	2020
SK	100	50	2020

	5. Were there any changes to the follow-up of living donors since 2014? (For example, in the frequency or duration of follow-up?	**Please specify the changes to the follow-up of living donors:**
AT	Yes	By starting the living donor registry defined and standardized examination times have been determined and established (before donation, shortly after donation, 3 months after donation and then every 2 years) The registry also covers the field of stem cell donors, also starting in December 2017, examination periods there is 2017 to 2020 at the moment. Also, there defined and standardized examination times have been determined and established (before donation, day 1 to 30 after donation, 1 year after donation). Initially, annual follow-ups were planned, since 2021 follow ups of stem cell donors are planned every 5 years instead.
BE	No	
BG	No	
CY	No	
CZ	No	
DE	No	
DK	No	
EE	Yes	Annual check-up system was established in 2017.
EL	No	
ES	Yes	In 2010, this registry was integrated into the ONT information systems', deriving in a general improvement in terms of governance, record linkage and data base operations. Variables and follow-up are essentially the same.
FI	No	
FR	Yes	Better long-term follow up.
HR	No	
HU	Yes	The implementation itself
IE	No	
IT	No	
LT	No	
LV	No	
NL	No	
PL	No	

PT	Yes	The National Programme for non-directed or anonymous renal donation has been implemented. Specific rules were defined for the psychological and/or psychiatric follow-up of these donors.
SE	No	
SI	No	
SK	No	

	6. Is a register or record of organ recipients kept in your country?	**When was this register or record established? Please provide the year of establishment and, if possible, the month:**
AT	No	
BE	No	
BG	Yes	Year 2010
CY	Yes	1/2011
CZ	Yes	Since 2004 - the establishment of our organization
DE	Yes	Registry on QA 2006, Transplantation Registry 2019
DK	Yes	1995, January
EE	Yes	2017
EL	Yes	2011
ES	Yes	Liver started in 2005, while kidneys in 2010.
FI	Yes	Since 1965, new register platform 2015->
FR	Yes	1996
HR	Yes	on transplant centres level
HU	Yes	2018
IE	Yes	July 1972
IT	Yes	2002
LT	Yes	Heart, Lungs
LV	Yes	Kidneys and pancreas 1973, heart 2002, liver 2018.
NL	Yes	NOTR exists since 2002
PL	Yes	2006
PT	Yes	2018
SE		
SI	Yes	2018
SK	Yes	1995

	For which organs does such a register or record exist? Please select all that apply.		Please indicate for which other(s) organ(s) there is a register or record:
AT			
BE			
BG	Kidneys	x	
	Livers	x	
	Others	x	Heart
CY	Kidneys	x	
	Livers		
	Others		
CZ	Kidneys	x	
	Livers	x	
	Others		
DE	Kidneys	x	
	Livers	x	
	Others	x	Hearts, Lungs, Pancreas, Intestines
DK	Kidneys	x	
	Livers	x	
	Others	x	Heart Lung Pancreas Pancreatic islet Intestine
EE	Kidneys	x	
	Livers	x	
	Others	x	All recipient records are kept in YASWA, but there is an additional national register for kidneys.
EL	Kidneys	x	
	Livers		
	Others		
ES	Kidneys	x	
	Livers	x	
	Others		
FI	Kidneys	x	
	Livers	x	
	Others	x	All transplant recipients are registered: kidney, pancreas, liver, heart, lung, intestine, face.
FR	Kidneys	x	
	Livers	x	
	Others	x	All transplantable organs

HR	Kidneys	x	
	Livers	x	
	Others	x	heart, lung, pancreas
HU	Kidneys	x	
	Livers	x	
	Others	x	Lungs, pancreas
IE	Kidneys	x	
	Livers		
	Others		
IT	Kidneys	x	
	Livers	x	
	Others	x	heart, lung, small bowel, pancreas
LT	Kidneys	x	
	Livers	x	
	Others		
LV	Kidneys	x	
	Livers	x	
	Others	x	Heart and pancreas.
NL	Kidneys	x	
	Livers	x	
	Others	x	heart, lungs
PL	Kidneys	x	
	Livers	x	
	Others	x	hearts, lungs, pancreas, vascularized tissue allografts
PT	Kidneys	x	
	Livers	x	
	Others	x	heart, lung, and pancreas
SE			
SI	Kidneys	x	
	Livers	x	
	Others	x	hearts, lungs, pancreas in combination with kidneys
SK	Kidneys	x	
	Livers	x	
	Others	x	Heart, pancreas

	Please describe how this register or record works and by which authority it is hosted (for example: is it kept at hospital/national/international level? Is it an IT tool, or shared excel sheets, or any other system? …)
AT	
BE	
BG	National level – IT tool and Excel sheets, kept by Executive Agency 'Medical Supervision' and the hospitals
CY	Hosted by the Transplant Clinic in Nicosia General Hospital, it is on an excel sheet
CZ	It is kept in our organization generally for CZ, also in TC for their own. IT tool + excel sheets
DE	On the national level the register on kidney, liver, heart, and lung donation as part of the mandatory quality assurance measures covered by Section 137a of the Fifth Book of the Social Code is presently hosted by the Institut für Qualitätssicherung und Transparenz im Gesundheitswesen (IQTIG) under the responsibility of the Federal Joint Committee. In addition, the national Transplantation Registry was established in 2019. The Gesundheitsforen Leipzig GmbH have been assigned by the Central Federal Association of the Health Insurance Funds, the German Medical Association, and the German Hospital Federation to host the national Transplantation Registry under Section 5b of the Transplant Act. The registry is presently being built up.
DK	The register is hosted and managed by Scandiatransplant in a dedicated IT-tool. Additionally, all liver, heart, and lung transplantations before 1995 have been reconstructed in the database. There are not follow up registries on all organ type within Scandiatransplant, but graft and patient survival are updated on all (95%)
EE	Data is collected and entered by Transplantation centre and the register belongs to Scandiatransplant. Scandiatransplant is responsible for hosting.
EL	It is kept at a national and hospital level
ES	These systems are integrated into the "National Donation and Transplant Information System" which, in accordance with Royal Decree 1723/2012, is hosted, maintained, developed, and safeguarded by the ONT. Also, the operating procedures are agreed upon between the ONT and the autonomous communities. The system is uploaded with information coming from the hospitals, directly or indirectly (uploaded from an autonomous community). The data are periodically analysed, and the corresponding exports are made public annually. The systems fully respect the data protection regulation.
FI	Transplant surgery is centralized nationally in the Helsinki University Hospital. Register is kept by this hospital (organ transplantation centre, at national level)
FR	Register hosted by the Agence de la Biomédecine. It is an IT tool comprised of several different applications.
HR	IT tool

HU	It managed centrally and nationally by the HNBTS There is a separate module of the national organ donor registry called transplantation follow up registry
IE	It is kept at National kidney Transplantation unit Beaumont Hospital. It is an IT database.
IT	The register is held at national level, it is part of the national transplant info system, hosted by the Italian Ministry of Health
LT	National, IT tool
LV	In Latvia we use living donors only for kidney transplantation and only in the one and only transplantation centre of P. Stradin's University Hospital. The register contains information about all cases of donation/transplantation (date, relation between donor and recipient) since its establishment in 1973. The register currently is in electronic format (Excel), kept by the Latvian Transplantation centre. Medical follow-up records are kept in electronic hospital system. Follow-up is organised according to Latvian Transplantation centre's quality and safety procedures. Register for all transplanted kidneys and pancreas exists since 1973 (paper format for 1973-2014, electronic since 2014), heart - since 2002, liver - since 2018.
NL	National level, hosted by the DTF, IT tool, data are collected form the transplant centres
PL	In 2006 National Transplants Registry was created in Poland for proper monitoring and evaluation of transplantations performed in Poland [1,2]. Transplants Registry has two main functions: (1) gathering information on every organ transplantation performed within the country (registration function) and (2) monitoring of quality of performed transplantations by collecting data on graft function and recipient's survival in the short- and long-term follow-up (in the day of transplantation, 3 and 12 months after transplantation and every following year till graft loss or recipient death) (follow-up function). According to current legal regulations the entity responsible for administering of Transplants Registry is Polish Transplant Coordinating Centre Poltransplant (national competent authority in donation and transplantation), which cares about personal data safety, prevents data loss or destruction, and performs statistical analysis.
PT	The register is made using a digital platform (RPT) from the donor institutions to the transplant units and centralized in the Portuguese Transplant Coordination.
SE	
SI	It is kept at hospital level, but the system serves as the national level because we have only one University Medical centre where transplants of solid organs are performed. Excel sheets and paper folders on the national level and IT system used at Eurotransplant- completeness at ET is about 70-80% (2018).

SK	National level National transplant registry, waiting list for organs, donor register, transplantation register. Detailed medical records at transplant centres.

	Among all recipients who received an organ during the last year for which you have complete data (2021, otherwise 2020) in your country, which percentage: are included in your register/record? Please give a percentage:	**Among all recipients who received an organ during the last year for which you have complete data (2021, otherwise 2020) in your country, which percentage: have a correct set of completed follow-up data? Please give a percentage:**	**The data reported for recipients relate to the year:**
AT			
BE			
BG	100%	No	2021
CY	100	100	2021
CZ	100	100	2021
DE	No Data presently available	No Data presently available	2020
DK	100%	95%	2020
EE	100	100	2021
EL	100%	100%	2021
ES	100	100	2020
FI	100	100	2021
FR	100%	65% for kidney recipients 100% for liver recipients 41% for heart recipients 100 % for lung recipients	2021
HR	100	100	2020
HU	100	100	2021
IE	100	100	2021
IT	99,5%	74%	2020
LT	22,2	100	2021
LV	100	100	2021
NL	87-96 %	87-96%	2020
PL	100%	100%	2020
PT	100%	100%	2021
SE			
SI	100	100	2020
SK	100	70	2020

UK(NI):

4. Is a register or record of living donors kept in your country?	**When was this register or record established? Please provide the year of establishment and, if possible, the month:**
Yes	June 1976. Maintained by NHSBT.

Please describe how this register or record works and by which authority it is hosted (for example: is it kept at hospital/national/international level? Is it an IT tool, or shared excel sheets, or any other system? …)
It is a national registry stored in an oracle database with HTA requirement to report all living donors in a timely manner. Follow-up is collected at 1 year, 5 years and every 5 years thereafter for living donors. Number in registry for NI is 53 in 2021.

Among all living donors who donated an organ during the last year for which you have complete data (2021, otherwise 2020) in your country, which percentage: are included in your register/record? Please give a percentage	**Among all living donors who donated an organ during the last year for which you have complete data (2021, otherwise 2020) in your country, which percentage: have a correct set of completed follow-up data? Please give a percentage**	**The data reported for living donors relate to the year:**
We expect this is 100% of transplants as there is a regulation that all transplants must be reported to NHSBT.	We have 100% follow-up immediately post-transplant, but for the majority, 1 year follow-up will not yet be due.	2021

5. Were there any changes to the follow-up of living donors since 2014? (For example, in the frequency or duration of follow-up?	**Please specify the changes to the follow-up of living donors:**
Yes	We started the expanded paired/pooled and altruistic donor schemes in the UK on 1 April 2015 and so started collecting additional information around these transplants. Also introduced collection of DROMS and DREMS in November 2019.

6. Is a register or record of organ recipients kept in your country?		**When was this register or record established? Please provide the year of establishment and, if possible, the month:**
Yes		August 1970
For which organs does such a register or record exist? Please select all that apply.		**Please indicate for which other(s) organ(s) there is a register or record:**
Kidneys	x	
Livers	x	
Others	x	Heart Lung Pancreas

		Intestinal
Please describe how this register or record works and by which authority it is hosted (for example: is it kept at hospital/national/international level? Is it an IT tool, or shared excel sheets, or any other system? …)		
It is a national registry stored in an oracle database with HTA requirement to report all recipients of a transplant in a timely manner. Follow-up is collected at 3 months, 12 months, and every year thereafter for transplant recipients. Number on registry for NI in 2021 is 106.		
Among all recipients who received an organ during the last year for which you have complete data (2021, otherwise 2020) in your country, which percentage: are included in your register/record? Please give a percentage:	**Among all recipients who received an organ during the last year for which you have complete data (2021, otherwise 2020) in your country, which percentage: have a correct set of completed follow-up data? Please give a percentage:**	**The data reported for recipients relate to the year:**
This is 100% of transplants as there is a regulation that all transplants must be reported to NHSBT.	We have 100% follow-up immediately post-transplant, but for the majority, 1 year follow-up will not yet be due.	2021

3. Biovigilance

	7. Were there any changes to the reporting system for information concerning SARE since the last report?	**7.1 Please briefly outline how your reporting system works in practice. Please explain at what level the system is organised (e.g., EOEO, regional, or other):**
AT	No	The implementation works in line with the legal framework, between EOEO (Eurotransplant), the Competent Authority and the transplantation centres.
BE	No	Reporting to Eurotransplant
BG	No	Every establishment (procurement organizations or transplantation centres), that has license to work in the field of transplantation of organs, tissues and cells has the obligation to report if a serious adverse reaction (SAR) or incident (SAE) occurs. All establishments send reports to the Medical Supervision Executive Agency, which is the competent authority in the field of organ, tissue and cell transplantation and assisted reproduction for Bulgaria. The Agency shall register, investigate, and inspect each individual case of SAR or SAE. If other Member States are involved, this case is reported

		through the RATC system (Rapid Alert Tissues Cells). Our system is organized at a national level.
CY	No	Regional
CZ	No	regional and national cooperation
DE	No	The German organ procurement organization (Deutsche Stiftung Organtransplantation (DSO)) in close cooperation with Eurotransplant is responsible at the national level for reporting, investigating, documenting, and transmitting relevant and necessary information concerning serious adverse events and serious adverse reactions that may influence the quality and safety of organs in accordance with para.9 and para. 10 of the Regulation on the Quality and Safety of Organs under the Transplant Act. In case of cross-border organ exchange all centres from the different countries that received an organ are involved. The initial and final report is provided by the Competent Authority / Delegated Body of the respective donor country.
DK	Yes	The SARE reporting are handled through the Scandiatransplant systems and reported to centres and CAs
EE	Yes	All the SARE reports and final investigation reports are sent to State Agency of Medicines, where they are assessed and registered. Relevant information that may influence the quality and safety of organs is exchanged between transplant centres. All this must be covered with handler's biovigilance system. This is a national system and requirements are outlined in the law. For organs, which are sent to other countries notification system was established by Scandiatransplant, so all transplant centres and competent authorities receive the first notification at the same time. Further communication and investigation depend on the countries involved.
EL	No	National level
ES	No	The system is organized at three levels, as a mirror of the transplantation system and the healthcare system in the country. Cases appear at the hospital level but are transmitted bottom up for analysis and evaluation at the regional / national level, depending on the geographical and administrative distribution of the cases affected (whether it is within a particular region or affects several regions). The immediate measures are taken at hospital level and reported. The measures are agreed upon by the affected levels. The follow up contacts are made as per a national protocol agreed upon by all regions. A final report of every case is delivered. The system is advised by a committee of experts.
FI	No	FIMEA receives national SARE-reports from organ transplantation centre (Helsinki University Hospital) and all Scandinavian SARE-reports from Scandiatransplant.

FR	Yes	In 2016, the Agence de la Biomédecine became the CA for Organs vigilance. The system is a national one: the CA coordinates vigilance organization at national level, develops tools, provides help for SAREs investigations, publishes an annual report, organizes training… Locally, there are local biovigilance coordinators (MD or a nurse under the responsibility of a MD) located in each health establishment in charge of organs procurement and transplantation. These vigilance coordinators must collect and notify to the CA, SAREs that occur along the chain from the selection of donors to the follow-up of the recipients. They are implicated in the investigations and whenever possible in the management of correctives measures. There is another system for alerts. It is a 24/24 system managed by ABM (at CA level) in charge of allocation of the procured organs. There are operational links between vigilance system and alert system since an alert can lead to a vigilance notification (e.g., following a bacterial or viral contamination of the graft, following tumour identified on the graft). The purpose of both systems is complementary, one (ALERT) gives information to the clinician in charge of the recipients to help them quickly adapt the recipient care, second (VIGILANCE) is to improve the system (process, organization, etc.) and avoid recurrence of deleterious events.
HR	No	EOEO, national level
HU	No	Nationally and internationally as well in cooperation with Eurotransplant
IE	No	The CA function is delegated through Department of Health to Organ Donation Transplant Ireland (Clinical) Health Product regulatory authority (Non-Clinical). Dual reporting to which then determine clinical/non-clinical status. Clinical reports are managed through the National Organ Donation Transplantation Advisory Group which oversees investigations, corrective/preventative actions and continuous improvement measures agreed.
IT	No	An ad-hoc reporting function has been developed in the national transplant info system, where hospitals can report to Clinical Risk Manager and Regional Transplant Centre. A national protocol has been adopted for the purpose of reporting and managing adverse events and reactions.
LT	No	National and international
LV	No	National, through the delegated body - P. Stradin's University Hospital, National Transplant Coordination Department
NL	No	First alert sent by Eurotransplant; final report by Dutch Transplant Foundation for Dutch donors
PL	No	Polish legal regulations are adapted to Directive. The regulations define SARE and the procedures by which SARE should be monitored (in organ donation, procurement, testing, preservation, distribution, and transplantation), impose registration requirements on

		donation and transplant centres and require reporting of SARE with detailed information describing events or reactions as well as the procedures enacted to resolve and prevent future problems. Poltransplant is the authority that refers and manages the data on SARE related to organ transplantation in web-netted tool. The National Transplantation Council appointed by the Minister of Health analyses the aggregate data on SAREs to evaluate its effect on the quality and safety of the transplantation system and submits proposals for improving the quality of the current system.
PT	No	National
SE	No	-
SI	No	EOEO-reporting, collecting data and cases investigation, co-preparing corrective measures National: 24/7 reactivity on the level of Slovenija transplant, reporting to and from donor and transplant centres, collecting data, investigation of cases, preparing corrective measures to increase quality and safety for patients in cooperation with clinicians, issuing annual reports,
SK	No	System is organized at national level. Due to law all medical providers must report SARE to National transplant organization.

	8. Do you have operating procedures in place for the notification, in due time, of any SARE to the Competent Authorities and to the concerned procurement organisation or transplantation centre?	**8.1 Do you have operating procedures in place for the notification, in due time, of the management measures with regards to SARE to the Competent Authority?**	**8.2 Please explain how this notification system works in practice:**
AT	No	No	Notification of SARE must be done immediately with the report of the EOEO (Eurotransplant) and within three working days to the delegated body. Additionally, there is an exchange of information in case of involvement of tissue procurement.

BE	Yes	Yes	Each SARE coming in from Eurotransplant is discussed in a national workgroup
BG	Yes	Yes	In Bulgaria we have published normative acts in which it is defined in which case it is reported, there are published serious adverse reaction or event (SAR/E) forms, there are certain responsible persons who are responsible for reporting, deadlines and the sequence of actions are determined.
CY	Yes	Yes	Reports are sent to MOH
CZ	Yes	Yes	SARE have been implemented into Czech legislation through Regulation No. 111/2013 Coll. (on setting requirements for working procedures to ensure the system of quality and safety of human organs intended for transplantation) as of April 30, 2013. SARE has been implemented into practical procedure of reporting serious details of an adverse reactions/effects (SARE) on the special forms - reporting measures taken in respect of the incident. Both forms have been distributed to individual transplant centres, the centres were instructed how to report, and filled-in reports are being regularly checked by KST. Apart from that, empty forms are easily accessible on the website of KST. The Ministry of Health is informed about the most serious events.
DE	Yes	Yes	The DSO has – based on the German Transplant Act – issued guidelines for the reporting of SAEs and SARs by donor hospitals, laboratories/pathologies, and transplant centres to the DSO. After the initial reporting the DSO takes care of the work-up of the cases as described und 7.1
DK	Yes	Yes	All the transplant centres in the Scandiatransplant area are in direct contact with each other 24/7 by phone, e-mail etc. as follows: Non-urgent: E-mail is sent out the day after reporting at 10.00 to CAs and transplant coordinators Urgent: E-mail is sent to CAs and E-mail + SMS is sent to all transplant coordinators at time of reporting
EE	Yes	Yes	Please see answer to question 7.1.
EL	Yes	Yes	Direct and immediate reporting to any involved professional and authority
ES	Yes	Yes	The answer considers notifications bottom up, and top down. The donor transplant coordinator detects a possible case and makes an initial notification triggering the system. Initial measures are decided by the hospital and notified bottom up. Those include a notification to the centres possibly affected and to the Tissues and cells system. The biovigilance contact person fills up a predesigned form. After the analysis of the case at an upper level, the measures to be taken are decided,

			agreed upon, notified top down, and then carried out. The case is supervised and followed up as per a national protocol. A final report is made and issued to all the centres affected.
FI	Yes	Yes	Organ donation hospitals report all events to organ transplantation centre (Helsinki University Hospital). Organ transplantation centre reports all SARE to FIMEA (CA). Operating procedures for the notification are inspected regularly during official inspection.
FR	Yes	Yes	ABM's IT application centralizes SAREs notifications and allows national analysis and publishes annual national vigilance report In the IT system, the local biovigilance coordinator (LBC) describes SAR or SAE. The CA can identify the donor or the recipient and can access us with additional information (like medical history) through living donors registry, deceased donors' registry, or recipients' registry. The application informs the concerned procurement or transplant centre that can follow each step of the investigation. In the application, the LBC can assess imputability and severity for SAR. For the SAE, the LBC can detail the steps where the SAE occurred and mention possible causes. Each LBC needs to provide an annual report summarizing relevant corrective measures implemented in their establishment. Since 2021, CA organises training on vigilance for the LBCs. We also published a guide to help them in their biovigilance tasks.
HR	Yes	Yes	Rapid alert from donor or transplant centres to NCA and Eurotransplant
HU	Yes	Yes	All identified SAE/R cases are reported to the HNBTS, which investigate all cases, prepare reports that are sent to the Ministry of Human Capacities
IE	Yes	Yes	Currently notification is through the National Organ Donation Transplant Advisory Group and local centre procedures. The biovigilance system is currently undergoing review. Objective to further align with latest guidance and best practice.
IT	Yes	Yes	All adverse events/reactions should be reported and classified in terms of seriousness/likelihood of recurrence. Actions by regional and national CAs are requested on the basis of higher scores. A panel of 6 experts at national level revises the self-

			evaluated scores and takes decisions about remedial action and audits (if necessary).
LT	Yes	Yes	If SARE happens, centre must inform competent authority and institution which took, distributed, or received organ, tissue, or cells without any delay. After that, centre should carry out an investigation and notify the competent authority with reasons of SARE and conclusion.
LV	Yes	Yes	We have only one procurement organization - P. Stradin's University Hospital, National Transplant Coordination Department, which manages all reports and SARE investigations. P. Stradin's University Hospital is also delegated body for tasks regarding Article 5,6, 7 of Directive 2012/25/EU including SARE reports) and acts as a 24/7 contact-point required by Directive 2012/25/EU (http://www.txcontactlist.eu/index.php?action=details&id=lv). In order to provide information also for State Agency of medicines (SAM) as the competent authority in the field of organ transplantation as per Directive 2010/53/EU Article 17, SAM maintains online SARE reporting (Annex I, and II of Directive 2012/25/EU; bilingual - Latvian, English) tool with possibility to download report in PDF after submitting and subsequently to send it to other transplant centres and procurement organizations in case of organ exchanges (https://dati.zva.gov.lv/biovg/?&t=org-bn-s and https://dati.zva.gov.lv/biovg/?&t=org-bn-f).
NL	Yes	Yes	Written procedure and national registration of incoming SAER; short annual report
PL	Yes	Yes	As it is described in 7,1
PT	Yes	Yes	Notified in the digital platform (Biovigilância), with a specific codex, to be analysed and validated by the competent authority.
SE	No	No	-
SI	Yes	Yes	Usually, Slovenija transplant is receiving first info. Based on the nature of case or situation the first report is sent to the target centre in Slovenia or to Eurotransplant. The collection of data is starting in cooperation with clinicians. If the situation is not urgent then we are collecting data and preparing final report in due time. If the situation is urgent, we send alarm to target centres and Eurotransplant to stop using organs, send to pathology and based on the results prepare the report. Our communication with all involved experts and centres is made on the non-blaming principle and we try to be precise and correct as much as it is possible.
SK	Yes	Yes	National transplant organization is working at 24/365 basis. In case of SARE the duty office can connect every procurement

			and transplant centre. Also is in connection with transplant coordinators. Management goes on in close coordination with relevant medical and other actors.

	9. Is an interconnection in place between the reporting system for organ transplantation of Directive 2010/53/EU and the notification system established for the transplantation of tissues and cells in accordance with Article 11(1) of Directive 2004/23/EC?	**Please specify how this interconnection is organised:**
AT	Yes	The information exchange is between the delegated body organs and tissue vigilance and is done by email.
BE	Yes	tissue banks are informed by the transplantation centre
BG	Yes	All establishments (procurement organizations or transplantation centres) send reports to the Medical Supervision Executive Agency, which is the competent authority in the field of organ, tissue and cell transplantation and assisted reproduction for Bulgaria. The Agency is one institution (Competent Authority) for organs, tissues and cells and there is no need to make a connection between them. We don't have connection with Blood sector.
CY	No	
CZ	No	
DE	Yes	According to para 40 subsection 3 of the Drug and Active Ingredient Manufacturing Regulation the tissue establishments are obliged to report SAE/SAR to the DSO, in case the tissue or cell donor had also donated organs. Respectively the DSO is obliged according to para. 9 subsection 3 of the Regulation on the Quality and Safety of Organs under the Transplant Act to report SAE/SAR to the tissue establishment in case the organ donor had also donated tissues or cells. For this purpose, a designated system has been established to allow a reliable linkage between the organ procurement organization and the different tissue banks in case a donor donated both organs and tissues or cells.
DK	Yes	There is not an "automated electronic" link. Relevant information will be passed through phone or mail (see above).

EE	Yes	It's the same reporting system with the principal requirements outlined in the law. If SARE that may affect organs is found by tissue handlers, organ transplantation centre is also notified.
EL	No	
ES	Yes	The CA is the same, so, as soon as a case is reported, possible affected T&C recipients or tissue establishments are identified and notified as well as organ transplantation centres.
FI	Yes	All SARE (organ/tissue) reports are reviewed by same authority (same register) and same official.
FR	Yes	Agence de la Biomédecine is the CA for organs, tissues and cells, and the same biovigilance tool is used in all those fields.
HR	No	
HU	Yes	As many of organ donors are also tissue donors, we involve all tissue establishments, if they procured tissue
IE	Yes	There is an arrangement between both functions which will be further developed as a result of service review.
IT	Yes	The Competent Authority in charge of both notification systems is the same. A flow chart has been developed to ensure proper notification between different involved actors.
LT	Yes	Same procedure of reporting SARE between organs and tissues and cells
LV	Yes	It is managed by the same biovigilance officers in SAM.
NL	No	
PL	Yes	Tissue donation from organ donors is coordinated by the same institution (Poltransplant). Info on SARE in organs are referred to Poltransplant and via this institution to tissue entities - and vice versa.
PT	No	
SE	No	
SI	Yes	We have a common 24/7 on-call team for organs and tissues and cells vigilance system. In this way, the system is very rational and practical. For Slovenia is only realistic to organize a common system in order to cover requirements for being vigilant and able to react in all urgent cases.
SK	Yes	National transplant organization has the register of deceased and living donors of tissue and can connect the TE and transfer information and manage the SARE.

	10. Please describe the procedure for you to contact competent authorities/delegated bodies of other Member States in case of a related SARE within your country that might affect other Member States:	**10.1 Please describe the procedure for you to be contacted by competent authorities/delegated bodies from other Member State(s) in case of a related SARE within the other Member State(s) that might affect your Member State:**
AT	The information exchange is done via EOEO (Eurotransplant).	The information exchange is done via EOEO (Eurotransplant).
BE	The transplantation/donor centre informs Eurotransplant which in turn the other centre or country	Eurotransplant inform me which SARE from which country and I send the information to the transplant/donor centre
BG	The Medical Supervision Executive Agency will report by the RATC system (Rapid Alert Tissues Cells). The Agency is going to create a new signal to the other affected Member States.	When we receive a signal through the RATC system that includes our country, we register it, analyse it, investigate it, and take action, if necessary, in each case.
CY	Communication between Cyprus MOH and the Competent Authority of the other member state regarding SARE	
CZ	NA	
DE	s. 7.1 – The key element guaranteeing the information and involvement of the CAs of all countries that either donated or received an organ in case of an SAE/SAR is the international organ allocation office Eurotransplant (Leiden/The Netherlands) Eurotransplant is responsible for the allocation of the organs and the documentation of all parties involved, allowing full linkage between donor and recipient. The individual donor country is responsible for the work-up of the case. Eurotransplant facilitates the process, so that the DBs/CAs of all countries are involved. The procedure is regulated in para. 10 of the Regulation on the Quality and Safety of Organs under the Transplant Act.	s. 7.1
DK	This is rarely - if ever - needed because the transplant centres in the Scandiatransplant area have well established procedures for such events. If needed the CAs can contact each other individually by phone or mail.	Ensure that the relevant transplant centre is also informed in a relevant manner.
EE	For organs, which are sent to other countries notification system was established by Scandiatransplant, so all transplantation centres and competent authorities receive the first notification at	Competent authorities/delegated bodies from other Member States will be contacted if there is a need for it. The decision to contact other

	the same time. Further communication and investigation depend on the countries involved.	Member States is based on the information in the initial report.
EL	E-mail	E-mail
ES	It is established that the CA of other MS are notified, and any information transmitted as for a national centre. The procedure stated in Directive 2012/25/EU is fulfilled. Whenever an organ from a donor in Spain is transplanted abroad (EU MS) and a case of vigilance might affect this case, the biovigilance team at the ONT notifies the case to the corresponding competent authority. Updates of the situation as per protocol are communicated to the CA of the other MS. The other CA is also asked actively for information for a comprehensive analysis of the case. The final report is transmitted to the CA of the MS transplanting the organ.	According to a national protocol, It is established that MS different from Portugal should contact and inform OCATT and this one informs ONT as NCA. Portugal must contact directly ONT as NCA to exchange information. ONT issues the information to the regions / hospitals, except Catalonia, which is informed by OCATT.
FI	FIMEA informs Scandiatransplant which organize all organ exchange between Finland, Denmark, Sweden, Norway, Iceland, and Estonia.	FIMEA receives all SARE reports from Scandiatransplant.
FR	We have no specific procedure regarding vigilance information that must be shared with other competent authorities. The majority of organs are collected and transplanted in France. If needed, we contact directly known colleagues in the country concerned. It was the case notably during the COVID-19 pandemic crisis. A system like RATC/RAB might be a useful tool for information sharing between competent authorities regarding alert and vigilance events in the field of organs.	It might be the same informal circuit described in the question 10.
HR	Rapid alert from our donor or transplant centres to Eurotransplant	Also, rapid alert from Eurotransplant through SARE national contact person who immediately reports our donor or transplant centres
HU	It is always centrally managed by Eurotransplant. All initial and final reports are sent to them.	It is also managed centrally via Eurotransplant
IE	When an organ has a SARE reported, ODTI reports this out to the impacted transplant centres for immediate action. When further action is deemed necessary it is reported to the relevant competent authority in conjunction with the recipient centre.	Reverse of 10 above.

IT	The list of Competent Authorities for SARE linked to organs, available at http://txcontactlist.eu/, allows to alert other CA, that could be affected by a SARE within our country.	The contacts of Italian National Transplant centre are available at http://txcontactlist.eu/
LT	Other Member states about related SARE would be informed directly by phone and email	Other Member states about related SARE would inform us directly by phone and email
LV	http://www.txcontactlist.eu/index.php?action=details&id=lv RATC/RAB bilateral inquiry.	http://www.txcontactlist.eu/index.php?action=details&id=lv RATC/RAB bilateral inquiry.
NL	SAER alert is sent to Eurotransplant; Eurotransplant send the first alert SAER to each transplant centre that received an organ	see 10
PL	Phone and/or mail. The list of competent authorities is accessible on Poltransplant pages: https://ec.europa.eu/health/system/files/2020-02/competentauthorities_organs_en_0.pdf	Phone and/or mail to Poltransplant coordinating office working 24/7
PT	Portugal has an organ exchange agreement with a member state (Spain). This agreement follows Directive 2012/25/EU of October 9th, 2012, regarding information procedures for the exchange of organs including the report of serious adverse events and reactions. These procedures are also applied to the crossover kidney donation under the South Alliance for Transplantation (SAT).	1) Through ONT. 2)
SE	-	-
SI	Notification goes via Eurotransplant, which is in charge to inform target country or countries. All next steps go as on the national level in all directions and with cooperation between responsible clinicians via competent authorities and Eurotransplant.	The circulation of info goes in the same way if Slovenian patients are affected, or our country is only in the position to transfer info and data of the case. Sometimes we have just to check our patients if the results are ok and at the end, we distribute the results.
SK	National transplant organization is responsible for contact of other member states if it is the case.	The contact place is national transplant organization. www.nto.sk

UK(NI):

Were there any changes to the reporting system for information concerning SARE since the last report?	**7.1 Please briefly outline how your reporting system works in practice. Please explain at what level the system is organised (e.g., EOEO, regional, or other):**
No	All incidents must be reported to NHSBT who undertake an assisted function role on behalf of HTA. NHSBT reports any SAE or SAR that meet the relevant legislative criteria to HTA. We have regular meetings to ensure quality and governance of this process. This is organised at a national level.

8. Do you have operating procedures in place for the notification, in due time, of any SARE to the Competent Authorities and to the concerned procurement organisation or transplantation centre?	**8.1 Do you have operating procedures in place for the notification, in due time, of the management measures with regards to SARE to the Competent Authority?**	**8.2 Please explain how this notification system works in practice:**
Yes	Yes	There is a template national operating procedure which each transplant centre adapts to reflect their local practice and defines how to report incidents to NHSBT. NHSBT has standard operating procedures of their own which set out how they must report SAE and SAR to the HTA.

9. Is an interconnection in place between the reporting system for organ transplantation of Directive 2010/53/EU and the notification system established for the transplantation of tissues and cells in accordance with Article 11(1) of Directive 2004/23/EC?	**Please specify how this interconnection is organised:**
Yes	This detail is set out in the Service Level Agreement for example, ensuring the HTA reporting system for SAE or SARs involving tissues and cells records whether a tissue donor was also an organ donor. Some HTA staff work across the teams looking at SAE & SARs for organ

	transplantation and tissue and cells, so there is an ability to link relevant cases.
10. Please describe the procedure for you to contact competent authorities/delegated bodies of other Member States in case of a related SARE within your country that might affect other Member States:	**10.1 Please describe the procedure for you to be contacted by competent authorities/delegated bodies from other Member State(s) in case of a related SARE within the other Member State(s) that might affect your Member State:**
As part of NHSBT's assisted function, NHSBT will ensure that the information transmitted relating to the reporting of SAEARs, following the exchange of organs between Member States, is carried out in accordance with Article 4 of the Implementing Directive.	NHSBT would be contacted by the relevant Member State to follow up any cases of a related SAEAR within that might affect NI.

4. COVID-19

	11. Has your country taken steps to adapt your national procedures for organ donation and transplantation in your country in response to COVID-19 and the associated needs? Please select all that apply:								
	Streamline harmonized safety and quality protocols and standards across Member States, also to allow for the cross-border exchange of organs, based on guidance such as that from ECDC on testing protocols?	Facilitate logistics, including those required for cross-border exchange of organs and travel?	Support the implementation of organ preservation technologies that allow longer ex-vivo time windows to facilitate transplants when logistics are more complex, e.g., in the case of local outbreaks?	Implement digital solutions for EU-wide data collection and monitoring of post-transplant outcomes and vigilance?	Strengthen capacities and skills of critical care professionals, donor coordinators, transplant professionals, organ procurement organisations and/or inter/national transplant organisations to deal with these changes and challenges?	Strengthen common research to answer questions on the effects of communicable diseases on transplantation?	Others*	None	**Please specify which other steps you have taken:*
AT		x							
BE	x	x	x	x	x				
BG	x	x		x	x				
CY	x	x			x				
CZ	x	x	x		x				
DE	x	x	x		x	x			

DK							x		The countries in the Scandiatransplant area were very early in the pandemic able to test thoroughly for Covid and take the derived issues into account. Most of the transplant activities therefore continued as usual without any greater or sustained drop of transplant activities.
EE	x	x	x	x	x	x			
EL	x	x			x				
ES		x			x	x	x		ONT has been working thoroughly on this situation from the very beginning. Transplantation was declared to be a healthcare priority, so donation should be prioritized whenever possible.

									A specific data collection was launched regarding COVID-19 to gradually acquire knowledge of the disease in the area of D&T. A task group composed of professionals in donation and transplantation /D&T), and infectious diseases, was created to discuss and establish measures to prevent / mitigate any SARS-COV-2 transmissions in the field of transplantation. These protocol and recommendations are updated regularly according to the bibliography and the results. A donation recovery protocol

									was drawn up with different phases for the gradual incorporation of the D&T activity. A protocol for the vaccination of those transplanted has been developed and kept up to date. No transmissions of SARS-COV-2 have been detected so far. Please note the question does not match the answers (beyond MS).
FI	x							x	
FR									
HR	x	x	x		x				
HU	x	x			x				
IE			x	x					
IT	x	x	x		x	x	x		Organization of webinars for patients/transplant recipients, setting up a platform for monitoring mortality risk for

									transplant recipients, periodical update of safety protocols based on pandemic evolution, issuing of a national protocol for use of COVID-19-positive donors, indications for vaccination of immunosuppressed patients, identification of COVID-free pathways inside hospitals
LT	x					x			
LV	x				x				
NL	x	x			x	x			
PL	x	x		x			x		Adopting legal procedures of centres accreditation to on-line forms.
PT	x				x	x			
SE								x	
SI	x	x	x	x	x	x			
SK	x	x							

	11.1 Which of those items remain relevant to your country?
AT	Every information regarding crossing the border and entering the country.
BE	following the ECDC guidelines
BG	- Facilitate logistics, including those required for cross-border exchange of organs and travel, - Implement digital solutions for EU-wide data collection and monitoring of post-transplant outcomes and Vigilance, - Implement digital solutions for EU-wide data collection and monitoring of post-transplant outcomes and Vigilance, - Strengthen capacities and skills of critical care professionals, donor coordinators, transplant professionals, organ procurement organisations and/or inter/national transplant organisations to deal with these changes.
CY	1,3,5
CZ	Strengthen capacities and skills of critical care professionals.
DE	As long as the SARS-CoV-2 pandemic is ongoing, monitoring and if necessary/appropriate adaptation of the above indicated aspects remain relevant.
DK	(See above for this and the following)
EE	At the moment all the ticked items remain relevant.
EL	All the mentioned above
ES	All of them.
FI	1. Protocols are based on the first pandemic wave and basically all test positive donors were not used for organ tx, as well as recipients positive for covid were not operated unless for vital indications.
FR	None
HR	safety and quality protocols
HU	Advanced organ preservation technology: Machine Perfusion
IE	All of the above
IT	All of the above
LT	All previously mentioned
LV	In line with the planned collaboration with Scandiatransplant, all our procedures will be harmonized according to Scandiatransplant procedures.
NL	harmonization of criteria, procedures and exchange of best practices common rules and practices between Eurotransplant countries
PL	Streamline harmonized safety and quality protocols and standards across Member States, also to allow for the cross-border exchange of organs, based on guidance such as that from ECDC on testing protocols?
PT	1) Definition of national contingency protocols. 2) All-year professional courses and clinical/technical updates.
SE	The covid-19 pandemic has not had a negative impact on transplantation frequency in Sweden; in 2021 we had a record number of transplantations.
SI	1,2,3,4,5,6

SK	For Slovakia remains a/ implementation for organ preservation technologies, b/ strengthen capacities of ICU professionals and donor coordinators, c/strengthen common research in transplantation not only the communicable diseases

	11.2 Which challenges have you faced in the context of implementing measures responding to COVID-19?
AT	Lack of collaboration and information exchange with the national crises management. Rapidly changing situations and measures.
BE	making guidelines and protocols regarding covid
BG	- Organ shortage. - Difficulties in finding solutions for our patients, for which we do not have a transplant program.
CY	Shortage of donors because ICU units were full of Covid 19 patients, difficulties in having operation theatres available for surgeries during the pandemic, less hospital beds for patients and donors
CZ	collaboration with laboratories
DE	The SARS-CoV-2 pandemic is characterized by extreme dynamics both due to the changes in the characteristics of the virus (virus variants) and the continuous advances in scientific knowledge about the medical aspects (epidemics, clinical manifestation, impact on society, donor hospitals, transplant centres, organ donors and transplant recipients). Therefore, national, and international (Eurotransplant countries) standing working groups had to be established to monitor the most recent developments and to adapt policies and procedures where necessary.
DK	.
EE	The international transport logistics has been problematic. Since there are a lot of COVID-19 cases, some risk-based decisions must be made.
EL	Time-consuming transportations, donor/ recipient screenings
ES	All the former mentioned measures obey to a systematic approach of the problems found over time. Still there are others that cannot be forgotten: The lack of information at the beginning. The fear of transmitting the disease to transplant patients, who are undergoing immunosuppression therapy. The exhaustion of the personnel of the critical care units. The shortage of critical equipment and beds, mostly destined for the COVID patient.
FI	Lack of proper scientific data at the moment when would have needed that (first pandemic wave).
FR	PCR negative donors, Covid-free hospital circuits. In France, an expert group provided recommendations on donor testing in order to avoid transmission of COVID to the recipients. These recommendations are taken into account

	the nature of the organs (vital versus non vital organs). The main difficulties were the territorial location of the laboratories able to test the donors and provide results in due time. Another difficulty was to adapt quickly in order to take into account the rapid evolving scientific knowledge.
HR	Lack of healthcare workers involved in donor /transplant program because of lack of intensivist due to the redistribution of intensive care specialists in COVID departments
HU	Appointment of responsible SARS-CoV-2 PCR laboratory. Additional transport logistics for the samples. Additional information collection regarding COVID-19 risk or infection of the deceased. Evaluation and judgment regarding COVID-19 contact potential organ donors.
IE	- Transplantation infrastructure is not ring fenced in our health service. COVID impacted on ICU capacity which directly impacted donation and transplant services - Keeping up to date on guidance as it was published and ensuring the system was 1) informed 2) had capability to adapt
IT	Difficulties in managing the pressure on ICUs which suspended in some cases the donation activity; inhomogeneous epidemic spread in different regions; setting up COVID-free pathways inside hospitals for waitlisted/transplanted patients
LT	Transplantation of organ after overwhelmed COVID disease when result of PCR test is still positive
LV	Sometimes additional time is needed to repeat Covid19 tests Absence of Covid free hospital has significantly deceased transplantation activities
NL	coordinating the development and continuously adaptation of national protocols tune actions to enable international exchange of organs; synchronisation of definitions, criteria, and logistic conditions
PL	-
PT	Adequate in-time application and implementation due to the novelty effect of the COVID-19 pandemic, and rapid technical and clinical changes/updates.
SE	We would welcome more frequent updates of the recommendations for testing and deferral of donors from the ECDC.
SI	In the period of pandemics, we were facing many different challenges. To keep transplant medicine active many meetings between Eurotransplant member countries were needed as well constant online contacts on a national level between responsible experts. We had to inform all involved people with topical information related to preventive measures, related to novelties in connection with a virus, vaccination, complications after Covid-19, etc. Patients on the waiting list were very afraid of the Covid -19 and even of vaccination. We were trying to collect as much info as it was available and relevant. Cross-border organ exchange required balancing between different country measures and using a new combination.

SK	The problems arise from capacities of health care system (ICU capacities considerable influenced the donor program). Organization of health care for transplant patients, especially with COVID-19 at transplant centres.

	12. Which aspect(s) do you think should be prioritised to ensure that detrimental effects of COVID-19 in the organ sector are mitigated and the sector is strengthened in the long term?
AT	Raising awareness of decision-makers, that organ donation and transplantation is a life saving measure. Development and maintenance of an information network with cross border partners.
BE	EU related guidelines and protocols
BG	- Streamline harmonized safety and quality protocols and standards across Member States, also to allow for the cross-border exchange of organs, based on guidance such as that from ECDC on testing protocols, - Facilitate logistics, including those required for cross-border exchange of organs and travel, - Support the implementation of organ preservation technologies that allow longer ex-vivo time windows to facilitate transplants when logistics are more complex, e.g., in the case of local outbreaks, - Implement digital solutions for EU-wide data collection and monitoring of post-transplant outcomes and Vigilance, - Strengthen capacities and skills of critical care professionals, donor coordinators, transplant professionals, organ procurement organisations and/or inter/national transplant organisations to deal with these changes and challenges.
CY	Developing safety protocols in order to assure that transplant activity will not be decreased again in case of a new pandemic wave
CZ	close cooperation with regional transplant centres
DE	The SARS-CoV-2 pandemic had direct and indirect effects on organ donation and transplantation. Direct effects are linked to the medical risk related to the disease for transplant recipients and the medical staff (nurses and doctors) involved in donor management, organ procurement and transplantation. International scientific cooperation including comprehensive data collection and exchange would help to speed up developing evidence-based approaches to this and potential future pandemics. Many recommendations in this field were and are still based on expert opinion, scattered small case series etc. Indirect effects derive a) from the availability of resources (perfusion fluids, medical devices (testing)). Another indirect effect of the pandemic was the extreme burden for the health care personal.
DK	.

EE	Problems in international organ exchange and logistics should be addressed. An updated guide from ECDC would be very helpful.
EL	Procedures' harmonisation / digital harmonisation
ES	More resources. Rapid recommendations and a space to share them with the NCA and allow them to put national recommendations in common for comments or suggestions.
FI	Cooperation of experts - common recommendations
FR	N/A
HR	Contingency plans need to be drawn up and Sops implemented in practice
HU	Studies that exclude or prove organ specific SARS-CoV-2 transmission to maximise organ transplantation maintaining quality and safety.
IE	- Streamlined protocols across member state jurisdiction -Strengthen capacity and capability of donation and transplantation personnel and organisations to deal with necessary changes and challenges - support for ring fencing of donation and transplantation services in member states.
IT	Need to establish emergency plan to cope with possible epidemic; need to increase the number of ICU-dedicated staff and ICU beds; widespread implementation of telemedicine tools to ensure remote follow-up of patients
LT	European recommendations
LV	Common strategies and practices in EU MS regarding COVID19 positive donors, HCV positive donors and similar situations in donation and transplantation.
NL	availability of ICU beds, for patients and potential donors, vaccines for both professional and patients and materials to protect professionals
PL	-
PT	Broaden allocation criteria for solid organs, based upon scientific evidence, Professional on-going educative courses.
SE	Difficult to say, as we did not experience a dip in transplantations.
SI	Topical information and constant refreshing of knowledge to keep HCP motivated and dedicated to work.
SK	The priority in our country is strengthening the capacities of critical care professionals and ICU. The second is additional hospitalization capacity for COVID-19 transplanted patients at transplant centres.

	12.1 Which aspects do you think would benefit from further EU coordination?
AT	Implementation of EU-wide recommendations from EU experts, e.g., from ECDC.
BE	Registration of weak positive donors, recover covid donors, follow-up of recipients who received organs of recovered donors with covid...
BG	Organ exchange
CY	Usage of grafts from Covid 19 positive patients based on experience from some EU countries, facilitating logistics within EU
CZ	No opinion

DE	S. 12. Indirect effects of the pandemic derive from the availability of resources (perfusion fluids, medical devices (testing)). Many of these products come from outside the EU, it might be advisable for the EU to be more self-sufficient in this area. Another indirect effect of the pandemic was the extreme burden for the health care personal. European Strategies to address the challenges in this area should be considered.
DK	.
EE	Updated and harmonised guidelines would be useful. Common EU risk analysis on utilisation of COVID-19-positive donors and COVID-19 positive recipient management would be appreciated.
EL	Exchange experience and knowledge
ES	Increasing the donor pool for those with difficulties in reaching an organ.
FI	Strengthen role of ECDC? Strengthen common research to answer questions on the effects of communicable diseases on transplantation?
FR	Harmonization of donor testing measures
HR	In order how to respond to a critical situation, to avoid or minimize damage and to provide direction on staffing, resources and communication, the help of further EU coordination and support in this time of crises (contingency plan) is more than welcomed.
HU	Sharing real-time the changes in national organ donation protocols regarding COVID-19, preferably in English.
IE	- Member state rapid response forum as a resource to inform on updates to guidance as they happen, - Streamlined protocols across member state jurisdiction, - support for ring fencing of donation and transplantation services in member states.
IT	Strengthen common research to answer questions on the effects of communicable diseases on transplantation
LT	European recommendations of donation and transplantation with past or active COVID-19
LV	all aspects, mentioned in Q11
NL	synchronization of measurement, same conditions for cross border exchange
PL	-
PT	Big-data platforms can improve scientific knowledge, Harmonization and standardization of some procedures and/or criteria, Improve donation and transplantation efficacy due to allowing access to a much larger number of individuals.
SE	Recommendations and guidelines for testing and deferral of donors.
SI	Financial support of education, presenting of good clinical practices, composing working groups to collect topical info and news, building on on-line EU office with relevant experts on call 24/7 or at least during the day to help different experts in conflicting situations
SK	The recommendations and guidelines are a great help in management of procurement and transplantation.

UK(NI):

11. Has your country taken steps to adapt your national procedures for organ donation and transplantation in your country in response to COVID-19 and the associated needs? Please select all that apply:								
Streamline harmonized safety and quality protocols and standards across Member States, also to allow for the cross-border exchange of organs, based on guidance such as that from ECDC on testing protocols?	Facilitate logistics, including those required for cross-border exchange of organs and travel?	Support the implementation of organ preservation technologies that allow longer ex-vivo time windows to facilitate transplants when logistics are more complex, e.g., in the case of local outbreaks?	Implement digital solutions for EU-wide data collection and monitoring of post-transplant outcomes and vigilance?	Strengthen capacities and skills of critical care professionals, donor coordinators, transplant professionals, organ procurement organisations and/or inter/national transplant organisations to deal with these changes and challenges?	Strengthen common research to answer questions on the effects of communicable diseases on transplantation?	Others*	None	**Please specify which other steps you have taken:*
x	x	x	x	x	x			
11.1 Which of those items remain relevant to your country?								
Sharing of policies and procedures / any changes to practice amongst Member States and being able to share deceased donor and transplant related data across Member States.								
11.2 Which challenges have you faced in the context of implementing measures responding to COVID-19?								
Capacity of critical care units, transplant units and access to ICU beds to care for recipients have been a challenge. This has been due to periods of high critical care bed occupancy from COVID-19+ve patients over winter January 2021 but more latterly an impact of NHS staffing within winter December - January 2022. We have good, clear communication pathways externally within NHSBT from the Clinical Team, Chairs of Advisory groups and recipient coordinators enabling implementation of any changes.								
12.1 Which aspects do you think would benefit from further EU coordination?								
Continued clarity of Member States testing for SARS-CoV-2 upper / lower respiratory tract samples for example if centre in NI accept an organ, are they clear on what tests have been undertaken?								

5. Open Comments

	13. Have you encountered any difficulties when implementing the requirements in accordance with Directive 2010/53/EU?	Please describe your difficulties:
AT	Yes	Because of the federal structure of Austria various of disseminated stakeholders are involved and the coordination is complex.
BE	No	
BG	No	
CY	No	
CZ	No	
DE	No	
DK	No	
EE	No	
EL	No	
ES	No	
FI	No	
FR	No	
HR	No	
HU	No	
IE	Yes	This was a large undertaking at National level as it required collaboration and consolidation of a number of sectors in order ensure continuity of services. As the quality framework and regulations were being introduced to the area for the first time. Introducing regulators and QMS was challenging and led to an extensive learning phase. This is only now maturing to allow move to next level. QMS focus needs to focus on continuous improvement and International Council for Harmonisation Q10 focus as opposed to traditional quality model.
IT	No	
LT	No	
LV	No	
NL	No	
PL	No	
PT	No	
SE	No	
SI	No	
SK	No	

	14. Have you encountered any difficulties when interpreting the requirements in accordance with Directive 2010/53/EU?	**Please describe your difficulties:**
AT	Yes	There should be clear and legally written definitions, e.g., supervision.
BE	No	
BG	No	
CY	No	
CZ	No	
DE	No	
DK	No	
EE	No	
EL	Yes	
ES	No	
FI	No	
FR	No	
HR	No	
HU	No	
IE	No	
IT	No	
LT	No	
LV	No	
NL	No	
PL	No	
PT	No	
SE	No	
SI	Yes	Actually not. We tried to meet all requirements and principles in line we our capacities and availability of facilities and HCP. Very helpful was a fact that we succeeded in putting in place already in 2002 the competent authority with many tasks defined later in the directive 53/2010. All those tasks were defined in our transplant law from 2020.
SK	No	

	15. The Directive does not prevent any Member States from maintaining or introducing more stringent rules. Has your Member State maintained or introduced more stringent rules?	**Please specify in which respect or on which aspects:**
AT	No	
BE	No	
BG	No	
CY	No	
CZ	No	
DE	No	
DK	No	
EE	No	
EL	Yes	
ES	No	
FI	No	
FR	No	
HR	No	
HU	Yes	Hungary annually evaluates the national organ donation and transplantation programme, which is publicly available as Annual Reports. The national organ donation registry collects data about all discarded organs (via pathology reports), and quality reports of the organs at procurement and transplantation phase, and Hungary has hospital level quality assurance programme for organ donation
IE	No	
IT	No	
LT	No	
LV	No	
NL	No	
PL	No	
PT	No	
SE	No	
SI	No	
SK	No	

	16. Are there aspects of the revision of the framework for Blood, Tissues, and Cells that you find relevant to the organ sector?	**Please specify which aspects:**
AT	No	
BE	No	
BG	No	
CY	No	
CZ	No	
DE	No	
DK	Yes	Deceased organ donors are occasionally also tissue donors. A clearer link between the T&C and organ legislation e.g., with respect to SAREs would be welcome.
EE	Yes	It is difficult to say since the adoption of the revision has not been completed, but it is stated in Directive 2010/53/EU that quality and safety requirements for organs should complement and be linked with the existing Union system for tissues and cells, so revision of Blood, Tissues, and Cells directives can have an impact to organ regulation.
EL	No	
ES	Yes	As said before, - donor protection for other purposes other than transplantation. - profit and affordability of the health care systems (costs for the healthcare system from new therapies, or costs derived from new requisites, e.g., transport containers with a limited number of uses)
FI	Yes	Should the infection test requirements be the same (serological tests and PCR tests for HIV, HBV and HCV) for all allogenic donors?
FR	Yes	Harmonization of preventive measures for the transmission of pathogens would be good. The role of ECDC might be reinforced in that perspective.
HR	Yes	living donor protection and follow up, especially in light of commercialisation and growing demand, biovigilance, traceability etc.
HU	No	
IE	Yes	The involvement of European Expert Bodies to draft guidelines, share knowledge would be of benefit. This could lead to resources being available for training programmes provided to key personnel and teams. Stakeholder meetings and

		workshops to build channels for communication and for gathering information etc.
IT	No	
LT	No	
LV	Yes	No commercialisation of SoHO field.
NL	Yes	concerning 16: is already put forward, but not published yet
PL	No	
PT	No	
SE	No	
SI	Yes	I think that revision shouldn't go in the way that all three segments would be completely separated. There are the same principles that should be covered by the legislation for organs, tissues and cells and to some extent even for blood as donation principles and promotion activities of altruistic donation. Transparency, traceability, quality and safety of organs, tissue and cells require absolutely the same principles and should be covered by one legislation, and this is of immense importance for development in the future. If the field of tissues and cells will be joint only with the blood issues and will be distanced from organs, commercialization of the field might come on the scene and donation of human body parts for the purpose of treatment will become a subject of processing and profit-making matters. Why? The substrate for processing will be interpreted as a technical issue and not as part of a human being which requires strong focus on dignity and taking care of human rights more than just for technical substrates.
SK	No	

	Do you have any other comment not covered in the previous questions?
AT	
BE	
BG	
CY	
CZ	
DE	
DK	Regarding 2.2: Does your country exchange organs with third countries? There has previously existed occasional collaboration with Great Britain. How this will proceed is currently unknown. Regarding: 2.1 Does your country exchange organs with other EU Member States?

	Yes - Norway on regular basis and Schweitz on rare occasions. However - both countries have collaboration agreements with the EU Scandiatransplant is a collaboration between transplant centres in Denmark, Sweden, Norway, Finland, Iceland, and Estonia - for exchange of organs. Scandiatransplant host an IT-system which include a dedicated IT-tool. This system is hosted and managed by Scandiatransplant (in Aarhus, Denmark). The core Scandiatransplant transplantation registry was established January 1995. Basic data on all living donors from this date and forward are found in the Scandiatransplant living donor. For further information see: www.scandiatransplant.org
EE	-
EL	
ES	Thank you for your attention. Kind regards.
FI	
FR	The BTC directive appears to implement decisions that would reinforce the role of ECDC, which should allow for a better harmonisation of biological qualification of donors. A harmonised organ qualification approach would also encourage exchange among the EU countries, especially taken into account that organ donors might as well be cell and/or tissue donors.
HR	
HU	
IE	Nil
IT	
LT	
LV	
NL	
PL	-
PT	NA
SE	Please note that I put in the answer "no" as default on every question in section 3. This is not the true answers, but I have no other answers to give, as these questions are under the responsibility of another authority, and they do not have the possibility to participate in this survey.
SI	I hope that the suggestions given found out of this survey and of other discussions will be taken into account for the future steps related to preparing of refreshed EU legislation. We all, who are working at the moment in the field of using human body parts for the purpose of treatment and research are responsible for future progress. We all are obliged to create the basis for our offsprings which should keep human body parts as very special drug donated for people in a very bad condition with the intention to help them and create positive atmosphere on our planet.
SK	

UK(NI):

13. Have you encountered any difficulties when implementing the requirements in accordance with Directive 2010/53/EU?	**Please describe your difficulties:**
No	
14. Have you encountered any difficulties when interpreting the requirements in accordance with Directive 2010/53/EU?	**Please describe your difficulties:**
No	
15. The Directive does not prevent any Member States from maintaining or introducing more stringent rules. Has your Member State maintained or introduced more stringent rules?	**Please specify in which respect or on which aspects:**
No	
16. Are there aspects of the revision of the framework for Blood, Tissues, and Cells that you find relevant to the organ sector?	**Please specify which aspects:**
Yes	Based on our understanding of the proposals being considered, some of these would also be relevant to the organs sector. For example, unequal approaches to oversight across EU Member States leading to barriers to exchange, legislation that lags behind innovation, supply vulnerabilities and the evaluation and clinical efficacy of novel products (in the organs sector this could be relevant to novel organ transplants). We would value an opportunity to review early any changes that may be considered to impact on the organs sector.
Do you have any other comment not covered in the previous questions?	
For ease and clarity, we are submitting one joint country response from HTA and NHSBT, applicable to NI for 2015-2021.	