

Ministers' Deputies

CM Documents

CM(2015)128 add final 18 September 2015

1235 Meeting, 15-16 September 2015

6 Social cohesion

6.2 European Directorate for the Quality of Medicines and Healthcare (EDQM)¹ –

European Committee on Organ Transplantation (Partial Agreement) (CD-P-TO) –
Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing –
Explanatory Memorandum

Explanatory Memorandum

Resolution CM/Res(2015)11

on establishing harmonised national living donor registries with a view to facilitating international data sharing

This Explanatory Memorandum to Resolution CM/Res(2015)11 provides the detailed list of parameters intended for inclusion in any national living donor registry, defining a mandatory data set and an expanded set of variables, as well as those to be included in a 'registry of registries' aimed at international data sharing. It also contains a glossary of terms intended to provide clarity on the way each parameter should be measured or collected and to facilitate harmonised international data sharing.

The set of variables and the glossary of terms are the ones developed under the EU Joint Action 'Achieving Comprehensive Coordination in Organ Donation throughout the European Union (ACCORD)' (www.accord-ja.eu).

The parameters detailed in the data set may be revised in the future in keeping with developments in the field.

This Explanatory Memorandum contains the following sections:

1. **National registry: KIDNEY**
 - 1.1 Donor demographic information
 - 1.2 Pre-donation data
 - 1.3 Peri- and post-operative data (until discharge)
 - 1.4 Follow-up data

¹ States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine and United Kingdom.

2. Registry of Registries: KIDNEY

- 2.1 Donor demographic information
- 2.2 Pre-donation data
- 2.3 Peri- and post-operative data (until discharge)
- 2.4 Follow-up data

3. National registry: LIVER

- 3.1 Donor demographic information
- 3.2 Pre-donation data
- 3.3 Peri- and post-operative data (until discharge)
- 3.4 Follow-up data

4. Registry of Registries: LIVER

- 4.1 Donor demographic information
- 4.2 Pre-donation data
- 4.3 Peri- and post-operative data (until discharge)
- 4.4 Follow-up data

5. Glossary of terms

The proposed parameters for each of the above sub-sections are classified as 'Mandatory' (M) or 'Optional' (O).

1. NATIONAL REGISTRY: KIDNEY

1.1 DONOR DEMOGRAPHIC INFORMATION

No.	Item	Definition	Units	Mandatory/ Optional
1	Identification (ID number)	The unique identification code that is given by the national authorities to each person		M
2	Date of birth		DD/MM/YYYY	O
3	Age	Actual age at the time of donation	years, no decimals	M
4	Gender		Male/Female	M
5	Weight		kg, no decimals	M
6	Height		cm, no decimals	M
7	Blood group	Menu: - A - B - O - AB	Choosing one item from this menu	M
8	Address		Open field	O
9	Country of residence		ISO code 3166	M
10	Nationality		ISO code 3166	M
11	Ethnicity	Menu: - White - Asian - Black - Oriental - Mixed, please specify ... - Other, please specify ...	Choosing one item from this menu and free text field for 'specify...'	O

1.2 PRE-DONATION DATA

No.	Item	Definition	Units	Mandatory/ Optional
1	Relation type	A living donor has one of the following three possible relationships with the recipient ² : - A/ Related - A1/ Genetically related: a. 1st degree genetic relative: parent, sibling, offspring b. 2nd degree genetic relative: e.g. grandparent, grandchild, aunt, uncle, niece, nephew c. Other than 1st or 2nd degree genetically related, for example cousin - A2/ Emotionally related: spouse (if not genetically related), in-laws, adopted, friend - B/ Unrelated: non-related = not genetically or emotionally related	Choosing one item from this menu	M
2	Blood pressure	Actual blood pressure (independent of the method of measurement)	mmHg	O
3	Hypertension		Yes / No	O
4	Antihypertensive treatment	Menu: - Nothing - Diet only - Medication: - Diuretics - Beta blockers - ACE blockers	Choosing one or multiple items from this menu	M

² WHO, Global glossary of terms and definitions on Donation and Transplantation

No.	Item	Definition	Units	Mandatory/ Optional
		<ul style="list-style-type: none"> - A2 antagonists - Vasodilators/Calcium channel blockers - Other 		
5	Creatinine		Umol/L or mg/dl	M
6	Proteinuria	<ul style="list-style-type: none"> - 24 hour urine collection - Spot urine in gram per litre - Dipstick - PCR (protein creatinine ratio) 	g/24h g/L Y/N mg/mmol creat	M*
7	Any significant co-morbidity	Menu: <ul style="list-style-type: none"> - No - Yes, specify: <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Renal / urinary tract disease, specify... - Other, specify... - Unknown 	Choosing one or multiple items from this menu and free text field for 'specify: ...'	M

* at least one of these options should be completed.

1.3 PERI- AND POST-OPERATIVE DATA (until discharge)

No.	Item	Definition	Units	Mandatory/ Optional
1	Donor hospital (centre) name	List to be built by countries		M
2	Country of donor hospital	The country in which the donation takes place	ISO code 3166	M
3	Date of donation		DD/MM/YYYY	M
4	Left or right kidney		Left / Right	M
5	Operation technique	Menu: <ul style="list-style-type: none"> - Open technique <ul style="list-style-type: none"> a. Classic technique <ul style="list-style-type: none"> - Costal resection - No costal resection b. Mini-incision - Laparoscopic <ul style="list-style-type: none"> a. Standard b. Hand-assisted laparoscopic - Other, specify... 	Choosing one item from this menu	M
6	Complications during operation	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Kidney damaged during retrieval <ul style="list-style-type: none"> a. Kidney can be used for transplantation b. Kidney is discarded for transplantation 	Choosing one or multiple items from this menu and free text field for 'specify...'	M

No.	Item	Definition	Units	Mandatory/ Optional
		<ul style="list-style-type: none"> - Other organ damaged during surgery - Switch from laparoscopic procedure to open technique - Cardiac arrest - Other severe complications (i.e. pneumothorax, anaphylactic reaction), specify... 		
7	Complications after operation – until first discharge	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Need for re-operation - Infection (urinary, wound, other) - Thrombo/embolic complications (DVT, pulmonary embolism) - Renal Replacement Therapy, specify... - Cardiac arrest - Other severe complications, specify ... 	Choosing one or multiple items from this menu and free text field for 'specify...'	M
8	Length of hospital stay (LOS)	The number of days in hospital during the first admission (from day of surgery until discharge)	Number of days	O
9	Number of days in ICU	The number of days in Intensive Care Unit during the first admission (until discharge)	Number of days	O

1.4 FOLLOW-UP DATA

No.	Item	Definition	Units	Mandatory/ Optional
1	Follow-up centre	List to be built by countries		M
2	Date of follow-up		DD/MM/YYYY	M
3	Donor lost to follow-up		Yes / No	M
4	Death		Yes / No	M
5	Cause of death	All coding systems are allowed		M
6	Date of death		DD/MM/YYYY	M
7	Weight		kg, no decimals	M
8	Blood pressure	Actual blood pressure (independent of the method of measurement)	mmHg	O
9	Hypertension		Yes / No	O
10	Antihypertensive treatment	Menu: <ul style="list-style-type: none"> - Nothing - Diet only - Medication: <ul style="list-style-type: none"> - Diuretics - Beta blockers - ACE blockers - A2 antagonists - Vasodilators/Calcium channel blockers - Other 	Choosing one or multiple items from this menu	M
11	Creatinine		Umol/L or mg/dl	M
12	Proteinuria	<ul style="list-style-type: none"> - 24 hour urine collection - Spot urine in gram per litre - Dipstick - PCR (protein creatinine ratio) 	g/24h g/L Y/N mg/mmol creat	M*

No.	Item	Definition	Units	Mandatory/ Optional
13	Health issues	Menu: <ul style="list-style-type: none"> - No - Yes, specify: <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Renal / urinary tract disease, specify... - Renal Replacement Therapy, specify... - Pregnancy, specify (when)... - Diabetes mellitus, specify... - Other, specify... - Unknown 	Choosing one or multiple items from this menu and free text field for 'specify: ...'	M
14	Did the donor return to previous activity level? (This item should only be collected during the 12 month follow-up visit.)	Menu: <ul style="list-style-type: none"> - Yes, within ... months - No - Unknown 	Choosing one item from this menu and free text field for '... months'	O

* at least one of these options should be completed.

2. REGISTRY OF REGISTRIES: KIDNEY

2.1 DONOR DEMOGRAPHIC INFORMATION

No.	Item	Definition	Units	Mandatory/ Optional
1	Identification (ID number)	The unique identification code that is given by the national authorities to each person		M
2	Date of birth		DD/MM/YYYY	O
3	Age	Actual age at the time of donation	years, no decimals	M
4	Gender		Male/Female	M
5	Weight		kg, no decimals	M
6	Height		cm, no decimals	M
7	Blood group	Menu: <ul style="list-style-type: none"> - A - B - O - AB 	Choosing one item from this menu	M
8	Country of residence		ISO code 3166	M
9	Nationality		ISO code 3166	M
10	Ethnicity	Menu: <ul style="list-style-type: none"> - White - Asian - Black - Oriental - Mixed, please specify ... - Other, please specify ... 	Choosing one or multiple items from this menu and free text field for 'specify: ...'	O

2.2 PRE-DONATION DATA

No.	Item	Definition	Units	Mandatory/ Optional
1	Relation type	Menu: - Related a. Genetically b. Non-genetically - Unrelated	Choosing one item from this menu	M
2	Antihypertensive treatment	Menu: - Nothing - Diet only - Medication: - Diuretics - Beta blockers - ACE blockers - A2 antagonists - Vasodilators/Calcium channel blockers - Other	Choosing one item from this menu	M
3	Creatinine		Umol/L or mg/dl	M
4	Proteinuria	- 24 hour urine collection - Spot urine in gram per litre - Dipstick - PCR (protein creatinine ratio)	g/24h g/L Y/N mg/mmol creat	M*
5	Any significant co-morbidity	Menu: - No - Yes, specify: - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Renal / urinary tract disease, specify... - Other, specify... - Unknown	Choosing one or multiple items from this menu and free text field for 'specify:.....'	M

* at least one of these options should be completed.

2.3 PERI- AND POST-OPERATIVE DATA (until discharge)

No.	Item	Definition	Units	Mandatory/ Optional
1	Country of donor hospital	The country in which the donation takes place	ISO code 3166	M
2	Date of donation		DD/MM/YYYY	M
3	Left or right kidney		Left / Right	M
4	Operation technique	Menu: - Open technique a. Classic technique - Costal resection - No costal resection b. Mini-incision - Laparoscopic a. Standard b. Hand-assisted laparoscopic - Other, specify...	Choosing one item from this menu	M

No.	Item	Definition	Units	Mandatory/Optional
5	Complications during operation	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Kidney damaged during retrieval <ul style="list-style-type: none"> a. Kidney can be used for transplantation b. Kidney is discarded for transplantation - Other organ damaged during surgery - Switch from laparoscopic procedure to open technique - Cardiac arrest - Other severe complications (i.e. pneumothorax, anaphylactic reaction), specify... 	Choosing one or multiple items from this menu and free text field for 'specify...'	M
6	Complications after operation – until first discharge	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Need for re-operation - Infection (urinary, wound, other) - Thrombo/embolic complications (DVT, pulmonary embolism) - Renal Replacement Therapy, specify... - Cardiac arrest - Other severe complications, specify ... 	Choosing one or multiple items from this menu and free text field for 'specify...'	M
7	Length of hospital stay (LOS)	The number of days in hospital during the first admission (from day of surgery until discharge)	Number of days	O
8	Number of days in ICU	The number of days in Intensive Care Unit during the first admission (until discharge)	Number of days	O

2.4 FOLLOW-UP DATA

No.	Item	Definition	Units	Mandatory/Optional
1	Date of follow-up		DD/MM/YYYY	M
2	Donor lost to follow-up		Yes / No	M
3	Death		Yes / No	M
4	Cause of death	All coding systems are allowed		M
5	Date of death		DD/MM/YYYY	M
6	Weight		kg, no decimals	M
7	Antihypertensive treatment	Menu: <ul style="list-style-type: none"> - Nothing - Diet only - Medication: <ul style="list-style-type: none"> - Diuretics - Beta blockers - ACE blockers - A2 antagonists - Vasodilators/Calcium channel blockers - Other 	Choosing one item from this menu	M
8	Creatinine		Umol/L or mg/dl	M
9	Proteinuria	<ul style="list-style-type: none"> - 24 hour urine collection - Spot urine in gram per litre - Dipstick - PCR (protein creatinine ratio) 	g/24h g/L Y/N mg/mmol creat	M*

No.	Item	Definition	Units	Mandatory/Optional
10	Health issues	Menu: <ul style="list-style-type: none"> - No - Yes, specify: <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Renal / urinary tract disease, specify... - Renal Replacement Therapy, specify... - Pregnancy, specify (when).... - Diabetes mellitus, specify... - Other, specify... - Unknown 	Choosing one or multiple items from this menu and free text field for 'specify:.....'	M
11	Did the donor return to previous activity level? (This item should only be collected during the 12 month follow-up visit)	Menu: <ul style="list-style-type: none"> - Yes, within months - No - Unknown 	Choosing one item from this menu and free text field for '... months'	O

* at least one of these options should be completed.

3. NATIONAL REGISTRY: LIVER

3.1 DONOR DEMOGRAPHIC INFORMATION

No	Item	Definition	Units	Mandatory/Optional
1	Identification (ID number)	The unique identification code that is given by the national authorities to each person		M
2	Date of birth		DD/MM/YYYY	O
3	Age	Actual age at the time of donation	years, no decimals	M
4	Gender		Male/Female	M
5	Weight		kg, no decimals	M
6	Height		cm, no decimals	M
7	Blood group	Menu: <ul style="list-style-type: none"> - A - B - O - AB 	Choosing one item from this menu	M
8	Address		Open field	O
9	Country of residence		ISO code 3166	M
10	Nationality		ISO code 3166	M
11	Ethnicity	Menu: <ul style="list-style-type: none"> - White - Asian - Black - Oriental - Mixed, specify ... - Other, specify ... 	Choosing one item from this menu and free text field for 'specify: ...'	O

3.2 PRE-DONATION DATA

No.	Item	Definition	Units	Mandatory/ Optional
1	Relation type	A living donor has one of the following three possible relationships with the recipient: ³ <ul style="list-style-type: none"> - A/ Related - A1/ Genetically related: <ul style="list-style-type: none"> a. 1st degree genetic relative: parent, sibling, offspring b. 2nd degree genetic relative: e.g. grandparent, grandchild, aunt, uncle, niece, nephew c. Other than 1st or 2nd degree genetically related, for example cousin - A2/ Emotionally related: Spouse (if not genetically related), in-laws, adopted, friend - B/ Unrelated: non-related = not genetically or emotionally related 	Choosing one item from this menu	M
2	Any significant co-morbidity	Menu: <ul style="list-style-type: none"> - No - Yes, specify: <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Other, specify... - Unknown 	Choosing one or multiple items from this menu and free text field for 'specify: ...'	M

3.3 PERI- AND POST-OPERATIVE DATA (until discharge)

No.	Item	Definition	Units	Mandatory/ Optional
1	Donor hospital (centre) name	List to be built by countries		M
2	Country of donor hospital	The country in which the donation takes place	ISO code 3166	M
3	Date of donation		DD/MM/YYYY	M
4	Segment donated	<ul style="list-style-type: none"> - 2 - 3 - 2-3 - 2-3-4 - 5-6-7-8 	Choosing one item from this menu	M
5	Percentage of remnant donor liver	Menu: <ul style="list-style-type: none"> - <30% - 30-40% - 41-50% - 51-60% - >60% 	Choosing one item from this menu	M

³ WHO, Global glossary of terms and definitions on Donation and Transplantation

No.	Item	Definition	Units	Mandatory/Optional
6	Complications during operation	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Liver graft damaged during retrieval <ul style="list-style-type: none"> a. Liver can be used for transplantation b. Liver is discarded for transplantation - Remaining liver damaged during surgery - Other organ damaged during surgery - Cardiac arrest - Other severe complications, specify... 	Choosing one or multiple items from this menu and free text field for 'specify...'	M
7	Complications after operation – until first discharge	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Need for re-operation - Biliary fistula - Biliary stenosis - Infection (wound, other) - Non-infected collection - Thrombo/embolic complications (DVT, pulmonary embolism, arterial thrombosis, portal thrombosis) - Cardiac arrest - Liver insufficiency - Other severe complications, specify ... 	Choosing one or multiple items from this menu and free text field for 'specify...'	M
8	Length of hospital stay (LOS)	The number of days in hospital during the first admission (from day of surgery until discharge)	Number of days	O
9	Number of days in ICU	The number of days in Intensive Care Unit during the first admission (until discharge)	Number of days	O

3.4 FOLLOW-UP DATA

No.	Item	Definition	Units	Mandatory/Optional
1	Follow-up centre	List to be built by countries.		M
2	Date of follow-up		DD/MM/YYYY	M
3	Donor lost to follow-up		Yes / No	M
4	Death		Yes / No	M
5	Cause of death	All coding systems are allowed		M
6	Date of death		DD/MM/YYYY	M
7	Weight		kg, no decimals	M
8	Maximum bilirubin (within 15 days after surgery)		Umol/L	M
9	Maximum INR (within 15 days after surgery)		%	M

10	AST (at 15 days after surgery)		U/L	M
11	ALT (at 15 days after surgery)		U/L	M
12	GGT (at 15 days after surgery)		U/L	M
13	Platelets (at 15 days after surgery)		10 ⁹ /L	M
14	Complications (within the first 12 months)	Menu: <ul style="list-style-type: none"> - Nothing - Thrombo/embolic complications (DVT, pulmonary embolism, arterial thrombosis, portal thrombosis-) - Infection (wound, surgical site infection, infected collection, other) - Non-infected collection - Biliary stricture - Biliary fistula - Liver insufficiency - Hemorrhage - Pleural effusion - Other complications, specify 	Choosing one or multiple items from this menu and free text field for 'specify: ...'	M
15	Readmission (within the first 12 months)	Menu: <ul style="list-style-type: none"> - Yes, length of hospital stay - No - Unknown 	Choosing one item and length of admission in days	M
16	Health issues	Menu: <ul style="list-style-type: none"> - No - Yes, specify <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Pregnancy, specify (when).... - Diabetes mellitus, specify... - Liver disease, specify... - Other, specify... - Unknown 	Choosing one or multiple items from this menu and free text field for 'specify:.....'	M
17	Did the donor return to previous activity level? (This item should only be collected during the 12 month follow-up visit.)	Menu: <ul style="list-style-type: none"> - Yes, within months - No - Unknown 	Choosing one item from this menu and free text field for '... months'	O

4. REGISTRY OF REGISTRIES: LIVER

4.1 DONOR DEMOGRAPHIC INFORMATION

No.	Item	Definition	Units	Mandatory/ Optional
1	Identification (ID number)	The unique identification code that is given by the national authorities to each person		M
2	Date of birth		DD/MM/YYYY	O
3	Age	Actual age at the time of donation	years, no decimals	M
4	Gender		Male/Female	M
5	Weight		kg, no decimals	M
6	Height		cm, no decimals	M
7	Blood group	Menu: - A - B - O - AB	Choosing one item from this menu	M
8	Address		Open field	O
9	Country of residence		ISO code 3166	M
10	Nationality		ISO code 3166	M
11	Ethnicity	Menu: - White - Asian - Black - Oriental - Mixed, please specify ... - Other, please specify ...	Choosing one or multiple items from this menu and free text field for 'specify: ...'	O

4.2 PRE-DONATION DATA

No.	Item	Definition	Units	Mandatory/ Optional
1	Relation type	Menu: - Related a. Genetically b. Non-genetically - Unrelated	Choosing one item from this menu	M
2	Any significant co-morbidity	Menu: - No - Yes, specify: - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Other, specify... - Unknown	Choosing one or multiple items from this menu and free text field for 'specify:.....'	M

4.3 PERI- AND POST-OPERATIVE DATA (until discharge)

No.	Item	Definition	Units	Mandatory/ Optional
1	Country of donor hospital	The country in which the donation takes place	ISO code 3166	M
2	Date of donation		DD/MM/YYYY	M
3	Segment donated	<ul style="list-style-type: none"> - 2 - 3 - 2-3 - 2-3-4 - 5-6-7-8 	Choosing one item from this menu	M
4	Percentage of remnant donor liver	Menu: <ul style="list-style-type: none"> - <30% - 30-40% - 41-50% - 51-60% - >60% 	Choosing one item from this menu	M
5	Complications during operation	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Liver graft damaged during retrieval <ul style="list-style-type: none"> a. Liver can be used for transplantation b. Liver is discarded for transplantation - Remaining liver damaged during surgery - Other organ damaged during surgery - Cardiac arrest - Other severe complications, specify... 	Choosing one or multiple items from this menu and free text field for 'specify...'	M
6	Complications after operation – until first discharge	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Need for re-operation - Biliary fistula - Biliary stenosis - Infection (wound, other) - Non-infected collection - Thrombo/embolic complications (DVT, pulmonary embolism, arterial thrombosis, portal thrombosis) - Cardiac arrest - Liver insufficiency - Other severe complications, specify ... 	Choosing one or multiple items from this menu and free text field for 'specify...'	M
7	Length of hospital stay (LOS)	The number of days in hospital during the first admission (from day of surgery until discharge)	Number of days	O
8	Number of days in ICU	The number of days in Intensive Care Unit during the first admission (until discharge)	Number of days	O

4.4 FOLLOW-UP DATA

No.	Item	Definition	Units	Mandatory/ Optional
1	Date of follow-up		DD/MM/YYYY	M
2	Donor lost to follow-up		Yes / No	M
3	Death		Yes / No	M
4	Cause of death	All coding systems are allowed		M
5	Date of death		DD/MM/YYYY	M
6	Weight		kg, no decimals	M
7	Maximum bilirubin (within 15 days after surgery)		Umol/L	M
8	Maximum INR (within 15 days after surgery)		%	M
9	AST (at 15 days after surgery)		U/L	M
10	ALT (at 15 days after surgery)		U/L	M
11	GGT (at 15 days after surgery)		U/L	M
12	Platelets (at 15 days after surgery)		10 ⁹ /L	M
13	Complications (within the first 12 months)	Menu: <ul style="list-style-type: none"> - Nothing - Thrombo/embolic complications (DVT, pulmonary embolism, arterial thrombosis, portal thrombosis) - Infection (wound, surgical site infection, infected collection, other) - Non-infected collection - Biliary stricture - Biliary fistula - Liver insufficiency - Hemorrhage - Pleural effusion - Other complications, specify... 	Choosing one or multiple items from this menu and free text field for 'specify: ...'	M
14	Readmission (within the first 12 months)	Menu: <ul style="list-style-type: none"> - Yes, length of hospital stay... days - No - Unknown 	Choosing one item and length of admission in days	M

No.	Item	Definition	Units	Mandatory/Optional
15	Health issues	Menu: <ul style="list-style-type: none"> - No - Yes, specify <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Pregnancy, specify (when).... - Diabetes mellitus, specify... - Liver disease, specify... - Other, specify... - Unknown 	Choosing one or multiple items from this menu and free text field for 'specify: ...'	M
16	Did the donor return to previous activity level? (This item should only be collected during the 12 month follow-up visit)	Menu: <ul style="list-style-type: none"> - Yes, within months - No - Unknown 	Choosing one item from this menu and free text field for '... months'	O

5. GLOSSARY OF TERMS

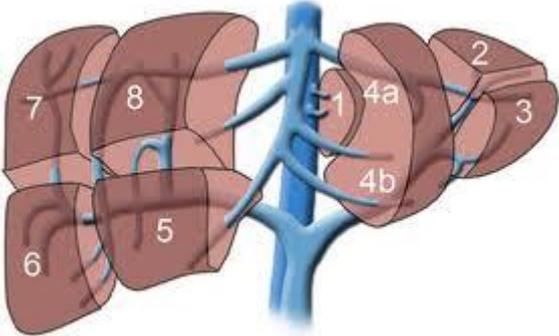
This glossary of terms is intended to provide clarity on the way each parameter should be measured or collected and to facilitate harmonised international data sharing.

Item	Definition
Antihypertensive treatment	<ul style="list-style-type: none"> - Nothing: this means that a donor does not use any diet and/or drugs - Diet only: diet is not specified. Anything a person calls a diet and is appropriate to control the person's blood pressure is considered a diet - Medication: The following classes of antihypertensive drugs can be identified: <ul style="list-style-type: none"> - Diuretics - Beta blockers - ACE blockers - A2 antagonists - Vasodilators/Calcium channel blockers - Other <p>It is assumed that every patient with a class of antihypertensive drugs has had diet advice before the treatment with medication started.</p>
Any significant co-morbidity (KIDNEY)	Menu: <ul style="list-style-type: none"> - No - Yes, specify: <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify...

Item	Definition
	<ul style="list-style-type: none"> - Psychological disorder, specify... - Renal / urinary tract disease, specify... - Other, specify... - Unknown
Any significant co-morbidity (LIVER)	Menu: <ul style="list-style-type: none"> - No - Yes, specify: <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Other, specify... - Unknown
Blood pressure	Actual blood pressure (independent of the method of measurement): the method to collect the actual blood pressure is not defined
Cause of death	All coding systems are allowed
Complications during operation (KIDNEY)	Complications during operation means from the start of the surgery until arrival at the recovery room. Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Kidney damaged during retrieval: this means that the kidney that is procured from the donor (graft) is damaged <ul style="list-style-type: none"> a. Kidney can be used for transplantation b. Kidney is discarded for transplantation - Other organ damaged during surgery: this means that another organ (not the procured organ) is (physically) damaged during the operation. - Switch from laparoscopic procedure to open technique - Cardiac arrest - Other severe complications (i.e. pneumothorax, anaphylactic reaction), specify...: this will be a free text field
Complications during operation (LIVER)	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Liver graft damaged during retrieval: this means that the liver graft that is procured from the donor is damaged <ul style="list-style-type: none"> a. Liver can be used for transplantation b. Liver is discarded for transplantation - Remaining liver damaged during surgery - Other organ damaged during surgery - Cardiac arrest - Other severe complications, specify...
Complications after operation – until first discharge (KIDNEY)	Complications after operation means from the arrival at the recovery room until discharge from the hospital. Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Need for re-operation - Infection (urinary, wound, other): therapeutic use of antibiotics - Thrombo/embolic complications (DVT, pulmonary embolism) - Renal Replacement Therapy, specify... - Cardiac arrest - Other severe complications, specify...

Item	Definition
Complications after operation – until first discharge (LIVER)	Menu: <ul style="list-style-type: none"> - No complications - Blood loss: need for transfusion - Need for re-operation - Biliary fistula: when bilirubin concentration in drained fluids is 3 or more times higher than in serum - Biliary stenosis - Infection (wound, other) - Non-infected collection - Thrombo/embolic complications (DVT, pulmonary embolism, arterial thrombosis, portal thrombosis) - Cardiac arrest - Liver insufficiency - Other severe complications, specify...
Complications (within the first 12 months)	Menu: <ul style="list-style-type: none"> - Nothing - Thrombo/embolic complications (DVT, pulmonary embolism, arterial thrombosis, portal thrombosis) - Infection (wound, surgical site infection, infected collection, other) - Non-infected collection - Biliary stricture - Biliary fistula - Liver insufficiency - Hemorrhage - Pleural effusion - Other complications, specify...
Country of residence	This is the country where the person lives during 7 months of a year
Did the donor return to previous activity level?	This item should only be collected during the 12 month follow-up visit. This should be based on the person's answer and should not be an objective measurement. Menu: <ul style="list-style-type: none"> - Yes, within ... months - No - Unknown
Donor lost to follow-up	A donor is lost to follow-up if he/she has regularly been invited to follow-up appointments but did not show up for 10 years. Because the mandatory follow-up frequency, at discharge, is 1 year after donation and then every 5 years post-donation, this means that the donor did not show up for at least three consecutive visits.
Ethnicity	Menu: <ul style="list-style-type: none"> - White - Asian - Black - Oriental - Mixed, please specify ... - Other, please specify ...
Health issues (KIDNEY)	Menu: <ul style="list-style-type: none"> - No - Yes, specify <ul style="list-style-type: none"> - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify... - Renal / urinary tract disease, specify... - Renal Replacement Therapy, specify... - Pregnancy, specify (when)... - Diabetes mellitus, specify... - Other, specify...

Item	Definition		
Health issues (LIVER)	Menu: - No - Yes, specify - Abdominal surgery, specify... - Malignancies, specify... - Hematological disease, specify... - Neurological disease, specify... - Cardiovascular disease, specify... - Respiratory disease, specify... - Gastrointestinal disease, specify... - Psychiatric disease, specify... - Psychological disorder, specify - Pregnancy, specify (when)... - Diabetes mellitus, specify... - Liver disease, specify... - Other, specify... - Unknown		
Hypertension	Hypertension: Yes / No Hypertension should be considered 'yes' when a person uses a diet or medication to treat the hypertension. If a person does not use a diet or medication, but has a blood pressure >140/90 mmHg, the person is also considered hypertensive.		
Identification	The national authorities in (almost) every member States give a unique identification code to each individual. This code could be used to identify a person without collecting their name. If a country decides not to use the unique identification code, another method should be used to prevent collecting data about the same person twice. For example a combination of initials and date of birth.		
Length of hospital stay (LOS)	The number of days in hospital during the first admission from day 0 to the day of discharge, with day 0 being the day of surgery		
Nationality	In case of a dual nationality, register both.		
Number of days in ICU	The number of days in Intensive Care Unit during the first admission (until discharge)		
Percentage of remnant donor liver	Menu: - <30% - 30-40% - 41-50% - 51-60% - >60%		
Readmission (within the first 12 months)	Menu: - Yes, length of hospital stay (in days) - No - Unknown		
Relation type	The definition that is applicable for the national kidney database differs from the definition of the Registry of registries. To be able to collect the information, the national and international registries should be able to communicate with one another. The possibilities available from the national database should match the simplified definition: <table border="0" data-bbox="563 1682 1457 2040"> <tr> <td data-bbox="563 1682 1007 2040"> National: - A/ Related - A1/ Genetically related: a. 1st degree genetic relative: parent, sibling, offspring b. 2nd degree genetic relative: e.g. grandparent, grandchild, aunt, uncle, niece, nephew c. Other than 1st or 2nd degree genetically related, for example cousin </td> <td data-bbox="1007 1682 1457 2040"> International → Related → Genetically related → Genetically related → Genetically related → Genetically related </td> </tr> </table>	National: - A/ Related - A1/ Genetically related: a. 1st degree genetic relative: parent, sibling, offspring b. 2nd degree genetic relative: e.g. grandparent, grandchild, aunt, uncle, niece, nephew c. Other than 1st or 2nd degree genetically related, for example cousin	International → Related → Genetically related → Genetically related → Genetically related → Genetically related
National: - A/ Related - A1/ Genetically related: a. 1st degree genetic relative: parent, sibling, offspring b. 2nd degree genetic relative: e.g. grandparent, grandchild, aunt, uncle, niece, nephew c. Other than 1st or 2nd degree genetically related, for example cousin	International → Related → Genetically related → Genetically related → Genetically related → Genetically related		

Item	Definition	
	<ul style="list-style-type: none"> - A2/ Emotionally related: Spouse (if not genetically related); in-laws; adopted, friend - B/ Unrelated: non-related = not genetically or emotionally related 	<ul style="list-style-type: none"> ➔ Non-genetically related ➔ Non-related: this means donor and recipient do not know each other
Segment donated	<p>The liver could be divided into 8 different segments.</p> <div style="text-align: center;">  </div> <p>The part of the liver (segment) that is procured from the donor should be specified:</p> <ul style="list-style-type: none"> - 2 - 3 - 2-3 - 2-3-4 - 5-6-7-8 	