WP 4 'LIVING DONOR REGISTRIES'

A REPORT ON THE CURRENT EXPERIENCE WITH LIVING DONATION AND LIVING DONOR REGISTRIES

January 2013

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CONTENT

SUMMARY

This report is the first planned deliverable of ACCORD work package 4 (WP4). ACCORD is an abbreviation of 'Achieving Comprehensive Coordination in Organ Donation'. This project is initiated by the European Committee to collect, generate and disseminate information, knowledge and experience on organ donation throughout the European Member States. WP 4 specifically focuses on the collection of living donor follow-up data, facilitating countries without a digital follow-up data collection to implement a database or registry and setting up an international Registry of Registries.

This deliverable describes the current experience within the Member States with living donation and living donor follow-up registries or databases. In July 2012, a questionnaire was send to all associated and collaborating partners to collect information about the use of databases or registries, the current items that are collected, the definitions that are used, the frequency of follow-up, the governance of the registry, et cetera.

Fifteen so-called associated partners and 5 collaborating partners are involved in WP 4. A total of 13 partners completed the questionnaire. Evaluation of the results show that there are quite some differences between the WP4 partners, regarding experience with living donation, donor follow-up and the collection of (digital) follow-up data. Five of the responding Member States do not have a method for digital follow-up data collection yet.

The items that would be collected in a 'Registry of Registries' are to be defined in the upcoming months. Even though there is no consensus about the items and definitions yet, it looks promising to achieve this within the given time frame, since every associated and collaborating partner that responded seems willing to co-operate.

1. INTRODUCTION ACCORD

1.1 ACCORD

This report is the first planned deliverable of ACCORD work package 4 (WP4). ACCORD is an abbreviation of 'Achieving Comprehensive Coordination in Organ Donation'. This project is initiated by the European Commission to strength the full potential of European Union Member States (MS) in the field of organ donation and transplantation, to improve cooperation among them and to contribute to the effective implementation of *Directive 2010/53/EU*[1] and the *Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between MS*[2]. This is to be achieved through the collection, generation and dissemination of information, knowledge, experience and tools on organ donation and transplantation throughout the European countries.

1.2 WORK PACKAGE 4

WP 4 specifically focuses on the collection of living donor follow-up data, aiming at facilitating countries without a digital follow-up data collection to implement a database or registry and setting up an international Registry of (living donor) Registries. *Directive 2010/53/EU* sets down the provision that '*Member States shall ensure that a register or record of the living donors is kept, in accordance with Union and national provisions on the protection of the personal data and statistical confidentiality*' (article 15.3) and that '*Member States shall endeavor to carry out the follow-up of living donors and shall have a system in place in accordance with national provisions, in order to identify, report and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation'* (article 15.4). At the same time, the Action Plan sets down priority action number 3, '*Promoting the exchange of best practices on living donation programmes',* through which the Commission intends to help MS to develop adequate tools to facilitate the proper collection of information on the medical, psychological, financial and social consequences of living donation in the short and the long term.

Annex 2 shows the associated and collaborating partners of ACCORD WP 4.

[1] *Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. European Commission website. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF. Last access: October 2012.*

[2] *Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States. European Commission website. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0819:FIN:EN:PDF. Last access: October 2012.*

2. LIVING DONATION

Donor shortage is an issue in every EU MS. MS are searching for different possibilities to help people who suffer from diseases which can be treated with an organ transplant. Besides post mortal organ donation, the use of organs from living donors is another possibility. Of course, this is not possible for every type of organ, but it can be a possibility for patients waiting for a kidney, liver or lung.

Some MS have much experience with living donation, others are focusing on other aspects of donation and transplantation. Not every country has had the opportunity yet to expand their current practice on donation and transplantation with this alternative donor pool. Other countries try to investigate other ways to help more people on the waiting list, for example by research on medication, designing technical devices or using organs from other categories of deceased donors, for example donors after circulatory death (DCD) or Expanded Criteria Donors (ECD).

2.1 THE CONCEPT OF LIVING DONATION

In case of living donation, a healthy person wants to help a patient with terminal organ failure by donating one of their own organs. Donating one kidney, a lung lobe or a part of the liver during life time is possible. The fact that donating (a part of) an organ is a possibility, does not mean that it is a risk-free procedure. Every surgical operation carries a certain risk, and particularly donation of a part of the liver, or a lung lobe is risky.

The current developments within the EU move towards expanding living (kidney) donation, as long as donor protection is ensured and efforts in maximizing deceased donation are maintained. To protect the donor's health and safety, an appropriate framework of donor care should be established. Such an appropriate framework should include proper selection, both physical and psychological, a proper (independent) informed consent procedure, and a possibility to follow a donor's health, including the collection of information on both short- and long-term outcomes. Current experience within MS that have turned out to be safe and effective should be used as example for those countries who want to set up or improve their framework.

2.1.1 Living kidney donation

Kidney transplantation is considered the best therapeutic strategy for many patients with end stage renal disease, providing better results than renal replacement therapy with dialysis, both in terms of survival and quality of life.[3, 4, 5] The main problem that

[3] Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. Wolfe R, Ashby V, Edgar MA et al. N Engl J Med 1999;341:1725-1730.

precludes the full development of kidney transplantation is the limited availability of kidneys to meet the transplantation needs of the patients. Therefore, transplantation of kidneys from live donors is considered today as a necessary adjunct to satisfying the transplantation needs of a given population. Resolution 57.18 of the *2004 World Health Assembly* urges Member States '*to extend the use of living kidney donations when possible, in addition to donations from deceased donors*'.[6] In figure 1 the transplantation rate with kidneys from a living donor for each European country is given[7]. There are large differences between countries in extensiveness of living donation.

There are different programs for 'types' of living donors. Examples of different programs are: genetically related or unrelated living donation, direct donation to a specific person or altruistic donation to the most appropriate patient on the waiting list (Good Samaritan), cross-over donation, donation across blood group or positive cross match.

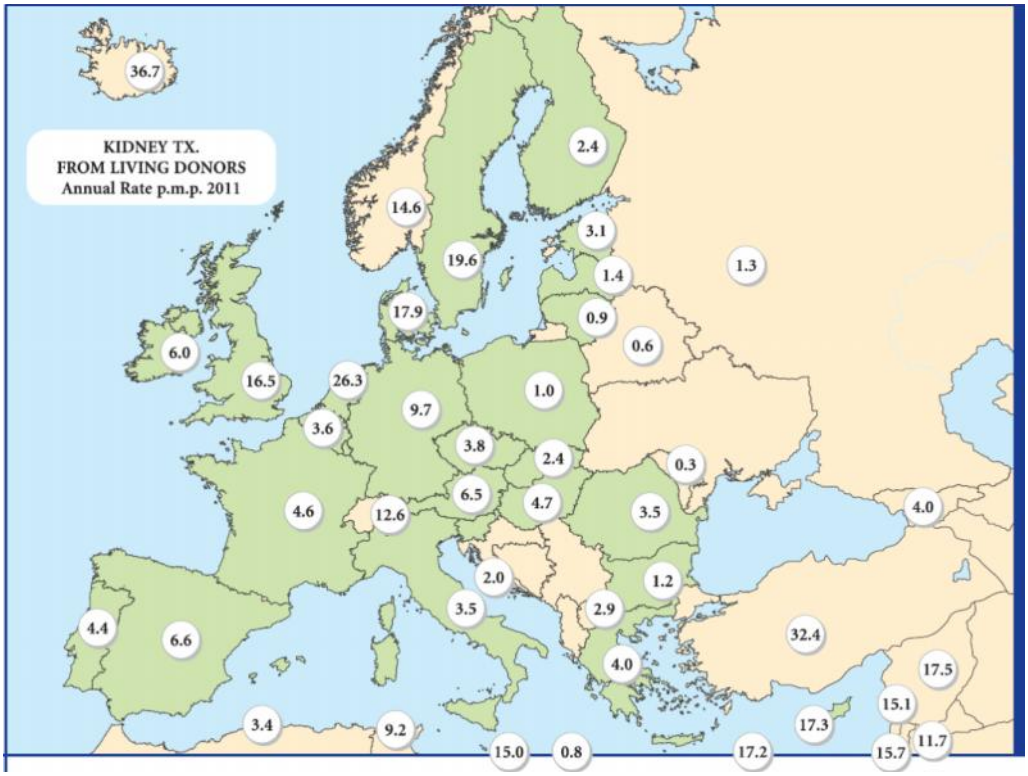

Figure 1: Number of kidney transplants with grafts from living donors p.m.p within Europe[7]

[4] Benefit of kidney transplantation beyond 70 years of age. Heldal K, Hartman A, Grootendorst DC et al. Nehrol Dial Transplantation 2010 ;25 :1680-1687.

[5] Survival of patients older than 60 years with kidneys transplanted from Spanish expanded criteria donors versus patients continued on hemodialysis. Navarro JM, Ortega M, Gutierrez MJ et al. Transpl Proc 2009;41:2376-2378.

[6] World Health Assembly Resolution 57.18. Global Observatory on Organ Donation and Transplantation website. Available at: http://www.transplant-observatory.org/SiteCollectionDocuments/wha57resen.pdf. Last access: June 2012.

[7] International figures on donation and transplantation 2011, Council of Europe, *Newsletter Transplant Vol 17, No 1, September 2012*

2.1.2 Living liver donation

Due to the ongoing and increasing shortage of livers from deceased donors, a number of transplant centers around the world have adopted living donation as a partial solution to this shortage. Within Europe living liver donation is a procedure in which a living person donates a portion of his or her liver to another, mostly a child. Because the liver can regenerate itself, both the transplanted section and the remaining section of the donor's liver are able to regrow into a normal sized liver.

Based on 2011 data, 245 liver transplants were performed within the EU with a liver from a living donor[8].

2.1.3 Living lung donation

A living lung donation procedure differs from living kidney and liver donation procedures. Living lung donation requires two donors: one person giving one lobe, or portion of their left lung, and the other giving a lobe of their right lung. The two lobes are transplanted into one single recipient.

Donating a lung-lobe during life is very rare. Scientific publications are scarce. Within Europe, it appears that only the United Kingdom has experience with a living lung donation program. If we look across the European borders, living lung donations still seems a rare procedure. From 2002-2004 the number of living lung donors in the United States was stable at 25-29 per year, whilst in 2005 there were only two living lung donors[9].

[8] International figures on donation and transplantation 2011, Council of Europe, *Newsletter Transplant Vol 17, No 1, September 2012*

[9] Organ Donation and Utilization in the United States, 1996–2005, Puncha JD, Hayesb DH, LaPortec FB, McBrided V and Seelye MS, *American Journal of Transplantation* 2007; 7 (Part 2): 1327–1338

3. LIVING DONOR FOLLOW-UP

3.1 LIVING DONOR FOLLOW-UP IN EUROPE

Traditionally, transplantation with an organ from a deceased donor results in most countries in follow-up of the *recipient* and the functioning and survival of the graft. By collecting this data, research is possible for example on many variables that could influence the health and survival of both recipient and graft.

In case of living donation, additional follow-up of the *donor* is necessary. By collecting data on predefined donor items, the circumstances at the time of transplantation and during long term follow-up, research is possible. This research can lead to new insights and developments in the field of (living) donation. Especially the long term safety and possible health risks of living donation for the donor are issues that need further research. To be able to collect living donor follow-up data, of course the donor´s consent is an absolute requirement.

Follow-up of a recipient after transplantation is assumed to be implemented in (almost) every EU MS. Digital data collection of follow-up data of a living donor after donation, however, is not yet implemented in every EU MS. Chapter 4 shows the current situation within the WP4 partners. The previous chapters show that living kidney donation is by far the procedure which occurs most, compared to living liver and living lung donation. Therefore, it is not surprising that most of the MS with a living donor follow-up database have created this for living kidney donors.

The aim of ACCORD WP4 is to offer support to those countries that do not use digital databases or registries to collect data after living donation (of kidney, liver and lung). The outcomes of the WP4 project could help those countries by giving suggestions on practical, technical, governmental and additional aspects regarding follow-up data collection. This meets the regulations which arise from the EU Directive 2010/53/EU[10].

Some MS already have a great deal of experience with the collection of living donor data. This experience can be called upon by other MS. Also EULID, an abbreviation of European Living Donation and Public Health, has made a first step towards collecting follow-up data from living donors with the aim of protecting the living donor. The experience of EULID will be used as a stepping stone by the ACCORD WP4 partners.

[10] *Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. European Commission website. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF. Last access: October 2012.*

3.2 LIVING DONOR FOLLOW-UP OUTSIDE EUROPE

The United Network for Organ Sharing (UNOS) in the United States has experience with the collection of follow-up data of living donors. Since June 2006, UNOS has provided a patient safety system for transplant centers to report medical problems experienced by living donors. Centers must report any living donor deaths, as well as instances in which a donor's native organ (remaining kidney or other organ of which a portion was donated) fails to function, within 72 hours of becoming aware of this information. Transplant centers must report these incidents for two years after the donation surgery occurs.

Based upon OPTN data from 1999 through 2008, of the 3313 individuals who were living liver donors, at least five have been listed for a liver transplant due to complications related to the donation surgery. Of the 60,644 individuals who were living kidney donors from 1999 through 2008, at least seven have been listed for a kidney transplant. However, the medical problems that caused these kidney donors to be listed for transplant may or may not be connected to the donation[11].

3.3 THE CONCEPT OF A REGISTRY OF REGISTRIES

Scientific research on living donor follow-up is already of great value to the (international) donation and transplantation society. National databases and registries can provide researchers with national data. There has already been international effort to combine different registries. A recent example is the EFRETOS project[12] which had the same intention as this ACCORD WP4 project but focused on the collection of follow-up data of transplanted patients. An active international European registry where MS frequently sent in their follow-up data of *living* donors to expand the amount collected data is lacking so far. ACCORD WP4 aims to develop the basis for such a registry of registries.

[11] Living donation. ´Information you need to know´, http://www.unos.org/docs/Living_Donation.pdf
[12] EFRETOS stands for European Framework for the Evaluation of Organ Transplants. This European project to promote a follow-up Registry of Registries was finished in 2011. www.efretos.org

4. CURRENT EXPERIENCE WITHIN THE ACCORD WP4 PARTNERS

4.1 METHODOLOGY

A questionnaire was prepared and agreed upon among associated and collaborating partners, participating in WP4 of ACCORD. It was send to all partners to investigate the MS's current experience with living donation and living donor follow-up. The questionnaire is attached to this report as Annex 1.

The questionnaire was divided into 5 focus areas:

A. General information
B. Current experience with living donation and current living donor follow-up
C. Technical specification on the database
D. Detailed specification on the content of the database
    a. Data for evaluation of the donor
    b. Data concerning the donation procedure
    c. Data for follow-up of the donor
E. Practical information about using the database

It was decided, that a predetermined set of items would be named in the questionnaire. Each WP4 partner was asked to complete the questionnaire and to answer whether the items were mandatory and what definitions were used.

4.2 OUTCOMES

A brief summary of the completed questionnaires is given in the following paragraph, again divided into the 5 focus areas.

4.2.1 'General information' and 'Current experience with living donation and current living donor follow-up'

Associated partners	Experience with living donation	A system to gather living donor follow-up data	Collected in a digital registry
Netherlands	Y, kidney and liver	Y, kidney	Y
Spain	Y, kidney and liver	Y, kidney and liver	Y
France	Y, kidney and liver	Y, kidney and liver	Y
Italy	Y, kidney and liver	Y, kidney and liver	Y
Croatia	Y, kidney and liver	N	N

Germany	Y, kidney and liver	Y, kidney and liver	Y
Latvia	Y, kidney	Y, kidney	N
Lithuania	Y, kidney	Y, kidney	N
Norway	Y, kidney	Y, kidney	Y
Romania	Y, kidney and liver	Y, kidney and liver	N
United Kingdom	Y, kidney, liver and lung	Y, kidney	Y

Collaborating partners	Experience with living donation	A system to gather living donor follow-up data	Collected in a digital registry
Scandiatransplant*	Y, kidney	Y, kidney	Y
Hopital Clinic Universitari of Barcelona (EULID)	Y, kidney and liver	Y, kidney and liver	Y

*Scandiatransplant is in charge of the corresponding data collection for Denmark, Finland, Iceland, Norway and Sweden.

A total of 13 partners completed and returned the questionnaire. This included 11 MS and two collaborating partners. Every respondent has experience with living kidney donation. Eight MS and one collaborating partner have, in addition to kidney donation, also experience with living liver donation. One MS has had experience with a living lung donation program in the past.

Seven MS and two collaborating partners already collect their data in a digital registry. Of the four MS without a digital registry, one has indicated to have no interest in such a national registry in their own country. This country prefers a local registry. The other three countries are very much interested in a national registry. They were asked to complete the questionnaire with a preferred / ideal situation in mind.

Some countries just started with the collection of follow-up data of the living donors (Spain, 2010) whereas others have had years of experience collecting data (Norway, 1997). The other countries started mainly between 2000 and 2005.

4.2.2 Technical specification on the database

Most of the partners, 7 in total, have a registry performing on Oracle applications. Three of the partners that use an Oracle product combine this with another system, for example Access or SQL server. An Excel database will preferably be used by Lithuania and Romania, the last one in combination with FileMakerPro.

Overall, a member of the transplant team is responsible for the data collection. Transplant doctors, transplant coordinators, nephrologists and living donor coordinators are some of the terms mentioned, but it seems like different names are given to people with the same function or at least working in the same department.

Overall, national authorities are responsible for hosting the database, either the Ministry of Health or the national organization that is responsible for organ donation and/or transplantation.

4.2.3 Detailed specification on the content of the database

This inventory has some bias, since some countries decided not to answer (all) of the questions concerning the specification of the items because they do not apply a digital data collection yet. They have given some answers to the questions with a preferred situation in mind, but some answers were kept blank. This has not influenced the overall impression of the current situation within the associated MS.

The definitions that were given by the respondents for each predefined item differ in some cases. It is suggested that internationally accepted definitions should be discussed and agreed upon by ACCORD WP4 in the further development of a registry of registries.

a. Data for evaluation of the donor

The following items were predefined and partners were asked to answer whether the items are collected in their database or registry, whether the items are mandatory and what definitions are used. One country without a registry has not answered the questions.

Item	Definition	Mandatory Yes	Mandatory No	Not collected
Age	Age in years at the moment of transplant Date of birth	12	0	0
Gender	Male / female	12	0	0
Relation type	Relationship between donor and recipient, by some countries specified in every possible type of relation. There is no unanimous definition yet.	11	0	1
Weight	Weight in kg.	5	6	1
Length	Length in cm, only EULID uses meters.	5	6	1

Creatinine	Different metrics are applied: - Umol/L - Mg/dl	9	2	1
Blood pressure	mmHg RR Office or automatic Hypertension Y/N Sitting BP before donation	6	5	1
Anti hypertensive drugs	Some countries gave no definition, others answered: - Diet, one drug, two drugs, three or more drugs - Current (at time of donation)	5	3	4

b. Data concerning the donation procedure

Item	Definition	Mandatory Yes	Mandatory No	Not collected
Operation technique	Answer: Surgical technique used: - Open lumbotomy - Laparoscopy - Hand assisted laparoscopy - Mini lumbotomy Answer: - Posterolumbar incision - Posterolumbar incision in conversion of coelioscopy - Coelioscopy - Under costal	5	4	3
Left or right kidney	Organ donated: left kidney or right kidney	6	3	3
Complications during operation	Answer: 1. No complications 2. Wound infection 3. Bleeding 4. Pain 5. Other 6. If other, specify Answer: 1. Bleeding 2. Infection 3. Thrombosis 4. Pneumothorax 5. Splenectomy 6. Re-operation	5	5	2

	7. Other significant complication that can be specified			
Blood group	A, B, 0, AB	9	1	2
HLA type	Split, A, B, DR, DP, DQ	8	2	2
EBV	Pos/neg, IgG, IgM	3	4	5
CMV	Serology: Pos/neg, IgG, IgM	4	5	3
Hepatitis B, C	- HBsAg, HBcAb, HBsAb, AntiHCV - HIV, HCV, HBV, Delta virus: pos/neg/not tested - Pos/neg	4	4	4

c. Data for follow-up of the donor

Item	Definition	Mandatory Yes	Mandatory No	Not collected
Weight	Weight in kg.	3	7	2
Height	Length in cm, only EULID uses meters.	1	7	4
Creatinine	Different metrics are applied: - Umol/L - Mg/dl	8	3	1
Proteinuria	- g/24h - g/L - Dipstick urinalysis and urinary PCR if dipstick is positive	7	3	2
Blood pressure	- mmHg - sitting BP mmHg	8	3	1
Anti hypertensive drugs	Some countries gave no definition, others answered: - Diet, one drug, two drugs, three or more drugs - Any started within the last year at annual review - Yes, No, Unknown	6	4	2
Complication after operation	Answer: 1. Sepsis 2. Lung embolism 3. Deep venous thrombosis 4. Wound infection 5. Bleeding	7	4	1

	Answer: 1. No complications 2. Wound infection 3. Bleeding 4. Pain 5. Other 6. If other, specify Answer: Collected 13 items, including 4 socio-economic complications Answer: Within the past year since last review visit Answer: Within 30 days post donation Answer: Death within one month after donation			

d. Additional items that are already collected by MS, or items that MS would like to collect

Data for evaluation of the donor

Item	Times mentioned	Mandatory Y	Mandatory N
Address of donor	2	2	
Albuminuria in spot urine	1		1
Bilirubin for living donors	1	1	
Cholesterol	1	1	
Creatinine levels	1		1
Cross match	1	1	
Date of review	1	1	
Donor lost to follow-up	1		1
Endogenous Creatinine Clearance / Glomerular Filtration Rate / Cockroft-Gault	5	2	3
Ethical committee	1	1	

Fasting blood glucose	2	1	1
GOT (AST) for living donors	1	1	
GPT (ALT) for living donors	1	1	
HDL	1	1	
HIV	1	1	
ID number	3	3	
Microalbuminuria	2	1	1
Name	2	2	
Nationality	3	1	2
Organ: liver / kidney	1	1	
Other diseases (specify)	1		1
Place of birth	1		1
Race	1		1
Residence country	2	2	
Smoking	2	1	
Treatment	1		1
Triglycerides	1	1	

Data concerning the donation procedure

Item	Times mentioned	Mandatory Y	Mandatory N
Blood pressure at discharge	1		1
Cause of reintervention	1		1
Cold ischemic time	1	1	
Creatinine levels at discharge	1		1
Date of hospital discharge	3	3	
Date of nephrectomy/donation/surgery/ explantation operation	5	4	1
Date of review	1	1	
Endogenous Creatinine Clearance / Glomerular Filtration Rate / Cockroft-Gault	5	2	3

Hemoglobin	1		1
Hospital (name) / donation center	3	3	
Microscopic haematuria	1		1
Number of arteria	1		1
Number of veins	1		1
Proteinuria at evaluation	3	2	1
Reintervention	1	1	
Reintervention date	1		1
Urine changes at discharge	1		1
Urine test at discharge	1		1
Warm ischemic time	1	1	

Data for follow-up of the donor

Item	Times mentioned	Mandatory Y	Mandatory N
Albuminuria in spot urine	1		1
Bilirubin for living donors	1	1	
Cause of death / death related to donation	5	1	4
Cause of readmission	1		1
Cholesterol	1	1	
Creatinine levels	1		1
Date of attendance for follow-up	1		1
Date of death	3	1	2
Date of readmission	1		1
Date of review	1	1	
Death	4	2	2
Diabetes	3	1	2
Donor diagnosis after donation	1	1	
Donor lost to follow-up	1		1

Employment status	1		1
Endogenous Creatinine Clearance / Glomerular Filtration Rate / Cockroft-Gault	5	2	3
Fasting blood glucose	2	1	1
Follow up status (i.e. lost, transferred)	1		1
Follow-up center	1	1	
Glucose curve	1		1
Glycosylated Hb	1		
GOT (AST) for living donors	1	1	
GPT (ALT) for living donors	1	1	
Hemoglobin	1		1
HDL	1	1	
Hospital readmission	2	1	1
Major health issues since last review	1		1
Malignancy	1		1
Microalbuminuria	2	1	1
Microscopic haematuria	1		1
New disease description	1		1
Other diseases (specify)	1		1
Smoking	2	1	1
Time until to normal activity	1		1
Treatment description	1		1
Triglycerides	1	1	
Urological or nephrological disease	2	1	1

All items that are mentioned in these schedules, should be discussed and agreed upon during the next steps of the WP4 project group. Especially nephrologists should be included in this discussion to determine which data are absolutely necessary to fulfill the project goals and which data should be determined as ´nice to have´ or only necessary in a local database but not in an international Registry of Registries.

4.2.4 Liver data collection

As mentioned earlier, the emphasis seems to be on living kidney donation. Of course, also follow-up information on living liver donors will be collected in a registry. In the next steps of the ACCORD WP 4 project, we need to focus on defining a dataset and data dictionary for living liver donors. Specific hepatologists and liver transplant specialists will be involved in every MS to give their insight in necessary data collection.

4.2.5 Practical information about using the database

The number of hospitals or transplant centers in the MS that share their data in a digital registry vary from 1 to 53. The number of donors included in the registries differ from 22 up to 11761 donors. As mentioned earlier, by far the most donors that are included in these registries are living kidney donors. To give an impression: the United Kingdom has a registry containing 11761 donors of which 11519 living kidney donors, 218 living liver donors and 24 living lung(lobe) donors.

The follow-up frequency for each donor between the associated countries is on average 3 times in the first year. The exact moment of follow-up differs. Some patients have to visit their doctor for a follow-up on the first, third and sixth month, others only have a yearly appointment set after the time of transplantation. Figure 2 shows the follow-up moments and the number of countries to which this is applicable.

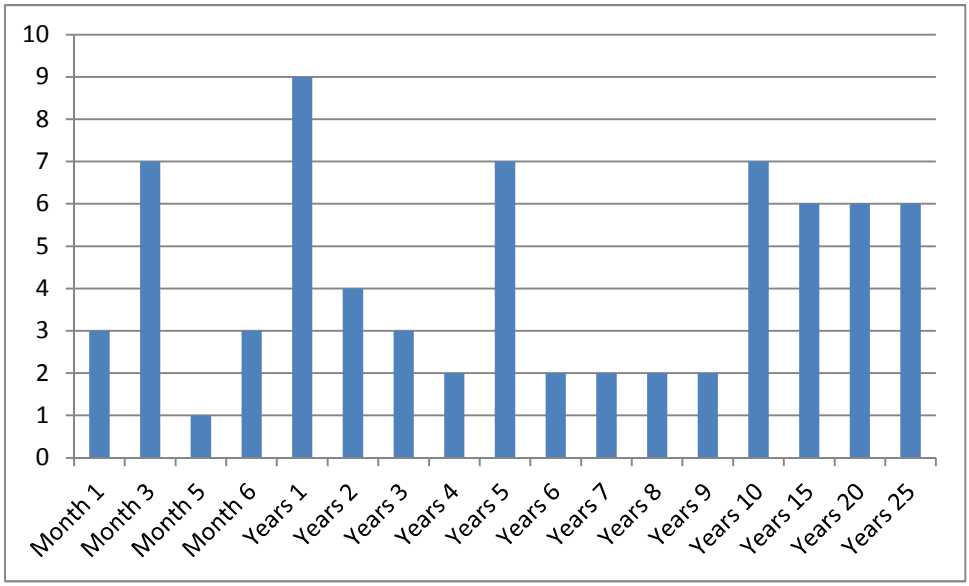

Figure 2: Living donor follow-up frequency *during* the first year and *after* the first year post donation

Two of the MS have a long-term follow-up frequency of one year, four MS have a long-term follow-up frequency of five years.

Most of the associated and collaborating partners use a consent form to obtain consent from the donors for using their data in the registry.

It is not feasible to give an exact insight in the completeness of the different databases or registries. The involved partners calculate their completeness in different ways, some partners could not specify the way the completeness is calculated and some partners could only give an estimated number, but have no tools to calculate an exact outcome. Therefore, the numbers are uncomparable and unclear. Three MS specify a 'baseline' completeness. They mention a completeness of 94.7%, 99% and 100%. EULID, an EU project coordinated by collaborating partner Hopital Clinic Universitari of Barcelona, states that EULID is a research database with a period of data collection from 2007-2009 which calculates no 'level of completeness'. Since this is the outcome of the questionnaire, it only says something about the current situation. It is absolutely necessary in the next WP4 project steps to define what is commonly meant by completeness and what formula will be applied within the WP4 partners to ´speak the same registry language´.

It is dissimilar but also unclear for some countries to state the person or committee that determines if a request for data is granted. Some countries have a special 'governing committee' or 'advisory board', others work with protocols. Ten out of thirteen responding partners answered that a specific person is responsible for answering questions and/or analysis of the registry.

5. CONCLUDING REMARKS

Overall, we may conclude that living donation is already implemented in all collaborating WP4 partners that completed the questionnaire. The emphasis is clearly on living kidney donation. It turns out that a lot of experience on living donation has been gained so far.

The registration of living donor follow-up information is not yet implemented in every MS. There is a great variety between the MS in the number of hospitals that already share their data in a digital database or registry, the number of patients that are included and the number of follow up items that are collected. We conclude that the exchange of knowledge and experience is still of great value, especially for those countries with a (relatively) small number of transplants with grafts of living donors.

MS without a digital registry or database have shown interest in setting up a system in order to meet the EU Directive 2010/53/EU '*Member States shall endeavor to carry out the follow-up of living donors and shall have a system in place in accordance with national provisions, in order to identify, report and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation'* (article 15.4).

This report will be useful to state the current experience and to collect ideas about items that should be collected in a national and/or international registry. All medical, technical, but possibly also social, financial and legal consequences of LD should be addressed. The input from the questionnaire will be used for the further steps that need to be taken to accomplish the intention and aims of this WP. Therefore, meetings will be scheduled to discuss which items should be included in the datasets for local/national databases and for an international Registry of Registries, and what the definitions of those items are. To achieve a registry that is suitable and accessible for all MS, a minimum dataset should be defined with items that can be delivered by all MS. Apart from the minimum dataset a more expanded dataset should also be defined. For this dataset it is not necessary for MS to collect all data. This is the way to accomplish that as many MS as possible can cooperate in a Registry of Registries.

The current techniques that are used within the MS to collect data vary, as expected. By composing an international Registry of Registries, we should not only focus on the dataset and definitions, but also address the technical requirements to make a Registry of Registries work and to make it accessible to every MS. There are several options to develop an international Registry of Registries. Even though a thorough study of these options should take place, the intention should be to work towards a solution that has the most benefits against the lowest costs and efforts. Participating in the Registry of Registries and delivering data should be easy to realize for the MS, preferably by automatically extracting data from existing local/national registries.

On the other side, the management aspects should also be discussed, which for example include an answer to the questions ´Who owns the data´, ´Who is responsible for the data delivery, but also for the quality of the data´, and ´Who should be held responsible for the evaluation of data requests´, et cetera.

The experience gained by previous projects like EFRETOS and EULID may be helpful. By joining forces in a supranational Registry of Registries between the MS it is possible to obtain a large amount of data in order to achieve a better understanding of the impact of living donation on the donor. This understanding will provide the MS with new insights or could lead to new scientific evidence on the aspect of living donation. The access to so much (inter)national data makes it possible for countries, but also for individual centers, to compare their results with other centers and/or MS. Structural feedback is also an aspect that could help centers and countries to anticipate or influence trends and also to improve clinical practice. ACCORD WP 4 will be of great value to achieve this. The more data we can collect, the better research is possible on the long term follow-up of living donors. This research may lead to improving the existing programs and in possible implementation of living donation programs in MS without a LD program yet.

ANNEX 1: QUESTIONNAIRE

QUESTIONNAIRE WP4

A. General information

Participating partner (country) or Collaborating partner	
Name of representative (person who filled in this questionnaire + email address)	

B. Current experience with living donation and living donor follow-up

1. Does your country have experience with living donation? 0 YES, kidney only 0 YES, both kidney and liver 0 NO
2. Does your country systematically gather information on living donor follow-up? 0 YES, kidney only 0 YES, both kidney and liver 0 NO
3. Is this information collected in a digital registry? 0 YES → *if yes, please skip question 4.* 0 NO → *if no, please answer question 4.*
4. If your country does not yet collect data in a digital registry, does your country want to have such a registry? 0 YES → *if yes, please fill out the questions in this questionnaire with a <u>preferred</u> situation in mind* 0 NO
5. Please specify if this is gathered in a national or local registry 0 Local 0 National
6. Is the information from your local registry shared in a national registry? 0 YES 0 NO
7. What was the starting date of data-collection in the registry?

C. Technical specification of the database

8. What kind of database does your country have? 0 Excel 0 Access 0 Oracle 0 DB2 (IBM) 0 SQL Server (Microsoft) 0 Other, please specify……
9. How is this database hosted and by whom? (name + email address)
10. Who is responsible for data collection in the hospitals / transplant centers?

D. Detailed specification on the content of the database

11. Please specify if the following items are collected in your registry, what definitions are used and if these items are mandatory:

Data for evaluation of the donor

Item	**Definition**	**Mandatory Y/N**
Age		
Gender		
Relation type		
Weight		
Length		
Creatinine		
Blood pressure		
Anti hypertensive drugs		

Data concerning the transplantation

Item	Definition	Mandatory Y/N
Operation technique		
Left of right kidney		
Complications during operation		
Blood group		
HLA-type		
EBV		
CMV		
Hepatitis B, C		

Data for follow-up of the donor

Item	Definition	Mandatory Y/N
Weight		
Height		
Creatinine		
Proteinuria		
Blood pressure		
Anti hypertensive drugs		
Complications after operation		

12. What other items does your country collect in a database, what definitions are used and are these items mandatory:

Item	Definition	Mandatory Y/N

13. What other variables, –that are currently not collected in your own database- would you prefer to collect in a(n international) registry of registries?

Item	Definition	Mandatory Y/N

E. Practical information about using the database

14. How many hospitals / transplant centers share their data in your registry?
15. How many donors are yet included in your registry?
16. What is the follow-up frequency for each donor?
17. Please specify the procedure to obtain consent from the donors:
18. Could you estimate the completeness (%) of your registry and describe how your completeness is calculated.
19. Who determines if the request for data from your registry is granted?
20. Is there a specific person responsible for answering (helpdesk) questions about the database, performing statistical analysis, etc? (name + email address)

ANNEX 2: WORK PACKAGE 4 PARTNERS

Associated partners:

- Croatia
- France
- Germany
- Ireland
- Italy
- Latvia
- Lithuania
- Netherlands – project leader
- Norway
- Poland
- Portugal
- Romania
- Spain
- Sweden
- United Kingdom

Collaborating partners:

- Hopital Clinic Universitari of Barcelona
- Eurotransplant
- Scandiatransplant
- European Directorate for the Quality of Medicines and Healthcare (EDQM)
- World Health Organization (WHO)