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ACHIEVING COMPREHENSIVE COORDINATION IN ORGAN DONATION THROUGHOUT THE EUROPEAN UNION: ACCORD

IN THIS ISSUE

INTRODUCTION

The project "Achieving Comprehensive Coordination in Organ Donation throughout the European Union- ACCORD", is a Joint Action (JA) funded by DG SANCO (European Commission).

With a duration of 42 months, the project lifetime extends from May 2012 to November 2015. Developed by a Consortium of 23 Associated Partners and 10 Collaborating Partners, this JA is led by the Spanish National Transplant Organization (ONT).

The main goal of the project is identifying common procedures regarding coordination of deceased donation, registries for living donor follow ups and organizational issues.

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MANAGEMENT

WP1 is aimed to manage and coordinate the project and make sure that it is implemented as planned, managed following the European Commission´s rules and procedures, and funded through a correct distribution, execution and justification.

During the whole ACCORD JA and in its role of Coordinator, ONT has to:

1. *Coordinate the project:* leading the design of the work packages (WPs) in close collaboration with the corresponding WPs leaders, supervising vertically the work carried out in each WP, assuring the expected deadlines are met and high quality deliverables are produced, assuring permanent exchange of information on WP progress, monitoring transversally the participation of each partner and continuously ensuring the balancing of the activities.

2. *Guarantee quality working procedures,* oriented to results and aims, transparent and balanced within the transnational consortium: designing a General Working Plan for the JA and coordinating specific working plans within each WP, assuring a permanent and transparent communication within the transnational consortium, and dynamizing the JA implementation, motivating all partner organizations for assuring a balanced participation; organizing transnational and coordination meetings.

During the first year, in its role of coordinator, ONT has performed the following tasks:

• *Establishment of project working bodies and procedures.* Different roles comprise a variety of actions: Project director, ONT director - with the overall responsibility for the whole JA, Coordination Unit, constituted by ONT staff monitors the progress of the JA, establishes communication with the WP Steering Committee on a regular basis and reports to the Director of the JA; Project Committee, constituted by all partners involved in the Consortium – main decision making body, WPs Steering Committee, composed of the members of the coordination unit and the leaders of the WPs – operational group in representation of the entire consortium.

• *Development of the Consortium Agreement* including all the commitments in terms of technical and financial aspects, as well as communication procedures, signed by all associated partners.

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• *Production of a Manual for the financial and administrative management of the JA,* where the different reporting periods have been defined, along with the management rules and procedures.

• *Creation of a web based platform* for facilitating the internal communication among the partners and for dissemination purposes.

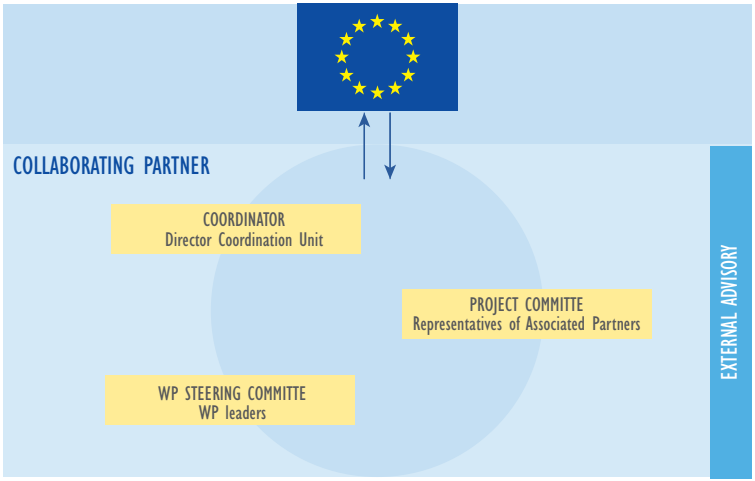

FIG. 1 SCHEME OF ACCORD ACTION MANAGEMENT

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EVALUATIONN

Lead by the Spanish National Transplant Organization (ONT), the aim of the Evaluation work package (WP) is to assure and verify that ACCORD is implemented as planned and that it accomplishes the defined objectives. The WP has also to assure that the produced knowledge and outcomes meet high quality standards, are visible and have a relevant impact.

• The evaluation strategy of the JA has been structured in three main elements:

• An Evaluation System focussed on project processes.

• An External Advisory Board (EAB) focussed on results' quality and future impact of the deliverables produced.

• A comprehensive final evaluation report on both, the project execution and the quality and potential impact of the outcomes.

1. The Evaluation System, is oriented on results and follow-up, with two components:

- a periodic collection of information on the developed activities within the WPs, through the WP leaders, on a half yearly basis;
- an annual report on the progress of the project, including information on the accomplishment of objectives and on any detected deviation. This report mainly aims at including proposals for Improvements Implementation.

2. The EAB is composed by three world-wide recognized experts in the field of organ donation and transplantation: Francis L. Delmonico, MD, President of The Transplantation Society; Peter Doyle, MD, United Kingdom and Philippe Morel, MD, Head of the Visceral and Transplantation Surgery at the University Hospitals of Geneva. The EAB aims at assuring and improving the quality of the produced work and the impact of the results and outcomes of ACCORD.
To that end, the EAB: is participating at the general meetings, is reviewing the main deliverables of core WP (4, 5 and 6) to contribute to improve them with comments, suggestions, recommendations, etc… and will elaborate a final report on quality and impact of the JA results.

3. A final evaluation will be developed to analyze aims accomplishment, achievement of foreseen objectives, produc-

tion of deliverables, accomplishment of working plans, the correct running of transnational communication and coordination, the adequacy of working procedures, the success on implementation of proposed improvements, the dissemination and distribution of the results of the project and, in particular, the transferability and applicability of the results.

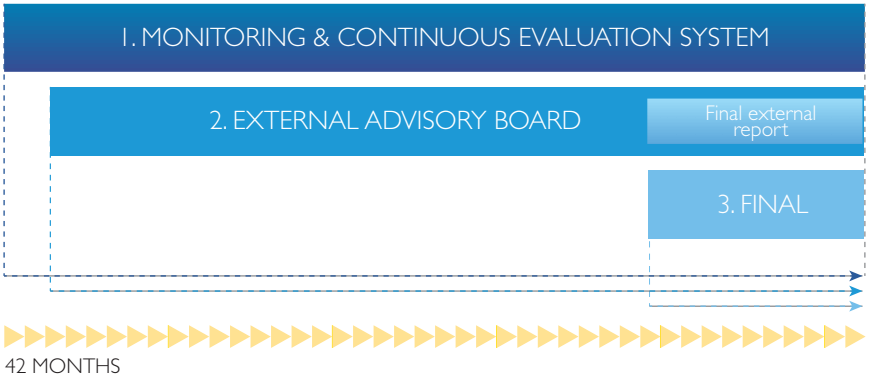

FIG. 2 SCHEME OF EVALUATION WORKPACKAGE TIME SCHEDULE

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Living Donor Registries

Objective: to provide recommendations on the implementation of live donor registries and to set down a model for supranational data sharing. (WP Leader: the Dutch Transplant Foundation, the Netherlands).

During the past year, the participating and collaborating partners of WP4 met three times. The first meeting was the kick-off meeting in Madrid where they set the goals and the working plan for the work package. In the summer of 2012, a questionnaire was sent to every partner to collect information on the current status of living donation and the experience with living donor registries. The information from the questionnaire was processed into the first deliverable: a 'Report on the current experience with living donation and living donor registries'.

In November 2012 a second meeting took place in Amsterdam. During this meeting they agreed upon the mandatory and optional datasets for the national living donor registries (kidney and liver) and the datasets for the supranational registry of registries for living donors.

During the third WP4 meeting on February 5th 2013 in Amsterdam, they defined the data dictionary. The data set, data dictionary and glossary of terms were delivered in May 2013.

Next challenge is to describe the governing, operational and technical requirements enabling to start the pilot period and to, eventually, come with recommendations for national living donor follow-up registries and a supranational living donor registry of registries.

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Planned activities

1. Description of existing live donor registries.

2. Elaboration of a report on the state of the art.

3. Definition of a minimum and expanded data set and elaboration of a data dictionary for national live donor registries and for a supra-national registry of live donor registries

Purposes ans plans

The purpose of the very first activity of WP4 was to elaborate a map of existing live donor registries in Europe. With this aim, the DTF, as WP4 leader, planned and implemented a set of necessary actions:

• Organization of WP meetings, including the presentation of national practices on live donation and live donor registries in Europe.

• Elaboration of a Questionnaire on Live Donation and Live Donor Registries to be filled in by the Associated and Collaborating Partners.

• Coordination of the feed-back received from Associated and Collaborating Partners through the questionnaire. A total of 13 Work-package 4 partners completed the questionnaire.

• Elaboration of a draft Report on the current experience with living donation and living donor registries. (Deliverable 5).

• Assessment of the feed-back information received from Associated and Collaborating Partners and the EAB on the draft report and preparation of a final version of the Report on the current experience with living donation and living donor registries. (Deliverable 5).

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Participants:

DTF (Netherlands)
WP 4 leader

MOSHSW (Croatia)
ABM (France)
DSO (Germany)
ISS-CNT (Italy)
PSCUH (Latvia)
NTB (Lithuania)
HDIR (Norway)
Poltransplant (Poland)
IPST (Portugal)
ANT (Romania)
NHSBT (UK)
ONT (Spain)

Activities developed

It was concluded from the questionnaires that quite a lot of experience with living donation has been gained so far within the EU. Every WP4 partner that responded on the questionnaire (13) has a living kidney donor program. The emphasis is clearly on living kidney donation; only eight Member States (MS) and one collaborating partner also have experience with living liver donation. However, the (digital) registration of living donor follow-up is not yet implemented in every MS. Seven MS and two collaborating partners already collect their (follow-up) data in a digital registry. The number of donors included as well as –for example- the follow-up frequency varies between the different registries. There is a great challenge in harmonizing the data collection in a supranational Registry of registries.

In addition to the first deliverable, the Associated Partners involved in this WP have developed several tasks:

- Description of variables, including definitions and coding at their corresponding national registries.
- Description of governing, operational and technical rules applied at their national registries.
- Contribution with the provision of the relevant information to the Questionnaire on Living Donation and Living Donation Registry. Reactions received from: Croatia, France, Germany, Italy, Latvia, Lithuania, Netherlands, Norway, Romania, Spain, and United Kingdom (Scandiatransplant and Hospital Clinic Universitari of Barcelona (EULID) also contributed as Collaborating Partners).
- Contribution to the draft Report on the current experience with living donation and living donor registries (Deliverable 5), prepared by the DTF. Participation in the discussions and the WP meeting held in Madrid (1st of June, 2012), where Associated Partners presented their experience with live donor registries.

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The preparation of recommendations for a national live donor registry and for setting down the basis for a supra-national registry of live donor registries started with the definition of a minimum and an expanded data set of variables and a related data dictionary. This was to be built based on what currently exists as reflected in Deliverable 5 and on expert discussions and debates with (transplant) nephrologists, surgeons and transplant professionals from WP4 MS and collaborative partners. Such discussions were maintained at two dedicated WP meetings:

• **27-11-2012 Amsterdam:** The objective of this meeting was to come to a data set (minimum and expanded) for national Live Donor Registries and for a supra-national registry of Live Donor Registries. The input from the questionnaire was used to compose a long list with possible variables. This list was used as input for the discussion during the meeting. It was agreed upon to distinguish a mandatory data set from an optional data set, both for kidney and liver donor follow-up. Eventually it was decided to create four data sets with mandatory and optional items: a national kidney data set, a supranational kidney data set, a national liver data set and a supranational liver data set.

The classification of data collection for every data set is as follows:

1. Donor demographic information
2. Pre-donation information
3. Peri - and post-operative information (until discharge)
4. Follow-up data

The following items are agreed upon:

KIDNEY	
Donor demographic information	Identification (M)*, Date of birth (O)**, Age (M), Gender (M), Weight (M), Height (M), Blood group (M), Address (O)[1], Country of residence (M), Nationality (M), Ethnicity (O)
Pre-donation data	Relation type (M), Blood pressure (O)[1], Hypertension (O)[1], Antihypertensive treatment (M), Creatinine (M), Proteinuria (M), Any significant co-morbidity (M)
Peri-and post-operative data	Donor hospital (center) name(M)[1], Country of donor hospital (M), Date of donation (M), Left or right kidney (M), Operation technique (M), Complications during operation (M), Complications after operation (until first discharge) (M), Length of hospital stay (O)[2], Number of days in ICU (O)[2].
Follow-up data	Follow-up center (M)[1], Date of follow-up (M), Donor lost to follow-up (M), Death (M), Cause of death (M), Date of death (M), Weight (M), Blood pressure (O)[1], Hypertension (O)[1], Antihypertensive treatment (M), Creatinine (M), Proteinuria

[1] *Only for national database, not in Registry of registries*
[2] *Recommended by External Advisory Board*
* *Mandatory*
** *Optional*

LIVER	
Donor demographic information	Identification (M), Date of birth (O), Age (M), Gender (M), Weight (M), Height (M), Blood group (M), Address (O)1, Country of residence (M), Nationality (M), Ethnicity (O)
Pre-donation data	Relation type (M), Any significant co-morbidity (M)
Peri-and post-operative data	Donor hospital (center) name(M) 1, Country of donor hospital (M), Date of donation (M), Segment donated (M), Percentage of remnant donor liver (M), Complications during operation (M), Complications after operation (until first discharge) (M), Length of hospital stay (O)2, Number of days in ICU (O)2
Follow-up data	Follow-up center (M) 1, Date of follow-up (M), Donor lost to follow-up (M), Death (M), Cause of death (M), Date of death (M), Weight (M), Max. bilirubin (M), Max. INR (M), AST (M), ALT (M), GGT (M), Platelets (M), Complication (within the first 12 months) (M), Readmission (within the first 12 months) (M), Health issues (M), Did the donor return to previous activity level (O)

An annual follow-up is recommended. Follow-up after 1 year and every 5 years after donation is mandatory.

• **05-02-2013 Amsterdam:** This meeting was used for further contribution to the decision on the minimum and expanded data set of variables for a national and supra-national live donor registry, and related data dictionary. Again the input from the questionnaire was used to suggest possible definitions for the items. Extensive discussions lead to the eventual data dictionary. In some occasions the definitions for the national databases (kidney and liver) differ from the definitions that will be used for the Registry of registries. In these cases the 'national' definitions are more detailed. Of course in these cases it is necessary that the databases can communicate with each other and the definitions can correspond.

As well for the data set as for the data definitions, additional input was requested by the DTF to national liver expert groups that were convened by the different Associated Partners.

The activities as mentioned above allowed the DTF to draft part of the next deliverable of WP 4 (Recommendations for the development of a Live Donor registry and for setting up a European Union registry of Live Donor registries. Report on pilot study- Deliverable 6): a description of a Data set and Data Dictionary for national live donor registries and for a supranational registry of live donor registries. The Associated Partners have also contributed to the preparation of a more advanced version of the draft which is now receiving comments from the members of the EAB.

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Activity results: deliverables and achievements

1. Report on the current experience with living donation and living donor registries (Deliverable 5).

2. Four different data sets with mandatory and optional items: national kidney, supranational kidney , national liver and supranational liver.

3. Data definitions for the items in each data set.

4. Report on Data set and Data Dictionary for National Registries and Supranational Registry of Registries. Part of the content of Recommendations for the development of a living donor registry and for setting up a EU registry of living donor registries. Report on pilot study (Deliverable 6).

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Aims:

The aim of Work Package 5 (WP5) of the ACCORD Project is to increase the availability of organs from deceased donors by strengthening the cooperation between intensive care units (ICU) and donor transplant coordinators (DTC).

The specific aims of the project are:

1. To describe the usual pathways applied to patients with a devastating brain injury and to explore their impact on the potential of donation and on the realisation of the deceased donation process across the European Union (EU) countries.

2. To develop and prove by implementation an acceptable and effective rapid improvement toolkit that supports modifications in end-of-life management that promote donation, adapted to each identified end-of-life care model.

Participation:

There are 72 hospitals, spread across 15 Member States, participating in the review of variations in end-of-life care pathways for patients presenting with a devastating brain injury. The map (Figure 1) demonstrates the geographical spread of the participating hospitals.

Figure 1: Location of hospitals participating in WP5

Note[1]: there are 4 hospitals participating in Lithuania, two of which are located in Vilnius.

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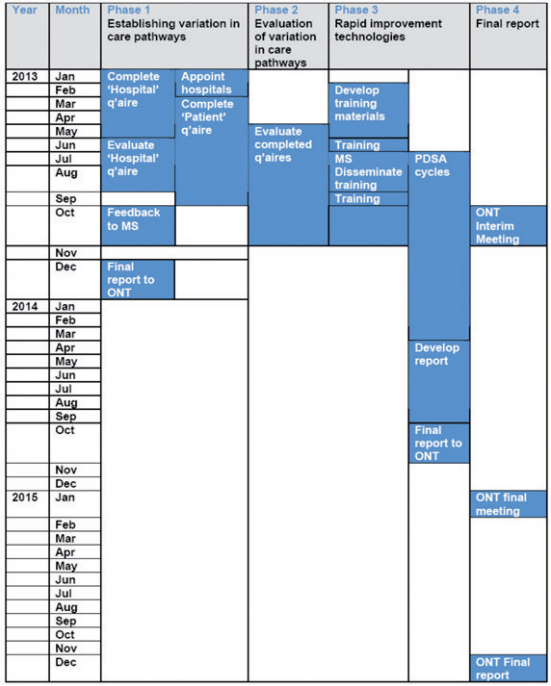
Methodology:

Work Package 5 is separated out into four main phases:

- **Phase 1**: Study of variations in end of life care practices for patients with devastating injury
- **Phase 2**: Evaluation of variation in care pathways
- **Phase 3**: Rapid improvement technologies
- **Phase 4**: Final report

Figure 2 shows the broad timescales for Work Package 5.

Figure 2: Timescales for ACCORD Work Package 5



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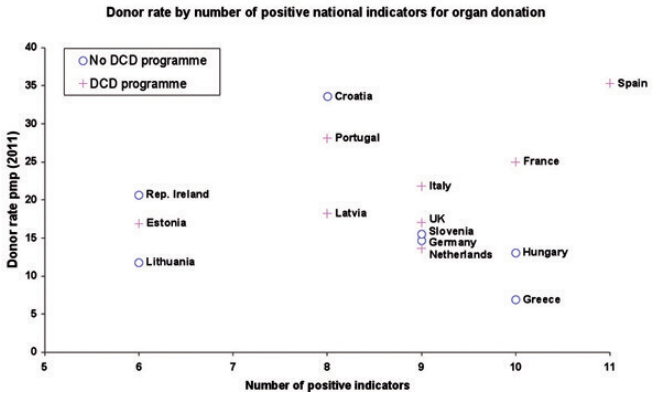
Phase 1 & 2: Study and evaluation of variations in end of life care practices for patients with devastating injury.

Phases 1 and 2 comprise of a study in the variations in practice in the end of life care for patients who die following a devastating brain injury. This comprised of a series of 3 questionnaires:

1. Country questionnaire: to examine variations in policy, law and ethics in each participating Member State. The country questionnaires have been completed and the results analysed by the WP5 project team (Figure 3).

Figure 1: Location of hospitals participating in WP5



The graph demonstrates numbers of donor's pmp against a number of positive national indicators for each country determined in the questionnaire. Examples of the positive indicators were existence of legal definitions for death, professional guidance for clinicians involved with organ donation, independent ethical guidance and provision of formal training for healthcare professionals in the organ donation process.

2. Hospital questionnaire: to examine variation in the availability of resources to facilitate the organ donation process.

3. Patient questionnaire: to examine variation in the end of life care that a patient has received who is dying from a brain injury and the impact that care has on the potential for organ donation.

Copies of these questionnaires are available on the WP5 page of the ACCORD website at http://www.accord-ja.eu/

The impact of any differences in end-of-life care on the potential for organ donation, and on the number of potential donors who actually go on to donate, will be explored. This analysis of the questionnaires will provide a steer for hospitals to identify local barriers to organ donation and to explore how those barriers could be overcome and co-operation/ consultation between clinicians and donor transplant coordinators could be improved.

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Phase 3: Rapid Improvement Technologies

Using the analysis of data provided in Phases 1 and 2, hospitals will be trained in 'Service Improvement' and 'Plan, Do, Study, Act' (PDSA) methodology. The aim of this phase is to enable ICU clinicians, DTCs and any other relevant people within each hospital to examine the data provided and explore what could be done to address potential barriers to donation, focussing on small-scale changes that have the potential to deliver increases in organ donation. Further information about this methodology can be found at: www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/plan_do_study_act.html

Three training days on Service Improvement methodology have been planned between June and September 2013, to which representatives from each of the seventy one participating hospitals have been invited. Following the training sessions, participating hospitals are asked to work with the WP5 Project Lead in their country and senior clinicians, to identify and implement service improvement plans and put in place 'PDSA' cycles. Data will be captured throughout this process, to demonstrate the impact of the PDSA cycle.

Phase 4: Final report

Analysis will be undertaken of the various PDSA cycles introduced and the effectiveness of this approach, along with the development of a service improvement toolkit, to enable other hospitals to adopt service improvement methodology after the ACCORD Joint Action has closed.

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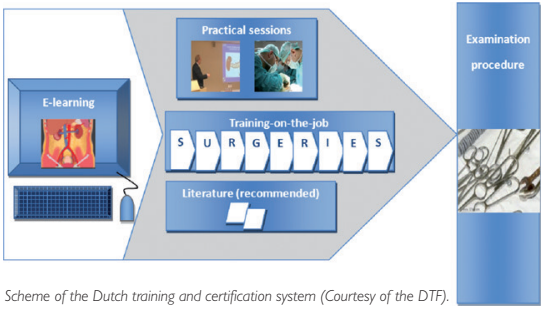
Twinning in Organ Donation and Transplantation

Twinning activities led by the Agency of biomedicine in France consist in providing direct support to Member States from one to another by the mean of practical collaborations on the lines of the EU "Action Plan on Organ Donation and Transplantation" (2009-2015) Plan and the "Organ Directive 2010/53/EU". Thanks to this concrete transfer of expertise, the overall aim is to enhance day to day supported Member States efficiency of organ donation and transplantation system. Supported Member States seeking developments identified areas of interest and collaboration was organized with a supporting Member States showing extensive experience in the targeted area. Finally, three different twinnings were programmed.

Twinning to develop a training programme for organ procurements in Hungary

With The Netherlands as the supporting country: the Dutch Transplant Foundation (DTF) as the main partner (in collaboration with the Universities Medical Centre of Leiden & Groningen, and ESOT) and Hungary as the supported country: the Hungarian National Blood Transfusion Service (HNBTS) more specifically the Organ Coordination Office (in collaboration with the surgeons from Semmelweis University). The first aim of this twinning is to set up a National training programme in organ procurement in Hungary, increasing safety and quality criteria of organs to be transplanted; with the broader potential to have a new international training tool available at EU level for other Member States. In the Netherlands, the curriculum for organ recovery surgeons entails: an e-learning platform, practical (hands-on) sessions and a set of procurements from a deceased donor to perform either as a main surgeon or as an assistant, and a final examination procedure prior to the certification.



Scheme of the Dutch training and certification system (Courtesy of the DTF).

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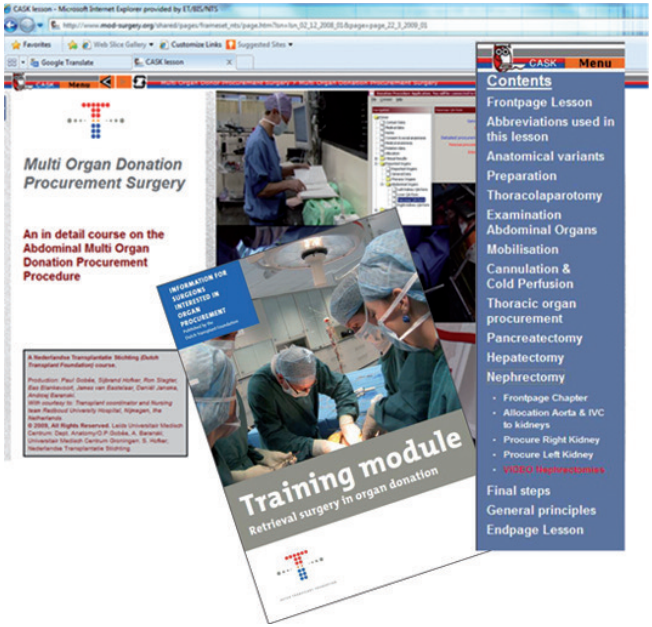
In order to reach the aim of this twinning, the Dutch IT tools had to be modified to be suitable for all browsers and tablets, and translated into English.



View of the adapted Dutch e-learning content and training module guide (courtesy of DTF and partners).

Then the 6 Hungarian surgeons (3 juniors and 3 seniors, who could in turn teach) followed the training for liver, kidney and pancreas procurements. Additionally, the Hungarian surgeons completed the first practical session and evaluated information provided by the e-learning platform. As a complement, in order to gather wider opinions, 47 UK surgeons also played the game and evaluated the IT tool. Similar appreciations were collected such as: "Learned a lot/considerable amount", "Really helpful to get a broader view on organ procurement", "Good to excellent level", "updated procedures", "Well balanced between theory and active elements", "Easy to use", "time dedicated to learning was just right" (...). Additionally, testers issued valuable recommendations to even further improve the platform. Keeping on schedule, the Hungarian surgeons followed the first practical (hands-on) session (see picture beside).

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The first practical (hands-on) session organized in The Netherlands, Hungarian surgeons on the right (Courtesy of the DFT and partners).

In parallel and as a complement to their training, the participating Hungarian surgeons started to report the list of organ retrieval procedures already performed either as a main surgeon or as an assistant. At that stage, the effective and perennial implementation of this training system is under discussion in Hungary for the organisation, administration, nomination of training professors, conditions for candidates' admission etc.

One year after the beginning of this twinning, the e-learning and the first practical session have been completed already and the training-on-the-job procedures are on-going. At the end of the year, the second hands-on session will be held in Hungary, and the Hungarian surgeons will be evaluated by the Dutch trainers. This opportunity will be also seized to introduce this training programme to a broader assembly of Hungarian surgeons. Finally, it is noteworthy that some other Member States already showed interest for this training tool.

Twinning to develop the Bulgarian Transplant system

agence de la biomédecine → РЕПУБЛИКА БЪЛГАРИЯ Изпълнителна агенция по трансплантация Министерство на здравеопазването

With France as the supporting country: the Agency of biomedicine (and the transplant team of Robert Debré Hospital in Paris), and Bulgaria as the supported country: the Executive Agency for Transplantation (and the transplant team of Pirogov Hospital in Sofia).

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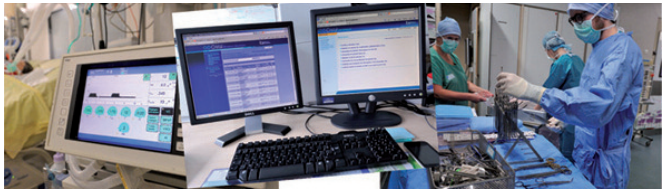
The aim of this twinning is to support the development and organization of the organ procurement system at national and regional levels and to support paediatric kidney transplantations through the completion of the training of the Bulgarian transplant team. Regarding this latter, the surgical and care training started a few years ago already but could unfortunately not be completed at that time. Thanks to this twinning, it had the opportunity to be carried on. According to the previous evaluation, in order to be fully autonomous, the Bulgarian team has to be supported by the same French transplant team for 3 additional transplantations.



(Photos of French facilities, ©Benoit Rajau for the Agency of biomedicine).

Onsite visits of procurement and transplant centres in Bulgaria and in France were carried on and allowed the French experts to assess the needs of their partners, and Bulgarian experts could experience steps and procedures of the French donation, procurement, allocation and transplant system. Twinning visits also greatly helped the Bulgarian partners to measure the potential for the development of the Bulgarian system and more importantly of key elements to be implemented in priority.

Starting from the beginning, in order to organize the Bulgarian procurement system, onsite visits highlighted that practical tools and guidance were required. As a first step, a profile and tasks

(Photos of French facilities, ©Benoit Rajau for the Agency of biomedicine).

of the hospital donation coordinator were drafted and acted. Then special attention focused on Standard Operating Procedures (SOPs) that are compulsory for the processing of an efficient system, notably ensuring harmonization, compliance with regulation and higher quality and security criteria. These procedures are step by step detailed explanations on the tasks to be performed. It entails all considerations for actions and actors: whom, when, where, with which material if necessary and how it has to be executed. These SOPs are to be distributed to targeted Units of all sites and to be available for employees.

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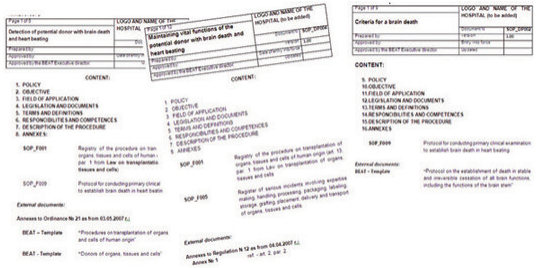

To date, SOPs have been focusing on:

- "Detection of potential donor with brain death and heart beating": covering activities related to detection of a potential donor in all hospitals;

- "Criteria of brain death": a protocol for conducting primary clinical examination to establish the brain death diagnosis (irreversible cessation of brain functions) for heart beating potential donors;

- "Maintaining vital functions of the potential donor with brain death and heart beating": dealing with activities related to the maintenance of vital functions of the potential donor with brain death in the presence of cardiac activity. These SOPs are mainly directed at the key personnel of Anasthesiology Units, Intensive Care Units and of the Department of Neurology.

The complementary SOPs for the "Family approach", the "Clinical donor selection", the "Organs characterisation/qualification", and for the "Declaration of Serious and Adverse Events and Reactions" will shortly follow. These SOPs will provide direction and structure and will be of high value for the organisation of the donation and procurement system.

Regarding the support of the paediatric kidney transplantation, patient cases were discussed during a first meeting of both transplant teams in Sofia. Two children were eligible for transplantations (a 13 year-old boy who is currently under haemodialysis, the kidney living donor is his 34 year-old father; a 10 year-old girl who is currently under peritoneal dialysis, the kidney living donor is her 39 year-old mother).

The first transplantation is programmed for the beginning of July. The last medical tests and verifications are currently under process. Additionally, the French partners prepared documents to be compiled in a guide and distributed to the personnel involved in the living kidney transplantation.

This guide deals with paediatric drugs, medical equipment and devices as well as a nursing protocol for paediatric kidney transplantation.

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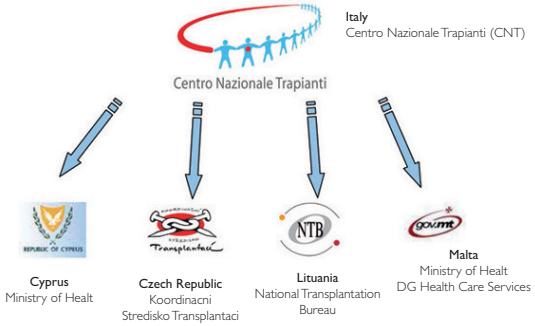
These documents shall be updated following this first transplantation, in accordance with further detected needs and will be translated into Bulgarian. This guide could even be distributed more widely in Bulgaria.

In 2011, none of the paediatrics patients (<15 years old) were transplanted in Bulgaria and in total for all organs: 25 patients were transplanted (for 4755 in France; 2012 Newsletter Transplant). This twinning is aiming at developing the overall Bulgarian system of Organ Donation and Transplantation, focusing on organ donation and retrieval from deceased donors and is as well aiming at providing to children an access to kidney transplantation. To sustain perennial activities, of course more than this framework is required among which: funding, communication to the public at large to restore a positive attitude towards organ donation and transplantation and towards the health care system, etc. Nonetheless, this twinning gave a new impulse to Bulgaria and raised awareness. This twinning brings concrete support to a Member State seeking to develop its organ donation and transplantation system and showing a need to be supported, which was indeed the all-purpose of these twinning activities.

Twinning to develop an Authorization and Audit system for Transplant Centres



With Italy as the supporting country and Cyprus, Czech Republic, Lithuania and Malta as supported countries. This twinning is aiming at developing of an authorization and audit system for Transplant Centre, based on the Italian model but adapted to each National Health Systems in place in supported countries, taking into account potential local issues.

Funded by the European Commission

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(Photos: ©Benoit Rajau for the Agency of biomedicine)

To start with, each supported country reported on national current status of: i) legislation (in place and expected due to the transposition of Directive 2010/53/EU), ii) designated Competent Authority or delegated organisation for organ donation and transplantation (structure, role and tasks), iii) existing National Audit System if any (Who? When? How? What?), iv) evaluation process in place if any (quality indicators, data collection and analysis, routine inspections, Vigilance and Surveillance), v) all authorized Transplant Centres (name, type, year of authorization), and last but not least: vi) strengths and weaknesses of their system in place, areas for improvement, and potential obstacles for implementing a new system. These National reports not only allowed evaluation and comparison of supported countries, but also facilitated harmonization and enabled the Italian partner to design the Guide on Essentials for developing Authorization and Audit systems for Transplant Centre.

(Photos: ©Benoit Rajau for the Agency of biomedicine)

This guide deals with Authorization procedures, Evaluation of transplant outcomes, Vigilance system, reporting of adverse events and reactions and of course with Auditing. Additionally, it also includes 2 technical annexes with list of aspects to be considered when alternatively auditing Kidney or Liver transplant centres. Importantly, this Guide is to be easily adapted to every Member State.

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Since further analysis on more practical aspects is required to have a complete picture of each National system, onsite Twinning visits of Transplant Centre have been scheduled in July 2013 by the supporting country, sending the Italian experts to evaluate each supported country. These onsite visits will be the opportunity for a first evaluation, verification to compliance and for recommendations. Moreover, the Italian experts shall also visit the designated Competent Authority or delegated organisation, seizing this opportunity to highlight the need for implementing the Directive requirements at officials' level.

The e-learning will be hosted on the CNT's distance learning platform and accessible through the Internet at: http://www.cntfad.org (free of charge).

In parallel, the Italian partner has set up a team of inspectors and auditing experts for the design of the e-learning training programme for National Inspectors/Auditors nominated by the supported countries. This platform shall also entail relevant and informative documents and guides. Future inspectors and auditors training through this platform will also perform a virtual audit and be evaluated by the Italian experts.

As a complement, Italy is supporting twinners in transferring and adjusting the proposed authorization and audit system to their local needs. When more advanced, before the end of the twinning, joint inspections composed of nonnational/ external auditors will be performed in supported countries, to validate the new system. In this regard, since some twinners are developing their transplant system, adopting a strictly National audition would lead to self-evaluation; in order to avoid any potential conflict of interest this proposition of joint inspection was adopted.

This multiplet twinning is facilitating the implementation of the "Organ Directive" and is concretely promoting more harmonized practices and processes among the supported Member States. Furthermore, since this Guide of Essentials for Developing an Authorization

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and Audit System for Transplant Centres is to be easily adapted to every National Health system within the EU, it has the potential to be widely distributed and adopted by other member States, and so could be the e-learning training programme for inspectors and auditors.

Added value of Twinning activities

The first aim of Twinning activities is to develop Donation and Transplantation system in a Member State seeking to implement or improve a targeted area, thanks to a concrete and direct transfer of expertise from a supporting Member State. Nevertheless, developed tools have the potential to be shared at EU level and adopted by other Member States. Additionally, on the top of reporting results of twinning activities in a Deliverable, the Agency of biomedicine and the Twinners shall as well generate a Twinning Guide building up on the experience gained through twinning activities by pairs and by multiplet. This guide is aiming at facilitating new initiatives once the ACCORD Joint Action will be completed.

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