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

CURRENT ACTIVITIES:

LIVING DONOR REGISTRIES

STRENGTHENING THE COOPERATION BETWEEN CRITICAL CARE PROFESSIONAL AND DONOR TRANSPLANT COORDINATORS

TWINNINGS

COORDINATED BY ONT, SPAIN
ACHIEVING COMPREHENSIVE COORDINATION IN ORGAN DONATION THROUGHOUT THE EUROPEAN UNION: ACCORD

The project ‘Achieving Comprehensive Coordination in Organ Donation throughout the European Union’ (ACCORD) is a Joint Action co-funded by the European Commission and a consortium composed of 23 Associated Partners (Figure 1) lead by the Oragnización Nacional de Trasplantes - ONT (Spain). The project further counts on the participation of 10 Collaborating Partners inclusive of the Council of Europe and the World Health Organization. The project started in May 2012 and will finish soon, in October 2015. A final dissemination event is planned for June 2nd, 2015 in Madrid (Spain).

ACCORD emerges in a European Union where countries are not able to cope with the transplantation needs of their patients, and with extraordinary variable rates of both living and deceased organ donation. The project is developed within a community determined to build on common standards for the quality and safety of human organs intended for transplantation, as made evident by Directive 2010/53/EU.

1 World Health Organization, Council of Europe (European Directorate for the Quality of Medicines and Health Care, European Hospital And Healthcare Federation (HOPE), European Society Of Intensive Care Medicine (ESICM), European Donation and Transplant Coordination Organization (EDTCO), Eurotransplant, Scandiatransplant, Hospital Clinic of Barcelona (Spain), Organisation des Établissements de Soins (Belgium), University Clinic of Gent (Austria).
ACCORD aims at strengthening the full potential of Member States in the field of organ donation and transplantation, by improving the cooperation between these countries and by contributing to the effective implementation of both, the Directive 2010/53/EU and the Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States.

ACCORD has three main objectives, each representing a specific area of work:

1. To improve the information systems of European Union Member States on living organ donation, particularly through the provision of recommendations for national Living Donor Registries and through setting down a model for supranational data sharing in this field.

2. To facilitate the cooperation between two professional groups, critical care professionals and donor transplant coordinators, in order to optimize the realization of the process of donation after death.


The project is structured in 6 different Work Packages (WPs), three horizontal WPs (1, 2 and 3) and three core WPs (4, 5 and 6). Each core WP is targeted to each of the main objectives of ACCORD. The specific objectives of each WP and its leader is detailed below:

- **WP1** - Coordination: To manage the project and to make sure that it is implemented as planned. Leader: Organización Nacional de Trasplantes, Spain.

- **WP2** - Dissemination: To ensure that the results and deliverables of the project are made available in the most appropriate manner to the relevant stakeholders. Leader: ISS-Centro Nazionale Trapianti, Italy.
• **WP 3** - Evaluation: To verify that the project is implemented as planned, reaches its objectives and is sustainable and with a potential high impact. Leader: Organización Nacional de Trasplantes, Spain.

• **WP 4** - Living Donor Registries: To provide recommendations for the design, development and management of national Living Donor Registries. Moreover, it intends to set down a model for supranational data sharing in this field creating the basis for a European Registry of (national) Living Donor Registries (that will be piloted). Leader: Dutch Transplant Foundation, The Netherlands.

• **WP 5** - Cooperation between Critical Care professionals and Donor Transplant Coordinators: To analyse end-of-life practices applied to patients with a devastating brain injury across the European Union and to assess their impact on organ donation. The WP intends to go practical through the provision of a rapid improvement methodology (Plan Do Study Act) for strengthening cooperation between the two targeted professional groups. Leader: NHS Blood and Transplant, United Kingdom.

• **WP 6** - Twinnings: To implement specific collaboration initiatives between European Union countries in the area of organ donation and transplantation according to national priority actions and based on comprehensive and specifically designed protocols. Based on the experience acquired, it is intended to develop guidelines for future twinnings initiatives. Leader: Agence de la biomédecine, France.

This Newsletter provides an overview of the activities developed during the ACCORD project until December 2014 and its achievements.
ACCOMPLISHING COMPREHENSIVE COORDINATION IN ORGAN DONATION THROUGHOUT THE EUROPEAN UNION: ACCORD

FOREWORD FROM DR. RAFAEL MATESANZ, DIRECTOR OF ACCORD

Cooperation in donation and transplantation in Europe has a long history. It is fair to highlight the important contribution of the Council of Europe through its Committee of Transplantation to this field, by setting down common standards, facilitating the exchange of best practices and promoting international benchmarking. The role of the European Union in this particular area of health care was set down in article 168 of the Treaty on the Functioning of the European Union. The Community has since then promoted an impressive number of very relevant projects that have been critical in building knowledge, sharing expertise and creating a very solid network of Competent Authorities. Having personally participated of all this activity since the early nineties, I must say that ACCORD can already be recognized as a landmark project for a number of reasons.

First, because of its comprehensiveness. The project has addressed the three challenges already identified by the European Commission in the field of organ donation and transplantation: the limited organ availability, the unequal effectiveness of transplantation systems, and the lack of common quality and safety standards for organs intended to be used for transplantation.

Second, because the project has been practical, confronting real problems with effective solutions. Let me provide you with some examples of what we have been able to achieve with ACCORD.

Several countries are already embarked in creating their national Living Donor Registries (or modifying their already existing Living Donor Registry) by taking into account the standards and recommendations that have been provided during the project lifetime. Spain has launched a national programme inspired in the work carried out in WP5, but with tools and questionnaires adapted to our local needs. Seventy one hospitals across the country are participating in what we have named ‘ACCORD Spain’, collecting information about the outcome of persons dead as a result of a devastating brain injury, and ready to receive training in the PDSA methodology and to undertake PDSA cycles for rapid improvements in the process of donation after death.
Some of the tools that have been generated during the twinnings (Italy supporting Czech Republic, Cyprus, Lithuania and Malta to build a system for accrediting and auditing transplant centres, the Netherlands supporting Hungary in the development of a national curriculum and accreditation programme for organ procurement surgeons and France supporting Bulgaria in structuring its donation and transplantation system) are being left as extraordinarily useful tools for many other European countries.

All these achievements will be presented in detail at the final public conference of the project that will be held in June 2nd, 2015 in Madrid (Spain). You are all invited to attend. It will be three years after we held the kick-off meeting of this project. We started then with commitment and enthusiasm, and as you will see we are going to be able to finish with pride, because ACCORD can really make a change in Europe. Allow me to take advantage of this space to thank all partners to the project, without whom nothing would have been possible. Very particularly, I would like to thank all WP leaders for the impressive work performed. I would also like to deeply thank the members of the External Advisory Board for their dedication to ensure the good quality of the products deriving from ACCORD. For me personally, it has been an honour to lead this project and to lead this fantastic group.

Rafael Matesanz
Supporting the development of Living Donor Registries and promoting International Data sharing on the impact of donating an organ during lifetime

Key Messages

Living donation is expanding in the European Union contributing to increasing the number of organs available for transplantation. A holistic approach to the protection of living donors is a fundamental pillar of these programs and is grounded on existing international standards, as Directive 2010/53/EU. This Directive sets down the obligation of Member States to develop a system for the collection of data on the outcome and the eventual complications related with living organ donation.

ACCORD has reviewed the current situation of living donation and living donor follow-up in Europe, with a detailed report on the experience available (http://www.accord-ja.eu/sites/default/files/download_documents/Experience_with_Living_Donation.pdf).

Based on the existing knowledge and expert opinion, recommendations have been produced for the development and consolidation of living donor registries including the data set and data dictionary for these registries and the technical, organizational and governance requirements (http://www.accord-ja.eu/sites/default/files/download_documents/ACCORD%20WP%204%20FINAL%20Data%20set%20and%20dictionary.pdf).

Recommendations have also been provided for the construction of a European Registry of Living Donor Registries, which have recently been piloted. Nine countries have provided information on the 1 year follow-up of persons who donated a kidney during the years 2010 and 2011, collected through a secured central web site. In the upcoming months, ACCORD will produce a report describing the experience with this pilot, leading to recommendations for the creation of a Supranational Living Donor Registry in Europe which will help to increase the evidence on the risks of donating an organ during life time.
A report on the current experience with living donation and living donor follow-up was the first Milestone of Work Package (WP) 4 (http://www.accord-ja.eu/sites/default/files/download_documents/Experience_with_Living_Donation.pdf). The second Milestone was the development of a common data set and data dictionary for national and international living donor registries. Especially this data set was a great achievement and even in this situation where the project is not yet finalized, this Milestone is used as a good set of data that should be collected in a living donor follow-up registry. These Milestones were already described in the first ACCORD Newsletter which focused on the work undertaken during the first year of the project (2012-2013).

**Milestone 3: Technical, organizational and governance requirements**

The years 2013-2014 lead to additional results. A document in which the technical, organizational and governance requirements for living donor registries and for a supranational registry of living donor registries are described was another of the objectives of WP4. It took some time and discussion to realize this, since essential structures had to be described. Meetings took place in Madrid in October 2013 and in Amsterdam in January 2014. Concerning the technical requirements, the basic principles were set down. For example the functionality to enter data by direct key entry or by file upload, but also the possibility to download data from the registry and aspects concerning data safety and security. The chapter ‘governance and organization’ handled the different elements that are necessary to make a (international) registry work. Since different stakeholders with different back-grounds from different countries will be working with an application from different locations, it is imperative to make clear agreements. Policies need to be draught and also professionals need to be appointed to carry the responsibility for entering the data into the registry and a database staff needs to be installed to perform every day support and continuous management. Suggestions on how to establish such an organization were provided. Data ownership and a steering committee were complicated topics as well, making this a valuable document with recommendations (http://www.accord-ja.eu/sites/default/files/download_documents/ACCORD_WP_4_Technical__organisational_and_governance_requirements.pdf ACCORD WP4 Pilot Registry).
The recommendations as described in the previous Milestones are of course reviewed by the External Advisory Board, but they also need to be piloted to lead to a final report including all final recommendations from this project. A pilot plan was written and agreed upon by all WP4 partners in March 2014. This consensus was the starting point to arrange all formalities to start a pilot period. Nine countries signed up to participate actively in the pilot by sharing the follow-up data of their living donors. Five countries without an existing (national) living donor follow-up registry participated by directly entering their living donors follow-up data (direct key entry). Four countries with an existing national living donor registry tested the file download module by extracting the follow-up data from their registries and uploading them -using a predefined template- into the ACCORD registry. The cohort that was chosen to include was 'one year follow-up data of living kidney donors who donated a kidney in 2010 and 2011'. The kidney dataset from Milestone 2 was used to set the parameters to collect in the registry. Hospital Clinic (Barcelona, Spain) was chosen as partner in facilitating the ACCORD WP4 pilot. Their experience with the previously EU-funded project EULID led to a database structure that could also be used for the ACCORD pilot within the given budget and time schedule. A subcontract between the Dutch Transplant Foundation as project leader and Hospital Clinic was signed. The direct key entry facility was available in May 2014. The file upload module was ready in July 2014. In October 2014 all countries had completed the data inclusion.

**Pilot results**

Information on a total number of 2,909 living kidney donors in Europe have been included in the pilot registry. A statistical analysis and an evaluation of the experience during the pilot will be provided at a dedicated report on the ACCORD WP4 pilot. This report is expected in December 2014 and was one of the main topics that was discussed during the final meeting in January 2015 in Madrid.

**Final report**

All the work that has been done and the Milestones that are achieved in WP4 will be collected in a final report. This report will be available in February 2015 (month 34) and will contain the final piloted recommendations on how to establish a (n inter) (national) living donor follow-up registry.
KEY MESSAGES

Donation should be placed as an option at every end-of-life care pathway, not only as a duty in progressing towards self-sufficiency in transplantation, but also in respect for the overall best interests of the dying patient. In practice however this principle seems not to be consistently implemented. ACCORD intends to facilitate its implementation by strengthening the cooperation between critical care professionals and donor transplant coordinators.

ACCORD has undertaken a description of end-of-life practices relevant to organ donation in patients dead as a result of a devastating brain injury through a prospective observational study inclusive of 67 hospitals from 15 European Union countries (www.accord-ja.eu/intensive-care). This is the first exercise of this kind undertaken internationally that provides insights into possibilities for improving donation after death at the European level and at each of the participating countries. Professionals from selected European hospitals have been trained on the ‘Plan, Do, Study, Act’ (PDSA) methodology and its application to the process of donation after death. In the upcoming months, a detailed report on the experience with the practical implementation of this methodology will be provided by ACCORD, along with a toolkit of materials and recommendations for the implementation of the PDSA approach to organ donation. Such implementation seeks cooperation between critical care professionals and donor transplant coordinators in convening efforts to systematically explore the option of donation at the end-of-life.

The overall aim for Work Package (WP) 5 of the ACCORD Joint Action is to increase the availability of organs from deceased donors by strengthening the cooperation between Intensive Care Units (ICUs) and Donor-Transplant Coordinators (DTCs).
The specific aims of the project are:

**Part 1**: To describe the usual end-of-life care pathways applied to patients who die as a result of a devastating brain injury in Europe, and to explore their impact on the potential for donation.

**Part 2**: To develop and prove by implementation an acceptable and effective rapid improvement toolkit supporting modifications in end-of-life management that maintain the possibility of donation, adapted to each identified end-of-life care model.

WP 5 is led by the UK. Fourteen other EU Member States (MS) are taking part in the Project: Croatia, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Portugal, Slovenia and Spain.

**Part 1**: To describe the usual end-of-life care pathway for patients who die as a result of a devastating brain injury a transnational, multi-centre, observational study was undertaken in participating hospitals across Europe. Data collection was focused on patients dying as a result of the brain injury from March 1\textsuperscript{st} 2013 to August 31\textsuperscript{st} 2013.

The study consisted of three questionnaires:

1. **Country questionnaire** – to examine variations in policy, law and ethics between each participating member state.
2. **Hospital questionnaire** – to examine variation in the availability of resources to facilitate the organ donation process.
3. **Patient questionnaire** – to examine the variation in end-of-life care for patients who die from a devastating head injury and the impact on the potential for organ donation. The patient questionnaire was constructed to follow the organ donation care pathway and is shown schematically in Figure 1.
ACHIEVING COMPREHENSIVE COORDINATION IN ORGAN DONATION THROUGHOUT THE EUROPEAN UNION: ACCORD

CURRENT ACTIVITIES:

Q1 & Q2 General Qs...

Q3: Intubated and Ventilated

Q4: Clinical condition consistent with brain death

Q5: Brain death tested

Q6: Brain death confirmed

Q7: Donation after Circulatory Death considered

Q8: Potential Donor referred to the DTC

Q9.1: Family approached considered

Q9.2: Who approached family

Q10: Did donation occur

FIG. 1 PATIENT QUESTIONNAIRE DESIGN
Participating hospitals were required to identify and collect data on a maximum of 50 consecutive patients who died as a result of catastrophic brain injury anywhere within the hospital within the six month study period. Data for the ‘patient’ questionnaires were entered electronically via a secure on-line database on the ACCORD central website. 67 participating hospitals from across the European Union collected data on 1670 patients.

For the whole patient cohort, it is clear that at every stage of the clinical pathway opportunities for both Donation after Brain Death (DBD) and Donation after Circulatory Death (DCD) are lost (Figure 2 and Figure 3).
A full description of the methodology and analysis of the results for the entire cohort and each participating country can be found in the WP5 interim report ‘Variations in end of care pathways for patients with a devastating brain injury in Europe’ published in March 2014 and available on the WP5 page of the ACCORD website www.accord-ja.eu/intensive-care.

Part 2: A total of 66 participants attended workshops held in June and September 2013, which provided training in the principles of the service improvement methodology (Figure 4) and guidance on the application of those principles to the patient data collated during Part 1 of this WP.

All participating member states were represented at the workshops and the audience consisted of intensive care and emergency care clinicians, donor transplant coordinators and project leads (Figure 4).

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

CURRENT ACTIVITIES

Participating hospitals were asked to follow the PDSA methodology and use the analysis of the data they had submitted during the ‘patient questionnaire’ phase to explore the local barriers to organ donation and develop plans for how they could make small changes to address them. From 67 hospitals that entered data into the online patient questionnaire, 54 returned service improvement plans to project leads ad the UK project team for review.

Implementation of the PDSA methodology by participating hospitals started between September and November 2013 and ran for a maximum of 6 months. During the implementation of their PDSA plan, hospitals collected further data to measure the impact of their intervention. When the PDSA cycle finished, the hospital submitted a report to the UK project team, who analysed the impact of the intervention. Analysis of the results from the service improvement phase will be produced in the WP5 final report (due to be published at the beginning of 2015).

The final report will be accompanied by a service improvement methodology and PDSA cycle toolkit for organ donation. The toolkit will build on the momentum gained during the project and support other hospitals to adopt the service improvement methodology, thereby promoting the long-term benefit of the WP.
Twinning activities on Organ Donation and Transplantation

Twinning activities led by the Agence de la biomédecine in France consist in providing direct support to Member States from one to another by means of practical collaborations on the lines of the EU "Action plan on Organ Donation and Transplantation" (2009-2015) and Directive 2010/53/EU. Thanks to this concrete transfer of expertise, the overall aim is to support candidates in developing or strengthening their organ donation and transplantation systems. Supported Member States seeking developments identified areas of interest and collaboration was organized with a supporting Member State 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 Centres of Leiden and of Groningen, and ESOT] and Hungary as the supported Country [the Hungarian National Blood Transfusion Service-Organ Coordination Office (HNBTS-OCO) in collaboration with the surgeons from Semmelweis University]. The first aim of this twinning was to set up a surgical National training programme for abdominal organs retrieval in Hungary, not only to standardise procedures and to increase safety and quality criteria of organs to be transplanted, but also to optimise multiorgan donations. In The Netherlands, the curriculum for surgeons specialized in organs retrieval 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 (training-on-the-job), and a final examination procedure prior to the certification (Figure 1).
The first steps of this twinning were to modify the Dutch E-learning platform so as to be suitable for all browsers and tablets, to translate the content into English and to test it (this was done by 52 surgeons in total) (Figure 2). Surgeons testing the platform gave a really positive feedback and issued valuable recommendations to further improve the platform such as enhancing the anatomical background.

Since this transfer of expertise followed the train-the-trainers methods, 3 senior and 3 junior Hungarian surgeons were selected, completed the E-learning phase, participated at the first practical hands on session organised in The Netherlands and kept on with the registration of the training-on-the-job (organ retrieval procedures performed within the hospital). Having established Hungarian tutors, the pool of junior trainees was enlarged, successfully completed the E-learning phase and the OCO kept track and reported each organ retrieved either as a main surgeon or as an assistant.

Keeping on schedule, the OCO supervised the setting of the first National Practical (hands-on) Session organised in Hungary at OCO Headquarters (see picture below) and at Semmelweis University in Budapest, in collaboration with the Department of Human Morphology and Developmental Biology (mastering body preparation). The Hungarian surgeons were assessed according to a standardized technical skills evaluation form.

**Fig. 2:** View of the adapted Dutch e-learning content and training module guide (courtesy of DTF and partners).
Two years after the beginning of this twinning, all actions have been successfully completed. At that stage, the perennial implementation of a curriculum is under discussion in Hungary for the organisation, administration, nomination of training professors, conditions for candidates' admission etc.

During this twinning, thanks to its international adaptation, the E-learning ‘Multi-Organ Donor procurement surgery’ has been granted with EACCME accreditation of the UEMS (4 credits). In turn, OCO included this training option within the educational programme for medical doctors, granting the E-learning platform training by 8 credits and the practical 2 day session completion by 20 credits.

The broader potential of this twinning is to have a new international training tool available at EU level for other Member States, it is noteworthy that some other Member States already showed interest for this training tool.

**Twinning to develop the Bulgarian Transplant system**

With France as the supporting country [Agence de la biomédecine (ABM) and the transplant team of Robert Debré Hospital in Paris], and Bulgaria as the supported Country [Bulgarian Executive Agency for Transplantation (BEAT) and the transplant team of Pirogov Hospital in Sofia]. The aims of this twinning were to support the development and organisation of the organ procurement system at national and regional levels, to assist BEAT in the upgrading of the donation and transplant registry, to collaborate on the drafting of an activity report and to support paediatric kidney transplantations through the completion of the training of the Bulgarian transplant team (the surgical and care training started a few years ago already but could unfortunately not be completed at that time).
On-site visits of procurement and transplant centres in Bulgaria and in France were carried out, allowing the identification of Standard Operating Procedures (SOP) as key elements to be drafted and implemented in priority.

The resulting SOPs are under final revision: “SOP 1 - Donor Coordinator’s Missions”, “SOP 2 - Identification of potential donors after brain death”, “SOP 3 - Brain death diagnosis”, “SOP 4 - Family approach”, “SOP 5 - Organ donor maintenance”, “SOP 6 - Maintenance of the Paediatric Organ Donor”, “SOP 7 - Donor and organ characterisation”, “SOP 8 - Packaging and transport of organs”, “SOP 9 - Management of serious adverse events and reactions”.

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 will provide directions and harmonisation of practices. SOPs are to be distributed to targeted Units of all sites and to be available for the Hospital personnel.

Regarding the completion of the paediatric kidney transplant team which started a few years ago- according to the previous evaluation, in order to be fully autonomous, the Bulgarian team had to be supported by the same French transplant team for 3 additional transplantations.
Candidates for kidney transplants were discussed during a first meeting of both transplant teams in Sofia, two children were selected. However, while going on with medical tests, it appeared that cases were more complicated than anticipated. In addition, unfortunately, the dedicated anaesthesiologist of the Bulgarian team left, leading to the impossibility of completing the training. The French team proposed to follow those two patients in France; discussions are on-going and complete medical check-ups are now being performed in Paris. Recommendations were made for Bulgaria to seek for a long term solution.

The third sub-section of this twinning was targeted to improve BEAT information system for traceability and for more transparency, with the concrete objective of producing and disseminating an annual activity report.

Following the visit of the French ABM expert and recommendations for improvements, experts at BEAT dedicated the past months to improve their information system, and the ACCESS based registry for organ donation and transplantation activities. ABM experts reviewed the BEAT existing monitoring and evaluation system (at BEAT Headquarters and on site in Hospitals) and recommendations for improvements and development were issued.

BEAT appointed an expert, the next step for further improvement of the BEAT’s information system was to transfer the web-based applied system on the MS SQL server to achieve faster and easier data processing. The BEAT expert was trained at ABM Headquarters. Secondly, the BEAT expert dedicated to the information system sent to the French counterpart some data from the suggested listing. Data provided covers: Living donors, deceased donors, and transplantations. Data are currently being processed by the Agence de la biomédecine, and a proposal for an activity report is being drafted. This report will nicely reflect Bulgarian donation and transplant activities and would be worthwhile uploading on the BEAT website for information to the professionals and to the public at large.
This twinning is aiming at developing the overall Bulgarian system of Organ Donation and Transplantation, and since its beginning in 2012, transplantation activities have more than doubled in Bulgaria (see table below). Data activities are clear and concrete indicators reflecting altogether the commitment of the Executive Agency for Transplantation, the participation of all categories of professionals involved in the donation and transplantation processes and also the success of on-site twinning operational activities along with twinning actions at national level.

<table>
<thead>
<tr>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased donors</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Living donors</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Kidney transplants</td>
<td>13</td>
<td>28</td>
</tr>
<tr>
<td>Liver transplants</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Heart transplants</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Total transplants</td>
<td>19</td>
<td>39</td>
</tr>
</tbody>
</table>

Donation and transplantation activities in Bulgaria (absolute values).

To sustain perennial activities and to go even further, 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, further on site activities with professionals, actions toward supplementary national guidance and regulation etc.

Nonetheless, this twinning already gave a great new impulse to Bulgaria, raised awareness, drew attention to the needs, and importantly it motivated again key personnel. Furthermore, it is noteworthy to highlight that the Executive Agency for Transplantation is now an active member of the Transplant EU network and has set valuable contacts with other Member States Transplant agencies, should support and advices be sought in the future.

**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 was aiming at developing an authorization and audit system for Transplant Centres based on the Italian model, but adapted to the national requirements and needs of supported countries.

entailing: legislative status (Directive 2010/53/EU), structure, role and tasks. At first, each supported country provided a national report of the regulating authority/ies, existing National Audit System (if any), evaluation process in place (if any quality indicators, data collection and analysis, routine inspections/audits, Vigilance and Surveillance), authorized Transplant Centres, a self-evaluation of strengths and weaknesses of the system in place, areas for improvement, and potential obstacles for implementing a new system. Those reports allowed the Italian partner to design the Guide on Essentials for developing Authorization and Audit systems of Transplant Centres. The guide deals with Authorization procedures, Evaluation of transplant outcomes, Vigilance system (reporting and management of adverse events and reactions) and of course with Auditing (along with technical annexes listing specificities for auditing Kidney and also Liver Transplant Centres). Importantly, this Guide is to be easily adapted to each Member State.

Visits to Transplant Centres (and Competent Authorities) were then conducted in supported countries: discussions between National experts were fruitful, guidance and suggestions for future developments were provided. As a complement, Italy continuously supported twinners in transferring and adjusting the proposed authorization and audit system to their local needs.

(Photos: ©Benoit Rajau for the Agence de biomédecine)
So as to complete this transfer of expertise, a training of nominated auditors (2 to 4 per country) was set by Italy. This 3 week training was hosted under the CNT E-learning platform; material includes all relevant and informative documents and guides. Trainees also completed a final assessment not only for the implementation plan at national level but also to suggest for further improvements of this training E-learning tool.

The E-learning phase was followed by a face-to-face training consisting of an audit exercise organised in an Italian Transplant Centre. Trainee auditors much appreciated this simulated audit which greatly allowed them to concretely apply knowledge gained thanks to the Guide on Essentials for developing Authorization and Audit systems of Transplant Centres and through the E-learning platform. Since some twinning countries are not as much geographically extended as others, adopting a strictly National audition would lead to self-evaluation. In order to avoid any potential conflict of interest, a proposition of joint audits with Italian experts was then adopted by Czech Republic and by Lithuania. Audits led to identify possible issues and areas for improvement. Discussions between experts were productive, propositions for possible actions and next steps were submitted. Malta - being a small island facing notably anonymity problems - favoured a broad on-site meeting at the Transplant Centre. Allocation criteria, waiting list, registries, transplant outcomes etc. were discussed, views were exchanged by counterpart experts, decisions for next steps have been made. This multiplet twinning is facilitating the implementation of Directive 2010/53/EU and is concretely promoting more harmonized practices and processes among the supported Member States. Furthermore, since this Guide on Essentials for developing Authorization and Audit systems of 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 auditors. Indeed, experiences gained by the multiple partnerships are useful for detecting specific aspects that would allow the common system to run within a diverse environment of legislations and particularities. Additionally, the design and implementation of this especially dedicated course for auditors can be used as a baseline for creating a unique model for training National Transplant Centre auditors. CNT has developed a challenging multiple twinning project, secured by pragmatic actions and had planned adaptation to each country in this transfer of expertise, showing realistic experimental approach of potential national differences and issues. Thanks to the CNT expertise and to the twinner’s commitment and volunteered participation as tester of such a transfer of expertise, this multiplet project is already a success. As the National Transplant Bureau twinner from Lithuania stated: “audits are now positively considered by professionals on-site as opportunities for changes and improvements.”

**Added value of Twinning activities**

The first aim of Twinning activities was 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. Nonetheless, developed tools have the broader 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 Agence de la biomédecine 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.