WP6

Deliverable 9

Twinning activities on Organ Donation and Transplantation

ACCORD "Achieving Comprehensive Coordination in Organ Donation" is a 3-year Joint Action (calling all Member States Competent Authorities are invited to participate), co-funded by the European Commission Health Programme. ACCORD" is aiming to strengthen the full potential of Member States (MS) in this field, to improve cooperation between them and to contribute to the effective implementation of the Organ" Directive 2010/53/EU and the Action Plan on Organ Donation and Transplantation" .
ACCORD is led by the Organización Nacional de Trasplantes (ONT) in Spain. Within ACCORD, one section (Work Package 6, WP6) is devoted to Twinning activities and led by the Agency of biomedicine in France. Such Twinning activities concern the provision of operational, direct and cost-efficient transfer of expertise from an experienced supporting MS to a seeking supported MS.

Accordingly, Twinning activities were defined as a direct support to Member States from one to another by the mean of practical collaborations. Twinning concepts herein were developed as a complement of actions usually provided by EU projects or joint actions that are rather more theoretical than practical, and that do not target a specific MS to transfer an operational expertise (on site implementation), but that rather aim at a global EU impact and rather at a more long-term implementation of results and guidance generated.

Twinning activities in ACCORD were anticipated to promote that the expertise, knowledge or practical tools developed by one MS are transferred to other(s) who need and request such transference. Depending on each MS, different aspects of the Organ Donation and Transplant system can be reinforced through cooperation, but areas to be addressed were to be in line with the MS national Action Plan and/or the Directive.
As a complement, as a result of the experience gained by all twinners through the design, implementation and results of the twinning initiatives developed in ACCORD, a guideline for further twinning actions was proposed to be drafted, facilitating new Twinning initiatives once the ACCORD Joint Action would be completed.

CONTENT

I- INTRODUCTION:

Twinnings were defined as "*a concrete and direct transfer of expertise from volunteered and matching supporting MS to a wishing and willing supported MS*". Indeed expertise and/or tool developed by a given MS could meet the need of others. Therefore, the building up capacities by sharing of Twinning activities could be considered as complementary and necessary actions to strengthen the development of a MS health care system by addressing identified disparities, gaps and weaknesses.

To promote international exchange of best practices and consolidated expertise in organ donation and transplantation, with regards to the areas set down in the Directive and the Action Plan, through specifically designed and practical collaborations between EU countries.

Member States were invited by coordination (ONT, Spain) to participate to the ACCORD Joint Action. Following this call notably entailing the Twinning activities proposal, "Member States (*MS) willing to be supported are to specify the area(s) of interest based on national needs, in line with the Action Plan and the organ Directive. Proposals shall specify and justify the need to be addressed, objectives, plan of action, expected outcomes and resources required, for a maximum duration of two years and a budget of 80,000€ per pair. Twinning proposals shall not consider areas covered by other core Work Packages, nor overlap with twinnings developed in other EU projects. Proposals are to be submitted to and worked out with the Work Package leader (WP6). Twinning proposals are to be evaluated by the ACCORD Steering Committee. Projects were to be selected based on the following: supported MS has concrete identified needs and requests specific support; supporting MS owns the expertise and abilities to provide such support; pre-existing relations between the collaborating MS, mutual knowledge of counterparts and former experience of cooperation.* However, a given MS could come forward with either a need or a tool to share and would then rely on Agence de la biomédecine for the matchmaking.

A Twinning outline document provided by Work Package leader was sent to MS showing interest. Those MS were invited to contact WP6 leader either as single or twinned in order to build up both scientific and budget (financial sheet) proposals. Candidates all received the same information in order to ensure clear and transparent processes and so equity for all applicants:

“MS had to write their Project proposal according to recognized area of development for MS seeking support and in recognition of MS expertise for the supporting MS. According to MS project proposal, preferences to MS pairs” shall be given to:

Supported MS showing a need for support on specific areas in organ donation and transplantation;

Supporting MS providing experience and concrete practices to support MS in meeting their needs shall show expertise in the targeted area; Supporting MS' abilities to provide expertise and know-how could be partly reflected by the level of transplantation activity, strong involvement in EU projects, status of the expert (*i.e.* Competent Authority, National Reference).

Pre-existing relations between the coupled MS, mutual knowledge of counterparts and former experience of cooperation is considered as an advantage to assess capacities on both sides.

The content of the Project proposal shall preferably be i) in line with the Action Plan on Organ Donation and Transplantation (2009-2015), ii) follow area of development set in National Action Plan, iii) possibly be designed toward the application and/or implementation of the Organ Directive.

However, the Twinning project proposal shall exclude activities related to the other core WPs of ACCORD *i.e.* the development of registries for living donation (WP4) and the strengthening of the

relationship between intensive care units and transplant donor coordinators (WP5) and shall avoid overlapping with other ongoing EU funded projects;

Supported MS not already participating in the other WP of this Joint Action.

Twinning projects shall be programmed for a maximum two year period with a maximum budget of app. 80 000 Euros per pair (indicative budget, that might be subject to changes).

Agreement was set on clear deadline for proposal submission and transparent procedures. And for operational actions of two years and one year for sustainability (and potential delays).

Proposals are to be submitted to and worked out with the WP leader. Twinning proposals are to be evaluated by the WP Steering Committee. Projects are to be selected based on the following: supported MS has concrete identified needs and requests specific support; supporting MS owns the expertise and abilities to provide such support; pre-existing relations between the coupled MS, mutual knowledge of counterparts and former experience of cooperation.

Stage 1: Refinement and organization of twinning proposals with WP leaders and WP participants.

Stage 2: Execution of twinnings: twinnings implemented; close follow-up of collaborations will be ensured by continuous reporting, evaluation and input from other participants (WP meetings will address specific problems encountered and propose concerted solutions); each twinning will be comprehensively described, enclosing results achieved.

Stage 3: Development of guidelines for twinning, based on the knowledge gained"[1]*.*

Finally, three different twinnings were programmed:

- a Twinning to develop a surgeon training programme for abdominal multiorgan retrieval in Hungary,
- a twinning to develop the Bulgarian Transplant system,

and

- a Multiplet to develop an Authorization and Audit system for Transplant Centres in Cyprus, Czech Republic, Malta and Lithuania.

[1] From the Twinning outline document.

II- Twinning to develop a surgeon training programme for abdominal multiorgan retrieval 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 and of Groningen, and ESOT) and Hungary as the supported Country: the Hungarian National Blood Transfusion Service- Organ Coordination Office (HNBTS- OCO; in collaboration Semmelweis University).

The first aim of this twinning was to set up a surgical National training programme for abdominal organs retrievals 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, a National complete trajectory from training of surgeons in abdominal organ procurement surgery to the quality assessment of the procured abdominal organs was implemented in 2010. In the Netherlands, this mandatory trajectory for surgeons specialized in organs retrieval entails (figure 1): 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, table 1), and a final examination procedure prior to the certification.

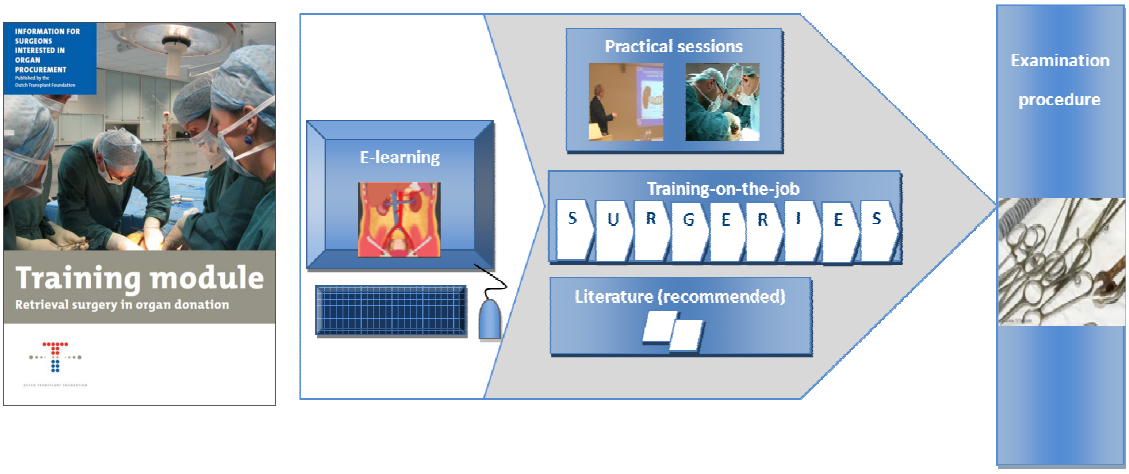


Figure 1:View of the training module guide and scheme of the Dutch training and certification system (Courtesy of the DTF).

	Assisted	Performed
Procurement of kidneys from deceased donors	20	20
Procurement of pancreases (incl. retrieval for islets)	10	2
Procurement of livers from deceased donors	10	10

Table 1: the minimum numbers of procedures for the training -on -the job.

II- a - Tools adaptation:

The first step of this twinning was to modify the Dutch E-learning platform so as to be suitable for all browsers and PC, MAC and tablets (see screen shots below), Cross-Operating System playability was extended, resulting in an increased speed, content and Training module guide was translated into English (see annex I) and tested by 52 UK surgeons in total (volunteers ESOT members recruited by the UK ESOT twinning partner). Testers gave really positive feedback and issued valuable recommendations to even further improve the platform such as enhancing the anatomical background.

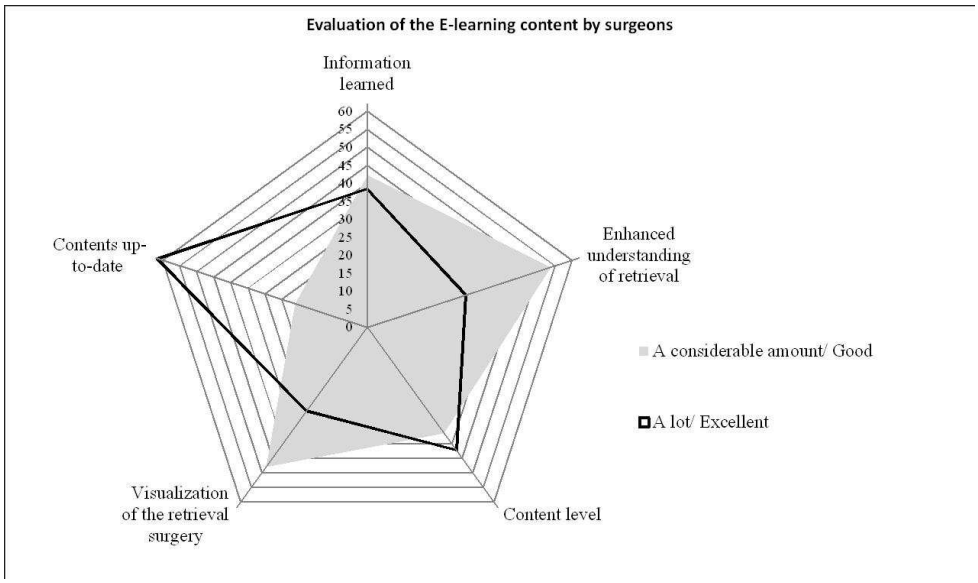


Figure 2: Evaluation of the E-learning platform by 52 surgeons. Opinion of Hungarian and United Kingdom expressed as percentage; limited to answers from most significant questions. Answers to be selected from: nothing/ not at all/ poor, very little/ mediocre, sufficient, a considerable amount/ good or a lot/ excellent. Figure from the published article on this twinning[2].

HNBTS-OCO was the Hungarian administrator, and as such was able to create, modify or delete user accounts, to grant access to the E-learning and importantly could follow trainees' modules completion. Users are given a log in and can also follow completed modules.

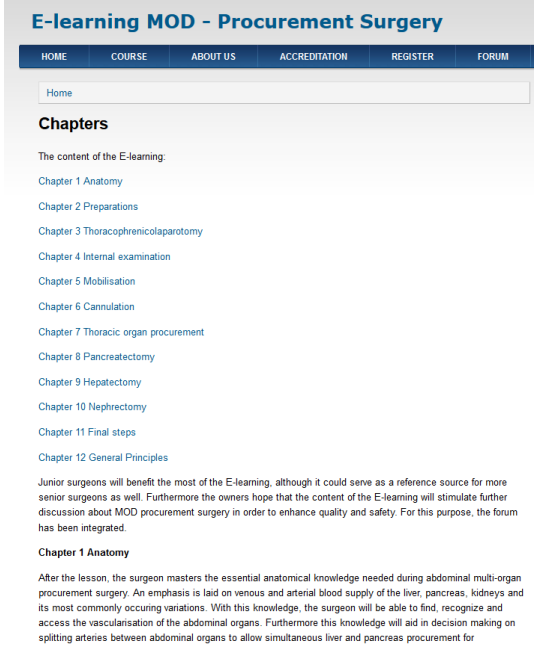
[2] **Exchange of Best Practices Within the European Union: Surgery Standardization of Abdominal Organ Retrieval.** Article published in Transplantation Proceedings, Volume 46, Issue 6, July–August 2014, Pages 2070–2074), Available online 14 August 2014.

Figure 3: View of the developed platform adapting the Dutch E-learning content (courtesy of DTF and partners).

The E-learning platform was accredited by the European Union of Medical Specialist and European Accreditation Council for Continuing Medical Education (UEMS-EACCME®).

"Our reviewers have found your material very good and have decided to grant 4 European CME credits to it." N.P., EACCME Co-ordinator. European Union of Medical Specialists (UEMS) European Accreditation Council for CME (EACCME)

Figure 4: Screen shot of the E-learning platform and accreditation reference (courtesy of DTF and partners).



Content of the E-learning platform. The E-learning can be completed by surgeons at anytime and anywhere using web-based online access. This E-learning includes expertise transfer so as to better understand, perform and complete an abdominal multi-organ retrieval procedure. Moreover, it is subdivided into several sections and steps that can be completed separately and at different time points. It also includes relevant questions that have to be answered to allow continuation and completion. Last but not least, it is supported by visualization of the surgery using photographs, video-clips and drawings.

Figure 5: Chapters available on the E-learning platform (Screen shot courtesy of DTF and partners).

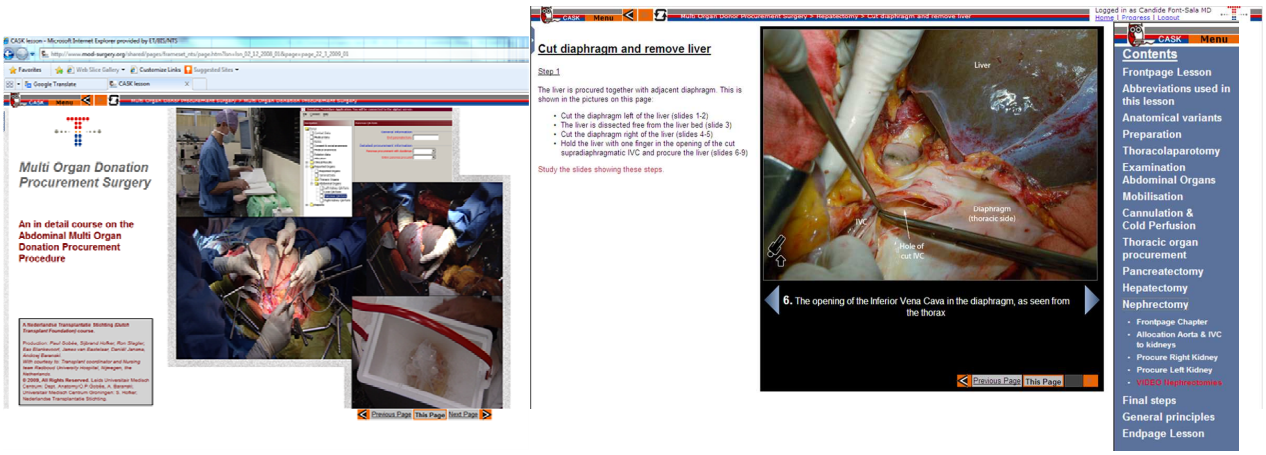


Figure 6: View of the adapted Dutch e-learning content and training module guide (courtesy of DTF and partners).

II- b - Implementation:

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 (gave feedback on the platform), and assisted to the first practical hands on session: the International European Donor Surgery Masterclass which is annually organized by ESOT in collaboration with the Leiden University Medical Centre in The Netherlands. Additionally, junior surgeons trained kept on with the registration of the training-on-the job to be reported to OCO (organ retrieval procedures performed within the hospital, see table below).

Surgeons	*Kidney retrieval*		*Liver retrieval*		*Pancreas retrieval*	
	Assistant	*Main surgeon*	*Assistant*	*Main surgeon*	*Assistant*	*Main surgeon*
Junior trainee 1	1	6	0	7	0	1
Junior trainee 2	1	6	0	7	0	1
Junior trainee 3	5	1	3	1	0	0

Table 2: Junior Surgeons abdominal organ retrievals recorded by OCO at M16 (31rst August 2013).

Figure 7: Pictures of the two Hungarian surgeons participating in the Masterclass in Leiden (courtesy of the two surgeons).

The participating surgeons reported on the Masterclass: "*All the presentations were interesting, useful, well documented, and everybody from the audience had the opportunity to interrupt the presenter, ask questions, which made the lectures more interactive. The presentation about the Donor risk index in the Eurotransplant area gave a new viewpoint on evaluating the donor`s parameters and accepting a marginal donor. I would like to highlight the last presentation entitled Organ Procurement Outside Your Own Hospital performed by Vassilios Papalois from London, UK. It conveyed a very good approach how the surgeon`s attitude ought to be during the whole procedure of the organ retrieval. This course was a great tool to a get better and deeper knowledge on organ procurement. The participation is recommended for everyone, taking part in organ retrievals for transplantation."*
"This distinguished course gave the possibility for knowledge transfer for the planned Hungarian Courses and was fundamental for me to develop the Hungarian ones."

Then having established and trained Hungarian tutors, the pool of junior trainees was enlarged, thanks to a regional satellite Masterclass organised in Debrecen.

Satellite Donor Surgery Course in Debrecen (Hungarian regional masterclass)
On 1-2nd October 2013, a training course was held in University of Debrecen, Institute of Surgery for surgeons who are involved in organ procurements or would like to candidate for participation in the 1st Hungarian Donor Surgery Masterclass. During this two-day course ACCORD Project introduced to participants who were granted access to the E-learning platform. New junior trainees successfully completed the E- learning phase, and as a mandatory complement, the OCO kept track of each abdominal organ retrieved either as a main surgeon or as an assistant.

Then, 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). Height trainees (2 of each of the 4Transplant Centres were selected, completed the E-learning, declared their training-on-the job activities to OCO, and attended the National masterclass to be evaluated by senior surgeons.
The Hungarian surgeons were assessed according to a standardized technical skills evaluation form.

Budapest Masterclass

The first day at NHBTS-OCO focused on providing the trainees with the full scope of abdominal organ transplant and dealing with organ retrieval at large, starting with general principles and logistics, to target then more specifically the donor surgery and some surgical specificities of organ procurements (see agenda in annex II).

Figure 8: the first day seminar session at NHNTS-OCO. The OCO Director supervising the twinning on the Hungarian side introduced organ donation programmes in Hungary, including the legal background (Courtesy of OCO Director).

The second day was dedicated to the practical session with kidney, liver and pancreas retrievals from human bodies prepared by the Department of Human Morphology and developmental Biology and also held Department of Human Morphology and developmental Biology at the of Semmelweis University. Height trainees in total from all over Hungary.

Figure 9: the Department of Human Morphology and developmental Biology hosting the second day, and photo of the Introductive OCO Director speech (Participants courtesy).

During this practical session which was organised with two trainees and HU-NL tutors per retrieval bench and one Dutch master in abdominal Multi Organ Donor (MOD) retrieval (E-learning contributor) supervising from one bench to another, providing guidance and ensuring the step by step MOD retrieval.

"For the National Masterclass in Budapest, the Department of Human Morphology and Developmental Biology and the Department of Transplantation and Surgery of SU are cooperating to support liver surgery, especially the split liver technique. The working group at the Department of Human

Morphology and Developmental Biology elaborated a dye technique which can visualize arteries, veins and bile ducts beyond the CT scan imaging. Hence, it is possible to study the anatomical variants of these structures"[2].

Figure 10: the first National practical (hands-on) session organized in Budapest, 8 participating Hungarian surgeons as trainees (Courtesy OCO and participants). Two trainees per bench and one to two tutor(s) for their evaluation.

Evaluation of Surgeons trainees during the Budapest practical (see Annex III for the questionnaire).

Objective Structured Assessment of Technical Skills: Evaluation of trainees by their senior supervisor

- Process of indication:

Half of the trainees were rated as having the “general understanding in anatomy” and the other half as having “mastered the material”.

- Tissue feeling:

Five out of eight trainees were rated as “showing careful tissue treatment with incidental tissue damage” and three trainees as “showing consistent tissue careful treatment with minimal tissue damage”.

- Handling and knowledge of tools: (surgical instruments)

One trainee was given "sometimes stiff and awkward, usually makes good choice and use of instruments” and five trainees had the best evaluation: “allow smooth motion and make judicious use of the right tools”. Two trainees were not evaluated on this criterion.

- Use of assistance:

Four trainees were rated as having “most of the time adequate use of assistance and instruction” and two trainees had the best evaluation: “optimal use of assistance and instruction”. Two trainees were not evaluated on this criterion.

- Progress of surgery:

Two trainees were evaluated as having “frequent stops, asking for instruction or instruction has much needed”, and most of the trainees as “demonstrating forward planning but still need guidance”. One trainee was granted “makes clear planning, is independent and confident”.

- Knowledge of procedure:

One trainee showed “insufficient knowledge and must be continuously supervised”, four trainees they “know the most important aspects of the operation” and three trainees “demonstrate considerable knowledge”.

- Total assessment specialist (introspection):

On the trainees displayed knowledge, skill and behaviour during this procedure: most of the trainees (7) were rated as “at expected level, satisfied” and one trainee was even granted of the highest score: “above expected levels, very satisfied”.

- Total assessment supervisor:

To the question “What is the opinion of the supervisor on the displayed knowledge, skill and behaviour of the trainee surgeon during this procedure?” six trainees out of eight were rated as “at expected levels: as expected, possibly something extra attention” and the two other trainees as “above expected level: good development in line with or above expectations”.

The supervisor considered that the trainees with regard to this procedure:
Level A: masters the knowledge and skills to assist adequately.
Level B: masters the knowledge and skills to act adequately under strict and controlled supervision.
Level C: masters the knowledge and skills to act adequately under limited and controlled supervision.
Level D: masters the knowledge and skills to act adequately without supervision.
Level E: masters the knowledge and skills to supervise and teach adequately.

Four training surgeons were considered as having reached Level C. Three training surgeons respectively reached Level A, Level B, Level D; and one training surgeon was even granted the highest Level E rate.
Trainees had different surgical experience, as a consequence they were granted with different evaluation in accordance to their overall knowledge and skills. In the end, seven of them qualified for kidney, pancreas and liver retrieval and one trainee qualified for kidney retrieval.

• <u>Trainees evaluated by tutors evaluated the Masterclass in turn:</u>

- To what extent did the Masterclass met your expectations?

All of trainees answered “a lot”.

- To what extent did the Masterclass helped to enhance their appreciation and understanding of the abdominal MOD organ procurement as a whole?

Seven trainees out of height declared “a lot” and one “a considerable amount”.

- The effectiveness of the Masterclass was evaluated under different aspects:

The level of the presentations was considered as “good” for two trainees and as “excellent“ for the other six trainees.
The balance between theory and practical hands-on was rated as “excellent” by seven trainees and as “just good” by one trainee.
Importantly, the level of the practical hands-on was ranked “excellent” by all trainees.

- The length of the Masterclass:

All trainees agreed that it was neither a” bit too long” nor “a bit too short” but “just right”.

- Rating the Masterclass in overall in regards of usefulness and level of interest:

Seven trainees agreed on “excellent” in both aspects and one gave a “good” evaluation on both criteria.

- Comments on the strengths and advantages of the Masterclass:

Three out of eight trainees declared that the practical hands-on was great and interesting, and that they had enough time to practice the method. For one trainee, it was great opportunity to practice the MOD retrieval method on a prepared body instead of on a real live patient, and another trainee appreciated the quality of the body preparation. Two trainees out of the eight mentioned that the theoretical part had perfect lectures and that the speakers were very good. One trainee referred to the online training modules as brilliant and another one highlighted the perfect organisation of the Masterclass.

In connection with the opportunities for further improvements regarding the Masterclass: four of the trainees estimated that it was absolutely perfect, and so no improvements would be needed. The opportunity to keep a good international balance and to keep the contact with the other transplant teams were mentioned.

One trainee would welcome more practice and another trainee better instruments.

It was indeed noticed by participants that some surgical instruments need to be improved in accordance to the organ retrieval specificities.

=> This point will be taken into account for the next Masterclass.

Last but not least, one trainee highlighted that it was good to have the opportunity to put into practice the knowledge that was accumulated.

The last action of this twinning (on-going) is to upgrade the OCO registry with organ retrieval quality forms to be filled in by the transplant surgeons at reception of the organ.

The first three junior surgeons enrolled at the very beginning of the twinning continued with the training on the job procedures registration, an update of their activities recorded by OCO at t M33 (31rst March 2015) can be found in the table below:

Surgeons	*Kidney retrieval*		*Liver retrieval*		*Pancreas retrieval*	
	Assistant	*Main surgeon*	*Assistant*	*Main surgeon*	*Assistant*	*Main surgeon*
Junior trainee 1	*16*	*21*	14	19	*1*	*1*
Junior trainee 2	*5*	*25*	*3*	*33*	*1*	*7*
Junior trainee 3	*10*	*17*	7	30	*2*	*0*

Table 3: Junior Surgeons abdominal organ retrievals recorded by OCO at M16 (31rst March 2015).

E-learning and Masterclass II, HU accreditation request

HNBTS-OCO as secreteriat of the Donor Surgery Masterclass Programme, now applies accreditation of the E-learning and the Hungarian Donor Surgery Masterclass as optional course in the continuous education programme for medical doctors in Hungary. The 1st Hungarian Donor Surgery Masterclass accredited with 20, the E-learning platform with 8 credits.

Honorary certification of Hungarian surgeons in abdominal donor surgery

Criteria of Hungarian Honorary Certificate in abdominal donor surgery is under collation with the Scientific Committee of the Hungarian Donor Surgery Masterclass, the Hungarian Transplant Society and the OCO.

II- c - Toward sustainability:

OCO supported the establishment of the Scientific Committee of the Hungarian Donor Procurement Surgery Training Program, has to June 2015. Finalize the proposed for the programme curriculum and syllabus to Hungarian local needs. The scientific committee is to be operational by the 31th January 2015.

The Scientific Committee will have to assess the potential needs (number of candidates) in the 4 Hungarian medical universities. According to the budget spent in the 1st Hungarian Donor Surgery Masterclass (30-31st January 2014) estimated costs of a course 10.000 Euro for 8 participants. Beside the professional activity of the Scientific Committee HNBTS, OCO as a Competent Authority provides the administrative background of the training programme, it is estimated 1000 Euro per course.

Potential challenges and obstacles identified, the amendment process of the current legislation about the regional competency and competency for organ retrieval by transplant centres can be time-consuming, and the necessary budget not granted a source of funding still have to be found.

A collation between the Scientific Committee, the leaders of all Hungarian transplant centers, College of Medical Professionals and Competent Authorities: National Institute of Quality and Organizational Development in Healthcare and Medicines, Hungarian National Blood Transfusion Service. Commercialization of the course in Middle-Eastern Europe for transplant surgeons could provide the financial background.

II- d - Conclusion:

This twinning has 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.

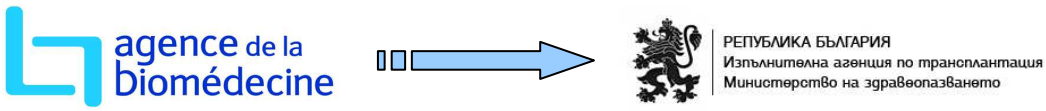
Since the broader potential of this twinning is to have a new international training tool available at EU level for other Member States, it is noteworthy that some other Member States already showed interest for this training tool.

As leader of twinning activities, the Agency of Biomedicine is the first to be aware of potential tools developed under twinning activities which could be used by other MS. As a consequence, the Agency

of Biomedicine bought some connections (40) for the Abdominal Multiorgan procurement E-learning tool that was translated from the Dutch twinning partner. This E-learning tool has been translated to English and is now available for all MS and running under PC, Mac, tablets and all browsers. This E-learning in abdominal multiorgan retrieval for surgeons already started to be used in France: 6 surgeons were trained in September 2014, and 12 more surgeons will be trained by the end of 2014, Next year (2015) 100 connections will be available for French surgeons.

The Organ Coordination Office (OCO) is responsible for the development of a proposal for establishing a national education program to improve quality and safety of abdominal organ retrievals in Hungary. So as to reach this aim OCO has to support the establishment of the Hungarian abdominal retrieval surgery masterclass training programme in collaboration with the Semmelweis University and all Hungarian abdominal transplant centres.

III- Twinning to develop the Bulgarian Transplant system



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

The aim of this twinning is 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).

III- a - the development and organisation of the organ procurement system:

The methodology followed was based on on-site visits in Bulgaria and in France, involving both agencies and hospital professionals.

During a 3 day visit of an ABM organ donation expert in December 2012, two meetings were organized with BEAT team to continue the work on national and regional organization of the organ procurement system. During a visit to the public hospital of the province of Montana, the potential of development of deceased donation was presented based on data collected on the number of brain death cases per year, and the management of the donor was discussed with the Intensive care units staff and the Hospital executive director.

On-site visits of procurement and transplant centres in Bulgaria and in France were carried out, allowing the identification of Standard Operating Procedures (SOPs) as key elements to be drafted and implemented in priority.

A three-day visit of 4 Bulgarian experts in France (1 from BEAT, 1 from the Ministry of Health and two regional hospital coordinators (Varna and Stara Zagora) aimed at studying the French organization at national and regional level. Meetings were scheduled with several experts at the ABM headquarter and in ABM regional office being a donation and retrieval centre.

Detailed presentations of the French system: organization, management, IT tools, registries etc. discussion on the French experience and troubleshooting of encountered during the development of the French system.

Figure 11: Photos of French facilities ©Benoit Rajau for the Agency of biomedicine.

Visits of two ABM experts to Bulgaria for presentation and discussion of a model of organization of procurement and transplantation - The organization of a workshop with external participants was not possible due to the lack of resources at BEAT and the expectation of the first instalment of the project.

During this visit two long meetings were hold at BEAT offices, discussions were based on the draft document on future design of the system at national and regional level in Bulgaria. A visit to Plovdiv St George hospital and meeting with Intensive care Unit and donor coordination unit was organized. During a meeting at the Ministry of Health on 20th of September, expectations on the implementation of the project and the cooperation between the twinning were discussed with representatives of the Ministry of Health.

The main outcome on the visit: a document established by BEAT to review the weak points of the Bulgarian transplantation system and the expectations of improvement by the project.

The identified SOPs (restricted to professionals): "*SOP 1-Donor Coordinator's Missions*", "*SOP 2-Identification of potential brain dead donors*", "*SOP 3-Brain death diagnosis*", "*SOP 4-Family approach*", "*SOP 5 – Adult Organ donor maintenance*", "*SOP 6 –Paediatric Organ Donor maintenance*", "*SOP 7 -Donor and organs characterisation*", "*SOP 8-Packaging and transport*", "*SOP 9 -Serious adverse events and reaction management*".

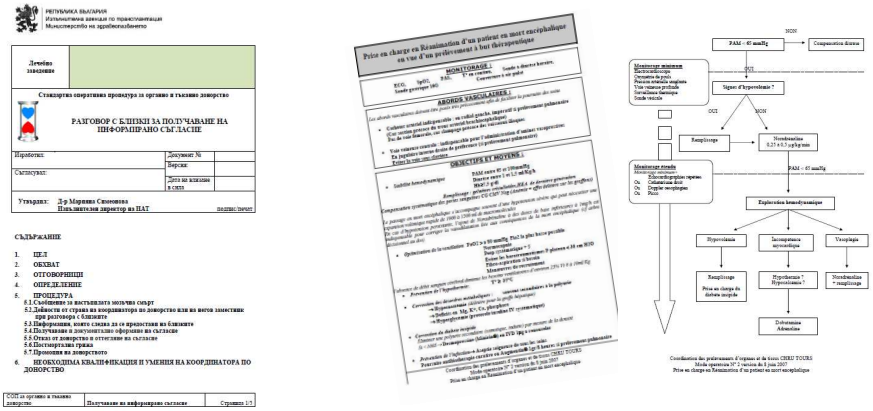


Figure 12: View of a BEAT SOP under process and an example of a French SOP used as a basis for discussions (Courtesy of twinners).

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.

As a whole, those SOPs will provide directions and national harmonisation of practices.

In order to have a counter- part to discuss with on the top of BEAT director, the second step was to draft a Job description and evaluation form of the hospital coordinator and an Evaluation form of the hospital coordinator (see annex). A job description and an attestation card for key donation personnel (KDP) coordinator of donation activities, and not for his main activity as a MD (medical doctor) in (Intensive Care Units, in case of absence, this senior MD could be replaced by MD with less experience, or a nurse. A fix payment/lump sum was also proposed in accordance to this extra activity. BEAT appointed to four donation coordinators (Medical Doctors) each in charge of a Bulgarian geographical area. Each SOP was then drafted from discussions and exchanges between all actors. The French ABM dedicated expert has been regularly discussing progresses and has been available upon request to provide support and guidance.

The SOPs are currently under finalisation and are to be gathered in a Donation and Transplantation manual to be printed in Bulgarian and to be distributed to targeted Units of all sites and to be available for the Hospital personnel, this document is restricted to a professional dissemination.

III- b - The training completion of the paediatrics kidney transplant team:

Regarding the training completion of the paediatrics 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. It is important to remind that the Robert Debré hospital transplant team already performed 6 children kidney transplantations with their Bulgarian colleagues in Sofia between 2006 and 2010. Despite the interruption of the Bulgarian children transplant programme in 2010, links were always maintained between the professionals of the two teams through the management of complex medical cases and of complex urologic cases.

During the meeting hold in October 2012 (M6) at BEAT some issues could not be discussed because of the absence of the representatives of nephrology society and of the ”N.I. Pirogov” Hospital direction where transplant used to be and shall be performed, additionally, it was highlighted that it was highly urgent and important to implement a sustainable and performing care system for paediatrics kidney transplanted patients in Bulgaria including the follow-up of those children once adults.

Nevertheless, candidates for kidney transplant were discussed during a first meeting of both transplant teams in Sofia, *two children were selected during a three day visit to Bulgaria* of MD paediatric nephrologist at Robert Debré hospital, working part-time as an expert at the ABM, and of a Professor in Paediatric Surgery at Robert Debré hospital.

The first case reviewed was a 13 year old boy with diagnosis of right kidney agenesia and left kidney hydronephrosis. He has an ureterocutaneostomy and is under hemodialysis. The proposed living donor would have been his father (34 years old).
The second case reviewed was a 10 year old girl. She suffers from a nephrotic syndrom diagnosed in 2003 with focal renal segmented sclerosis confirmed by renal biopsy in 2004. She is currently under peritoneal dialysis. The proposed living donor would have been her mother (39 year old).

However, while going on with medical tests, it appeared that both cases were more complicated than anticipated. In addition, unfortunately, the dedicated paediatric anaesthesiologist of the Bulgarian team left, adding to the lack of hospital material and equipment led 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 performed in Paris.
Recommendations were made for Bulgaria to seek for a long term solution to provide such therapeutical option to paediatric patients and to seek for budget to upgrade hospital equipment.
The French counterpart provided detailed recommendations on equipment to purchase, the Director of the Hospital went to the Ministry of health and some founding were granted to the hospital and will hopefully be indeed given and allow to buy material that would be worthwhile for any department of the Hospital.

However, it is important that BEAT and the Ministry of health support the development of a sustainable care network for children end stage renal failure therapy as well as those transplanted paediatrics patients follow-up once adults.

III- c - Reinforcement of the monitoring and evaluation system of donation and transplantation:

The third sub-section of this twinning targeted the improvement of BEAT information and informatics system for traceability and for more transparency, with the concrete objective is to produce and disseminate an annual activity report. Thanks to a very good collaboration with the Bulgarian team, the objectives of the twinning visits on the evaluation and monitoring system could be fulfilled.
The methodology followed consisted in a first five-day working visit of the ABM expert in monitoring and evaluation to two Transplant Centres in Sofia and then at BEAT headquarters:

i) presentation and detailed overview of the Bulgarian "Transplant" information system. Shared views on the current shortcomings of the system and proposals for improvement and optimal management and functionality.

ii) meetings at BEAT with the Informatics and Technologies (IT) specialists from BEAT and from IT companies, as well as with immunologists working directly with the system

iii) visit in two Transplant Centres : University hospital “Alexandrovska” (nephrology and kidney transplantations) where the main data for the National Waiting List are reported and of the Military Medical Academy (liver transplantation). On-site and direct assessment of the management and workflow of the system.

iv) example of a detailed analysis run on selected data, extracted from the system. Demonstration of better ways of working with the system, more especially on how to get detailed and precise statistical analysis.
Participants:
ABM team: Head of the evaluation division.
BEAT team: Director, the nephrologist Head of Organ Transplantation Division, Expert in Transplantation, International relations, Data administrator, data base reporter, Twinning manager; from the Transplant Centre: Donation Coordinator, transplant surgeon, Immunologist; and IT workers from the subcontracting Informatics company (software development).

One year after the beginning of this twinning BEAT appointed an expert in information technologies part of whose functions is supporting the implementation of component "Monitoring and evaluation system" and improvement of the information systems in the Agency. By the end of the reported period the specialist got acquainted with the existing information system and is currently involved in the process of establishing the necessity of data that needs to be managed by the Agency.
A questionnaire was sent to hospitals authorized for organ donation in order to collect data on activity and organization in the field of organ donation. The answers are summarized in the document below:

Summary of the Survey on Donation site (Hospitals) in Bulgaria

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1. General Information

The questionnaire was filled in by representatives from 7 hospitals (HP) in Sofia: (the Military Medical Academy, the "N.I. Pirogov"UHATEM, UMHAT "Tsaritsa Yoanna", the National Cardiological Hospital, Tokuda Hospital, UH "Lozenets", the MHAT "St. Anna") and 9 hospitals national wide (Varna, Rousse, Veliko Tarnovo, Gabrovo. Lovech, Kyustendil, Sliven, Stara Zagora, Smolyan).
Among these 16 hospitals only two declared having transplantation units within their healthcare institutions ("N.I.Pirogov" and "MMA" both in Sofia), while all of them do have Emergency Units.
Ratio between the number of HP beds and the number of ICU beds:

Hospitals in the country	Varna	Rousse	Veliko Tarnovo	Gabrovo	Lovech	Kyustendil	Sliven	Stara Zagora	Smolyan
Number HP beds	1106	600	360	320	247	300	500	600	320
Number of ICU beds	14	22	10	6	7	9	8	22	6

Hospitals in Sofia	Military Medical Academy (MAM)	"N.I. Pirogov"	UMHAT "Tsaritsa Yoanna"	National Cardiological Hospiital	Tokuda Hospital	UH "Lozenets"	MHAT "St. Anna"
Number of HP beds	2500	795	700	311	600	167	433
Number of ICU	22	8 units	18	58	24	26	33

Table 4: Ratio between the number of hospital beds and the number of ICU beds in 2013.

2. Transplant coordinator/ Key Donation Personnel

All above hospitals have transplant coordinators/ key donation personnel (KDP). Some of the hospitals have only one MD, some two (MMA, UMHAT "Tsaritsa Yoanna" and the National Cardiological Hospital in Sofia; HP of: Veliko Tarnovo, Varna, and Sliven) or even three MD (Stara Zagora). All transplant coordinators are anesthesiologists except in Tokuda Hospital in Sofia, since the KDP is a surgeon. All KDP work in the ICU in the corresponding hospitals and are under the authority of the hospitals' Executive Directors.

The question dealing with the job description of the KDP – most of the MD answered YES (10 out 16). Regarding the next question – availability of SOPs on donation process – all of hospitals in Sofia answered YES, while this is not the case with the other hospitals in the country – only 4 hospitals mentioned that they have SOPs (Lovech, Rousse, Varna and Sliven), the remaining 5 hospitals either do not answer the question or they notified that they do not have SOPs dealing with the donation sub-process.

Regarding the training on the organ donation process, most KDP answered that they have been trained in Bulgaria (except KDP from Lovech, Smolyan, and UMHAT "Tsaritsa Yoanna"). Few KDP are trained abroad (KDP from Tokuda Hospital was trained in France, KDP from MMA was trained in Spain (TPM training), KDPs from the National Cardiological Hospital and from the University Multiprofile Hospital for Active Treatment "G.Stranski"-Pleven both were trained in Spain under MODE project (EU joint Action co-funded by the European Commission under the Health programme). Two KDPs from the country are trained abroad (KDP from Sliven is trained in France and the KDP from Varna is trained in Austria). From MHAT -Rousse – KDP : Dr. T.Nedeva was trained in Italy and from the University Multiprofile Hospital for Active Treatment " St,Georgi" – KDP: Dr. K.Chifligarov – trained in Italy and Spain (ETN Project).

Reported donors (encephalic death) to BEAT:

9 hospitals from the country		**7 hospitals in Sofia**	
2010	11	2010	9
2011	8	2011	6
2012	8	2012	5

Table 5: Reported donors (encephalic death) to BEAT.

The number of the organ procurement performed according to the questionnaires filled in:

9 hospitals from the country		**7 hospitals in Sofia**	
2010	6	2010	32
2011	2	2011	2
2012	3	2012	4

Table 6: Reported organ retrieved on organ donors (encephalic death) to BEAT.

Visits on-sites and investigations through the questionnaire allowed highlighting that the BEAT information system uses software for matching the donor base filled in by hospital coordinators and the waiting list of recipients filled in by the transplant hospital teams.

The review of the existing data collection and analysis system of BEAT showed various problems regarding data collection and reporting at different levels:
- definition and nature of data to be collected
- organization of the data collection process, in particular the connection between BEAT and professionals of Transplant Centres;
- quality of data (notably completeness, these data have to be filled in at Hospital level);
- security and access to data.
- the word “dissent” is used for “refusal” – BEAT manages the national registry of refusals, the word "dissent" is a bit confusing.

As a consequence, ABM strongly suggested the drafting of guidelines on data collection procedures and on indicators, guidelines implementations and follow-up. Considering the problems met when collecting the data, a valid data analysis could not be performed as it should have been and all collected data are not fully reliable (we had to collect data back in time before BEAT creation to get a minimum volume of data to allow processing).
Also ABM strongly invited to more interaction between the hospital transplant teams and BEAT, and to increase the management of the system at BEAT that cannot be done without appointing at least one dedicated expert.

The discussions on the development of a new version of the software was the opportunity to raise several issues on the process of data collection and analysis and on the need to clearly define the objectives and criteria for the registry before going any further with the software development.

The ABM expert drafted a report and recommendations after his visit. After submission to BEAT for comments and discussion, this document is used as a support to improve the information system.
Different important points and problems were raised:
- Data extraction:
The first problem is that there is no possibility to extract data from the online software for analysis purposes As a consequence, it is not possible to perform data neither check nor data control (formats, values, exhaustibility, etc….)
Some patients are fictive but they remained included and mixed among the real data.
- Data reporting:
Data reporting for donors: performed by the coordinator who is the only person who validates and modifies these data.

The coordinators can read the data of active donors only, but it is not possible to evoke the question of the possibility to edit other donors data from a different coordination
Data reporting for patient: partially performed by the hospital’s staff and by BEAT’s staff (after reception of the documents they can also edit and correct previous data entries)

- Duplicates of patients’ ID:
Duplicated patients with different code and different data updates (even though we can follow the historical data modification).
Different data history could be found for the same patient

- Data security and access:
Patients can be viewed and edited by anyone who has access to the software
During the visit of HLA laboratory and the nephrology unit in the hospital three important points arose. It seems that password is changing at any time without prior information to the staff involved.
- The data reporting software is not user friendly:
The software takes lots of time (15 minutes) to handle the donor receiver HLA matching algorithm.
Data cells are presented on one long page, it takes time to find the right cell to enter or edit data
- A new version of software is in development:
During the discussion with medical team of BEAT and the informatics company in charge of developing the new software, it appeared that the process for developing the new software was not very clearly defined.
i) There is a need for discussions between BEAT and the professionals of organs transplantation, in order to clearly and define their objectives
ii) Data collection and storage should be based on needs and answer to some specific questions.

The BEAT team was aware of all the point raises and could clearly not deal with those aspects without new personal. There is a need of resources on one hand and of guidelines in data reporting, management, and analysis on the other hand. Problems were identified at different steps of the pre-existing BEAT system for data collection and analysis. As a consequence the system needs to be developed to be fully reliable. More communication and interaction between BEAT and the transplantation professionals and the creation of a national working group of experts could be worthwhile for the system to be fully operational.
The development of a new version of the software used for donation and transplantation was indeed the opportunity to reconsider the whole information system. BEAT staff was highly opened to suggestions and eager to start working on a new plan of action

In order to improve the BEAT monitoring and evaluation system on donation and transplantation there is a need to design a plan of action including the development of the new version of the software already initiated. In order to define a new information system, it was necessary for BEAT to:

- redefine the information needed according to the BEAT twinning visit, in order that the information system fulfils the BEAT twinning visit optimally;
- assess the needs for continuous management and maintenance of the system by BEAT;
- improve communication between BEAT and the professionals of organs transplantation, in order to clearly define their mutual objectives and tasks
- designate one BEAT staff as the counterpart of the ABM expert to work on this plan.

Then BEAT appointed an expert in information technologies part of whose functions is supporting the implementation of component “Monitoring and evaluation system” and improvement of the information systems in the Agency. Although this task was delayed, by the end of the reported period the specialist got acquainted with the existing information system and is currently involved in the process of establishing the necessity of data that needs to be managed by the Agency.

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

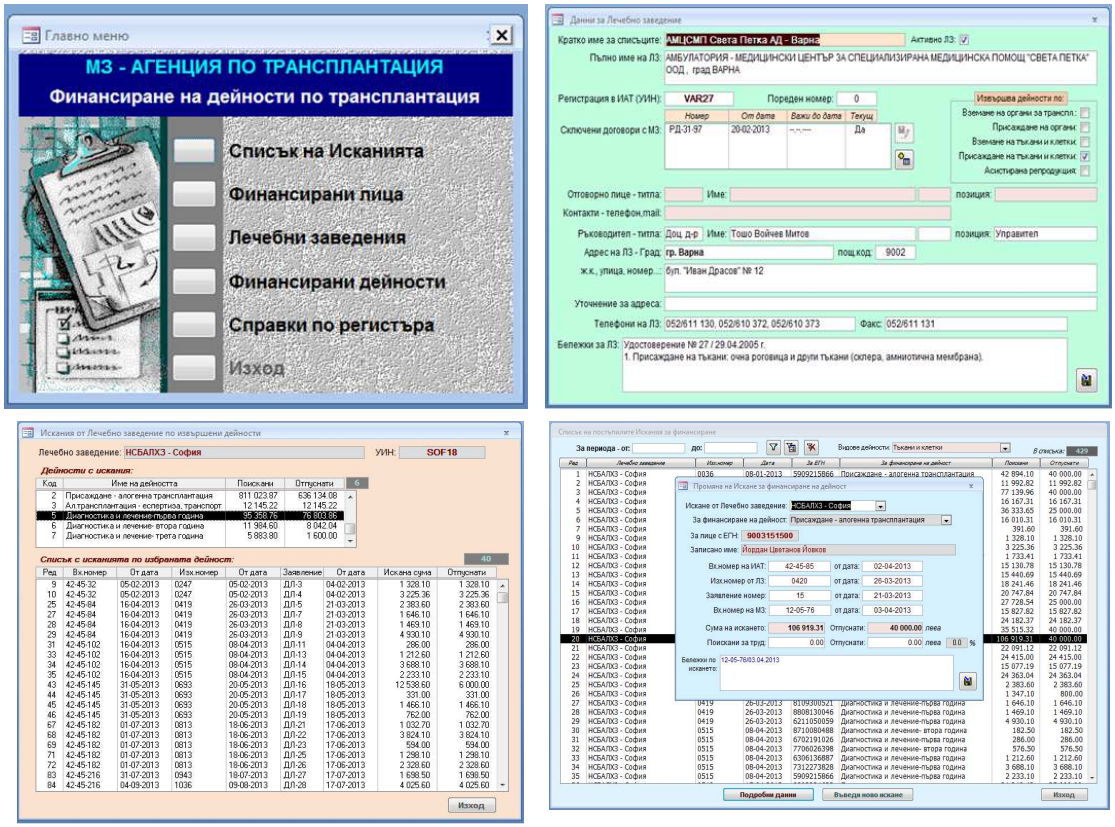

Figure 13: Screenshots of the BEAT registry for donation and transplantation activities (BEAT Courtesy)

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.

BEAT expert dedicated to the information system have started to send to the ABM expert some data that were listed and suggested by the French counterpart. Data provided covered:

Donation data:

Living donors: Donor ID/ Date of birth/ Sex/ Blood group/ Relation type/ Family relation/ Hospital Date (or year)/ Transplanted organ/ Recipient ID/ Date of birth/ Sex

Deceased donors (Brain death cases only) : Donor.ID / Date of birth/ Sex (M/F)/ Blood group/ Date of death (sorted)/ Donation center/ City/ Organ procurement/ Kidney/ Liver/ Heart/ Lung/ Pancreas/ Procurement center/ City/ Procurement team from Hosp.2/ Organs transplanted/ Kidney/ Liver/ Heart/ Lung / Pancreas/ Notes/ Family refusal/Medical reason/ Other reason

Retrieval data:

actual Donors (encephalic death): at least one organ recovered for transplantation purposes

Donor ID / Date of birth / Gender / Blood group / Date of death (sorted) / Donation center / City / Organ procurement / Kidney / Liver / Heart / Lung / Pancreas / Procurement center / City / Procurement team from Hosp.2 / Organs transplanted / Kidney / Liver / Heart / Lung / Pancreas / Notes

Transplantations:

Kidney transplants: recipient ID / Date of birth / Gender / Lst.Hosp. / Country / Code / City / Hospital / Transp.date (sorted) / Organ Donor / Note

Liver transplants: recipient ID / Date of birth / Gender / Lst.Hosp. / Country / Code / City / Hospital / Transp.date (sorted) / Organ Donor / Note

Heart transplants: recipient ID / Date of birth / Gender/ Lst.Hosp. / Country / Code/ City / Hospital/ Transp.date (sorted) / Organ Donor

Like previously stated, due to the low volume of activities and the need to reach a certain level of activities, data had to be collected from years before the creation of BEAT (under Bultransplant) and sometimes data also had to be collected at hospital level, which was time consuming and which generated delays.

Once all data were received by the ABM expert, data were assessed in terms of completion and consistency. Then, during the visit of a BEAT expert to ABM, training was provided on data management and analysis for the evaluation of donation and transplantation activities, while managing and analysing the data provided by Bulgaria. Data analysis and elaboration of a data report were to be carried out at ABM. The BEAT expert left with a first report of donation and transplantation activities in Bulgaria prepared, but also with the knowhow and guidance for the preparation of future activity reports.

Here are some of the transplantation data (as complement of the donation data that can be found on BEAT website):

Kidney

Transplanted patients from the waiting list (comparison with total patients registered on the waiting list):

year	Gender				Total Transplanted	Total
	Female Transplanted	Total Female	Male Transplanted	Total Male		
2009	5	**39**	27	**84**	32	**123**
2010	9	**88**	19	**146**	28	**234**
2011	10	**45**	17	**87**	27	**132**
2012	6	**48**	13	**72**	19	**120**
2013	4	**35**	3	**86**	7	**121**
Total	34	**255**	79	**475**	113	**730**

Table 7: Kidney transplanted patients from the waiting list.

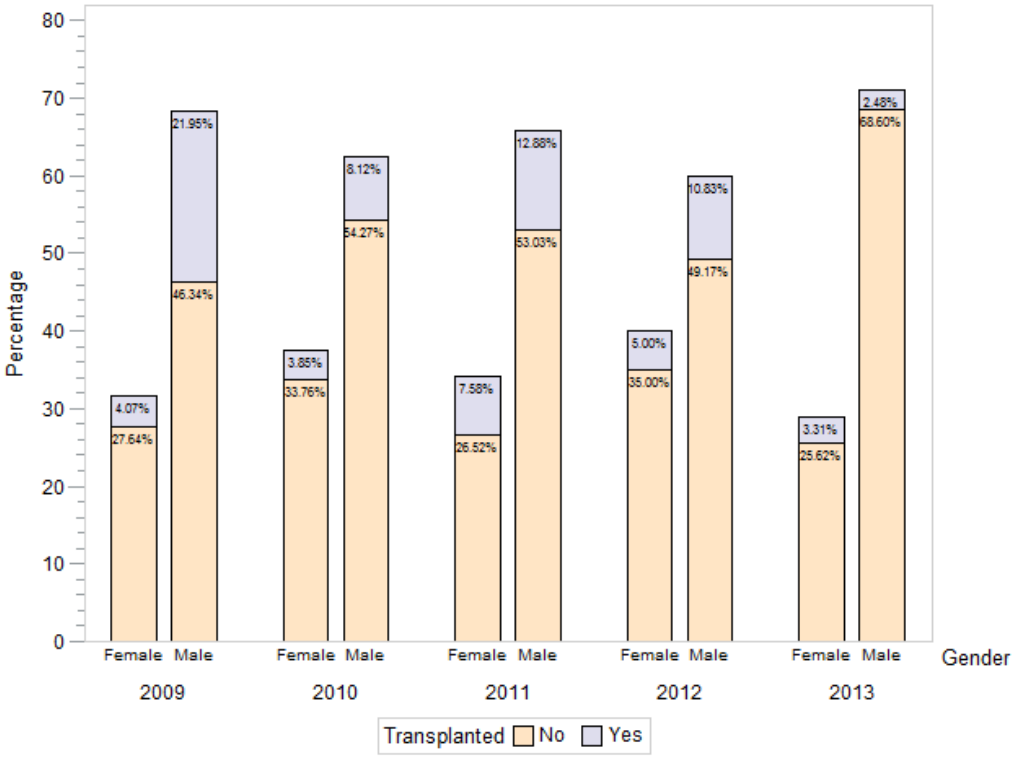

Figure 14: Kidney transplanted patients from the waiting list.

Types/origin of kidney Donated to transplanted patients (registered on the waiting list)

year	Brain dead donor		Living donors		Unknown		Total
	Female	Male	Female	Male	Female	Male	
	N	N	N	N	N	N	N
2009	4	10	1	11	0	6	**32**
2010	2	3	7	10	0	6	**28**
2011	0	7	10	10	0	0	**27**
2012	1	6	5	7	0	0	**19**
2013	0	1	3	1	1	1	**7**
Total	7	27	26	39	1	13	**113**

N = population size

Table 8: origin of kidney Donated to transplanted patients.

Patients registered on the waiting list and under dialysis

year	No		Yes		Total
	Female	Male	Female	Male	
	N	N	N	N	N
2009	10	35	29	49	**123**
2010	23	45	65	101	**234**
2011	14	30	31	57	**132**
2012	10	19	38	53	**120**
2013	6	10	29	76	**121**
Total	63	139	192	336	**730**

N = population size

Table 9: Patients registered on the waiting list and under dialysis.

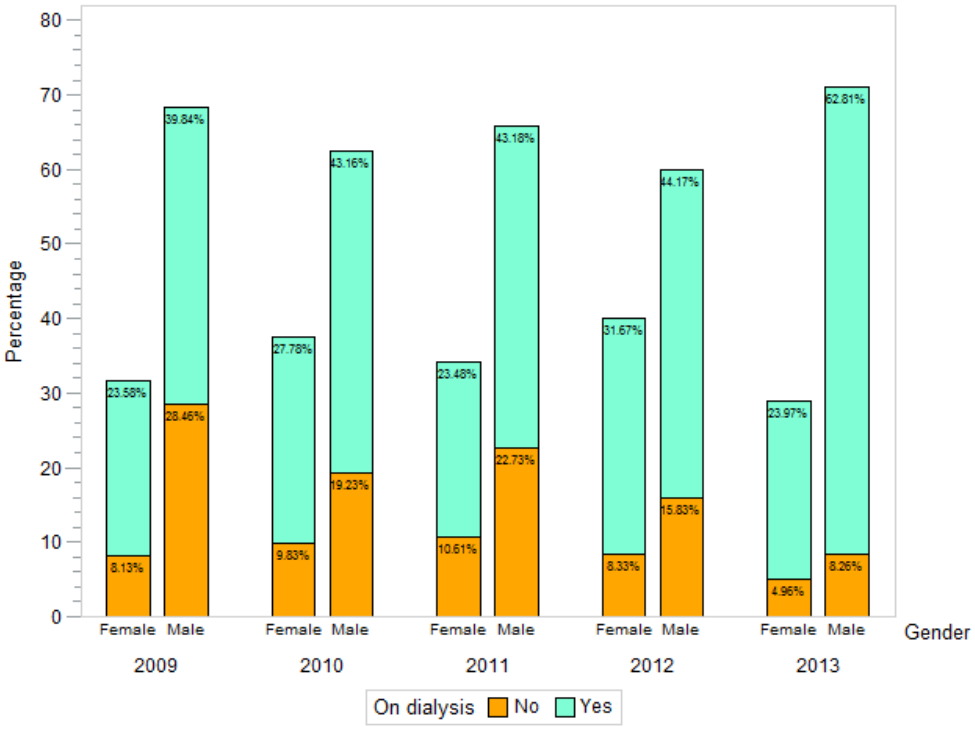

Figure 15: Patients registered on the waiting list and under dialysis.

Blood group types of patients registered on the kidney waiting list

year	A+		A-		A1+		A1-		A1B+		A1B-		A2+		A2-	
	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M
	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
2009	4	13	0	1	8	22	3	1	1	6	0	0	2	4	0	0
2010	22	35	2	2	8	15	1	5	2	1	1	0	0	2	1	0
2011	23	30	3	7	0	2	0	0	0	0	0	0	0	0	0	0
2012	13	29	1	5	1	3	0	0	0	0	0	0	1	0	0	0
2013	11	34	1	4	0	1	0	0	1	0	0	0	0	0	0	0
Total	73	141	7	19	17	43	4	6	4	7	1	0	3	6	1	0

N = population size

year	A2B+		AB+		AB-		B+		B-		O+		O-		Unknown		Total
	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	
	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
2009	0	0	2	4	0	2	5	5	1	2	11	21	2	3	0	0	**123**
2010	0	0	5	9	2	1	13	22	0	4	30	44	1	6	0	0	**234**
2011	0	0	2	7	0	0	7	12	0	2	9	26	1	1	0	0	**132**
2012	0	0	3	3	0	1	4	9	2	1	18	20	3	1	2	0	**120**
2013	0	1	3	3	0	0	6	11	0	2	11	27	2	3	0	0	**121**
Total	0	1	15	26	2	4	35	59	3	11	79	138	9	14	2	0	**730**

N = population size

Table 10: Blood group types of patients registered on the kidney waiting list.

Age of patients registered on the kidney waiting list

year	Female			Male		
	N	Mean age	STD	N	Mean age	STD
2009	39	44.42	2.12	84	47.97	1.34
2010	88	46.79	1.47	146	47.19	1.03
2011	45	44.20	1.65	87	45.38	1.42
2012	48	37.89	2.03	72	44.89	1.60
2013	35	41.11	2.18	86	43.48	1.38
Total	255	43.51	0.85	475	45.98	0.59

Table 11: Age of patients registered on the kidney waiting list.

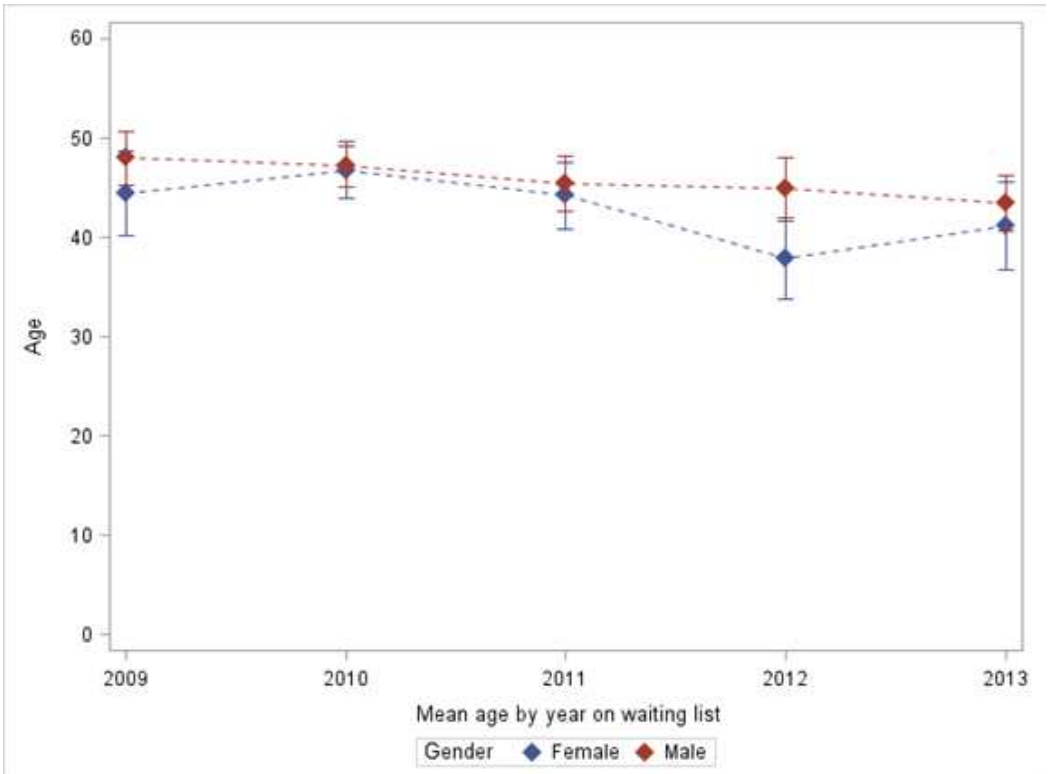

Figure 16: Age of patients registered on the kidney waiting list.

Median time waiting (month) for transplant (patients registered on kidney waiting list)

year	Female			Male		
	N	median time to transplant	STD	N	median time to transplant	STD
2009	5	6.85	2.28	27	12.75	2.45
2010	9	17.28	5.31	19	8.43	3.28
2011	10	9.44	2.56	17	13.11	2.24
2012	6	9.03	2.03	13	6.92	1.69
2013	3	1.57	2.74	3	4.79	1.27
Total	33	9.44	1.90	79	9.02	1.30

N = population size – STD = standard deviation

Table 12: Median time waiting (month) for kidney transplant.

Transplanted patients from the waiting list (comparison with total patients registered on the waiting list):

year	Gender				Total Transplanted	Total
	Female Transplanted	Total Female	Male Transplanted	Total Male		
2009	5	**7**	4	**10**	**9**	**17**
2010	5	**10**	11	**21**	**16**	**31**
2011	3	**4**	5	**14**	**8**	**18**
2012	0	**4**	6	**16**	**6**	**20**
2013	0	**3**	2	**9**	**2**	**12**
Total	**13**	**28**	**28**	**70**	**41**	**98**

Table 13: Transplanted patients from the waiting list.

Figure 17: Transplanted patients from the waiting list.

Types/origin of donated Liver for transplanted patients of the waiting list

year	Br.death		Living		Unknown		Total
	Female	Male	Female	Male	Female	Male	
	N	N	N	N	N	N	N
2009	3	4	2	0	0	0	**9**
2010	3	9	2	0	1	2	**17**
2011	1	3	2	2	0	0	**8**
2012	0	4	0	2	0	0	**6**
2013	0	2	0	0	0	0	**2**
Total	7	22	6	4	1	2	**42**

Table 14: Origin of donated Liver for transplanted patients of the waiting list.

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Blood group types of patients registered on the Liver waiting list

year	A+		A-		A1+		A1-		A1B+		A1B-		A2+	
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
	N	N	N	N	N	N	N	N	N	N	N	N	N	N
2009	2	0	0	0	0	2	1	0	0	0	1	0	0	1
2010	2	3	0	0	1	5	1	0	1	1	0	0	0	0
2011	2	4	0	1	0	1	0	0	0	1	0	0	0	0
2012	0	4	0	0	1	3	0	0	0	1	0	0	0	0
2013	1	3	0	1	1	2	0	0	1	0	0	0	0	0
Total	7	14	0	2	3	13	2	0	2	3	1	0	0	1

year	AB+		B+		B-		O+		O-		Total
	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	
	N	N	N	N	N	N	N	N	N	N	N
2009	0	0	1	3	0	0	2	4	0	0	**17**
2010	0	0	2	2	0	1	2	9	1	0	**31**
2011	0	2	0	2	0	0	2	3	0	0	**18**
2012	0	0	0	5	0	1	3	2	0	0	**20**
2013	0	0	0	1	0	0	0	2	0	0	**12**
Total	0	2	3	13	0	2	9	20	1	0	**98**

Table 15: Blood group types of patients registered on the Liver waiting list.

Age of patients registered on the liver waiting list

year	Female			Male		
	N	Mean age	STD	N	Mean age	STD
2009	7	22.13	7.23	10	34.19	5.78
2010	10	40.68	6.54	21	41.86	3.36
2011	4	23.96	13.39	14	37.66	5.12
2012	4	23.83	11.77	16	37.85	5.43
2013	3	28.64	14.07	9	34.64	6.35
Total	28	29.96	4.13	70	38.08	2.19

Table 16: Age of patients registered on the liver waiting list.

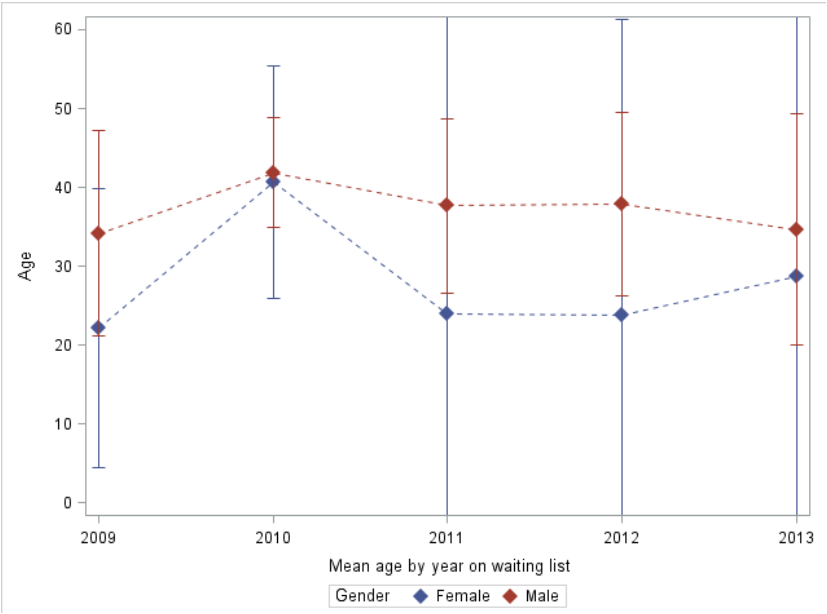


Figure 19: Age of patients registered on the liver waiting list.

Heart

Transplanted patients from the waiting list (comparison with total patients registered on the waiting list):

year	Gender				Total Transplanted	Total
	Female Transplanted	Total Female	Male Transplanted	Total Male		
2009	1	1	4	9	**5**	**10**
2010	1	7	2	12	**3**	**19**
2011	0	2	1	7	**1**	**9**
2012	1	8	1	12	**2**	**20**
2013	0	1	1	5	**1**	**6**
Total	**3**	**19**	**9**	**45**	**12**	**64**

Table 17: Transplanted patients from the waiting list.

Blood group types of patients registered on the heart waiting list

year	A+		A-		A1+		AB+		B+		B-		Unknown		O+		O-		Total
	F N	M N	F N	M N	F N	M N	F N	M N	F N	M N	F N	M N	F N	M N	F N	M N	F N	M N	N
2009	1	3	0	1	0	0	0	0	0	0	0	0	0	0	0	3	0	2	**10**
2010	3	2	1	2	0	1	0	0	1	2	0	0	0	0	2	5	0	0	**19**
2011	0	2	0	0	0	0	1	0	0	1	0	2	0	1	1	1	0	0	**9**
2012	3	3	1	1	0	0	0	2	3	0	0	0	0	0	1	6	0	0	**20**
2013	0	2	0	0	0	0	0	1	1	0	0	0	0	0	0	2	0	0	**6**
Total	7	12	2	4	0	1	1	3	5	3	0	2	0	1	4	17	0	2	**64**

Table 18: Blood group types of patients registered on the heart waiting list.

Age of patients registered on the heart waiting list

Registration year	Female			Male		
	N	Mean age	STD	N	Mean age	STD
2009	1	39.35	.	9	45.57	3.58
2010	7	26.31	5.61	12	44.50	3.44
2011	2	41.47	4.08	7	48.77	3.62
2012	8	39.83	3.85	12	39.02	3.30
2013	1	21.00	.	5	37.96	5.88
Total	19	34.00	3.05	45	43.19	1.71

Table 19: Age of patients registered on the heart waiting list.

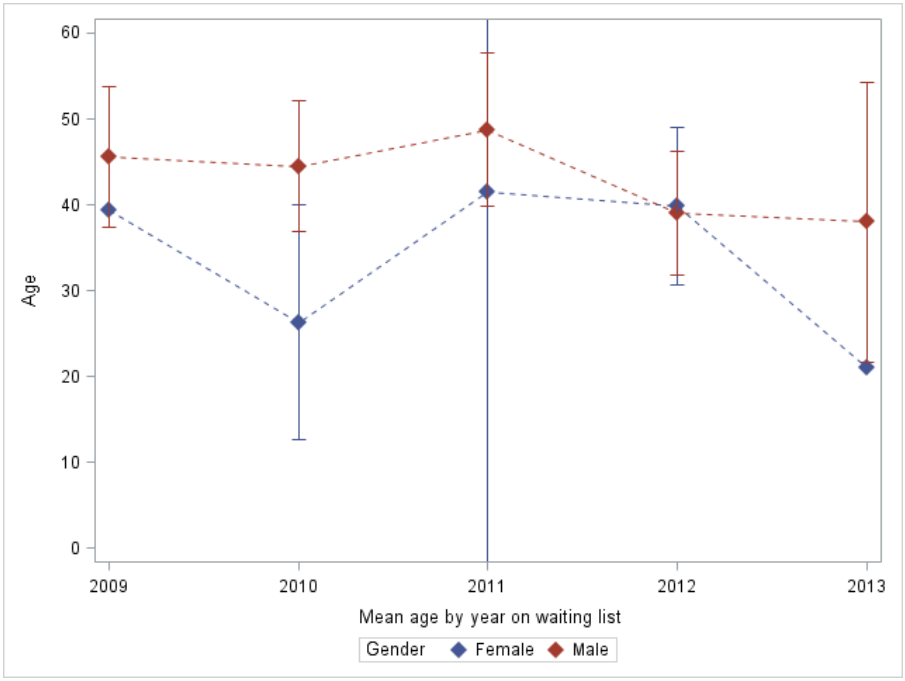


Figure 20: Age of patients registered on the heart waiting list.

Data are currently processed by the Agency of biomedicine and BEAT for selection. Some of those data and analysis are going to be uploading on the BEAT website for information to the professionals and to the public at large.

III- d - Conclusion:

Considering the appointment of two new directors during the period between the project design and the start of the implementation phase, teams of both agencies had to adjust their working methods.
Out of the nine planned working visits during the M2 – M10 period, five were carried out. During this period delays in the activities implementation are related to some institutional difficulties encountered in the Bulgarian transplantation system and health system in general.

From the Bulgarian side, the personal change in the BEAT high management and the new head of the Agency shows decisiveness to re-launch the system of organ transplantation in Bulgaria as well as willingness to actively implement the twining project together with the ABM team in the frame of ACCORD Joint Action.

This twinning was aiming at developing the overall Bulgarian system of Organ Donation and Transplantation, and since its beginning in 2012, transplantations 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.

	2012	**2013**	**2014**
Deceased donors	2	10	22
Living donors	11	11	12
Kidney transplants	13	28	56
Liver transplants	4	7	19
Heart transplants	2	4	4
Total transplants	**19**	**39**	**79**

Table 20: 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.

From the Bulgarian side, the personal change in the BEAT high management and the new head of the Agency shows decisiveness to re-launch the system of organ transplantation in Bulgaria as well as willingness to actively implement the twining project together with the ABM team in the frame of ACCORD Joint Action.

IV- Twinning to develop an Authorization and Audit system for Transplant Centres

Italy
Centro Nazionale Trapianti (CNT)

Cyprus
Ministry of Health

Czech Republic
Koordinacni Stredisko Transplantaci

Lithuania
National Transplantation Bureau

Malta :
Ministry for Health DG Health Care Services and Mater Dei Hospital

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 National requirements and needs.

Figure 11: Photos of French facilities ©Benoit Rajau for the Agency of biomedicine.

IV- a - Partners profile:

IV- a - a - Italy (CNT):

The Italian National Transplant Centre (CNT) was established under Law 91 dated 1st April 1999. Before the creation of the National Transplant Centre (CNT), national and international activities were carried out by the three inter-regional NITp, AIRT and OCST, while neighbouring countries had been represented for several years by a national authority.
The CNT was established in continuum and in respect for the existing bodies, namely regional and inter-regional coordination. The law provides that the Centre comprise a General director nominated and appointed by the Health Minister, and representatives of the Inter-regional or Regional Centre, nominated by the State-Regions Conference and appointed by decree of the Minister, while the chairman is the President of the National Institute of Health.
The law allotted the CNT many tasks aimed at promoting and coordinating organ and tissue donation and transplantation nationwide.

CNT is the competent authority responsible for:

1. Preparation and update of guidelines which define criteria and procedures for the identification of structures qualified in performing organs and tissues transplantation, taking into account:
   - The retrieval and procurement of organs and tissues;
   - Time schedule of transplant activities in line with the required standards;
   - The evaluation of performance indicators;
   - The evaluation of the quality of results and the quality of the regional organization for the donation of organs;
2. Defining structural and logistical standards in accordance with the Italian Institute of Health (ISS)
3. Auditing on the achievement of the prescribed standards (every 2 years)
4. Data collection and evaluation (Informatics System - SIT)
5. Annual publication of the transplant outcomes (per transplant)

The CNT also participates in many projects both at a National and European level. Its involvement is in some cases as the coordinator of the whole project, and in others as a simple partner. In the last few years the Centro Nazionale Trapianti international activity has been growing steadily, through common projects and relationships with other national institutions and that such activity has also strongly benefited from a general positive climate of cooperation that has recently been established throughout Europe.

IV- a - b - Czech Republic (KST):

The National Agency for Transplantation: Koordinacni Stredisko Transplantaci (KST) was established in 2003 by the Ministry of Health.

The main tasks of KST involve coordinating activities of transplantation teams, administering specialized national transplantation registries: i) of Patients Waiting for an Organ Transplantation, ii) of Organ/Tissue Donors and ii) of Organ/Tissue Transplantations. KST also coordinates procurements and transplantations, is responsible of choosing the most suitable recipients for retrieved organs, and evaluates transplantation activities notably through annual reports, monitors professional developments and trends in the field of transplantations and evaluates possible uses for transplant , and is involved in the training for professionals. Additionally, KST has to coordinate international collaboration in transplantations, as well as other tasks mandated by the Ministry.

KST has been substantially focused on quality from the very beginning of its creation. Having met the requirements of the international standard ISO 9001, KST gained an international certificate of quality management. With regards to the fact that the main activity of KST is based on work with personal data of patients, donors and recipients of transplanted organs, KST has also been certified for ISO 27001, the international standard for information safety management. Gaining these two prestigious international certificates, KST is not only meeting the highest demands of quality and data protection in its work, but also shows its capability to assist in application of these quality systems in other medical facilities.

After new amendments to the Czech Transplantation Act, which are expected to be adopted by the Czech Parliament in August/September 2012, the role of KST will be even stronger in setting standard operating protocols for transplant centres and checking their application. Auditing mechanisms, as an expected outcome of the Project, as well as training of auditors and application & performance support will mean a great help in KST´s effort to meet the demands of quality and safety.

IV- a - c- Cyprus (MoH):

Cyprus has a long history of transplantation dating back to 1986 when the Paraskevaidion Surgical and Transplant Centre of Cyprus (PSTC) was founded as a charitable and non-profitable organization. This Centre was primarily designed for the performance of kidney transplant and advanced general and vascular surgery and for 24 years was the only transplant centre in Cyprus, offered its services to the Government. All the activities concerning transplantation were performed at that Centre (Coordination, Organ Procurement and Allocation, patients treatment and follow up, statistics, data, records, "Informal registries''). Until recently (2010), more than 950 kidney transplants had been carried out in Adults and Children (paediatric). Around 55% of those were from living related kidney donors.

From January 2011, Cyprus has entered a new era in transplantation. The Government (Ministry of Health) decided to take control of the Transplant Program and a new transplant program with new staff was developed in the New Nicosia's General Hospital, the biggest and the only referral centre in the country. PSTC postponed its function/work. Very recently (June 2012) the first successful combined kidney/pancreas transplantation was performed and a Software system for Organ Allocation from

Deceased Donors - to ensure Transparency and Equal Opportunity for Access to organs - was established. It is obvious that the new transplant program is currently under development.
Cyprus Ministry of Health is the competent authority regarding organ donation and transplantation. A new legislation for Organ Transplantation, adjusted to the Directive 2010/53/EU, has been adopted very recently (July 12, 2012) by the House of Representatives. Accordingly, licensing/observation of the Transplant Centre will be performed by the New National Transplant Advisory Body to be set up in the proposed legislation. An ''accreditation'' for Transplant Centre has to be developed.

IV- a - d - Lithuania (NTB):

The Lithuanian National Transplantation Bureau (NTB) was established in 1996, and originally named the National Bureau on Organ Transplantation. NTB was created with the main aims of fostering further development and ensuring universal accessibility of transplantation services, optimal and effective distribution of transplantable organs and tissues, and protection of rights of donors as well as recipients.
NTB has to implement public policy on human tissue, cell and organ donation and transplantation and communicate to the public at large on human tissue, cell and organ donation and transplantation, coordinate and organize human tissues, cells, organs and substances of human tissue and cell products, intended for human, donation, procurement, testing and distribution, and to issue donor cards – in accordance to the law – for individuals who agreed to donate.
In 2002, on a NTB initiative, the *Balttransplant* association was created, networking transplant coordination between Estonia, Latvia and Lithuania. Also NTB collaborates with „Eurotransplant" and two neighbouring countries – Latvia and Estonia – in order to activate exchanges of organs between Baltic and European countries and to perform more transplantations operations. Cooperation agreement with the international fund Eurotransplant" signed in 2010 and cooperation declaration in the field of transplantation with Latvia and Estonia signed in 2013 by ministers of health of Baltic States. In 2004, Lithuania was among the 15 European countries along with the representatives of the European Commission and the World Health signed the "*Prague Declaration"*. This declaration provided for improved international cooperation in the field of organ donation and transplantation through the establishment of a European Transplant Network.
Additionally, in accordance with the terms of this agreement, several NTB specialists improved their skills every year during international courses.
According to the statistics, in 2009 Lithuania had 14.7 donors pmp for a population of 3.4 inhabitants. In 2013 Lithuania had 16.7 donors pmp for a population of 3 million inhabitants. There are two transplantation centres in Lithuania, so transplantation are actively running for all organs: in both of them are carried out kidney, liver and heart transplant surgeries and only in one centre for lung, heart-lung and kidney-pancreas transplants.

IV- a - d - Malta (MDH):

The Republic of Malta joined the EU in 2004. With a population of 0.4 million inhabitants, it is the smallest Member State.

Transplantations started with a kidney transplant in 1983, followed later on by the first heart transplant in 1996. The first living kidney unrelated transplant was performed in 2004. There is one acute hospital in Malta (825 beds) and one in the small island of Gozo (80 beds). Malta has also a small private hospital of 80 beds and several small clinics which do not undertake complex surgery. Transplants and retrieval have been carried out only in the main hospital since 1982, although neither lung nor liver or pancreas transplantations are performed.

Malta has no specific Transplant Authority and until now no Law on Organ donation and Transplantation. However, according to Article 248C of the *Criminal Code*, exploitation of individuals for the purpose of organ trafficking is illegal.

Organs are retrieved mainly from deceased donors through an opting-in consent system using a donor card system. Written consent is given by the relatives or next of kin, even if the potential donor carries a donor card.

A Bioethics committee is in place, which role is also to debate issues related to living wills, organ donation and definition of death since there is so far no legal definition of death.

On the operational level, Malta has a National Organ Transplant Registry since 1999, for which data reporting is based on voluntary notification. This registry entails data of all organs procured in the islands of Malta and Gozo and transplanted locally or abroad. It also keeps data about organ donors and of recipients transplanted locally. The Registry also regularly issues statistics on organ transplantation in the Maltese Islands[3].

On the international level, Malta has signed bilateral agreements with Italy (in 2009, refer to section 3.1.) and with United Kingdom for liver transplantations of Maltese patients. A recently signed agreement between Malta and ISMETT of Palermo in Sicily allows for exchange of organs and the possibility of lung transplants in Palermo for patients living in Malta.

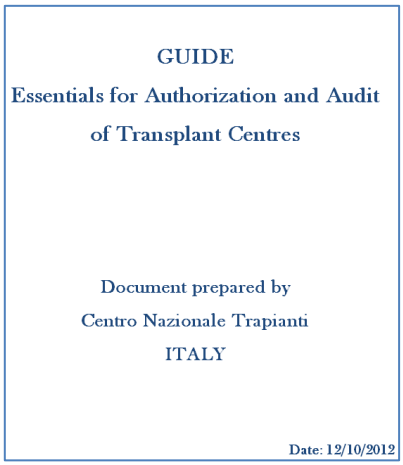
IV- b - Methodology:

At first, 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.

[3] https://ehealth.gov.mt/HealthPortal/strategy_policy/healthinfor_research/registries/transplants.aspx

Those 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.

Figure 12: Photos of French facilities ©Benoit Rajau for the Agency of biomedicine.


GUIDE

Essentials for Authorization and Audit of Transplant Centres

Document prepared by

Centro Nazionale Trapianti

ITALY

Date: 12/10/2012

This substantial guide deals with Authorization procedures, Evaluation of transplant outcomes, Vigilance system, reporting 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 (annex V) is to be easily adapted to each Member State.

Figure 13: Cover page of the Guide.

Since further analysis on more practical aspects was 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. Those onsite visits were the opportunity for a first evaluation, verification to compliance and for recommendations; 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.

IV- c - The first on-site visits:

Italy performed exploratory visits to all supported countries in order to have a better understanding of their current situation, to meet with the stakeholders: designated Competent Authority or delegated organization, seizing this opportunity to highlight the need for implementing the Directive requirements at officials' level and also at local transplant centres level, and to seek agreements on the future actions that need to be designed.

In the four visits took place during the summer and autumn and were considered of extreme added value from both sides. Italy has sent a representative team of experts (some being also members of

the national audit committee) from the competent authority and from the transplant centres with the largest activity and experience in self-evaluation.

IV- c- a - Lithuania:

Lithuania was the first country to be visited (June 2013). The meetings took place at the NTB office with the director and responsible staff members. Members of NTB introduced the donation and transplant coordination and organization, the legal framework, NTB structure, functions of the competent authorities, and statistics.
Italian experts introduced the Italian Authorization and Audit System (structure, actors, tools, software).
Discussion was mainly focused on waiting list management, allocation criteria, donor selection and patient follow-up.
The team afterwards visited the transplant centre of the Vilnius university hospital and met with the responsible and medical staff of the Renal and Liver transplant programs. The following day the Italian team together with NTB members visited the second Kaunas transplant centre.
Valuable discussions took place between transplant experts and sharing of practices and guidelines was agreed. The Competent Authorities representatives that were present will make sure to include quality criteria in their national protocols.

The meeting fulfilled NTB expectations and also reinforced NTB conviction in the need of their Twinning sub-programme activities to develop an Accreditation and Audit system for transplant facilities. This meeting also proved that NTB was on the right track in donation and transplantation and have moved forward strongly in this area and that work performed by NTB corresponds to European practice and standards.

NTB highlighted that it was useful to get acquainted with the Italian auditing system. The team of Italian experts provided a lot of examples of good practice, which will help them to prepare guidelines and criteria for transplant centres of deceased donors organs utilisation; NTB could provide Italians' reports and statistical data to transplant physicians as arguments for increase of deceased donors livers for transplantation.

During the meeting, it was agreed that NTB would send additional information: Italian transplant centre members will translate audit questionnaire into English and submit it to the NTB. Additionally, Italian experts dedicated to Liver Transplantation Centre provided recommendations – for liver recipients concerning inclusion on the waiting list (MELD score) and the criteria for liver donors.

The Lithuanian audit questionnaire of transplant centres was prepared based on the Italian accreditation and auditing system model.

NTB specialists appreciated this meeting very well: Italian experts have confirmed NTB opinion that transplantation surgeons could make more liver transplantations and use deceased liver donors for transplantations and not wait for the “ideal donor”.

Main findings of the Italian experts during the meeting in Transplantation centres:

Kidney transplantation programmes were evaluated positively by the Italian experts:

- Transplantation programme in Vilnius Kidney Transplantation centre corresponds to EU standards;
- Transplantation programme in Kaunas Kidney Transplantation centre could be expanded by starting to perform transplantations from a living donor kidney.
-
- A small number of liver transplantation is carried out;
- Liver transplantations from a living donor are not carried out;
- Only the ideal donor is being used;
- Criteria of Recipients involved in the waiting list to be reviewed - standardized (MELD index - at what index is included).

Italian experts noticed that according to available resources, skills and experience the centres have all the basics – doctors, donor blood and etc., so the liver transplantation can be enhanced, if there will be an active use of livers not only of the ideal donors, but also marginalized or the elderly age donors.

IV- c- b - Czech Republic:

Czech Republic was the second twinning country to be visited (June 2013). The meeting was held at the KST headquarters were a general introduction of the Czech organizational and legal system was done by the director and vice director of the agency. The Italian team presented their national system and discussed the items that could be potentially transferred.

Following there was a meeting at the Ministry of Health with the director of International affairs and responsible for the national transplant program. The outcomes of this meeting were that Czech Republic is indeed on the right track having transposed and implemented already many aspects of the EU Directive. The support of the Ministry of Health was achieved for adopting and implementing the new system that will be the outcome of the twinning

The visit was concluded on the next at the IKEM transplant centre and it was indeed very successful since the amount of information shared was crucial. The Italian transplant experts approved and congratulated the centre for the level of organization (surpassing the Italian standards in some aspects) and it was agreed that this model would be the base for preparing national standards and recommendations for the other Czech centres.

At the Ministry the auditors were explained the basics of the Czech transplant programmes, the structure, the players and their key roles, the new structure of legal environment (new Health Services Act in force as of the end of 2011 and the new Transplantation Act as of April 2013). The Ministry experts explained how transplant centres are approved, what their responsibilities are and the relations and responsibilities between Ministry of Health and KST.

KST was present at the meeting, extending explanations and giving practical examples to general rules and practices. It was important to see the whole structure, and all actors: the Ministry of Health as the Competent Authority, KST as the executive body, and the IKEM Centre at le local level.

The positive points of the visit were the presentation of the whole system (not only the centre itself) and the successful confrontation with the Italian (foreign) requirements.
Indeed KST saw the possibilities for adaptation and implementation in Czech Republic of the Italian tool for Authorization and Audit of Transplant Centres (the core of the tool that can be transferred).

Regarding the visit to the IKEM transplant centre, the Italian Accreditation and Audit System (structure, actors, tools, software) was introduced and its relation to the new Directive. Both sides were quite satisfied and the meeting fulfilled all expectations.

The feedback That KST received from professionals of IKEM was positive, and helped a lot in implementation of the new Transplant Act, since KST was newly responsible for creating a set of operation procedures for transplant centres; therefore creating auditing system at the same time is very advantageous for KST.
In conclusion, as a beneficiary for this sharing of expertise and the one testing this new action, KST highly appreciated the auditing system, notwithstanding that International comparison was highly valuable.

IV- c- c - Malta:

Malta was visited on July 2013. The Italian team met first with the Superintendence of Public Health officers who have been nominated as the Competent Authority for the transposed “Organ directive”. Currently the Competent Authority was working on developing protocols and standards so it was decided to share those drafts with the Italian experts as a second opinion before going into public consultation.
Following there was a meeting at the Mater Dei Hospital (transplant centre) with Nephrologists and Surgeons and various associates of the donation/transplant program.

IV- c- d - Cyprus:

Finally Cyprus was visited on September 2013. The activity of the Nicosia General Hospital Transplant program was presented and all members (Surgeon, Intensive Care Unit director, HLA laboratory, Transplant coordinators, and hospital administration) were present. The Italian team also presented their system and the discussion dealt with various technical and quality indicators. It was agreed that he Italian audit software would be transferred.
Following this meeting, a second meeting was organized at the new National Transplant Council (established December 2012), discussions mainly focused on collaboration and assistance in developing protocols and on standards sharing.

IV- d - The nomination and training of National twinners auditors:

The next twinning action was to implement the training course for auditors, each supported Twinners had to nominate two to four national auditors to be trained. The Italian team organised the training programmes in two steps: a E-learning phase and a face-to-face training.

The E-Learning phase that took place in November-December 2013 (3 weeks duration, annex VI). This 3 week training was hosted under the CNT E-learning platform; material includes all relevant and informative documents and guides.

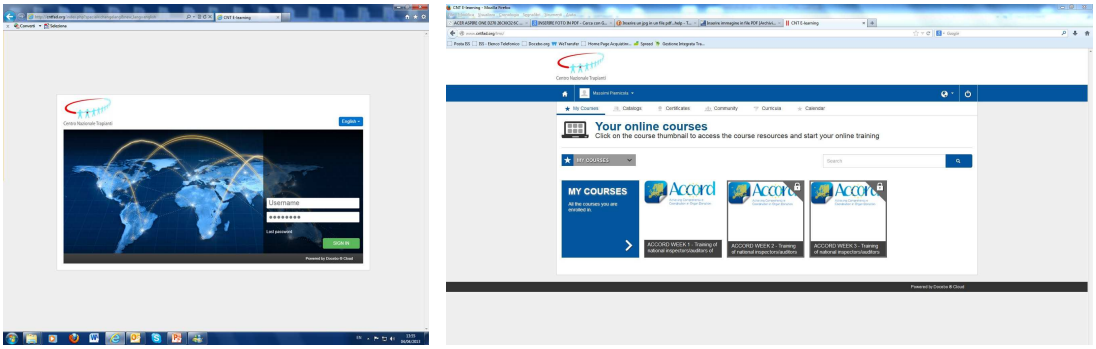


Figure 24: The e-learning hosted on the CNT's distance E-learning platform and accessible through the Internet at: http://www.cntfad.org (free of charge; screens shots Courtesy of CNT).

The e-learning module started on November 18th and ended on December 6th 2013 (platform was left open with the possibility to access educational material till end of January 2014).
It was divided in three modules of one week duration each. Access to each module was granted at the beginning of each week.
The main objective of e-learning phase was getting acquainted with relevant documents at national level (such as Italian or French systems) or international (Council of Europe recommendations).
Each week instructions were provided in relation to goals and tasks that were required to complete.
A common forum was open during each module, to interact with tutors and other participants. Participants were strongly recommended to access the forums.

At the end of each week, participants were assigned a simple task to check on the acquired knowledge. The total foreseen workload during each week was assessed to be of to five hours.

The contents of the single modules were specified as follows (annex VI):
Week 1: Course introduction, getting to know each other, detailed discussion general discussion of the WP6 Document "EAA guide" – which are the aspects to be evaluated, how to select them. Discussions were stimulated by tutor's inputs on the forum.

Week 2: The audit procedure: how it works and how to evaluate a transplant centres (different methodologies: desk-based, self-evaluation, national external audit, international audits such as

ELTR). The audit form: how to structure and use this – how to build the audit form which data are to be asked for – which are compulsory – which are optional – which are necessary for a proper evaluation.

Week 3: Methodology for an assessment of transplant outcomes (setting up national committees, identification of case mix). Vigilance and surveillance.

As final practical work, participants were asked to study the document and report through a power point presentation, specifying what they found useful and how they could implement information that was provided to their systems, or what they would change in such scheme and why. The deadline for delivering such final work was set for the next month.

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.
Auditors E-learning and training: Lithuania: 4, Czech Republic: 3; Cyprus 2 started but did not complete the E-learning phase, Malta: 2.

The E-learning phase was followed by a face-to-face training consisting of an audit exercise organised in an Italian Transplant Centre. This face-to-face training took place in Rome (3 days) during February 2014 (annex VII), it was interactive with many case studies, role play on how to investigate/audit and sharing ideas for optimizing the system.
The Italian team invited external facilitators from France (WP leader) since they have established as a complement of their system, a self-evaluation of transplant teams.
The face-to-face training was the opportunity to enlarge not only the Italian system but also to broader systems like the French one, thus creating a real European model that anyone can select its components according to local needs.

Figure 25: The two team of trained auditors during the audit simulation at one Italian transplant centre in Rome (Courtesy of participants).

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.

Figure 26: Debriefing and End of the training with an auditor/ audited experience. "Audit not only means to hear but also to understand the system proceedings" (Courtesy of participants).

Importantly, 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 area of improvements. Discussions between experts were productive, propositions for possible actions and next steps were submitted.

As a complement, Italy is supporting twinners in transferring and adjusting the proposed authorization and audit system to their local needs.
Some twinning countries called for some joint audits to be performed before the end of the Twinning activities. Joint inspections teams composed of non-national/external auditors were set in some supported countries, in order to validate the new system implemented. Taking into account that 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.

Malta–being a small Ireland facing notably anonymity problems–favoured a broad on-site meeting at the Transplant Centre. Allocation criteria, waiting list, registries, transplant outcomes etc. were discussed; tips and views were exchanged by counterpart experts, decisions for next steps have been made.

Cypriot experts were not able to participate in the residential training course and therefore they could not be certified but nonetheless they did have access to all the material and information that was available through the e-Learning platform and CNT made sure to send them also the material from the residential course.
Further discussions following the seminar were initiated with the Transplant Council and in particular regarding the evaluation of outcomes. The experts from the Nicosia transplant unit had the opportunity

to study the Italian evaluation system and they got in touch with the IT managers that developed the model.
After discussions it was decided that this model could not be implemented at the current phase in Cyprus because of the characteristics of their transplant program which is based mainly on living kidney donation whereas the Italian algorithms are designed for deceased donation. Specifically it was impossible to implement the “case mix” factor for the risk evaluation.
The two sides agreed that for the time being and given the number of centres (only one) and deceased donation rates (5.5 *p.m.p*) it was best to suspend any intervention and keep in touch for future support when needed. Italy is currently developing a program from increasing living donation and therefore all tools will be revised and redesigned.
The added value of this twinning has been the initiation of a bilateral “accord” that will be sustained even after the conclusion of the joint action.

IV- e - Joined visits/audits and last Twinning actions:

Having trained and certified 9 experts from the participating countries (CZ, LT and MT) it was agreed between partners to finalize the supporting activity with a second visit by an Italian for a joined audit altogether with the newly certified local experts.

IV- e - a- Joined visit/audit in Czech Republic:

Shortly after the training in Rome discussions started between KST and CNT for organizing a second visit in the form of a joint audit.
IKEM transplant centre in Prague had been visited by the Italian team earlier (summer 2013) and the activity referring to donors, kidney and liver transplantation were evaluated, however, the centre requested to have the full scope of their activities audited, that is to say also heart. Therefore it was agreed that the audit of 2014 could be only extended to heart transplantations activities.

This time for the joint audit, a second transplant centre was planned to be audited: CKTCH Brno. This centre the second biggest transplant centre in the country, and the scope would be donors, liver, kidney and heart transplants.
Since heart was not included in the training, KST offered to provide a local “heart auditor” but in the end CNT enrolled an Italian heart expert in the auditing team (dates were set for the 12th and 13th of May 2014).

Ahead of the joined audit, CNT recommended KST to define beforehand the criteria on which their centres may be audited. A short document with such national requirements was and shared with external (visiting) experts to allow them to be informed and prepared on the national features.

The visiting team was composed of the Italian CNT staff and Kidney, Liver, Heart experts, the trained Czech auditors and a representative of the Czech Ministry of Health.

The model followed was a short introduction in the beginning by the head of the unit and then each Italian expert met with the relative clinician whereas KST, Ministry of Health and CNT representatives performed part of the audit with the local quality manager.
As far as regards the audit of CKTCH Brno it was confirmed the compliance with the entire requested document listed in the checklist. Although a National Audit system was not yet established, they already have an internal procedure for auditing the transplant centre which is similar to the one proposed in this part of ACCORD WP6- Twinning activities.
Special recommendations were issued for the Heart programme of both centres since this activity was new under the audit /visit.

IV- e - b- Joined visit /audit in Lithuania:

The second visit to Lithuania was performed on May 2014 and the participants from CNT had the opportunity to visit/audit both Lithuanian Transplant centres of Vilnius and Kaunas.
Before the actual audit the two teams from CNT and NTB had the opportunity to meet and discuss the current and future development of the Lithuanian system. They shared view of the approach adopted by NTB for the implementation of quality assurance programme of transplant centres in Lithuania and in particular the legislative proposal for implementing some articles of Directive 2010/53/EU that are linked to quality of transplant centres.

After the ACCORD training course in Rome, the Competent Authority prepared a model of auditing questionnaire that circulated among to the two liver transplant centres and were filled by their staff.
The visiting and local newly certified “auditors” had a group session to study the replies to those questionnaires before meeting with the staff of the centres. Feedback was given by the Italian team on the structure and contents of the questionnaires optimisation and to avoid misunderstandings which may impact on the accuracy and quality of the data collected.

Following the cross analysis of data by both teams, the next organised meeting was with the responsible and staff of the Liver transplant unit at the Vilnius hospital. Discussions were mainly focused on the waiting list management, referral of patients to the list and the donors above 50 years old.
After the conclusion of the meeting with the staff the two teams went back to NTB seminar room in order to discuss the outcomes of the visit. The Italian experts gave useful recommendations and offered the possibility to perform training for liver surgeons at the Turin transplant centre under inter-university agreements.

On the second day the team visited the Kaunas transplant unit and met with local surgeons and hepathologists. The discussions focused on the analysis of questionnaire results, on the conclusion and recommendations regarding potential areas of improvements in the structure, organisation and procedures.
The chief staff and NTB auditors mention the possibility to revise the existing protocols, and CNT reiterated the offer to host some visiting professors from Kaunas University at Italian transplant centres

through academic agreements. The team from Kaunas also asks for the availability of Italian experts to take part in a seminar that could be organized in Kaunas to discuss how to expand criteria of acceptance and he confirms his availability for this. Finally, NTB staff confirmed they are going to verify the possibility to make agreements with adjoining countries (such as Poland or other country) in order to give the possibility to the liver surgeons to receive livers in case of need of a super urgent retransplantation.
After the end of the auditing visit, visiting experts recommend to invest some energy in supporting the Kaunas team that seems to be strongly committed and open-minded in an effort for improvement. This could turn out to be a propelling element for liver transplantation activity in Lithuania.

IV- e - c- Joined meeting in Malta:

The meeting took place during April 2014 and the Italian team was joined by the French Twinning WP leader. The meeting was held at the Mater Dei Renal Unit seminar room and it was attended by both the Competent Authority and the Hospital representatives.
First there was a presentation by the Competent Authorities of the legislative framework, outlining the major features of the Act by which the Maltese government transposed in 2012 the European Directive 2010/53/EU. During the presentation, the Law articles covering the issue of licensing of transplant centres and conduct of inspections were discussed.
During this meeting was also discussed the development of criteria for a kidney transplant Waiting List and the maintenance and audit of the waiting list. Explanations were given by the local experts and interaction with the Italian team was focused on the HLA typing and allocation criteria were it was agreed to check on the possibility of cooperation with Italy until a local laboratory could be established.
Follow-up of patients and living donors and the need to have registries and standard protocols were also recommended.
Regarding organ retrieval and donor evaluation, having a list of standard tests and the possibility of using extended criteria donors was suggested. Malta seized the opportunity of ACCORD and the work performed under WP4 for the guide on Living donor follow-up registry (items, organisation *etc.*) and created one straight away.
Last item was the evaluation of transplant outcomes and the possibilities of interface with existing hospital information system. A hypothesis was to facilitate the transplant centre in the collection of possible necessary data from those already available within the hospital information system and a set of variables was discussed (adapted to local needs and resources).

IV- f - Achievements and next steps:

IV- f - a- Cyprus:

Cyprus twinner has to assess internally first what would be the most suitable next step in accordance to their system in place. Italy remained and remains available for support.

IV- f - b- Czech Republic:

Achievements

Regular auditing and accreditation of Transplant Centres has been implemented into the Czech legislation and adopted by the authorities.

KST has been established by the Ministry to carry our specific tasks necessary for ensuring quality and safety and in preparing operation procedures.

Obligations of a transplant centre in the field of quality and safety are derived from the law requiring them to prepare and maintain an internal system of quality and safety in all phases of the transplantation process.

The National Action Plan for Transplantations specifically dictates the need for:

- international certification of transplant coordinators,
- creating conditions to ensure quality of health care provided by transplant centres and
- building up systems of best professional practice in individual centres.

Next steps to be implemented

Evaluation of the results from the first audits will be done by KST and reported to the Ministry of Health.

The new system of Transplant Centre accreditation and auditing will be presented to the professional public in October 2014 and at the same time a regular system for auditing all centres will be set on a three year basis (to be implemented from 2015).

Obstacles

The main challenge was to enrolled the Transplant Centre to participate in the system of accreditation and auditing. On the other hand, the existing Law lays down an obligation of Transplant Centre to create and maintain a system of quality and safety management. The only potential obstacle then appeared to be some possible risks of lack of cooperation. This should be avoided by increased collaboration with the Transplant Centre and the professional Czech Transplant Society in preparing the terms of audits and consulting audits methods and objectives.

Conclusions/Proposals

No extra resources were required since KST has been authorized by the Ministry of Health to carry out some kind of a regular control over the Transplant Centre regarding quality and safety and, at the same time, has been charged with preparing a system of General Working Procedures for them. The training course has provided KST with three auditors, and the twinning provided also the opportunity to ask other Project partners to act as additional members joining the national auditing team. No extra costs were involved, apart from travel and accommodation expenses in case of (possible) participation of foreign auditors.

AUDITNÍ OSVĚDČENÍ

bylo prověřeno v souladu s podmínkami ACCORD JA
Authorization and Audit system for Transplant Centers (AATC)

Toto osvědčení platí pro dobu 3 let od data vystavení a podléhá pravidelnému ročnímu samohodnocení
podle pravidel AATC a VPP 1.5

V Praze dne: prof. MUDr. Miloš Adamec, CSc., ředitel KST

JUDr. Přemysl Frýda, mezinárodní auditor AATC

Mgr. Eva Klemenová, Ministerstvo zdravotnictví ČR.

The situation in Czech Republic today, a word from KST:
"Two Transplant Centres have been audited in 2014, auditing of other Transplant Centres are already scheduled for this year"

Figure 27: KST Audit certificate (Courtesy of KST).

IV- f - c- Lithuania:

Achievements

- Review of the legal framework in terms of the functions of the Competent Authority;
- Change in the structure of Competent Authority: establishment of Law and Supervisory Division (nomination of two dedicated auditors);
- Development of legislative proposal for implementing articles of Directive 2010/53/EU that are linked to quality of transplant centres;
- Prepared and approved an order of planned an unplanned inspections, questionnaires;
- Routine and non-routine procedures are published in the database of legal documents;
- Accomplished an audit of two liver transplant centres (joint visit in May 2014)
- Submitted to the Ministry of Health proposals for activation of liver transplant centres.

Next steps to be implemented

- Routine inspection planned for 2015 shall be published in November, in website www.transplantacija.lt
- Translation of documents from Lithuanian into English will be completed in December of 2015.
- Need to review requirements for liver donor – to use liver from older and/or marginal donors;
- Need to look for opportunities for Lithuanian liver surgeons to improve their skills in other countries (for example in Italy);
- For NTB to expand co-operation with neighbouring countries - transplant centres for organ donor exchange, for example, with Poland, Latvia, Estonia, in order to ensure rapid retransplantation opportunities.

Obstacles

- There are no independent national experts who can inspect the transplant centres;
- There are no specific standards for transplant centres (number of transplant operations that must be performed each year);
- There is no centralized system for collecting the information (reports) about activity in transplant centres;
- Shortage of funds.

Conclusions/Proposals

Participation in the "Twinning" project for audits was useful because of "good experience" examples from Italian and French representatives. Audit is a mandatory activity not only for fulfilling the requirements of EU directives but mainly in order to ensure the quality of services.
The Lessons learned and information gathered helped to formulate questionnaires for auditing and made it possible to create a positive attitude about auditing process (that it isn't the way of control or punishment, but a way to figure out potential issues and find some solutions).
The Transplant centres volunteered participated in the auditing process benevolently, because they were interested in identifying problems, seizing opportunities for improvements. It also stimulated reasonable competition among the centres, promoted professional development of surgeons/specialists and in overall increased the number and quality of transplantations.
The formation of a Committee of experts in audit under EU Commission would be highly beneficial for small countries. Member States could delegate their experts to this Committee but in order to do so, it is important to agree on the criteria used for the selection of these international experts.
Last but not least, it should also be discussed how to develop a unified audit system of the donation institutions across the EU.

The situation in LT today, a word from NTB:
"The legal basis for auditing is created; Specialists of National Transplant Bureau know how to do it; Transplant centres will be auditing by approved and published plan (once in two years)."

IV- f - d - Malta:

Achievements

The Human Blood and Transplant Act (L.N. 345 cap 483), by which Maltese government transposed the Directive 2010/53/EU, contains articles covering the issue of licensing of transplant centres and conduct of inspections. The licensing Authority is explicitly mentioned to be the Superintendent of Public Health and draft checklists for licensing of transplant facilities have been prepared and are under discussion at this Authority level. Conditions for inspections in particular are specified in the law.

Next steps to be implemented

The Competent Authority will invest in using the persons who have been trained to audit transplant centres in training other suitably qualified staff so as to promote capacity building in the area. Standard Operative Procedures for audit are also to be prepared. There will be a plan for external auditors to review the national activity.
Concerning the development of particular actions, the Maltese Authority would like to implement a system for collecting relevant post-transplant follow-up information for all transplant recipients and living donors. Concerning procurement, a well-structured protocol, is already adopted by the intensive care units and the consent law will shortly be changed in order to have explicit consent with registry implemented. Brain death diagnosis and consent are not legally ruled so far.

The present rules adopted for the management of the waiting list will be reviewed and an assessment will be done on the impact of using HLA criteria. A collaboration with Italy will be set up for HLA typing and cross matching.
For the follow up of living donors a registry needs to be set up and some protocol for limitation of drop outs.

Obstacles

There is a limited human resource and training of staff is needed from the Competent Authority. Also, due to limited secretarial there will be an increase in administrative work.
The problem with small size of transplant activity can lead to very skewed results (especially when comparing to larger countries).

Conclusions/Proposals

Standards Directorate (the Competent Authority) will be utilizing any other future twinning opportunities/EU funded training to achieve the above plan.


Health Care Standards Directorate
Superintendence of Public Health
Checklist For Licensing of Transplant Facilities
Name of Hospital :
Address of the Hospital
I. GENERAL INFORMATION
Owner :
Chief of Hospital/CEO/Medical Director
Ownership : Government ☐
Private ☐
Hospital License Held and Validity
II. ADMINISTRATION

Organization/Program Setup and Goals	Yes	No
An organizational chart and structure, showing the scope of authority, function and responsibilities of the various personnel and the lines of communication among them, is available.	☐	☐
A Hospital Organ Donation Program is created to oversee organ donation activities and process in the hospital.	☐	☐

III. QUALITY MANAGEMENT

Quality Management	Yes	No
The hospital has an established, documented and maintained quality management program on organ donation and transplantation that reflects continuous quality improvement principles.	☐	☐
Availability of Quality Manager	☐	☐
Availability of Written Policies and Procedures	☐	☐
The hospital has a Manual of Operations or Quality Manual on Organ Donation and Transplantation and includes, among others, the following: • Operating procedures for the verification of donor identity • Operating procedures for the verification of the details of	☐	☐

The situation in Malta today, a word from Mater Dei Hospital:
"Documents for Transplant Centre Accreditation have been developed; The serious Adverse Reactions/Events process was also created".

Figure 28: KST Audit certificate (Courtesy of KST).

IV- g - Conclusion:

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 twinners 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.

V- Added value of Twinning activities:

The first aim of Twinning activities was to develop Organ Donation and Transplantation system in a Member State seeking to implement or improve a specific area – thus facilitating the implementation of the 201/53/EU Directive, of each National Action Plan in Organ donation and Transplantation and of the European Commission 2009-2015 Action Plan on Organ Donation and Transplantation – thanks to a concrete and direct transfer of expertise from a supporting Member State. Nonetheless, some of the developed tools have broader potential to be shared at EU level and adopted by other Member States.

The multiplet twinning concretely promoted more harmonized practices and processes among the supported Member States. Furthermore, since the 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, specificities and needs. 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.

The E-learning platform for 'Multi-Organ Donor procurement surgery' that has been granted with EACCME accreditation of the UEMS is also now a tool available for broader countries tan The Netherlands and Hungary. France actually already started to train surgeons on abdominal organ retrieval with this platform. Additionally, some other countries showed interest as well. So indeed, tools developed by a Member State can meet the needs of others.

On the top of reporting results of twinning, 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 Twinning initiatives once the ACCORD Joint Action will be completed.

In overall, twinning activities of ACCORD showed direct measurable results and led to valuable transfers of knowledge and expertise between Italy, The Netherlands, Hungary, Malta, Cyprus, Lithuania, Czech Republic, France and Spain. Twinning activities also contributed to strengthen the Network at Competent Authority level and to facilitate collaborations.
The ACCORD Project will enable a higher level of accreditation and auditing thanks to the guidance and practical experience provided by the Italian twinning partner.

Acknowledgements:

The authors would like to highlight that The European Commission, by co-financing projects under the Health Programme, is greatly contributing to the field and is promoting a better, safer and wider National and European landscape for organ donation and transplantation.

VI- Annexes

VI- a - Annex 1

Job description of the hospital coordinator and evaluation form

Job description to be approved by Executive Director /Head of Medical Establishment

I. GENERAL INFORMATION

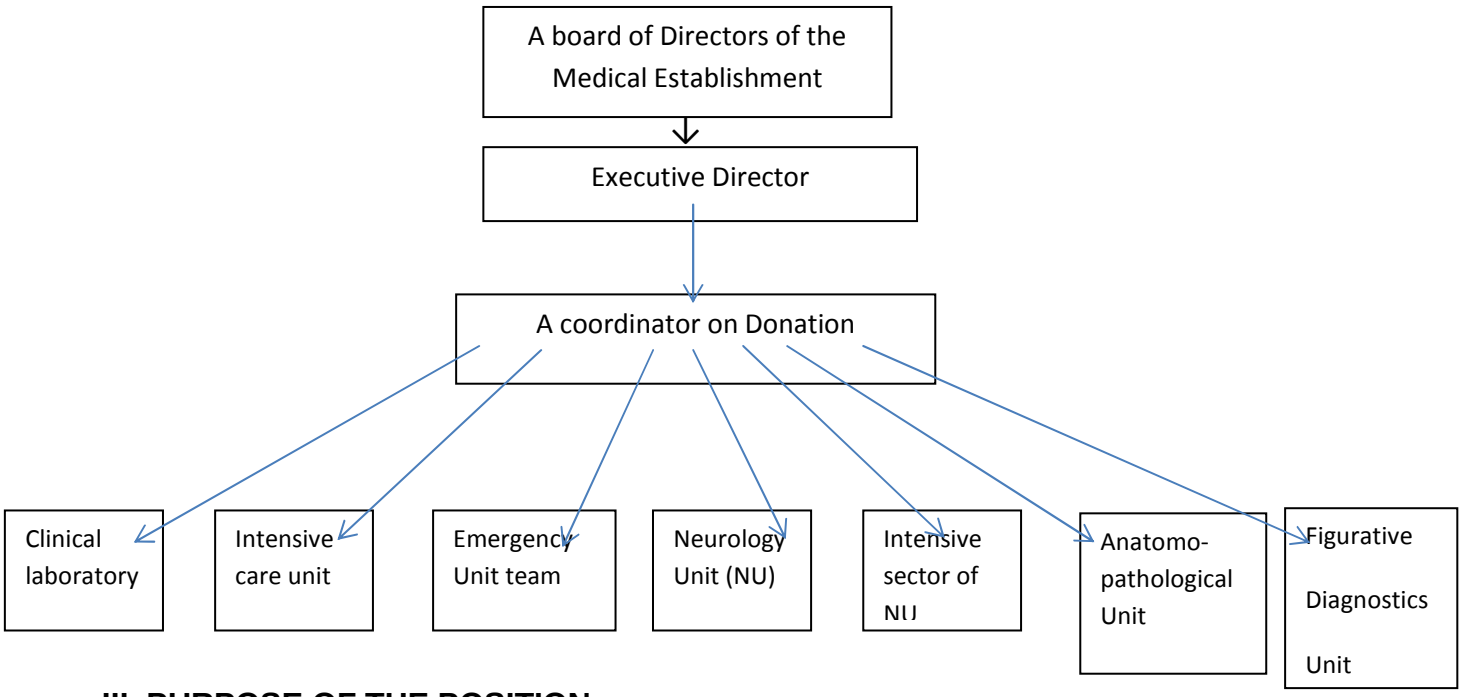
Medical Establishment…….

Administration/Anesthesiology Reanimation and Intensive care unit

Position – A responsible person according to article 15d of Law on Transplantation of Organs, Tissues and Cells

(A coordinator on organ donation **of a medical establishment)**

II. A PLACE OF THE POSITION IN THE ORGANIZATION (SUBORDINATION)



III. PURPOSE OF THE POSITION

Every medical establishment, which carries out activities in transplantation, shall appoint a coordinator on organ donation from its staff, who should:

-organise, control and carry responsibility for the expertise, the collection, handling, processing, labelling, storage, delivery and transplantation of organs, tissues and cells and notification about serious adverse reactions and serious adverse events;

- organize, supervise and is responsible for all stages and activities on finding out, establishment and maintenance of the vital functions of a potential donor with brain death.

IV. AREAS OF ACTIVITY

1. Within the scope of the occupied position are all activities on organ transplantation of donors with established brain death.
2. Activities related to the participation in the organization of the staff training, methodical assistance and assessment of performance.
3. Follow-up activities of the national standards in the field of transplantation with the leading ones in the field of organ donation and transplantation.
4. Activities related to the preparation and control of the documentation in regard to the organ donation.

V. BASIC OBLIGATIONS AND RIGHTS

1. Monitor compliance with the legislative requirements during the implementation of the activities of examination, sampling, handling, processing, packaging, labelling, storage, transplantation, attaching, providing and transport of organs, tissues and cells in the tissue establishment, as if he establishes any kind of infringement shall inform the Director of the hospital;
2. Draw up an annual report on the carried out activities on transplantation and shall submit it to the Executive Agency for transplantation.
3. Provide information to the Executive Agency for transplantation about the accomplished activities on transplantation and about the related problems;
4. Organize and monitor the training and the improvement of qualification of the officials involved in transplantation;
5. Control the organization of work in the medical establishment and in regard to the activities which may affect the transplantation;
6. Supervise and organize the registration of all activities on transplantation carried out by the medical establishment, as well as compliance with the requirements for registration;
7. Control documentation of all activities on transplantation, as well as the proper entrance of the information in the drafted documentation;
8. Apply and update the system control of ensuring the quality of transplantation activities based on established medical standards and the principles of good practices;
9. Ensure the activities on organization of traceability of organs, tissues and cells;
10. Check the materials used, the working environment and its characteristics for compliance with the legislative requirements;
11. Monitor the compliance with the established standard operating procedures in the medical establishment;
12. Provide information to the Executive Agency for transplantation as per the introduction of new methodologies in transplantation and take actions for their including in the updated standard operating procedures;
13. Supervise the places for packaging and storage in order to prevent any violation of the functionality or integrity of the tissues and cells;
14. Organize and coordinate the conclusion of contracts and the introduction of procedures to ensure that upon termination of the hospital tissues and cells that are present in it, will be submitted to other hospitals, holding a permit or certificate for transplantation;
15. Organize and coordinate the conclusion of contracts with third parties for the provision of goods and services, which may affect the quality and safety of organs, tissues and cells;
16. Inform the Executive Agency of transplantation for people with suspected brain death;

17. Coordinate and monitor compliance with procedures for the determination of brain death and the maintenance of the vital functions of the potential donor;
18.Carry out or coordinates the conduct of conversation with relatives of deceased persons on the possibility of organ donation;
19. Coordinate and organize events on promotion of voluntary and unpaid donation of organs, tissues and cells;
20. Take action in informing citizens on moral-ethical and medical issues of transplantation;
21. Ensure the availability of necessary quantities of medicinal products, medical devices (solvents, reagents, etc.) and good equipment for the transplantation activities and notify in a written form the Director of the hospital about their availability and about elimination of twinning visits;
22. Conduct reference to the official register of the Executive Agency for transplantation for a written dissent for removal of organs, tissues and cells of deceased persons;
23. Participate in training courses, seminars and conferences in the field of the organization and coordination of the transplantation activities in order to maintain a high level of qualifications in these areas.

Rights:
1. Makes proposals to his direct head how to improve the activity.
2. Has all rights under the Law for healthy and safe working conditions and the legislative acts of its application, the Rules of order of internal labor.
3. Uses and requires professional information concerning the implementation of its obligations as a responsible person under article 15 (d) of the Law on transplantation of Organs, Tissues and Cells.
4. Decides on the everyday problems of an operational nature.
5. Requests and receives the information needed for the performance of his duties.
6. Has the right of education, with a view to improving their qualifications.
7. Has the right to have a site of work, corresponding to the sanitary-hygienic requirements, as well as equipment and materials, ensuring normal conditions for the performance of his duties as a responsible person under article 15 (d) of the Law on transplantation of Organs, Tissues and Cells.

VI. ASSIGNMENT AND PLANNING OF WORK

The Tasks on the implementation of activities under the job description are assigned by the Executive Director.
After the assignment of the obligation, the way of implementation of the action has to be planned:
a) by the coordinator within the legislatively or administratively established deadlines and with the instructions of the official who has assigned the task or
b) with the assistance of the Executive Director for the assigned task or by an indication of performance

VII. RESPONSIBILITIES RELATED TO THE ORGANISATION OF WORK AND THE USE OF RESOURCES

The coordinator is responsible as per:

- the proper, correct and within the due terms saving of the documentation.
- the damages caused to the employer due to non-fulfillment of the assigned tasks.
- the property he is put in charge of and for shortages, laid down in the proper order.

- compliance with the legislative requirements and the internal regulations and rules for safe operation and fire safety, as well as for the protection of the environment, as he is responsible for the damages in an accident, which was caused in culpable violation of the above rules.

VIII. DECISION-MAKING

Within the framework of the general rules and the instructions given the coordinator expresses his personal opinion and judgment, taking into account the nature of the assigned task.
The decisions shall be taken:

(a) by himself in the framework of the guidelines or rules to carry out the activity;
(b) in consultation with colleagues and employees to whom the task has been assigned
(c) following an assignment of a task by the Executive Director, depending on the nature of the activity and the specific task.

IX. CONTACTS

- Contacts have been established with other units within the medical establishment such as neurology, neurosurgery, figurative diagnostic, cardiology, microbiology, virology, clinical laboratory and to all other organizational units and the administration.
- There are contacts with other external medical establishments and laboratories with whom contracts have been concluded on organ donation activities
- Contacts with competent organizations on organ transplantation – EXECUTIVE AGENCY FOR TRANSPLANTATION, THE MINISTRY OF HEALTH, medical institutions and other governmental and non-governmental organizations and institutions.

X. REQUIREMENTS FOR TAKING UP THE POST

1. Educational degree: Bachelor/Master
2. Professional field: Health care/Medicine
3. Additional qualification: Need to know:

- Legislative acts in the field of health as well as on the transplantation activities – eg. The Law on Health , the Law on medical establishments, medical institutions, the Law on transplantation of organs, tissues and cells, the Data protection Law, and all the acts issued as per their application and to implement their provisions.
- Knowledge of the internal structure and organization of the work of the hospital.
- Knowledge and application of good practices in the profession.
- Knowledge and work with MS Office and Internet and with the specialized software on transplantology.

XI. SKILLS AND COMPETENCES

1. Ability to plan, organize and perform the work covering the quality requirements and accurately and carefully tracking and storing information.

2. Personal requirements to the contractor and behavioral characteristics — tactfulness, sociability and emotional stability, communication skills and ability to solve conflicts, flexibility, diplomacy and the ability to quickly find alternatives, independence, organization, loyalty and honesty.
3. Ability to work under pressure and taking personal responsibility.
4. Ability to work with outside persons and organizations and work in a team.
5. Skill for taking personal and team responsibility.
6. Ability to analyze information, synthesize and present the results.

Drafted by: ..... date: .....
(name, surname, signature)

Approved by:.....date: .....
(name, surname, signature)

I am acquainted with the job description and a copy was handed to me: ..... date:.....

Превел:
/Десислава Бъчева-Цонева/

Evaluation form of the hospital coordinator

A FORM	
for individual performance assessment of the person according to Art. '15 under Law on transplantation of Organs, Tissues and Cells - "A Coordinator on donation"	
Of:	
(name, surname)	
Position:	Clinic / unit:
Coordinator on donation	Health establishment:
Period of Assessment from *:	: to
General assessments of individual performance of the position coordinator of donation	
I. Work Plan:	

Description of the purposes	Period for implementation	Method of proving the implementation
Qualification and certification of activities on establishing brain death	from ..... to…….	Certificate and Diploma
Number of patients on apparatus ventilation support - a potential donor for the establishment of brain death		monthly statements
Number of patients with proven brain death - Unaccomplished		monthly statements
Number of accomplished donors with brain death		monthly statements
Assess and number of performed activities on live donation		monthly statements
Observance and knowledge of the regulatory framework for organ donation		Prepared statements SOP and other documentation referred to the regulatory framework
Reporting and documentation - to IAT and to the medical institution		
Activity for training of the junior coordinators - personally		an individual training
Training according to IAT programs and programs of the European institutions (EI)		Certificates from IAT and EI

Comments:
. 1. The objectives in the work plan can be in regard to the achievement of concrete results and to improving the individual

qualities of the evaluating person, including his professional qualification and changes in his behavior. The objectives in the work plan should be formulated as per the priority direct obligations of the job description				
2. The objectives in the work plan should be to the maximum extent specific, measurable, achievable, orientated towards results and defined in time.				
".3. The period for execution the relevant purpose should be fixed from date to date and / or include a scheduling, plan or similar document, as it is uncceptable to exist a recorded text such as"a constant deadline".				
4.The way of proving the performance should be specified - for example, achieving a certain value of indicator / indicators and / or concrete facts confirming that (an analysis, forecast, draft legislation received certificate and etc.).				
Date:				
Signature of the evaluating manager.....	Signature of the evaluated person:.....			
(name, surname)	(name, surname)			
II. Intermediate Meeting:				
date				
Comment of the evaluating manager and / or of the evaluated person (if there is any comment):				
Signature of the evaluating manager:	Signature of the evaluated:			
(name, surname)	(name, surname)			
III. A common rating:				
A. Degree of realization of the objectives of the work plan		evaluation		
NB. The evaluating manager notes with an "x" the designated assessment.		1	2	3
Motives of the evaluating manager:				
B. Degree of fulfillment of the obligations defined in the job description of the position		evaluation		
		1	2	3
NB. Evaluating manager notes with an "x" the designated assessment.				
Motives of the evaluating manager:				
C. Indicators of competence				
1. Analytical competencies - awareness and use of regulations related to organ donation and organ transplantation and national standards in the field of organ donation and transplantation; skills for collecting and reporting of diverse as per volume, type and origin kind of information		evaluation		
Motives of the evaluating manager:		1	2	3
2. Orientation towards results - skills for simultaneously effective implementation of activities, accompanying the organ donation and transplantation, good management of time and organizational skills, abilities to manage difficult and medical emergency medical cases.		evaluation		
Motives of the evaluating manager:		1	2	3

Motives of the Executive Director of the medical establishment:	1	2	3
3.Construction of relations - capacity to work as part of a multidisciplinary team; potential to deal with stressful situations and to take responsibility;	evaluation		
Motives of the evaluating manager:	1	2	3
Motives of the Executive Director of the medical establishment:	1	2	3
4. Knowledge of stakeholders, knowledge on the implementation and organization of the organ donation and organ transplantation; skills to respect rights and to respect the interests of the religions denominations ofthe patients and relatives of the donor.	evaluation		
Motives of the evaluating manager:	1	2	3
5. 5. Communicative and competence - good communication skills with patients, staff, relatives of the donor; skills to clearly and accurately interpreting the information received in verbal communication, written communication skills.	evaluation		
Motives of the evaluating manager:	1	2	3
Motives of the Executive Director of the medical establishment:	1	2	3
6. General assessment of the competences:	evaluation		
The overall assessment is determined based on the prevailing number of assessments on the separate performance evaluations of competence.	1	2	3
NB. The evaluating manager notes with an "x" the designated assessment.			
Comment of the evaluating manager on the general achievements and the overall behavior of the evaluated:			
Overall assessment of the performance for the period:			
The overall assessment is determined based on the marks on individual performance by adding the assessment on the			

number of achieved donors (5 to 0):	
1 "Exceptional performance" - five donors achieved	4 "The performance does not fully meet the requirements, needs improvement" - two donors achieved
2 "Performance over requirements" - four donors achieved	
3 " The implementation meets the requirements" - 3 donors achieved	5 "Unacceptable Performance" – there is no donor achieved
Plan for training and development of the evaluated:	
Future potential:	
Signature of the evaluating manager and the executive director of the medical establishment: 1. ..... 2.	 Date: ..... Date: .....
(name, surname)	
Comment the evaluated:	
Signature of the evaluated	Date: .....
(name, surname)	
Comment of the controlling manager:	
Signature of the controlling manager.....	Date: .....
(name, surname)	
Signature of the evaluated:.....	Date: .....
(name, surname)	

The assessment period is from 1 January to 30 June and from 1 July to 31 December. In the absence of the evaluated or the evaluating person, the end date of the period is extended with seven work days.

VI- b - Annex 2

Questionnaire for donation hospitals

1. General information

- Region/City:
- Name of the hospital :
- Total number of beds of the hospital:
- Intensive care unit - Number of beds:
- Does this hospital have a transplantation unit? Yes No
- Does this hospital have an emergency unit? Yes No

2. Transplant coordinator/Key donation Personnel (KDP):

- Is there a KDP appointed? Yes No
- Name of appointed KDP:
- Year of appointment :
- Profile of the KDP

Physician: Yes No

If yes what is his speciality:

Nurse: Yes No

- In what department does the KDP work?
- Under which authority is the KDP?

- Does the KDP have a job profile? Yes No
- Does the KDP have SOPs on donation process? Yes No

(if yes) What are the SOPs?

- Did the KDP receive training on organ donation process? Yes No

(if yes)<u>In Bulgaria</u> Yes No

Name of the training session(s)

Date of the training session:

<u>In another country</u> Yes No

Name of the training session:

Date and location of the training session:

Number of brain deaths reported to BEAT

Year 2010	Year 2011	Year 2012

Number of organ procurement performed

Year 2010	Year 2011	Year 2012

Full name and position of the person filling in the form:

Date:

VI- c - Annex 3

E-learning structure

ACCORD – Training of national inspectors/auditors of transplant centres

WEEK 1

- **INTRODUCTION**
- **E-LEARNING AGENDA**
- **WORKING DOCUMENTS**
  - Coe Recommendation documents
    Rec 2001_5 on management of waiting lists
    Rec 2004_19 on criteria for authorisation of TFs
    Rec 2006_15 on functions of NTOs
  - EAA - Essential for Authorization and Audit
    ACCORD WP6 EAA Guide
  - Italian technical guidelines for authorization of transplant centres
    Italian Standards for Operating Theatres
- **BACKGROUND DOCUMENTS**
  - European Directives
    Decision 2010_453_EU Inspection of Tissue Establishments
    EC manual Tissue Establishment Inspection
    Organ Directive EU 45_2010 EN
    Organs Action Plan EN
    Tissue Directive 2004_23_EC
    Tissue Directive Tech. 2006_17_EC
    Tissue Directive Tech. 2006_86_EC
- **WEEK 1 - ASSIGNMENT**
  Template for Week 1 Assignment

WEEK 2

- **WORKING DOCUMENTS**
  - ITALIAN LEGISLATION
    Deed n.1966 of 29 April 2004
    Structural and Instrumental Requirements for Accreditation
  - MODE Joint Action _ Audit in Italy
    Accreditation procedures
    Audit activity
    Introduction Quality Pathway
  - ITALIAN KIDNEY Transplant Centre AUDIT
    List of Information that Kidney Transplant Centres should provide
    Check-List for the Audit of Kidney Transplant Centres
  - ITALIAN LIVER Transplant centre AUDIT
    Proposal for Structure of a National Liver Audit Committee
    List of Information that Liver Transplant Centres should provide
- **SUPPORTING DOCUMENTS**
  - FRENCH SELF EVALUATION MANUAL

ABM manuel_autoevaluation_equipes_greffe_2012
French self-evaluation manual (english version)

- **WEEK 2 - ASSIGNMENT**
  Template Week 2 Assignment

WEEK 3

- **EVALUATION OF OUTCOMES**
  Evaluation of Transplant Outcomes in Italy
  The Italian Survival Calculator {www.D-MELD.com}

  - SUPPORTING DOCUMENTS
    MODE_Quality Outcome Indicators in Liver Transplant
    EFRETOS_Report on use of European Registry of Registries
    ELTR_Mortality after Liver transplant predictive models for outcome
    ELTR_Quality Controls: Results of Audits
    ELTR_Assessing Quality of Data in a transplant Registry
    ELTR_Present Evolution of Liver Transplantation in Europe

- **VIGILANCE & SURVEILLANCE**
  Management of Adverse Events in Italy
  MODE_Adverse Events in Italy

  - SUPPORTING DOCUMENTS
    MODE_Elements of Vigilance
    EFRETOS_Recommendations on Organ Vigilance
    EUSTITE_Vigilance Recommendations
    EUSTITE_Tools and Examples

- **FURTHER READING**
  Alliance-O White Paper
  NOTIFY_Didactic Report on Vigilance & Surveillance
  Quality and Safety in Italian Donor Evaluation Process
  HIV Transmission - Adverse Event in Italy
  Liver transplantation in Europe: is there a room for improvement?
  ELTR_Normalised intrinsic mortality risk in liver transplantation
  ELTR_Evolution of Liver Transplantation in Europe
  Registries for Evaluating Patient Outcomes

- **FINAL ASSIGNMENT**

VI- d - Annex 4

Structure of the training course for auditors

PROGRAMME TRAINING COURSE

ADDRESSED TO COMPETENT AUTHORITY STAFF MEMBERS INVOLVED IN THE QUALITY ASSURANCE PROGRAMS FOR TRANSPLANT CENTRES

PARTICIPANTS: staff members from National Competent Authorities from Malta (Paul Calleja, Miriam Azzopardi), Cyprus (Michalis Voniatis, Xenia Ashikales), Czech Republic (Pavel Brezovsky, Premysl Fryda, Eva Pokorna) and Lithuania (Audrone Buziuviene, Asta Kubiliene, Vita Gembutiene, Vytautas Zekonis) for a total of 11 participants from National Competent Authorities.

Course organizers: S.Chatzixiros, M.Gentile, P.Di Ciaccio

Faculty: V.Sparacino, R.Romagnoli, P.Berloco, F.Nudo, D.Fehily, L.Furian, C. Font-Sala, H.Cresvaux (ABM, France)

COURSE STRUCTURE: 3-week e-learning plus face to face

E-Learning Course – November-December 2013

1. Course introduction, presentation of methodology and detailed description of the Document "EEA" – which are the aspects to be evaluated, how to select them.
2. The audit procedure: how it works and how to evaluate a transplant centres (different methodologies: desk-based, self-evaluation, national external audit, international audits such as ELTR)
3. The audit form: how to structure and use this – how to build the audit form which data are to be asked for – which are compulsory – which are optional – which are necessary for a proper evaluation
4. Methodology for an assessment of transplant outcomes (setting up national committees, identification of case mix

As final practical work, participants will be asked to study the document and report through a power point presentation and/or an online questionnaire, specifying what they find useful and how they could implement it in their systems, or what they would change in such scheme and why

Face to face Course – February 5-7 2014 - Rome

February 5th: 14.00 – 18.00 - AULA ZAMPIERI Via Giano della Bella, 34

14.00 – 14.30 Welcome and presentation
14.30 – 15.10 Audit methodology - external evalutation ***V.Sparacino & S.Chatzixiros, CNT IT***
15.10 – 15.50 Self-evaluation of transplantation teams: The French experience to improve quality of care and patients safety ***H. Cresvaux & C. Font-Sala, ABM, FR***
15.50 – 16.00 Question and remarks
16.00 – 16.30 Coffee break

16.30 – 17.15 Presentation of power point elaborated from each participating country (10 minutes each)
17.15 – 17.45 Round table: Feedback and suggestion - ***S.Chatzixiros, V.Sparacino, C.Font Sala***
18.00 Closing

February 6th: 09.00 – 13.00 POLICLINICO UMBERTO 1° Dept Paride Stefanini, 3rd floor, Room Manlio Carboni

Onsite Visit at Multiorgan Transplant Centre at Policlinico Umberto I°, Viale del Policlinico 155, Rome

09.30 – 9.45	Simulation of audit visit. ***F. Nudo, V.Sparacino, F.D'Alessandro, S.Chatzixiros - IT*** Participants are divided in two groups of auditors. A filled audit form is distributed and time is allotted for revision of answers.
09.45 - 10.00	Transplant centre staff available for questions from auditors groups to clarify doubtful items
10.00 – 10.15	**Coffee Break**
10.15 – 10.45	An auditor/audited experience **– *P.Berloco – IT***
10.45 – 13.00	Feedback from groups with critical discussion on methodology, proposed forms, which aspects should be analyzed in each country's reality *Moderators:* **F.Nudo, V.Sparacino, F.D'Alessandro, S.Chatzixiros**
13.00 – 14.30	**Lunch**

February 6th – 14.30 – 18.00 AULA ZAMPIERI, Via Giano della Bella, 34

14.30 – 15.00	Evaluation of transplant outcomes– ***M. Caprio - IT***
15.00 - 15.30	Adjusted vs crude survivals – ***M. Caprio - IT***
15.30 – 16.00	**Coffee break**
16.00 – 16.30	Questions and Remarks
18.00	**Closing**

February 7th: 09.30 – 13.00 AULA ZAMPIERI, Via Giano della Bella, 34

Inspiration from other sectors

9.30 – 10.15	The tissue experience: EUSTITE and SOHOVS training for inspectors – ***D.Fehily- IT***
10.15 – 10.45	**Coffee Break**

Transplant centres from authorization to certification – National and international standards:

10.45 – 11.30	Kidney Transplant Centre – ***L. Furian – IT***
11.30 – 12.15	Liver Transplant Centre – ***R. Romagnoli – IT***
12.15 – 12.30	Question and remarks
12.30 – 13.00	PRACTICAL WORK (to be discussed)
13.00	**Closing**

GUIDE

Essentials for Audit and Accreditation of Transplant Facilities

Document prepared by

Centro Nazionale Trapianti

ITALY

Document Outline

1. Introduction

Quality assurance and evaluation of efficiency are crucial determinants of the improvements of the standard of care, and important leverages to conform medical practice to both patients' needs and societal requirements. The investigation of cost-effectiveness ratio in each healthcare system and its impact on societal expenditure has become a real necessity. These assumptions have considerable consequences on organ transplantation activity where high quality medical and health care activities join with relevant and particular organizational, social and ethical specificities.
Fundamental criteria for assessing healthcare performances are efficacy, efficiency, equity and degree of satisfaction of users. Such criteria are normally fixed through pathways of accreditation and certification, which are therefore essential prerequisites for improving the quality of delivered healthcare assistance. Accreditation and certification are words that are often misunderstood. Confusion arises from the fact that these words take different meanings in different countries. In the UK for example accreditation means certifying that something meets the required standards, what in Italy is called certification instead, whereas certification means proving or guaranteeing that some standards have been met. The International Organization for Standardization has somehow solved this semantic problem given precise definitions: accreditation is a "third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks" whereas certification is "third party attestation related to products, processes, systems or persons" (1).
In this framework EU Directive 53/2010 (2) has added a legal requirement of a national framework for quality assurance of the whole process from donation to transplantation. Based on the Directive and its Action (3) plan contents, as far as transplant facilities are concerned, it would be proper to outline an effective quality management pathway, based on key elements such as the authorization of the centre by national authorities, evaluation of post-transplant outcomes and reporting of serious adverse events and reactions and periodic auditing. This document intends somehow to provide a quality management system guide that could be used to setting up a quality and safety assurance system for transplant centres.

2. Authorization/accreditation procedures for transplant centres

Since definitions of authorization/accreditation procedures for transplant centres are incumbent on national authorities, the contents of this document are mainly focused on a pathway of certification that includes basic structural, technological, professional and organization requisites for implementing health activities. For the sake of completeness, it is worthwhile mentioning that authorizations/accreditations are normally granted for general hospital standards, for which some international reference can be found in some specialized documents such as the Joint Commission International Standards for Hospitals (4). In addition to authorization/accreditation of healthcare structure, some additional requirements may be requested for authorizing/accrediting the facility for transplantation

activities, essentially in terms of structural and technological features of operating theatre such as:

- differentiation of clean /dirty zones
- rooms for personnel to change, wash, and rest
- preparation and recovery rooms for patients
- storage and cleaning facilities
- offices
- dedicated corridors
- necessary supportive units
- lightening
- air conditioning system endowed with air filtration system ensuring air quality control
- electric power plant features and backup systems
- Infection control/sterilization equipment

3. Evaluation of transplant outcomes

Any assessment of a healthcare program should take into account the measurable therapeutical effects after a given time span from the treatment administration. Some specific indications on the importance of this, as far as organ transplantation is concerned, come from the recital of the European Directive 53/2010, its Action Plan and the European Parliament resolution dated April 22, 2008 where the EU Parliament acknowledges that post-transplant and post-donation results should be monitored and evaluated and that a common methodology of data analysis should be promoted on the basis of the best practices currently employed by Member States in order to allow optimal compatibility of results across Member States. Under priority 9 of the Directive 53/2010 Action Plan "Evaluation of post-transplant outcomes", it is highlighted that this has to be considered as a step for developing and promoting good medical practices on organ donation and transplantation.

Since there is a permanent risk of rejection even after many years from the operation, transplanted patients have to undergo periodic controls that allow monitoring of transplant outcomes. It is therefore possible to evaluate the outcome of transplant in time, but since many factors contribute to such outcome, in addition to crude graft and patient survival rate it is necessary to take into account some features of donor and recipient as well as other specific parameters that allow evaluating the risk factors of a single transplantation. Among these, we can quote:

- the overall number of carried out transplants
- mortality and/or morbidity in waiting list
- number of refused organs
- organ-specific data (for example: number of mismatches, ischemia time and time on dialysis for kidney, number of UNOS status 1 or 2A cases and split transplants for liver, donor heart cardiography ejection fraction and recipient original disease for heart, to name but a few)

Otherwise put, it is necessary to adjust survival curves on the basis of case-mix and other centre efficiency indicators. The set of indicators will be selected for different transplanted organs and on

the basis of centre activity. Additional reference on the setting up of a transplant evaluation registry can be found in the "Report on the use of the European Registry of Registry", where the main results of EFRETOS (European Framework for the Evaluation of Transplant Outcomes) project, co-funded by the European Commission Public Health program, are described. It may be downloaded from the website: www.efretos.org, (5) under the final results section.

The publication of an annual report of the analysis of collected data is recommended, since it has an invaluable impact on the trust of patients in the national health system.

4. Vigilance system and reporting of adverse events and reactions

Quality and safety are concepts that cannot be addressed separately, this particularly applies to organ transplantation where the probability of occurrence of a harmful end point is present due to potential deviations in the complex donation-transplant chain. As it was stated in the WHO Guiding Principles on the transplantation of organs, tissues and cells, "the level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health products of an exceptional nature, must be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reaction reported, both nationally and for exported human products". A traceability and vigilance system have therefore to be set up as pivotal step in preventing occurrence of health problems to organ transplant recipients.

Generally speaking, a good traceability system should keep record of the following phases of the donation-transplant process, possibly through an integrated IT system:

- Register and collect the expressions of consent/refusals of citizens as to organ and tissue donation;
- Keep a record of waiting lists of patients waiting for a transplant;
- Keep a register of deaths due to serious cerebral lesions from all procurement hospitals;
- Register the data flow on organ and tissue donations and retrievals, organ transplants, and tissue distribution to certified banks;
- Manage the register of transplants from living donors;
- Track the follow-up of patients that have received transplants, as well as of living donors.

As far as the vigilance system is concerned, many European Countries are presently working in this field and very useful reference on this point may come again from EFRETOS deliverable 11 (final results) at www.efretos.org (5) and the paper *"Prevention and management of adverse events in the process of procurement and transplantation of organs: critical elements of the system and clinical governance"* (6) by Venettoni et al.

5. Auditing

Auditing is an essential tool of quality management and should be conducted regularly in an independent way, by designated trained and competent persons not directly involved in the activity being audited. Findings and corrective actions must be documented.

An audit is a "documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to written SOPs, standards, or government laws and regulations" (7). The purpose of performing audits is to guarantee that all the activities are performed in a professional manner. During an audit, performance is reviewed to ensure that what should be done is being done, and if not so, it provides a framework to allow improvements to be made. Usually the methodology foresees that data is collected and performance is observed to measure current practice and compare it against those standards, and subsequently, any changes that are considered necessary are implemented. This process involves assessing the Standard Operating Procedures (SOPs) for compliance with the regulations, and of course to certify that what is stated in SOPs is actually being done.

Audit visits have also been reported as a tool for quality assurance of international, multicenter data collection – such as in the European Liver Transplant Registry (ELTR) –, and for assessing the completeness and consistency of the reported information.

Despite their limitations, due to time and economic resource constraints, and scarcity of audited vs auditable data, audit visits may be a valuable tool to catch a glimpse picture of the activity in a given transplant center (TC). A prerequisite is that the audits must be explicitly oriented to adhere to predefined efficiency, efficacy and outcome parameters. In addition, the audit process should be based on collaboration between auditors and auditees, since the final goal of the audit process should be an official certification of the efficiency and efficacy of a centre, and with a view to quality improvement and not of censoring attitude.

Since European standards regarding regulatory issues, logistics, personnel, functional and result aspects have yet not been defined, this document wants to provide some guidance on a possible audit methodology, indications for the composition of auditing commissions, and for the possible aspects that such commissions should take into account during its activity, giving an overview of the basic quality management system requirements any transplant centre should take into account and then supplying a sample list of aspects to be checked during audit procedure (see Annexes 1 and 2).

The proposed methodology used for such activities entails first of all the definition of the body that will coordinate the audits. It would be proper that this activity is organized by the national Competent Authority or its delegated body and entrusted to a team of external auditors. Next a list of parameters which have to be accomplished by the audited structure under the control of an auditing team should be defined. At the end of the procedure the auditing, or inspection team, release an evaluation on the audited structure certifying the full accomplishment or specifying which point were missing or not sufficiently accomplished (non compliances).

At European level following indication reported in EU Directives 24/2003, 17/2006 and 86/2006 (8,9,10) in cell and tissues banking, many experiences were reported also based on

results of EUSTITE and SOHOVS projects (see www.sohovs.org for further references (11)). These experiences cannot be automatically transposed in the organ transplantation field. Nevertheless using single countries or international organism experiences it is possible to define the main contents for developing a European shared model for audit activity in the field of organ transplantation.
External joint commissions composed of three transplant physicians (from other transplant centres) and if possible of a representative of the national competent authority body should be set up. Auditing visits date can be agreed upon between the organizing body and the transplant centre (TC); a list of the necessary documentation to be audited is sent to each center by the organizing body at least one month before the visit. The audit visits should be performed with the aid of the TC medical and nurse staff, thus facilitating data retrieval and assessment. During the visit, each audit team evaluates the clinical data charts of at least ten patients chosen randomly comparing such data with those recorded at national or regional level, through existing transplant information system if any (five charts from waiting lists, and five from already transplanted recipients), in order to assess the consistency of recorded clinical data. Each audit visit ends up with a formal report, approved by both the auditors and the auditees, and sent to the national organizing body for further validation.

Concerning the aspects of centre activity that should be audited, any transplant centre should be run according to some basic principles of quality assurance that cover the following aspects:

- organisation, personnel and definition of responsibilities:
  organisational chart, identification of responsible person, definition of roles and responsibilities including quality management responsibilities and clinical responsibilities;
- premises, equipment and materials;
- third party agreements and contractual arrangements;
- documentation and record keeping;
- selection, procurement, testing and processing/handling;
- traceability;
- management of non-compliances, adverse events and reactions.

Personnel and organisation

There must be sufficient, suitably trained and qualified personnel to carry out all tasks. Their tasks and responsibilities must be clearly understood and documented. All personnel should have clear, documented and up-to-date job descriptions. The competency of the personnel must be evaluated at periodical intervals specified in the quality system and the results of the evaluation have to be recorded. There should be an organisational chart showing the hierarchical structure of the organisation and clear delineation of lines of responsibilities.

a. Key personnel

Key personnel in all organisations involved in the transplantation process (from the initial donor selection stage to the final delivery of organs) should include a responsible

person (RP), and a medical specialist/advisor, who may or may not be the RP, which is responsible of all the medical activities, such as donor selection and evaluation, review of clinical outcomes of applied tissues and cells, or interactions with clinical users. In addition, for tissues and cells, the organisation should include a head of quality assurance (QA Manager), independent from the processing activities. Medical teams should have certified skills proved by specific documents and personal CVs including records of transplant cases dealt by each member. Such documents should be kept not only for surgical teams but also for all the teams dealing with patient healthcare during the different steps of the transplant process. Documents should be kept by hospital authorities where activity takes place and should be revised periodically.

b. Training

Personnel should receive initial and continued training appropriate to the duties assigned to them. The effectiveness of all training programmes should be monitored by regular assessment of personnel competency. Training should be documented and training records maintained. Personnel should also be trained in quality principles and in the organisational framework relevant to their work.

Personnel who handle organs, tissues or cells should have relevant knowledge of microbiology and hygiene and should be constantly aware that microbial contamination of themselves, donors, recipients, organs, tissues, cells and premises should be avoided. Hygiene and infections control protocols must be present in each department and these instructions should be understood and followed strictly by all individuals (personnel, patients and guests/visitors).

Premises, equipment and materials

Premises and equipment must be designed, located, constructed, adapted, monitored and maintained to suit the operations to be carried out. Their layout and design must aim to minimise the risk of errors and permit operations to proceed in an orderly sequence, and should allow effective cleaning and maintenance in order to avoid cross-contamination and accidents. These aspects are normally covered by authorization/accreditation requirements.

a. Premises

Donor family interviews should be performed in suitable conditions, allowing for confidentiality. Facilities where each step in the transplantation process is performed should comply with recognised existing regulations.

The environment where the transplantation activities are performed should have special features in terms of air quality and cleanliness, in order to minimise the risk of contamination, including cross-contamination between donation operations. The effectiveness of these measures must be validated and monitored.

Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and components. There should be dedicated secure areas for the storage of tissues and cells, with effective and clearly separate segregation of quarantined and released products.

Storage conditions for tissues, cells and materials should be controlled and monitored. Appropriate alarms should be in place to indicate when storage temperatures fall outside acceptable levels. Alarms should be regularly checked to ensure appropriate functioning. Standard Operating Procedures (SOPs) should define the actions to be taken in response to alarms.

There must be written policies and procedures for controlled access, cleaning and maintenance, waste disposal and for the provision of services in an emergency situation.

Post-transplant stay should preferably take place in single-bed isolated rooms or in a devoted ward, air-controlled, clear ward.

Some additional requisites may be established for specific organ transplant centre, such as the presence of an hemodyalisis ward for kidney, of an hepathology centre for liver replacement therapy for liver and so on.

b. Equipment

All equipment that might influence the quality or safety of the product should be designed/selected, validated and maintained to suit its intended purpose and should not present any hazard to donors, recipients or operators. It should permit effective cleaning. Maintenance, monitoring, cleaning and calibration should be documented and records kept. Manuals of use for the equipment, with instructions in the users' language, must be present and available at the workplace.

c. Materials

Detailed specifications for the purchase of reagents and other materials that might influence the quality or safety of the product are required. Only materials from qualified suppliers that meet the documented requirements should be used.

Equipment and materials should conform to international or European standards and national licensing arrangements where these exist.

Inventory records should be kept for traceability and to prevent use of materials after their expiry date. Apparent deviations in the quality and performance of equipment and materials should be investigated and documented promptly. The outcomes of these investigations should be reported in a timely manner to the responsible person and corrective actions should be taken.

Third parties agreements/Contractual arrangements

Written agreements with a third party should be in place each time an external activity takes place which influences the quality and safety of organs, tissues and cells performed in cooperation with a third party. The agreements with third parties shall specify the responsibilities of each party and detailed the procedures to be followed as part of the agreement.

Third parties shall be evaluated and selected on the basis of their ability to meet the quality and safety standards and should be monitored for their performance.

On-site audits of third party contractors may be performed to ensure their compliance both with professional standards and technical manuals and their own requirements. For example third party services may include contracts for transportation service of personnel or organs, packaging services, sterilization equipment.

Documentation and record keeping

Documentation must enable all steps and all data affecting the quality of the organs, tissues and cells to be checked and traced, from the donor to the recipient and vice-versa (i.e. coding, donor eligibility, procurement, processing, preservation, storage, transport, distribution or disposal, including aspects relating to quality control and quality assurance). Written documentation ensures that work is standardised and prevents errors that may result from oral communication.

Donor documentation in general and donor referral records in particular must be subject to the same controls.

Documentation should normally include the following items:

- a quality manual;
- standard operating procedures (SOPs)
- standard forms
- specifications (materials, labels, equipment, organs, tissues, cells, reagents);
- identification of risks and a risk mitigation plan;
- other procedures (e.g. cleaning and maintenance);
- records of operations performed (e.g. donor selection records, quality control results);
- clinical protocols
- training and competency records on personnel

All documents must be periodically reviewed, approved and dated. Any change to a document must be reviewed and approved by an appropriate and authorised person(s). Documents should not be handwritten except for those parts where data have to be entered. Any alterations made on a handwritten record should be dated and signed.

A document control procedure must be established to provide for the history of document reviews and changes and to ensure that only the current version of all documents is in use. There must be a written procedure describing the controlled distribution of new and amended versions of all documents to all relevant staff.

Records must be legible and indelible and may be handwritten or transferred to another validated system, such as computer and microfilm.

Records relating to safety, quality and traceability of organs, tissues and cells should be retained for a minimum of 30 years after clinical use or expiry according to international and national regulations.

Any deviations from the standard documented procedures should be recorded and reviewed and corrective action should be undertaken.

Records of equipment validation, maintenance and repairs (and subsequent revalidation),

and whenever applicable calibration, should be maintained.

A computerised record-keeping system may help to ensure the authenticity, integrity and confidentiality of all records and can generate true paper copies. The hardware and software of computers should be regularly checked to ensure reliability. Computer programs should be validated before use. Only authorised persons should make changes to computerised systems and any such changes should be validated before use. Facilities should have an alternative system that ensures continuous operation in the event that computerised data are not available.

Standard Operating Procedures (SOPs)

Standard operating procedures are a very important element of a quality system. Standard Operating Procedures are sets of instructions that describe the steps of a specific process, including the materials and methods to be used.

The content of a standard operating procedure should include:

1. Definitions
2. Responsibilities
3. Objective and field of application
4. Relation between SOP and other documents
5. Descriptive part, development (how to do it). This part should be systematized (for example: materials, reagents, previous calibration of instruments, execution, calculations…)
6. Protection of operators, where relevant
7. Record of the versions of the document
8. Dates, code, version, signatures (author, reviser, approver)

Selection, procurement, testing and processing/handling

a. Donor selection

The final quality of organs, tissues and cells depends on many factors and starts with the selection of donors. Donors should be carefully selected according to agreed principles and possible to national donor safety guidelines, that could on one side prevent transmission of disease from donor to recipient and on the other allow a proper use of all available organs.

b. Organ, tissue and cell procurement

The procurement procedure should be carefully controlled. Systems should be in place to ensure traceability and provide a complete audit trail. Preventive measures should be in place to minimise any contamination. Findings that may adversely affect the quality of the organs, tissues and cells must be documented and dealt with by the RP.

c. Packaging and Shipping

These procedures are now also ruled by Art 8 of the European Directive 53/2010. Its

prescriptions should be given proper attention (2).

Traceability

Possibly a system enabling to trace the path taken by each donation to be traced, from the donor to recipient/disposal and vice versa should be established at national level. This system must fully respect the confidentiality of both donor and recipient. In this framework transplant centre should keep records and report to the Competent Authorities requested data, in particular:

- Follow up data of transplanted patients
- Notification of serious adverse events and reactions

In the national system each donor/component should be assigned a unique identifier that may serve also as a lot number to identify the material during all steps from harvesting to allocation and utilisation. This unique number should be used to link the donor to all records, grafts and other material, and for tracking purposes, to the recipient. Records should include identification, clinical and laboratory evaluation of the donor and should indicate its final destination.

Management of non-compliances, adverse events and reactions

All complaints and other information that raise concern regarding the graft should be documented, carefully investigated, dealt with as quickly as possible. Effective written procedures must exist for recalling defective/suspect materials. These written procedures must encompass any look-back procedures which may be necessary. The procedures should be communicated to the end user. A mechanism for appropriate review and assessment of actions taken to address complaints should be established

Organisations involved in the transplantation process should document adverse events and reactions and deviations from established procedures and specifications. Procedures should be in place to identify the problems to be corrected, and to inform the relevant authorities as appropriate.

Priority should be given to investigation and reporting of incidents with demonstrated or potential risk to cause serious adverse events (for further details see reference under section 5).

6. References

1. ISO/ IEC 17000:2004. Conformity assessment – vocabulary and general principles.
2. Directive 2010/53/EC of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. Official Journal of the European Union. L207, 6.8.2010, p. 14.
3. Decisions adopted jointly by the European Parliament and the Council Decision no 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13). Official Journal of the European Union. L301, 20.11.2007, p. 3.
4.
5. EFRETOS project (European Framework for the Evaluation of Transplant Outcomes), Report on the use of the European Registry of Registries. Deliverable 11, available at url: http://www.efretos.org. Last access: October 2012.
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8. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standard of quality and safety for the donation, procurement, testing, processing, preservation, storage, distribution of human tissues and cells. Official Journal of the European Union. L102, 7.04.2004, p 48.
9. Commission Directive 2006/17/EU of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells. Official Journal of the European Union. L38, 9.2.2006, p. 40.
10. Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/Ec of the Parliament and of the Council as regards traceability requirements, notification of serious adverse reaction and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. Official Journal of the European Union. L294, 25.10.2006, p. 32.
11. SOHOV&S project

ANNEX 1. SAMPLE LIST OF ASPECTS TO BE CONSIDERED IN AUDITING KIDNEY TRANSPLANT CENTRES

The Commission should evaluate, for each transplant centre, the following conditions:

a) technical features of the surgical facility;
b) management of the waiting list;
c) transplant activity from cadaveric donor;
d) transplant activity from living donor;
e) results;
f) donations, retrievals and transplants within the area;
g) other parameters indicated by the commission and by the national transplant centre.

The Commission should verify for each transplant centre the following aspects:

TECHNICAL FEATURES OF THE TRANPLANT CENTRE (**point a)**

- Documentation of the structural and technical features of the centre (taking also into account the planimetry and the description of the existing equipment);
- Description of specialized activities related to the transplant centre;
- Description of the clinical and surgical activity of the transplant team in the previous year;
- Activity of the center in terms of months / years, specifying any periods of closure;
- Indicate the department which houses the clinical data of patients on waiting list;
- Indicate the department where the patient is admitted in the post-transplant;
- Indicate the structure (department) where follow-up visits are carried out;
- Report the annual percentage of patients assessed as not suitable to be wait listed during the three previous years;

MANAGEMENT OF THE WAITING LIST **(point b)**

- File with the personal data and the main clinical data of the patients on the waiting list;
- File with the data of the patients that have run out of waiting list for any cause;
- Average characteristics of the composition of the list (age, regional origin, distribution ABO groups, HLA, distribution between active and suspended patients, distribution of hyperimmunized patients);
- Algorithm used for the selection of the candidate for transplantation;
- Follow up requested and timing in order to remain in the active waiting list;
- Average time to complete the evaluation process of the recipient from the first visit;
- Average time for effective insertion in the list from the acquisition of the complete documentation;
- Number of patients in waiting list to the December 31st of the previous year;
- Number of patients inserted in waiting list per year during the three previous years;
- Number of deceased patients in waiting list during the previous years;
- Average waiting time to be transplanted during the three previous years (in months);
- The percentage of the annual meeting of the demand during the three previous years;

TRANSPLANT ACTIVITY FROM CADAVERIC DONOR **(point c)** ***reference period three previous years***

- Number of kidney transplants carried out from the starting of activity to December 31st of the previous year 2003 and in the reference period;
- Number of pediatric kidney transplant carried out from the starting of activity to December 31st of the previous year 2003 and in the reference period;
- Number of combined kidney transplant carried out from the starting of activity to December 31st of the previous year 2003 and in the reference period; (divided per kind of combinations);
- Average graft ischemia time referred to previous year (from the clamping of aorta in the donor to the reperfusion of the organ in the recipient);
- Distribution of the transplants carried out taking in to account the case mix of the recipient in the reference period;
- Criteria of non-admission in the waiting list adopted by the centre;
- Average waiting time (in moths) of the patients transplanted in the reference period;
- Check for the presence of the minutes of the allocation of the organs.

TRANSPLANT ACTIVITY FROM LIVING DONOR **(point d)** ***reference period three previous years***

- Number of kidney transplants carried out from the starting of activity to December 31st of the previous year 2003 and in the reference period;
- Number of kidney transplants carried out between consanguineous from the starting of activity to December 31st of the previous year 2003 and in the reference period;;
- Number of kidney transplants carried out between non consanguineous from the starting of activity to December 31st of the previous year 2003 and in the reference period;
- Description of the clinical-organizational procedures adopted by the centre for the assessment of viability of the transplant from living donor;
- Composition of the medical commission and of the third party;
- Number of procedures suspended and motivation during the previous three years;
- Follow-up of the donor during the previous three years;
- Description of any major complications in the donor.

RESULTS **(point e)** ***reference period two previous years***

- File with the data of the patients that have been transplanted and their follow up (from the beginning of the activity)
- Outcomes at present date of the transplant centre after 1 and 5 years in terms of survival of the organ and of the patient, both from cadaveric and living donor (calculated in the 1998 – 2003 period); ***note:*** *for deceased patients also the organ is considered as not functioning;*
- Number of kidney retransplants in the reference period (within one year from the transplant, after one year from the transplant);
- Average duration of hospitalization in the reference period;
- Number of patients lost at follow up in the reference period;
- Number of patients transplanted in the reference period and followed annually during follow up;

- Number of follow ups carried out annually on transplanted patients in the reference period

Other parameters indicated by the Commission and by the National Competent Authority or its delegated body (point g)

- Description of the methodology for the determination of the tissue typing of the donor and of the recipient used by the Centre (serology, genomic or other, divided in class I, and class II both for the donor and for the recipient);
- Description of the methodology for the determination of the cross-match adopted by the centre
- (linfocitotossicity, citofluorimetries, others).

ANNEX 2. SAMPLE LIST OF ASPECTS TO BE CONSIDERED IN AUDITING LIVER TRANSPLANT CENTRES

The commission proposes to evaluate, for each transplant centre, the following conditions:

h) technical features of the surgical facility;
i) management of the waiting list;
j) transplant activity from cadaveric donor;
k) results;
l) donations, retrieval and transplant in the area.

Transplant centres undergoing AUDITS should provide to the Commission the following documentation:

TECHNICAL FEATURES OF THE SURGICAL CENTRE **(point a)**

- Documentation of the structural and technical features of the Centre (together with a description of the existing equipment);
- Description of the specialized services linked to the Transplant Centre;
- Percentage of time dedicated to the activity of retrieval and transplant or to linked pathologies (eg hepatic resection) taking into account the time dedicate to the global activity;
- Activity of the center in terms of months / years, specifying any periods of closure;

MANAGEMENT OF THE WAITING LIST **(point b)** ***year of reference: previous year***

- File with the personal data and the main clinical data of the patients on the waiting list;
- File with the data of the patients that have run out of waiting list for any cause;
- Average characteristics of the composition of the list (age, regional origin, distribution ABO groups, HLA, distribution between active and suspended patients, distribution of gravity of the patients following agreed and predefined criteria);
- Algorithm used for the selection of the candidate for transplantation;
- Follow up requested and timing in order to remain in the active waiting list;
- Average time to complete the evaluation process of the recipient from the first visit;
- Number of patients in waiting list;
- Number of patients inserted in waiting list per year;
- Number of deceased patients in waiting list;
- Average waiting time before transplant;
- The percentage of the annual meeting of the demand;

TRANSPLANT ACTIVITY FROM CADAVERIC DONOR **(point c)** ***year of reference three previous years***

- Number of kidney transplants carried out from the starting of activity during the previous three years;
- Number of kidney pediatrics transplants and split carried out from the starting of activity to present date and in the reference period;

- Number of liver requested in urgency from the starting of activity to present date and in the reference period;
- Average graft ischemia time (from the clamping of aorta in the donor to the reperfusion of the organ in the recipient);
- Distribution of the transplants carried out taking into the status of the patient in the last 3 years and in the reference year;
- Number of fulminant hepatitis treated with BAL yearly or with transplant in the last 3 years and in the reference year;
- Criteria of admission in the waiting list adopted by the centre;
- Number of kidney transplants from living donors carried out from the starting of activity to present date and in the reference period;
- Number of liver resections carried out from the starting of activity to present date and in the reference period;

RESULTS **(point d)** ***reference period: three previous years****

- File with the data of the patients that have been transplanted and their follow up;
- Results to present of the transplant centre after 1 year and 5 years in terms of survival of the organ and of the patients, both from cadaveric donor and living donor;
- Number of liver transplants in the reference period (within one year from the transplant, after one year of the transplant);
- Average duration of hospitalization;
- Declaration of presence of two autonomous surgical teams for liver transplant;
- Declaration to participate to a programme with other centres for liver transplant from living donor.