

3 rd QUARTERLY REPORT

Improvement of the safety, quality and availability of organs, tissues and cells for transplantation

Member State Partner

The Ministry of Health of Italy
In cooperation with National Transplant Centre

Beneficiary Country Partner

Ministry of Health of the Slovak Republic

BC Final Recipient

University Hospital Ružinov in Bratislava (Slovak Republic)

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ABBREVIATIONS

BC	Beneficiary Country (Slovakia)
CA	Contracting Authority
CFCU	Central Financing and Contracting Unit
CNT	Centro Nazionale Trapianti (Italian National Transplant Centre)
CTB	Central Tissue Bank
DPL	Deputy Project Leader
DPM	Deputy Project Manager
FRP	Final recipient of the Action (University Hospital Bratislava)
HCB	Hemopoietic Cell Bank
IEB	International Eye Bank
IT	Italian Republic
MoH	Ministry of Health
MS	Member State (Italy)
MSP	Member state partner (CNT)
PL	Project Leader
PLs	Project leaders
PM	Project Manager
RTA	Resident Twinning Advisor
RTA-A	Resident Twinning Advisor - Assistant
SC	Steering Committee
SCOT	Slovak Center for Organ Transplantation
SG	Subgroup
SR	Slovak Republic
STE	Short Term Expert
TA	Technical Assistance
TS	Technical Specifications
UHB	University Hospital Bratislava

Section 1. Project data

Twinning Contract No.	200501746404-0201-0001
Project title	Improvement of the safety, quality and availability of organs, tissues and cells for transplantation
Twinning partners	Ministry of Health (IT), in cooperation with the National Transplant Centre (IT) Ministry of Health (SK), University Hospital Ružinov in Bratislava (SK)
Report	3 rd Quarterly Report
Period covered by the report	05 June 2007 – 04 September 2007
Duration of the project	24 months

Rapporteur Member State

Rapporteur Beneficiary Country

Mr. Alessandro Nanni Costa, project leader

Mr. Richard Rasi, project leader

Section 2. Content

2A – Background

Policy Developments

1. 1. Beneficiary Country policy developments in the sector

The Ministry of Health of Slovak Republic (MoH SR), as a central state administration body in the health sector, is responsible for implementation of Directive 23/2004/EC in general and it has appointed, by its decision, tissue establishments to be responsible for direct implementation and execution of that Directive in the praxis.

In the area of tissue, cells and organ procurement and transplantation there are two main types of organizations: 1) tissue establishments and 2) organ transplantation centres.

1. 2. Beneficiary institutions and other parties involved

The first tissue establishment in the Slovak Republic was linked to Ružinov General Hospital in Bratislava and started its activity in 1988. The list of currently existing tissue establishments under the competence of the SR Ministry of Health is as follows:

1. Central Tissue Bank, University Hospital Ružinov, Bratislava, multi-tissue bank
2. Associated Tissue Bank, University Hospital and Medical School, Košice, multi-tissue bank
3. International Eye Bank, Petržalka University Hospital, Bratislava, eye bank
4. International Eye Bank, F.D.Roosevelt Hospital, Banská Bystrica, eye bank
5. Hemopoietic Cell Banks (HPC banks) - 3 in Bratislava, 1 in Banská Bystrica, 1 in Martin, 1 in Košice, 1 in Prešov

In addition, there are non-governmental and private organisations such as:

6. Slovak Register of Cord Haemopoetic Cells (EUROCORD), Bratislava, cord blood bank
7. Private Hospital Košice - Šaca Tissue Bank

As regards organ transplantation centers, all of them are under the responsibility of the MoH as follows:

- Slovak Centre for Organ Transplantation – Slovak Medical University (SCOT) with 5 Regional Transplantation centres
 1. Transplant centre University Derer's hospital, Bratislava (kidneys, liver)
 2. Transplant centre, Slovak institute for heart diseases, Bratislava, (heart)
 3. Transplant centre University hospital, Martin (kidneys)
 4. Transplant centre Roosevelt hospital, Banská Bystrica (kidneys, pancreas)
 5. Transplant centre, University hospital, Košice, (kidneys)

The public awareness towards organ, tissues and cells donation is very low in Slovakia. The main reason for this is a lack of public awareness and a lack of financial resources. The result is a very low rate of donations, which achieves annually less than 10.2 donations in 2004 per 1 million of inhabitants in organ transplantation.

A reason why problems such as a lack of donors and long waiting lists for organ donations occur is the presently unsatisfactory information system that is not unified, and

interconnected, neither between the tissue establishments, nor with the Central donor and non-donors register located at the SCOT in Bratislava. This means that for example information about a possible donor in one tissue establishment is not at disposal in the whole network. Secondly, the information system for organ transplantation does not include the requirements of tissue and cell establishments and it is not compatible with the requirements of the Directive 23/2004 EC. A central information system managing waiting and donor lists for organ donations is already 10 years old and needs to be upgraded. The required data confidentiality, data protection, and data storage time cannot be as yet fully assured.

Additionally, each tissue establishment elaborated its own quality management system, which mostly does not conform to contemporary regulatory and quality requirements of the European Communities. These systems strongly need to be unified as well as updated according to the latest EC Directive 23/2004/EC.

Regarding the institutional framework of the quality control, it is monitored by national authorities: Slovak National Accreditation System (SNAS) and State Institute for Drug Control (SIDC). SNAS controls the good laboratory praxis, and SIDC is responsible for good manufacturing praxis.

Establishments have to fulfil the accreditation criteria as ruled by the above-mentioned authorities. The project will give a framework for compatibility of national and EC requirements for safety and quality management in field of organ, tissue and cell transplantation.

Project assumptions

The assumptions as formulated in article 3 of the Work plan are

- Current legislation in force
- Trained staff will stay on their positions, using the acquired knowledge
- Institutions involved in the unified info system cooperate and actively use the system
- Willingness of particular institutions to participate and provide data
- Relevant staff available for planned training
- Technical facilities available for the training

The above mentioned assumptions imply that, using the current legislation in force, in particular the ones entered into force on 2006 and at the beginning of 2007, the institutions and all involved staff will actively participate at the project taking advantage of the planned training, using their acquired knowledge, providing data and actively using the unified info system. Staff and hospital facilities will be fully available for planned training.

Project objectives

- **General:** Ensure a high standard of quality and safety for donation, processing and distribution of human tissues and cells in the Slovak Republic to achieve a satisfactory implementation of the European Community Directive 2004/23/EC.
- **Specific:** Introducing quality management for organ transplantation, tissue and cell banking, to assure the highest possible level of public health protection.

Benchmarks

- The facilities included in the project accredited by the beginning of 2009, fulfilling the requirement of the directive 2004/23/EC. Following some delays in the finalization of the Twinning Contract and the start up of the project on 4th December 2006 with its conclusion on November 2008, it has become necessary to postpone the date of accreditation of the facilities, which originally was foreseen by the end of 2007.
- Increasing the number of successful transplants
- Increasing the number of real donors from indicated donors by 10%.
- Decreasing the insufficient number of donors by 5%.
- 100 employees of tissue and cells establishments and organ transplant centres trained on QMSG
- tissue and cells establishments and organ transplant centres using new developed system by the end of the project (in the contract originally foreseen by the end of 2007)

Achievements of mandatory results

- Audit report produced and corrective and preventive actions plans in place / Component I
 - QMS for tissue and cells establishment and transplantation centres developed and introduced:
 - Quality management system guide (QMSG) developed*
 - Tissue establishment and transplant centre staff trained / Component II*
 - Unified information system for transplantation centres, tissues and cell establishments (developed and implemented within TA contract) and tested / Component III
 - Proper public dissemination of the project outcomes/Guidance brochure / Component IV

The following **MANDATORY RESULTS** were completed:

Component 2:

- Developed Quality Management System Guide for organ, tissue and cell establishments in Slovakia

Activities in the reported period

Here below is a table summarising the STE missions.

Activities	Name of expert	Dates of mission	Topic	Total days in the work plan	Days worked	Completed %
Activity 3.1	Preparation of the unified information system			13	3	23,07 %
	GHIRARDINI Angelo	19-20 June 2007	Information system		1,5	
	SCAGLIA Stefania	19-20 June 2007	Information system		1,5	

Activities of Component II : Design and implementation of unified management system

All the Activities will be described in this section and commented in the Assessment section.

- Elaboration of Quality Management System Guide (QMSGuide)

■ **2.1 Elaboration of QMSGuide:**

A major objective of the project is the design and implementation of the Quality Management System Guide which aims to provide tools which will help to raise the quality of the whole transplantation process of organs, tissues and cells in Slovakia. The main aim of this activity

was to apply the above mentioned EU Directives on tissue and cells to the transplantation system of Slovakia, adding some suggestions on organ transplantation. The Quality Management System Guide was written and developed with the aim of improving overall quality management in tissue, cell and organ establishments in Slovak Republic, taking into account the previous Audit reports. It was written and edited by a group of STE: Mr Piccolo and Mr Kuba (organ transplantation experts); Mr Koller, Mr Rosocha and Ms Fehily (tissue transplantation experts); Mr Migliaccio, Ms Bariani and Mr Mistrik (cell transplantation experts).

The STE met in Bratislava back to May 2007, during two different missions, planning the development of the Guide all together. Ms Jarabinska (Tissue Bank-Bratislava) participated at the discussion upon the guide as well.

The QMSGuide is divided into six chapters plus few annexes to the chapters:

- Chapter 1 is an introductory chapter
- Chapter 2 is focused on the legal framework
- Chapter 3 is focused on the quality management system
- Chapter 4 is focused on donor management
- Chapter 5 is focused on guidance to tissue establishments
- Chapter 6 is focused on transplantation practices

The general part covers the following points:

- general principles of good clinical and laboratory practices.
- general guidelines for QMS (Quality Management System)

The specific part covers mainly:

- guidance for writing the standard operating procedures
- training and reference manuals for staff
- reporting forms
- donor records and follow up forms for the transplanted organs, tissues and cells.

This guide has been developed by technical experts from the fields of organs, tissues and cells from Italy and Slovakia. The platform for the definition of quality and safety standards was provided by three European Union Directives; Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and its two associated technical directives, Directive 2006/17/EC and Directive 2006/86/EC. A number of Italian, Slovak and international documents have been consulted in the course of its development, notably the Council of Europe Guide to Safety and Quality Assurance for Organs, Tissues and Cells (3rd Edition). The guidance provided here is consistent with current transplant legislation in Slovakia.

The scope of this guide extends to quality assurance standards for procurement, preservation, processing and distribution for organs, tissues and cells of human origin (allogeneic and autologous) used for transplantation purposes. Blood, blood products and somatic and genetic cell therapy products and tissue engineered products are excluded from the scope of these guidelines. Reproductive cells are not included inside the guide. Genetically modified human materials are considered to be medical products (EU Directive 2004/27/EC) and additional requirements apply which are not included in this Guide.

The Guide is produced in Slovak and English language.

The deadline for producing the English and Slovak version of QMSGuide was July 31st 2007, but it was postponed to end of September 07 to allow the SK experts to review the draft of the chapters written in english by IT STE and to allow time for translation into slovak language. This agreement was taken by SPO Mr Skorvaga and RTA Mr Lauro during July monthly meeting and it did not require a side letter (as per CFCU statement).

The guide is included as Annex 1 to this report .

Activities of Component III: Development of a specific software

All the Activities will be described in this section and commented in the Assessment section.

■ 3.1 Preparation of the Unified Information System

The unified information system is being developed in parallel to activities of component 2. In general terms it has to respond to the requirements set up by the Directive 23/2004/EC and it has to be compatible with similar information systems used in other EC countries.

The activities are carried out by Italian STE Mr Ghirardini supported by additional Italian IT specialist Ms Scaglia. Both STEs prepared complete software specification (terms of reference) for a unified information system for transplantation centers, tissue and cell establishments, in full cooperation with SK Working group, represented especially by DPM Mr Kuba, who is responsible for old central software at SCOT.

IT STEs also are preparing the system of assessment and evaluation criteria that will be applied when evaluation of the service is performed. The recommendations of how to control particular phases of the software (SW) development process are being prepared as well.

These experts will define the conditions, outputs and inputs and functionality of the special software, data model, and structure, hierarchy and user rights in the information system. Special attention will be given to data and network safety, encryption of personal data and means/channels to transfer historic data from previous system to new developed software. The SW specification as per twinning contract was reported in the 2nd quarterly report.

A mission was held in the middle of June 2007 by Ms Scaglia together with Mr Ghirardini in Bratislava: the mission was directed to make STEs familiar to the present version SCOT national software.

Mr Kuba explained to STEs the computerized network between SCOT and transplant centres, underlining the need to update the software. Two further main topics were discussed: the tender for Slovak IT company and the need for hardware, as previously described in the 2nd quarterly report.

The tender for the IT company will be held by the end of year, in order to be able to start working on the development of the new software by December 2007.

A further mission is foreseen for this activity 3.1 , after the tender for the IT company: on December 2007 the STE will come to Bratislava in order to define and plan the work with the chosen IT company and with DPM Mr Kuba.

Timing & Delays

Adherence to schedule

In the third quarter, there have been implemented the activities of Component 3 according to the schedule of the twinning work-plan with a minor change in this activity due to another mission planned after the tender.

Project Month		5	6	7	8	9	10	11	12	13	
Component 3. Development of a specific software											
3.1 preparation of the unified information system											



Expected to be delayed

Recuperation of delays

Component 2.1 (Elaboration of QMSGuide) will be completed by September 30th 2007, delayed in order to allow the SK experts to review the draft of the chapters written in english by IT STE and to allow time for translation into slovak language.

Component 2.2 (Short and Medium Term Courses) will be delayed due to re-designing of short term courses and the need to implement maximally their attendance while the delay on medium term courses was due to the need to complete the QMSGuide and to increase the attendance to these courses as well. Both courses were originally foreseen during July and August 07: Medium Term Courses will be completed by September 07 while Short Term Courses by October 07.

Regarding Component 3, activity 3.1 (Preparation of Unified Information System) will foresee another mission after the tender (month 13) for the reasons explained above while activity 3.2 (public procurement for Slovak IT company plus beginning of activity of Slovak IT company) is foreseen in adherence with TW project time frame.

ASSESSMENT

Overall assessment of progress

The Audits performed last February 07 were the first necessary step in order to develop and write an appropriate QMSGuide, updated and adherent to the real transplant situation of Slovakia: therefore the application of EU Directives (main aim of the QMSGuide) is performed with adherence to the Slovak transplant reality in 2007.

Under this point of view, the participation of Slovak experts in organ, tissue and cell field was implemented in order to have even a better picture of the legal framework and the real need of the transplant centres. On the other hand, the QMSGuide was really necessary in order to update and substitute the quality system guides owned by single transplant centers, and to make EU Directives fully fostered by transplant centers. Furthermore, every Guide needs to be read and applied on the field: this was the reason to run Short and Medium Term courses inside the twinning project, in order to foster the conformity with the EU Directives reported inside the QMSGuide for Slovakia.

The need to implement a real network between coordination centres, SCOT and transplant centres -and to have a real updated tool in order to obtain this goal-was the main reason to develop a new specific software. It was necessary to perform the mission carried out last June by STEs Mr Ghirardini and Ms Scaglia in strict collaboration with Mr Kuba: in this way, STEs could get a clear picture of the real situation of the old software at SCOT in Bratislava and of the unified information system that is nowadays being used in Slovakia among transplant centres, in order to write the appropriate requirements of public tender for the Slovak IT company. The need to implement a new hardware was added as well, in order to support better the development of the software. As previously reported, a new mission of STE will be necessary when the IT Company will be chosen, in order to make a common plan of action.

Activities and goals : *Component II and I. part of Component III*

The main goal of activity 2.1 is fully achieved: the elaboration of a QMSGuide, updated to EU Directives and adherent of 2007 real situation among transplant centres in Slovakia, was performed under the care of Italian and Slovak experts, working together in Ruzinov hospital facilities as it was foreseen in the project. The guide was developed in English, drafted at first by iT experts and then reviewed by SK STE and it will be translated into Slovak by September 30th 2007.

Activity 3.1 and its goal was achieved as well: the new unified information system was prepared and developed inside the requirements of the public tender, in order to have the new IT company fully ready to start its activity by December 2007 with the support of STEs, even though a new mission of STE is foreseen when the IT Company is ready to start to work on software development.

Following activities :

- **2.2 Provision of set of specialized trainings (short term courses and medium term courses for cells, tissues and organs)**

2.2.1 SHORT TERM COURSES

These courses were foreseen in the twinning contract with the aim to cover general aspects of organ donation and procurement. As it was explained in the 2nd quarterly report, the topic was

slightly improved and changed to the level of expertise of Slovak local anesthesiologists and coordinators and the course moved to October 2007, in order to obtain the maximum number of participants. A side letter will follow on this issue. The 2-days short term course, organized by STE Ms Ridolfi and based on her May site visits to SK coordination centres and SCOT (together with STE Mr Ghirardini and Ms Peritore), will foresee:

- a first day dedicated to an “interactive course”:
 - 1) Slovak coordinators and anesthesiologists, interacting with Italian STE, in order to actively discuss the way of improving the network between coordination centres and SCOT and between coordination centres themselves;
 - 2) designing a common “organizational model “of a coordination centre in Slovakia
- a second day should be more conventionally dedicated to two topics like the use of marginal donors and tissue procurement: in STE opinion, derived by Audits and Site Visits, these two topics need to be reinforced in order to optimize the donation process in Slovakia.

Making a summary, STE will add to the already designed topics of these courses lectures on tissue procurement, marginal donors, common organizational model of coordination centre and improving network between SCOT and centres and between centres themselves.

There will be the involvement of few STE for the lectures, coming from different coordination areas from Italy, interacting with the SK local coordinators.

The venue should be in two different towns, like Martin and Kosice (best coordination centres as a number of donations-up to September 2007) to allow the maximum number of participants from west/middle and east Slovakia. It was an idea of STE Ms Ridolfi and Mr Ghirardini to spread the courses through Slovakia in two different towns (in the middle/west and east Slovakia) instead of doing it in one town only. Although it is apparently more expensive, it is indeed more cost-effective in order to obtain the maximum attendance from the Slovak trainees and to avoid further travel and accommodation expenses by the trainees themselves. Simultaneous translation will be provided.

It is worthwhile to remind that a letter from Martin coordination center (Ms Grandtnerova) was written to Ms Ridolfi in order to clarify some issues arisen during her Site visit.

This issue was fully debated during July monthly meeting between RTA, SPO and DPM.

It was followed by Ridolfi's written reply to Martin centre, in order to clarify all the arisen issues.

Both letters are added at the end of the report as Annex 2.

2.2.2 MEDIUM TERM COURSES addressed to cell and tissue establishments

In the Twinning Contract MEDIUM TERM COURSES are dedicated to transplant centre trainees in order to teach them how to apply and use on a daily working basis the QMSGuide, developed by STE. They are 8-days courses organized by STE Ms Fehily. Every course will last two days, in order to allow a reasonable number of participants for each course and a close interaction between trainees and lectures. Such courses will be delivered as contribution of STEs to the already designed 1-year training for tissue bank personnel that was performed in SR. Particular contents were agreed by IT and SK in-the-field experts upon discussion of the syllabus of this course in the period of QMSG development. The main change, decided by Slovak and Italian experts during the development of QMSGuide, was to add the **HPC bank**

trainees to the tissue course, as the QMSGuide is dedicated to cell transplantation as well. The course was postponed to second half of September 2007 to allow the SK STE to review the draft of the Guide written in english at first by IT STE , to allow translation of the QMSGuide into english language and to obtain the maximum number of participants from Slovakia. Simultaneous translation and CME credits will be provided. The course will be held in Bratislava at Ruzinov hospital.

2.2.3 MEDIUM TERM COURSES addressed to organ transplantation centers

Even in this case MEDIUM TERM COURSES are dedicated to transplant centre trainees in order to teach them how to apply and use on a daily working basis the QMSGuide. This course is organized by STE Mr Piccolo and lasts 8 days in Bratislava, simultaneously to the previous one, following the same organizative fashion.

The course will focus on the application of quality management principles derived from the quality system management guide as far as organ transplantation centers are concerned.

In this case the experts will make some suggestions, because there are still no precise EU directives on QMSGuide for organs. Even this course was postponed to second half of September 2007 for the reasons already explained. Even in this case simultaneous translation and CME credits will be provided.

It is worthwhile to report that, during last monthly meeting held on July at MoH in Bratislava, it was stated by MoH that the “extra” financial support for the medium term courses (asked by RTA to SPO Mr Skorvaga for travel and accomodation expenses of trainees) is unfortunately NOT available.

COMPONENT III

Component III will be developed by December 2007, in close collaboration between Italian STEs Mr Ghirardini and Ms Scaglia and Mr Kuba, responsible for the software at SCOT-Bratislava. The starting activity of IT company will be carried out no later than end of the year (as foreseen in the project). We have already discussed the need for another mission of STE on December 2007.

Finally the pilot testing (activity 3.3) for the new software will be performed between August and November 2008.

COMPONENT IV

Component IV will be developed between September and November 2007, with the only exception of activity 4.3 (Closing Conference), that will be held on November 2008.

Activity 4.1 will consist of preparation of a brochure as a tool of better coordination and management of organs, tissues and cells donations, and will be used by medical professionals and transplant coordinators. The brochure will have a general part explaining the Directive 2004/23/EC. The brochure will report the relevant Slovak legislation and will be focused on removal of the critical aspect identified in the audit activity and its general conclusions. The final part will regard the aspects related to the detection and handling of potential donors.

The brochure will be a synthetic version on paper of the guidelines (QMSGuide), and will be either produced in the form of a CD (500 copies).

The STE involved in this activities will be Ms Di Ciaccio , Mr Piccolo, Ms Fehily, supported by Ms Agger, plus a scientific journalist to be approved by Slovak counterpart.

The brochure will be prepared by the STEs and 5000 copies will be printed within the project budget. The languages for brochures and guidelines are Slovak and English.

The reason why **Activity 4.2** is foreseen is the fact that the project strives to improve the interaction and communication between the health care institutions and social community especially in regard to organ donation and transplantation.

The dissemination materials will be prepared taking into consideration that a possible subsequent public awareness campaign will be launched by the Slovak competent authorities.

There will be a provision of effective information on how to assure the Slovak community of:

- the procedures used from the ethical and health authority point of view for organ transplants
- the important life saving results of those interventions
- the results obtained in other European countries.

Information material will cover organization of centers, coordination, control and evaluation programs, features that ensure transparency and quality of the Service as well as the main activities carried out by the National Transplant Center. Particular attention will also be devoted to organ donation, taking into account Slovak legislation in this specific field. The information leaflet and CD or DVD materials for the general public will be prepared.

Issues arisen

Unified information system and development of software (and hardware)

It was stated by STE that software developed in the project will require a complementary hardware (server) to be fully operational and to secure sustainability at the same time.

Therefore there is a necessity to add some additional finances from the Ministry of Finance (for the Ministry of Health) to provide the hardware: more financial support for the maintenance and upgrading of the software will be needed in the following years. This issue was arisen during activity 3.1 and it needs to be fully considered in order to have a real operative computerized network.

Relationships between transplant centres and MoH: the idea of a “transplant community” and the need of financial support to SCOT and transplant centres

Italian PL Mr Nanni Costa suggested that the best way to improve the relationship between transplant centres themselves and with MoH is to act all together as a whole transplant community, fully interconnected and tied up by clinical and scientific relationships. Another option should be to empower SCOT, creating a different institution acting as a National Transplant Centre. This National Transplant Centre in Slovakia could support and manage the whole process of organ donation in cooperation with the regional coordinating units, having a

better knowledge of local factors. It could either implement operational policies covering all aspects of the donation/transplant process and at the same time guarantee the fairness, transparency and safety of the whole system. Therefore this Central Institution should guarantee the well-knowledge of the problems related to donation and transplantation, showing ability in problem solving and also controlling the entire process.

But anyhow, in order to create a “new” SCOT as an institution fully independent and functioning, a financial support will be necessary.

The same need of financial support was claimed by all the transplant and coordination centres, during RTA first trip along Slovakia and during the Audits and Site Visits as well: this issue must be fully considered by SK competent health authorities.

Meetings with selected public bodies (scientific societies) convened by the RTA and his RTA Counterpart

This activity is foreseen by twinning team as an essential part in order to increase the awareness along Slovakia towards the development and goal of the TW project, and it can be foreseen as a part of the next activity 4.2.

In strict collaboration with PM Mr Koller and DPM Mr Kuba, the twinning team planned meetings with some scientific societies where RTA was invited to present the project, as reported inside the 2nd quarterly report.

Apart from the previously described meetings, RTA was invited at NUSCH Bratislava on 21.06.07 : he presented and discussed the twinning project at the Heart Transplantation Centre (**NUSCH**) in **Bratislava**, underlining the remarks and suggestions made by Mr Di Bartolomeo during his Audit (increase number of transplants and use more marginal donors) and reporting the progress of the project. It was stated the need from people working at NUSCH to attend the following medium Term Courses.

The meeting represented a good opportunity to better explain the steps of the project, to answer any issues arisen by the audience and to keep in touch with the transplant community, in order to give the audience the feeling of being fully involved in the twinning project development.

Liver Transplantation: the “extra twinning activity”

The following part of the text (liver transplantation: the extra-twinning activity) is mentioned only with an informative aim because it is not foreseen inside the twinning contact and it is clearly an extra twinning activity.

RTA and IT PL Nanni Costa continued even in this third trimester their meetings in order to facilitate the re-start of a liver transplantation activity in Slovakia, as previously reported.

RTA had few meetings with **Mr Olejnik** and later with **Mr Danninger** (Kramare hospital), both head-surgeons working at the previously active liver transplant centre in Bratislava, and with **Mr Laca** (national expert on liver transplantation) as well, in order to discuss all the possible solutions to the present situation in Slovakia about liver transplantation.

At the same time, Italian PL Mr Nanni Costa was actively working on the same topic in collaboration with RTA Mr Lauro: Mr Nanni Costa met in Roma (at the beginning of September) a member of national Slovak Health Commission **Mr Urbani** to discuss about the present liver transplant situation in Slovakia, foreseeing possible solutions through the help of Italian partnership, and obtained the support to the whole project of the President of Health Commission of the Italian Senate **Mr Marino**, worldwide recognized expert on liver transplantation.

Meanwhile, the **Slovak Hepatology Society** (represented by the President Mr Jarcuska), in agreement with RTA Mr Lauro, produced a written statement (added as Annex 3), remarking the need of an initial support on liver transplantation in Slovakia by the Italian partner.

This possible common project on liver transplantation between Italy and Slovakia was useful to the twinning project for the following reason, even if it is clearly an extra twinning activity, outside the goal of the project:

marginal donors were taken into account as potential liver donors to be offered abroad, if not used for Slovak cirrhotic patients.

Up to beginning of September 2007 Italy, through a CNT organization called “Italian Gate to Europe” in Rome, got 10 marginal livers from Slovakia for 10 cirrhotic recipients since two days visit of Slovak experts on March 2007: 2 livers went to Bologna, 4 to Modena, 2 to Ancona, 1 to Torino and 1 to Roma.

All these 10 recipients were transplanted and in good conditions after liver transplantation.

Other two marginal livers were offered by Slovakia to Italy but not used for problems related to the flight connection.

This fact has contributed to increase the total number of Slovak donors collected so far (**above 80 donors** up to date since the beginning of year 2007): in fact, comparing to the same period of year 2006, the number of donors in Slovakia has raised notably, probably as a “twinning” effect and because of the new laws on transplantation discussed in the previous report.

Recommendations

The development of a **QMSGuide** was advisable in order to replace old own quality system guides inside transplantation centres and to foster the EU Directives. Still it will be necessary to apply it by means of training courses, as the newly designed Short and Medium term courses.

It was highly recommended to MoH, inside the previous report, to give and “extra” financial support to **Medium term courses**, in order to obtain the maximum attendance by Slovak trainees but unfortunately it could not be realized.

The same need (“extra financial support”) could arise in order to realize the **Short Term courses in two different towns**, and it will need to be fully debated during the following period of time.

The old **software** needed to be updated and it will be realized by the project, taking into account that also a hardware should be necessary in order to fully support the SW.

SCOT needs to be empowered as well as the network between coordination and transplant centres, realizing a real “**transplant community**”, interacting scientifically and medically.

Financial support needs to be foreseen in next years to support the SCOT and this transplant community.

Liver transplantation needs to be implemented in Slovak Republic.

All possible agreements with other countries must be foreseen as just an initial step towards full independence of Slovakia on an own liver transplantation programme: the mortality rate

of cirrhotic patients in Slovakia is still to high compared to other EU countries and it must be addressed and corrected by appropriate action.

EXPENDITURE TABLE

Section No.	Name of services / goods purchased or direct costs	Date(s) of services	Supporting Document	Date of invoice	Breakdown and clarification	Amount paid in local currency (if applicable)	INFO-EURO exchange rate	Amount paid in EUR	Amount foreseen in original budget
1	Resident Twinning Adviser Augusto Lauro (13 months)								
	Basic salary	June - July - August 2007	salary slips		Gross salary			€ 9 320,30	€ 71 604,26
	Non-wage labour costs (36,031 %)							€ 3 582,24	€ 25 799,73
	6% of salary and non-wage labour costs							€ 774,15	€ 5 844,24
	Total RTA remuneration							€13 676,69	€ 103 248,23
2	Resident Twinning Advisor Allowances								
	Daily Allowances (50%) 13 months	June - July - August 2007	salary slips		June = 18 per diem July = 18 per diem August = 14 per diem			€ 4 375,00	€ 34 562,50
	Allowances for RTA for first 30 days								€ 5 250,00
	Health and accident insurance for RTA								€ 2 600,00
	Accommodation	June - July - August 2007	apartment rent receipts	June - July - August 2007				€ 2 100,00	€ 12 000,00
	Excess luggage								€ 175,00
	Estate Agent's Fee								€ 400,00
	Travel to and from place of duty - RTA (one for each period of secondment)								€ 1 400,00
<u>Monthly allowance for special economically priced return trips</u>	June - July - August 2007	RTA statements use of car			June = 375 € adjusted to days worked July = 375 € adjusted to days worked August = 225 € adjusted to days worked			€ 975,00	€ 6 050,00

	Total RTA Allowances							€ 7 450,00	€ 62 437,50	
3	RTA Training									
	Return fare Brussels								€ 700,00	-€
	3 per diems BE								€ 450,00	-
	Total RTA Training								€ 1 150,00	-
5	Project Preparation									
	RTA/PL Leader fees (2 people x 1 mission of 2 days each)									
	'Project Management Costs'									
	Per diems									
	International travel (2 trips x 2 people)									
Total Project Preparation										
6	Project Co-ordination/Management Costs									
	Participation of PL/DPL in PSC meetings Fees (4 missions of 2 days-preparation+meeting)								€ 2 000,00	
	'Project Management Costs'								€ 3 000,00	
	Per diems								€ 2 100,00	
	International travel								€ 2 800,00	
	Visibility costs[1]								€ 2 000,00	
	Audit certificate costs[2]								€ 4 000,00	
	Total Project Co-ordination/Management Costs							€	€ 15 900,00	
7	PROJECT ACTIVITIES									
	Component 1: elaboration of an audit analysis of the current situation in the field									
	Activity no. 1.3 Audit									
	Expert fees								€ 12 250,00	
	'Project Management Costs'								€ 18 375,00	
	Per diems (3)								€ 12 250,00	
	International travel								€ 4 900,00	
	local travel								€ 2 750,00	
	RTA and RTA-A local travel								€ 1 700,00	
	RTA per diem for missions outside Bratislava								€ 700,00	
	Translation								€ 2 000,00	
	Translation Andrej Klapica July 2007 Mr. Klapica debit note July 2007 Translations of 19 pages of documents for Audit								€ 374,00	
	Total Activity no. 1.3							€	€ 54 925,00	
COMPONENT 2 "design and implementation of a unified quality management system"										
	Activity no. 2.1 elaboration of QMSG									
	Expert fees 3 Member State exp., 5 days each								€ 3 750,00	

'Project Management Costs'								€ 5 625,00	
Per diems (3)								€ 3 150,00	
International travel								€ 5 600,00	
Translation							€ 1 637,00	€ 2 800,00	
Translation Andrej Klapica	July 2007	Mr. Klapica debit note	July 2007	Translations of 82 pages of documents for QMSG			€ 1 637,00		
Total Activity no. 2.1							€ 1 637,00	€ 20 925,00	
COMPONENT 3 development of a specific software									
Activity no. 3.1 preparation of the unified information system									
1 MS expert-5 days and 1 MS IT expert-8 days Expert fees							€ 750,00	€ 3 250,00	
'Project Management Costs'							€ 1 125,00	€ 4 875,00	
Per diems (3)							€ 350,00	€ 3 150,00	
International travels							€ 980,12	€ 1 400,00	€
Translation								€ 1 000,00	
Total Activity no. 3.1							€ 3 205,12	€ 13 675,00	
4th Mission of GHIRARDINI Angelo	19-20/June/2007	MC n. 1/III		Arrival 19/06/2007 Bologna/Vienna 10:55/12:35 flight n. OS 548 Departure 20/06/2007 Vienna/RomeFCO 17:30/19:10 flight n.OS 503					
Fees				1,5 x 250			€ 375,00		
'Project Management Costs'				1,5 x (1,5 x 250)			€ 562,50		
Per diem				1 x 205 € of which 60 € are charged to the contingencies following the change from the 18th of December			€ 175,00		
Air ticket		Travel Agency Cisalpina Invoice n. 22616 and 14736/04.	June 2007	Economy Class Bologna/Vienna/Roma: €598,41.			€ 598,41		
Sub Total							€ 1 710,91		

1st Mission of SCAGLIA Stefania	19-20/June/2007	MC n. 2/III		Arrival 19/06/2007 RomaFCO/Vienna 10:35/12:25 flight n. OS 506 Departure 20/06/2007 Vienna/RomeFCO 17:30/19:10 flight n.OS 503				
Fees				1,5 x 250			€ 375,00	
'Project Management Costs'				1,5 x (1,5 x 250)			€ 562,50	
Per diem				1 x 205 € of which 60 € are charged to the contingencies following the change from the 18th of December			€ 175,00	
Air ticket		Travel Agency Cisalpina Invoice n. 22616 and 14736/04.	June 2007	Economy Class Roma/Vienna/Roma: € 381,71.			€ 381,71	
<i>Sub Total</i>							€ 1 494,21	
Surplus status line after SL 3								€
OVERALL TOTAL WITHOUT ASSISTANT AND CONTINGENCIES							€26 342,81	€ 474 885,54-

ANNEX 1

Quality Management System Guide

ANNEX 2



TRANSPLANT CENTRE UNIVERSITY HOSPITAL MARTIN Kollárova 2, 036 59 Martin

Dear Doctor Lauro.

I would like to react on the 2nd quarterly report that you sent to Professor Laca, especially on issues concerning Transplant centre Martin.

We do not have “only one doctor coordinating donations (24 hours and 365/365 days)”. During the time of audit we had 4 coordinators, two preparing themselves for specialization in anesthesiology and two for specialization in surgery, all four colleagues absolved training courses in Italy.

All coordinators in our University Hospital receive extra money (a fix amount) from the hospital for activities in donor identification and organization of retrieval.

We have an administrative worker (a nurse) for a full time job.

Our significant strengths that have not been mentioned at all are in our deceased donor activity that is since our beginning (2004) highest in Slovakia. Already during the first 6 months of 2007, we reached 20.3 deceased donor pmp, so the project target 30 pmp will be outnumbered. Each one of Depts of anesthesiology in regional hospitals in our district has a local coordinator. Result of the four year education of our colleagues (meetings in TC Martin 2-3 times yearly during first two years, regular visits and seminars in local hospitals during the last two years) are background of this success. Financial involvement of local coordinators was only transient (participation in a scientific- medical project of donor preconditioning wit dopamine supported by University Hospital was running for two years). To sum up present status, we accomplish situation, when donor identification and announcement to TC is a part of daily routine of Depts of anesthesiology in our transplant region!

All coordinators in TC Martin have experience in multiorgan harvesting (vast majority of livers, if not all, sent from Slovakia to Italian gate were from TC Martin during this year). Distance to nearest airport did not influence transplantability of these livers that is why I am surprised that in chapter Transport, TC Martin is not mentioned between centers with airport accessibility.

We do have access to the emergency labs for 24 hours regularly, not only on *ad personam* availability.

We do have access to biopsies for 24 hours for 7 days per week- we regard them as the only warranted way how to safely use marginal kidney donors (UNOS criteria) and according our local directive this biopsy is mandatory before kidney allocation. We have the highest number of marginal donors in Slovakia. As a sequel of twinning agreement with Italy concerning marginal liver donors, urgent liver graft biopsies are available from the beginning of this year, too. After all, postponing of retrieval in order to carry out the exams is quit understandable, if the exam was mandatory angiography, which was just busy because of the 5-6 hours coiling of intracerebral aneurysm.

Our significant weakness is, I suppose, suboptimal mastering of English language from the site of transplant coordinator during your one day visit in May. This was a reason, despite an interpreter presence, of above mentioned misunderstanding.

Sincerely yours

Barbara Grandtnerova, MD, PhD
Head of Transplant Centre
University Hospital Martin

Martin, 17.7.2007

**Centro
Riferimento
Trapianti
Emilia-Romagna
Responsabile Dott.ssa LORENZA RIDOLFI**

Bologna, 20 Luglio 2007

To Dr Barbara Grandtnerova, MD, PhD
Head of transplant Centre
University Hospital Martin
c/c Dr Augusto Lauro
RTA Twinning Project

Dear Dr Grandtnerova,

We would like to thank you for your letter of July 17th2007 and for the clarifications enclosed. The detailed description that you provided strengthens our assessment of the local coordination at the University Hospital Martin as an outstanding model. We fully agree that perhaps the misunderstanding was due to some problems with the translation. Moreover, we would like to provide you with some comments on the points that you raised in your letter:

1. We believe that four medical doctors are enough to coordinate the donations in your area;

2. If so Martin, together with Banska Bystrica, have already met such an important requirement for the donation system;
3. It is fine with us if the nurse is also dedicated to support the activities of the donation coordination centre;
4. The medical doctor who attended the audit was not able to provide the activity report;
5. TC Martin was not mentioned because Zilina Airport is open for international flights only in the mornings;
6. We are happy with this information;
7. We are happy with this information.

We would like to renew our congratulations for the excellent professional level of the staff involved in the donation and transplantation processes in Martin and we are looking forward to meeting you soon,

Our kindest regards,

Angelo Ghirardini

Lorenza Ridolfi

ANNEX 3

Slovak Society for Hepatology

Košice, September 2nd, 2007

Titl.
Augusto Lauro M.D.
RTA, FNsP Ruzinov, Ruzinovská 6
826 06 Bratislava

Support for Liver Transplant Programme between Slovak Republic and Region Emilia Romagna

Dear dr. Lauro,

We have no functional liver transplant programme in Slovak republic at this time and many Slovak patients die for end-stage liver failure. There exists only one chance for these patients

today: transplantation in foreign countries, but patients with advanced liver cirrhosis, older patients with liver failure or patients needed combined organ transplantation aren't included often common in waiting list for liver transplantation. Agreement between Slovak Republic and Region Emilia-Romagna could solve problem of these groups of patients, especially patients with high MELD score.

The second important point of „Agreement“ is possibility of education of Slovak physician and other medical staff in liver transplantation in Bologna University Hospital. Conditions of this educational stays for our staff are excellent and I hope, that this form of cooperation is optimal way for starting functional liver transplant programme in Slovakia in the future. Slovak Society for Hepatology with pleasure supports Agreement for Liver Transplant Programme between Slovak Republic and Region Emilia Romagna.

Best regards,

Peter Jarčuška, MD, PhD., Associate Professor
President of Slovak Society for Hepatology
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