MUTUAL ORGAN DONATION AND TRANSPLANTATION EXCHANGES

IMPROVING AND DEVELOPING CADAVERIC ORGAN DONATION AND TRANSPLANTATION PROGRAMS

MODE – MUTUAL ORGAN DONATION AND TRANSPLANTATION EXCHANGES
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1st January 2011 – 30th June 2012

The MODE Project is co-funded by the European Comission Public Health Programme

Grant Agreement number: 2010 21 01

TABLE OF CONTENT

FOREWORD

DEAR COLLEAGUES,

Cooperation is a natural attitude in the field of organ donation and transplantation, for a series of reasons. Indeed, our works requires us to work in teams, to be supportive, to incentivate solidarity and above all to set up a network of structures working together for a common goal. It is no wonder, therefore, that international cooperation in our field started long ago, in well-structured networks like Eurotransplant Foundation or in self-organized groups of organizations, such as the group of European Organ Exchange Organizations that has been meeting annually for over ten years, in order to discuss the possibility to find common solutions to common problems, such as the identification of clinical data to be shared when assessing an organ or a donor for the safety of organ exchanges, the issue of multiple listing and cross-border donations and transplantations, the safety of living donation, organ transportation and many others. In 2004 the Ministers of Health of the Newly Acceding Countries of the EU (Malta, Cyprus, Czech Republic, Hungary, Poland, Lithuania, Latvia, Estonia, Slovak Republic, Slovenia) declared the intention to undertake to **work together** …" and upon this declaration an intergovernmental organization was created and cooperation was started in education programs, overview of quality and safety standards, development of optimal organ sharing policies and standardization of information systems.

From 2003 onwards, after the Conference on Safety and Quality of Organ Donation and Transplantation held in Venice on September 17 2003, the European Commission has started drawing the attention of our community to the need of a common legislative framework and in order to pave the way to this, started contributing to the building of our cooperation activities through project funding. From 2003 to present date, a number of projects and joint actions have been or are still funded by the Union, under different programs: EURODONOR (E-ten Program), ALLIANCE O and DOPKI (VI FP), ETPOD, EULID, EFRETOS, COORENOR (Public Health), to name but a few.

MODE is another brick in this wall, pinpointing a new form of cooperation, that of twinnings. Indeed in the original idea of MODE, our consortium had thought to organize single one-to-one twinnings on selected subjects, but due to the limited funding this turned out to be not possible. The innovative aspect of the project was however to allow partners to highlight their fields of interest through an analysis of strengths and weaknesses and next their training needs in those specific fields. But what's more, in the preparatory phase, this was probably an opportunity for all partner countries to analyse the organizational situations of donation and transplantation in their own country, from the point of view of Directive 53/2010 implementation.

To me, as the coordinator of this project, it is clear that, due to the complexity of the process and the variables in the organizational situations, each country has something to "offer" and much to learn from others and that I have the feeling that in our action such comparison has always been constructive, allowing the knowledge and understanding of "different worlds" and the acquisition of new skills that cannot maybe be imported tout court, but are however a great stimulus for our mutual growth.

MODE Scientific Coordinator
Dr Alessandro Nanni Costa

PARTNERS

WP leaders

Centro Nazionale Trapianti (Italy) **WP1, Coordination**

Országos Vérellátó Szolgálat (Hungary) **WP2, Dissemination**

Lithuania - National Transplant Bureau (Lithuania) **WP3, Evaluation**

Koordinacní Stredisko Transplantací (Czech Republic) **WP4, Transfer of best-practices**

Organización Nacional de Transplantes (Spain) **WP5, Provision of set of specialized trainings**

Associated partners

Autoridade para os Serviços de Sangue e da Transplantação (Portugal)

Slovenija Transplant (Slovenia)

Pauls Stradins Clinical University Hospital (Latvia)

Tartu University Hospital (Estonia)

Bulgarian Transplant Executive Agency (Bulgaria)

Mater Dei Hospital (Malta)

INTRODUCTION

For many patients, organ transplantation represents the only life saving treatment available, a successful therapy for some categories of patients suffering from serious organ failures. This treatment has a positive outcome on the medium and long term, roughly in 80% of the patients. This therapeutic opportunity is however precluded to a number of patients due to organ shortage.

The European Commission has therefore committed to identify the major policy challenges in this field, among which ensuring the quality and safety of human organs, increasing organ availability and enhancing the efficiency and accessibility of transplantation systems in the European Union. These three challenges are effectively addressed by the "Directive on standards of quality and safety of human organs intended for transplantation" (3) (2010/53/EU) adopted by the EU Parliament on July 7 2010 and by Action Plan on Organ Donation and Transplantation, aiming at strengthening cooperation between Member States. The Directive provides for the appointment of Competent Authorities in all Member States, for authorization of procurement and transplantation centers and activities, for traceability systems, as well as for the reporting of serious adverse events and reactions and European Union Member States have to implement such requirements in their legal systems by 27 August 2012.

As it is well indicated in the white paper issued in 2007 by the Commission "Together for Health: A strategic approach for the EU: 2008-2013"(4), Member States have the main responsibility for health policy and provision of healthcare to European citizens but there are areas where Member States cannot act alone effectively. Organ donation and transplantation is a great example of application of such strategy, that the whole transplant community hopes will prove to be successful in the near future.

WP1 – PROJECT COORDINATION; CENTRO NAZIONALE TRAPIANTI (ITALY)

The Italian National Transplant Centre has acquired a sound experience in project coordination and has taken part in 11 projects as partner since 2003. In addition, during the years, 2006-2008 it has successfully managed a twinning program between the Italian and Slovak Health Ministries entitled “Improvement of the safety, quality and availability of organs, tissues and cells for transplantation”. Co-ordination activities aim at the support for all actions on going to the achievement of the objectives and tracking the execution of the project by all partners.
Administrative management has covered the execution of all administrative, legal and financial responsibilities. Management activities will cover both project development and support and coordination of actions. A secretariat will be established to this aim and support from the central administrative offices of the Italian National Institute of Health will be provided as for the previous projects. As far as the other partners are concerned, most of them have already taken part in projects under the Public Health program and therefore are familiar with funding mechanisms and management of activities.
WP1 deals with the management of the project and emphasis will be placed on ensuring an optimal organization, management and decision making structure of the project.
WP1 on Project Management is a horizontal WP which continues throughout the duration of the project and contributes to the overall objectives by supporting and managing the technical WPs. The Scientific Responsible will be in charge of the overall management and is responsible for the correct execution of the contract. He will also be the main interface to both the EC and the outside world.

KEY OBJECTIVES ARE:

- Ensuring a good co-ordination of the partners’ activities
- Efficient legal, contractual, financial and administrative management
- Assuring high quality of the project work and results

WP LEADER WAS RESPONSIBLE FOR IMPLEMENTING THE FOLLOWING ACTIVITIES:

- Co-ordination of the partners’ activities
- Ensuring effective communication, collaboration and cooperation within the Consortium by laying down and monitoring documents, reporting and control procedures
- Interface with the EC and the outside world
- Monitoring and control of the time schedule and the timing of the related activities
- Ensuring timely release, technical high quality and accuracy of deliverables
- Editing meeting agendas and minutes of the project meetings
- Exploitation of the results
- Implementation of a website

The Scientific director would also report first to the consortium and, if the case, to the Commission, on any problem that may arise with regards to the efficient use of resources or the timely release of technical deliverables. WP1 will thus contribute to the achievement of the overall project objectives by redirecting the project if needed and by discussing with the partners concerned how to re-allocate effort in order to compensate for the delays.

WP 2 – DISSEMINATION OF THE PROJECT; ORSZÁGOS VÉRELLÁTÓ SZOLGÁLAT (HUNGARY)

Each partner was responsible for dissemination of the project in their own country, by attending local and national conferences in order to present the project and its results to experts in the field and communicating the findings to relevant stakeholders. In addition the following joint activities carried out:

- Definition of target groups;
- Identification of tools and strategies for diffusion;
- Identification of events;
- Publication of articles;
- Production and printing of dissemination material.

AIMS

- To ensure a smooth communication flow among the partners,
- To disseminate the project with its results to the different stakeholders: general public, health care officials, scientific societies, national and international policy makers, European Institution, National Institution, also taking into account those countries not participating to the project.

TOOLS OF THE DISSEMINATION

1. **Project Website**: In the ***private area*** all on-site vist programs, agendas and minutes of the meetings are available and downloadable to the all project partners and the European Commission. In the ***public part*** there are a description of the project, a brief description of the partners and the workpackages also. The public area also will contain the layman brochure in pdf and finally will include the results of the WP-s.
2. **Layman’s Brochure:** For patients and general public, a layman’s brochure worked out, which explains the contents of the project and its aims. This brochure will be produced in electronic form and made available through the website and also printed at month 6.
3. **National/International Congresses:** each partner has a responsibility about the project dissemination, so the results and the guidelines of the project could be presented as abstract or poster on national and international congresses and events.
4. **Articles:** each partner and workpackage leader has to publish theirs results and guidelines in the national or international scientific journals. A special attention will be devoted to those countries not involved in the project.
5. **Newsletter:** at the end of the project, promotional material produced by dissemination WP which will highlight the main findings of the project, ensuring that this information is properly distributed to identified Target groups.

PERFORMED DISSEMINATION ACTIVITIES:

- Website: www.mode-ja.org
- Layman’s Brochure: distributed in 500 pieces.
- International Events:
  - 3rd Competent Authority Meeting 2011
  - 4th Competent Authority Meeting 2012
  - High Level Conference on EU Health Programme
- National Congresses, Events: 24 presentations in 4 countries

TARGET GROUPS

- EU Commission authorities (DG SANCO, DG Research, European Council);
- National policy makers (Ministries of Health, Regional Health Authorities);
- Professionals (national and international scientific societies of surgeons, coordinators, intensivists, nephrologists such as ESOT, ETCO, ISHLT, EDTA, IPITA, ERA-EDTA, ESICM, etc.);
- National and international organizations, such as European Organ Exchange Organization members, European Transplant Network members, national agencies in charge of organ exchange with foreign countries;
- Patients' associations (haemodyalized patients, transplanted patients) at national and international level and general public.

WP3 – EVALUATION; NATIONAL TRANSPLANT BUREAU (LITHUANIA)

Lithuania in MODE project worked in WP3 – carried out internal auditing of the project. MODE project was implemented in several ways:
1. Preparation of the questionnaire, summary of the responses, working group members' and project participants' meetings in Rome (Italy) - period - 2011 January – 2012 June:
Meetings – Technical Meeting in Rome (Italy), I meeting in Luxembourg, II meeting in Rome, III meeting in Rome, IV Meeting in Rome;
All meetings were organized by Italian transplant center (Centro Nazionale Trapianti, Instituto Superiore di Sanita); in the meetings there was provided information and analysis of questionnaires.

2. Workshops - sharing of best practices - 5 practical meetings. Organized Czech Republic and Italy;

3. Workshops - good practice's interception in Spain in 3-day face-to-face and on-line trainings.

National Transplantation Bureau (NTB) representative participated in all meetings - theoretical and practical, so whole project can be evaluated not only by the answers to the questionnaires but also on the basis of own experience.

EVALUATION OF THE JOINT ACTION

As first step a presentation about the work of the WP3 was delivered at the meeting in Luxembourg (organized by ES representatives).
Phase I – 5 workshops - they were coordinated by representatives of Czech Republic, Centro Nazionale Trapianti. In every practical meeting they provided the participants with questionnaires where were submitted theoretical, practical and organizational areas of the sessions.
Phase II – 2012 January - February NTB organized a questionnaire and coordinated it with the administrator of the project – Centro Nazionale Trapianti, Instituto Superiore di Sanità. The questionnaire was sent to all 11 participants in April.
Phase III – On-line training, April 27th - May 3rd;
Three sessions face-to-face in April 7-9th , in Madrid, Escuela Nacional de Sanidad (National School of Health).

MODE PROJECT'S INTERNAL EVALUATION RESULTS

Participants were given a form with questions about each working group. Responses were received, processed and summarized. Results are given below (it has to be highlighted, that theoretically there are 11 countries participating in MODE project but from one of them there were any news so it didn't answer to the questionnaire).

WP1 - COORDINATION OF THE JOINT ACTION

WP1 represents actions undertaken to manage the project and to make sure that it is implemented as planned. It includes organization and conduct of meetings, filling in the financial reporting.
To the first 4 questions it was asked to answer only 10 Member States (MS), because Italy was responsible for the organization of meetings.

Figure 1. shows that 8 participating countries got invitations to meetings reasonably ahead of schedule .

Figure 1. *Did you get the invitation reasonably ahead of schedule?*

The agenda of meetings was submitted on time and the items on the agenda were formulated precisely and clearly. It is very important to prepare a meeting thoughtfully in order to avoid any disruptions.
8 of 10 MS answered that all information (location, time, etc.) was submitted clearly, 1 country thinks that not always it was done plainly. Detailed meeting place, the address is one of the most important aspect when planning a meeting. This allows you to come on time and avoid unnecessary delays.
The presentations were made accurately and clearly and the duration of the meetings was appropriate **(Figure 2.)**.

Figure 2. *Were the presentations submitted accurately and clearly? Was the duration of the meetings appropriate?*