



MODE

Mutual Organ Donation
and transplantation Exchanges

Improving and developing
cadaveric organ donation
and transplantation programs

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

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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.

Aim

The main objective of this joint action is the transfer of best-practices in the field of organ donation and transplantation and the creation of positive synergies among participating Member States apt to support authorities in possible decision-making and policy contexts.

The consortium has chosen to foster the exchange of best-practice through a series of exchange visits followed by the provision of a set of specialized trainings.

Main topics

- existing donation and/or transplantation laws and how they influence the transplant activity;
- transplant activities;
- procedures for brain death diagnosis and quality programs for donation;
- approaches to the traceability from donation to transplantation;
- distribution of essential structures;
- organizational networks;
- quality program for transplantation.

Specific objectives

Transfer of best-practices in participating countries

The Joint Action tool is the best suited to allow partners to give a further contribution to the process identified by the Commission, since a formal commitment is required by Member States that delegate partners to perform the action. The Joint Action “Mutual Organ Donation and Transplantation Exchanges – MODE” is an 18-month project co-funded by the European Commission under the Public Health Program (DG Health and Consumer Protection), Grant 20102101. It started on January 1st 2011. The contribution of this joint action to the ongoing EU policy is to allow diffusion of best practices in the three above-mentioned fields (quality and safety, organ donation, efficiency and accessibility of transplant systems) identified by the Directive as priority sectors of action. In Table 1 herebelow, the major criteria used for definition of “best practice” in each of these fields are reported.

Table 1. Criteria for definition of best practices

Quality and safety	Overview of quality/safety national programmes and evaluation of programme results, with special attention to programmes for notification of adverse events and reactions
Organ donation	Overview of national programmes for monitoring devastating brain injuries in ICUs and analysis of donation rates
Efficiency and accessibility of transplant systems	Analysis and comparison of existing national programmes for evaluation of transplant outcomes

This action is meant to complement Member State policies in this field through cross-border cooperation. Such best-practice transfer know-how is being implemented through a series of actions starting with the identification of interest sectors, following by exchange visits focused on identified items and specific training. The expected outcome is that since even European Union countries with well-developed services show significant differences in organ donation and transplantation activity, all participating countries will benefit from investigating foreign donation and transplant systems in place. Another positive effect will be the creation of positive synergies among participating Member States apt to support authorities in possible decision-making and policy contexts.

The consortium partnership is a good representative sample of Member States from different EU areas and allowed to gather a number of different approaches to the Joint Action issue.

During the first months of the project, in order to set up the exchange visits, each country presented its strengths and weaknesses through a questionnaire based on the Organ Action Plan. Each country also pointed out its training needs. The partner responsible for such activity (KST from Czech Republic) worked out a chart flow with answers that was discussed by the consortium and a SWOT (Strengths/Weaknesses/Opportunities/Threats) analysis was applied at national level, replies to the questionnaire were collected and then processed in a point diagram showing the score and level of intensity of individual replies.

Five topics and five countries were singled out and onsite visits were organized accordingly. Each country had the opportunity to take part in each of the five exchange visit. Table 2 summarizes the topic of the visit, date and location, together with reference to Organ Action Plan goal.

Table 2. Summary of on-site exchange visits

Date	Hosting Partner	Organ Action Plan priority	Main Topic
7 June 2011	ONT Spain	(1) Increasing organ availability	Quality improvement programs
9 June 2011	KST Czech Rep.	(2) Enhancing efficiency and availability of transplant systems	Supporting and guiding organizational models

20 June 2011	ASST Portugal	(2) Enhancing efficiency and availability of transplant systems	Supporting international exchange of organs for transplantations
7 July 2011	ST Slovenia	(2) Enhancing efficiency and availability of transplant systems	Increasing deceased donation to their full potential
12 July 2011	CNT Italy	(3) Improving quality and safety of transplants	Evaluation of post-transplantation results

At the end of the five visits, each partner wrote a memorandum explaining if the topic chosen could be implemented in his country and how or the reasons why implementation would be difficult to be achieved. As a result, in October 2011, a final detailed report of such visits describing their outcome was drawn up.

Provision of set of specialized trainings

On the basis of onsite visit outcomes and identified training needs, three topics were selected and training courses were developed by the responsible partner, ONT from Spain, in close collaboration with the whole consortium. The topics are the “Reporting on adverse events and reactions”, the “Quality assurance program of the donation process” and the “Quality assurance of the transplantation process”. Some of these topics are completely new and focus on important aspects of the implementing Directive such as biovigilance and surveillance on substances of human origin in Europe, fundamentals of risk management and tools to support decisions, quality indicators for the transplant and donation processes, organization of registries and methodologies for analysis of transplant outcomes. Courses were held from the 7th to the 9th of May 7th 2012 in Madrid and are mainly addressed to the staff from national organizations or Competent Authorities that are closely involved in the field of organ donation and transplantation. From March 1st to 31st, attendees were enrolled and they were provided with educational material. Next, they were assigned a user-id and password to access an e-learning platform through which they took part into an e-learning session from April 16th to 26th that included tests and surveys and forum discussions. Eventually, from May 7 to 9th three face-to-face courses (eight hours each) were held in Madrid at Escuela Nacional de Sanidad (National School of Health).

The specialized training courses were focused on the following topics, related with the challenge points of the Commission Action Plan:

- On the traceability and bio-vigilance in organ transplantation, analyzing how are performing the organizations in Europe and in other developed countries, and what are the more useful tools to implement to comply with the mandate of the Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation.
- On quality assurance on the donation process, as mean to evaluate the potential for organ donation and standardize the procedures and guidelines for improving the donation of organs from brain death donors.
- On accreditation of transplant centres and how to improve safety and quality in the allocation of organs and the evaluations of the outcomes of the transplantation processes.

The faculty for the courses was selected by looking for European experts in each of the fields, who had participated in different European projects related with the Action plan, and by taking advantage of the experience in teaching the same topics in previous events and courses.

The immediate evaluation of the courses has been made by mean of a satisfaction questionnaire filled in by the attendants to the courses, which has shown a high degree of achievement.

Outcomes

Since the project will be thoroughly achieved by end June 2012, it is time to assess the impact of our attempt to transfer best practice between partner countries. No doubt the approaching date for implementation of EU directive has given a further momentum to our initiative and we therefore hope our efforts will soon produce sound and measureable results. On the other side however, in our opinion, investment of resources and organizational efforts are more than ever needed in order to achieve desired results in organ donation and transplantation field, and unfortunately the present economic situation in Europe does not foster such approach. However, the identification of fields where best practice transfer is most needed and the possibility to train dedicated staff from Competent Authorities on such topics has surely been a first step forward. For further follow-up of our project, please visit the website: <http://www.mode-ja.org/>.

References

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2. (Council of Europe, Newsletter Transplant 2011, Vol 16 n.1 Sept 2011)
3. Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. OJ L 207, 6.8.2010
4. Commission of the European Communities. White Paper "Together for Health: a Strategic Approach for the EU 2008-2013" COM (2007) 630 final.
5. Council of Europe Newsletter transplant, <http://www.ont.es/publicaciones/Documents/Newsletter2011.pdf>

Partners

WP leaders

Centro Nazionale Trapianti (Italy) WP1, Coordination
Országos Vérellátó Szolgálat (Hungary) WP2, Dissemination
Lithuania - National Transplant Bureau (Lithuania) WP3, Evaluation
Koordinační Středisko Transplantací (Czech Republic) WP4, Transfer of best-practices
Organización Nacional de Trasplantes (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)

