

## THE EURODONOR PROJECT: AN ATTEMPT OF HARMONIZATION

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**Keywords:** transplant, network, data harmonization, common protocols

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**Abstract:** The EURODONOR project aims at providing a telecommunication-based information channel on a trans-European scale to the transplant sector. Its first goal is the creation of a European Donation and Transplant Activity Registry, on the basis of common protocols for data acquisition and processing and on the harmonization of the terminology used in data collection for organ donation, transplantation and waiting lists. Secondly, updated and official information should be delivered to transplant professionals, in-the-field institutions and citizens through a dedicated portal. Through such tools, EURODONOR approach is therefore expected to facilitate co-operation among European countries and increase public awareness and sensibility towards the value of donation at the social and human level.

### **Introduction**

Organ and tissue transplants are the result of an organizational process that begins with identifying a potential donor and ends up with the actual transplant operation itself. Such process is made of many steps that are very difficult to be measured and coded univocally, since for example, in different European countries, the same terms are often used to define different steps in the process, thus resulting in not comparable figures.

Presently, the situation of data collection and related infrastructure is highly heterogeneous throughout Europe. The most advanced supra-national database (ENIS) and linked Web Portal has been developed by Eurotransplant (ET): donor, recipient and transplant data are entered in real time by and available to some 70 transplant centers and 50 tissue typing laboratories in the 6 ET countries (Austria, Belgium, Germany, Luxembourg, Slovenia and the Netherlands). A linked and daily updated ET Web Portal is accessible to the general public, with a password-protected access to the medical profession for more specific areas of interest.

France, **Spain**, Italy and the U.K. have national databases and networks that are already partially or fully operational. In Italy, inter-regional and regional Organizations have been interconnected. The Italian, **Spanish** and U.K. systems are already “open”

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and based on Web technology, that means ready to be connected with other national Organizations.

In all the other countries, data about donors, transplants, organs and waiting lists are being collected locally in single transplant centers and sent by local networks to national Organizations. This entails long processing times and lack of homogeneity in data collection.

In 2001 the Italian National Transplant Centre (CNT) conceived a project proposal concerning the provision of a telecommunication-based information channel on a trans-European scale to this specific healthcare sector, which was submitted to the attention of other Organ Exchange Organizations.

A consortium was then built for submitting the proposal and Eurotransplant, the Greek National Transplant Organization, Donor Action Foundation, the Spanish Organizaciòn Nacional de Transplantes and UKTransplant accepted to join in such project. Two technical partners, FINSIEL and EUTELIS, were also called to be partners in the project to take care of the technical aspects of the proposal itself.

Indeed, a pre-requisite for building such system is the inventory of which data are presently being collected, existing legal constraints, existing information system through which data are collected and above all harmonization of terminology. Such telecommunication-based channel would also have eased a structured information flow between all key-role players (medical, para-medical and general public), to the benefit of patients, of their families and of national healthcare budgets.

TEN-Telecom (trans-European Telecommunications Networks) program was identified as the most apt for supporting such project. It is a Community Action that supports the trans-European deployment of e-society applications and services. It promotes the use of global telecommunications networks in areas of high socio-economic value, by aiding new trans-European multimedia applications and generic services of common interest that such infrastructures make possible.

### ***The project***

The project was called "EUROpean DONors and Organs Registry", and EURONOR was chosen as acronym. It aims at contributing to the positive evolution of the donation and transplant sector supplying the Institutional leading European Transplant Organizations of the Member States that take part in this project with a ground for common co-operation.

In order to do so, EURODONOR first goal is creating a European Donation and Transplant Activity Registry, coordinating the accomplishment of the national and international Organs Exchange bodies. The activities consist in defining and implementing - together with the Transplant Organizations in the Project - common EU protocols for data acquisition and processing on organs donation, and harmonizing the terminology used in data collection on organ donation, transplantation and waiting lists.

Secondly, the project aims at delivering updated and official information to professional operators and institutions, accessible via internet on real-time. Such objective is achieved by means of a portal (i.e. an internet virtual space) where the European transplant community - made by official institutions, transplant Organizations, European Health Ministries, health professionals (directly involved in donation and transplant activity, such as transplant surgeons, or not-directly involved as nephrologists or general practitioners), medical associations, voluntary associations and citizens - may develop a trans-national information exchange with modulated access to data for each category.

As far as the first objective is concerned, the work will be carried on through the following activities:

- Analysis of users needs by means of data collected with a questionnaire (donation structures, transplant centres national and international, coordination centres, trends, legislation, research activities results etc.);
- Analysis of different situations at national level concerning medical and logistic terminology, applied to the different phases of the donation process;
- Analysis of different national and supranational laws and rules which rule transplant sector;
- Technical and organizational analysis of present ICT infrastructures to exchange data and information.
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Common EU protocols for data acquisition and processing will be agreed and, as a consequence, harmonised data will be collected, namely concerning donation, retrieval and transplant activities carried out in the European country whose transplant Organizations participate in the project and also from those Organizations that are not partners in the project but are willing to put data into the database.

Data to be collected can be divided in two main groups:

- Those supplied by Organ Exchange Organizations that are mainly quantitative data (number of potential organ donor, number of utilized organ donors, number of potential organ available, number of transplanted organ donor, number of waiting list patients, number of patients inserted in the waiting list, number of organs exchanged with other organization, etc.).
- Those relating to donor detection and identification, that are the results of the analysis of Death Audit records. In this case data are supplied by the Donor Action Foundation that collects them in single hospitals, made anonymous to be analysed and allow to focus on the first phases of the donation-transplant process, highlighting failures to identify donors in Intensive Care Units.

The second objective concerns supplying of official and updated information to all professional operators and citizens. These exchanged information include part of the

database, operative protocols, professional knowledge and health care services available or not available for foreign citizens.

The Web Database will be the core of the system and its information should be defined with the view to maximize the opportunity for co-operation, data sharing, optimization of the resources, dissemination of the information, harmonization and build-up of a European dimension in this sector.

The EURODONOR Portal Platform, represents the system where the users can have access to the required data, accordingly to their role and their level of access to the system. The overall offer includes services related to national transplantation policy, legal information, international regulations, short notes, statistics and news from the overall world of transplantation. Furthermore it will be possible to require personalized information, medical advice, list of the National Centers and activity, procedures for booking visits, etc.... (Fig.1)

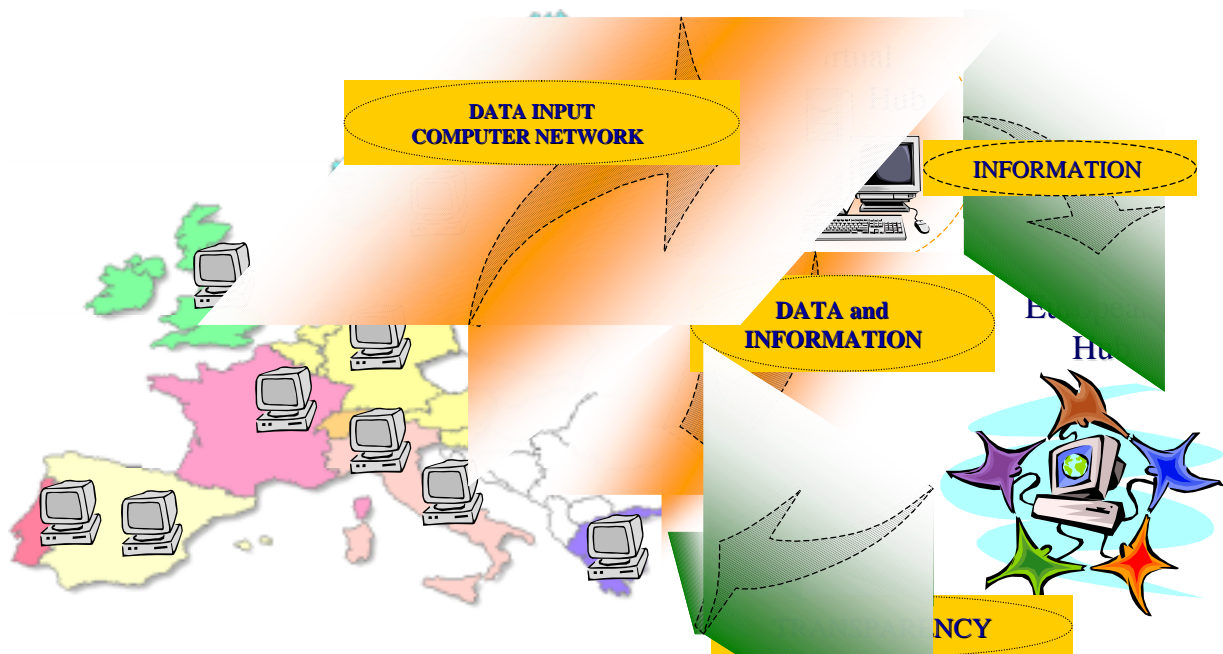


Figure 1. Prospective situation

The results reached in the feasibility phase will allow to precisely evaluate hazards, critical factors (weak points or strong points) and risks related to the creation of a European Organ Data Exchange Portal and Data Base - open in perspective both to partners funded by the EU and other members through Internet access - and to determine whether and what actions were needed to manage these risks.

The portal will be designed for the following aims:

- Being an internet virtual space for supplying updated information concerning the activities of involved transplant Organizations and also for the scientific societies

- operating in the transplant field (European Society for Organ Transplantation, National and Supranational organ procurement Organizations);
- Providing information about the activities in the transplant community to the Council of Europe Committee of Experts on the Organizational Aspects of Cooperation in Organ Transplantation;
  - Links to the national and supra-national transplant Organizations and also to the EC and to European Parliament;
  - Disseminating the initiatives taken in single countries concerning information campaigns on donation and also the European Donation Day;
  - Integrating into the system the data from transplant Organizations.

The database will hold raw aggregated data as well as predefined indicators of transplant activity uploaded by contributing Organizations.

The activity will be carried out by using technical approach based on existing mature procedures and technologies such as business to business model, HTTP, HTTPS, SMTP, FTP, XML, WIDL to be exploited for the design, configuration and implementation both of the database and vertical portal (Figure 2).

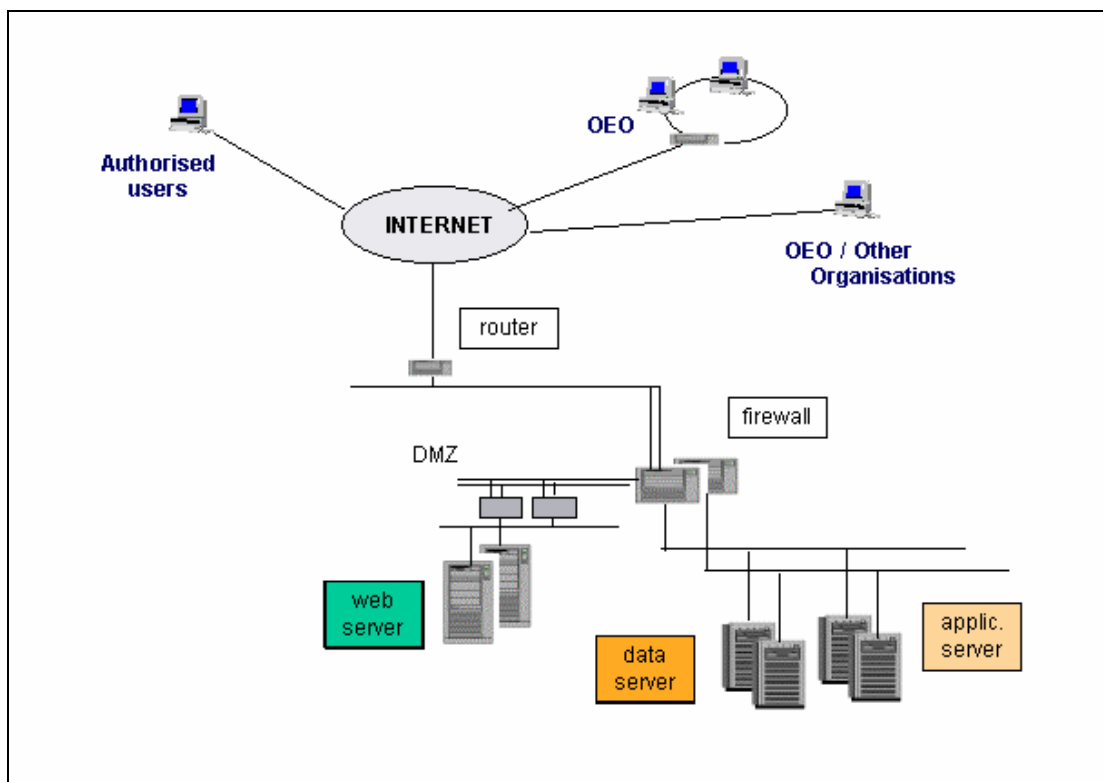


Figure 2. Scheme of Eurodonor possible network organization.

## **Description of the services**

The feasibility phase will allow to thoroughly analysing which data will be necessary to feed the Web Database; the following categories will be considered:

- Description and features of the national and/or international Organizations;
- Data about active waiting lists as well as donation, retrieval and transplant activities carried out in the European Countries of OEOs participating in the Project;
- Information about transplant centres;
- Information about enforced laws in each Member State;
- General information about transplant activities and news about different kinds of events (science, education, information) to be promoted at European level concerning donation and transplants;
- Potential Donor Medical Record information non confidential (*collected per patient, hospital/region/country*);
- Hospital Attitude Survey information (*collected per Critical Care Unit staff member, per hospital/region/country*).

The services, related with data collected in Web Database, will concern:

- Donation and transplant activities;
- Statistics and trends of donation and transplant activities;
- Efficiency indicators;
- Organizational information about OEOs;
- Medical journals and reports;
- Enforced legislation on organ donation, distribution, transplantation etc;
- OEOs informative, disseminating strategies;
- Research activities results, current studies.

Accordingly with the nature of information provided with the Data Base and the different types of services, the users can be subdivided into four categories:

- OEOs;
- Medical practitioners and hospitals;
- Government bodies, Council of Europe, professionals, public and/or private organization not directly involved in transplant activities but interested in specific aspects of the sector (Social Security Organization, Insurances, Pharmaceutical market, etc.);
- Citizens and patients.

Each class of users/clients/actors will be provided with different services/information, according to their necessities, the role that they play in the transplant sector and the available tools (for instance pc, mobile phones, information points in hospitals etc.).

### ***Prospective situation***

One of the most significant outcomes of EURODONOR concerns the capability of increasing information exchange and comparisons (between European countries, between regions in the same country or in different countries, between hospitals sited in the same region or in far-away districts) together with the capability of allowing comparisons between the trend of activity in one area or in one hospital at different times (2002 vs. 2001, January vs. July, and so on).

The process consists in two phases, Web Data Base feeding and Data access:

- periodically national and international transplant Organizations provide quantitative data to the Web Data Base (number of potential organ donors, number of utilized organ donors, number of potential available organs, number of transplanted organ donors, number of patients on the waiting list, number of organs exchanged with other Organizations, etc.). Data could be inserted either once a week or once a year on the basis of the activity at national, regional or even single centre level;
- data access, via front office Portal functionalities, is easy for each reference centre (national and/or regional), does not request special processing, does not refer to confidential information on single patients and therefore is not subject to legal restrictions. The data analysis allows a qualitative evaluation of donation and transplantation processes, requires a short time of work, and ensures to members (not necessarily to partners only) the visibility of the whole Data Base.

This process represents a significant breakthrough compared with the present situation. In fact nowadays exchange of data between EU countries is made once a year. Definitions are not clear and official data do not compare standardized items. At the present moment, no country exchanges data with other countries through computerized systems.

### ***Pilot trials and final dissemination***

A number of pilot-trials will be considered as belonging to the market validation phase and a number of specific representative pilot trials will be realised involving OEOs participating in the project;

During the feasibility phase only some transplant centers from EURODONOR partner Organizations (11 countries: Spain, Italy, UK, Ireland, Germany, Netherlands, Belgium, Austria, Luxembourg, Slovenia and Greece), will be involved in pilot trials, whereas in the deployment one, all the other countries that have already shown their interest for exchanging data in EURODONOR database will fully participate (9 more



countries: Scandiatransplant area, Swisstransplant, Poltransplant, Hungarotransplant, Czechtransplant, Cyprus and Georgia).

First of all will be defined, agreed upon and listed methodology and assessment criteria for the system validation, before starting operational phases of pilot trials.

The pilot trial operations will run with selected Organizations over the pilot network. This test will allow conducting a comprehensive European “market” survey to assess potential supply and demand for this type of market. Furthermore the task will allow refinements and improving of the services.

Afterwards the validation of the trials will be performed based on the satisfaction of the end users in terms of contents received, methodology used, performance and accessibility of the service.

Finally, dissemination activity is particularly required in order to ensure the widest visibility of the project results to the public and contribute to the harmonization policy in the sector.

### ***Project Management***

The Project is supervised by a Steering Committee (SC), which has full responsibility for the strategical resolutions about the Project. The SC is composed of one representative for each partner of the Consortium.

For the operative management of the Project an “Organisational Board” (OB) was set up, chaired by the Project Director. Members of the OB are the Project Director and the Workpackages leaders.

The Project Director (PD), is in charge of the day-to-day management of the project and will be responsible for implementing tasks as co-ordination of the partners activity; successful and effective communication, collaboration and cooperation within the Consortium; interface and all communications with the European Commission; supervision of dissemination and exploitation of the project results; supervision of the progress activity.

Workpackage Leaders (WLs) are responsible for the work carried out in the WP and have to ensure the timely submission of Workpackage deliverables. The WLs report directly to the PD.

Specifically each WL will guarantee:

- that each technical and/or scientific task/deliverable is completed in due time, and if not, to discuss with the partners concerned how to re-allocate effort in order to compensate for the delay;
- the technical and scientific high quality and the accuracy of deliverables.

With the scope that the Project’s outcome have an extended value, beyond the participant countries, and in order to pave the way for full cooperation among the EU states, the Project avails also of a quality and validation Committee named “Peer Review Committee” (PRC), established at the beginning of the Project

This PRC, chaired by the Project Director, includes experts in the field and representatives from Member States that are not in the Consortium. The following members were appointed

- M.Bernard Loty (Etablissement Francais des Greffes);
- M.Nils H.Persson (Scandia Transplant);
- M.Martin Molzahn (DSO);
- M.Marty Manyalich (ONT);
- M.Januz Walazewski (Poltransplant) and M.Josè Teixeira (Portugal);
- the Project Co-ordinator, M.A.Nanni Costa (Italy).

The role of the PRC, who operates along with the Steering Committee and the Organisational Board, is to help the project follow the right track in terms of work and to produce good quality deliverables; to control that project pursue goals and procedures described in the Technical Annex; to verify that results are correctly obtained and communicated to the international transplant community; to carry out a consensus document in order to harmonise operational standards and procedures in represented European countries; to verify the correspondence of the project activities to the future users expectations and quality standards.

### ***Conclusions***

EURODONOR objectives will pave the way for better cooperation among the European Member States in the health sector and in the specific field of organ exchange. A great requirement for co-operation and harmonization in this sector is of the utmost importance to solve the lack of current co-operation. For instance, the terminology used from one national situation to another is very different, and one of the first objectives of the project will be to build a common layer of concepts and protocols common to all the countries participating

Besides, the development of the information technology applications in the health sector is highly differentiated in the EU member states, both for sectors of application and for levels of development. This situation could become a heavy factor to be managed internally to the Consortium, where it will be necessary to build a common consensus at a level of achievement that could be considered too high for some partners and too low for some others.

The IT systems already in place in this sector in some of the partner countries of the Project have often been developed within a policy of dedicated closed systems, both for lack of requirements of large communication and because this policy was managed up to now mainly at national level. Issues of harmonization of the existing procedures and systems shall therefore be raised as one of the key pre-requirements of the migration towards an open portal architecture.

Finally, the portal for data exchange for organ sharing will be an important milestone in the development of a new policy in this field. Nevertheless issues such as the safety of the equipment solutions and the security of the data will be at the core of

the consensus among the participants in the project on how far these applications could be developed. The issue of data security is indeed a key requirement in the e-society, and the project realization should be able to offer the maximum guarantee.

Therefore, we all hope such effort will set the grounds for something really new in this field that would even help facing jointly major common problems and In the long run, EURODONOR approach is expected to facilitate co-operation among European countries building a European culture and deontology, foster positive effects on health management (social security, insurance, pharmaceutical...etc.), increase public awareness and sensibility towards the value of donation at the social and human level.