

**ORGAN DONATION AND TRANSPLANTATION
POLICY OPTIONS AT EU LEVEL**

CONSULTATION DOCUMENT*

27 June 2006

** This document does not represent an official position of the European Commission or its services. It serves as a tool to explore the views of interested parties on a suggested preliminary approach. The suggestions contained in this document do not prejudge the form and content of any future proposal by the European Commission.*

CONTENTS

INTRODUCTION..... 3

FACING COMMON PROBLEMS 5

 Quality and Safety 5

 Organ Shortage..... 5

 Organisational Systems and Organ Transplantation 8

ARRIVING AT COMMON SOLUTIONS 10

 Quality and Safety 10

 Organ Shortage..... 11

 Organisational Systems and Organ Transplantation 12

 International cooperation..... 13

THE ROLE OF THE EU. The legal basis 14

POLICY OPTIONS AVAILABLE..... 16

 a) First level: Use of existing programmes only 16

 b) Second level: Active coordination between Member States on organ quality, safety and availability. 17

 c) Third level. Second level + Minimum harmonisation on quality and safety + Initiative on Organ trafficking 18

QUESTIONS FOR CONSULTATION 19

REFERENCES 20

INTRODUCTION

Organ transplantation is the therapeutic use of human organs involving the substitution of a non-functional organ for another one coming from a donor.

Clinical organ transplantation began in the mid 1950s with kidney transplantation procedures between twins. Simultaneously with kidney transplantation, the first heart (1967) and liver (1979) transplantation were performed.

The use of human organs for transplantation has steadily increased during the past decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, and for end-stage failure of organs such liver, lung and heart, it is the only available treatment. Transplant procedures continue to develop and in the future may offer practical treatment for other unmet medical needs such as diabetes mellitus and some forms of malignant and metabolic diseases.

The use of organs in therapy poses a risk of transmission of diseases to the recipient. Infectious or cancerous diseases could be transmitted. Transmission of HIV, Hepatitis B and C, bacteria, fungi and parasites, as well as new emergent diseases, through transplantation have been described in scientific literature.

On the other hand, the shortage of organs is a major factor affecting transplantation programmes. Nearly 40.000 patients are now on waiting lists in western Europe. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%.

An organ transplant is lifesaving and is in most cases the only available treatment. In terms of quality and safety the benefit-to-risk ratio is a fundamental approach for organ transplantation. Due to the organ shortage and the life threatening indications of organ transplants, the benefits of an organ transplantation are high and more risks can be accepted than with blood or most tissues and cells treatments. In this context the clinical doctor has an important role in the decision on the acceptance of organs for transplantation.

Every year, a number of organs are exchanged between EU Member States. Cross border exchanges imply that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions. However the number of organs interchanged between Member States constitutes a low percentage of the total organs used for transplantation.

In 2003, the Commission carried out a survey on legal requirements related to organ transplantation in the EU. The survey showed discrepancies in quality and safety requirements within Member States. Results can be found at:

http://ec.europa.eu/health/ph_threats/human_substance/documents/organ_survey.pdf

From 1999 onwards, Article 152 of the Treaty has enabled the European Parliament and Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives (1). The Community has already adopted Directives of the Parliament and the Council on blood, and on tissues and cells (2).

It is recognised that organs need a different approach from blood or tissues. An expert conference on organ transplantation, held in Venice on 17-18 September 2003 organised by the Italian government during its Presidency of the EU Council, listed the shortage of organs

and organ trafficking as the main priorities in this area and underlined that the quality and safety aspects have to be considered fully within the framework of supply and demand for organs.

One of the potential consequences of the scarcity of organs is the trafficking of human organs carried out by organised criminal groups, tracking down and removing organs in developing countries and handing them on to recipients within the European Union. The Greek Presidency of the EU presented in February 2003 an initiative (3), with a view to adopting a Council framework decision concerning the prevention and control of trafficking in human organs and tissues, under the legal basis of Articles 29, 31(e), and 34(2)(b) of the EU Treaty (third pillar). The discussions on the initiative were suspended, pending further detailed information on the situation, especially based in concrete cases. Europol has been asked to issue a report on the situation of Organ trafficking in the EU

The objectives of this consultation document are:

- 1) Describing the state of play in the area of organ donation and transplantation, identifying the main problems
- 2) Identifying and proposing future initiatives that can be taken at Community level and that could have added value in addressing the challenges of organ shortage and quality and safety.

FACING COMMON PROBLEMS

Quality and Safety

The use of organs in therapy poses a risk of diseases being transmitted to the recipient. Transmission of HIV, Hepatitis B and C, bacteria, fungi and parasites through transplantation has been described in scientific literature, as has transmission of different types of cancers and new emergent diseases, such as melanoma. Ensuring the quality and safety of human organs in Europe is at the core of Community activities in this field, as this aspect is prioritized in the Treaty on European Union.

The transmission of disease by a deceased donor organ can result not only in loss of the allograft but also in the death of the immune suppressed recipient. Despite the shortage of deceased organ donors, every donor must be evaluated thoroughly for the potential transmission of infectious disease, because the consequences of the organ donor events can have a profound effect on the outcome of the transplant.

However it has to be recognised that no organ is perfect. All organs will carry some risk of failure or transmission of disease. In every case there is a balance of risks and benefits to be considered, the risk associated with the organ versus the consequences of not getting a transplant.

Article 152 of the Treaty on European Union has enabled the European Parliament and Council to adopt health measures setting high standards for the quality and safety of human organs. Every year, a number of organs are exchanged between EU Member States. Cross border exchanges imply that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions. However the number of organs interchanged between Member States constitutes a low percentage of the total number of organs used for transplantation in the EU. A common set of minimum requirements on quality and safety within the EU could facilitate the interchange of organs in the Community.

In addition every year a number of EU citizens undertake organ transplantation in a Member State other than their country of origin. Basic minimum standards will ensure basic health protection of the recipients throughout the EU

Organ Shortage

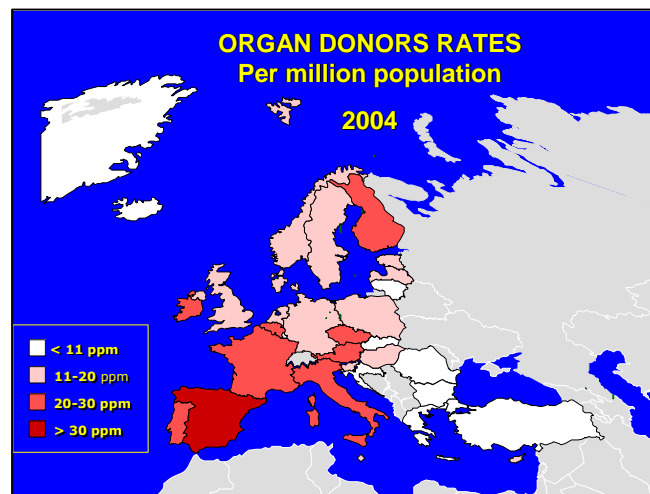
The severe shortage of organ donors remains the main challenge that Member States in the European Union face with regard to organ transplantation (4).

The need for transplants has increased much more than the available organs. The excellent results of transplants during the last decade, in terms of life years gained and improvement of the quality of life, has multiplied the indications of these therapies.

Every day nearly ten patients die waiting an organ in western European societies. Waiting lists have increased in all EU countries, regardless of the different criteria for admission on the lists or the number of indications for transplants in the different Member States. And this

is probably only the tip of the iceberg. The unmet need for organs may be much higher. Due to the scarcity of organs, transplant clinicians are extremely selective about the patients they include in the waiting list. Only those patients with a clear likelihood of benefiting from an organ are considered for transplantation. Today it is not possible to offer an organ to every patient in need.

It is also clear that there are important differences in the organ donor rate in the EU. Donor rates in 2004 in different European countries vary widely (5): 34.6 donors per million of population (ppm) in Spain, 13.8 ppm in UK; 6 ppm in Greece or 0.5 ppm in Romania. These differences cannot be explained only by differences in the general or specific mortality rates.



There are different reasons for the shortage of donors. The majority (more than 90%) of the organ donors are patients who died in hospitals after an irreversible cessation of all brain functions, known as brain death. These patients are in Intensive Care Units where their cardio-respiratory functions are artificially preserved. Less than 3% of the deaths in hospitals are diagnosed with brain related criteria before cardiac arrest, and therefore the number of potential organ donors is low.

The use of living donors is an increasing alternative given the failure to meet the growing need for organs with cadaver donation. However, it presents a unique ethical dilemma, in that the physician must risk the life of a healthy person to save or improve the life of a patient. The use of living donors varies widely within Europe, from countries like Spain where they currently account for less than 4% of transplants, and other countries, mainly in Northern Europe and North America where the percentage of living donor transplants represents between 20% and 50%.

In addition organ transplants are subject to time pressure. The process from the procurement to the transplantation should be done in a few hours (in order to preserve the organ viability). There are no intermediate steps like in the case of blood or tissues and cells which can be processed, preserved and stored for long time before their use.

In order for organs to be transplanted, the donor has to match with the recipient. In organ transplants ABO (blood type) matching is required, although in some situations can be overridden. Good HLA (human leukocyte antigens) matching between donor and recipient is usually desirable for renal, pancreatic and small bowel transplants, but may not be required for other organ transplants. For thoracic and liver transplant recipients, a match in body size is an important consideration. Paediatric organs should preferably be offered to paediatric recipients.

The organisational structure is key in the organ donation/transplantation systems. It has an important role in the quality and safety of organs and also in their availability. The Donation / Transplantation process is complex involving many different steps; each transplant can require more than 100 professionals and more than 20 hours of continuous work.

On the other hand, organ donation and transplantation are the only medical treatments that require the participation of society for their full development. There are many complex and sensitive ethical issues in this area, and it became clear that several of these aspects are dealt with differently in different countries. The main areas in the field of ethics and organ transplantation are:

Donation - donation should be voluntary and altruistic with legal and ethical contexts clearly defined.

Consent – Member States should ensure that there is a legal basis for ensuring valid consent or objection to organ donation.

Financial gain - Measures should be taken to prohibit financial gain, except full reimbursement of expenses for medical or social costs to remove disincentives to donation.

Organ trade – Organ trafficking should be banned as should any trade in people for the purpose of organ retrieval. Patients with transplanted organs from unknown or uncontrolled origin should be offered follow-up care.

Anonymity and Confidentiality - Data from donors and recipients should be protected, provided that traceability is ensured, except in the case of a living donor with a close relationship to the recipient.

Transparency, Equity and Accessibility - All transplant systems rules (allocation, access to transplant services, activity data, etc.) should be made public and be properly controlled. Any unjustified discrimination in the access to transplant waiting lists and/or therapeutic procedures should be avoided. Due to basic differences in the geographic and organizational structures in Member States, such rules need to be established and followed nationally. Cooperation between Member States should be stressed. Efficient systems for information to the population, patients and professionals should be put in place. Cooperation between all groups involved (public, media, professionals, etc) should be stressed.

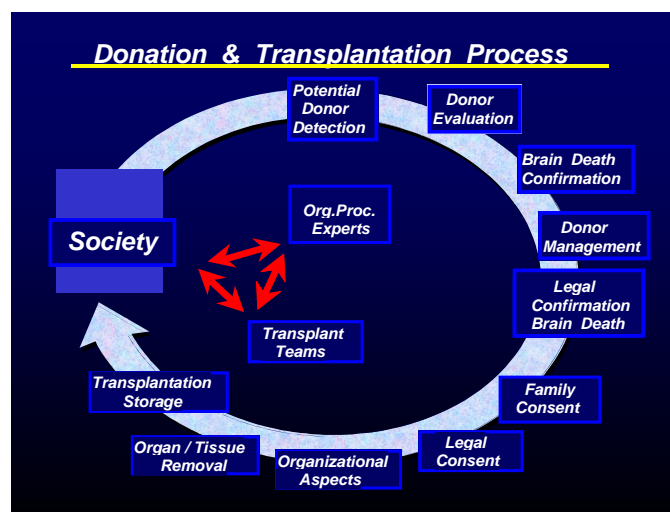
Death certification - Organ retrieval from the deceased may take place only after death certification. Death certification should be a matter of national legally binding rules that should be made public.

Family refusals to donation also vary widely within Europe, ranging from 6% in Portugal to 42% in the UK. These differences again are not easy to justify. They could be explained by the wide variability of procedures in the law of donor consent, for living and deceased donors, the different practices on donor registers, and also other important cultural, economic or social factors that influence the perception of the society of the benefit of donation.

Organisational Systems and Organ Transplantation

As mentioned before, the organizational structure is key in the organ donation/transplantation systems. There is a need for a well organized and effective transplant system. This system needs an appropriate legal framework, a good technical approach and organizational support. Assuming that the main obstacle to the full development of transplant programmes is the shortage of organs, it has also been recognized that part of the problem is not only the lack of donors, but the failure of the system to transform potential donors into actual donors.

As part of this organisation, an effective allocation system is essential. This system has to take into account the short time that organs can be maintained in good conditions prior to transplantation, and the necessity to ensure that the organ is assigned to the most suitable recipient, according to predefined criteria.



The different organisation systems in Europe are the result of their origin and history, type of health systems and available resources, and also of the personal profiles of their founders and directors.

Even among EU countries with well-developed services, there are considerable differences in organ donation and transplantation activity and it seems that some organisational models are performing better than others. In some countries the transplantation activity exceeds 80 transplanted organs pmp, compared to others with a rate of 40 pmp, and these differences are not necessarily explained by the donation rates.

The rates of transplantation of different organs also vary; in some countries the rate of non-renal transplanted organs exceeds the number of kidney transplants, whereas at the other extreme the rate of all other organs is only 20% of the kidney transplant rate. These

differences can not be explained by the incidence of the major causes of death or the incidence of end organ failure in the population.

Also the number of transplant centres per population differs widely. For example, the number of liver transplantation centres vary from more than 0.5 centres per million of population in Belgium to less than 0.1 in Hungary or no centres in some Member States. That should be considered given the relation between the accessibility to organ transplantation and the donation rates.

The new Member States face greater health problems than the rest of the Union but have less economic means to address them. Their health systems are therefore under particular pressure, in particular when it comes to the process from organ donation to transplantation, which is such a complex process that it could be especially difficult to address. This leads to enormous differences within Member States in terms of accessibility to transplants and the length of waiting lists. Collaboration at EU level can bring particular benefits to those systems.

Organ transplantation provides the possibility of saving lives and also has the best cost / benefit ratio in terms of economic gains and quality of life. It has been calculated that 10,000 renal patients living with a functioning kidney graft saves over 200 million € annually (in terms of differences of the economical costs of the different replacement therapies for end stage kidney patients, when comparing cost of transplantation versus costs of dialysis treatments). The average prevalence rate of end stage renal failure in Europe is around 1,000 patients p.m.p. Among those between 20 and 30% are waiting for a kidney. Annual incidence is around 140-150 new patients p.m.p.

Recently several studies have shown that investing in organ procurement is a good health investment. Even considering the lack of data to complete the analysis, it is highly likely that obtaining additional donors will be cost effective even at a much higher average cost per donor.

ARRIVING AT COMMON SOLUTIONS

Quality and Safety

Experts have suggested measures to be introduced into every stage of the transplant process in order to improve the quality and safety of organs while not affecting their availability.

The first of these measures is to increase the organ donation rates. Obviously an adequate supply of organs to maximize the choice is a key factor in high quality and safe organ transplantation.

It will also be important to have a system in place for the authorization of establishments and programmes of organ donation and procurement based on quality and safety criteria. This system would provide a complete list of authorised centres throughout Europe, accessible to the public and the professionals.

The Council of Europe recommendation Rec (2004)19 of the Committee of Ministers adopted on 15 December 2004 (6) recommends that that the governments of its member states take all necessary measures to ensure that criteria for the authorisation of organ transplantation facilities were in place. The recommendation considered that given that organ exchange and circulation of patients is becoming a more frequent phenomenon, minimum common standards should be guaranteed to the citizens.

The maintenance of donor records and quality systems have also been identified as key steps towards quality and safety. As have the need for a system to facilitate the transmission of the full donor record -a common basic set of donor data- and other relevant information within The EU, so that a proper risk-benefit analysis can be made by the transplant team independently of the origin of the organ. Risks should be identified and documented to allow allocation to a proper recipient.

The management of the donor during the process is important not only for safety and quality but also for maximising organ procurement. The staff involved should have appropriate training and experience.

Standard procedures for procurement and requirements for organ preservation and transport should be in place. The procurement team has an important role in inspecting the donor in order to complete the donor record. Appropriate training and experience is needed.

It also important to ensure that there is effective transportation of organs which minimises ischemic times and avoids organ damage. While maintaining medical confidentiality the organ container must be clearly labeled and should contain the necessary documentation.

The transplant system must maintain traceability from donor to recipient(s). The system must have the capacity to alert other recipients of organs from the same donor or a living donor, to an unexpected complication. A system should be in place to detect and investigate serious or unexpected adverse events to maximize safety and quality and implement corrective actions.

It would be desirable to have all these measures in place throughout the Community to ensure a high level of protection for patients. The Committee of experts on the organisational aspects of cooperation in organ transplantation (SP-CTO) of the Council of Europe has actively worked in this field over the last decade. This committee has recently submitted a questionnaire to its members, in which the majority of the respondents felt that safety and quality measures should be introduced in every stage of the transplant process, favoured the validation of transplant practices against accepted standards and supported that these standards should be harmonised by EU recommendations and/or Directives. With this aim the Council of Europe publishes annually a Guide to safety and quality assurance for organs, tissues and cells (7).

Organ Shortage

The adequate supply of organs is key for high quality and safe organ transplantations. A number of different alternatives, related to the organisation of donation systems and current practices, could help to reduce the gap between organ supply and demand.

The combination of an efficient system for organ donor identification and detection and procurement has been identified as a key element in increasing the cadaver donation rate in those countries that have not reached their full potential. It has been said that many donors are lost due to a lack of evaluation, a lack of referral or because the option of donation is not presented to the relatives.

In many Member States, the training and employment of health care professionals responsible for detecting potential deceased organ donors and organising the donation process has increased the efficiency of the procurement of organs and improved the functioning of local and national transplant systems. Such professionals can also increase the rate of donation of tissues for transplantation. The Council of Europe has adopted a recommendation regarding the role and training of professionals responsible for organ donation (transplant “donor coordinators”) (8).

There is recent evidence that developments in the screening of seriously ill patients and changes in intensive-care practices may lead to fewer patients dying in an intensive care unit and meeting the criteria for determination of brain death. In order to expand the donor pool it is important to promote donations from living donors and the procurement of organs from non-heart-beating donors.

Although living donors have always been critical for transplantation, the use of living donors has dramatically increased over recent years for kidney and portions of liver. The increase in living organ donation can be attributed to multiple factors, including pressure created by the shortage of deceased donors, surgical advances, and strong evidence of favourable transplant outcome and low donor risk.

Another alternative approach is to consider other potential donors (expanded donors) who are not ideal candidates due to positive serology, congenital and inherited disorders, history of malignancy or other characteristics such as donor age or a history of hypertension and diabetes. Obviously some of these alternatives could have consequences on the quality and safety of organs. The cooperation between countries leading to the compilation of sufficient

information is decisive in determining the acceptable levels of risk in the use of expanded donors and in deciding the best donor-recipient cross match for the use of expanded donors.

Public awareness and opinion could have an important role in increasing organ donation. The most cost effective means of increasing public willingness to donate seems to be improving the knowledge of health professionals (not directly involved in transplantation) and the media about transplantation issues. Continued education should form an essential element of any communication strategy. People should be encouraged to speak about organ donation and transplantation and to communicate their wishes to their relatives. Because both positive and negative messages can affect the public's willingness to donate organs, there is a need for a professional attitude towards, and support from experts in the field of communications.

The creation of a European organ donor card, as proposed by the European Parliament in the context of the Opinion on first reading of 16 March 2006 on the Commission proposal for a Health and Consumer Protection Programme, could also contribute to increasing public awareness.

Organisational Systems and Organ Transplantation

As mentioned before, organisational structures have an impact on the quality and safety of organs, including in the organ donation systems and therefore in the availability of organs in the Community. Addressing these questions at Community level could have an important “European added value”.

Part of this analysis has been undertaken by the mentioned (see introduction) Commission survey, and further work has been carried out by the committee of experts on the organisational aspects of co-operation in organ transplantation (SP-CTO) of the **Council of Europe**. This committee has recently prepared a draft recommendation on the background, functions and responsibilities of a national transplant organisation (NTO) based on a questionnaire submitted among its members. Of the responses, 69% considered that an NTO must have a sound legal basis. One third considered that an EU Directive would be essential to ensure a legal basis for NTOs, and 68 % of the respondents favoured collaboration with a supranational body to ensure quality and safety, traceability, transparency and quality management.

The main **European organ exchange organisations (EOEOs)** (Swiss transplant, Italian Transplant Centre, Hungaro transplant, UK Transplant, Organização Portuguesa de Transplantação, Etablissement Français des Greffes, Skandiatransplant, Poltransplant and the Spanish Organización Nacional de Trasplantes, grecia) meet on a regular basis. These organisations have already stressed the need to analyse the differences between the EU countries in the accreditation / authorisation / licensing / registration systems (training of professionals, authorisation of centres and transplant programmes, import/export...etc) and the consequences of these differences in the availability of organs and their quality and safety.

The EOEOs have stated that, given the increasing mobility of people within the EU, it is necessary to identify the main problems at the EU level for the interchange of organs and patients. They have recommended that systems for offering excess organs and the exchange of patients between countries should be developed, taking into account the reimbursement of costs, common transplant list admission criteria, prevention of registration on multiple transplant lists, among other subjects, that need prior discussion.

Finally, they recommend identifying the best initiatives for promoting the exchange of experiences and information between the EU countries in order to improve organisational aspects.

It has been accepted that the larger the pool of donors the better the match. Urgent patients and difficult recipients (children, highly sensitive patients, ect...) can not be treated efficiently within the scope of a small organisation, this is of particular concern for small Member States in the EU.

However, on the donation side, the involvement of the local actors (hospital transplant teams and transplant coordinators) in the decision-making process has helped to motivate the actors to and led to the results more efficient.

A flexible system combining a decentralised network formed by local organisations mainly focused on organ procurement, and the promotion of donation with large organisations focused on promoting organ sharing and cooperation, seems to be the most effective organisational approach.

International cooperation

International cooperation is desirable to help maximise organ donation and equalise access to transplantation between countries.

Governments should actively promote such co-operation. Priority should be given to international co-operation which improves standards of training, exchange of experience, and which helps to guarantee the safety of organs and the ethical standards by which they are retrieved and transplanted.

Finding matches, in particular for sensitive patients, may be very difficult. For some renal patients it is unlikely that they will find a match within their own country, especially in the small Member States. International cooperation and the exchange of organs is necessary to increase the chances of providing organs for patients in life-threatening situations.

Some examples of European organisations are already in place, which proves the need and importance of wider –European- cooperation.

The Council of Europe, which groups together 46 countries, including 21 countries from Central and Eastern Europe, has been actively involved in this area. The Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation (SP-CTO) was set up following the 3rd Conference of European Health Ministers in Paris in 1987 on the ethical, organisational and legislative aspects of organ transplantation.

The Conference considered that the organisational aspects of organ transplantation were particularly important in meeting the organ shortage and that European co-operation was needed to ensure efficient organisation. The established leading principles guiding the work of the Committee in this area are: ensuring the dignity of the human being; maintenance and further realisation of human rights and fundamental freedoms; non-commercialisation of substances of human origin and the protection of donors and recipients

The **Eurotransplant International Foundation** is responsible for the mediation and allocation of organ donation procedures in Austria, Belgium, Germany, Luxembourg, the Netherlands and Slovenia. In this international collaborative framework, the participants are all transplant hospitals, tissue-typing laboratories and hospitals where organ donations take place. The Eurotransplant region numbers well over 118 million inhabitants.

Scandiatransplant is a Nordic organ exchange organisation and it covers a population of 24 million inhabitants in five countries. According to the by-laws, the purpose of the Scandiatransplant association is fourfold: (1) Scandiatransplant shall effect the exchange of organs and tissue between the participating transplant centers; (2) It shall operate a database and communicate information from it; (3) It shall contribute to promoting the provision of human organs and tissue for transplantation; (4) It shall support scientific activities. Scandiatransplant was founded in 1969 on the initiative of Nordic pioneers within the organ transplantation field.

Two other organisations can be considered as having international scope: **Balttransplant**, an NGO operating in Estonia, Latvia and Lithuania, and **UK Transplant** which scope is extended to UK and Ireland.

On April 2004 the Ministers of Health of Italy, Austria, Cyprus, Czech Republic, Estonia, Hellenic Republic, Hungary, Latvia, Lithuania, Malta, The Netherlands, Poland and Slovak Republic signed the Prague Declaration which declared, among other things, the constitution of the **European Transplant Network** to be the official intergovernmental organisation of participating countries, designated for mutual cooperation in the field of organ and tissue donation and transplantation. Members of ETN are the new Member States of the EU plus Italy Greece and Austria. The organization is open to any country who would like to join it, and Croatia has applied recently. The organization was founded with the aim of establishing close collaboration and exchange of experience among the members in different aspects of the sector for achieving higher standards of efficiency of the involved organizations, which so far present different levels of development.

THE ROLE OF THE EU. The legal basis

Since 1999 , Article 152 (par.4 a) of the Treaty has enabled the European Parliament and Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. These measures shall not prevent any Member State from maintaining or introducing more stringent protective measures.

The same article 152 (par.2) states that Community action shall also complement national policies directed towards improving public health. In fact, the Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. In this respect Member States shall, in liaison with the Commission, coordinate their policies and programmes among themselves. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

One possible tool to be considered is the 'open method of coordination' (OMC). The OMC was established during the European Council in Lisbon of 2000. The European Council presented OMC as a methodology aimed at improving the cooperation between Member States in the fields of (modernising systems of) social protection as part of an integrated socio-economic strategy for Europe, for the decade leading to 2010 (the Lisbon strategy). The European Council described OMC as a tool to spread 'best practices' and increase policy convergence in the EU in areas where the Community itself has only limited competence.

In first instance, the application of OMC was aimed at the issues of social integration and pensions. Afterwards, the model was also applied to other areas, among which was public health.

The European Commission's White Paper on governance (9) lists a number of characteristics of OMC and describes how it can be used. At the heart of it, OMC is a flexible tool that can be used in areas of policy for which the principle of subsidiarity applies

The OMC is useful when Member States want to use each other's knowledge and experience in certain policy domains on EU level, without there being a direct necessity or desire for transferring competency from national level to Community level (although this will remain possible). OMC can be applied in various ways. The following is a list, ranging from least to most intrusive:

- The exchange of experiences (in a structural way)
- The (passive or active) distribution of best practices
- Determining common EU guidelines for national policy, and formulating the objectives for the short, medium and long term, where necessary in combination with national plans monitoring and comparing national systems, based on a determined set of indicators, organizing peer reviews and benchmarking.

Articles 29, 31(e), and 34(2)(b) of Title VI of the EU Treaty (third pillar) could provide a legal basis for the prevention and control of trafficking in human organs and tissues. Article 29 refers to approximation, where necessary of rules on criminal matters, in accordance with Article 31(e). Article 31(e) provides for the progressive adoption of "measures establishing minimum rules relating to the constituent elements of criminal acts and to penalties in the field of organised crime, terrorism and illicit drug trafficking.

Article 34(2)(b) describes the nature and purpose (approximation of national laws) of framework decisions, and Article 31(c) refers to "ensuring compatibility in rules applicable in the Member States, as may be necessary to improve" judicial co-operation in criminal matters.

In this respect, it is worth recalling that there has been a Greek initiative based on these provisions in February 2003 (see introduction);

POLICY OPTIONS AVAILABLE

Given the mandate of Article 152 of the Treaty, the main objective at EU level should be to ensure high quality and safety standards for human organs used in therapy.

This overall objective should be linked to specific objectives related to the main problem identified by the experts in this area, the shortage of organ donors. Therefore, it will be equally important to analyse actions at EU level to increase the availability of organs used in therapy, in order to achieve two objectives: to increase the donation rate in all Member States, and to promote the accessibility to these therapies in the Community.

There are three levels of possible intervention. Level one “further work under existing Community programmes.” would mean continuing the current level of activity. A second level would consist of implementing an active system of coordination between Member States and stakeholders in order to achieve common objectives, and a third level, building on the previous one, that would add EU legal instruments.

a) First level: Further work under existing Community programmes.

This option will mean continuing the current work under the different Community programmes (Public health, Research, Information Society and Justice, freedom and security) to support this area, without any further coordination (10,11,12, 13).

During the past years, the Commission has put considerable effort into supporting the area of organ transplantation. In the area of Information Society, the Commission is supporting the creation of a European registry on organs, cells and tissues through the EURO CET (14) project. This project is a second phase building on the results of a previous project, EURO DONOR.

In the field of research the Commission has also been very actively involved in this area. ALLIANCE-O, an ongoing project, is the first-ever coordination of donation and transplant national or regional research activities across seven different EU countries, which aims to identify the best possible framework for efficient organ donation and transplantation strategies across Europe.

A second important project, DOPKI, has started this year focusing on improving knowledge and developing applicable methodology that could be used to increase the potential of organ donation. In order to achieve such an objective, the project aims to promote cooperation and sharing of information and practices among seven EU countries. A third interesting project, RISE T (15), is based on basic research oriented to reprogram the immune system for the establishment of tolerance to organ transplants.

A fourth project is BOTIA, aims at improving the safety of blood and organ supply by creating the research infrastructure to monitor emerging pathogens and develop new screen tests through more cost-effective safe and inexpensive procedures. A fifth project, TRI E, should start before the end of 2006 and is expected to prepare the groundwork for a possible large-scale initiative in transplantation research in the European Union aiming at improving

coordination of national research programmes in transplantation. This project will work closely with ALLIANCE-0."

In the area of Justice, Freedom and Security, under the AGIS program, a project is starting that aims to compile national legislations and identify the main problems and potential solutions to ensure the avoidance of organ trafficking. Under the Public Health Program the Commission is finalizing the negotiation phase of a new project intended to develop a EU Training Program on Organ Donation.

The results of all these projects will provide for a considerable amount of information useful for active policies in this area. In December 2005, the Commission organised a Workshop on organ transplantation with the objective of promoting EU cooperation on organ donation and transplantation on the basis of the existing projects. One of the main conclusions of the workshop was the need for these projects to become operational.

b) Second level: Active coordination between Member States on organ quality, safety and availability.

Article 152.4 constitutes the legal basis for the EC to adopt common measures to ensure high standards of health and safety of organs. Within this framework, Member States remain responsible for a number of significant issues linked to quality and safety, particularly with respect to the organisation of donation systems and health care.

The use of an open method of coordination, specifically adapted to this concrete field, and as a complement to the legislative framework, will provide the necessary policy mix to achieve a gradual approach to the development of an EU policy. This approach will be based, in the first stage at least, on the identification and development of common objectives for which it is agreed that a Community response is necessary, on agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

Actions:

Coordination on organ transplantation activities between Member States. These could include

- Identifying standards of quality and safety.
- Putting a system in place to facilitate the transmission of the full donor record -a common basic set of donor data- and other relevant information within Europe.
- Sharing experiences and best practices on establishing efficient systems for organ donor detection and procurement.
- Promotion of on-going training of professionals as a key element in this process.
- The cooperation between countries leading to the compilation of sufficient information will assist in determining the acceptable levels of risk in the use of expanded donors. Promoting EU registers on transplantation or cooperation between national registers should be one of the priorities.
- International co-operation on the promotion of organ donation is desirable to help increase public awareness, maximise organ donation, and equalise access to

transplantation between countries. Governments should actively promote such co-operation.

- Identifying the main problems at EU level for the interchange of organs and patients. Systems for offering excess organs to other countries should be developed and in particular exchange of organs for urgent patients and difficult recipients (children, highly sensitive patients, ect).
- Exchange of patients, reimbursements of costs, common transplant lists, admission criteria, prevention of registration on multiple transplant lists, among other subjects, need discussion.
- Agreeing a common ethics code on organ transplantation.

c) Third level. Second level + Minimum harmonisation on quality and safety + Initiative on Organ trafficking

It could be proposed that this open method of coordination should be implemented for an initial period upon which an evaluation on the need for a Directive on quality and safety is undertaken. After this “phasing in period” and in the light of the evaluation of the implementation of the coordination method, the introduction of additional legislative instruments should be considered. It could also be proposed that the coordination method starts in parallel with the elaboration of legislative instruments. In any case, an impact assessment shall be performed before deciding on the appropriateness to the introduction of additional legislative instruments

This option builds on the previous level. In addition to the actions described, it incorporates appropriate community legal instruments in order to ensure there are comparable basic levels of quality and safety throughout Member States.

Actions:

1) EU Directive on Quality and safety for the donation, procurement, testing, preservation, transport and distribution of human organs, under Article 152 of the Treaty

- Establishing common quality and safety standards for the authorization/accreditation/licensing of establishments and programs of organ donation and procurement.
- Ensuring quality management system, with a description of the standard operation procedures.
- Having a basic set of donor information and a system in place to facilitate the transmission of information within Europe, so that a proper risk benefit analysis can be made by the transplant team independent of the origin of the organ.
- Ensure effective preservation and transportation of organs to minimise ischemic times and avoid organ damage.
- Ensuring traceability and the reporting of serious adverse events and reactions.

2) Follow up the Greek initiative based on the results of the Europol report to evaluate how to best ensure the coordination between an EC proposal based on art. 152.4 of the Treaty and any initiatives undertaken on the basis of art. 29, 31(e), and 34(2)(b) of Title VI of the EU Treaty (third pillar)

QUESTIONS FOR CONSULTATION

It is called on all interested organisations to submit responses to the issues raised in this Consultation document , no later than 15 September 2006, to the following address (preferably by e-mail):

European Commission
Directorate-General Health and Consumer Protection
Unit C6 – Health Measures
E-mail: sanco-openconsultationc@ec.europa.eu
Postal address: Rue Froissart 101; F101 07/74 B-1049 Brussels
Fax: (+ 32) 2 2959580

The replies to the consultation document should focus in particular on the following questions:

- 1. This document describes the situation at EU level in the area of organ transplantation, identifying the main problems. Are all the basic problems identified? Are the problems identified correctly described?**
- 2. The document also describes a number of actions oriented to tackle the main problems. Is there any other initiative that you consider useful?**
- 3. The shortage of organ donors is being described as the main problem in the field. Do you think that EU action would have an added value? Do you think that the initiatives described in the document in this direction are sufficient ? Are there any other actions that should be promoted at EU level?**
- 4. Accessibility to transplants varies widely in the EU. Do you think that the Commission should foster the coordination between Member States to improve the situation? Do you think that the initiatives described in the document in this direction are correct? Are there any other actions that should be promoted at EU level?**
- 5 From the three policy options suggested as potential future initiatives at EU level: Which one you consider the most adequate? Could you enumerate and explain the reasons to choose this particular option? Would you modify / add / remove some of the contents included in the option?**

Please use the format attached.

Unless respondents make a declaration to the contrary, their responses, or parts thereof could be published on DG SANCO's website

REFERENCES

1. Directive 2002/98/EC of the European Parliament and of the Council, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, OJ L33 of 8.2.2003, p.30.
http://ec.europa.eu/health/ph_threats/human_substance/blood_en.htm
2. Directive 2004/23/EC of the European Parliament and of the Council, setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ L102 of 7.04.2004. p 48.
http://ec.europa.eu/health/ph_threats/human_substance/tissues_en.htm
3. Initiative of the Hellenic Republic with a view to adopting a Council Framework Decision concerning the prevention and control of trafficking in human organs and tissues. Official Journal C 100 , 26/04/2003 P. 0027 – 0030
4. Meeting the organ shortage: current status and strategies for improvement of organ donation. A European consensus document. Council of Europe web site.
http://www.coe.int/t/e/social_cohesion/health/Activities/Organ_transplantation/04MEETING%20THE%20ORGAN%20SHORTAGE%20PUB%20Eng.asp#P642_83727
5. Newsletter Transplant. International figures on organ donation and transplant activity. Council of Europe web site.
http://www.coe.int/T/E/Social_Cohesion/Health/NEWSLETTER%20TRANSPLANT%202005.pdf
6. Recommendation Rec(2004)19 of the Committee of Ministers to member states on criteria for the authorisation of organ transplantation facilities.
<https://wcd.coe.int/ViewDoc.jsp?id=802901&BackColorInternet=B9BDEE&BackColorIntranet=FFCD4F&BackColorLogged=FFC679>
7. Guide to safety and quality assurance for organs, tissues and cells. 2nd Edition. Council of Europe.
http://www.coe.int/T/E/Social_Cohesion/Health/Activities/Organ_transplantation/06Guide%20to%20safety%20and%20quality%20assurance%20for%20organs%20-%202nd%20Edition.asp#TopOfPage
8. Recommendation Rec(2005)11 of the Committee of Ministers to member states on the role and training of professionals responsible for organ donation (transplant “donor coordinators”).
<https://wcd.coe.int/ViewDoc.jsp?id=870643&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75>
9. European Governance. A white paper. COM(2001) 428 final
http://europa.eu.int/comm/governance/white_paper/index_en.htm

10. Council Decision of 22 July 2002 establishing a framework programme on police and judicial cooperation in criminal matters (AGIS). 2002/630/JHA. Official Journal L203, 01/08/2002 P.0005-0008.
11. Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006) Official Journal L 232 , 29/08/2002 P. 0001 – 0033
12. Regulation (EC) No 1159/2005 of the European Parliament and of the Council of 6 July 2005 amending Council Regulation (EC) No 2236/95 laying down general rules for the granting of Community financial aid in the field of trans-European networks OJ 2005/L191/16 of 22.07. 2005.
13. Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008). Official Journal L271, 09/10/2002 P.0001-0012. http://europa.eu.int/comm/health/ph_programme/programme_en.htm
14. EURO CET project <https://www.eurodonor.org/eurocet/>
15. RISE T Project <http://www.risetfp6.org/cgi-bin/WebObjects/Riset>