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ORGAN DONATION AND TRANSPLANTATION: POLICY ACTIONS AT EU LEVEL

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1. INTRODUCTION

Over the past 50 years organ transplantation has become established worldwide, bringing immense benefits to hundreds of thousands of patients.

Organ donation and transplantation are sensitive and complex issues, with important ethical dimension, which require the full participation of the societies for their development. Several aspects are dealt with differently in different Member States depending on cultural, legal, administrative and organisational issues.

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, while for end-stage failure of organs such as the liver, lung and heart, it is the only available treatment.

The excellent results of transplants, in terms of life years gained and improvement in quality of life, have multiplied the indications of these therapies. Transplant procedures continue to develop and in the future may offer practical treatment for other unmet medical needs.

The use of organs in therapy however poses a risk of transmission of diseases. Every year, a number of organs are exchanged between EU Member States. Cross-border exchanges mean that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions.

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 Europe. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%. There are large differences in the deceased and living organ donor rate within the EU. These differences cannot be easily explained. 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.

One of the potential consequences of the scarcity of organs is the trafficking of human organs carried out by organised criminal groups, who track down and remove organs in developing countries and hand them on to recipients within the European Union.

This Commission Communication on organ donation and transplantation intends to respond to these challenges based on the mandate in Article 152(4)(a) of the Treaty, which enables the European Parliament and Council to adopt harmonised health measures on the basis of the codecision procedure pursuant to Article 251 EC, by setting high standards of quality and safety of human organs. It sets out the actions the Commission is planning to take to respond to the main policy challenges in relation to organ donation and transplantation: ensure quality and safety of organs, increase organ availability and fight organ trafficking.

2. ORGAN DONATION AND TRANSPLANTATION: CURRENT CHALLENGES

2.1. Transplant risks

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.

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 organ must be evaluated thoroughly.

Every year, a number of organs are exchanged between EU Member States. The number of organs interchanged represents a small proportion of the total number of organs used for transplantation in the EU, with the exception of those areas covered by international agreements (Eurotransplant), where the interchange of organs accounts for up to 20% of total organ transplants. In addition, every year a number of EU citizens undertake organ transplantation in a Member State other than their country of origin. It seems that the phenomenon of patients from one country trying to get a transplant in another country with higher donation rates than in their own is increasing. However, the legal quality and safety requirements differ amongst Member States[1]. Ensuring a high level of protection of patients throughout Europe is therefore a priority.

2.2. Organ shortage

The severe shortage of organ donors remains the main challenge that EU Member States face with regard to organ transplantation.

Every day nearly ten patients die waiting for an organ in European societies. Waiting lists have grown longer in all EU countries. Even in cases where there have been sustained increases in the number of donors, it is very difficult to reduce numbers of patients and time spent on waiting lists. Demand for transplants is increasing faster than organ donor rates. However, the increase in the number of available donors will help to reduce the gap between supply and demand if not achieving an absolute reduction in the waiting list.

There are different reasons for the shortage of donors[2]. There are also large differences between Member States' successes in increasing their donor pool. Donor rates vary widely in different European countries: the deceased donor rate ranges from 0.8 donors to 35.1 per million population. These differences cannot be easily explained. They are probably due to a complex mix of cultural, historical and social factors combined with aspects related to the characteristics of the health service and the organisational aspects of the donation system within a country.

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

2 Information detailed in the IA attached to the Communication.

2.3. Organ trafficking

As already mentioned, the supply of organs is very limited.

Although so far no evidence has been given in criminal proceedings, it is possible that international criminal organisations have identified the lucrative opportunity created by the gap between organ supply and demand, putting more pressure on people in extreme poverty to resort to selling their organs.

Organ trafficking is not a new problem worldwide. In the 1980s experts began to notice what was to become known as "transplant tourism" when prosperous Asians began travelling to India and other parts of Southeast Asia to receive organs from poor donors. Since then other routes have opened up.

While current estimations indicate that organ trafficking remains on a relatively modest scale in Europe, the issue is nevertheless of serious political and ethical concern.

3. THE ADDED VALUE OF EU ACTION

In recent years, the Commission has put considerable effort into supporting the area of organ transplantation under different Community programmes. A large number of projects have been funded[3]; the results of which have generated a considerable amount of information and knowledge useful for activating EU policies in this area. It is now time for these ideas to be put into effect.

In June 2006 the Commission launched an open consultation on organ donation and transplantation. Based on the outcome of this consultation, the Commission now proposes future initiatives to be taken at Community level that have added value in addressing the challenges ahead.

Ensuring the quality and safety of human organs in Europe lies at the core of Community activities in this field, as this aspect is prioritised in the Treaty establishing the European Community[4]. An expert conference organised by the Italian government during its Presidency of the EU Council in 2003, 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. In order to address the identified challenges adequately, an integrated approach of three actions is needed.

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3 A description of the projects is available in the Impact assessment attached to this Communication.

4 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. The Community has already adopted Directives of the Parliament and the Council on blood, and on tissues and cells.

3.1. Framework for quality and safety of organ donation and transplantation

A number of measures can be introduced into every stage of the transplant process in order to improve the quality and safety of organs.

Pre-transplant evaluation of potential donors is an essential part of solid organ transplantation. This evaluation must provide enough information to undertake a proper risk-benefit analysis by the transplant team. Risks and characteristics of the organ must be identified and documented to allow allocation to a suitable recipient.

The maintenance of donor records and quality systems has been identified as key steps towards quality and safety. Standard procedures for procurement and requirements for organ preservation and transport must be in place.

Effective transportation of organs which minimises ischemic times and avoids organ damage must be ensured. While maintaining medical confidentiality, the organ container must be clearly labelled and must contain the necessary documentation.

The transplant system must ensure traceability from donor to recipient(s). The system must have the capacity to alert of an unexpected complication. A system must be in place to detect and investigate serious or unexpected adverse events.

Many times an organ donor is also a tissue donor. Quality and safety requirements for organs shall complement and be linked with the existing community system for tissues and cells[5]. An adverse reaction in an organ donor recipient should be traced and reported on the tissue vigilance system if needed.

The key role of national competent authorities in ensuring the quality and safety of this process has been stressed, as well as the importance of establishing systems for the authorisation of establishments and programmes of organ donation and procurement based on common quality and safety criteria. This system would provide a complete list of authorised centres throughout Europe, accessible to the public and professionals.

Binding safety and quality criteria should not have as a consequence a reduction in the actual number of donors. It is important to have a clear understanding of the disease transmission risk inherent in each case. Although a definition of risk based upon the donor's profile is critical to rational decision-making, each decision also depends upon the recipient's characteristics. 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.

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[5] Directive 2004/23/EC of the European Parliament and of the Council setting high standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

3.2. Cooperation between Member States

Organ shortage is a common dilemma in all European countries, and sharing of expertise across the EU Member States has already proved useful in increasing organ donor rates in some countries.

3.2.1. Organ availability

Some Member States have put in place diverse initiatives focusing on the organisation of donation systems and current practices that have been shown to increase organ availability.

The establishment of an efficient system for identifying persons that could become organ donors upon their death, once all mandatory consent requirements in Member States have been met, has been identified as a key element in increasing the donation rate. It has been indicated that many donors are lost due to lack of evaluation, lack of referral or because the option of donation is not presented to relatives.

In some Member States, the training and employment of health care professionals responsible for identifying persons, that could become organ donors upon their death and organising the donation process has increased efficiency in the procurement of organs and improved the functioning of transplant systems.

In order to expand the donor pool it could be important to explore the promotion of altruistic donations from living donors, on the basis of appropriate safeguards concerning the protection of the living donors and the prevention of organ trafficking. Living donation in Europe represents 17% of kidney transplant activity and 5% of liver transplantation. Although living donors have always been critical for transplantation, the donations from living donors has dramatically increased over recent years. 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. The extent to which living donors volunteer for donation also varies widely within Europe.

In specific circumstances an additional option is to consider other potential donors ("expanded donors") who are not ideal donor 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.

3.2.2. Public awareness

Public awareness and opinion also has an important role to play in increasing organ donation.

Organ donation and transplantation are medical treatments that require the full participation of society for their development. There are many complex and sensitive ethical issues in this area, and it has become clear that several of these aspects are dealt with differently in different countries depending on cultural values.

In 2006, 56% of Europeans[6] declared themselves ready to donate their organs to an organ donation service after their death. Answers to the question differ widely between countries.

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[6] Eurobarometer survey 2006.

Family refusals to donate organs of their deceased relatives fluctuate in Europe from 6% to 42%. Again, these differences are not easy to understand. They could be explained by the wide variability of procedures in the law of donor consent, for living and deceased donors, different organisational practices, and also other important cultural, economic or social factors that influence society's perception of the benefit of donation.

The most cost-effective means of increasing public willingness to donate seems to be improving the knowledge of health professionals and the media about transplantation issues. Because both positive and negative messages can affect the public's willingness to donate, there is a need for a professional attitude towards donation and support from experts in the field of communication.

Continued education should form an essential element of any communication strategy. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives. Only 41% of European citizens have discussed organ donation within the family[6]. There is an important positive correlation between having discussed it within the family and willingness to donate organs.

The creation of a European organ donor card which indicates the willingness of the holder to donate organs or not, will contribute to increasing public awareness. 81% of European citizens[6] support the use an organ donor card to make it easier to identify people willing to donate organs after their death. In spite of this only 12% of Europeans currently have an organ donation card.

3.2.3. Organisational aspects

Comparison between countries shows that final national donation rates do not always correlate with the percentage of people who have previously declared themselves ready to donate in these countries. This clearly indicates the importance of having an efficient transplant system in place ensuring that the organs of people willing to donate become available.

A prerequisite for any action in this area is the establishment of adequate transplant systems at national level. This system needs an appropriate legal framework, a good technical approach and organisational support. The role of competent authorities is crucial in the organisational system. These authorities must ensure compliance with basic standards and organise the donation and transplantation activities.

The different organisation systems in Europe are the result of their origin and history. Even among EU countries with well-developed services, there are considerable differences in organ donation and transplantation activity and some organisational models seem to be performing better than others.

Organ transplants are subject to time pressure. The process from procurement to transplantation should be completed in a few hours (in order to preserve organ viability). In addition, for organs to be transplanted the donor has to match with the recipient. This makes the organisational structure a key element of organ donation/transplantation systems.

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 and the need to ensure that the organ is assigned to the most suitable recipient, according to predefined criteria.

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, notably when it comes to the process from organ donation to transplantation, whose complexity may make it especially difficult to address. This leads to huge differences between Member States in terms of accessibility to transplants and length of waiting lists. Collaboration at EU level can bring particular benefits to those systems.

It has been accepted that the larger the pool of donors the better the match. Urgent patients and difficult recipients (children, highly sensitised patients, etc.) cannot be treated efficiently within the scope of a small organisation; this is of particular concern for small Member States. At the same time, on the donation side, involvement of the local actors (hospital transplant teams and transplant coordinators) in the decision-making process has helped to motivate the professionals concerned and produced more efficient results.

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.

The Council of Europe's Agreement No 26 on the exchange of therapeutic substances of human origin in 1958 became the starting point for cross-border activities in this field. Tne work of the Council of Europe, Eurotransplant, Scandiatransplant, European Transplant Network or the regular meetings of the European organ exchange organisations are good examples of the need of European cooperation[7].

3.3. Fighting organ trafficking

Article 3 of the EU Charter of Fundamental Rights states that everyone has the right to respect for his/her physical integrity. Moreover, the Charter contains the prohibition of making the human body and its parts as a source of financial gain, and the prohibition of trafficking in human beings. As part of the general phenomenon of trafficking in human beings, trafficking for the purpose of the removal of organs constitutes a serious violation of the freedom and physical integrity of its victims.

The Council of Europe[8] and the World Health Organisation[9] have repeatedly called for action to counter organ trafficking. The ban on trafficking in human organs and tissues is already in force via international legal instruments, such as the Oviedo Treaty on Human Rights and Biomedicine and its Additional Protocol on the Transplantation of Organs and Tissues of Human Origin. Furthermore, the Protocol on the Prevention, Suppression and Punishment of Trafficking in Human Beings, which complements the UN Treaty against International Organised Crime, requires the contracting parties to criminalise this form of human trafficking and adopt proportionate and dissuasive penalties.

The Commission is consistently referring to these important International instruments and it will closely monitor any developments in the organ trafficking field both inside the EU and worldwide.

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7 Detailed information could be found in the IA attached to this Communication.

8 Recommendation Rec (2004) 7 of the Committee of Ministers.

9 WHO resolution WHA 42.5 condemning the purchase and sale of organs of human origin.

4. CONCLUSIONS AND FOLLOW-UP ACTIONS

Work under the different Community programmes will continue in the forthcoming years. It is important that the results of these projects have continuity and are endorsed at political level; the results need to be made accessible to all players.

The following have been identified as the main areas of action in organ donation and transplantation:

- **Improving quality and safety**

The Commission will define the precise, balanced scope of the EU legal framework on quality and safety for human organs taking into account the dialogue it has had so far with the Member States on the issues. This framework needs to be backed up by cooperation between Member States leading to the compilation of sufficient information that will assist in determining the acceptable levels of risk in the use of expanded donors and by the promotion of good medical practices and evaluation of post-transplant results ("organovigilance").

- **Increasing organ availability**

The Commission will promote cooperation between Member States in order to share experience and best practices with a view to establishing efficient systems for identified those citizens that could become organ donors upon their death.

Other areas where cooperation is important are the promotion of training of professionals based on best experience, exploring the promotion of donations from living donors and evaluate the use of organs from "expanded" donors (donors that from a medical point of view can only be considered for specific recipients under specific circumstances), taking into account the quality and safety aspects.

It will also be important to pool efforts and expertise in order to increase public awareness. In this context the creation of a European organ donor card or its incorporation into the existing European insurance health card is to be considered.

- **Making transplantation systems more efficient and accessible**

Like other healthcare access issues, this question has to be seen in relation to other initiatives at Community level in this area.

Initiatives will be focused on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local characteristics. Those Member States whose transplant systems are not yet sufficiently developed can be supported and guided in their efforts to improve patient care.

Other actions will be geared to identifying needs at EU level for the interchange of organs between national authorities. Guidelines for systems for offering surplus organs to other countries can be evaluated, with special reference to the exchange of organs for urgent patients and difficult-to treat patients.

The increasing mobility of people within the EU makes it necessary to identify the main problems regarding patient mobility. It will also be important to secure EU-wide agreement on all issues concerning transplant medicine for extra-Community patients ("non-residents").

The Commission proposes the following mechanisms of action:

- **Action plan on strengthened cooperation between Member States**

Analysis of the organ transplantation situation in the EU has revealed large differences in the deceased and living organ donor rate within the EU and also considerable differences in transplantation activity. These differences cannot be easily explained and it is clear that some models are performing better than others. There is scope for sharing expertise among EU Member States and for cooperation between countries to help maximise organ donation and equalise access to transplantation. The Community will identify the best of the best models and support its application throughout the EU while respecting cultural and organisational diversity.

Already in the resolution adopted by the Council of Ministers for Health in 1991[10] concerning fundamental health choices, the Council took note that analysis of the Community's possible contribution concerning the availability of organs for transplants was identified as one of the topics which warranted joint consideration, regular joint discussions and/or joint efforts to assist Member States in framing their health policies. The main European organ exchange organisations have also recommended identifying the best initiatives for promoting exchange of experience and information between EU countries in order to improve organisational aspects.

An action plan for closer cooperation between Member States, specifically tailored to this concrete field, will provide the necessary policy mix to achieve a gradual approach to the development of an EU policy. This approach should be based on the identification and development of common objectives for which it is agreed that a Community response is necessary, agreed quantitative and qualitative indicators and benchmarks, regular reporting, and identification and sharing of best practices.

- **EU legal instrument on quality and safety of organ donation and transplantation**

The Community has already adopted Parliament and Council Directives on quality and safety standards for blood[11] and for tissues and cells[12]. A possible European Directive setting standards of quality and safety for organs could address similar topics; however the risk-benefit ratio is a fundamental approach for organ transplantation. Owing 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. The Commission proposal will take into account these specificities of organ donation and transplantation.

The conclusion of the impact assessment attached to this Communication is that, based on further cooperation with the Member States, an appropriate and flexible European legal framework could be an adequate community response to meet the mandate provided in Article 152(4)(a).

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10 Resolution of the Council and the Ministers for health (OJ C 304, 23.11.1991, p. 5).
11 OJ L 33, 8.2.2003, p. 30.
12 OJ L 102, 7.4.2004, p. 48.

The future legal instrument based on a separate impact assessment, could include the principles needed to establish a basic quality and safety framework, such as:

- the establishment of national oversight authority or authorities responsible for implementing the requirements of the Directive;
- a common set of quality and safety standards for the authorization of establishments and programs of organ donation and procurement, and also for an effective preservation and transportation of organs;
- ensure traceability and reporting of serious adverse events and reactions;
- establishment of inspection structures and control measures;
- ensure a complete characterisation of the organ, in order that the transplant team could undertake the appropriate risk assessment.