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ORGAN DONATION AND TRANSPLANTATION: POLICY ACTIONS AT EU LEVEL

Summary of the Impact Assessment

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SUMMARY OF THE IMPACT ASSESSMENT[1] ON A COMMISSION COMMUNICATION ON ORGAN DONATION AND TRANSPLANTATION

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

The use of organs in therapy poses a risk of transmission of diseases to the recipient. Infectious or cancerous diseases could be transmitted. In assessing the quality and safety aspects, the benefit-to-risk ratio is a fundamental approach for organ transplantation.

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.

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 exchanged between Member States constitutes a low percentage of the organs used for transplantation, with the exception of those areas covered by international agreements (Eurotransplant) where the interchange of organs between Member States is up to 20% of the total of organ transplants.

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[2].

From 1999 onwards, Article 152 of the Treaty has enabled the European Parliament and Council to adopt measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives.

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.

1. QUALITY AND SAFETY

1.1. The Risks

1. Transmission of communicable diseases. The use of organs in therapy poses a risk of communicable diseases being transmitted to the recipient. Viral, bacterial, and fungal infections have been transmitted via transplantation of organs.

2. Transmission of malignant diseases. Transmission of different types of cancers through organ transplantation has also been described[3].

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1 On the basis of SEC(2005) 791 of 15 June 2005 (Impact Assessment Guidelines).

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

3 Consensus Document Criteria for Preventing the Transmission of Neoplastic Diseases in Organ Donation. Organizacion Nacional de Transplantes Spain http://www.ont.es/Consenso?id_nodo=263&&accion=0&keyword=&auditoria=F

1.2. The different steps of quality and safety in the transplant process

1. Donor testing and suitability. To minimise the risks to the recipient, it is essential to screen donors and establish the presence or absence of disease transmission risk in their organs.

2. Living donors. Living donors of organs will face risks associated both with testing to ascertain their suitability as a donor and the procedure to obtain the organ, tissue or cells. All possible measures must be taken to minimise the risks to the donor.

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

4. Conditions of procurement, processing and transportation. Organ contamination has been described during procurement and processing of organs for transplantation. The maintenance of donor records and quality systems has also been identified as key steps towards quality and safety. Standard procedures for procurement and requirements for organ preservation and transport should ensure the best quality and safety.

5. Transplantation programmes. Transplant procedures should be performed according to the state of the art, only in units which have the necessary facilities and human resources to maximise the safety of the recipient.

6. Traceability and vigilance of adverse events and reactions. It is important to ensure that all transplanted material can be traced forward to recipients and back to the donor.

2. ORGAN SHORTAGE

2.1. Main factors affecting the organ shortage

1. Growing waiting lists. Waiting lists have increased in all EU countries and in the rest of the world.

2. Increased demand of transplants. The excellent results of transplants during the last decade have multiplied the indications of these therapies.

3. Limited donor pool. Shortage of organs is a common European problem. However, there are important differences in the deceased organ donor rate within the EU. Moreover, there are large differences between Member States' success in increasing their donor pool.

The critical shortage of organs, the morbidity and mortality of patients waiting for transplantation have mandated careful reconsiderations of other potential donors who are not ideal candidates (expanded donors).

The use of living donors has increasingly been considered as a possible alternative given the failure to meet the growing need for organs from cadaver donation. The use of living donors varies widely within Europe.

4. Complexity of the process. 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. As part of this organisation, an effective allocation system is essential.

5. Ethical issues. There are many complex ethical issues in this area (e.g. consent, anonymity, allocation criteria) that could have repercussion on the availability. EU Member States deal with these aspects in different ways.

6. Participation of the society. Organ donation and transplantation are medical processes that require the participation of the society. One of the reasons of the shortage of organs is the family refusal to donation. These refusals vary widely within Europe.

3. ORGANISATIONAL SYSTEMS

Organisation has not only an impact on quality and safety of organs but also on the detection, referral and hence the availability of organs. There is a need for a well organised and effective transplant system. This system needs an appropriate legal framework, a good technical approach and organisational support.

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 addition there are examples of European organisations, which proves the need and importance of wider European cooperation..

4. RATIONAL FOR EU ACTION

The Treaty in its Article 152(4)(a) provides expressly the possibility for the EU to adopt harmonising measures to ensure safety and quality on organs. National legislations differ between Member States. A national approach would not ensure a harmonised standard of quality and safety.

Organ interchange already exists in Europe. In the Eurotransplant area the average exchange rate of kidneys between partner countries was around 20% over the last five years. Common quality and safety rules are needed in this context.

There is a need to develop systems for exchange of organs for urgent patients and difficult-to treat recipients (e.g. children, highly sensitized patients). These patients can not be adequately treated in small Member States with limited donor pool, and can clearly benefit from an EU initiative.

Also the possibility of donation in a different Member State should be considered. In Spain, for example, close to 10% of the donors last year were foreigners. Cooperation to introduce initiatives that facilitate information to citizens about the different donation systems in Europe and facilitate donations of foreign citizens will have an added value.

Also the movement of patients should be considered. Having harmonised minimum binding standards of quality and safety will be an important mechanism to ensure a high level of health protection all along the EU.

It is also important to consider the link with the quality and safety requirements for tissues and cells. Often an organ donor is also a tissue donor. An adverse reaction in an organ donor recipient should be traced and reported on the tissue vigilance system if needed.

Organ shortage is a common dilemma in all European countries. However, the experience shows that some organisational models are performing clearly better than others. Identifying those elements in the different systems that could be promoted at community level will bring a clear European added value.

European cooperation is crucial for the evaluation of measures intending to enhance post transplant results and to make the use of organ donors more effective and safe. This can be addressed more efficiently from a community perspective.

5. OBJECTIVES

Ensuring quality and safety and increasing organ availability are the two main goals of the proposal. Quality and safety of organ donation and transplantation are also the core of Article 152(4)(a) of the Treaty. Actions on quality and safety could have an effect on organ availability. There is an important trade-off to consider in this respect.

The availability of organs has also impact on the quality and safety. Maximising the donor pool will allow to select the best organ for the patient in need.

Avoiding organ trafficking is important. Any criminal or ethically doubtful activity in this area would undermine the trust of the population in the donation-transplantation process. A loss of trust can seriously lower the donation rates. Illegal trafficking could also undermine the quality and safety of the process. On the other hand organ trafficking is a consequence of the scarcity of organs. Actions oriented to increase organ availability will help to combat organ trafficking.

6. POLICY OPTIONS

Three possible scenarios were outlined for future EU action:

1. To maintain the status quo, continuing certain basic projects already being carried out under different EU programmes without any further coordination.

2. To establish an EU mechanism that would promote active coordination between Member States on organ donation and address the identified problems.

3. To implement an active method of coordination between Member States as outlined in point 2 above, while the Commission would consider EU legislation to complement and reinforce these actions.

7. ANALYSIS OF IMPACTS

7.1. Political impact

Following the provisions ofthe Treaty of Amsterdam the Community adopted Directives of the Parliament and the Council on blood[4] in 2003 and on tissues and cells[5] in 2004. The third step in this process would be to ensure the quality and safety of human organs.

Organ shortage is a common problem in all European countries, and sharing expertise across the EU members has proved to be useful. Already in 1991 in a resolution on health and fundamental health choices, the Council of Ministers took note of the analysis of the Community's possible contribution to increasing organ availability. The shortage of organs for transplants was identified as one of the topics which require join consideration, regular joint discussions and/or joint efforts to assist Member States in framing their health policies.

Transplantation might contribute to the idea of cross-border cooperation and solidarity in the EU, to rekindle the spirit of the Community.

7.2. Economic impact

Diseases that can be treated or cured by transplantation usually carry a significant burden of morbidity and mortality. Therefore they have a significant impact on the national health care budgets. It is estimated that, at present, more than 3% of the health care budgets of European Member Sates are dedicated to patients waiting for a transplant.

Organ transplantation provides the possibility of saving lives and also has the best cost / benefit ratio in terms of economic gains as well as quality of life.

Several recent studies have shown that investing in organ procurement is clearly a good health investment.

The most important benefit for the grafted patients is measured in terms of survival and improvement of the quality of life, and consequently integration into the working and family life and productivity.

The need of standards of quality and safety could increase the cost of the process. On the other hand they may help to reduce costs associated with adverse events and facilitate the exchange of organs across the borders.

The latest cost/benefit analysis of the introduction of quality and safety standards has been undertaken by Health Canada. The analysis indicates strong support in favour of adopting the regulation.

7.3. Assessing the impact on health and social welfare

Increasing organ availability will increase organ transplants and thus increase healthy life years of many patients and their families. It has proved to have a net social benefit.

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4 OJ L 33, 8.2.2003, p. 30.
5 OJ L 102, 7.4.2004, p. 48.

There is a need to increase the number of available organs but not at any price. Safety and quality levels need to be established at the same time.

Basic quality and safety requirements will have an impact on risk reduction. On the other hand a very stringent set of binding safety and quality criteria could have as a consequence a reduction in the actual number of donors. A clear understanding of the disease transmission risk inherent in each case is important.

The new Member States face greater health problems than the rest of the Union but have less economic means to address them. There are also 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 and enhance the accessibility to these therapies to a large number of European citizens.

8. COMPARING THE OPTIONS

Projects funded by the Commission have proved to be a valuable tool to progress forwards a better understanding of the problems and finding possible solution. These programs have involved the professionals in the field and offer enough flexibility for Member States to tailor the results of the initiatives to their own national situations.

The projects have a limited time frame and limited resources with the risk that once the project is finished the continuity of the results is not ensured. In addition they not always have the capacity to transfer the results to the political level in order to make them operative.

The outcome of these projects will only be useful if health authorities abide by their conclusions. The Community should get the best of the best models and support its application in the entire EU. It is clear that what Europe needs is not so many short-lived programs that are hard to translate into real practice, but rather a full flagged agenda of priorities.

Coordination between MS has often proved not to be such an effective tool without any legal instrument supporting the actions. This would most likely lead to not fully meeting the objectives under Article 152. Basic common binding principles should be in place.

The legislative proposal should not imply undesirable practical consequences for MS. Finding the appropriate risk-benefit balance for the patient is a key aspect. While respecting the clinical role of the doctor in the decision on the acceptance of organs for transplantation, community binding legislation would have an added value in terms of ensuring the basic quality and safety requirements across the Community. An appropriate and flexible European legal framework seems to be the best response to the clear mandate provided in Article 152(4)(a).

9. CONCLUSIONS

An EU initiative on organ donation and transplantation has an added value. 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.

9.1. The preferred option

The Commission should define the exact and balanced scope of the EU legal framework on quality and safety for human organs and present a proposal to Parliament and Council, taking into account its previous and extensive discussions with Member States.

This legal framework should be complemented by cooperation between Member States. Strengthening of cooperation between Member States, specifically adapted to this concrete field, 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 a Community response is necessary, on agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.