

ORGAN DONATION AND TRANSPLANTATION POLICY OPTIONS AT EU LEVEL

HOPE ANSWERS TO THE CONSULTATION DOCUMENT

HOPE is the acronym of the European Hospital and Healthcare Federation, an international non-profit organisation fostering efficiency, effectiveness and humanity in hospitals and health care. HOPE is made up of members coming from 24 member states of the European Union (EU), plus 3 observer members. Those members are national hospital federations. Where there are no national hospital federation, members are local and regional authorities, owners of hospitals, or representatives from the national health systems. As an association, its mission is to promote improvements in the health of citizens throughout the countries of the EU and a uniformly high standard of hospital care throughout the EU. Further information can be obtained on www.hope.be

HOPE, the European Hospital and Healthcare Federation welcomes the initiative of the European Commission to start a consultation process on the policy options at the EU level dealing with organ quality and safety, within the framework of the provisions made in Article 152 of the EC Treaty.

As organ quality and safety refers clearly to transplantation processes that are carried out by hospitals, HOPE members are indeed directly concerned by any EU initiative in this field. The question of organ transplantation has for a long time been a key issue for HOPE. One of its publications was for example devoted in 1989 to "Organ Transplant". The organ transplantation process itself is a very complex subject; it is interrelated strictly to the issues such as patient safety, patient mobility, waiting lists, quality of care, ethics and training of health professionals, other issues on which HOPE is working on.

ANSWERS TO THE "QUESTIONS FOR CONSULTATION"

- 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?**

It would have been helpful to have a brief medical appendix giving the basic facts of organ transplantation such as indications (including prognosis without transplantation), expected results, cost-utility, QoL and frequency maps of the most common procedures (not just total number) in the EU member states.

COMMENTS ON THE “INTRODUCTION”

Important facts are mentioned in the introduction:

- the use of human organs for transplantation has steadily increased during the past decades; but the shortage of organs is affecting transplantation programmes;
- there are discrepancies in quality and safety requirements between Member States (within Member states, as mentioned in paragraph 8 referring to the 2003 survey? The survey does not give results on discrepancies within Member States but between them); but also important differences in the organisation of transplantation processes;
- trafficking of human organs is a real issue;
- the number of organs interchanged between Member States constitutes a low percentage of the total of organs used for transplantation.

Those important facts will structure the rest of the document. However, it would have been helpful also to clarify the relation between quality and safety of organs in general and transplantation processes which are a way of dealing with organs.

It would have also been helpful to distinguish three different fields as far as added value of having a European investment is concerned: to improve in general the quality and safety of organs; to improve in particular cross-border donation and transplantation; to reduce trafficking.

COMMENTS ON “FACING COMMON PROBLEMS”

Quality and Safety

Quality and safety of transplantation has indeed some specificity compared to other healthcare issues. But mixing quality and safety with the legal bases allowing the EU to work in this field makes this chapter sometimes difficult to understand.

As quality and safety of all health care activities is high on the member states' agenda the interesting point would have been to develop what is specific to transplantation processes compared to other issues.

It seems clear that the angle to be taken is not the mobility of organs between borders, which seems a minor issue, at least quantitatively. It would have been worth mentioning at least that there are already a lot of initiatives (high level group, EU financed projects...) dealing with patient mobility.

A minor point concerning the first paragraph “transmission of different types of cancers and new emergent diseases such as melanoma”: melanoma is a form of cancer.

Organ Shortage

The interesting aspect that could have been emphasized is not only the general shortage but the fact that there are huge differences in the organ donor rates in the EU Member States and also within Member states (although the culture and general healthcare organisation are the same). There is still some research to be done to explain the reasons for such differences and this can lead to an EU added value.

Page 6, line 4: “*Today it is not possible to offer an organ to every patient in need*”. This is not possible in *any* field of medicine as needs always exceed resources. It is not possible to set priorities so that organ transplantation, still luxury in the global context, should be provided to everybody in any degree of need. It is more and more generally accepted that also indications to various treatments should be transparent, widely accepted and - if possible – evidence based. This should also be discussed in the EU consultations: what is the common ground if any? It is not sufficient to say that organ transplantation is often “the only available therapy”, “life-saving” or “cost-efficient” (e.g. page 9, paragraph 4). This is a very important point if the mobility of patients is to be facilitated and the variability of procedure rates is to be reduced.

Page 7, paragraph 3: it is not true, because too restrictive, to write that organ transplantation would be “*the only medical treatment that requires the participation of society for their full development.*” What about mental health for example?

Page 7, paragraph 6: concerning “*financial gain*” the broader issue of financial incentives (for professionals and institutions and not only for donors) in the transplantation process should have been mentioned.

Page 7, paragraph 8: “*anonymity and confidentiality*” this issue should take into account the general context of the development of electronic patient records and also the work of the High level group.

Organisational Systems and Organ Transplantation

This chapter is right in mentioning that there are different organisational models (as there are different healthcare systems) and that some are performing better than others. It is however important to clarify the criteria of performance, which are not only the number of transplantations.

It would have been useful mentioning the source of the figure on page 8, and giving some explanation in annex for example (difference between brain death confirmation and legal confirmation brain death for example?).

On page 9, it is mentioned that new member states have less economic means which is true, but it implies that this explains the difference with other EU member states. The previous chapter has shown that the transplantation activities are not always correlated to the financial resources of the country devoted to health.

Still on page 9, the cost/benefit example of transplantation/dialysis has to be taken carefully and might not be transferable to other transplants. In any case it is always important to mention the source.

Page 9, last paragraph: it would have been interesting to get the references. Does this refer to the Donor Action Program?

2. The document also describes a number of actions oriented to tackle the main problems. Is there any other initiative that you consider useful?

COMMENTS ON “ARRIVING AT COMMON SOLUTIONS”

Quality and safety

This part starts by mentioning experts. It would have been helpful to know which ones, although one assumes that this refers to the work of the Council of Europe.

Concerning the authorization of institutions a clear balance should be found between two components of article 152: responsibility of member states in organising their healthcare system and responsibility of the EU. The existing quality and safety EU initiatives have also to be considered.

Due to the scarcity of organs, transplant clinicians are extremely selective about the patients they include in the waiting list. As a consequence only those patients with a clear likelihood of benefiting from an organ are considered for transplantation. The patient selection is then a medical professional problem. Trying to reach a European consensus (guidelines or practice recommendations, which would cover the indications of organ transplantation, organ by organ, including patient specificities) would certainly be helpful to improve transplantation procedures and activities; but this has to be done with all stakeholders.

Furthermore, the emphasis should be put on local transplant registries and procurement systems, which are able to coordinate the activities.

Organ shortage

Page 11, paragraph 5: one should be more careful with the statement that promotion from living donors should be promoted as use of living donors is not actively favoured in many countries. What are non-heart-beating donors? This should have been precised.

Concerning organ shortage, there is a general agreement on the importance on active organ harvesting according to best practices taken in the EU Member States in which transplant programmes are well organized. All sorts of issues could then be clarified including financial ones.

Organisational Systems and Organ Transplantation

The idea of systems for offering excess organs and the exchange of patients between countries should be carefully handled; taking into account the pressure this would create for some member states. This should also be related to the work done in other arenas (such as the High level group) in particular when issues such as reimbursement of costs, common transplant list admission criteria, prevention of registration on multiple transplant lists, among other subjects, that need prior discussion are concerned.

International cooperation

HOPE considers the international cooperation as a very important issue and stresses the importance on European level of the transnational registries and follow-up of transplant

activities and patient prognosis. A total of five international networks are listed. Do they cooperate? If yes, what are there results and if not, why?

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?

The EU action in this field should be first to facilitate exchanges of best practices.

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?

HOPE considers the accessibility to transplantation as a complex issue, like other healthcare access issues and that it cannot be separated from its general healthcare environment.

Coordination between Member states will certainly be a factor to improve the situation but will not be the only one. Access to transplant requires for example financial and human resources on the long run.

5. From the three policy options suggested as potential future initiatives at EU level: Which one do 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?

HOPE considers that active coordination between Member States and affiliated countries in the framework of the open method of coordination is the most adequate option for any work in this field.

But this should be done by clarifying the goals and making priorities. What do we want to improve? The goal is certainly not only to produce a directive at the end, but what? To improve quality and safety of organs? To increase the number of donations? To increase the quality of transplantation results? To reduce trafficking? As mentioned in the consultation document the first step will be to identify common objectives. Regarding the concrete actions, those listed may create confusion and sometimes lack precision: standards of quality and safety of what? Training of which professionals and on what?

Further work financed by EU programmes should certainly be necessary for some aspects. This should come second as a tool for the coordination between member states, after gaps in knowledge have been identified. In any case, coordination between projects in particular when financed by different sources and organisation of linkage with decision-makers (in that case with the open method of coordination) should be prioritised.

As a conclusion, a balance will have to be found so that this initiative would not create an artificial environment for transplantation processes, disconnected from the rest of healthcare activities, whatever common objectives could be found. One way among others to avoid this risk would be to involve actively healthcare stakeholders.