Organ donation and transplantation

Policy options at EU level

Questions for consultation

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?

The Consultation Document “Organ Donation and Transplantation and Policy Options at EU level” suggests a European Commission scope initiative based on the article 152 of the Treaty of the European Union. This article enables the European Parliament and Council to adopt health measures setting high standards for the quality and safety of human organs. We agree that it is important to expand quality and safety issues, but the most important efforts should be oriented to solve the shortage of organ donors and the equity of access to transplantation. Despite extensive description, the authors fail in illustrating the main causes responsible for the ever shrinking resource of organ grafts. Transplantation is facing worldwide a challenging dilemma, since organ demand is constantly outstripping organ supply, but we feel that the reasons for the extreme variation in organ procurement across Europe have not been provided in full details.
The European scenario of deceased organ donation is extremely varied with a few nations with yearly donor rates over 20 per million population (pmp) (Spain, France, Italy, Estonia, Belgium, Austria, and Latvia); a major block of countries with yearly rates between 10 and 16 pmp (Ireland, Norway, Finland, Poland, Sweden, The Netherlands, Switzerland, Slovakia, Denmark, Lithuania, Germany, the UK, and Malta), and a few like Greece and Cyprus whose deceased donor rates fall below 5 pmp. At first glance, we might blame that political, social and cultural differences are the main causes for such a huge discrepancy within the EU. However, what really differentiates high and low-donor-rate countries is the organizational level, i.e. the way donation and transplantation activities have been organized and disciplined by national/regional authorities. To this regard two different models are present in the EU: one consists of law-approved, institutional-centered, national transplant organizations (NTOs) based on the principle of local and regional coordination, whereas the other consists of multinational organ exchange organizations (OEOs) whose main objective it is to allow for adequate donor-recipient matching through international organ sharing. In light of these two different models, the EU transplant geography can be split into two areas: countries with NTOs based on the principle of local and regional coordination - such as Spain, Italy, France, and Portugal - and countries grouped into multinational exchange organizations, such as Eurotransplant (Germany, Austria, Belgium, The Netherlands, Luxembourg, Slovenia, and Croatia) or Scandiatransplant (Denmark, Sweden, Finland, and Norway). Even among those nations that have recently joined the EU, some have opted for a NTO-like model (Poland, Hungary), while other, smaller countries have gathered in an OEO-like fashion (Balttransplant for Estonia, Latvia and Lithuania).

What is really essential to the NTO-like model adopted in Spain, Italy and France and differs from the OEO-model currently working in Central and Northern Europe is a different
Organ donation and transplantation: policy options at EU level. Question 2.

concept of transplant organization. In a NTO model, transplantation is not simplistically a mere medical discipline, but a complex healthcare process requiring active participation from healthcare professionals, stakeholders and local/regional/central authorities. With the exception of UKTSA (the UK Transplant Service Authority), virtually all major NTOs are centrally-governed, institutional organizations, officially endorsed by public laws and/or bills and in charge of disciplining, monitoring of and planning of all donation and transplantation activities within their borders.

On the opposite, OEOs operate mainly to assure appropriate donor-recipient matching, and resultant favorable results of organ transplantation, by enlarging the recipient pool. The principle OEOs were founded upon was that the larger the organ recipient pool on file, the better the possibility of appropriate HLA donor-recipient matching. This idea led to birth of international transplant exchange organizations in Central and Northern Europe, initially limited to renal transplantation and later expanding to the field of liver, heart, lung and tissue transplantation. It was – and still is - beyond the scope of OEOs to implement strategies to improve organ procurement rates, which rely upon national initiatives outside a convened-upon, multinational action plan.

However, the successful achievements carried out in Spain at the beginning of the Eighties have demonstrated that - beyond enlargement of the exchange area - organ transplantation needs introduction of scope-oriented, properly-trained, institutional staff personnel within a network of local, regional, and national coordination. Such nationwide networks are based on efficient merging of central and local authorities, national and regional perspectives, civil servants and healthcare professionals and have proved one of the most successful recipes ever introduced in the field of transplantation. Application of
this model has resulted in a steady increase in organ donor rates in Spain, and has paved the way to the subsequent increase in countries like France, and Italy.

Little information on this process – if none at all - has been provided in the current paper, with the result that not all the necessary measures to further improve organ procurement rates might be properly highlighted. We believe that only by appreciating the impact of the NTO-like model originally set up in Spain can we account for the discrepancy across Europe and plan adequate solutions to increase donation rates.

Another issue that has not been addressed – though not a basic one - is the growing number of non-EU citizens waitlisted for organ transplantation, namely in regions of the European borders. Quite a few times the EU paper makes reference to organ sharing mobility of citizens throughout Europe, as well as to reimbursement costs, but does not mention the predicament that regions at the EU borders are facing due to non-EU citizens seeking transplantation in the EU healthcare system. This increases the current shortage of organs and at the same time faces the EU with ethical dilemmas, namely misuse of a limited resource due to inadequate follow-up care when patients get back to their home countries. We feel that the analysis carried out in the EU document on organ donation and transplantation is excessively nation-centered and lacks regional perspectives, thus not allowing for identification of some relevant issues.

The issue of equity of access to transplantation has not been adequately identified either, but the differences in donation rates alone are not enough to explain inequalities in access to transplantation throughout Europe. It is true that the organizational efforts carried out in nations like Spain, France and Italy have succeeded in increasing the organ donation rates. However, access to transplantation – expressed by the number of transplants per million population (pmp) – often shows variations difficult to explain based on organ donation rates alone. Namely, in 2005 the liver transplantation rate in Southern Italy was
7.7 pmp vs. 30 in the Center and North. In France the liver transplantation rate ranged from 6.6 in the region of Poitou-Charentes to 19.4 in the one of Midi-Pyrénées. In Spain, similar differences exist as is the case of Extremadura (8.3 pmp) vs. Galicia (31.5 pmp). These differences are partly due to differences in donation rates, as is the case for Southern vs. Central-Northern Italy. However, in Spain Galicia and Extremadura have slightly different donation rates (29 donors pmp vs. 25, respectively). Therefore, the reasons for the different transplant rates are also dependent on efficiency of transplant centers, on use of different indications, on region-centered policies of organ allocation, on the lack of real consensus on the management of waiting lists, on the presence/absence of transplant centers, with resultant migration of transplant recipients from native regions to regions where transplantation is available.

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

Over the recent years numbers of initiatives have been undertaken by the EU in order to improve the organ donor rates and allow an ever greater percentage of waitlisted patients to benefit from organ transplantation. However, with current organ demand constantly outstripping organ supply, these initiatives have not proved useful to a very limited extent, as is testified by the overall donation rates being stable over the recent past1. How to achieve more favorable results?

1. **A society-oriented approach**

Possibly, the major limitation of the initiatives undertaken so far at the European level is their healthcare-oriented scope. Transplantation is not merely a question of HLA matching,
surgical expertise or management of immunosuppression. It represents by large one of the most complex healthcare activities, and one that calls for active participation of medical professionals, stakeholders and authorities: i.e., of society as a whole. Any initiative aiming at increasing the level of performance in the field of organ donation and transplantation must rely on integration of all the actors playing in the process, through a bottom-up approach. Recognition of the innate complexity of the whole transplantation process and of the consequent need for active participation of all its actors is the basic step for further advancement of organ procurement rates. Therefore, it is crucial to count on all the social actors included in the process (healthcare professionals, media, opinion and religious leaders, education professionals, judges, patients associations, etc ...).

2. **Get the best of best models**

Pivotal to overcoming the current organ shortage is recognition of the role that national/regional/local authorities may play in any successful strategy. The history of countries like Spain, Italy, and France highlight the importance of authority-endorsed, public initiatives in increasing organ procurement rates. However, improvement in organ donation rates is not always synonymous with equal access to transplant procedures. To this regard, the “NTO-like model” should also be critically assessed, because national organizations have not always been able to correctly address the inequality of access to transplantation across regions.

Due to the complexity of organ transplantation medicine, it is paramount to:

- single out those organizational models that have produced the best results (NTOs in Spain, Italy, France, etc…);
- to identify their main features, namely integration of healthcare professionals, stakeholders and authorities at a regional and central level;
- to endorse this model and favor its expansion throughout Europe.
Expansion of the Spanish model is neither obligation to conform nor giving up long-standing organizational practices. It is rather adoption of those features of the model that might prove useful for organ donation in one’s own local practice, i.e. merging of local habits and general principles, of local autonomy and global plans.

3. **Fewer initiatives, clear objectives, no splitting of resources**

The panorama of the initiatives the EU has so far undertaken or endorsed on organ donation and transplantation is one of a myriad of often conflicting, overlapping and somehow confusing action plans, where personal leadership, bipartisan alliances, resource allocation and politics have counted more than practical solutions. What we need is not so many short-lived programs that are hard to translate into real practice, but rather a full-fledged agenda of priorities. Spitting scanty resources into a multitude of projects and/or research funding may turn out detrimental for full expansion of worthy initiatives. The EU should finance projects that really include most of the European countries, in such a way that the economic efforts are centered on a lower number of projects but of a stronger potential impact. The role of the EU should be to facilitate cross-talk between healthcare professionals and politics at the organizational level, i.e. institute a framework for resolution of practical problems, where ideologies, religion, political influences be abandoned in favor of pragmatism.
Undoubtedly, any EU initiative on organ donation and transplantation has an added value. It is basic to address the regional perspective in designing any action oriented to organ donation and transplant related questions. This is in close relation to the fact that organ shortage is a common dilemma in all European countries, and that sharing of expertise across the EU members has already proved useful in increasing organ donor rates in some countries. However, if the EU is pivotal to higher organ donation rates and more favorable results of organ transplantation, transplantation itself is paramount to Europe. Transplantation might contribute to reinforce the idea of Europe throughout its borders, to rekindle the spirit of community, especially after the recent enlargement of its members number. Transplantation requires striving for common objectives, sharing of experiences, active participation, and knowledge exchange. So close is the interrelation between transplantation and Europe, that it appears plausible to state that there will be no major advancement in transplantation for any EU member outside Europe, as there will be no real Europe outside transplantation. In a sense, transplantation is the unique field where the ideals that laid the foundation of Europe are put into practice and may stand the test of time.
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 the EU level?

Limited accessibility to transplantation is a major consequence of the ever shrinking organ donor rate. Improvement in accessibility to transplantation requires increasing the organ donor rates. However, that may not be entirely true. Experiences carried out in the USA have shown that social and racial minorities may not entirely benefit from organ resources and that even for transplantation they may bear the consequences of non justifiable discrimination. But also within the EU there are huge differences in access that cannot merely be explained by differences in donation rates. Accessibility means to work hard on organ shortage, but also set up transparent healthcare processes, expand these processes to all social classes and racial categories, and constant monitoring of organ allocation modalities. Again, these goals are to be achieved only through active integration of all the actors involved in the transplant process: healthcare professionals, stakeholders and authorities. However, advances in reducing the regional variability of access to transplantation requires not only coordination among member states, but also creation of tools to balance the regional inequalities to transplant access within single nations. So far central authorities have not succeeded in overcoming access inequalities, and we strongly feel that any initiative to this regard should count on collaboration between Regions, if we want to succeed.
From the three policy options suggested as potential future initiatives at the 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?

The option we favor the best is the second: active coordination between Member States on organ quality, safety and availability. This option corresponds to the basic requirements we have mentioned previously (question 1 and 2), i.e. allow for integration of all actors involved in the transplant care process.

Given the undisputed complexity of organ donation and transplantation, coordination among the EU members seems a more adequate action, rather than working under existing programs (option 1). However, we would suggest a slightly different methodology for coordination of donation and transplant activity, based on a bottom-up (upstream) rather than a downstream approach. In words this would imply:

1. call for a panel of internationally-acknowledged leader regions/countries with long-standing experience in the field and where all actors are to represented (local/regional coordinators, local/regional authorities/, stakeholders);
2. analyze and discuss current modes of action, organizational solutions and results across the different regions/countries (state-of-the-art analysis);
3. track down successful strategies and rule out useless initiatives (get-the-best-of-best-models approach);
4. promote expansion and integration of the NTO-like model within local practice (get-the-best-of-best-models approach);
5. allow for technical and organizational cooperation among regions/countries with best performance rates and those with lower performance rates (as per international data);

6. set out a list of priorities (organ shortage; quality, safety, and risk management);

7. select a few initiatives, based on scientific and practical grounds, and allocate resource consistently (European donor record registry; deceased donor detection programs; donor risk strata definition and monitoring; introduction of benchmarks, quality indicators, etc…);

8. produce a schedule of selected initiatives;

9. monitoring of and assessment of results;

10. discuss results, confirm or change strategy if necessary (critical appraisal).

Due to the increasing importance that the European regions are playing in the global panorama of the EU, the development of a regional conscience of civil participation, involvement of regional rather than national/central authorities is highly favored so as to allow for greater impact of EU initiatives at a local level. Furthermore, integration of all the actors involved in the transplant care process is easier to be achieved at a local/regional level before expansion to a larger scale.

References