Consultation document on Organ Donation and Transplantation Response Form

Contact details of person and/or institution submitting comments

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1. This document describes the situation at European level in the area of organ transplantation, identifying the main problems. Are all the basic problems identified? Are the problems identified correctly described?

(max 750 words)

This is an excellent, well-balanced analysis of the current situation of organ transplantation in Europe, the problems this medical discipline is faced with, and the solutions the EU is proposing.
Please allow me to add some minor comments:

'Facing common problems':

- Re: *"...number of organs interchanged between Member States constitutes a low percentage..." (p. 5)*. In my opinion, this is an underestimation of the reality. Within Eurotransplant, Europe's largest Organ Exchange Orgainisation (OEO) servicing about 120 million citizens, the exchange rate of kidneys between partner countries has ranged from 5% for 6 HLA mismatches to **42.8%** for 0 HLA mismatches (23% of all transplants) (average exchange rate: **19.7%**) over the last 5 years *(see EUROCET D7.2)*.

- Re: *'Organ shortage ... donor rates per million population' (p. 6)*. Since years already, experts in the field have been trying to explain why the 'donors pmp' expression should be avoided as irrelevant to compare countries' donation performance, and for mainly two reasons. Firstly, despite previous Council of Europe attempts to harmonize terminologies, figures reported by individual OEOs continue to be based on substantially different 'donor' definitions, hence a serious bias in most international comparisons. The main objection, however, against the 'donors pmp' expression is the fact that it does not take into account large variations between Member States as to their potential for donation based on mortality rates from selected death causes *(see EURODONOR D7.1 for more accurate performance indices)*.

- Re *'Organisational Systems and Organ Transplantation' (p.8)*, one minor remark: the slide shown *(Donation & Transplantation Process)* seems to be fairly outdated since being based on brain death confirmation only, and not taking into account the increasingly successful alternative pathway of non-heart-beating donation, with death confirmed on the basis of cardio-circulatory criteria.

- What is missing, surprisingly, as a pending problem is the phenomenon of **transplant tourism** (potential recipients from one country shopping to get a transplant in another country with higher donation rates than in their own country). Since this is a hot item in a few EU countries and their OEOs, it would be useful to elaborate in depth on this problem and suggest solutions, taking into account also the distinction between transplant tourism within the EU and the problem of non-EU citizens trying to get their transplant in one of the EU countries.

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

(max 750 words)

Arriving at common solutions

1. ***Quality and Safety***
   - Most, if not all, of these *suggested* quality and safety measures are already in place since many years in the largest European OEOs (ET, ONT, Agence de la Biomédicine, UKT). It would be sufficient to aggregate this wealth of knowledge as a **EU Standards of Practice**, to be used in less experienced new Member States. A small working group with experts from the most representative OEOs should be able to accomplish this task within a few months and produce e.g. a draft of an EU Directive on 'Quality and Safety in Organ Donation'.
   - Re: *'The management of the donor during the process is important….the staff involved should have appropriate training and experience' (p. 10):* please know that the **Donor Action Foundation** has been developing an e-learning training course on **Adult Donor Care** as part of its larger **'Virtual Donor'** project. Needless to say that such a web-based e-learning tool and resource, accessible 24hrs/7days, has an enormous potential of improving donor management practices without the costs and hassle of training courses that need physical presence of course applicants
2. ***Organ shortage***
   - In a Consultation Document of this kind it is not sufficient to admit that *'many donors are lost due to lack of evaluation, lack of referral or because the option of donation is not presented to the relatives'* (p. 10). It would be good to also explicitly mention existing methodologies to identify these shortcomings and their ability to increase donation rates after implementing corrective measures in the donation process (see further: International cooperation - Donor Action Foundation)
   - *'..creation of a European organ donor card…'*. Though such a card may increase public awareness to some extent, one should weight costs against benefits. To my knowledge, no hard data is available in the literature to support the impact of donor cards on increasing donation rates. More importantly, launching one European donor card could create confusion amongst citizens in countries with a presumed consent legislation where more sophisticated systems such as electronic non-donor registries are in place already (Belgium, France, Poland,..). It would be far more efficient to enter an individual's will on donation on the microchip of future electronic ID cards.
3. ***Organisational systems***

   'The main European organ exchange organisations…'. The largest existing OEO servicing 120 million citizens in Austria, Belgium, Luxemburg, Germany, The Netherlands, Slovenia and Croatia (**Eurotransplant**) is missing in the list of OEOs which meet on a regular basis.
4. ***International Cooperation***

   Though not an OEO itself, one other organisation should be considered as having a truly international scope in this field. Since many years, the **Donor Action Foundation (DA)** has profiled itself as the only international organisation with activities in 10 European countries. DA has organised multiple international, national and regional training courses to familiarize users with its methodology. With currently >30,000 records, DA has the by far largest international database of medical records from potential donors. DA has been able to increase donation rates with **50** to **70%** in hospitals, regions and countries that have implemented the DA methodology, (see www.donoraction.org). DA is consortium partner of EURODONOR and EUROCET.

   References:

1. Donor Action: a quality assurance program for intensive care units that increases organ donation (C. Wight, B. Cohen, L. Roels, B. Miranda, J Intensive Care Med 2000; 15:104-114)

2. Donor Action: an international initiative to alleviate organ shortage (L. Roels, C. Wight, Progress in Transplantation, Vol 11(2) 90-97, 2001)

3. Joining Efforts in Tackling Organ Shortage: The Donor Action Experience. (L. Roels, B. Cohen, C.Gachet & B. Miranda, Clinical Transplants 2003, Eds. M.Cecka & P. Terasaki, UCLA)

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?

(max 750 words)

The role of the EU

- The European Commission should encourage Member States to invest in existing methodologies that accurately measure the conversion rate of potential donors into actual donors as a measure of performance of national organ donation programs. As mentioned before, only one organisation in Europe (see www.donoraction.org) has developed an internationally applicable, multilingual, web-based **Medical Record Review** tool to measure donation performances in hospitals. This tool has been approved by a number of national health authorities *(Belgium, Finland, France, Hungary, Switzerland, Israel, Japan)* or individual regional centers *(in Sweden, Denmark, Poland, Italy, UK, Canada, Australia)* to measure and improve their performance in donation.
- Surprisingly, the Donor Action Foundation has not been involved in the DOPKI project that *…'focuses on developing applicable methodologies to increase the potential of organ donation…'*. Nor has Donor Action been involved in the Public Health Program the Commission is planning on a new project to develop a EU Training Program on Organ Donation *(P. 17 of this EU Consultation Document)*. Why re-inventing the wheel with European tax-payers' money if the expertise is available but not fully exploited?
- See further comments under *5. Future EU policy*
- As mentioned before, one would expect the EU being the key role player in tackling the transplant tourism problem.

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?

(max 750 words)

In my opinion, the Commission should foster initiatives to:

- **measure** correctly **the potential for donation** in all Member States in the first place. With all necessary tools already in place, the Donor Action Foundation is willing to offer its expertise in the field
- **increase** the **conversion rate** of **potential** donors in **actual** donations in Member States that show below average donation performance. Again, DA is willing to assist in this process.
- Only when above measures are implemented successfully, the EU Commission can start tackling the problem of equal access to transplantation for all EU citizens

5 The document presents the following three options for future EU policy on organ transplantation.

(1) Use of existing programmes only

(2) Active coordination between Member States on organ quality, safety and availability

(3) Minimum harmonisation on quality & safety, plus EU initiative on organ trafficking

Which one of these options do you consider the most appropriate? Would you wish to modify / add / remove some of the contents included in the option? Please explain your reasons

(max 750 words)

1. **Use of existing programs only**

   My major criticism of a policy of using the existing programs is:

   - they're stand-alone projects launched by different DGs but frequently have overlapping topics without knowing from each other's content. There doesn't seem to be any watch dog above DG level to evaluate the added value of these projects and monitor their success *(who's accountable to whom for spending tax-payers' money?)*
   - participation to the projects is rather arbitrary (hidden agenda's of project coordinators?) and therefore key-role players are sometimes excluded from participation *(examples: the European Association of Tissue Banks was excluded in the EUROCET project, the Donor Action Foundation was excluded from DOPKI and the scheduled new project on Training Programs on Organ Donation)*
   - there's absolutely no guarantee that any of the existing projects will increase the availability of organs and tissues for transplantation *(money well spent?)*
   - all this is in sharp contrast with the US approach of Governmental funding of projects to increase donation and access to transplantation: The HHS's Collaborative Breakthrough Initiative has linked funding of meticulously scrutinised key-role players with well-defined national targets, such as average conversion rates of potential into actual donors from 43 to 75%, target organs-per-donor yields, an increase of donations up to 1900 donors/year and transplants up to 6000/year. Three years after launching this initiative, several targets could be achieved already by the selected partners.

2. **Active coordination between Member States on organ quality, safety and availability**

   Definitely the most realistic short-term approach to eventually develop a common EU policy, however:

   - such coordination should rather be established **between OEOs** than between Member States since, in reality, several OEOs (some of them already working on a supra-national scale) have the know-how in place, are respected by individual countries as the expert partners in matters related, and are cooperating already with other OEOs.
   - expert international groups other than OEOs should be involved as well (e.g.: **Donor Action Foundation** when it comes to methodologies to better identify donors, improve donation processes and training of procurement professionals; IT companies active in the field, etc.)
   - throughout this consultation document only *organs* are mentioned. To avoid repetition, it would be wise to think already now about using the same approach for ***tissue*** **donation** and transplantation. For the large public there's only a thin line between organs and tissues anyway…

3. **Minimum harmonisation on quality & safety, plus EU initiative on organ trafficking**

   - If not already partially achieved by the second level, this third level approach definitely is worth to be considered as a long-term strategy.
   - The creation of the proposed *EU Directive on Quality and Safety for the donation, procurement, testing, preservation, transport and distributing of human organs* as mentioned under Article 152 of the Treaty should be the ultimate goal and should be prepared by the Level 2 approach.

In conclusion, the Donor Action Foundation is requesting the EU Commission to acknowledge this organisation as a key role player in the field of organ and tissue donation in Europe and beyond, and capable of offering efficient solutions to tackle the problem of organ shortage in all Member States.