Consultation document on Organ Donation and Transplantation
Response Form

Contact details of person and/or institution submitting comments

<table>
<thead>
<tr>
<th>Name of person</th>
<th>Dr Håkan Gäbel, MD, PhD, Ass. Professor of Transplantation Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>e-mail address</td>
<td><a href="mailto:Hakan.gabel@Socialstyrelsen.se">Hakan.gabel@Socialstyrelsen.se</a></td>
</tr>
<tr>
<td>Name of Institution</td>
<td>National board for health and welfare</td>
</tr>
<tr>
<td>Address</td>
<td>SE-10630 Stockholm, Sweden</td>
</tr>
<tr>
<td>e-mail address</td>
<td></td>
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</tbody>
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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)

Yes, I think the main problems have been identified and correctly described in the consultation document.

Some comments can be imported from the attached document below.

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)

Most of the actions have been listed and described but some of them such as transmitting donor information and full donor records within Europe may seem superfluous and burdening.

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)

I fail to see how EU action, most probably in the form of a directive would be the solution to the shortage of organ donors. A directive would have to deal with quality and safety issues and not much with the organisation of organ and tissue procurement. I wonder how much organisational guidelines that would be acceptable to the member states - it has to do with the type of health care system and more. In Sweden too decentralized and need for more national initiatives.
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)

The accessibility to transplants varies widely since the number of donors, living and deceased varies widely between the European countries. It is assumed that the shortage of deceased donors results mainly from a failure to transform potential donors into actual donors, but sooner or later one has to estimate the number of potential donors, which may vary from one country to the other. One now speaks about conversion rates: the rate of conversion potential into actual donors and the goal of the Collaborative (US program) is 75%. The collaborative is focused on best practices- we can learn from each other.

When it comes to improving conversion rates there is much to be done in Europe and we all should –even without a EU-directive do as the successful programs do.

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)
If the current national and regional organizations and considering the limited exchange of organs between these organizations are not considered sufficient to achieve high standards of quality and safety - then there is need for action on a EU level.

Third level is preferable but great caution must be exercised in a directive to regulate practices that already work well in national and multinational transplant organizations. Most of the bulletpoints (page 18) have already been implemented.

There must not be an EU - organizational suprastructure- the information on donors does not have to be transmitted within Europe since the exchange of organs is limited to exchange in the national and multinational transplant organizations.

First level with current work under the different Community programmes is not delivering – it does not seem to increase the number of donors. It can be questioned whether the projects mentioned in the text will become/ can be made operational

Second level. There is really no need for a system to facilitate the transmission of the full donor record – a common basic set of donor data –and other relevant information within Europe
Background on organ donation and transplantation

EC has previously adopted blood and tissue directives in reference article 152 of the Treaty to adopt health measures setting high standards of quality and safety in the interest of the population.

It can be seen as a natural move for the EC now to engage in the quality and safety of organs recognizing “that organs need a different approach from blood and tissues” - which is pointed out in the consultation document.

It will be interesting to see how a possible EXU- directive on organs might interact with the tissue directive.

A Document on Advanced therapy is in the pipeline – DG enterprice.

It should be acknowledged that much of the work of the commission in the field of blood, tissues and organs is based on the work of the Council of Europe committees of experts on blood and organs/tissues. The Guide on the Quality and Safety of organs and tissues is the basis for the work on tissues/cells and organs and the Tissue directive.

The work of these Council of Europe committees result in non binding recommendations to member states, but the work has nevertheless been most important. Unfortunately the work in these committees will cease.

Many of the documents and the Recommendations of the Committee of ministers are listed among the references and merit further study. In spite of the fact they are mere recommendations they contain much information that can lead to action in the member states. There are recommendations on authorization of organ transplantation facilities (#6) and there are recommendations on the role and training of professionals responsible for organ donation (transplant “donor coordinators”) #8

Some of these recommendations will hopefully be considered by the National Council for Organ and Tissue Donation and by the National council on specialized care. The documents contain important information. Restricting the number of hospitals doing transplants would most probably be advantageous. In each Norway and Finland there is only one transplant center- in Sweden and Denmark there are many transplant centers.

Moreover the Council of Europe Expert Committee (the SP-CTO) has regularly published international figures on organ donation and transplantation in the member states (Newsletter transplant #5) These figures have been most useful.
To be sure the community competence of the EC is restricted to the field of safety and quality of transplantation, but both the safety and quality would benefit from good organization of organ procurement and transplantation.

The crucial question is whether this organizational framework has to be on a European level or whether it can be on regional levels.

Organ donation and transplantation is now organized regionally by national or multinational organizations with protocols on quality and safety as well as on organ allocation agreed on by professionals and authorities and most of the actions listed on page 17 in bulletpoints have already been considered. Some of them deal with procurement and transplantation, some are mainly engaged in transplantation.

**Regional organizations**

Organs are now exchanged in transplant organizations such as Eurotransplant and Scandiatransplant. There are other such multinational organizations as well and there are national organizations such as ONT in Spain, Blood and Organs in the UK (page 12)

To my mind all these organizations have assumed the responsibility for the safety and quality of donation and transplantation.

Sweden is one of the national members of Scandiatransplant formed by the five Nordic countries in the 1960-ies. The current Articles of Association for “Foreningen Scandiatransplant “were adopted October 26, 1992”. There are amendments?

The units performing organ transplantations are members of the Scandiatransplant and are represented on the Council of Representatives. There is a board (of directors) consisting of 5 individuals appointed by the respective countries. The chairman of the Board (the fifth member) shall be elected by the Council of representatives upon recommendation from the four nationally appointed members of the Board.

More information on Scandiatransplant on request.

Scandiatransplant work on the quality and safety is based on a document: Prevention of transmission of infectious diseases from organ donors to recipients. Much of the work in this field in Scandiatransplant is based on the Council of Europe document Guide to safety and quality assurance for organs, tissues and cells now in its 3rd edition.

Scandiatransplant does not deal with tissues. There is however a collaboration of the Nordic Countries regarding the preparation and purification of pancreatic islet cells. There is a limited exchange of tissues and cells (corneas and heart valves) between the Scandinavian countries directly from one tissue establishment to another. The future exchange will be regulated by the Tissue act.

The National Board of Health and Welfare and the corresponding supervisisonal authorities /organizations meet once a year since 1997 with the Board of Scandiatransplant to discuss matters of common interest such as quality and safety as well as organ allocation. It is but
natural that there is such supervision by the authorities since Scandiatransplant deals with both quality and safety of the organs exchanged as well as such sensitive issues as allocation. There is no reporting of serious adverse events and reactions to authorities at the present time.

There are minutes from the meetings of the Nordic Transplant Committee. Available on request. The next meeting will be in Helsinki September 26, 2006.

The Swedish National board of Health and Welfare supervised all the Swedish Transplant Centers a few years ago.

In conclusion it can be assumed that the present state of affairs is sufficient and adequate for the quality and safety if organ donation and transplantation. Insight into the organizations by authorities is necessary.

**Comments on the body/text of the Consultation document.**

Most of it is based on the work of the SP- CTO and most of it is correct.

One comment on the use of a word. To be sure many patients are sensitive (page 13) but the correct word here is sensitized.

**Quality and safety**  
( page 5)

It is noted that the exchange of organs between Member states is low and it is suggested that a common set of minimum requirements on quality and safety within the EU could facilitate the interchange of organs in the community.

This statement can be questioned.

Fewer kidneys are now interchanged between the Scandinavian countries than before as less weight is given to HLA-matching than before. A number of Hearts, Lungs and Livers are interchanged between the Scandinavian countries to save the life of patients in urgent need of a transplant. Scandiatransplant has agreements with other European transplant organizations but few organs are exchanged between Scandiatransplant and these organizations now.

Det skulle kunna vara möjligt att ta fram data om utbyte av organ inom Scandiatransplant och mellan Scandiatransplant och Eurtransplant/UK transplant osv.

**Organ shortage**  
**Pages 5 and 6**

The need for organs is definitely not met, but I am not quite sure that transplant clinicians are extremely selective about patients listed on the waiting- lists. If more organs could be procured more patients could be transplanted and also professionals could be more selective in accepting deceased donors – not accepting borderline deceased donors – as I suggest is
sometimes done today, Considering the great need for organs there is a trend toward accepting extended criteria donors - donors of advanced age, donors with hypertension and other generalized diseases. If more donors were identified some of the extended criteria donors could be rejected in the interest of the results of transplantation.

The figures on page 6 ought to be updated. There are figures from each country for 2005 on the relative number of deceased and living donors. See reference # 5 (Newsletter transplant)

To my mind most of the Scandinavian countries have reached the limit for using living donors. In Sweden for example living donors are now more numerous than deceased donors. There ought to be a change of focus.

In Finland few living donors are used however and the same goes for Spain where focus is on the procurement of deceased donors.

Page 8

Some organisational models do better than others and most of the differences depend on the organisation. We have known this for a long time – now it is time to learn from the good examples. Maybe not by way of a EU-directive but by way of national legislation supporting good organisational models.

Arriving at Common Solutions

Organisational Systems and Organ Transplantation page 12

Experience shows that the organisational structure is key in the organ donation/transplantation systems

Re existing community programs
(Page 16)

I have heard about most of these. We in Sweden have been invited to participate, but discussions, mostly informal with transplant professionals and with Scandiatransplant have shown there is little or no interest in these programs for the time being,

There have been other initiatives as well:
One of them is described as follows:

On the basis of preliminary contacts with transplantation scientists And the European Commission, the "Fonds National de la Recherche Scientifique" (research agency of the French Community of Belgium) would like to invite you to explore the possibility to build an "Art 169-based European Research Initiative in Transplantation". You will find here attached a first document prepared by Kathryn WOOD (UK), Jean-Paul SOULILLOU (F) and
Michel GOLDMAN (B) which explains the rationale and presents the outline of such
An initiative. In a first phase, the work programme of the initiative would
focus on living donor transplantation (both solid organ and hematopoietic
stem cell transplantation).

A prerequisite for this initiative is a strong commitment of a
reasonable number of member states to join their forces to conduct a
high-level integrated research programme which should have an impact on
the clinical practice in living donor transplantation within a reasonable
timeframe. This commitment of member states should clearly include the
investment of financial resources from national origin.

This initiative came in the summer of 2005 by way of Henrik Ekberg in Malmö. Since there
was to be an investment I contacted the Swedish Medical Research Council (Håkan Billig)
but there was no interest in the project: