COMMISSION OF THE EUROPEAN COMMUNITIES

**COMMISSON STAFF WORKING DOCUMENT**

ANNEXES

# IMPROVING ORGAN DONATION AND TRANSPLANTATION IN THE EUROPEAN UNION

## ASSESSING THE IMPACTS OF EUROPEAN ACTION

**TABLE OF CONTENT**

# ANNEX I –COMPARATIVE TABLE QUALITY AND SAFETY BY OPTIONS

| Quality and safety principles | Base line Option | Action Plan + No Directive | Action Plan + Directive flexible approach | Action plan + Directive stringent approach |
|---|---|---|---|---|
| **Creation of Competent authorities** | Most of the Member States have already national organisations in place that are in charge of organ donation. The nature and responsibility of these organisations divers .<br><br>The Council of Europe will continue its annual meeting with its committee of experts. | It will create a Committee of national experts or designated representatives. However the situation is very different between MS and difficult to find the same level of representation and decision capacity. | It will establish the principle of national authority(ies) which is a basic element in the EU policy already proven effective in the area of blood and tissues and cells; these competent authorities are responsible for the implementation of the quality and safety framework. | It will establish the principle of national authority(ies) which is a basic element in the EU policy; already proven effective in the area of blood and tissues and cell these competent authorities are responsible for the implementation of the quality and safety framework. |
| **Authorisation of activities** | There are currently large discrepancies between EU countries in relation with the authorisation of activities. | The Action plan could establish guidelines as the existing ones of the Council of Europe; Experience shows that the implementation of these guidelines differs in different Member States.<br><br>The action plan could also promote as priority action a common (non binding) accreditation system for organ donation/procurement and transplantation programmes. | This approach will establish a common system for the authorisation of the conditions of procurement + basic European standards. It also will request the authorisation of transplantation centres under national standards.<br><br>These actions will be complemented with the action plan promoting a common accreditation system for organ donation/procurement and transplantation programmes. | This approach will establish a specific type of authorisation for every hospital and for each of the activities of the process: authorisation of the donation process; this process includes the detection, maintenance, testing and evaluation of the donor; authorisation of the different medical/surgical team; the third one on the conditions for the transport/preservation of the organs, often coordinated by a supra-hospital body and the last one is for the transplantation programmes where the legal framework should be limited to establish the need of an authorisation, but under national rules. |

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| | | | | These actions will be complemented with the action plan promoting a common accreditation system for organ donation/procurement and transplantation programmes. |
| **Register of establishments and reporting obligations** | Not in place at the moment<br><br>The Council of Europe with the support of the Spanish agency (ONT) will continue to produce its annual news letter with activity data.<br><br>EUROCET project will continue its work with the support of the committee of Competent authorities on Tissues and cells. (register on tissues and cells transplantation) | Not planned under the action plan | This approach will provide a record of the activities, including the number of donors, and the types and quantities of organs procured and transplanted, or otherwise disposed.<br><br>It will also provide for a publicly accessible register of establishments where procurement or transplantation of human organs takes place. | This approach will require an even more detailed record of activities, including the types and quantities of organs donated, procured, tested, preserved, and transplanted, or otherwise disposed.<br><br>It will also provide for a publicly accessible register of establishments where procurement or transplantation of human organs takes place. |
| **Donor/Organ risk assessment** | Wide variability between Member States<br><br>The Council of Europe has a guide on quality and safety on tissues and cells and organs. Experience shows that the implementation of these guidelines widely differs in different Member States | The action plan could promote the evaluation of post transplant results. This action would facilitate to promote a EU wide register or the comparability of the results of existing registers to follow-up on organ recipients, monitor their health and evaluate results. This will permit the elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results. This is of especial relevance in the case of the use expanded donors | This approach will introduce system of 'organ characterisation' means the collection of the relevant information on the characteristics of the organ and the donor needed to undertake an adequate risk assessment to minimise the risks for the recipient and to optimise the allocation of the organ.<br><br>This system implies a European donor data set and a system of transmission of this information.<br><br>Final decision of the acceptance of the organ is taken by the | This approach will introduce strengthen requirements related to the suitability of donors of human organs and the screening of donated organs.<br><br>This implies a detailed technical annex on selection criteria for donors, included exclusion criteria, and testing requirements. The final decision on the suitability of donors is given at least partially in the legal framework, status of the donor is not always considered.<br><br>See directive 2006/17 Annex I-II-III on tissues and cells |

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| | | | medical doctor taking into account the information on the characteristics of the organ and the status of the recipient.<br><br>These actions could be complemented with the action plan could also promote the evaluation of post transplant results. This action would facilitate to promote a EU wide register or the comparability of the results of existing registers to follow-up on organ recipients, monitor their health and evaluate results. This will permit the elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results. This is of especial relevance in the case of the use expanded donors | These actions could be complemented with the action plan could also promote the evaluation of post transplant results. This action would facilitate to promote a EU wide register or the comparability of the results of existing registers to follow-up on organ recipients, monitor their health and evaluate results. This will permit the elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results. This is of especial relevance in the case of the use expanded donors |
| **Traceability** | In many MS thee are not in place a consistent traceability system<br><br>The Council of Europe has guide on quality and safety on tissues and cells and organs. Experience shows that the implementation of these guidelines widely differs in different Member States<br><br>No system at EU level currently established to ensure traceability for cross border exchanges | Not planned under the action plan.<br>. | The approach will establish systems for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa. These rules will be established at national level, the commission will complement these systems in case of cross border exchanges. | The approach will establish systems for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa. Basic rules will be established by the commission including a detailed technical annex on the information that has to be kept to ensure full traceability also at national level. See 2006/86 Annex VI |

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| **Notification of serious adverse events and reactions** | More than one third of Member States have not this system in place<br><br>No system in place or guidelines for cross border exchanges | Not planned under the action plan. | The approach will establish systems for ensuring the detection and reporting of serious adverse event and reaction These rules will be established at national level, the commission will complement these systems in case of cross border exchanges. | The approach will establish systems for ensuring the detection and reporting of serious adverse event and reaction Basic rules will be established by the commission including a detailed technical annex on the information that has to be reported. An annual report to the Commission will be also required. See 2006/86 annex III-IV and V |
| **Import/export of human organs** | Only 15 Member States have regulation in place. | Not planned under the action plan | The approach will establish a system for the regulation of imports of human organs from third countries that ensure equivalent standards of quality and safety | The approach will establish a system for the regulation of imports of human organs from third countries that ensure equivalent standards of quality and safety |
| **Donor protection** | Wide variability between Member States in some aspects<br><br>The Convention of the Council of Europe on Biomedicine is in place. However it is not ratified by all Member States<br><br>The project LIVING donation funded by the EU under the public health programme aims to create a consensus on European common standards regarding legal, ethical, protection and registration practices in relation to organ living donors | Action plan could establish guidelines and sharing of best practices mainly for living donation programmes. | The approach will establish the basic rules for donor protection | The approach will establish the basic rules for donor protection |
| **Quality programmes** | Not in place in most of Member | Action plan could contribute to the quality programmes by promoting | This approach will request Member States to put in place | This approach will request that Member States take all necessary |

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| | States | methodology of quality improvement programmes for the donation process. | national quality programmes based on the principles of good practice which establishes standardised protocols. This programme should implemented and maintained throughout the entire process, from donation to transplantation, to ensure the compliance of the quality and safety requirements laid down in this framework. But is up to Member States how to organise these programmes. | measures to ensure that each establishment puts in place and updates a quality system based on the principles of good practice which establishes standardised protocols. The technical details of such quality systems will be establish in a implementing directive. See 2006/86 Annex I. and II, and 2006/17 Annex IV |
| **Inspections and control measures** | Wide variability between Member States | Not planned under the action plan | This approach will require under the national quality programmes to put in place control measures, including auditing where relevant, to evaluate and verify in a regular basis the procedures and the activities carried out that are relevant for the requirements of the quality and safety framework. | This approach will require Member States to put in place inspections structures and ensure that the competent authority or authorities organise inspections in a regular basis and that establishments carry out appropriate control measures in order to ensure compliance with the requirements of this EU legal framework.<br><br>Such inspections and control measures shall be carried out by officials representing the competent authority.<br><br>Guidelines concerning the conditions of the inspections and control measures and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance, shall be established by the Commission. |

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| **Personnel** | Wide variability between Member States | The action plan will address a number of actions on training of professionals and accreditation | This approach will establish basic requirements under the national quality programmes<br><br>This approach will be complemented with the action plan that addresses a number of actions on training of professionals. | This approach will establish personnel requirement as a part of the authorisation of the activities and under the specifications of the quality systems of the establishments. See 2006/86 annex I<br><br>This approach will be complemented with the action plan that addresses a number of actions on training of professionals |
| **Conditions of procurement** | Wide variability between Member States<br><br>The Council of Europe has guide on quality and safety on tissues and cells and organs. Experience shows that the implementation of these guidelines widely differs in different Member States | The action plan could promote as priority action a common (non binding) accreditation system for organ donation/procurement and transplantation programmes | This approach will establish basic requirements under the national quality programmes for the authorisation of the conditions of procurement | This approach will establish detailed specifications on procurement procedures as part of the authorisation of the activities and under the specifications of the quality systems of the establishments. See 2006/17 annex IV |
| **Transport of human organs** | Wide variability between Member States<br><br>The Council of Europe has guide on quality and safety on tissues and cells and organs. Experience shows that the implementation of these guidelines widely differs in different Member States | Not planed under the action plan. | This approach will establish basic requirements under the national quality programmes | This approach will establish detailed specifications on transport procedures and labelling as part of the authorisation of the activities and under the specifications of the quality systems of the establishments. See 2006/17 annex IV; 2006/86 Annex II |
| **Cooperation between** | No competent authorities are | It is the key element of the action | This mechanism could reinforce | This mechanism could reinforce |

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| **competent authorities** | officially designated.<br><br>The Committee of transplantation of the Council of Europe meets one-two times per year. This is however a technical committee of experts. Although recognising the work of the Council of Europe and the World Health Organisation in this area, there is not currently a effective framework discuss quality and safety issues between MS in the EU. | plan.<br><br>This approach should be based on the identification and development of common objectives , agreed quantitative and qualitative indicators and benchmarks, regular reporting, and identification and sharing of best practices.<br><br>The mechanism of coordination serves as a platform for discussion, exchange of expertise, and identification of best practices.<br><br>However the situation is very different between MS and could be difficult to find the same level of representation and decision capacity. | and complement the coordination action suggested in the action plan.<br><br>As already in place in the blood and tissues and cells area the designated CAs provide advice to the Commission, channelling communication between Commission and Member States. The Committee has a particular role in helping to achieve a coherent implementation of the Community acquis. Their tasks: Monitor the development of national policies and the enforcement of EU legislation by national policies; assist the Commission in the preparation of legislation or in policy definition and coordinates with Member States/exchange of views | and complement the coordination action suggested in the action plan.<br><br>As already in place in the blood and tissues and cells area the designated CAs provide advice to the Commission, channelling communication between Commission and Member States. The Committee has a particular role in helping to achieve a coherent implementation of the Community acquis. Their tasks: Monitor the development of national policies and the enforcement of EU legislation by national policies; assist the Commission in the preparation of legislation or in policy definition and coordinates with Member States/exchange of views |
| **Regulatory Committee and Comitology** | NA | NA | This approach will create a regulatory Committee in order to update:<br><br>(a) requirements for ensuring traceability at community level for cross border exchange at community level.,<br><br>(b) requirements for serious adverse events and reactions reporting for cross border exchanges at community level | This This approach will create a regulatory Committee in order to update:<br><br>(a) requirements for the accreditation, designation, authorisation or licensing of establishments where donation and procurement of human organs take place;<br><br>(b) requirements for the donation, procurement, testing transport and |

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| | | | (c) requirements for organ characterisation | preservation of human organs<br>(c) requirements for ensuring traceability, including labelling<br>(d) requirements for serious adverse events and reactions reporting<br>(e) information to be given to the donors and recipients<br>(f) Guidelines of inspections<br>(g) requirements for organ characterisation |

# ANNEX II –COMPARATIVE TABLE ACTION PLAN ELEMENTS BY OPTIONS

| Priority actions | Base line Option | Action Plan + No Directive | Action Plan + Directive flexible approach | Action plan + Directive stringent approach |
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| **Priority action 1**<br><br>**Promote the role of transplant donor coordinators in hospital where there is a potential for organ donation** | DG SANCO under the public health programme is running a project: EPTOD focused on training of health professionals on organ transplantation.<br><br>The European Transplant donor Coordination associations groups these professionals. | The action plan should designate this action as a priority, and promote its implementation thought:<br><br>(a) Incorporating in the national action plans the objective of gradually appointing transplant donor coordinators in every hospital with an intensive care Unit. Design indicators to monitor this action.<br><br>(b) Promote the international recognised standards for transplant donor coordinators programmes.<br><br>(c) Promote the Implementation of effective training programmes for transplant donor coordinators<br><br>(d) Promote the establishment of national or international accreditation schemes for transplant donor coordinators | It could contribute to this action of the action plan as it will require adequately qualification for the personnel directly involved in activities relating to the donation, procurement, testing preservation and distribution of human organs. It will also require adequate training. | It could contribute to this action of the action plan as it will require adequately qualification for the personnel directly involved in activities relating to the donation, procurement, testing preservation and distribution of human organs. It will also require adequate training. |
| **Priority action 2**<br><br>**Promote Quality improvement programmes in every hospital** | No current action at EU level. Could be a future objective under the public health programme | The action plan should designate this action as a priority, and promote its implementation | The Directive could contribute as it will request Member States to put in place national quality | The Directive could contribute to this objectives as it will request that Member States take all |

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| **where there is a potential for organ donation** | Donor action is a private, non for profit Foundation that develops training programmes, having activities in hospitals of 10 European countries. DA has been able to increase donation rates with 50 to 70% | thought:<br><br>(a) Incorporating in the national action plans the objective of gradually put in place quality improvement programmes in every hospital where there is a potential for organ donation. Design indicators to monitor this action.<br><br>(b) Promote the accessibility to specific methodology on quality improvement programmes. | programmes based on the principles of good practice which establishes standardised protocols. These programmes should be implemented and maintained throughout the entire process, from donation to transplantation, to ensure the compliance of the quality and safety requirements laid down in this framework.<br><br>Donation quality improvement programme could be easily incorporated. as part of the national quality programmes. | necessary measures to ensure that each establishment puts in place and updates a quality system based on the principles of good practice which establishes standardised protocols.<br><br>A donation quality improvement program could be incorporated also in the establishments as part of the quality system. |
| **Priority Action 3**<br><br>**Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors** | DG SANCO under the public health programme is running a project: EU living donor focused on To contribute to create a consensus on European common standards regarding legal, ethical, protection and registration practices in relation to organ living donors in order to guarantee these donors health and safety. | The action plan should designate this action as a priority, and promote its implementation thought:<br><br>(a) Creating a consensus on European common standards regarding legal, ethical, protection in relation to organ living donors.<br><br>(b ) Incorporating in the national action plans the promotion of altruistic donations programmes from living donors, on the basis of appropriate safeguards concerning the protection of the living donors and the prevention of organ trafficking. Sharing best practices from those MS more advanced.<br><br>(c) Promote registration practices | The Directive will contribute as it will establish rules for the protection of the living donor, and the registration of these activities. | The Directive will contribute as it will establish rules for the protection of the living donor, and the registration of these activities. |

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| | | regarding living donors to evaluate and guarantee their health and safety | | |
| **Priority Action 4 Increase Public awareness.** | No current action at EU level. Could be a future objective under the public health programme | The action plan should designate this action as a priority, and promote its implementation thought:<br><br>(a) Promotion of donation campaigns focus in specific groups and populations<br><br>(b) Facilitate the identification of organ donors across Europe in order to increase organ availability<br><br>(c) Improvement of knowledge about transplantation issues by health care professionals, the media and the general public | The Directive could contribute as donation rates in all countries depend on public confidence in the use of organs in therapy, and it is therefore essential that EU provisions ensure their quality and safety at similar level in the EU. A problem in one country can affect others, too.<br><br>People in a foreign country may become donors. Last year in Spain close to 10 % of the donors were foreigners, more than 50% of these were Europeans. This has steadily increased from 2 % in 2000. Legal certainty is needed to ensure that the organs available for therapy are not wasted. On the other hand, citizens also need to have trust and certainty in their handling by the donation system in the foreign country. | The Directive could contribute as donation rates in all countries depend on public confidence in the use of organs in therapy, and it is therefore essential that EU provisions ensure their quality and safety at similar level in the EU. A problem in one country can affect others, too.<br><br>People in a foreign country may become donors. Last year in Spain close to 10 % of the donors were foreigners, more than 50% of these were Europeans. This has steadily increased from 2 % in 2000. Legal certainty is needed to ensure that the organs available for therapy are not wasted. On the other hand, citizens also need to have trust and certainty in their handling by the donation system in the foreign country |
| **Priority Action 5**<br><br>**Facilitate the identification of organ donors across Europe and cross border donation in** | No current action at EU level. | The Action plan will focus on Collecting and disseminate information about citizen's rights concerning organ donation across the EU, and will explore | Common quality and safety rules of donor protection will reassure families and donors trust in the transplantation systems. | Common quality and safety rules of donor protection will reassure families and donors trust in the transplantation systems |

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| **Europe** | | mechanisms to facilitate the identification of cross border donors | | |
| **Priority Action 6**<br><br>**Enhancing the organisational models of organ donation and transplantation in the EU Member States** | No current action at EU level.<br><br>Some general indications were the results of Alliance O project funded by RTD (ERANET coordination action) . The project had 7 Member States partners (UK, Spain, France, Italy, Germany, Poland and Hungary). The project finished in 2007. A follow up group intends to meet regularly to continue the work on organ allocation tools.<br><br>The Committee of transplantation of the Council of Europe meets one-two times per year. This is however a technical committee of experts. | The action plan should designate this action as a priority, and promote its implementation thought:<br><br>(a) Ad hoc recommendations of the committee of experts to Member States on the basis of the regular reporting to be included in the national actions plans<br><br>(b) Promotion of twinning projects and peer reviews<br><br>(c) Assessment on the use of structural funds and other community instruments for the development of transplantation systems<br><br>(d) Promoting the development of transplant centres of excellence | The Directive could contribute as it will request to put in place the basic structure needed for a safe and quality performance of the transplant systems.<br><br>It will create competent authorities in Member States that will have a role of oversight. The committees of competent authorities will be a perfect body to discuss the different national plans.<br><br>It will also require the collection of information on transplant activities, needed to evaluate and design policies in this field. | The Directive could contribute as it will request to put in place the basic structure needed for a safe and quality performance of the transplant systems.<br><br>It will create competent authorities in Member States that will have a role of oversight. The committees of competent authorities will be a perfect body to discuss the different national plans.<br><br>It will also require the collection of information on transplant activities, needed to evaluate and design policies in this field. |
| **Priority action 7**<br><br>**Promote EU-wide agreement on issues concerning transplant medicine** | No current action at EU level.<br><br>The main European organ exchange organisations (EOEOs) (Eurotransplant, Swiss transplant, Italian Transplant Centre, Hungaro transplant, UK Transplant, Organização Portuguesa de Transplantação, Etablissement Français des Greffes, Skandiatransplant<br><br>Poltransplant, Greek transplant | The action plan should designate this action as a priority, and promote its implementation thought:<br><br>(a) EU Wide agreement on basic rules for internal EU patient mobility and transplantation<br><br>(b) EU-wide agreement on all issues concerning transplant medicine for extra-Community | Having common standards and equivalent systems for authorisation of activities could indeed contribute to these EU Wide agreements.<br><br>The Directive will provide this common ground. | Having common standards and equivalent systems for authorisation of activities could indeed contribute to these EU Wide agreements.<br><br>The Directive will provide this common ground. |

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| | organisation and the Spanish Organización Nacional de Transplantes, ) meet on a regular basis. Normally once a year.<br><br>The Committee of transplantation of the Council of Europe meets one-two times per year. This is however a technical committee of experts. | patients<br><br>(c)EU Wide agreement on monitoring organ trafficking<br><br>(d) EU Wide agreement on common priorities and strategies on future research programmes | | |
| **Priority Action 8**<br><br>**Facilitate the interchange of organs between national authorities** | No current action at EU level.<br><br>European Organ Exchange organisations will continue to meet once a year and will continue with its informal agreements.<br><br>Eurotransplant and Scandiatranlant areas will continue with the high level of exchanges:<br><br>The Eurotransplant International Foundation is responsible for the mediation and allocation of organ donation procedures in Austria, Belgium, Germany, Luxembourg, the Netherlands Croatia and Slovenia. The Eurotransplant region numbers well over 118 million inhabitants.<br><br>Scandiatransplant is a Nordic organ exchange organisation and it covers a population of 24 million inhabitants in five countries | The action plan should designate this action as a priority, and promote its implementation thought:<br><br>(a) Systems for offering surplus organs to other countries can be evaluated<br><br>(b) Systems for the exchange of organs for urgent patients and difficult-to treat patients | The Directive will contribute because for the optimal treatment of specific patients the available organs should be able to cross borders without unnecessary problems and delays. National legislations differ between Member States. A national approach could not ensure the same minimum standard of quality and safety for organs and the smooth exchange.<br><br>Any organ exchange should precise minimum quality and safety standards and a uniform donor data set, both will be provided by the Directive. | The Directive will contribute because for the optimal treatment of specific patients the available organs should be able to cross borders without unnecessary problems and delays. National legislations differ between Member States. A national approach could not ensure the same minimum standard of quality and safety for organs and the smooth exchange.<br><br>Any organ exchange should precise minimum quality and safety standards and a uniform donor data set, both will be provided by the Directive. |

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| | Some bilateral agreements on concrete programmes between MS will persue (e.g.Spain with Portugal, France and Switzerland or Italia and Slovakia). | | | |
| **Priority Action 9**<br><br>**Evaluation of post transplant results** | No current action at EU level. Could be a future objective under the public health programme<br><br>A project funded by DG RTD; DOPKI is looking into a register of rare diseases and guidelines for the assessment of these type of expanded donors.<br><br>DOPKI, focus on improving knowledge and developing applicable methodology that could be used to increase the potential of organ donation. In order to achieve such an objective, the project aims to promote cooperation and sharing of information and practices among seven EU countries | The action plan should designate this action as a priority, and promote its implementation thought:<br><br>(a) Develop common definitions of terms and methodology to evaluate the results of transplantation<br><br>(b) Development of register or network of registers to follow-up on organ recipients<br><br>(c ) Elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results, specially for the use of expanded donors | Fully complement the Directive and vice versa | Fully complement the Directive and vice versa |
| **Priority Action 10**<br><br>**Promote a common accreditation system for organ donation/procurement and transplantation programmes** | No current action at EU level. Could be a future objective under the public health programme | The action plan should designate this action as a priority: The aim is to develop methodology that could support the EU legal framework for the accreditation of programmes of organ donation, procurement and transplantation. This could help to build a common voluntary accreditation system at EU level. | Fully complement the Directive and vice versa | Fully complement the Directive and vice versa |

## ANNEX III -FOUR SCENARIOS OF FUTURE TRANSPLANTATION RATES

## METHODOLOGY: Scenario Development and Data Analysis

Data from *International Figures on Organ Donation and Transplantation Activity Year 2006*[1] is used for the quantitative scenario analysis.
Table A2 gives the organ types from the 2006 data that are used for the analysis.

Table Type of Organ Transplant

| | |
|---|---|
| Deceased | Kidney |
| | Liver |
| | Heart |
| | Lung |
| Living | Kidney |
| | Liver |
| Paediatric | Kidney |
| | Liver |
| | Heart |
| | Lung |

SOURCE: Council of Europe 2007

From the 2006 data, it has been observed that Spain has better transplantation rates as well as donation rates, compared to EU countries. On these grounds, four possible scenarios are defined to capture not only the most optimistic (but perhaps unrealistic) situation where all Member States reach the highest current donation rates (i.e. Spanish level), but also the 'most likely' situation where Member States achieve a moderate level of the European average.

The types of scenarios that are developed are given in the Table below. The procedure for developing these scenarios is explained in the next section.

Table Description of the scenarios

| **Transplant rate assumptions** | **Scenario 1** | **Scenario 2** | **Scenario 3** | **Scenario 4** |
|---|---|---|---|---|
| **Description** | All countries achieve the transplantation rate of the best performing country* | All countries achieve at least European average transplantation rates | All countries improve their transplantation rate by 30% | All countries improve their transplantation rate by 10% |
| **Transplantations from deceased donors** | | | | |

[1] {Council of Europe, 2007 #4}

| | | | | |
|---|---|---|---|---|
| Kidney, from deceased donors | At least Spanish rate 46 pmp | At least European average: 29.1 pmp | +30% | +10% |
| Liver, from deceased donors | At least Spanish rate 23.1 pmp | At least European average: 12.3 pmp | +30% | +10% |
| Heart | At least Spanish rate 6.1 pmp | At least European average: 4.3 pmp | +30% | +10% |
| Lung | At least Spanish rate 3.8.pmp | At least European average: 2.5 pmp | +30% | +10% |
| **Transplantations from living donors** | | | | |
| Kidney, from living donors | At least Norwegian rate 17 pmp | At least European average: 5.4 pmp | +30% | +10% |
| Liver, from living donors | At least Spanish rate 0.4 pmp | At least European average: 0.5 pmp | +30% | +10% |

*If national rates are higher, the higher national rate is maintained for these countries.

## Development of Scenarios

### Scenario 1

The transplant rates of each organ type for each country are calculated using the equation:

$$\mathbf{R_{cx} = O_{cx}/POP_c}$$

Where, $R_{cx=}$ Transplantation Rate for organ type *x* for country *c*
$O_{cx}$= Transplants for organ type *x* for country *c*
$POP_c$= Population of the country *c*

Spanish rates are used as the base for all transplant types excluding Living Kidney transplants, for which the Norwegian rate is used. The number of extra organs, if required, for each EU country to reach the Spanish rates (and Norwegian rate for Living Kidney transplants) are calculated using the following equations:

$$\textbf{Extra Organs Required} = (R_{sx}-R_{cx})*POP_c$$
$$\textbf{Extra Living Kidneys} = (R_{nx}-R_{cx})*POP_c$$

Where, $R_{sx=}$ Transplantation Rate for organ transplant type *x* for Spain
$R_{nx=}$ Transplantation Rate for organ transplant type *x* for Norway

**Scenario 2**

The average European Transplantation Rate for each organ type is calculated using the equation:

$$(AVE)_x = (OA)_x / \text{Tot.Pop.}$$

Where, $AVE_x$ = Average European rate for the organ transplant type *x*
$OA_x$= Total number of organs in the EU for organ transplant type *x*
Tot. Pop. =Total Population of the EU

The organ transplant types for each EU country having transplant rates less than the EU Average rate for that organ type are identified, and the extra number of organs required for that particular transplantation to reach the EU level is calculated using the following equation:

$$\textbf{Extra Organs Required}=[(AVE)_x-R_{cx}]*POP_c$$

**Scenario 3**

This scenario is arrived at by assuming a strong improvement in donation rates of 30% in the EU. The number of organs required to reach this donation rate are estimated in the following way:

**Extra Organs Required = Total number of Transplants per each organ transplant type * 0.3**

**Scenario 4**

This scenario is arrived at by assuming a slight improvement in donation rates of 10% in the EU. The number of organs required (if the country is not up to EU level) to reach this donation rate are estimated as follows:

**Extra Organs Required = Total number of Transplants per each organ transplant type * 0.1**

After the development of these scenarios, the type of organ transplants considered are further aggregated into four types Kidney, Liver, Heart and Lung transplants.

### Quality Adjusted Life Years Gained

The total number of Quality Adjusted Life Years (QALYs) gained for a scenario is the product of the number of the QALY's gained for each type of transplant and the number of transplants for each transplant type in that scenario, as below:

$$QALY_{isc} = QALY_i * O_{isc}$$

Where, $QALY_{isc}$ =Total QALY's gained for transplant type *i* in scenario s for country *c*
$QALY_i$ = Quality life years gained for each organ transplant type *i*
$O_{isc}$ = Number of organs *i* in scenario *s* for country *c.*

The number of QALYs gained for each type of organ transplant is given in the next Table .

Table QALYs gained for each organ transplant

| Tx (Transplantation Type, *i*) | QALY's gained |
|---|---|
| Kidney transplant | 3.1 |
| Liver transplant | 11.5 |
| Heart transplant | 6.8 |
| Lung transplant | 5.2 |

SOURCE: {Department of Health, 2008 #2}

### Productivity Estimation

The total Productivity is estimated by the following equation:

$$P_{isc}=W_c * LY_i * O_{isc}*EP_i$$

Where, $P_{isc}$= Productivity (in currency of the respective country) for organ transplant type *i* in scenario *s* for country *c*
$W_c$ = Average wage of a production worker in country *c*
*(*Source: OECD Health Data, July 07)
$LY_i$ = Life Years gained for organ transplant type *i*
$O_{isc}$ = Number of organs *i* in scenario *s* for country *c.*
$EP_i$ = Percentage of people employed after undergoing transplant type *i*

The next table shows the life years gained for each transplant type and the percentage of people employed after the transplant (assuming that every organ available and transplanted is successful).

**Table Life years gains and percentage of employed people after each transplant**

| Tx(Transplantation Type) | Life years gained | Employed after Tx |
|---|---|---|
| Kidney[1] | 2.0 | 47% |
| Liver[2] | 16.5 | 27% |
| Heart[3] | 6.0 | 39% |
| Lung[3] | 3.5 | 39% |

SOURCES: 1) Matas et al (1996); 2) Saab et al (2007); and, 3) Petrucci et al (2007)

Cost Estimation

Thirty-year discounted costs are estimated for each type of organ transplant (using UK wide data) from the following equations:

$$C_{isc} = HE_c * O_{isc} * pcf_i$$
$$pcf_i = N_i / HE_{UK}$$

Where, $C_{isc}$ = 30 Year discounted cost for organ transplant type *i* in scenario *s* for country *c* (In Euro)
$HE_c$ = Health Expenditure per captia for country *c* (Source: OECD Health Data)
$O_{isc}$ = Number of organs *i* in scenario *s* for country *c*.
$pcf_i$ = Per captia factor for organ transplant type *i*.
$N_i$ = 30-year discounted net costs per donor for organ transplant type *i*
$HE_{UK}$ = Health expenditure per captia in United Kingdom

The tavble below shows the discounted net costs (UK wide) for each type of transplant from 50% increase in donation rates.

**Table 30 year discounted net costs for each type of organ transplant**

| Cost component by organ type | 30-year discounted net costs (UK wide) from 50% increase in donation rate (£) | Donors baseline | Donors 50% increase | Difference | 30-year discounted net costs per donor ($N_i$) (£) | Per capita factor ($pcf_i$) |
|---|---|---|---|---|---|---|
| Kidney[1] | - 73,952,000 | 1914 | 2576 | 662 | -111,710 | -66.30 |
| Liver[2] | 23,816,000 | 610 | 911 | 301 | 79,123 | 46.96 |
| Heart[3] | 7,694,000 | 764 | 1147 | 383 | 20,089 | 11.92 |
| Lung[3] | 8,044,000 | 116 | 174 | 58 | 138,690 | 82.31 |

SOURCES: 1) Matas et al (1996); 2) Saab et al (2007); and, 3) Petrucci et al (2007)

## ANNEX IV THE SPANISH MODEL

The Spanish Model is widely acknowledged as an outstanding example of how organisational changes of the transplantation system can increase the number of available organs. Based on the premise that the greatest barrier to organ transplantation was not a lack of suitable donors but the failure to identify and "convert potential into real donors" the Spanish Government founded the National Transplant Organization (ONT) in 1989 and began to set up a nationwide system to monitor potential organ donors.2 Since then, the ONT coordinates and facilitates the donation, extraction, preservation, distribution, exchange and transplantation of organs and tissues for the Spanish health system. The agency is attached to the Ministry of Health. Each Autonomous Community, however, has sovereignty over the issuing of accreditations for the extraction and transplantation of organs and tissues.

The responsibilities and activities of the ONT include the following:

- maintain and manage waiting lists of patients for organ transplant;
- coordinate transplant processes;
- produce statistical data on organ and tissue transplants;
- promote continuing education, training and research in the field of organ donation and transplant (including training for healthcare professionals on all aspects of organ transplants, such as approaching grieving families, drawing up registries of potential donors, donor maintenance, and so forth);
- provide information to all stakeholders involved in organ donation and transplant;
- provide a 24-hour, 7-day-a-week phone service for public enquiries;
- collaborate with relevant national and international organisations with the aim of promoting organ donation and transplants.

The reorganisation of the Spanish procurement and donation system in 1989 increased donation rates by more than 130% within ten years. In 1989, 14.3 organs per million population were donated, in 1999 already 33.6 organs per million population were donated, and donation rates have since stabilised at this high rate - Spain has the highest donation rates in the world. In 2006 a total of 35.52 organs per million population (pmp) were donated among 17 autonomous health regions. The variation across the 17 health regions in Spain ranges from 24.4 to 48.4. The top 20% of health regions have donation rates ranging from 42 to 48.4 organs pmp. These increases have been the result of changes in logistics and process management.[3] In particular, the success of the Spanish approach to organ donation is commonly attributed to five interlinked elements of the Spanish system:[4]

[2] Miranda, et al. (1999).

[3] Healy (2006).

[4] See e.g. Miranda, et al. (1999).; Matesanz and Miranda (2002);Matesanz (2003).

1. The presence of hospital co-coordinators and coordinating teams in hospitals is one of the most salient features of the system (smaller hospitals may have only one or two healthcare professionals involved in transplant management). This 'grass roots' approach to the hospital-level management of transplants ensures that hospitals are involved and accountable for performance within the system. From 1989 the number of transplant coordinator teams rose from below twenty to 139 in 1998 [5,6]

2. The second crucial feature of the Spanish model is the system of funding and reimbursement to hospitals for organ transplant activity. Small hospitals which are not able to finance the entire transplant operation are reimbursed by the relevant authorities. This system, and the non-pecuniary support provided by the national and regional transplant authorities, enables these small hospitals to be involved in the transplant process.[7]

3. The third element is a comprehensive quality assurance system. The ONT has developed a quality assurance system (or programme), to control the process of organ and tissue donation, extraction and transplantation set up in 1998 with the aim to identify weakness in the process and develop ways to make improvements that would maximise the potential in organ transplants, including the pool of potential donors. The programme is in place in all Autonomous Communities. The programme consists of evaluations in each participant hospital, which is conducted in two phases. The first phase is an *internal evaluation* carried out by the transplant co-ordinating team in each hospital. The team reviews all clinical histories of deaths within the hospital's Intensive Care Unit and provides the ONT with a description of the circumstances, including the reasons for why a patient is not a donor. This evaluation must be conducted at least every three months. In the second phase, an *external evaluation* is conducted by a transplant coordinating team from another hospital, in which the data collected is verified, the efficiency of the process of organ donation and extraction is assessed, and areas for improvement are identified.

4. Adequate training of involved staff, in particular transplant coordinators has been identified as a key success factor in Spain. The Spanish case shows that family refusals, which are one key reason why potential donors are not used, can be substantially reduced if staff are well trained to adequately respond to and support the grieving relatives of deceased donors.[8]

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[5] Miranda, et al. (1999).

[6] Matesanz (2001).

[7] See for example: Miranda, et al. (2003).

[8] Matesanz (2001).

5. An important element in the Spanish Model is the adequate, proactive management of mass media opportunities. Much attention has been given by the ONT to informing the media, and to the provision of systematic and comprehensive, sensitive information to both healthcare professionals and the lay public about organ donation and transplantation *through* media outlets. Researchers have argued that the use of mass media in Spain on the issue of organ donation has greatly influenced the creation of a positive social atmosphere around organ donation and transplantation.[9] However, the Spanish did not invest heavily in public awareness campaigns or similar measures due to shortages of funds.

Previous efforts to adopt the Spanish model in other countries, in particular in Italy and South America, show that the Spanish model could be totally or partially replicable in other countries, but its effectiveness depends on a number of conditions. These include: the presence of universal healthcare provision, adequate reimbursement to hospitals on the basis of transplant activity, the availability of capacity within the medical community to develop expertise in the field, an adequate ratio of nurses to ICU beds/patients, and adequate availability of facilities for donor patients (Matesanz, 2003).

[9] Matesanz and Miranda (2002).. Also: Matesanz and Miranda (1996).

## ANNEX V- BACKGROUND ADFDITIONAL INFORMATION ON IMPACTS

### Health Impacts

### Donation and transplantation rates

- In re-organising its procurement system in the early 1990s, Spain substantially increased its donation rates. This can mainly be attributed to changes in logistics and process management.[10]. The positive effects of **Spain**'s model for improving processes have come from training and organisational innovation to improve the process of organ procurement,[11] namely training/personnel; inspections and control measures, or systematic audits, conditions of procurement and adequate reimbursement.

- Training programs for health professionals, specifically dedicated to every step of the donation process have contributed to the approach of obtaining consent from donor families.12 In addition, local transplant coordinators help increase the use of older donors who previously would not have been considered viable candidates for procurement.1314

- Similar positive impacts from these 'inputs' have been described for the Italian region of Tuscany. After regional transplant authorities in Italy copied the Spanish approach in its entirety, Tuscany alone "doubled its organ donation rate to 26.9 donors per million population in the space of just one year."15

- The health impact of instituting a formal responsible service of the Ministry of Health in Greece (i.e. the competent national authority) has been significant. Compared to 2001, the H.T.O. has resulted in 448% increase in potential donor referrals and 132% increase in transplantations performed.16 The latter results having a clear and significant health impact for patients.

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[10] Healy (2006).

[11] Matesanz (2001).

[12] Rosel, et al. (1999).

[13] Chang, et al. (2003).

[14] Miranda et al. (2003) attribute the 130% increase in donation rates over 10 years (from 14 to 34 donors per million population) to the permanent network of trained staff.

[15] Simini (2000).

[16] Karatzas, et al. (2007).

## QALYs and Life years

- In the UK, the average waiting time for an adult kidney transplant is 2.5 to 3 years while in Greece it is 5 years. In Poland, the mortality rate among patients undergoing dialysis treatment is about 13% per year, with cardiovascular illnesses being responsible for the majority of deaths.

- Estimates, on how improvement in donation process can result in QALY gains have also been conducted. For instance the DA Programme—demonstrated to increase donation rates by 59.2%—will result in 33 QALYs per million population17. In addition, we know that transplant coordinators help increase the use of older donors who previously would not have been considered viable candidates for procurement,18 leading to an amplification of QALYs gained as more organs become availability through policy measures to improve processes.

- In addition, by "enhancing the organisational model of organ transplantation" in Italy, ISMETT19 has had a clear positive health impact: one-year survival rates from transplantation (liver, kidney, heart, lung, pancreas) are 5-10% above the national average in Italy. More specifically, patients in the Liver Transplantation Program have over a 90% one-year survival rate and an 80% five-year survival rate, and the number of paediatric liver transplantations at ISMETT have risen steeply from less than 5 in 2003 to 30 in 2006—an increase paralleled in only Milan between 1997 and 1998.20

## Quality of life

- From the living donor perspective, living donors experience a boost in self-esteem and a greater sense of well-being: in one study, 96% of living kidney donors felt it was a positive experience and, in another study, 100% of kidney donors stated after donation that they would again favour it.21 Clemens et al. (2006) found that the majority of living kidney donors had no depression (77-95%) or anxiety (86-94%), with similar questionnaire scores as controls. In fact, Virzi et al (2007) found that there was somehow a reduction in depressive symptom frequency among donors from 37.5% to 33.3% and a decrease among 18 scores from 12.5% to 0%.

- In addition, Corley et al. (2000) determined that QoL scores were high for all donors and expected to improve in the next 5 years. Significantly

17 study by Roels et al (2003)

18 Chang, et al. (2003).

20 Gridelli (2008).

21 Cabrer, et al. (2003).

higher levels of predicted self-esteem and independence (i.e. mobility and choice of how to live one's life) were found in African-American donors, those with higher levels of education, and those who had recently donated a kidney. Nevertheless, some prospective studies describe a decrease in QoL after donation.22 Finally, while living donor kidney transplantation may not adversely affect the lives of donors and may significantly improve many aspects of the lives of recipients, physical and psychological aspects may be impaired by living donation.[23]

**Employment and social participation**

- The social outcome in a cohort of 366 French children who underwent kidney transplantation between 1973 and 1985 was investigated recently by Broyer et al (2004). The authors found that 73% of male patients (n=149) and 72% of female patients (n=95) had paid employment, whereas 6.5% and 10.5%, respectively, were unemployed.24

- In another study in the US, there was low pre-transplantation employment (39% of kidney-pancreas transplant recipients and 33% of kidney alone transplant recipients). However, post-transplantation, significantly more dual organ recipients were working (73%) compared with transplant recipients of kidney alone (27%). This US study also found that pre-transplant employment was independently associated with post-transplant work status. Similarly, in Italy, Petrucci et al (2007) found that having had an occupation previously and having been off work for less than 24 months were independent predictors of return to work: 87% of patients worked before thoracic organ transplantation and 39% of patients went back to work after transplantation and 3 of the 131 patients in total started working.25

- While there is thus little convincing evidence on social participation more general after transplantation, the literature provides some evidence on employment rates after transplantation, which were also used in this study to assess the productivity impacts of organ donation. Annex V Table 01 provides an overview of some estimates of employment rates after transplantation.

**Trust and confidence in the organ donation and transplantation system**

**Creating a competent authority**

[22] Clemens, et al. (2006).

[23] Virzi, et al. (2007).

[24] Broyer, et al. (2004).

[25] Petrucci, et al. (2007).

- While the evidence does not support the direct assessment of costs of establishing a national authority, there is evidence on the costs of the establishment of the Human Tissue Authority in the United Kingdom. The Human Tissue Authority is the national oversight authority to implement the EU Tissues and Cells Directive (EUTCD), and is responsible for licensing more than 500 establishments across five different sectors, and for approving donations of organs and bone marrow from living people.26 In creating a competent authority (as proposed in the soft Legal Directive), the total expenditure of HTA, as an example of a "new regulatory system," was over £2.8 million. Fifty two percent of the direct costs were related to staff salaries and include actions of investing in personnel who conduct the mandatory inspections and control measures. 27

**Authorisation of establishments**

- There is cost information available on the licensing of establishments under the Human Tissue Act in the UK. The Human Tissue Authority charges up to £ 7,600 for licensing an establishment.28 In Germany, the responsible authority charges up to € 25,600 for the licensing of tissue products.29

**Transplant coordinators**

- In an interview with the German DSO, our contact estimated the additional need for transplant coordinators to be around 80 to 90 staff in addition to the current 50 coordinators employed by DSO each at a cost of €60,000 to €70,000 for a physician coordinator and around €45,000 to €50,000 for a nurse coordinator. This would result in additional costs of between €4.8m and €6.3m for physicians and €3.6m and €4.5m for nurse coordinators.30

**Setting up and running national quality programmes**

6. Staff training courses form are another element of a quality programme. One provider of training courses for transplant coordinators reports costs of around €3,000 for an advanced training course as "organ donor

[26] HTA (2007).

[27] Ibid.

[28] http://www.hta.gov.uk/licensing/guide_to_licensing_and_application/fees_and_payment.cfm

[29] www.pei.de

[30] Interview with DSO official.

manager" at the local level and € 9,000 for a master programme as a "regional donor manager".[31]

7.

**Table. Information on national quality programmes in some European Countries**

| |
|---|
| One of the most comprehensive quality programmes is in place in **Spain**. The programme to control the process of organ and tissues donation, extraction and transplant was set up in 1998 with the aim to identify weaknesses in the process and develop ways to make improvements that would maximise the potential in organ transplants, including the pool of potential donors. The programme, in place in all Autonomous Communities, has also been adopted in other European countries (such as Italy) and in a number of Latin American countries. [32] |
| In **Germany**, there exist elements of a quality programme, but no systematic overarching programme. As an organisation, DSO is currently in the process of being ISO certified according to ISO:9001, and all transplant and procurement centres have to report their activities to DSO on an annual basis. In addition, organ donation and transplantation are covered by the Quality Assurance processes required by the general health legislation (§ 137 SGB V). The transplant and procurement centres have to report to the Bundesgeschäftstelle für Qualitätssicherung (BQS) on the performance of their activities. The BQS benchmarks this performance and targets outliers for in-depth scrutiny of processes and cases if necessary. This audit does however not include e.g. an analysis of the use of the donor pool. |
| In **Greece** there are no specific quality systems in place. Greece follows most of the European guidelines (CoE, EU, EOEO, ETCO/ESOT). Regarding donation, there is a minimum standard of information and criteria for suitability and quality of the donated organs. Ultimately, organ quality is a decision of the Transplant centres based on professional standards. |
| While following national and international guidelines in the process of transplantation, **Sweden** does not have a national quality programme for the whole transplantation process, due to its very decentralised infrastructure centred on the transplant centres and an only emerging role of national institutions such as the Swedish Council for Organ and Tissue Donation (donationsrådet). |
| In **Poland,** a quality and safety programme is emerging around four organ transplant databases/systems required and regulated by Polish law: a national transplant waiting list, national organ traceability system, national living donors' database, non-related donor bone marrow and umbilical cord blood |

[31] Personal communication SANCO- TPM

[32] ONT (www.ont.es)

database. It is envisaged that data in electronic form from all four databases/systems will be widely accessible when the systems are fully implemented and operating (work on the systems started in 2007). It would enable continuous safety and quality monitoring, reporting the data to and analysing the data by Ministry of Health and Quality in Medicine Monitoring Centre (Centrum Monitorowania Jakości w Medycynie) (currently Poltransplant produces reports on an annual basis).[33]

The **United Kingdom** has different elements of national quality systems already in place at all steps of the organ donation and transplantation, including transplant coordinators performance audit tool, a potential donor audit, best practice and staff guidance and medical follow up.

**Table** Quality Programmes in France, Germany, Hungary Italy and Spain (Alliance – O)

**Quality Programmes in France, Germany, Hungary Italy and Spain**

**Donation Sub-process**

In the majority of the countries, the local hospital is responsible for the phases of the donation sub-process, apart from some direct responsibility of the regional coordination or of the national organization. Moreover, the responsible unit is usually supported in the development of the activities by either the regional coordination or the national centre. All countries declared the presence of a quality programme made of trainings, procedures, guidelines and audits. Audits are deeply developed in France, Spain and UK, whereas the other countries developed a programme only for the phase of identification of a potential donor.

**Allocation Sub-process**

In this case most of the countries reported that the regional or the national organizations are responsible for the management of the phases belonging to the allocation sub- process. Laboratories and transplant centres usually cooperates with them for the development of some activities. All countries reported the presence of quality programmes as trainings, procedures, guidelines and audits. France, Hungary, Italy and Spain manage full procedure, guideline and auditing programmes either at a national level and/or at a local one.

**Transplantation Sub-process**

Transplant centres are the responsible units for the transplantation sub-process phases. In some countries transplant centres are supported by regional coordination, while in a few countries are supported by the national transplant centre. Italy, Spain and UK have a national auditing programme, while Germany, Hungary, Italy and UK apply procedures and guidelines to all

[33] Finansowanie, nadzór, monitorowanie, ocena jakości działalności transplantacyjnej w Polsce, PowerPoint presentation by Prof. Dr. Hab. med. Piotr Kalaciński, Przewodniczący Krajowej Rady Transplantacyjnej, from the Conference in Senate – Przeszczepianie narządów i szpiku. Potrzeby i możliwości. On 12th of June 2007 Available from <http://www.uniatransplantacyjna.pl/images/stories/senat/P_Kalicinski.pdf>, accessed 12Feb08.

phases, even though they are produced at different levels.

**Follow-up and quality of life sub-process:**

Transplant centres are responsible for the phases of the sub-process. In some specific cases, it is also foreseen the cooperation of the regional or national coordinating centre, this is the case of France, Germany, Italy and Spain. Quality programmes in this phase are not frequent: only Italy and Spain have an auditing programme in place, whereas Germany, Hungary and Italy developed procedures and guidelines regulating the phases of the sub-processes.

SOURCE: ALLIANCE-O (2007a)

8.

## Costs for setting up and running national registers and traceability systems

### Donor registers

9. The table below provides an overview of the existing registries in the Member States participating in the DOPKI project (without databases to register non-/consent.

10. In Sweden, registries for post mortem and living donation for traceability purposes are maintained at the transplant centre level. In Greece, the Hellenic Transplant Organization (HTO) maintains registries for organ & tissue donors and candidate recipients.
11.

### Existing registries in a sample of Member States

| Organisation | Country | Donor registry | | Recipient registry | |
|---|---|---|---|---|---|
| | | Post mortem | Living | From post mortem | from living |
| ./. | Austria | Yes* | Yes* | Yes* | Yes* |
| BTS | Belgium | On voluntary base in Tx centers-working group in the ministery of health | on voluntary base in tx centers | Database in tx centers, annual report for the Minister on the activities | Annual report for the Minister |
| MZSS | Croatia | | | | |
| KST | Czech Republic | Yes | Yes | Yes | Yes |
| ABM | France | Yes | Yes | Yes | Yes |
| DSO | Germany | Yes | Not at DSO | No, but annual report from tx-centres about activity | No |
| Hu-T | Hungary | No | No | Yes | Yes |
| CNT | Italy | Yes | Yes | Yes | Yes |
| Luxembourgtra | Luxembourg | Yes | Yes | Yes | Yes |

| | | | | | |
|---|---|---|---|---|---|
| nsplant | | | | | |
| NTS | Netherlands | Yes | Yes | Yes | Yes |
| Poltransplant | Poland | Yes | Yes | Yes | Yes |
| OPT | Portugal | Yes | Yes | Yes | Yes |
| Slovenija-Transplant | Slovenia | Yes | Yes | Yes | No |
| ONT | Spain | Yes | Developing | Yes | Included in the post mortem registry |
| Swisstransplant | Switzerland | Yes | Yes | Yes | Yes |
| UK - Transplant | United Kingdom | Yes | Yes | Yes | Yes |
| Eurotransplant | Netherlands | Yes | No | Yes | No |

* hospital based, ET based

SOURCE: DOPKI (2006)

12.

## Treatment costs

### All organs

13. The Organ Task Force in the UK modelled the impact of a 50% increase in donation rates on treatment costs over a thirty year period.34 Table VI Annex presents the cumulative cost effect and net savings35 from this increase in donation rates. Overall, the modelling shows that a 50% increase of organ donation rates would provide a net benefit, even without taking into account the additional life years saved and the gains in quality of life for the individual patients.

### Kidney

14. These benefits can be primarily attributed to the cost saving effects of kidney transplantation versus dialysis treatment. While transplantation has high initial costs, the post transplant costs are substantial lower than the dialysis costs, thus offsetting the initial investment.

### Liver, heart and lung transplantation

15. As a transplantation is the only available treatment for end stage liver, heart and lung diseases, the assessment of cost effectiveness is less clear cut, as there is no available treatment against which to compare the costs. In a situation of scarcity and decreasing resources for healthcare, transplantation has thus to be compared against other available treatments for other diseases. To do this, many countries use standardised effectiveness measures such as ICER (Incremental Cost-

[34] Ibid.

[35] At a discount rate of 3.5%

Effectiveness Ratios), comparing the costs for each life year, or each quality adjusted life year (QALY) gained. Treatments are considered cost effective, if they stay below a commonly accepted limit, which differs between societies.

**Productivity Impacts**

16. Besides the impact of treatment costs, organ transplantation can contribute to the economic performance of a country, by keeping people in the workforce or by allowing them to participate in the economy where they could not do so previously. A prime measure of productivity impact is the participation in the labour market. In a recent review, van der Mei et al. (2006) analysed seventeen studies, reporting employment rates after kidney transplantation ranging from 18% to 82%. For heart lung and liver transplantations, this number is lower and estimates are between 27% for liver transplants36 and 39% for thoracic organs.37

**Economic Impacts on Living donors**

17. Two studies reviewed produced an estimate of overall costs incurred by living donors, estimating the average costs at $ 837 per donor and $ 107 per donor. However the variation is very strong with, a range of $0 to $28,906 in the first study and $0 to $13,788 in the second study. These cost estimates are however likely to underestimate the true costs for the donors. Further on, this study cites estimates of lost income as another indirect impact of Living Donation. The study reports estimates of average losses of $3386 in the United Kingdom from one study, and $682 in another study from the Netherlands. Lost income from living organ donation affects between 14% and 30% of donors. In addition, the indirect costs for dependent care—an 'externality' of the organ donation pathway—were incurred by 9-44% of donors, while costs for domestic help were incurred by 8% of donors. Return to work usually occurs 16-105 days.

[36] Saab, et al. (2007).

[37] Petrucci, et al. (2007).

## ANNEX VI TRANSPLANT RISKS

### Transmission of communicable diseases

18. **Human immunodeficiency virus (HIV).** The majority of the cases of HIV-1 transmission through organ transplantation were described before the existence of the serological tests. However there are also cases of HIV-1 transmission described after the introduction of the tests, they were false negatives during the "window" period –the time delay between viral exposure and detectible antiviral antibodies.38 There are not cases described of HIV-2 transmission. The effectiveness of the transmission is difficult to know, but it is assumed that is nearly 100% through solid organ transplantation from a donor HIV positive39. HIVAc (+ ) donors carry a high risk of viral transmission, the infectivity of a small inoculum has been demonstrated by blood transfusion studies. All potential organ donors have been screened for HIV since 1985. The rare instances of HIV transmission despite negative HIVAc test results illustrate some limitations of serologic testing. In one instance, massive transfusion of blood and blood components decreased the antibody titer below the sensitivity limits of EIA. In a second case, transmission occurred from a donor during the "window period".The transmission through these false negatives should be prevented through a good clinical and behavioural history of the donor.

19. **Hepatitis B virus (HBV)** The cases of HVB transmission have decreased due to the serological screening, which normally includes Ag HBs test. Kidney was the first graft involved in a case of HBV transmission. There are studies that indicate that more than 1% of potential donors have an active HBV infection and over 12% in hyper endemic areas. 3-4% donors have a past history of HBV infection in countries with low prevalence like USA and over 10% in some European countries. The risk of transmission from donors with test against Antigen Hepatitis B (Ag HBV) positive is nearly 100%. However the transmission of HBV to the recipients is also possible from donors Ag HBV negative that have other serological markers positives40. The risk of transmission by liver transplantation from a donor with a serological antibody (HBVAb test positive against hepatitis B is higher because HBV resides principally within the hepatocytes.41 42 43 The donor's Hepatitis B Antigen status do not

[38] Green, et al. (2004)..

[39] Criterios de selección del donante de órganos respecto a la transmisión de infecciones. 2ª edición. 2004. Organizacion Nacional de Transplantes.
http://www.ont.es/Consenso?id_nodo=263&&accion=0&keyword=&auditoria=F

[40] Feng, et al. (2002).

[41] Frutos, et al. (2003).

[42] Dodson, et al. (1997).

mitigate transmission risks.44 This type of donors represent in some countries between the 5-15% of all donors.45

In contrast with liver transplantation, transplantation of kidneys from HBcore antibody positive donors seems to carry a minimal risk of clinical transmission. A meta-analysis of the literature shows that only 1 of 133 recipients converted to HBs Antigen positive after transplantation of a kidney from an HBc antibody positive donor.[46] [47] [48] It should be noted, however, that the actual rate of viral exposure as measured by development of anti-HBV antibodies (either HBsAb or HBcAb) is considerably higher. 27 % of kidney recipients from HBcAb + donors demonstrated seroconversion compared with 4% of kidney recipients from HBcAb - donors, for an odds ratio of 4.94 4.Some studies indicate that the risk of transmission is 15-78% for liver transplantation, 2% in kidney and 0% in heart transplantation.An additional problem that could be found in donors Ag HBs positive is the co-infection with the virus of hepatitis delta (VHD). It has been described the transmission of this virus trough kidney transplantation resulting on severe acute hepatitis.

20. **Hepatitis C virus (HCV)** Transplantation of an organ from an HCV+ donor is known to be an efficient mode of viral transmission 49 50 51 52. Approximately 5% of all potential donors in USA and Europe are positive for Antibody HCV 53 A positive HCV-RNA, indicative of viral replication, has been associated with a higher risk of transmission.54. The transmission from donors with RNA positive is estimated to be nearly 100%. The risk of transmission from a non RNA positive donor is not known. The consequences for the recipient of an organ from a HVC positive donor are the seroconversion in 50-67% of the cases and the percentage of development of hepatic disease is around 35%. Overall, limited available data validate the assumption that heart or lung transplantation presents a similar risk of HBV or HCV transmission as kidney transplantation. Finally with regard to outcome, no conclusions can be drawn because the specific impact of the donor's positive serology cannot be discerned from the available data.

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[43] Uemoto, et al. (1998).

[44] Dickson, et al. (1997).

[45] Data from ONT, Spain.

[46] Madayag, et al. (1997).

[47] Satterthwaite, et al. Ibid.

[48] Miranda, et al. (2003).

[49] Frutos, et al. (2003).

[50] Wreghitt, et al. (1994).

[51] Tesi, et al. (1994).

[52] Pereira, et al. (1995).

[53]Candinas, et al. (1994).

[54] Fishman, et al. (1996).

21. **Other Viruses** Human T- Linphotrofic virus (HTLV-I and II) is endemic in certain areas; out of these areas the prevalence of this infection is low (lower that 1 % or even 0.1%). Infection with HTLV progress after years or decades to associated myelopathy spastic paraparesis or to adult cell leukaemia/lymphoma (ALT); progression occurs in less that 1% and 2% respectively. Cases of ALT after transplantation have been reported.

West Nile virus (WNV) is a flavivirus which can cause meningoencephalitis. In the fall of 2002, transmission of WNV from a single donor to four organ donors has been reported. An additional case through liver transplantation has appeared. In August 2002, fever and mentalstatus changes developed in recipients of organs from a common donor; transmission of WNV through solid organ transplantation was suspected. Transplant recipients can acquire WNV in 1 of 3 ways: (1) transfusion transmission, (2) organ donor transmission, and (3) transmission in the community. Post transplant immunosuppression increases the risk of developing severe disease after WNV infection. In the general population, WNV causes severe neurologic disease in < 1% of infected patients. However, data from a seroprevalence study suggest that the incidence is as high as 40% in organ transplant recipients.Although prevention strategies are critical, there is disagreement within the transplant community about the use of nucleic acid testing for screening of organ donors for WNV because screening results can be affected by a number of factors, including local WNV activity, test availability, and test characteristics.

22. **Bacterial and fungal infections** A bacterial or micotic infection or colonisation can be present in 60 % of deceased organ donors and mainly affect the respiratory and urinary tract. Bacterial and fungal donor to host transmission with the allograft with result of loss of the infected graft or death of the recipient has been widely documented. Nevertheless an adequate antibiotic treatment of donor and/or recipient should prevent infection in the latter.

Micobacterium tuberculosis has been transmitted by transplantation, donor transmission accounted for approximately 4% of reported post-transplant TB cases in a large review of 511 patients.[55]

Transmission of histoplasmosis by transplantation has been described, but most cases appear to be the result of reactivation of past infection in the recipient. Transmission of Coccidiodomycosis by lung transplantation has also been reported.

23. **Parasitic infections** There are 342 parasitic species that are known to infect humans, mostly affecting those intropical and subtropical regions.[56] Recently however there are been a considerable spread of these infections to the rest of the world as result mainly of travel and

[55] Singh and Paterson (1998).

[56] Barsoum (2004).

migration. Only 5% of the known human pathogenic parasitic infections have been reported in transplant recipients.

Malaria transmission has been reported with kidney, bone marrow and multi-organ transplantation. Toxoplasmosis is a major concern particularly on heart transplantation. Toxoplasma has rarely been transmitted to liver and kidney recipients.

Transmission of Chagas diseases is a significant problem in endemic areas, and recently has been reported in the US.

24. **Prion infections** Creutfeld Jacob disease has been transmitted with treatment with growth factors and with transplantation of cornea and duramater grafts. In July 2004, the United Kingdom announced that a second instance of probable vCJD (new variant) transmission via blood transfusion had been identified. The patient received the blood donated by an individual who was confirmed in 2001 as a definitive vCJD case.

**Transmission of malignant diseases**

**Table B.1: Evidence on transmission of malignant diseases**

| Source | Findings |
|---|---|
| **United Network for Organ Sharing (UNOS) transplant tumour register**[57] | First report of the UNOS (1994-96) showed a frequency of donors with malignant cancer history of 1.7% and a rate of transmission of cancer from donor to recipient of 4.3%.<br>A more recent report from this registry (1994-2000 period) showed 14 donors with tumour from a total of 35.503 donors (4 per 10.000) and tumour transmission to 15 recipients of 109.749 transplants (1.3 per 100.000). The tumors transmitted were the following: 4 melanomas, 1 neuroendocrine tumor, 1 adenocarcinoma, 1 cancer of the pancreas, 1 nondifferentiated squamous carcinoma, 2 lung cancers, 1 small cell carcinoma, 1 oncocytoma, 1 papillary tumor, 1 breast cancer, 1 prostate cancer) |
| **Organización Nacional de Transplantes (ONT) register** | The frequency of donors with no detected tumour was 6.1 per 1000 donors during the last 15 years. Five of these donors transmitted the disease (2.9 per 10.000 donors). Ten recipients of the 155 that received an organ from a donor with undetected cancer developed a tumour (4.6%). The tumours transmitted were 1 sarcoma, 1 germ cells carcinoma, 1 undifferentiated carcinomatosis and two kidney carcinomas. |
| **Danish Register**[58] | Birkeland studied a cohort of donors during 27 years funding 13 malign tumours within 626 donors (2% of the donors) From these donor only one has transmitted the tumour (a melanoma) to the recipient (2 per 1000 donors) |
| **Centro Nazionale per i Trapianti (CNT) register** | The CNT has put in place a new strategy for the evaluation of donors since 2002. The analysis of the period 2001-2002 showed 2.9 % of donors with tumours. |
| **The Israel Penn International Transplant Register. (IPTTR)**[59] | The I. Penn register shows higher frequencies of tumour transmission that the ones above. During 1994-2001 it registered 68 recipients of organs coming from donors with renal carcinoma, with a tumour transmission in 43 of them (43%). 30 recipients of organs received from donors with melanoma, with tumour transmission in 23 (77%); 14 recipients received from donors with melanoma, 14 recipients with coriocarcinoma, with tumour transmission in 13 (93%). Other tumours that have presented transmission to recipients were lung (41%), colon (19%), prostate (29%), Kaposi Sarcoma (67%). |

SOURCE: DG SANCO 2003

[57] Kauffman, et al. (2000).

[58] Birkeland and Storm (2002).

[59] Feng, et al. Ibid.

## ANNEX VII

## IMPACTS BY POLICY OPTION

**HEALTH IMPACTS**

**Donation and transplantation rates**

If we use the assessment on the expected impact under high/low commitment and implementation from the Member States we would arrive at the increased number of transplantations depicted

**Possible increase in transplanted organs**

| Key element | Option 1: Baseline | Option 2: Action Plan | Option 3: AP + flexible approach* | Option 4: AP + stringent directive* |
|---|---|---|---|---|
| Low commitment and or low capacity Member States | No increase | No substantial increase | 2,636 to 4,983 | 2,636 to 4,983 |
| High commitment and sufficient capacity of Member States | | No substantial increase anticipated | 7,908 to 21,006 | 7,908 to 21,006 | 7,908 to 21,006 |

SOURCE: Europe

While the transplantation rate under Option 1 would remain stable, Option 2 could lead to a high increase in transplantations (between 7,908 and 21,006) - if Member States are committing to these largely voluntary measures, although there is a high uncertainty in this outcome. For Option 3 and 4, we expect at least a modest increase in transplantation to occur, even if Member States are reluctant to fully commit to improve their donation systems due to the mandatory nature of the proposal. Thus we expect a minimum increase of between 2,636 and 4,983 organs, and a maximum boundary defined by Scenario 3 and 1, i.e. a 30% increase in donation rates (a total of 7,908 more organs), or even transplantation rates of the current best performers Spain and Norway (21,006 more organs).

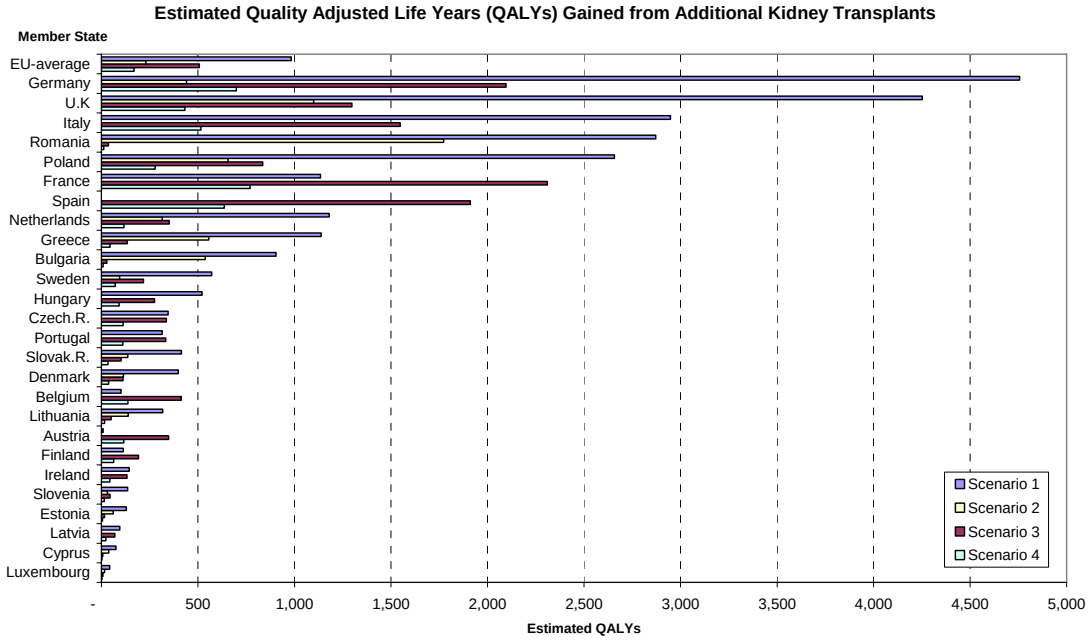
**QUALYs and live years**

The potential scope of the QALYs and Life years to be saved through policy measures in the field of organ procurement and donation can be assessed through the scenarios presented above. If the proposals lead to substantial gains in transplantation rates, more than 219,000 QALYs could be gained under Scenario 1 and at least 38,000, if transplantation rates would only slightly increase under Scenario 4. The gain in QALY and life years stem primarily from the transplantation of liver, lungs and hearts, as their currently exists no other life saving treatment. In turn, kidney transplantations predominately increase QALYs, while there are only modest increases in the number of life years that could be saved through increased transplantations of kidneys.

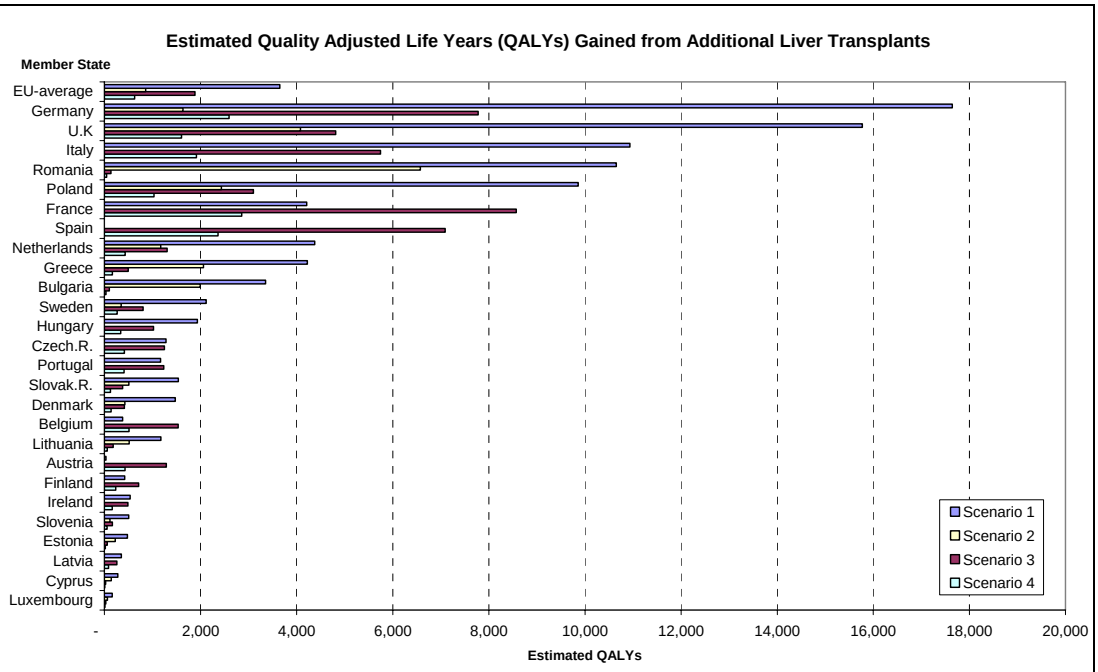
**Estimated QALYs and Life years gained**

| | Scenario 1 | | Scenario 2 | | Scenario 3 | | Scenario 4 | |
|---|---|---|---|---|---|---|---|---|
| | QALY | LY | QALY | LY | QALY | LY | QALY | LY |
| Kidney | 25,576 | 16,500 | 6,014 | 3,880 | 13,210 | 8,522 | 4,403 | 2,841 |

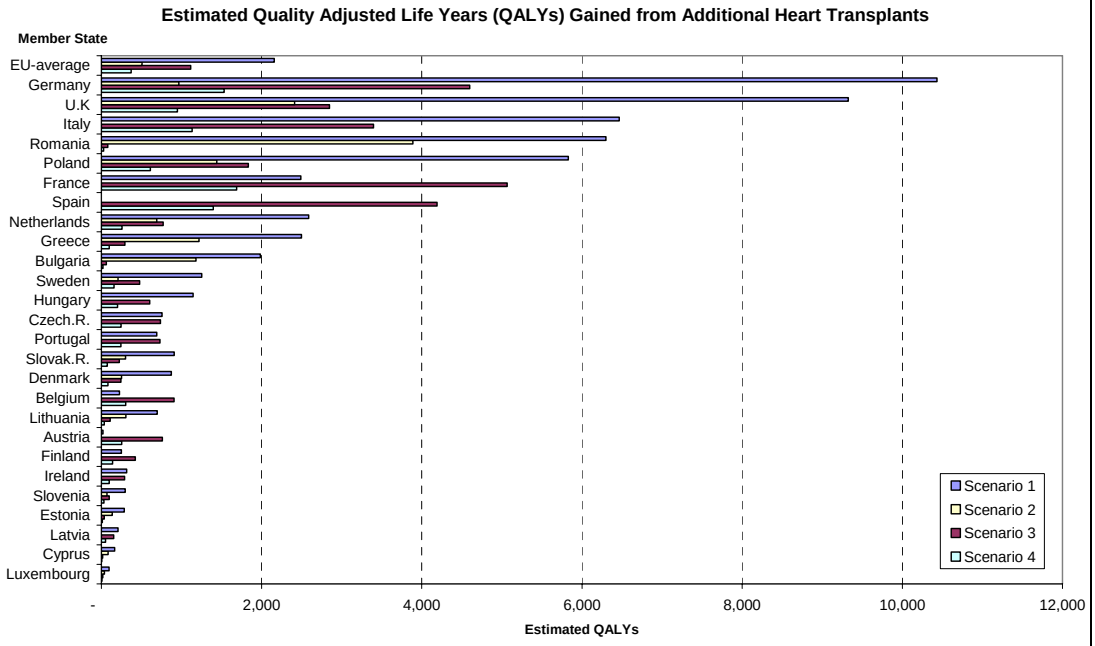
| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Liver | 94,877 | 136,128 | 22,310 | 32,010 | 49,004 | 70,310 | 16,335 | 23,437 |
| Heart | 56,101 | 49,501 | 13,192 | 11,640 | 28,976 | 25,567 | 9,659 | 8,522 |
| Lung | 42,901 | 28,876 | 10,088 | 6,790 | 22,158 | 14,914 | 7,386 | 4,971 |
| Total | **219,456** | **231,006** | **51,604** | **54,320** | **113,348** | **119,314** | **37,783** | **39,771** |



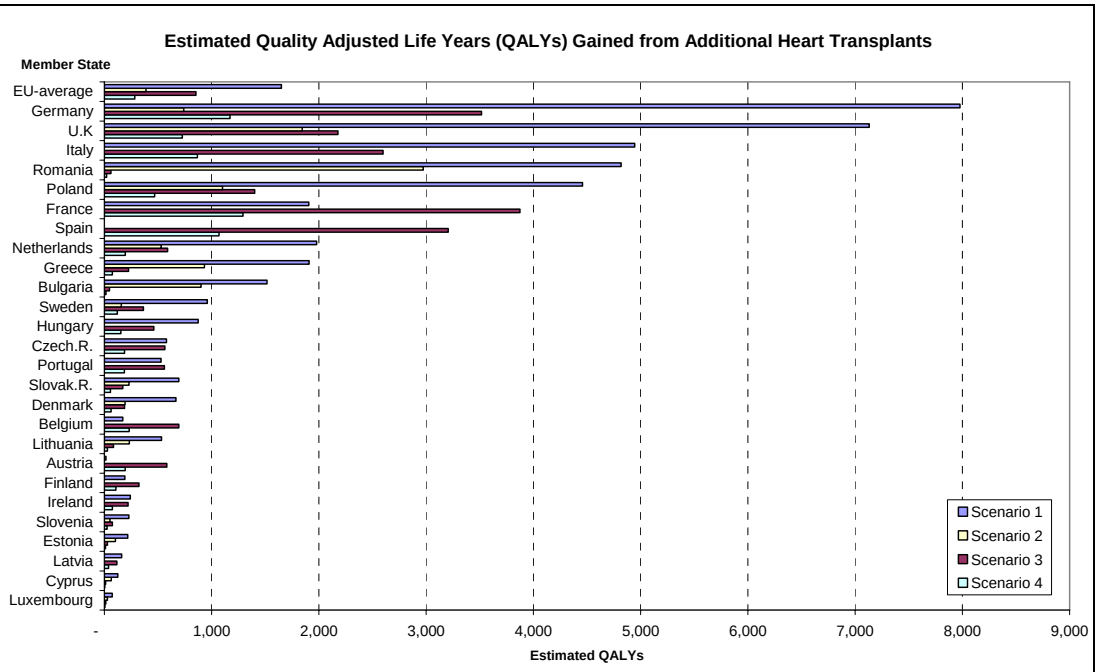

QALYs gained over 30 years through additional kidney transplantations




QALYs gained over 30 years through additional liver transplantations




QALYs gained over 30 years through additional heart transplantations




QALYs gained over 30 years through additional lung transplantations

If these estimates are assigned to the policy options ranges of possible life years saved and QALYs gained can be established for the policy options. The baseline Option 1 would not lead to additional life years saved and QALY gains, on contrary, under the assumption of stable donation rates, waiting lists are likely to further increase, which has negative repercussions on life expectancy and QALYs. First, with longer lists, patients are less likely to receive an organ, and secondly, if they receive an organ, they will be in a less good health condition, which reduces the QALY and LY gain per transplantation.

Under Option 2, the action plan, depending on the commitment of Member States substantial life year and QALY gains could be achieved. Using the estimates for Scenario 2 and 4, would give a maximum range of 119,314 to 231,006 life years to be gained, which would translate into a maximum of 113,348 to 219,456 QALYs, there is however a high level of uncertainty attached to this maximum estimate.

Due to their more stringent character, we expect Option 3 and 4 to reach a modest increase in donation rates with a high certainty, Using Scenarios 4 and 2, this would translate into 39,771 to 54,320 life years saved and a QALY gain between 37,783 and 51,604. The maximum effect that can be expected would be defined as for Option 2 as Scenario 1 and 3.

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| **Risk for patients** | Option 1 will lead to no changes in the currently diverse regulatory landscape of quality and safety standards across Europe. While there is a wide range of initiatives already to follow up medical results of transplantation and these different systems will be likely to further co-exist and improve, however no integration of system is expected across Europe. In addition, adverse events are not systematically captured in most member states leaving a large |

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| | potential to improve the processes of transplantation and donation as well as improving the medical outcomes of transplantation.<br><br>The action plan envisaged under Option 2 would introduce measures to improve the evaluation of post transplant results by agreeing on common definitions and by developing a European register or network of registers. While this option does not directly address the risks incurred by patients during transplantation, it will contribute to better treatment in the long term, as knowledge about transplantation outcomes increases.<br><br>Option 3 goes substantially further than Option 2 by establishing mandatory elements of European quality and safety standards. Under Option 3, common standards for the characterisation of organs would be established as the basis for organ matching and the decision-making of transplant teams. This data would be stored in such a way, that it can be transmitted quickly between Member States to facilitate the exchange of organs. Despite these European standards the final decision of transplanting a particular organ would still rest with the local transplant teams. The common system of organ characterisation would be supplemented with a reporting system for adverse events related at all steps of the organ donation and transplantation process. Overall Option 3 can be expected to reduce the risks for patients in countries with currently insufficient quality and safety standards and in addition supports cross border exchange of organs, which has been proven to be beneficial. Adverse event reporting systems have been proven to lead to improvements in the quality of processes and the quality of care, so the introduction of such systems will benefit patients in the medium and long term. Option 3 thus leads to substantial health benefits.<br><br>Under Option 4, similar quality and safety standards and adverse event reporting systems would be introduced, which will lead to the same positive health outcomes. The substantial difference is the regulatory approach. Option 4 would give the Member States less discretion in implementing standards and would even limit the decisions that can be taken by transplant teams, by e.g. defining a list of exclusion of certain types of organs |
| **Living Donation** | Option 1 will not change the current practice of living organ donation in European Member States, with a wide variation in donation rates and a large potential for increased donation and differing legal frameworks for the acceptance of living donation. Nevertheless, given the current organ shortage and witnessing the development in particular in the Nordic countries or the Netherlands, where living donation has become a very important substitute to donation from deceased donors, we can assume that even under option 1, the importance of living donation might increase in the medium and long term.<br><br>Option 2, in contrast, tackles three important elements of living donation: It would encourage Member States to ensure altruistic and voluntary donation while promoting living donation, it would promote the establishment of living donor registries to systematically follow up the health effects on the donors, and it aims to ensure adequate health protection and health care coverage for living donation. Estimates based on our scenarios see a maximum of 5,762 additional living donors possible across the EU, if all Member States would have living donation rates similar to Norway. As this is in particular under a voluntary agreement, a very optimistic assessment we would expect that under full commitment from Member States donation rates will be somewhat below this value.<br><br>However, it is clear that Member States could substantially increase their living donation rates if they learn from best practice. The second provision, the evaluation of the medical |

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| | status of living donors can contribute to bridging the current knowledge gaps about living donation and will help to decrease adverse effects for donors in the medium to long term. In addition, long term medical outcome data would help in providing more accurate advice to potential donors about the risks (health and other) of the donation. Finally the third provision, i.e. ensuring voluntary and altruistic donation, will reinforce national practice in the Member States and can contribute to building more trust in living donation in the transplantation pathway.<br><br>Options 3 and 4 are based on the action plan, but would anchor the protection of the living donor and the evaluation of outcomes in European law. While such legal protection would have no immediate effect on donation rates, this measure might increase the trust in the overall system and reinforce an increase in living donation rates. |
| **Exchange of organs** | Although the exchange of organs between Member States and with Third Countries is currently low, there are clear health benefits for special patient groups, including highly immunised patients, high urgency cases and paediatric patients. Under the baseline option 1, we expect numbers of exchange to remain largely stable, although slight increases are possible through emerging cooperation between Member States.<br><br>Facilitating the interchange of organs within the European Union is an identified priority action of the action plan under Option 2. Since it foresees the creation of improved and more efficient processes for offering surplus organs to other countries, in particular for urgent and difficult to treat patients, such measures are likely to increase the exchange of organs, as regional improvements show. And, as the importance of the exchange of organs for such patient groups in the Eurotransplant shows, any increase in cross border exchange will lead to benefits for difficult to treat and high urgency patients, in particular in small Member States that do not currently participate in international cooperation agreements.<br><br>Option 3 and 4 also enclose this provision, but supplement it by defining common quality and safety standards for the organs to be exchanged and by defining clear standards for the exchange of organs with non-Member States. Common quality and safety standards will both remove some barriers to organ exchange and ensure that the (increasing) exchange of organs is safe and adheres to best medical practice. As several stakeholders pointed out in our interviews, trust in other Countries' quality and safety standards is both important in their transplant teams' willingness to consider and accept organs, as well as in sending organs to other countries. It seems thus reasonably to assume, that Option 3 and 4 could further increase the exchange of organs, it is however important, that new authorisation requirements for the exchange of organs, do not lead to delays in the transport of organs, resulting in longer ischemia times and worse transplant outcomes. |
| **SOCIAL IMPACTS** | |
| **Quality of life** | As is apparent from the available evidence about the quality of life of organ recipients, it would be difficult to assess whether a policy intervention leads to an increased quality of life for individual organ recipients or donors, with the exception of living donation, there improved health care services might reduce some of the negative impacts on the QoL of organ donors. At the same time it is evident that increased donation rates will allow more patients to experience a better quality of life, which will be the main impact of the proposed |

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| | policy Options.<br><br>The status quo will persist under Option 1 and therefore it is unlikely that any change to the standard of living of organ recipients will occur. As there will be a wide variation in donation rates and differing legal frameworks, it is likely that there will continue to be diversity in the extent and level of quality of life experienced by organ recipients in Europe. Nevertheless, for those individuals who do receive a transplant, their standard of living will increase in terms of greater control over their lives and mobility through increased quality of life. For living donors, the mixed evidence on whether quality of life improves or worsens for these individuals underscores the great difficulty in predicting the baseline from which to compare the options.<br><br>There is potential for Option 2 to increase the quality of living organ donors as the Action Plan alone aims to protect their health by promoting the establishment of living donor registries to systematically follow up the health consequences of their altruism. Options 3 and 4 would make living donor protection a legal obligation, thus creating a higher level of protection for the living donors. Yet, it remains unclear whether these measures in themselves are sufficient to improve the standard of living of living donors by preventing or at least mitigating any adverse psychosocial outcomes. The main impacts are however to be expected from the possible increase in donation and transplantation rates. As Option 2, i.e. the Action plan without the supporting directive, is less likely to achieve large increases in donation; the positive social impacts of better quality of life for more patients will be smaller than for Option 3 and 4. Thus it is reasonable to expect that Options 3 and 4 will lead to higher standards of living for a greater number of transplant recipients, given that these policy options are intended to both increase the donation rates and improve the improved quality and safety of transplantation systems generally. |
| **Employment and social participation** | Policy Option 1 means that the current situation will basically continue with incremental improvements in treatment allowing for a small increase in social participation and employment. These small increases will be the same for all policy options as they are not likely and not designed to increase social participation and employment at an individual level, as none of the policy options will address the obstacles to employment and social participation identified in the literature. The options can however, through an increase in transplantation rates, increase the number of patients who will be able to work, either because their life has been saved or because they do not have to receive dialysis treatment three times a month. Based on this relationship we can expect better social impacts of policy Options 3 and 4, which would deliver increases in the donation rates with more certainty than Option 2. Overall the evidence base on the impact on social participation is still weak which has to be taken into account while assessing the options. |
| **Trust and confidence in organ donation and the transplantation system** | This section presented somewhat limited evidence on the trust and confidence impacts of the proposed policy options. Option 1 would see a continuation of the differences across Europe in trust and confidence. By promoting the role of trained transplant coordinators, which might involve training in management of potential donor families, Option 2 has the potential to increase the confidence of donors and donor families which might subsequently even lead to higher donation rates. Similarly, Option 3 and 4 support the training of key personnel |

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| | along the donation pathway which would support the action under Option 2. Quality and safety measures are, while encouraged under Option 2, primarily included in Options 3 and 4. These have the potential to improve the quality of the processes, and in particular they will establish a reporting system for adverse events. Such measures can increase the confidence in the transplantation system, in particular if the results of a quality and safety monitoring would be publicly available. The limited available evidence does not allow us to assess whether, for example, the existence of European quality and safety standards would have a positive impact on the general public's trust and confidence or whether measures to increase public awareness are a more efficient way of increasing wider trust and confidence in the system.<br><br>To summarise the comparison of options, we would expect positive impacts for all three options for donor families and transplant patients, with slightly higher benefits from Options 3 and 4 as these will make important elements of training and quality and safety mandatory. However, the evidence base for these qualitative findings is under-developed. |
| **ECONOMIC IMPACTS** | |
| **Start up and running costs for a national infrastructure and better processes** | Under **Option 1**, the status quo would continue. There would be no systematic change to the organ donation and transplantation infrastructure. It is reasonably to expect some countries to invest in improving the infrastructure and processes of organ donation, through quality programmes such as the Donor Action programme; however this will not lead to new costs for extending and running the national infrastructure<br><br>Although not prescribing the creation of a competent authority, **Option 2** implies that there is a national responsible body for reporting and liaising with the European Commission and the other Member States under the Open Method of Coordination. In addition, this option would promote quality programmes in the Member States and encourage the use of transplant coordinators, and finally tries to establish agreement on common accreditation standards for organ procurement and transplantation programmes. All of these measures would be on a voluntary basis and could take into account the current situation in the Member States to a maximal extent.<br><br>The designation of a competent authority, typically the department of health or a national organ donation agency would require little resources, as these organisations are typically already in place. The economic implication of the other measures to build up the national infrastructure depends on the Member States decision on how to implement common recommendations. Many Member States do already have some kind of quality system in place, run initiatives such as the donor action programme and do use transplant coordinators, which would reduce the costs of such measures. Accreditation and authorisation, as foreseen through common accreditation standards, might however involve substantial costs, judging from the available evidence from the UK and Germany and might in addition have the negative side effect of discouraging hospitals to participate in organ procurement. Similarly, increasing the number of transplant coordinators will create substantial running costs. Proposals to introduce transplant coordinators in the UK were costed at around € 14 million for 150 to 175 new transplant coordinators, i.e. a cost between € 80,000 to € 100,000 per transplant coordinator (including non pay costs), which is similar to estimates for Germany |

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| | of pay costs between € 45,000 and € 70,000 for a nurse or physician transplant coordinators. The total cost of this policy option will depend on the willingness and the necessity for Member States to increase the number of transplant coordinators.<br><br>Given the voluntary character of measures under the action plan, we would however expect the costs to Member States as being low under this action.<br><br>**Option 3** combines the measures of the Action Plan with supporting regulation: The requirement to designate a competent authority, the requirement for national authorisation schemes for transplant and procurement centres, the request to establish national quality programmes and enforcement and monitoring activities. There is little evidence available on how much the implementation of these flexible regulations would costs. The annual running costs of the Spanish National Transplantation Organisation of around € 4 million (≈ € 100,000 pmp), might give an indication of the maximum cost that would be incurred by implementing Option 3. As most Member States have substantial or some elements of such systems already in place, the additional costs can however be expected to be well below this boundary. The Donor Action, a quality programme for the procurement of organs costs as little as around € 8,000 annually per hospital, which illustrates that national quality programmes could be implement at relatively low costs.[60] For Canada, the running and maintenance costs of the Donor Action programme were estimated at € 45,000 pmp. Accreditation or authorisation of activities might create costs, depending on whether Member States would decide to designate or authorise/accredit activities. While the former can be achieved at no or very low additional costs, the latter might result in substantial additional burden In the UK licensing of facilities under the tissue and cell regime costs currently around € 10,000 per establishment. However, the majority of Member States runs some kind of authorisation and accreditation process already. If these costs are substantial, hospitals which are currently involved in organ procurement might however stop the identification of suitable donors all together, as they already nowadays feel, that they are not adequately reimbursed for the efforts of organ procurement.<br><br>**Option 4** covers the same policy measures as Option 3, but would introduce a more stringent approach, which would mean less discretion for the Member States in implementing the European initiative. Lesser discretion means however, that fewer elements of the current systems are already pre-compliant with the regulation and more changes to the current systems are required. Option 4 would use the same mechanism as Option 3 to establish competent national authorities, which should not result in substantial costs for Member States. The authorisation of activities would be prescribed in detail under Option 4, with separate authorisation programmes for each stage of the organ donation and transplantation process. In the comparison of options, this would lead to the highest costs for authorising activities, as Member States have to follow a common set of standards and cannot use their current authorisation schemes if existing. There is however not enough cost information available, to assess the costs of such an extensive authorisation activity. The cost information from the UK, which imply licensing costs of around €10,000 per establishment, would be incurred by not only the around 300 transplantation centres across Europe, but also by the much higher number of potential procurement centres, which basically are all hospitals with |

[60] This would e.g. result in total costs of around € 4.9 million for all 613 organ procuring hospitals in Germany.

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| | an ICU. Policy Option 4 proposes strict requirement, supported by an implementing directive, to put in place a quality programme in every hospital, rather than just prescribing a national quality programme as under Option 3. In most countries, such comprehensive quality systems are not in place yet and the proposed option would thus entail substantial cost. The € 8,000 per hospital or € 45,000 pmp for the Donor Action programme can be expected to be a lower boundary for costs per country to introduce a comprehensive quality system, as this quality programme, covers only the procurement and donation phase. In addition Option 4 clashes with the predominant form of governance in the Member States, in which quality control systems for procurement and transplantation of organs are established through guidelines rather than legal acts **Error! Reference source not found.**. |
| **Costs for setting up and running national registers and traceability systems** | As shown in the previous section, Member States do collect already substantial amounts of data about transplantation and organ donation and store information in various databases, however these systems are not necessarily integrated on a national level and data is provided to a multitude of recipients. Option 1 would leave the current system untouched and thus not create additional costs. However, this option would also do not help to achieve certain efficiency gains, if reporting about outcomes would for example be standardised across organ types and transplant centres.<br><br>The working plan foreseen under Option 2 would encourage Member States to develop systems to systematically evaluate post transplant results. Currently Member States, and often single transplant centres, provide medical outcome data voluntarily to various different registers and medical research projects, such as the Collaborative Transplant Study (CTS). As suggested by some stakeholders interviewed, common guidelines and a more centralised system of reporting have the potential to streamline this reporting, by reducing the number of places information has to be submitted to and the frequency of reporting. Clearly, this could lead to efficiency gains for transplant centres and Member States, while at the same time generating comparable data across the European Union.<br><br>Option 3 would supplement this voluntary improvement of the transplant result reporting by a requirement to introduce a publicly accessible register of establishments, a national donor register and traceability system, and a national adverse event reporting system, both complemented by European guidelines on the exchange of data between Member States. Given the small number of transplant centres, in each country (on average 28 transplantation programmes per country), a register of establishments will generate only marginal costs, in particular as it can be safely assumed, that the list of establishments is readily available and does not change frequently. The costs for a traceability and adverse event reporting system can only be roughly estimated. A British regulatory impact assessment of the tissue and cells directive estimated costs for a traceability system between € 130,000 and € 300,000 for the UK, with costs per establishment of € 550 and €1,300 per establishments. Costs per establishment would however be higher in the case of organ donation, as the number of transplant centres is low (e.g. 58 transplantation programmes in the UK, which would lead to per centre costs of between € 1,800 and € 4,100). This does not however take into account, the savings that could be achieved by integrating the organ traceability and vigilance system into the emerging reporting infrastructure for tissues and cells, and that some Member States |

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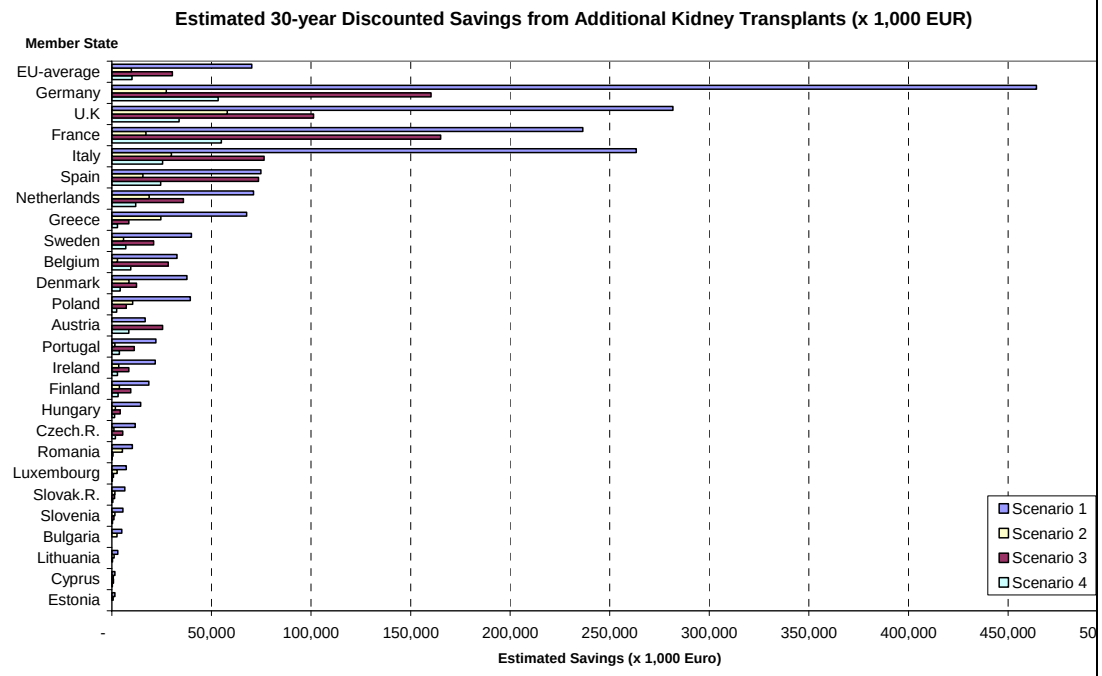
| | are already pre-compliant with the regulation.<br><br>Option 4 contains similar requirements as Option 3, but would base the traceability and adverse event reporting systems on a European directive, prescribing the characteristics of these systems in detail. There are no other cost estimates available for this option than for Option 3; however we can reasonably assume this option to be more expensive than Option 3. As shown in **Error! Reference source not found.** a substantial number of Member States has already some kind of traceability system in place, which would not necessarily comply with a uniform European system. While Option 3 would allow for some variation between Member States, Option 4 would not. This would clearly result in higher adaptation costs. |
| **Reporting obligation and administrative burden** | Each of the different options contains reporting obligations, potentially resulting in additional administrative burden for hospitals and Member States authorities.<br><br>Currently (**Option 1**) hospitals and Member States are reporting a variety of information to national and international bodies, including the Council of Europe, the supranational transplant organisations Eurotransplant and Scandiatransplant and international organisations such as the WHO. However, not all countries contribute equally to these national reporting systems. Option 1 would thus maintain this fragmented reporting at no additional costs for Member States and hospitals.<br><br>The Action plan foreseen under Option 2 would not fundamentally change this system, but would introduce reporting requirements under the open method of coordination, requiring to annually providing key data on donation and transplantation activities as well as progress in implementing the national action plans and quality programmes. As most of this data is already available, it can be assumed not to generate a high burden for Member States.<br><br>In addition, **Option 3** and **Option 4** require additional reporting about the activities of procurement and transplantation establishments, including the number of donors, the types and quantities of organs procured and transplanted or otherwise disposed etc. Option 4 would include a longer list of indicators. However, most of these indicators are already available, and should thus not put a major burden on the hospitals to collect and transmit this information to the competent authorities of the Member States. |
| **Treatment Costs** | Based on this evidence and not taking into account the value of a statistical life, it is clear, that a an increased number of kidneys will result in substantial cost savings, and that the costs of liver, heart and lung transplantation are usually considered to be cost-efficient, i.e. that costs do not exceed the commonly accepted limits of costs for treatment. As the treatment costs depend on the number of organs transplanted, we first present the possible ranges of treatment costs, before relating these to the policy options.<br><br>Using four scenarios calculated the impact on treatment costs across Europe. Table 11 provides an overview of the cost estimates of having additional transplants available. These savings would occur over a thirty year period for a single cohort of transplant patients, i.e. these would be the benefits of a single year of having high donation rates. Even in the most conservative scenario 4, assuming a 10% increase in transplantation from deceased and living donors, there would be substantial economic benefits of € 152 million across the |

European Union. Cost savings would even increase up to € 1,185 million in Scenario 1, which is the most optimistic scenario and assumes all countries would reach the transplantation rates of the best performers in deceased (Spain) and living donation (Norway).

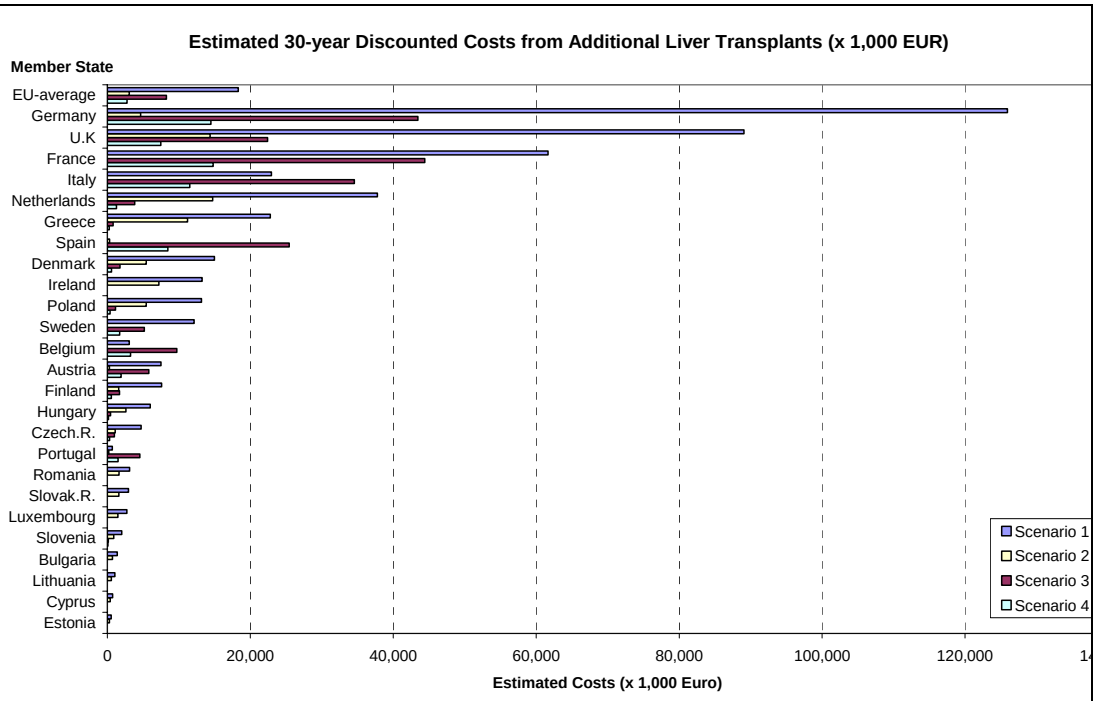
**Estimated 30 year discounted treatment costs/cost savings from additional transplants across EU-27 in 1000**

| | Scenario 1 | Scenario 2 | Scenario 3 | Scenario4 |
|---|---|---|---|---|
| Kidney | -1,755,691 | -246,961 | -759,949 | -253,316 |
| Liver | 457,657 | 76,619 | 206,343 | 68,781 |
| Heart | 17,371 | 6,720 | 17,512 | 5,837 |
| Lung | 95,375 | 31,413 | 78,015 | 26,005 |
| Total | -1,185,288 | -132,208 | -458,078 | -152,693 |

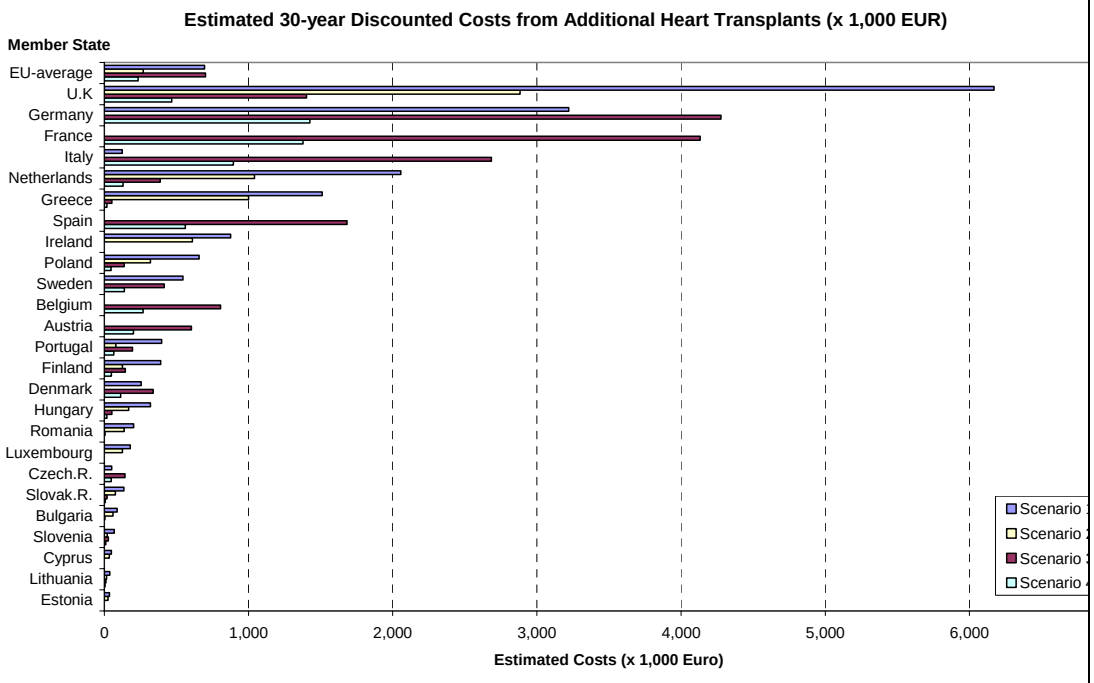
The cost saving effect is entirely due to the cost saving effect of kidney transplantation. Figures 5.12 to Figure 5.15 provide a detailed overview of the cost implications per organ type and country.



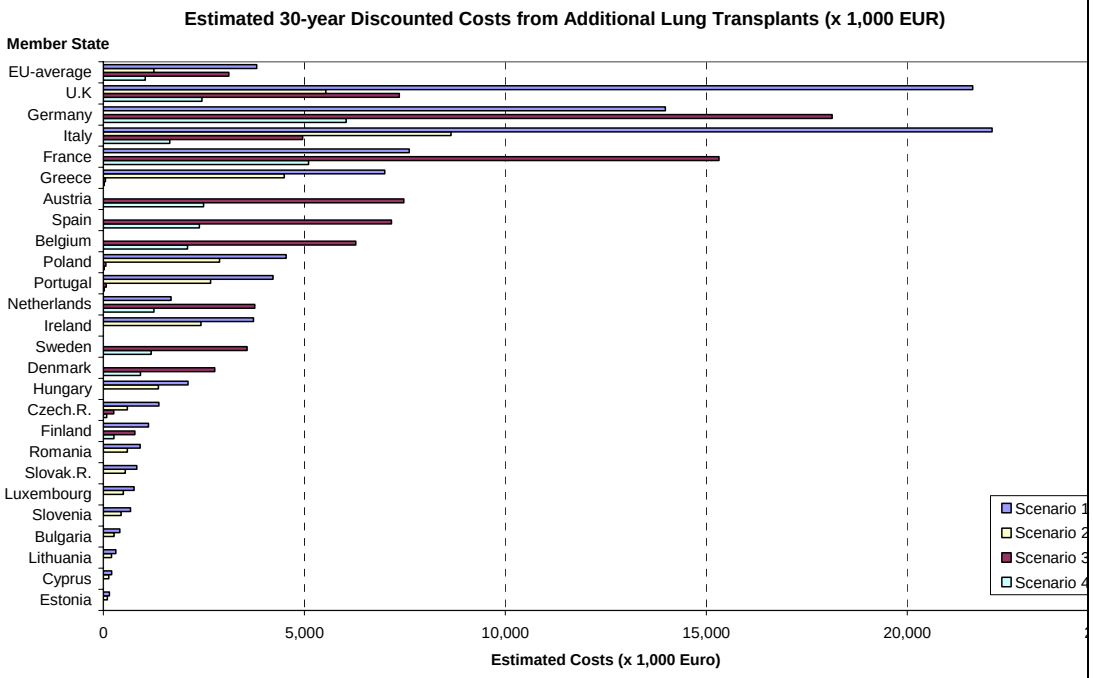

30-year discounted savings from additional kidney transplants




30-year discounted costs from additional liver transplants




30-year discounted costs from additional heart transplants




30-year discounted cost from additional lung transplants

Applying our assumptions of section **Error! Reference source not found.** on how the policy options would influence donation rates, we can illustrate the likely scope of the impacts on treatment costs. Under Option 1 no immediate changes to treatment costs can be expected, however Member States are likely to face rising treatment costs if waiting lists and prevalence of end stage renal disease increase in the medium and the long term.

For option 2, for which we consider the outcomes to be most uncertain, the calculation based on the treatment costs reveals a range of cost savings between € 458 million and € 1.2 billion, which can be attributed to savings from dialysis treatment. For Option 3 and 4, in which we assume at least a modest increase in donation rates, costs savings can be expected to be in the range between € 132 million and € 152 million at the lower end and between € 458 million and € 1.2 billion in the best case scenarios.

| | |
|---|---|
| **Productivity impacts** | It was calculated the possible productivity impacts from the four scenarios. Scenario 4 has the highest productivity impact with around € 5 billion for a cohort of patients, while scenario 2 would only have a productivity impact of around € 460 million over time. Due to the non live saving character of kidney transplants, the total impacts for this group are relatively small. |

| | |
|---|---|
| | **Productivity impacts of increased transplantation rates over a 30 year period (Euro)**<br><br>**Scenario 1** **Scenario 2** **Scenario 3** **Scenario 4**<br>Kidney 513,484,237 47,505,707 273,194,277 91,064,759<br>Liver 2,433,587,527 225,146,728 1,294,766,494 431,588,831<br>Heart 1,278,247,994 118,258,887 680,079,370 226,693,123<br>Lung 745,644,663 68,984,351 396,712,966 132,237,655<br>Total 4,970,964,420 459,895,673 2,644,753,107 881,584,369<br><br>Transferring the scenario estimates to the policy options again, Option 1 would not result in productivity gains, if patients are longer on waiting lists and have to receive dialysis treatment; they are less likely to work than transplanted patients. The maximal gains under Option 2 will be productivity gains of between € 1.3 billion and € 2.4 billion if Member States fully commit to implement all voluntary elements of the Action Plan. With the assumed minimum level of compliance under Options 2 and 3, productivity gains between € 460 million and € 882 million would be expected. For the best case scenario, the higher estimates of Scenarios 1 and 3, i.e. productivity gains between € 1.3 billion and € 2.4 billion seem feasible. |
| **Economic Impacts on Living donors** | Option 1 will not change the current practice of living organ donation in European Member States, with a wide variation in donation rates and a large potential for increased donation and differing legal frameworks for the acceptance of living donation. Nevertheless, given the current organ shortage and witnessing the development in particular in the Nordic countries or the Netherlands, where living donation has become a very important substitute to donation from deceased donors, we can assume that even under Option 1, the importance of living donation might increase in the medium and long term, which would result in more patients being exposed to the economic risks of living donation.<br><br>By promoting the provision of adequate healthcare coverage for living donors, DG SANCO's proposals will reduce the cost risks related to health care expenses for living donors, the proposed action would however not protect the living donor from other economic risks. There is however enough evidence to suggest, that living donors can incur substantial economic costs, through for example, reduced possibility to work or even partial disability in case of adverse physical and psychological events. However, due to the relative low number of living donors (5, 762 additional donors under best case scenario), the aggregated economic impact will be relatively small.<br><br>So while, we expect increasing numbers of living donors, the measures proposed will only cover the costs of health care, but no wider economic risks to the living donors. Similarly, Options 3 and 4 concentrate on the provision of health care, but do not touch upon wider economic impact of living donation on the living donors. |

# ANNEX VIII

# CAPABILITY APPROACH [61]

## 1. INTRODUCTION

This annex presents how 'capabilities approach' contributed to the analysis and presentation of the impact assessment (IA) on Organ Donation. This IA forms a pilot, the purpose of which is to verify whether the capabilities approach (CA henceforth) can be usefully applied in future IA's. Our task was not to do the input part but to use material provided by Rand[62].

The CA, as first formulated by Nobel Prize laureate Amartya Sen,[63] focuses on the well-being of the individuals, and thereby enriches the set of policy goals that is used in IA's. This enrichment can make the IA's more operational and more consistent. This is particularly true in the social dimension, for which it is difficult to make benefits operational using traditional methods.

The CA's focus on the individual and on freedom implies that it puts human beings central to the discussion. This is also in line with the citizens agenda. According to Sen, a person's well-being is a combination of achievements and opportunities. Both are important. For example, someone who has ample job opportunities but chooses not to work has a different level of well-being than someone who is involuntarily unemployed.

While the literature clearly shows that the move to a multi-dimensional framework could be a considerable enrichment for policy analysis, there is no consensus about how to define a multi-dimensional 'space' that can be applied to policy assessments[64].

Our first task was to define a pragmatic multi-dimensional space that could sharpen the goals on which one wants to achieve progress. This has led us to a list of nine dimensions (see Box below). The list is a consolidated version of lists that have been constructed in the literature, e.g. by Martha Nussbaum[65]. The list below is fully consistent with current IA practices and in first instance only regroups benefits into nine different categories.

These nine categories are all aimed at final goals (health, safety etc) but also include important elements of freedom and opportunities (ability to…). Together they form a closed set of well-being, i.e. there are no aspects of well-

[61] The paper was written by Marcel Canoy (Professor of health economics, TILEC, University of Tilburg, chief economist ECORYS. During most of this work Marcel was working for BEPA), Frédéric Lerais (BEPA), Erik Schokkaert (Professor of Economics, Catholic University of Leuven) in close collaboration with DG SANCO and using data input from RAND Europe.

[62] Rand Europe (2008): *Improving Organ Donation and Transplantation in the EU*, June 2008.

[63] See e.g. Sen, A. (1999). *Development as freedom*. New York: Knopf.

[64] See e.g. Schokkaert, E. (2007) 'The capabilities approach', Catholic University of Leuven, Centre for Economics Studies: *Discussion Paper* 07.34 and Alkire, S. (2002) 'Dimensions of Human Development' in *World Development* 30(2):181-205.

[65] Some modifications of the lists of the literature were needed, since the available lists were not designed for our purpose.

being that fall outside the scope of these categories, with two exceptions. The first exception is costs. While cost aspects of policy proposals could in theory be attributed to the categories, in practice it will often be more convenient to compare impacts on relevant categories with total monetary costs, without specifying to which category these costs belong. The second exception is that beyond well-being as measured by the categories, there could be overarching ethical issues that need attention.

Box 1 Applied basic capabilities*

1 ***Health, longevity.*** Being able to live to the end of a human life of normal length; not dying prematurely; in good health, including reproductive health.

2 ***Safety.*** Being able to be secure against violent assault and perceived danger, including sexual assault; being able to have adequate shelter; feeling safe.

3 ***Education.*** Being able to use the senses; being able to imagine, to think, and to reason-and to do these things in a way informed and cultivated by an adequate education; being able to use imagination and thought in connection with experiencing, and producing expressive works and events of one's own choice; being able to form a conception of the good and to engage in critical reflection about the planning of one's own life.

4 ***Standard of living.*** Material control over one's environment: being able to hold property (both land and movable goods); having the possibility to seek employment; being able to purchase goods and services beyond basic ones.

5 ***Productive and valued activities (Employment).*** Being able to find and keep a job at an adequate level, having adequate working conditions, having a good work-life balance, being able to develop oneself within job, being able to develop valued activities outside the job.

6 ***Quality of social interactions.*** Being able to live for and in relation to others, to recognize and show concern for other human beings, to engage in various forms of social interaction; being able to imagine the situation of another and to have compassion for that situation; having the capability for both justice and friendship. Being able to be treated as a dignified being whose worth is equal to that of others. Feelings of social justice.

7 ***Environment.*** Being able to live with concern for and in relation to animals, plants, and the world of nature. Being able to contribute to a sustainable world.

8 ***Culture and entertainment.*** Being able to enjoy oneself, to play, to enjoy recreational activities; engaging in sport and cultural activities.

9 ***Basic rights.*** Having freedom of speech and religious, absence of discrimination, freedom to move.

* based on a modified list proposed by Martha Nussbaum (Martha C. Nussbaum, Capabilities as Fundamental Entitlements: Sen and Social Justice (2003))[66]

[66] See also http://www.wku.edu/~jan.garrett/ethics/nussbaum.htm

## 2. THE FIVE STEPS TO APPLY CAPABILITIES

Since we want to test whether the CA can also be applied beyond this IA, we first explain its general mechanics. The way the capabilities list is used in policy assessments is as follows.

***Step 1: Selection*** The potentially relevant capabilities are selected. For most policy proposals only a subset of the nine capabilities is relevant. Others are omitted. Yet, because one always first considers the nine capabilities, attention is drawn to potential (negative or positive) side-effects of the policy proposal.

***Step 2: Impacts*** The impacts on the chosen capabilities will be assessed, using a variety of tools including traditional tools such as cost benefit analysis. It follows that the CA in itself does not replace traditional tools.

***Step 3: Distribution*** Distributional issues are an important part in the capabilities approach. Since an individual well-being approach cannot be realistically achieved in its full form, we mimic this by defining groups. These groups are relevant partitions of the people on which the policy proposal is expected to have impact.

***Step 4: Ethical considerations*** As discussed above, ethical considerations can go beyond the categories and hence need to be discussed separately, if relevant. One could also say that the evaluation of the impacts is in terms of "well-being freedom", while there are additional considerations with respect to "process-freedom". The former refers to the scope of individual choice, the latter to the process of choosing.

***Step 5: Overall assessment*** Combines steps 1 and 4 and adds costs considerations, inter alia also taking into consideration possible relationships (mutual reinforcements or trade offs) between categories.

The steps need to be replicated for each policy option. In fact, the full potential advantages of the CA in terms of coherency and consistency can be demonstrated best when it is applied to different IA's as it shows the various capabilities that can be at stake when dealing with a proposal. The next section will apply the CA to the organ donation proposals.

## 3. STEP 1: APPLYING THE CA TO ORGAN DONATION

### *Background*

The main challenge of the proposal (in whatever option) is relatively clear: there is an insufficient number of donors and hence also an insufficient number of successful transplants. There is a whole array of reasons behind that: lack of public awareness, lack of confidence in the system, lack of public respect for donors, lack of confidence in the quality of organs, lack of donor protection, lack of a proper training of medical personnel and lack of possibilities for cross-border exchange of organs, to mention a few. Because of this array and the persistence over time of the problem, the policy proposal - and in particular the

preferred option Action plan and flexible Directive - aim at the broad range of underlying reasons behind shortages. Partial methods have been tried before, but with mixed successes at best.

Many years of efforts by Member States have not closed the gap between the supply and demand for organs. Actions at EU level can only be motivated if they are likely to achieve something that has not been achieved before. To be able to do this, one has to be specific in what ultimately drives the number of high quality transplants and how this enhances the well-being of the citizens.

***The mechanism of benefits***

The Commission aims to enhance well-being through increases in high quality organ transplants. All elements of the Directive and the Action Plan are targeted at the different categories that influence organ availability (and successful transplants in the end). Enhancing organ availability requires sufficiently high quality, removal of disincentives to donate, enhancement of exchange, building public confidence etc.

***Final objectives***

DG SANCO has identified three objectives: enhancing efficiency, quality and safety and the number of successful transplants. These chosen objectives are useful since they are direct reflections of what the policy proposals aim at, and are recognizable as such for all involved parties. Most of the effects of the policy proposals indeed run through these objectives. Therefore they do not only perform a communication role but also an analytical one. However, they are intermediary objectives. In the end we are interested in final objectives, i.e. how the chosen proposals influence peoples' well-being, e.g. in the form of health. Converting the chosen objectives into final goals (i.e. well-being) is one of the benefits of the CA. *For this IA, well-being is measured by the capabilities: (i) health; (ii) safety; (iii) standard of living (iv) quality of social interactions; (v) productive and valued activities (Employment).*

There are at least three reasons for concentrating on objectives that directly influence individual wellbeing, i.e. impact on capabilities can be interpreted as final outcomes. The first reason is that final outcomes ultimately reflect better what the real impact for society is of any given policy proposal. Second, there is a risk that there are direct effects of the policy proposal that do not run through the three chosen intermediary objectives. In the current example of organ donation there are e.g. a number of actions that provide information to families of deceased donors or that provide protection to living donors. Such actions have impact on intermediary objectives (quality and safety) but also have direct benefits irrespective of their impact on the quality and safety or the number of transplants. Finally, there are causal relations between the chosen intermediary objectives, which may lead to confusion or double counting. For instance, improvements of quality and safety could lead to more transplants (if trust is enhanced), or to less transplants (if the quality requirements are increased). Conversely, increasing the number of transplants can be achieved by reducing

standards. Concentrating on final objectives with the aid of capabilities will reduce this problem.

Note that it is important to carefully distinguish the "instrumental" and the "final" value of the policy effects. To give an example: providing protection to living donors has a direct effect on the "health" outcome for donors; it may also be instrumental in leading to a higher number of transplants. The former effect is important even if the instrumental effect is absent. The value of the latter (instrumental) effect will be determined on the basis of the effect of the number of transplants on the final objectives.

***The mechanics of capabilities, irrespective of the chosen policy option***

From above it follows that there is merit in concentrating on capabilities. Since this has to be done for all policy options, we will first have to establish *in general* (i.e., irrespective of the policy proposal) what, e.g. an increase in the number of high quality transplants means for health, standard of living etc. So if we have established that e.g. policy proposal A is likely to yield and increase in X transplants, we need to establish a link between the number of transplants and the chosen capabilities. This is done in section 5.

## 4. STEP 2: IMPACTS ON THE FIVE CAPABILITIES

Step 2 involves assessing the impact of the policy proposal on the five capabilities. As discussed above we first need to establish the mechanics of measuring impacts, ie without going into the details of the different options.

We have chosen five basic capabilities as being relevant. One could say that health is a central capability for the policy proposal, for two reasons. First of all, there would be little merit in the proposal if no health effects materialize. Second, benefits on other capabilities directly follow from the health effect, i.e. the fact that people are healthier enables them to engage in a variety of activities that enhances their well-being in other dimensions. Health is also the effect that is most directly observable and measurable. While this is convenient from a communication point of view, it does not mean that just because it is easier to measure it is the only or most important issue.

To exemplify that point, consider the following case of dual causality. Indeed, a better health creates better conditions for other dimensions of well-being. But in the case of organ donation, we know from the policy experiences around the world, that health outcomes (in the form of increases in the number of transplants) can only be achieved if the public is better informed and has a greater confidence in the system, impacts that are mentioned in the capabilities 'safety' and 'social interaction'. It is for this reason that successful policy proposals (example Spain) target at these so-called softer goals.

### 4.1. Health and Standard of living

The impact on health of the policy proposals is well-documented. An increase in organ donations has an impact on death rates on waiting lists, direct health

effects after transplants, survival rates, reductions in the transmission of diseases and health effects on donors. All these dimensions can be expressed in QALY's.[67]

From the Rand report the most complete information on the general health impact of organ donation and transplantation comes from the UK Transplant Supplement Report[68]. For example, liver transplantation has the highest QALY gain (11.5); heart has 6.8 QALY gain and lung has 5.2 QALY gain. Compared to dialysis, the benefits of different treatment strategies for Type 1 Diabetes with End Stage Renal Failure range from 2.01 to 5.77 additional QALYs. In addition, evidence from the international literature shows that a typical donor generates about 13 QALYs[69].These benefits in terms of QALYs do only occur if increases in transplants are realized as a result of the policy proposals. Analyzing the Spanish (and also Italian and Greek) model reveals that policy proposals similar to the ones suggested by DG SANCO have led to substantial increases in transplants (Rand p.55). In the (unrealistic) case that all Member states achieve Spanish levels, the gains in QALYs are even in the order of 219,000 QALYs. But even under more moderate assumptions the gains can still be substantial (Rand p.61).

There is no consensus in the literature or among health practitioners how to monetarize the benefits of QALY's. The range is between 20,000 to 100,000 euro per QALY. The main reason behind this wide range is that there is no universally accepted way of measuring the monetarization of QALYs[70].71 The value can be measured on the basis of collective preferences, on the basis of medical practice, or on the basis of the value of a statistical life, all of which can yield different outcomes. What is accepted in the literature is that life saving medical activities should be assessed at the high end of the spectrum, since this reflects collective preferences for such activities. Although this range is wide, it still gives an indication of what a QALY is worth. Moreover, there is a large degree of consensus that in the case of life saving situations the upper part of the range is more appropriate. The reason why health and standard of living are taken together here, is that health is measured by QALYs, which typically involve benefits for patients in terms of standard of living. Adding separate effects of the proposals on standard of living (e.g. in terms of productivity gained) threatens to double count benefits.

In addition to the effects picked up with QALYs, there are also quality of life (QoL) studies which include elements of standard of living (being able to control one's environment, mobility). The few studies that link QoL to organ donation come to very positive results, but it is too early to draw definitive conclusions (Rand 77).

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[67] Quality Adjusted Life Years (QALYs)

[68] Rand Europe (2008) op. cit.

[69] Mendeloff et al., 2004.

[70] http://www.cpb.nl/nl/pub/cpbreeksen/document/152/doc152.pdf

## 4.2. Safety

This capability is highly relevant for policy proposals on organ donation. An indirect, but crucial, consequence of enhancing feelings of safety can be that more donors are available in the future. This however is an indirect effect leading ultimately to more QALYs. Therefore this effect is dealt with below in the category 'interactions between capabilities'. We have to bear in mind that the feeling of security should not to be confused with the physical safety of organs themselves, although there is obviously a link between the two.

In addition to the indirect effect, enhancing feelings of safety is also a benefit by itself in terms of well-being. It is very difficult to quantify in how far feelings of safety are enhanced as a consequence of public policy, nor is it easy to assess how important feelings of safety are for the citizens in this context. Special Eurobarometer 272 "Europeans and organ donation" shows that organ donation cards are perceived very positively by European citizens: 81% of them are in favour of their use, but such cards are for the time being rarely used, in particular in NMS10 countries (12% of citizens have an organ donation card). An enhanced public debate will likely have positive consequences. The importance that citizens attach to a donor card can be used as a proxy for the general importance of feelings of safety but it cannot be used to compare safety with the other capabilities, nor does it reveal much on the benefits of public policy (except for the NMS10 example mentioned above, where those benefits seem clearcut).

The fact that direct measurement is difficult does not disqualify the category: neither in general (Eurobarometer surveys show that citizens find safety one of the most important aspects of well-being), nor in the particular case of organ donation. We know that there exist benefits, but we have to assess them in a qualitative way. It is important to keep in mind that this category may vary according to the policy options. In this sense, it can also help to differentiate the outcomes of various options.

Feelings of safety can be specified into the following categories.

*(i) family of deceased donors will feel more secure;*

One intended consequence of enhancing quality and safety is that families of deceased donors feel more secure. The importance of this is exemplified by special Eurobarometer 272 "Europeans and organ donation": 41% of Europeans have discussed the organ transplantations with their family. The subject is far less frequently discussed in NMS10. 56% would be willing to donate one of their organs to a specialized organ donation service after their death, 54% would agree to donate an organ from a deceased close family member. The Canadian Council for Donation and Transplantation (2005) shows that 56% of people surveyed think that "if your loved ones would feel comforted by your donation" is an important reason to donate. Data suggest that training programs for health have contributed to the approach of obtaining consent from donor families. See

also De Jong et al for a discussion on the importance of family discussions. '*Public education has a limited but vital role to play in increasing organ donation. What happens at the hospital is key. Potential donors have to be identified, and the families have to be approached in the right way. All public education can do is "help the process be successful once the process has begun" (Davis 1991, 92). The goal should be to dispose families favorably toward donation so that they will grant consent.'*

*(ii) public has confidence in the system;*

Again there is a link between confidence in the system and the number of future donors (see below), but here the impact we focus on is the feeling itself. Experience from US and Spain have revealed that improving confidence was an outcome of successful policies (see e.g. DeJong et al).' In the UK the Living Donation Protection through the Human Tissue Act (HTA) has included the training of 140 Independent Assessors and 55 Accredited Assessors and, as the HTA annual report suggests, Living Donation Protection by HTA personnel has had the social impact of "giv[ing] everyone confidence in the system: clinicians, organ donors, recipients and families." The HTA helps clinicians find the right balance between the needs of the patient with kidney failure, for example, and the needs of the living organ donor. Furthermore, it is possible to tackle the complex issues around Living Donation Protection without creating extra barriers or over-complicating things. Apart from the indirect effect, enhancing feelings of confidence is a benefit in itself.

*(iii) feelings of safety by living donors;*

There are major ethical issues involved in living donors (there is abundance of literature on this). Clearly, ethical issues could be alleviated by improving feelings of safety by living donors. Such benefits clearly stretch out beyond any effect on numbers.

*(iv) reductions in trafficking and less fear of involuntary donors*

There are sufficient indications that the problem of organ trafficking exists (albeit less in Europe than in some other parts of the world), and that citizens consider this as an act of serious crime. Reductions will therefore enhance their feelings of safety. People probably do not want to live in a society where trafficking is needed to save lives. It is very difficult to quantify this, since it is not known what people are prepared to pay for such reductions. The WHO assesses the number of sold and trafficked organs to 5000–8000 per year, worldwide. Similar to other parts of crime one could perform a cost-benefit analysis on reducing trafficking, but no material seems available at this stage. Also there are serious ethical issues involved that cannot be easily monetarized. In Europe, organ trafficking is closely linked with criminal organizations that deal in human trafficking.

All in all, enhancing feelings of safety is an important goal of organ donation policy. This can be inferred from surveys, and numerous policy documents are backed up by the literature. The magnitude of the effects is very difficult to

quantify. Furthermore, there are ethical issues involved mainly around living donors and trafficking that warrant special attention.

### 4.3. Quality of social interaction

Quality of social interaction can be specified into the following categories.

*(i) belonging to a society that does not let patients die in waiting lists if it can be avoided.*

There is little evidence available that reports to what extent citizens' feeling of social justice is affected by the fact that people are dying on a waiting list for organs. Yet, according to Naci Mocan and Erdal Tekin (2005)[72], in Europe, individuals who reveal that they are familiar with the rules and regulations governing the donation and transplantation of human organs are more likely to donate. This has not only an indirect effect through the numbers of transplants but also indicates that education appeals to ethical and moral stance of the public, which constitutes a benefit in itself.

*(ii) belonging to a society that does not let recipients be exposed to unnecessary infectious risks;*

There is little evidence available that reports to what extent citizens' feeling of social justice is affected by the fact that recipients are exposed to infectious risks. Yet, that does not mean the category is unimportant.

*(iii) quality of social interaction after transplantation*

The literature is more important in this field. It mainly discusses quality of life after transplants and combines elements that are also relevant for the capabilities reviewed below. Quality of life (QoL) assessments are used to evaluate the physical, psychological and social domains of health, e.g. sexual function, pregnancy, schooling, sport and work. Burra and De Bona (2006) conclude that (i) A survey of sexual concerns among 768 organ transplant recipients showed that transplantation had a positive impact on sexuality: 69.9% reported having intimate relationships, 66.7% were satisfied with their relationship, and only 26% were not sexually active. (ii) Up to 40% of chronically ill children and adolescents experience problems at school, including learning difficulties, social maladjustment and problems with peer relationships. School performance was found to improve after renal transplantation, less so for heart and lung. (iii) Organ transplantation offers the best prospect of pregnancy in fertile women with various types of end-stage organ disease. (iv) Most transplanted people report a better QoL not only in psychological and social, but also in physical domains after surgery, returning to the same sort of physical activity as before their chronic illness.

In Clemens et al. fifty-one studies examined 5139 donors who were assessed an average of 4 years after nephrectomy. The majority experienced no depression

[72] The Determinants of the Willingness to be an Organ Donor, *NBER* w11316

(77-95%) or anxiety (86-94%), with questionnaire scores similar to controls. The majority reported no change or an improved relationship with their recipient (86-100%), spouse (82-98%), family members (83-100%) and non-recipient children (95-100%).

Broyer Michel et al give figures about various social aspects of life in the adulthood of children who had received a kidney: marital life (12% against 8% for the general population), educational level (31% reached the baccalaureate level. This is lower than the educational performance of the general population, but it shows than a activity is present after transplantation). From M. C. Corley, et al: scores on quality of life were high for all donors, and they expected that their quality of life would improve in the next 5 years. All these examples show that social benefits after transplants are significant. But this seems a relatively unexplored domain. As it is difficult to have a consistent view of all the results in this domain, the most effective way to communicate the results is qualitative, with a list of examples, although there could also be attempts to quantify as much as possible.

### 4.4. Productive and valued activities (employment)

There is a wide literature on the impact on employment. For instance, White K. et al. show that after transplantation (heart and lung), 39% of patients went back to work and 3% more started working[73]. An overview article (van der Mei et al 2006) provides a systematic review of social participation after a successful kidney transplant. Employment was the most used indicator of social participation. Employment rate ranged from 18% to 82%. For heart, lung and liver transplantations, this number is lower and estimates are between 27% for liver transplants74 and 39% for thoracic organs[75].

The social outcome in a French cohort of 366 children who underwent kidney transplantation between 1973 and 1985 was investigated recently by Broyer et al (2004). The authors found that 73% of male patients (n=149) and 72% of female patients (n=95) had paid employment, whereas 6.5% and 10.5%, respectively, were unemployed.[76] In another study in the US, there was low pre-transplantation employment (39% of kidney-pancreas transplant recipients and 33% of kidney alone transplant recipients). However, post-transplantation, significantly more dual organ recipients were working (73%) compared with transplant recipients of kidney alone (27%). Similarly, in Italy, Petrucci et al (2007) found that having had an occupation previously and having been off work for less than 24 months were independent predictors of return to work:

[73] *The Journal of Heart and Lung Transplantation*

[75] Saab S, Wiese C, Ibrahim AB, Peralta L, Durazo F, Han S, Yersiz H, Farmer DG, Ghobrial RM, Goldstein LI, Tong MJ, Busuttil RW. Employment and quality of life in liver transplant recipients. Liver Transpl. 2007 Sep;13(9):1330-8.

[76] Broyer et al 2004

87% of patients worked before thoracic organ transplantation and 39% of patients went back to work after transplantation, while 3 of the 131 patients in total started working[77].

### 4.5. Interactions between capabilities

The literature is full of examples that establish a link between the number of transplants and the feelings of safety as e.g. measured by increases in public confidence[78]. A similar story can be held for feelings of social justice. According to Naci Mocan and Erdal Tekin (2005)[79], in Europe, individuals who reveal that they are familiar with the rules and regulations governing the donation and transplantation of human organs are more likely to donate. Insofar as these indirect effects lead to increased transplants, this leads to positive health effects, and should therefore be added to the direct effects mentioned above. Therefore the Directive, though not directly contributing to increases in the number of transplants through this indirect channel, contributes not only to quality and safety, but also to the number of transplants.

### 4.6. Conclusion

Health outcomes and standard of living can be measured (in terms of QALYs). When the impacts of the various options in terms of QALYs are clear, it is possible to have a full cost analysis. Indeed, it enables one to assess for each policy option the impact in terms of expected euro per QALY minus costs (where a range is more likely than a point estimate). This will be the first important signal: expected euro per QALY minus costs brings together two types of impacts on capabilities (health and standard of living) with the costs. This number (whether positive or negative) can then be benchmarked against the three other types of capabilities, notably social interactions, feelings of safety and employment, which are all more difficult (and sometimes impossible) to quantify.

The table below presents a crude estimation of benefits and costs, using the following logic:

1. There is partial (country) information on implementation costs. Some of these costs can be attributed to the Action Plan, others to the Directive.
2. We calculate the upper bound of costs by multiplying full implementation costs in a large MS (U.K., Germany or Spain) by 27.

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[77] Petrucci L, Ricotti S, Michelini I, Vitulo P, Oggionni T, Cascina A, D'Armini AM, Goggi C, Campana C, Vigano M, Dalla-Toffola E, Tinelli C and Klersy C. (2007). Return to work after thoracic organ transplantation in a clinically-stable population. *European Journal of Heart Failure*, 9 (11): 1112-9.

[78] see e.g. '25 Years of Organ Donation: European Initiatives to Increase Organ Donation', G.R. Schutt, Transplantation Proceedings, 34, 2005–2006 (2002)

[79] The Determinants of the Willingness to be an Organ Donor, *NBER* w11316

3. We use the most pessimistic Rand benefit scenario in order to obtain a lower bound for the benefits.
4. We then compare the lower bound of benefits with the upper bound of costs.
5. The table below reveals that the very lower bound of net benefits in terms of QALYs gained are 440 million euro. In other scenarios the benefits are higher, sometimes much higher.
6. The large net benefits accrue even if we assume that all MS achieve only the EU average.
7. The reasons for the large net benefits are that the literature reveals that (i) transplants yield substantial QALYs gained; (ii) the QALYs gained are evaluated at 20.000 which is the very lower bound used in the literature; (iii) policy proposals that are similar to the ones suggested by DG SANCO have proven to yield substantial gains in terms of increases in the number of transplants.

   One caveat applies. One cannot establish a direct causal link between the policy proposals and the benefits. This is so because in order for the proposal to meet subsidiarity requirements important tasks are left to the MS to implement. This forces the researchers to use scenarios. Even in pessimistic scenarios the cost-benefit ratio looks very favourable though.

**Table 2 The maximum cost of the proposals**

**Illustration of the maximum annual cost for EU27, in million euros per year***

*Under two assumptions A1 or A2, reflecting two pieces of information*

| | | Maximum cost | | Comments | | | Reference to Rand Report*** |
|---|---|---|---|---|---|---|---|
| Start-up and running costs** | A1 | € | 60 | € | 2,2 | The UK of the national authority (HTA) | p80 |
| | A2 | € | 86 | € | 3,2 | Spain, Spanish national authority (annual cost) | p80 |
| Autorisation of establisment | A1 | € | 82 | € | 3,0 | Charge by HTA on licencing an etablisment in the UK | |
| | A2 | € | 346 | € | 12,8 | Charge licensing tissue product, Germany | |
| Transplant coordinators | A1 | € | 270 | € | 10 | Germany | p81 |
| | A2 | € | 281 | € | 10 | UK, for 250 coordinators | p81 |
| National quality programme | A1 | € | 14 | € | 0,50 | Implementation cost in Canada | p85 |
| | A2 | € | 14 | € | 0,50 | Idem | |
| Register | A1 | € | 5 | € | 0,19 | to implement serious adverse reaction | p91 |
| | A2 | € | 5 | € | 0,19 | Idem | |
| Administrative burden | A1 | € | - | | | No figures | |
| | A2 | € | - | | | No figures | |
| **Total cost** | **A1** | **€** | **431** | | | | |
| | **A2** | **€** | **731** | | | | |
| | | | | | | | |
| **Qalys Gains monetarized** | **A1** | **€** | **3.000** | € | 0,05 | per Qalys | |
| | **A2** | **€** | **1.200** | € | 0,02 | per Qalys | |
| | | | | | | | |
| **Net gains monetarized** | **A1** | **€** | **2.569** | | | | |
| | **A2** | **€** | **469** | | | | |

* We illustrate here the highest level possible of the cost by assuming that the cost of a typical country is applied to EU-27
It gives an upper bound of the cost and a lower of the net gain
The number Qalys gains is assumed to be 60 000
** the running cost here is a reccurent one. A one-off cost can be added, which was 4 million for Spain for instance.
****Rand Europe (2008): *Improving Organ Donation and Transplantation in the EU* , June 2008.

What can we conclude from this?

1. There is a policy option that has a favourable, possibly even very favourable, cost-benefit ratio.
2. We don't know yet at this stage of the analysis whether the preferred policy option is the Action Plan or the Action Plan plus Directive. But even if we use the lower bound for benefits of the Action Plan and we (unjustifiably) attribute all the costs to the AP, the cost benefit ratio is favourable. This is even more so since we only looked at QALYs in terms of benefits leaving other benefits undiscussed in the equation so far.

Below we discuss what is needed before a proper comparison of options is possible.

## 5. STEP 2 (CONTINUING): COMPARING OPTIONS

To evaluate the consequences of policy options, the above described approach needs to be replicated for each policy option. In our discussion here we limit ourselves to comparing the AP with AP plus flexible Directive (AP + D)[80]. This is because the AP already clearly yields positive net returns and the stringent Directive does not meet subsidiarity requirements.

On health, the Rand report estimates the ranges of possible life years saved and QALYs gained for the various policy options, using different scenarios depending on the extent to which Member States implement actions. What are the differences in impacts between AP and AP+D in terms of QALYs? Evidence on country studies reveals that success depends on approaches that are inclusive. The AP alone is therefore unlikely to yield the optimistic scenario where an increase of 30% transplants is assumed. The AP +D has a higher chance of achieving that, but with a lot of uncertainty still. It is very difficult to put numbers to the value added of combining the AP with a Directive. The following observations are relevant: (i) the success of inclusive policies; (ii) the substantial benefits that extra transplants yield and (iii) the fact that the Directive improves the quality of social interaction and feelings of safety, which indirectly yield a higher number of transplants.

This leads us to the tentative conclusion that the optimistic scenario (30% increase) might be achievable under AP+D, with a high bandwidth of uncertainty remaining.

Rand takes only direct effects into account, implying that the AP plus Directive (in whichever form) yields the same QALY range as the AP. But from our analysis above it follows that there are indirect effects working through the safety and quality of social interaction capability. The Directive and AP aim inter alia at enhancing quality and safety and at working on public awareness. Enhanced quality and safety improve public confidence which then feed into

[80] The policy options are fully described in the main text of the IA or in Rand(2008) p31

enhanced availability and ultimately into the number of transplants. This indirect effect has not been taken into account by Rand.

If we accept this reasoning and compare it to the table above it seems that it does not matter which costs are exactly attributable to the AP or the Directive, since the extra benefits of the Directive are so large that this effect always dominates. A caveat applies here though. In the table above we deliberately have been very pessimistic on the benefits of the AP. This was done to check whether positive net benefits could be sustained even under these pessimistic scenarios. If we want to compare options honestly, we should allow for more variation in the AP benefits, in particular since it remains true that most QALY gains are due to the direct effect created by the AP.

As regards the other dimensions, there are numerous pieces of information, but with (even) less clarity than for QALYs. For the non-health and non-productive capabilities we have to rely on using qualitative assessment through "+" and "++" signs in the tables.

The Action Plan has a positive effect on the various 'social' dimensions. For the "social" capabilities, the Directive has added value in these various dimensions, notably on feelings of safety and feelings of social justice. In a certain number of cases, the directive will not add much. This is typically the case for what we can call the "large" and "developed" countries. The main added value is the link to better quality standards. This is supposed to have two effects: an increase in the number of exchanges between countries, and probably an improvement of the "confidence in the system". This is very difficult to measure, but what seems important to have in mind is that the Directive will add value on small and undeveloped countries' social capabilities because it can probably help to increase the trade (then the number of organs), to reinforce the confidence of people in the system, and to improve (possibly strongly) the well-being of the living donors. This latter effect will become more important if the number of living donations increases. More on this in our section on distribution.

Table 3 Comparison of the impacts of proposed policy actions on capabilities

| Intervention | Option 2: Action Plan | | Option 3: AP + flexible Directive | |
|---|---|---|---|---|
| **QALYs**<br><br>**(health and standard of living)** | **Estimates of donation rates will lead to:**<br><br>**37,350 to 113,348 QALYs, most in the lowest part**<br><br>**(average 60 000)** | **≈**<br>**to**<br>**++** | **Estimates of donation rates will lead to:**<br><br>**37,350 113.348 QALYs , most in the upper part**<br><br>**(average 90 000)** | **+**<br>**to**<br>**++** |

| | | | | |
|---|---|---|---|---|
| **Safety** | **Some effects due to exchanges of best practices an awareness raising** | + | **Stronger effects due to improvements in quality and safety standards** | + **to** ++ |
| **Quality of social interaction** | **Some effects due to exchanges of best practices an awareness raising** | + | **Stronger effects due to improvements in quality and safety standards** | + **To** ++ |
| **Employment** | **Positive effects result of increases in transplants** | + | **Stronger effects due to higher increases in transplants** | + **To** ++ |

"++" substantial benefit; "+" some benefit; "≈" no substantial impact; "-" some additional negative impact; "- -" substantial negative impact;

To conclude: the AP+D yields higher returns on all dimensions (The QALY differences are due to indirect effects, and there are also direct effects on other capabilities that are in favour of the Directive. Whether these gains outweigh costs depend on the attribution of costs between AP and Directive, on which we have no information.

## 6. STEP 3: DISTRIBUTIONAL ASPECTS

Only looking at aggregate effects may be very misleading, as each and every policy proposal has always distributional consequences. In principle, the CA focuses on the distribution of individual well-being in society, but this is of course impossible to operationalize in its ideal form. An acceptable short-cut is to consider different groups in society. One then has to decide first what are the main distributional dimensions of the policy proposal and then to analyse the results for the resulting classification in groups.

In the case of organ donation, there are three main types of distributional aspects to take into consideration. The first one is related to the heterogeneity of Member States. Various options have various impacts according to the group of MS and the organ systems they have in place (developed, large). The second one is related to the position of different individuals in the process of organ donation itself. The effect of the policy is different according to the fact that we consider the recipients, living donors, family or potential donors. The third aspect to be taken into consideration is related to social and economic inequalities. We will discuss in some detail the results for the first dimension.

Since the data are sparser for the other classifications, our discussion of them will be more concise.

### 6.1. Country groups

We first consider the heterogeneity of the countries. Two dimensions are particularly relevant as regards the proposal: the size of the country (because of the trade aspect in particular) and the level of development of the system of transplants. We suggest measuring the first with the number of transplants and the second with the number of transplants per head. A reasonable classification of the countries could then be as follows:[81] (i) Large and developed as Spain; (ii) Large and undeveloped as Romania; (iii) Small and developed as Austria; (iv) Small and undeveloped as Bulgaria.

Let us now analyse the differential impacts of the policy proposal for this country classification. To facilitate our task and make the results more transparent we only consider two options: Flexible Directive + Action Plan / Action Plan only.

We have used a qualitative system from one + to four ++++. This is to be able to make a difference between the groups of countries and also between the different policy options. Of course, this qualitative scoring system gives only a first rough indication. Three caveats are in order. First, the "scores" in the different rows are not directly comparable, i.e. ++++ in health does not necessarily give the same numerical indication as ++++ in employment. Each row gives the relative effects per capability just to show the differences between the groups of MS. Second, at the bottom of the table we give an "overall" evaluation. This again has to be interpreted only as a qualitative indication. Third, it might seem that everything is positive, but this is misleading, since there are costs as well. In particular it seems that the option with the directive is always 'Pareto' superior (ie never worse and sometimes better), but this is not necessarily true if we also include cost considerations.

Some further comments on the Table:

– Small countries face problems because of the shortage of own supply. Therefore the directive would be beneficial for them since it is likely to enhance trade. Underdeveloped countries face the problems that they simply do not have enough high quality transplants, so that they benefit from the action plan mainly.

– For all options the benefits are the largest for small and undeveloped countries, as expected, and the smallest (but still positive) for large and developed MS.

– On the difference between the middle groups, it seems that the large and undeveloped do well with the directive. Notice, however, that the

[81] There is of course room for discussion about this classification. However, in principle other criteria could be used without problem

health effects are larger for small and developed countries, and that these health effects are the most important.

– Overall, the main difference between the options is that the directive produces more benefits in the green area, which is mainly linked to safety and feelings of social justice in undeveloped countries, and to health in small developed countries (for the trade reason). Again, from this it cannot be automatically concluded that the directive option is better since there are costs involved. Notice e.g. that for large developed countries the directive is probably strictly worse, since it does not add anything for them in terms of benefits, while it does increase the costs. This kind of differentiated conclusions is exactly what we aim at with this distributional analysis.

Table 4 Member State-distribution matrix: Action Plan plus flexible directive

| | Large and developed | Large and undeveloped | Small and developed | Small and undeveloped |
|---|---|---|---|---|
| Health | + | ++ | +++ | ++++ |
| safety | + | +++ | ++ | ++++ |
| Quality soc.interactions feeling of justice | + | +++ | ++ | ++++ |
| standard of living | + | +++ | ++ | ++++ |
| Employment | + | +++ | ++ | ++++ |
| Overall evaluation | + | +++ | ++/+++ | ++++ |

Table 5 Member State-distribution matrix: Action plan without directive

| | Large and developed | Large and undeveloped | Small and developed | Small and undeveloped |
|---|---|---|---|---|
| Health | + | ++ | ++ | ++++ |
| safety | + | ++ | ++ | +++ |
| Quality soc. interactions feeling of justice | + | ++ | ++ | +++ |
| Standard of living | + | +++ | ++ | ++++ |
| Employment | + | +++ | ++ | ++++ |
| Overall evaluation | + | ++/+++ | ++ | +++/++++ |

## 6.2. Groups of actors: donor, family etc.

There is no doubt that the policy proposals have differential impacts for the different groups in society that play a different role in the process of organ donation and transplantation[82].Although the information about these impacts has not yet been collected in a systematic way, the picture that results from the existing data is rather clear. Using the same qualitative method as used before (and hence with the same caveats attached), we present the distributional picture in the following table. At this stage, it is not very useful to distinguish between the various options. The table has to be seen as a first description of the different impacts to be expected for different groups in society (and in this case the different policy options are mainly a matter of degree). The red cells in the table refer to capabilities which are not relevant for the social groups concerned.
Again, some comments are in order:

[82] Note that we focus here on final outcomes, and hence, on groups of individual citizens. Of course, there are institutional stakeholders too (e.g. the transplant organisations and hospitals), but these are intermediary players. The effects on them have been captured when describing the effects of the policy proposals on the number of transplants.

- The recipients and potential recipients are of course the main beneficiaries of the policies. As described before, the main impacts work through the health dimension, but it is essential to bring into the picture also the derived effects on employment (and standard of living). The analysis has shown that it is necessary to make a specific column for recipients with special needs (such as paediatric patients): for them the positive effects of a better organisation of organ donation and transplantation (and more trade) will be even more outspoken.
- Taking distributional aspects explicitly into account also draws in a natural way attention to the living donors. A safer system of living donation will of course enhance the number of donations and of successful transplants. This effect is taken up in the first two columns. In addition, however, there are also direct effects on the capabilities of living donors, which go beyond the instrumental evaluation. Their feelings of safety will undoubtedly increase – with, in addition, positive effects for the other capabilities.
- To some extent, similar effects are found for potential donors. As mentioned before, empirical research shows that people who are better informed about the rules in their country, feel safer and are therefore also more willing to donate.
- Given the sensitive nature of the process of organ donation, the families of deceased donors are another crucial group. Of course, there will be no health effects for them. However, a well-structured system of organ donation will increase their feelings of being treated in a fair way, of being part of a just system – and may even increase the overall quality of their social interactions.

Table 6 Actor-distribution matrix

| | Recipients | Recipients (special needs) | Living donors | Family of deceased donor | Potential donors |
|---|---|---|---|---|---|
| Health | +++ | ++++ | ++ | | |
| Safety | +++ | +++ | ++++ | | +++ |
| Quality soc. interactions feeling of justice | +++ | ++++ | ++ | ++ | ++ |

| | | | | | |
|---|---|---|---|---|---|
| Standard of living | ++ | +++ | + | | |
| Employment | ++ | +++ | + | | |
| Overall evaluation | ++/+++ | +++/++++ | ++/+++ | ++ | ++ |

## 6.3. Social and economic inequalities

There is a large literature on socio-economic health inequalities and on differential access to the health care system. The Rand report used this literature extensively. There are various elements to take into consideration here. Rather than putting them in a separate table, as we did for the other distributional dimensions, we summarize some of the most important effects in a verbal way and we link our discussion to the groups appearing in the previous table[83].

First, given the (well documented) differential access to the health care system for different socio-economic groups, it is probably advisable to distinguish between different groups of recipients. There will be a positive health effect for all groups in society, but this positive effect may be less pronounced for groups with lower incomes and for BME-groups. At the same time, their needs for transplants are higher. So: all groups will gain, but some groups will probably gain more than others. The consequences for the feelings of justice in society are not yet clear.

Second, it seems that the willingness to donate may also be lower amongst BME-groups[84]. We could therefore also split in the previous table the last three columns "living donors", "family of deceased donors" and "potential donors". However, in the present state of our knowledge it is not possible to describe carefully the effects of the policy options for these specific categories. We know (cf. supra) that more and better information and transparency increases the feelings of safety and trust in the system and thereby the willingness to donate: we do not know, however, whether this effect will be stronger or weaker for those groups that now have a smaller propensity to donate.

It is clear that the information on this latter category of distributional issues is still very incomplete. The CA-approach as such cannot remedy this lack of

[83] In principle, the comments in this section could be taken up by splitting some of the columns in the previous table.

[84] See, e.g., Tekin and Mocan (2005), The determinants of the willingness to be an organ donor, *NBER Working Paper* 11316.

information. Yet, for the evaluation of policies, an informed guess is preferable over complete neglect. Moreover, taking up distributional issues explicitly (and not as a kind of afterthought) directs our attention to the remaining lacunae in our knowledge.

## 7. STEP 4 ETHICAL CONSIDERATIONS

There are lot of ethical considerations related to organ donation that move beyond the impacts on capabilities. Most of these are related not to the final outcomes, but to the process through which these final outcomes are reached. One can think of issues around opt out or opt in systems, impact on black market transactions and trafficking, implications of exchanges in organs, payment for organs, ethical issues in communication with families, issues around brain death.

The ethical issues can be grouped in three categories.

- ethical issues that fall out outside the realm of these policy proposals

Discussions on opt-out or opt in, on organ trade (payments) or issues around brain death fall in this category.

- ethical issues that are positive influenced by the proposal

The AP+D lead to an expected reduction in black market activities and trafficking. This is an important positive ethical side effect. The same applies to action geared at families of deceased donors. However, these ethical issues have already been taken into account in the quality of social interaction capability above.

- ethical issues that need to be discussed as a consequence of this proposal

Finally, there are ethical issues related to organ exchanges, living donation and acceptance of organs of lower quality.

## 8. STEP 5: CONCLUSION

### 8.1. Synthesis of the results of the IA

All in all, the Action Plan plus the Directive yields higher returns on all relevant capabilities. The QALY differences are due to indirect effects (on feeling of safety), and there are also direct effects on other capabilities that are in favour of the Directive. The proposals seem also be cost effective. Nonetheless, whether these gains stemming from the Directive outweigh costs due to the Directive depend on the attribution of costs between Action Plan and Directive, on which we have no information.

In terms of distributional impacts, the directive has bigger impact on capabilities in small and undeveloped countries (in terms of organ donation). It is mainly due to the safety and feeling of social justice in undeveloped countries and to health in developed countries. But the cost is not sufficiently detailed to

conclude. As regards, groups of actors, the proposals have of course an impact on the recipients of the organ. But the CA approach draws the attention on the impact on living donor through the feeling of safety and to the family of the donor trough social cohesion.

## 8.2. Added value of the application of the CA to IA

In our view, the CA had added value to the IA. he added value of the capabilities' approach is (i) to concentrate on final outcomes rather than on intermediary objectives; (ii) The focus on distribution and opportunities is justified from the fact that there are often major impacts of policies on these two dimensions, which tend to be underdeveloped in policy assessments and evaluations; (iii) it facilitates communication of policies to the citizens, because it deals with well-being in concrete terms; (iv) that it reduces the risk that important impacts are overlooked; (v) it provides a natural way to analyze interactions between various dimensions (capabilities). We have seen that is of paramount importance here when we deal with feeling of security.

But his added value had a cost in the sense that the approach requires more data. And some dimensions are difficult to quantify, this is the case for the feeling of safety and quality of social interactions. So we needed to rely on qualitative assessments.

The advantages of the capabilities approach are explained in detail in Box 2 (below).

Box 2 Advantages of the capabilities approach

We see the following advantages from integrating the capability framework into the Impact Assessments:

**1. completeness**

The applied capabilities list attempts to provide a full description of wellbeing as a basis for the evaluation of policy objectives and action. The list takes into account the various facets of well-being at an aggregated level to adapt the capability approach to policy-making.

**2. transparency**

The applied capabilities list of nine distinctive elements of wellbeing is more transparent than a list where a somewhat amorphous 'social category' is used as a wide umbrella for everything that is not environmental or economic. It paints a clearer, more accessible 'picture'.

**3. reinforcements and trade-offs**

As a consequence of the transparency gained, the list of nine allows for an easier public discussion on trade-offs and interactions between the different categories. Our list starts from the assumption that all pillars are a priori important (in the sense that we do not attach a priori weights to the different items, not that we attach equal weights). A discussion on trade-offs and interactions is a prerequisite for a fruitful policy debate: different conceptions of the good society differ precisely in their views about the relative importance of (and hence the desirable trade-offs between) the different capabilities.

**4. capabilities and distribution**

A further fundamental advantage of the applied capabilities list is that it purposefully and explicitly takes into account Sen's original idea, namely that not only achievements count, but also freedom. The importance of freedom is exemplified in the way the issues are described and in the way they are made operational. Moreover, the focus on individual (or group well-being) makes it possible to integrate distributional issues into the analysis in a natural way, rather than as a kind of afterthought following an aggregate analysis.

**5. consistency with traditional methods, no need for extra data**

A main advantage is that the CA does not require more data or new data, nor does it replace traditional methods such a cost-benefit analysis.

**6. universal applicability consistent with IA guidelines**

Given point 5 above, the CA can be applied to al all impact assessments without difficulty and without overhauling the IA guidelines.