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Improving Organ Donation and Transplantation in the European Union

Assessing the Impacts of European Action

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Prepared for the Directorate General for Health and Consumers of the European Commission (DG SANCO)
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This report presents findings from a study to support the European Commission Directorate General for Health and Consumers (DG SANCO) in assessing the impacts of European Action in the field of organ donation and transplantation. The research conducted by RAND Europe examines evidence for the key health, social and economic impacts that could be expected when implementing four policy options proposed by DG SANCO in the field of organ donation and transplantation. The main aim of this exercise is to support DG SANCO in assessing and comparing the different policies with regard to their effectiveness in achieving DG SANCO’s objectives to increase organ availability, improve Quality and Safety, and make transplantation systems more efficient and accessible, with the ultimate objective of achieving a high standard of health protection for all citizens of the European Union. This report will serve as an input into DG SANCO’s own regulatory impact assessment exercise, which is a mandatory part of the legislative process in the European Union.

In order to examine the possible impacts of the policy options proposed by DG SANCO, relevant evidence was collected, synthesised, analysed and grouped into three main types of impact: health, social and economic.

On the basis of the evidence available, a qualitative comparison of the potential impacts of the different policy options proposed by DG SANCO was then conducted. This was supplemented by a scenario modelling and benchmarking exercise to overcome some of the inherent uncertainties related to an impact assessment of fairly broad framework policy options.

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Executive Summary

This study assesses the impacts of proposed European action on organ donation and transplantation

Due to rapid advances in transplantation medicine, the use of human organs for transplantation has steadily increased during the past decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure and the only available, life-saving treatment for end-stage failure of organs such as liver, lung and heart. The advancement of transplantation medicine has led, however, to a shortage in available organs and poses new Quality and Safety challenges. The European Commission has an opportunity and an obligation to take action to meet the needs of organ transplant patients, donors, their families, medical practitioners and the wider community. Proposals for such action, including a directive and an Action Plan, have been put forward and are being considered in an impact assessment.

In this context, the Directorate General for Health and Consumers of the European Commission (DG SANCO) commissioned RAND Europe to provide support for assessing the impacts of four policy options to improve organ donation and transplantation in the European Union. This report thus serves as an input into DG SANCO’s own impact assessment exercise. By taking into account the possible health, economic and social impacts, RAND Europe weighs the costs and benefits of the proposed policy options and supports the identification of a preferred policy option to meet DG SANCO’s objectives of increasing organ availability, enhancing the effectiveness and accessibility of transplantation systems and improving the quality and safety of organ donation and transplantation.

There is considerable potential to increase organ donation rates

An analysis of organ donation and transplantation rates across Europe shows that there is considerable potential to increase the availability of organs in Europe. While Spain identifies more than 33 deceased organ donors per million population (pmp), some other Member States identify just one organ donor pmp. Similar differences can be seen in living organ donation rates: Norway has a very high rate of living organ donation, of 17 living donors pmp, while many new Member States have rates well below 1 living donor pmp. Thus, if good practice were to become standard, there would be a large potential for
increased organ donation (cadaveric and living) in Europe. In particular, there is ample evidence that shows that organisational changes and improvements could lead to substantial increases in organ donation rates.

The European Union faces challenges in the quality and safety of organ donation and transplantation

The use of organs in medical care poses a risk of infectious diseases being transmitted to the organ recipient. The risk includes communicable diseases such as Human Immunodeficiency virus (HIV) and Hepatitis B and C, as well as other bacterial, viral and fungal infections. Transplantation can also lead to the transmission of different types of cancers. There are currently no common standards of Quality and Safety in place in Europe; although cross-border exchange of organs, the mobility of organ recipients and potential donors, and the close link of organ donation to the use of human tissues and cells create major challenges to the diverse and heterogeneous regulatory landscape as it exists in Europe at present.

DG SANCO identified four policy options

To address the problems outlined above, DG SANCO identified four policy options which differ predominantly in their regulatory approach.

Under Option 1, the European Commission would continue with its current activities in the field of organ donation and transplantation, which primarily involve sponsoring research and pilot programmes in this field and participating in international cooperation such as in the Council of Europe.

Option 2 proposes a non-regulatory approach to the field of organ donation and transplantation. This option would establish a European Action Plan on Organ Donation and Transplantation for the period from 2009 to 2015. The Action Plan sets out a cooperative approach between EU Member States based on national action plans. This approach is based on the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

Option 3 combines the Action Plan described under Option 2 with a ‘flexible’ directive, supporting key elements of the Action Plan in the area of Quality and Safety. The regulatory approach of this directive would be very much a framework initiative, ensuring that national legislation was put in place to deal with key aspects of organ donation and transplantation, but without prescribing detailed policy measures.

Finally, Option 4 would combine the Action Plan described under Option 2 with a ‘stringent’ directive. This stringent directive would be modelled on the EU Tissues and Cells Directive inasmuch as it would contain detailed regulation for the Quality and Safety systems that Member States have to put in place, leaving little national discretion in implementing the directive. However, there is an important difference between the EU Tissues and Cells Directive and Option 4 with regard to organ donation: the consideration
of organ shortage, which will demand a different risk assessment and associated requirements for quality and safety of organs.

**A flexible European directive will be in line with the subsidiarity principle**

Article 152 of the Treaty of Amsterdam provides the European Community with an opportunity, as well as an obligation, to implement binding measures laying down high standards of Quality and Safety for the use of blood, organs and substances of human origin. Thus, the European Commission has a clear mandate to ensure the quality and safety of organ donation and transplantation and to improve public health. In 2006 the European Commission adopted a communication on organ donation and transplantation, defining the main policy challenges, setting out the key objectives for the European Commission and identifying areas for future European action, which this impact assessment now discusses. This communication has been welcomed by the European Parliament in a draft resolution in April 2008.

The analysis of the policy options shows that clear European added value can be expected from European action in the field of organ donation and transplantation. In particular, the policy actions will:

- encourage the exchange of best practice between Member States to increase organ donation rates;
- increase organ exchange between Member States, which in particular benefits difficult-to-treat, high-urgency and paediatric patients in small Member States;
- allow better evaluation of post-transplant results; and
- address the difficulties posed by donor and patient mobility.

Thus, the policy measures proposed by DG SANCO would provide substantial health and economic as well as social benefits. RAND Europe considers Option 3 to be the best option to reconcile the policy objectives with the principle of subsidiarity and proportionality. First, a flexible directive plus the Action Plan optimises the European Community’s contribution to public value by providing a platform for implementation and mutual learning that combines standardisation of reporting with diversity of delivery mechanisms. Secondly, a flexible directive plus the Action Plan allocates decision-making to the level where it can be most efficient and effective by distributing decision-making among the local (hospital) level, the Member State level and the European level.

**A variety of methods to assess possible impacts of European action has been used in this study**

To assess these policy options RAND Europe used a combination of methods and approaches that allowed an assessment of the most important impacts of the proposed policy options.
The starting point for the analysis of impacts was an extensive document and literature review. This review focused on uncovering literature that provided an understanding of the links between the proposed policy measures and health, economic and social outcomes.

Secondly, this literature review was followed by in-depth country studies of the organ donation and transplantation systems in a sample of six countries. The countries studied were Germany, Greece, Spain, Poland, Sweden and the United Kingdom. The country studies were used to establish the status quo of organ donation and transplantation in the European Union and to get a qualitative understanding of the impacts the different policy options would have. Where possible, the information was supplemented by information about a wider sample of countries, which could be obtained from previous EU research projects.

Thirdly, the study team conducted key informant interviews with ten stakeholders, including national country experts as well as stakeholders concerned with organ donation in general. The main purpose of these interviews was to address knowledge and data gaps. These were conducted as semi-structured interviews, using an interview template with targeted questions for each stakeholder.

Fourthly, to develop an idea of the scope of improvements that could be achieved, RAND Europe developed four scenarios of different changes in living and deceased organ donation rates, which were subsequently used to identify the likely health and economic impacts of the policy proposals. The key scenarios were as follows:

1. Scenario 1 is the best-case scenario, with all countries achieving transplantation rates of the currently best performing countries – i.e. Spain in deceased and Norway in living organ donation;
2. Scenario 2 assumes all countries reach at least European average transplantation rates;
3. Scenario 3 assumes a substantial increase in transplantation across all countries of 30%;
4. Scenario 4 is a small increase scenario, with a 10% increase across all countries.

The scenarios are used to define the scope of policy outcomes, based on assumptions about increases in the organ donation rates, and are subsequently used to define upper and lower ranges of possible policy outcomes for each option.

Fifthly, RAND Europe used a cost-consequence framework and an impact matrix to analyse the evidence, identify the key impacts and compare them across the policy options. In doing so, we examined social impacts by focusing on the wellbeing of individuals and considering the wider consequences which might be lost on a narrower, conventional cost-benefit analysis. For example, we explored evidence on the quality of life, employment and social participation as well as trust and confidence to assess potential social impacts of the policy options.
Conceptual difficulties in determining the impact of the policy options can be addressed by a benchmarking exercise and scenario analysis

There is considerable uncertainty about policy outcomes for a number of reasons, including, but not limited to, the voluntary and framework character of the European policy proposals; the importance of national transposition and national commitment of the Member States; the critical role of the hospital level in the implementation of policies; and the complex causal relationship between the policies, organ donation rates and other intervening factors. To address these uncertainties, RAND Europe benchmarked the proposals against the Spanish model, a well-established example of best practice, and conducted a scenario analysis. This provides insight into what it is reasonable to assume would happen rather than a prediction of what will happen.

The benchmarking exercise revealed that Options 3 and 4 meet four out of the five most important elements of the Spanish model, suggesting that an increase in organ donation rates is feasible, while at the same time it showed that Member States will have a pivotal role in implementing the measures and supporting the high-level European measures with adequate action on the ground.

All the policy options are likely to increase organ donation rates and reduce health risks to patients

The key health impacts of the DG SANCO proposals emanate from an increase in organ donation rates and reduced risks to patients. The policy options are likely to increase organ donation rates in Europe. However, there is a significant level of uncertainty about the degree to which rates can be increased. A best-case scenario developed by RAND Europe established a potential of up to 21,000 more organs transplanted per year in the European Union. This would translate into saving 230,000 life years or gaining 219,000 quality adjusted life years (QALYs) for a cohort of transplant patients over a 30-year period. In addition, the policy options are likely to increase the cross-border exchange of organs, which results in clear health benefits for paediatric, highly sensitised and urgent patients.

We note the risk that none of the policy options will have a direct impact on reducing existing health inequalities in organ donation and transplantation, and may even widen the gap – mainly because the policy options do not include organ allocation criteria as an area of policy intervention. As the various European studies show, current increases in organ availability alone will neither ensure fair allocation of organs nor ensure fair access to care across all social groups.

Option 1 would not change the current unsatisfactory status quo, with diverging Quality and Safety standards across Europe, an undeveloped potential for cross-border exchange of

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A Quality Adjusted Life Year (QALY) is a measure created to account for the quality of life. A QALY takes one year of perfect health-life expectancy to be worth 1, but regards one year of less than perfect life expectancy as less than 1. The measure can provide an indication of the benefits gained from a variety of medical procedures in terms of quality of life and survival for the patient. See (http://www.jr2.ox.ac.uk/bandolier/booth/glossary/QALY.html).
organs and no link between the tissue and cell vigilance system and organ donation. Option 2 could create substantial health gains though increases in organ donation rates; these increases are, however, uncertain as the option allows for a high level of discretion in national implementation. Option 2 would not have an impact on the quality and safety of organs, but would remove disincentives to become a living donor by ensuring access to health care for living donors.

Options 3 and 4 supplement Option 2 through legal standards and would have a more certain positive effect on organ donation rates since changes would become mandatory. It is likely that at least a modest increase of 2,600 organs transplanted could be achieved, resulting in 39,000 saved life years or 37,000 more QALYs. In addition, Options 3 and 4 would establish common Quality and Safety standards across the European Union, which would reduce risks to patients and stimulate the cross-border exchange of organs.

**An EU policy can lead to substantial economic benefits, but will require investment in national infrastructure by Member States**

The analysis of the policy options suggests that Options 2 to 4 could lead to substantial economic benefits across the European Union, although Member States would have to invest in the national infrastructure of organ donation and in efforts to improve processes (e.g. inspections and control measures, personnel training, transport of organs etc.) to realise these gains. However, the evidence does not allow for producing detailed cost estimates for Member States. The economic benefits arise primarily from saved treatment costs as transplanted kidneys replace dialysis treatment. Scenarios developed by RAND Europe, which assume different degrees of success in increasing transplantation rates, see a potential saving up to €1.2 billion in treatment costs, and productivity gains of up to €5 billion over a 30-year period for a single cohort of patients from the point of organ transplantation.

Option 1 continues the status quo and is expected to create no additional costs or economic benefits. Option 2 could generate substantial economic benefits of up €1.2 billion savings in treatment costs and an additional productivity impact of €5 billion at low costs for process and infrastructure improvement. Due to the voluntary nature of the Action Plan, RAND Europe recognises that the impacts are highly uncertain because the extent of implementation by Member States is unknown.

Option 3 combines the Action Plan with a flexible directive. Option 3 would lead to substantial costs in implementing national registers, reporting activities and a national vigilance system. However, due to the mandatory character of the option, cost savings and productivity gains would occur under less uncertainty, at a range between €132 million and €1.2 billion, and €460 million and €5 billion for productivity impacts. Finally, Option 4 is expected to bring the same economic benefits as Option 3 – however, at higher implementation costs as Member States have less freedom to use existing systems and devise tailor-made national solutions.
Increased organ donation and robust donation processes will have positive social impacts

Increased organ transplantation is expected to result in positive social impacts for organ recipients and donor families. Evidence shows that transplantation of organs increases the possibilities of patients participating in social and working life. In general, organ transplantation has a positive effect on the quality of life of organ recipients. Thus, the different options will generate additional social benefits, depending on the additional transplantations achieved.

European action can be expected to contribute to increased trust and confidence in the organ donation and transplantation system, by establishing common Quality and Safety standards, increasing public awareness and improving processes to deal with the relatives of deceased donors. However, the evidence available for such social impacts as social participation and improved standards of living does not allow for an adequate assessment of the precise impact to compare the options.

An Action Plan supplemented by a flexible directive is likely to achieve the best balance between costs and positive consequences

RAND Europe assessed the status quo option and three new policy options provided by DG SANCO to improve organ donation and transplantation in the European Union with the objectives of: 1) increasing organ availability; 2) enhancing the effectiveness and accessibility of transplantation systems; and 3) improving the quality and safety of organ donation and transplantation. In weighing up the evidence available, RAND Europe concluded that Option 3, which combines an Action Plan using the open method of coordination with a flexible directive creating a European framework regulation for Quality and Safety, would help to achieve DG SANCO’s objectives at the best cost-consequence ratio. The least costly option, Option 2, would not be sufficient to create a robust Quality and Safety framework, and the potential positive health and economic impacts are more uncertain than for the other options. Option 4 in turn would ensure common Europe-wide Quality and Safety standards and would have substantial economic benefits, but it would also have the highest implementation costs. In addition, expert experiences with the EU Tissues and Cells Directive have shown that a strict regulatory approach to organ donation might lead to substantial difficulties in implementation for the organ procurement and transplantation facilities, and there is serious concern among experts about the risk of having a negative impact on organ donation rates for some hospitals, particularly smaller ones.
We wish to thank all those who participated in our key informant interviews and who provided valuable support in understanding the field of organ donation and transplantation. In addition, we should like to thank the participants at DG SANCO’s Stakeholders Meeting on Organ Donation and Transplantation on 23 May 2008 who provided useful comments on a draft of this impact assessment report.

We should also like to thank all colleagues at RAND Europe who have made important contributions to our research. In particular, we wish to thank Kai Wegrich and Amanda Scoggins for their useful and insightful comments during the quality assurance process.

Finally, we should like to thank the project team at DG SANCO for their support, and for engaging constructively and collaboratively with us throughout the development of the research.
CHAPTER 1 Introduction and Methodology

1.1 Introduction

1.1.1 Organ donation and transplantation: the policy context

The therapeutic use of human organs involves the substitution of a non-functional organ for a functioning organ coming from a donor – a practice that has become established worldwide over the past 50 years. Organ transplantation has brought immense benefits to hundreds of thousands of patients and success rates in organ transplants have improved in recent years. It is now the most cost-effective treatment for end-stage renal failure (ESRF) and it is the only available treatment for end-stage failure of organs such as the liver, lung and heart. The excellent results of transplants, in terms of life years gained and improvement in quality of life, have increased the number of indications for which organ transplantation is considered a suitable therapy. Increasing steadily during the past decades, transplant procedures continue to develop and in the future may offer practical treatment for other unmet medical needs. However, there are major challenges for the use of organs in therapy in the European Union emerging.

Firstly, the use of human organs poses a serious risk of transmission of communicable, malignant and new emergent diseases (see Appendix A) as well as the risk of rejection of the transplanted organ from immuno-incompatibility between the recipient and the donor (i.e. graft rejection).

Secondly, there is an acute shortage of donated organs affecting transplantation programmes worldwide. More than 50,000 patients are now on waiting lists in Europe. Mortality rates while waiting for a heart, liver or lung transplant are substantial, and usually range from 15 to 30 per cent.

Thirdly every year a number of organs are exchanged between EU Member States, creating challenges for the quality and safety of organs used in therapy. Cross-border exchange of organs implies that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions. Potentially, without standardised Quality and Safety legislation at EU level, the above risks become all the more salient for patient protection.

Results from a survey of legal requirements related to organ transplantation in the EU, conducted in 2003 by the Commission, revealed important discrepancies within Member States (DG SANCO, 2003). There are large differences in the deceased and living organ donor rate within the EU and also considerable differences in transplantation activity. The
Commission therefore needs to define the precise, balanced scope of the EU legal framework on quality and safety for human organ donation and transplantation.

1.1.2 Background to this report

On 31 May 2007, the Commission adopted a communication on organ donation and transplantation which sets out the actions the Commission is planning to take to respond to the main policy challenges in this area: namely, to ensure quality and safety of organs, increase organ availability and fight organ trafficking. The Community has already adopted Parliament and Council Directives on Quality and Safety standards for human blood and for human tissues and cells. A European legal framework of quality and safety for organs would address similar topics. A fundamental approach in the context of organ donation and transplantation, however, is the risk–benefit ratio: in every case the risk associated with the organ must be balanced against the consequences of not getting a transplant, with a definition of risk taking into account both the donor’s profile and the recipient’s characteristics.

In this context, the European Commission, Directorate-General Health and Consumer Protection (DG SANCO), commissioned RAND Europe to contribute to the Commission’s impact assessment of an EU legal instrument on setting standards of Quality and Safety for the donation, procurement, testing, preservation and transport of human organs. To support this work, our assignment focused on providing an assessment of the anticipated impacts of four policy options to improve organ donation and transplantation in the European Union: no change in policy status quo, Action Plan, Action Plan plus a flexible legal directive, and Action Plan plus a stringent directive. The Action Plan aims to support Member States in not only combating organ shortages and making transplantation systems more efficient, but also improving the quality and safety of organ donation and transplantation. The proposed legal directive aims to set standards of Quality and Safety for the donation, procurement, testing, preservation and transportation of human organs, using either a flexible (framework) approach or a stringent (proscriptive) approach. We describe these policy options in further detail in Section 4.2.

To fulfil the purpose of this assignment, we analysed the health, social and economic impacts of the proposed policy options and weighed the potential costs and benefits/consequences of the proposed policy options in a qualitative way to identify a preferred policy option to meet DG SANCO’s objectives of increasing organ availability, enhancing the effectiveness and accessibility of transplantation systems and improving quality and safety of organ donation and transplantation. To do so we used a variety of methodologies and drew on a number of different sources – such as peer-reviewed journals, grey literature and specialists in the field – which are presented in the next section.

---

1.2 **Methodology**

1.2.1 **Literature review**

A comprehensive literature review was undertaken, starting with the peer-reviewed literature using the PubMed search engine. The ‘Mesh’ search terms we used in PubMed are as follows: ‘Tissue and Organ Procurement’ (Limits: Abstracts, English, Review); ‘Tissue and Organ Procurement/economics’; ‘Tissue and Organ Procurement/legislation and jurisprudence’; ‘Tissue and Organ Procurement/organization and administration’; ‘Tissue and Organ Procurement/standards’; ‘Tissue and Organ Procurement/statistics and numerical data’; ‘Tissue and Organ Procurement/supply and distribution’; ‘Tissue and Organ Procurement/trends’ and, ‘Tissue and Organ Procurement/utilization.’ We limited all of our Mesh search terms to Abstracts, English and Review, with two exceptions: ‘Tissue and Organ Procurement/supply and distribution’ (as it was found to have only four hits), and, ‘Tissue and Organ Procurement/utilization’ (as the stated limits resulted in one hit that was already retrieved; hence we removed our limits for this term). In addition, the first term resulted in 672 hits with the stated limits, and we reduced this number by adding economic impact as well as Europe. Using these Mesh search terms, we retrieved a total of 139 articles out of 297 hits reviewed.

We also searched the peer-reviewed literature in the NHS Economic Evaluation Database (NHS EED) as the main source of empirical data on potential economic impacts of different measures to increase organ availability, enhance the effectiveness and accessibility of transplantation systems, and improve quality and safety of organ donation and transplantation. We searched the NHS database, first using broad terms such as ‘transplantation’ and ‘organ donation’, and then using terms relevant to the key ‘areas of intervention’ we identified and describe in greater detail below (see Section 4.1), for example, ‘transplantation and reporting systems’ etc. Our search of the NHS EED database resulted in 13 retrieved articles.

Finally, we searched Google Scholar for additional literature on any social impacts of the key ‘areas of intervention’ (see Section 4.1), specifically in terms of the impact on the five capabilities (personal safety, and security, social cohesion / capital and social participation, standard of living, and employment) described in further detail below. Additionally, we used this search engine to supplement literature on economic impacts of the ‘areas of intervention’ which do not yield many results in either the NHS EED database or in PubMed. Other data sources included literature and references provided by the Commission.

1.2.2 **Country studies**

Following the literature review, our team conducted in-depth case studies of the organ donation and transplantation systems in a sample of six European countries identified by DG SANCO for this study: Germany, Greece, Poland, Spain, Sweden and the United Kingdom. Case studies were performed using a structured template to ensure harmonisation of data collection. The case studies were predominately based on desk research, but supplemented by key informant interviews to fill data gaps.

The country studies were used to establish the status quo of organ donation and transplantation in the European Union and to get a qualitative understanding of which
impacts the different policy option would have. Where possible, the information was supplemented by information about a wider sample of countries, which could be obtained from previous EU research projects.

1.2.3 Stakeholder interviews
We also conducted stakeholder interviews with ten stakeholders, including national country experts as well as stakeholders to organ donation in general – e.g. transplant surgeons and representatives from organ donation organisations as well as disease-related interest groups. The main purpose of these interviews was to address knowledge and data gaps in the literature review and case studies. These interviews were conducted as semi-structured interviews, using an interview template with targeted questions for each stakeholder. The questions focused predominantly on the anticipated social impacts, which were less amenable to our literature review methodology.

1.2.4 Scenario analysis
To overcome difficulties in determining and quantifying the impacts of the different policy options, we simulated the effects of four hypothetical scenarios of organ donation rates, and estimated the additional costs and benefits under each scenario in terms of:

- additional medical costs (or savings)
- QALYs and life years gained[^4]
- productivity gains.

Each scenario is defined by an assumption of different transplantation rates of organs from deceased as well as living donors. These assumptions are summarised in Table 1.1. The choice for the particular organ donation rates is explained in more detail in Section 5.4. It is important to note how the scenarios are used in this research. They are defined solely on the basis of different outcomes, and policy choices are assessed against the likelihood of delivering these outputs.

[^4]: A Quality Adjusted Life Year (QALY) is a measure created to account for the quality of life. A QALY takes one year of perfect health-life expectancy to be worth 1, but regards one year of less than perfect life expectancy as less than 1. The measure can provide an indication of the benefits gained from a variety of medical procedures in terms of quality of life and survival for the patient. See [http://www.jr2.ox.ac.uk/bandolier/booth/glossary/QALY.html](http://www.jr2.ox.ac.uk/bandolier/booth/glossary/QALY.html).
### Table 1.1: Key scenario assumptions

<table>
<thead>
<tr>
<th>Transplant rate assumptions</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>All countries in the EU achieve the transplantation rate of the best-performing country*</td>
<td>All countries achieve at least EU average transplantation rates</td>
<td>All countries improve their transplantation rate by 30%</td>
<td>All countries improve their transplantation rate by 10%</td>
</tr>
</tbody>
</table>

#### Transplantations from deceased donors

<table>
<thead>
<tr>
<th></th>
<th>Transplantations from deceased donar</th>
<th>At least Spanish rate</th>
<th>At least EU average:</th>
<th>+30%</th>
<th>+10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney, from deceased donor</td>
<td>At least Spanish rate</td>
<td>46 pmp</td>
<td>29.1 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Liver, from deceased donor</td>
<td>At least Spanish rate</td>
<td>23.1 pmp</td>
<td>12.3 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Heart</td>
<td>At least Spanish rate</td>
<td>6.1 pmp</td>
<td>4.3 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Lung</td>
<td>At least Spanish rate</td>
<td>3.8 pmp</td>
<td>2.5 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
</tbody>
</table>

#### Transplantations from living donors

<table>
<thead>
<tr>
<th></th>
<th>Transplantations from living donar</th>
<th>At least Norwegian rate</th>
<th>At least EU average:</th>
<th>+30%</th>
<th>+10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney, from living donor</td>
<td>At least Norwegian rate</td>
<td>17 pmp</td>
<td>5.4 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Liver, from living donor</td>
<td>At least Spanish rate</td>
<td>0.4 pmp</td>
<td>0.5 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
</tbody>
</table>

* Spain for deceased donation, Norway for living donation

SOURCE: RAND Europe

The scenario analysis comprised three steps, explained in detail below. For a more formal description and results, refer to Appendix B.

**Step 1. Obtaining costs and benefits per additional organ transplanted for each Member State**

The first step in our analysis was to obtain for each additional organ transplanted an estimate of the costs and benefits for each Member State. We obtained estimates from the literature on the 30-year discounted costs per additional transplanted kidney, liver, heart and lung in the United Kingdom (Department of Health, 2008b). Unfortunately, we were not able to obtain similar direct estimates for most other EU Member States. Because spending on healthcare exhibits substantial variation across Member States, we wanted to avoid simply converting the UK cost estimates to other Member States using exchange rates. Instead we made the assumption that the cost of transplanting an organ relative to overall per capita healthcare spending is relatively stable across Member States. Using data on overall per capita healthcare spending (readily available from Eurostat and the OECD),
we extrapolated the UK costs to other Member States. The following example clarifies our approach:

The UK study estimated the total 30-year discounted costs of transplanting 383 additional hearts as GBP (£)7,694,000, or £20,089 per organ (Department of Health, 2008b). The most recent (2005) estimate available (from the OECD Health Data) reports per capita overall healthcare costs as £1,685 annually (OECD, 2007). Thus the costs of transplanting an additional heart are 11.92 times (20,089/1,685) the annual per capita healthcare spending in the UK. Using this factor we can now derive the expected 30-year discounted costs for heart transplants in other countries. For example, annual per capita spending in France was EUR 3,040 in 2005, leading to an estimated 30-year discounted cost per additional heart transplanted of 3,040 * 11.92 = 36,243.

From the same study, we obtained estimates on the additional QALYs gained for each transplanted organ. These were reported as follows: 3.1 QALYs (per additional kidney transplanted), 11.5 QALYs (per additional liver transplanted), 6.8 QALYs (per additional heart transplanted), and 5.2 QALYs (per additional lung transplanted). We assumed these gains in QALYs per transplanted organ would be similar across all Member States.

Finally, we estimated the gains in productivity per additional transplanted organ. We obtained estimates for additional life years gained per additional transplanted organ, and multiplied these by the percentage employed after transplantation (obtained from the literature) and by the average wage of a production worker in each Member State (obtained through Eurostat).

**Step 2. Estimating the number of additional transplanted organs in each Member State for each scenario**

In the second step we estimated how many additional kidneys, livers, hearts and lungs would be transplanted in each Member State annually under each of the four scenarios. We obtained data on the number of organs currently transplanted from the Council of Europe Transplant Newsletter (Council of Europe, 2007) and estimated a population fraction by dividing these numbers by the population size of each Member State. We then calculated the number of additional organs under each scenario. The following example clarifies our approach:

In the year 2006 a total of 2,776 kidneys were transplanted in Germany (2,254 from deceased donors and 522 from living donors). To estimate the additional number of kidneys available in Scenario 1 in Germany, we first obtained the fraction of transplanted kidneys from deceased donors in Spain as 0.000046 (2,055 kidneys divided by 44.7 million citizens). Applying this fraction to the German population of 82.4 million yielded an estimated 3,788 transplanted kidneys under Scenario 1, or 1,534 additional kidneys (3,788 –2,254) from deceased donors. Applying Norwegian rates for kidneys from living donors, we repeated this calculation to obtain the number of additional kidneys from living donors in Germany.

In Scenario 2, we used a similar approach, but instead of applying Spanish and Norwegian organ donation rates we used the average rates across the EU (and applied these rates only to countries below the average). In Scenarios 3 and 4 this procedure was not necessary as we could apply the percentage increase to each country’s rates directly.
Step 3. Estimating the total costs and benefits of each scenario

In the final step we obtained estimates for the total costs and benefits for each Member State by multiplying the number of additional organs under each scenario (step 2) by the cost, QALY and productivity estimates per transplanted organ (step 1). In addition to the total costs and benefits per Member State, we also averaged and summed across the entire EU. Figure 1.1 summarises the scenario approach chosen by RAND Europe.

Figure 1.1: Scenario approach

1.2.5 The capability approach

At the outset of this project it was envisaged that the capability approach would be employed to structure and analyse the impacts of increased organ availability, improved quality and safety of organs, and greater efficiency and accessibility of transplantation systems. The capability approach was originally developed by Amartya Sen as an alternative framework to traditional approaches to measure the wellbeing of individuals. Sen challenges standard approaches to benefits based on economic growth and similarly questions a utilitarian approach based upon measuring happiness that fails to account for intrinsic values. Recently, Marcel Canoy, Frederic Lerais and colleagues have sought to operationalise Sen’s capability approach by identifying nine capabilities that can contribute to impact assessments which are more complete, more transparent, more amenable to analysing reinforcements and trade-offs, and allow distributional issues to be integrated better into the analysis. However, due to difficulties in operationalising the capabilities and acquiring the necessary evidence to be able to compare the impacts, the authors of this report reverted to a more traditional impact assessment approach. The categories used to assess the social impacts are a result of engaging with the capability approach.

5 The nine capabilities comprise health longevity, safety, education, standard of living, productive and valued activities, social cohesion and civil participation, environment, culture and entertainment, and basic rights (including employment); Canoy and Lerais (2007); Canoy (2007).

6 RAND Europe is currently preparing a project memorandum on the difficulties of applying the capability approach.
Due to rapid advances in transplantation medicine, the use of human organs for transplantation has steadily increased during the past decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure (ESRF) and the only available life-saving treatment for end-stage failure of organs such as liver, lung and heart. Organ donation has thus a very high potential for saving lives and increasing the quality of life for patients with kidney failure, who otherwise would have to rely on expensive regular dialysis treatment up to 13 times per month. This potential can only be realised, however, when a sufficient number of organs are available for transplantation, when there are adequate Quality and Safety measures in place to reduce the risks of diseases being transmitted through transplantation as well as other adverse events (e.g. organ damage), and when processes are organised efficiently and accessible to all who are in need of organ transplantation.

2.1 Organ availability

2.1.1 Demand for organs is increasing

Currently, the demand for organs exceeds the number of organs available in all Member States, and the demand for organs is increasing faster than organ donation rates in most Member States. Figure 2.1 illustrates the increasing gap between supply and demand for organs for the Eurotransplant area by comparing organs transplanted to the number of patients on the waiting list. In total, there are currently more than 56,000 patients waiting for a suitable donor organ within the European Union, while at the same time mortality on the waiting lists is high. In 2006, more than 5,500 patients died while on the waiting list in the European Union (Council of Europe, 2007). This is a conservative estimate based on incomplete data for some larger Member States from the Council of Europe newsletter and may not reflect those removed from the waiting list.

\[\text{References}\]

7 For the UK, see e.g. Department of Health (2008a); for Germany, see DSO (2007).

8 The Eurotransplant area covers Austria, Belgium, Croatia, Germany, Luxemburg, Slovenia and The Netherlands.
Organ donation rates and organ availability vary across Europe

While there is an increasing demand for organs, the availability of organs varies widely between the Member States of the European Union. Figure 2.2 shows the differences in the availability of deceased donors between Member States, ranging from 33.8 deceased donors per million of population in Spain to 1 deceased donor per million population in Romania.

In the case of kidneys and liver transplantation, living organ donation is an alternative to donation from deceased organ donors. Living organ donation rates also differ substantially between Member States, and not all countries realise their potential for living organ donation; instead it seems to substitute for the availability of organs from deceased donors. Figure 2.3 provides an overview of living organ donations performed in the European Union in 2006. In 2006, a total of 2,855 transplantations from a living donor (kidney and liver) were conducted (Council of Europe, 2007).
Figure 2.2: Deceased organ donors in the European Union

Figure 2.3: Living kidney and living liver transplantations performed in 2006
2.1.3 **Drivers of organ availability**

The availability of organs from deceased donors is driven by a multitude of factors. Availability is naturally limited by the supply of suitable donors, who are often victims of road accidents and strokes. Only around 3 per cent of all people dying in hospitals are potential donors (ALLIANCE-O, 2007b). The conversion of this potential depends on the willingness of patients and their families to donate organs and the participation of hospitals in organ retrieval activities. While public debate often centres on public awareness of organ donation and the organisation of consent systems, recent research and experience from piloting new approaches point to the organisational aspects of organ donation as one of the most important factors influencing organ procurement rates (DeJong et al., 1995).

Improvements in the complex process from donor identification to the transplantation of an organ can have a large impact on organ donation rates (Simini, 2000; Roels et al., 2002). The success of some Member States, in particular Spain, in increasing organ availability has been largely attributed to the organisation of the process and indicates that some ways of organising the organ donation process may be better suited to achieving high availability of organs than others (see also Section 5.3.1) (ALLIANCE-O, 2007b). Reviews of the organisational models for organ donation in Europe, conducted for the ALLIANCE-O and DOPKI projects, show a strong potential for the exchange of best practice and learning between Member States on these issues (DOPKI, 2006; ALLIANCE-O, 2007c).

Living organ donation in Europe is currently mostly driven by the lack of organs from deceased donors. In addition, evidence suggests that trust in the hospitals and healthcare system and the surgical procedures are an important determinant of the willingness to become a living donor. Moreover, research in the United States showed that the general public overestimates the risks from living organ donation, and that raising the public’s awareness of living organ donation and informing donors better about the potential risks might be a suitable strategy to increase organ donation rates (Boulware et al., 2002).

2.1.4 **European exchange of best practice**

The importance of organisational aspects of organ procurement and the large differences in practices and performance across Member States show a clear benefit of exchanging best practice between the Member States of the European Union. The implementation of elements of the Spanish model in Italy, for example, has been very successful in increasing organ donation rates. Another programme which allows for the exchange of best practice is the Donor Action Programme. Based on a rigorous review of current and past performance of individual Critical Care Units (CCU), the programme aims at quality improvements in the organ donation and transplantation process through training and continuous monitoring. This programme has been shown to be effective in a number of Member States, such as Finland, Belgium and Germany, already (Roels and Wight, 2001). Exchange of best practice would in particular benefit those Member States that are just starting national transplantation programmes and have not had the opportunity to learn from previous experiences.
2.2 Quality and safety in organ transplantation

The use of organs in therapy poses a risk of infectious diseases being transmitted to the organ recipient. The risk includes communicable diseases such as HIV and Hepatitis B and C, as well as other bacterial, viral and fungal infections. Transplantation can also lead to the transmission of different types of cancer.\(^9\) In addition, the quality and safety of organs can be at risk due to organ damage during the procurement process. To reduce these risks, most transplantation systems apply Quality and Safety procedures throughout the complex organ donation process. In addition, Quality and Safety standards ensure that people and institutions dealing with organ retrieval and transplantation are suitably qualified.

![Biological tests performed](image)


**Figure 2.4: Biological tests performed**

Currently Quality and Safety standards and their legal basis differ widely across the Member States. The tests performed to identify the donors’ characteristics vary across Member States, as shown by the survey conducted for DG SANCO in 2003 (DG SANCO, 2003). Figure 2.4 shows, for example, the biological tests used in the countries, indicating whether these tests are carried out on a routine basis or depending on donor characteristics. Moreover, Figure 2.5 illustrates the differences in the regulation of key steps in the organ donation process.

\(^9\) For a detailed description of the risks and prevalence of graft-related diseases, see Appendix B.
Once transplantation has been successfully performed, it is important to monitor the organ recipient, to record all adverse events and possible infections acquired through the transplantation process, and to be able to trace a potentially harmful organ back to a donor. This is of particular importance as usually multiple organs are retrieved from a single donor, and most organ donors are also tissue and cell donors. Such adverse event-reporting and traceability systems are also valuable tools for medical research to improve the knowledge about transplantation outcomes. Currently 25 of the 29 countries surveyed (EU + Turkey and Norway) have a national register containing data on the origin and destination of organs; in 18 of these, the register is legally binding. However, a system of reporting adverse events exists only in 20 countries, of which 8 have made it mandatory by legislation.

However, the cross-border exchange of organs, the mobility of organ recipients and potential donors and the close link of organ donation to the use of human tissues and cells create major challenges to the diverse and heterogeneous regulatory landscape as it currently exists in Europe. These challenges are discussed below.

2.2.1 Cross-border exchange of organs

The exchange of organs between Member States is already common practice. There are, however, large differences in cross-border exchange between Member States which set up bodies and rules for the international exchange of organs such as Eurotransplant and Scandiatransplant and other Member States outside these international cooperations.
Participants of the Eurotransplant area exchange around 20 per cent of all organs transplanted each year (around 3,300 organs) while only 2 per cent of organs leave or enter the Eurotransplant area. Within the Scandiatransplant area, the number of organs exchanged ranged from 10 per cent for kidneys to 27 per cent for hearts. Without such comprehensive exchange agreements Member States exchange far fewer organs, but the rate can increase if there are bilateral agreements in place.10 Unfortunately, the cross-border exchange of organs is currently not systematically captured and so the data are patchy. The information available is presented in Table 5.11.

The large differences in exchange rates indicate that the full potential of exchanging organs has yet to be reached. This is problematic as the cross-border exchange of organs has clear benefits. Given the need for organ matching between donor and recipient, a large donor pool is important to cover the needs of all patients on the waiting lists. If there is no exchange of organs between Member States, then recipients who need an infrequent match will have very low possibilities of getting an organ, while at the same time donors are not considered because there is not a compatible recipient on the waiting lists. This holds particularly true for difficult-to-treat patients (paediatric, urgent or hyper-sensitised patients who require very specific organ matching) and small Member States. Data from Eurotransplant show that in these cases, small Member States receive the organs from another Member State in the majority of cases (Eurotransplant, 2008). Small Member States not participating in these agreements often cannot identify a suitable organ for these patients. Hence, small Member States and difficult-to-treat patients are key stakeholders with a ‘specific need’ for cross-border exchanges and for adequate measures to ensure equal benefit from this activity.

2.2.2 Traceability and follow-up of organ donation

To manage the risks of organ transplantation, most Member States have registers to trace organs back to specific donors and to report acquired infections. Once transmission of a disease is found in a recipient, there is an urgent need to trace the organ to the donor in order to prevent the transmission of the disease to other potential recipients. There is currently, however, no system in place that would allow for such tracing in urgent cases, although there are more than 4,000 organs exchanged between Member States each year.

As organ donors are often also tissue and cell donors, it is additionally important that information about adverse events and infections in a solid organ transplant can be quickly traced to a donor and immediately relayed to the tissue vigilance system that is foreseen by the European Tissues and Cells Directive.11 Currently such a system for organs does not exist.

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10 e.g. Italy now exchanges more organs with Greece and Slovakia, with which it recently signed bilateral agreements, see IGE (2007).

Finally, a systematic and Europe-wide follow-up of the medical outcomes (post-transplant results) is required to improve the success of organ transplantations and reduce the risks of adverse events and reactions for patients. Currently the only register actually in place of sufficient size is in the United States. National registers of EU Member States are too small to achieve the reliability required of a transplantation monitoring system. A large enough sample of cases for scientific follow-up is especially important for new and emerging alternatives to increase the number of donors. This includes living organ donation and expanded criteria donors, as well as non-heart-beating donors.

2.2.3 Patient and donor mobility

The mobility of organ recipients and potential organ donors is the second major challenge for the current Quality and Safety frameworks.

In a recent pilot survey by the European Kidney Patients’ Federation, it is clear that a large proportion of dialysed patients cross state borders in Europe for both holiday-making and work (Table 2.1) and receive treatment in another Member State, and the same can be expected for transplanted patients (CEAPIR, 2006).

Table 2.1: Patients who travel to other European countries receiving haemodialysis in other centres

<table>
<thead>
<tr>
<th></th>
<th>Germany</th>
<th>Ireland</th>
<th>Latvia</th>
<th>Netherlands</th>
<th>Sweden</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>44.8%</td>
<td>18.7%</td>
<td>1.3%</td>
<td>45.2%</td>
<td>20.6%</td>
<td>35.5%</td>
</tr>
<tr>
<td>No</td>
<td>55.2%</td>
<td>81.3%</td>
<td>98.7%</td>
<td>54.8%</td>
<td>79.4%</td>
<td>64.5%</td>
</tr>
</tbody>
</table>


There is a strong need for all results of transplantations and potential adverse events and infections to be reported in a monitoring and learning system in order to ensure a high level of human health protection. If an organ recipient is a national from outside the Member State in which the transplantation was performed, it is especially important that there are systems in both Member States that allow for the reporting of an event and can be linked to trigger the necessary actions required to ensure the health and safety of other organ, tissue and cell recipients.

There is a chance that people might become potential organ donors while residing in another Member State. In 2007, close to 10 per cent of the donors (≈ 150) in Spain were foreigners, and more than 50 per cent of these were other Europeans. This has steadily increased from 2 per cent in 2000. To ensure that organs available for therapy are not wasted, it is important that there are no legal barriers to the use of these organs and that the families of these donors have trust in the organ donation system so that they do not refuse donation.

2.2.4 Living organ donation

Finally, living organ donation poses a third set of challenges to the current regulation in EU Member States through the mobility of living donors. As the removal of an organ from
a living donor is a substantial intervention which is related to a substantial morbidity risk,\textsuperscript{12,13} the living donor requires continuous follow-up after surgery and access to healthcare and social care. Currently, there are no rules in place concerning the long-term medical treatment (including social care) of the living donors, in particular if living donors decide to change their country of residence within the European Union.

As the total number of living organ donations within the European Union is currently still very small (2,855 in 2006 across all Member States), national data alone are not sufficient to establish the medical outcomes of living donation on organ donors reliably.

Finally, living organ donation opens up opportunities for non-voluntary and/or non-altruistic donations. While there is only limited evidence for the prevalence of organ trafficking and organ trade, all Member States have rules in place banning trade in organs and usually limiting the possible donors to relatives and spouses of the patients.

\subsection*{2.3 Subsidiarity – the case for European action}

\subsubsection*{2.3.1 The legal base to act and previous European activities in the field of organ donation and transplantation\textsuperscript{14}}

Already in 1958, the Council of Europe’s Agreement No. 26 on the exchange of therapeutic substances of human origin became the starting point for cross-border activities in this field. Though it specifically referred to human blood and its derivatives, provisions were made for the agreement’s extension to cover other therapeutic substances. Its main purpose was to facilitate exchanges of human substances between Member States of the Council of Europe in cases of urgent need and under the expressed condition that no profit was made. In 1986,\textsuperscript{15} the European Community became a contracting party to this agreement. Subsequent agreements, recommendations and guidelines that have emanated from the Council of Europe for more than 50 years are the starting point for what now occurs in relation to safety and quality of substances of human origin in Europe (Genetet, 1998).

In the resolution of the Council of ministers for health in 1991\textsuperscript{16} concerning fundamental health choices, the Council took note that the analysis of the Community’s possible contribution concerning the availability of organs for transplants was identified as one of

\textsuperscript{12} The risk of complications and adverse events ranges from 2\% to 16\% for kidney donation; these are short-term surgical (and medication-related) risk and long-term risks of impaired renal function, hypertension and psychological problems (Najarian (2005)).

\textsuperscript{13} Living kidney donation also entails a small mortality risk of 0.03\%, the morbidity risk for living liver donation is substantially higher.

\textsuperscript{14} This section has been provided by DG SANCO.


the topics that warrant joint consideration, regular joint discussions and/or joint efforts to assist Member States in framing their health policies.

In its 1994 report\textsuperscript{17} the Commission recommended the development of a blood strategy as a way towards restoring the confidence of Community citizens in the safety of the blood transfusion chain and fostering the goal of self-sufficiency. The Council adopted the elements of this strategy in its 1995 Resolution.\textsuperscript{18}

The reports throughout the 1980s of blood contaminated with HIV were undermining the public’s confidence in the blood supply, and at the same time public health experts were continuing to try to prevent the transmission by blood and other substances of human origin of the main types of disease-inducing agents – viruses, bacteria, parasites, and new emerging diseases. These highlighted the fact that national policies may sometimes have repercussions far beyond national frontiers. Certain public health problems call for an international response and hence close cooperation between the Member States.

The year 1997 was to see the Commission take a major step forward when it presented its first proposal under Article 129 of the Treaty of Maastricht.\textsuperscript{19} Adopted as a Council Recommendation,\textsuperscript{20} it aimed to set forth common criteria for the acceptance of blood and plasma donors as well as a set of screening tests that should be carried out in all Member States, whether the organ donation was intended for transfusion or for further manufacturing into plasma-derived products.

However, it was the entry into force of the Treaty of Amsterdam that was to provide the Community with an opportunity to put into place a more coherent legislative framework to address the elements that had been set out in the blood strategy and to ensure a high level of safety for both donors and recipients. From 1999 onwards, Article 152 of the Treaty has enabled the European Parliament and the Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. The Community has already adopted directives of the Parliament and the Council on Quality and Safety standards for blood in 2003, and on tissues and cells in 2004. However, it was already recognised during the discussions of the EU Tissues and Cells Directive that organs need a different approach. In this particular area the main priority is to reduce the organ shortage, and the Quality and Safety aspects have to be considered at the time of the shortage of organs for patients in need. In other words, since there are no shortages of human tissues and cells, the standards for Quality and Safety can be much more stringent than for organs which have different considerations in the context of severe, life-threatening shortages.

\textsuperscript{17} Communication from the Commission on blood safety and self-sufficiency. COM(94) 652 final of 21.12.1994.


The Venice Conference on Safety and Quality in Organ Donation and Transplantation in the European Union was held on 17–18 September 2003. The conclusions of this expert conference organised by the Italian government during its presidency of the EU Council listed the shortage of organs as the main priority in this area and stressed the importance of addressing the Quality and Safety aspects when fully considering the current framework of supply and demand for organs.

With the adoption of the EU Tissues and Cells Directive on 31 March 2004, the Commission made the following declaration to be entered in the minutes:

*The important differences between organ transplantation and the use of other human substances such as blood, tissues and cells mean that a specific approach for organs in order to ensure safety and quality is necessary. Such an approach in the current situation characterised by shortage of organs has to balance two factors: the need for organs' transplantation which is usually a matter of life and death with the need to ensure high standards of quality and safety. The Commission believes that before considering any proposal it is necessary to conduct a thorough scientific evaluation of the situation regarding organ transplantation. The Commission will present a report on the conclusions of the analysis it undertakes as soon as possible.*

In 2007 the Commission adopted a communication on organ donation and transplantation intended to respond to the main policy challenges in the field. The Commission communication proposed a combination of actions oriented to respond to the above-mentioned problems in order to strengthen cooperation between Member States through an Action Plan and a directive introducing the basic principles and the technical requirements for donation, procurement, testing preservation, transport and distribution of human organs.

On 6 December 2007 the European Council adopted conclusions on organ donation and transplantation. The Council recognised the importance of having high standards with respect to the quality and safety of organs for transplantation, in order to ensure a high level of protection for patients throughout Europe, and invited the Commission to continue its work under the proposed Action Plan aimed at increasing the availability of donor organs and, in consultation with the Member States, to continue its examination of the need for an EU framework on quality and safety for human organs.

On 22 April 2008 the European Parliament adopted a draft resolution on the communication. The Resolution fully shares the Commission’s analysis of the situation of organ donation and transplantation in the EU, and confirms the priorities for action outlined in the communication. It stresses the significant potential to share expertise between Member States, which can increase organ availability and equalise access to transplantation. It looks forward to the Commission Action Plan for strengthened cooperation between Member States and asks the Commission to establish an EU mechanism which would promote coordination activities between Member States in relation to organ donation and transplantation. The European Parliament recognises that it is ‘vitally important to improve the quality and safety of organ donation and transplantation’ to reduce transplant risks. Hence, the Committee looks forward to the Commission’s proposal for a directive setting requirements to assure the quality and safety for organ donation across the EU.
2.3.2 **European action is required: necessity test**

It may be helpful to review briefly the evidence presented thus far. We have noted that organ transplantation has increased significantly during recent decades. Medical improvements have made it the most cost-effective treatment for renal failure and the only treatment for liver, lung and heart failure. We shall also show that the cost–benefit analysis in favour of more organ transplantations is compelling. Yet organ donation rates and availability of organs vary considerably across Europe, with achievable good practice delivering far greater benefits in some Member States than others. Looking to the future, not only are more uses for transplantation to treat diabetes and metabolic diseases, for example, thought likely to prove successful, but also there is likely to be more transborder movement of the organs currently being transplanted. More generally there are significant risks in using organs in therapy that can be effectively managed through the application of Quality and Safety procedures. Such a system should also improve the traceability and follow-up of organ donation. A well-regulated organ donation and transplantation system is essential if organs are to be delivered on time, with accurate information and without unnecessary risk of transmitting disease to the recipient. An important contextual factor is the shortage of organs, with more than 56,000 patients on waiting lists in Western Europe. In the light of this evidence, arguments supporting EU action might be summarised as follows. First, transplantation poses a risk of transmitting disease to recipients. When organs cross borders, there is a transnational need to ensure traceability and report adverse reactions. Increasing movement of organs across borders, and increasing patient and donor mobility, are likely. Secondly, currently transplantation is carried out by professionals working under different jurisdictions. This both limits the transmission of good practice between systems and adds to the transaction costs of professionals moving from one national system to another. Thirdly, a European donor data set would allow for a more efficient allocation of organs for difficult-to-treat patients (and this might be especially helpful for smaller Member States). Fourthly, differences between national approaches may slow down medical treatment through (medically) unnecessary delays. Fifthly, as more people move across borders information will need to move with them to optimise organ donation and transplantation while maintaining citizens’ confidence in the system in the country they are visiting. Sixthly, perceptions of unfairness or waste in other countries may have an effect on donation rates if organs harvested in one country are to be transplanted in another. Seventhly, there would be benefits in coordinating organ donation and transplantation with steps already undertaken in the EU Tissues and Cells Directive. There is, therefore, a *prima facie* case for action at European level. However, in and of itself this case could simply imply a call for greater collaboration, common standards and interoperability. The Action Plan included in the policy options later to be discussed includes such a call for greater collaboration. The principal approach to European action in the field of organ donation and transplantation had already been subject to an impact assessment and had been scrutinised by the Impact Assessment Board (DG SANCO, 2007). The IAB was concerned that even a non-binding Action Plan might be an excessive response given the small number of organ interchanges, and this remains an important concern. The evidence supporting both an Action Plan and a directive is that the overall low number relates to those Member States that are not party to any international arrangements. The impact assessment showed that the average exchange rate of kidneys
between partner countries in the Eurotransplant region is 19.7 per cent (DG SANCO, 2007). As suggested above, this figure is likely to increase in the light of improvements in the transplantation currently common, the development of new opportunities in organ transplantation, and the increasing mobility of donors and patients (in Spain some 16% of donors are foreigners and more than 50% of these other Europeans). Furthermore, urgent patients and difficult recipients are especially poorly served by Member States with a more limited donor pool. Further support arises from public health considerations (Article 153) about the distributive justice of current arrangements and reducing preventable human harm as a human rights issue.

However, as the policy options discussed would include a legally binding directive going beyond voluntary collaboration, this requires additional justification. There are two complicating factors in making this case. The first is that subsidiarity is concerned with the relative advantages of central or decentralised discretion. The second is that the pursuit of the subsidiarity principle should be integrated with (and sometimes tempered by) the pursuit of other, equally beneficial principles (such as efficiency, fairness and innovation).

We should therefore consider what would have happened in the absence of the proposed action. In this case, we know that current arrangements have been sufficient to allow two voluntary agreements – Eurotransplant and Scandiatransplant – to emerge. Outside these, there is little cross-border movement of organs. Furthermore, there is an emerging European consensus about the Quality and Safety standards for organ and tissue transplantation. From a counterfactual viewpoint it is possible to imagine a future in which the desired outcomes of Quality and Safety are achieved through consensus and cooperation rather than a legal directive. It is therefore necessary to identify not only why a directive would improve on the current situation but also why alternatives would be less effective, solidaristic or efficient. The case (if a case can be made) for a directive to operate alongside the Action Plan is therefore that a directive adds value over and above a set of voluntary agreements. This addresses why legally binding European action would be better than national action.

### 2.3.3 The added value of European action: Why would (legally binding) European action be better than national action?

Our response to this question is shaped by two aims:

- Optimising the EU’s contribution (e.g. not asking Community bodies to do what they are too remote or too weakly endowed to do).

- Making best use of Europe’s diversity – this means fitting local solutions to local issues, of course, but also allowing European regions to learn from each other.

We are also aware that an excessively inflexible directive would either impose a one-size-fits-all solution or would provide a prescriptive starting point that might inhibit local self-expression and the revelation of diversity.

Factors that might helpfully be considered when assessing how to optimise the EU’s contribution include the following:

- quicker implementation

- lower transition costs in establishing the new Quality and Safety system
- reduced running costs
- greater fairness and contribution to solidarity
- enhanced donor and recipient confidence.

Considering these factors, some conclusions can be drawn. First, despite the growing consensus about Quality and Safety issues, requiring each Member State to conform to an identical Quality and Safety regime would conflict with the variety of health systems and would at the very least require considerable negotiations covering implementation. It might also fail to gain the sort of commitment and understanding at the local hospital level that is a pre-requisite for a successful Quality and Safety system. However, a flexible directive could accommodate these differences. Furthermore, by creating common reporting structures amongst diverse systems, not only would lessons be more easily transferred, and good practice identified, but by having a (minimal) level of compulsion the system would probably be implemented more quickly, with consequent benefits for potential recipients currently on waiting lists.

The implementation costs for an inflexible directive would be considerably greater than for a flexible directive. With an inflexible directive, Member States with effective Quality and Safety regimes may still be expected to change their existing regimes, with consequential additional costs. With a flexible directive, on the other hand, only those Member States with a weakly developed regime would face additional costs, and these would have cost benefits for those Member States, as argued above. Furthermore, a degree of compulsion would add to fairness by ensuring that all European citizens had access to reasonable Quality and Safety standards, and would provide a more effective conduit for learning and comparing across regimes. As organs are sourced on a more trans-European basis, and as patients and donors become more mobile, it would enhance confidence in the system. Furthermore, a flexible directive can support the principles not only of subsidiarity but also of fairness, efficiency and innovation. An inflexible directive would limit the level of natural diversity and so reduce the opportunities to innovate by learning from others. It would move decision-making further from clinician and patient level, with a potential loss of efficiency and responsiveness. It would also impose transition costs on Member States who already operate an effective system of Quality and Safety. On the other hand, an Action Plan on its own might lengthen the time required for uptake and fail to produce a standardised approach to reporting that would both improve transborder safety and enhance the opportunity to develop and spread good practice. Bilateral and multilateral freedom might also widen the gulf in care available across the Member States, with implications for fairness.

2.3.4 **Subsidiarity: some conclusions**
A flexible directive can be reconciled with the principle of subsidiarity on the following grounds:

- The European Community has a clear opportunity and obligation to implement binding measures laying down high standards of Quality and Safety for the use of blood, organs and substances of human origin.
• A flexible directive plus the Action Plan optimises the European Community’s contribution to public value by providing a platform for implementation and mutual learning which combines standardisation of reporting with diversity of service.

• A flexible directive plus the Action Plan allocates decision-making to the level where it can be most efficient and effective by distributing decision-making among the local hospital level, the Member States and the European level.

2.4 **Stakeholders affected by European action**

The organ donation and transplantation EC proposal has a direct impact on a broad range of stakeholders. They include individual patients such as organ recipients and living donors, as well as healthcare institutions such as hospitals with procurement and transplantation activity. In order to understand the effect of the European action in the field of organ donation and transplantation better, we first present the numbers of stakeholders concerned and later discuss how they would be affected by the proposal.

Information on the number of organ recipients and patients placed on the waiting lists is available in the recent Council of Europe Transplant Newsletter (Council of Europe, 2007). The data for 2006 have been presented in Table 2.2

**Table 2.2: Performed transplants and waiting lists in Europe, 2006**

<table>
<thead>
<tr>
<th>Organ</th>
<th>Transplants</th>
<th>Waiting list</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney (all combinations including &lt;15 yrs, single, double, living and non-heart beating (NHB))</td>
<td>16,819</td>
<td>44,485</td>
</tr>
<tr>
<td>Liver (all combinations, including &lt;15 yrs, split, domino, living, and NHB)</td>
<td>6,249</td>
<td>6,307</td>
</tr>
<tr>
<td>Heart (including &lt;15yrs, but excluding heart-lung)</td>
<td>2,019</td>
<td>2,549</td>
</tr>
<tr>
<td>Heart-lung (including &lt;15 yrs)</td>
<td>67</td>
<td>33</td>
</tr>
<tr>
<td>Lung (including &lt;15 yrs, single, double and NHB, but excluding heart-lung)</td>
<td>1136</td>
<td>1794</td>
</tr>
<tr>
<td>Pancreas (including &lt;15 yrs, excluding pancreas-kidney)</td>
<td>104</td>
<td>977</td>
</tr>
<tr>
<td>Small bowel</td>
<td>17</td>
<td>58</td>
</tr>
<tr>
<td>Multivisceral</td>
<td>146</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**Total** | **26,557** | **56,203**

Source Council of Europe [2007]
These data show that there are nearly three times more patients waiting for kidney transplant than the actual number of kidney transplantations. The DOPKI project\textsuperscript{21} showed that the gap between the number of patients on the waiting lists and the number of performed transplants is widening, although there is an increase in the number of transplantations year by year (DOPKI, 2006). Despite this widening gap, it is clear from the figures that an increase in organ donation through the EC proposal would affect a significant number of patients (tens of thousands) still waiting to receive organ transplants.

It is much more difficult to present the total number of difficult-to-treat organ recipients – a special needs group of patients. None of the sources identified by the project team provided data on the number of hyper-sensitised or urgent patients. The WHO Observatory on Donation and Transplantations data give some indication of the number of paediatric patients, providing figures for under-15-year-old organ donors (WHO, 2008). We can assume that organs retrieved from minor donors are transplanted to paediatric patients because the key factors considered when matching organs with potential recipients are the size of the organ and its developmental stage. According to the Council of Europe data, there were 930 organs transplanted among paediatric patients (<15 years), the bulk of which were divided between kidney (407) and liver (411) transplants (Council of Europe, 2007). In addition, the Council of Europe data show that 2,855 living kidney and liver organs were transplanted in 2006. The WHO database showed that there were 2,341 organs retrieved from living donors in 2006 (Council of Europe, 2007).\textsuperscript{22}

The Council of Europe Transplant Newsletter provides data on the number of transplant programmes per type of organ, and these data are summarised below in Table 2.3. As there are no European data available on the number of hospitals conducting transplantations, we listed the number of transplant programmes instead. However, a single hospital or transplant centre might house several transplantation programmes. As the most common transplantation programme is kidney transplant, and most hospitals performing liver, heart or lung transplantation also transplant kidneys, the total number of hospitals in which transplants are performed will be very close to the number of kidney transplantation programmes (around 300 in the European Union).

\textsuperscript{21} DOPKI’s consortium is composed of 13 organisations on behalf of 16 European countries, which represent 80% of the population and 80% of all the donation and transplantation activity in Europe. See DOPKI (2006).

\textsuperscript{22} EU-27 except from Luxemburg, Latvia and Malta.
Table 2.3: Total number of transplant programmes across EU-27

<table>
<thead>
<tr>
<th>Organ</th>
<th>Transplant centres across EU-27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>280</td>
</tr>
<tr>
<td>Liver</td>
<td>143</td>
</tr>
<tr>
<td>Heart</td>
<td>134</td>
</tr>
<tr>
<td>Heart-lung</td>
<td>7</td>
</tr>
<tr>
<td>Lung</td>
<td>77</td>
</tr>
<tr>
<td>Pancreas</td>
<td>95</td>
</tr>
<tr>
<td>Small bowel</td>
<td>16</td>
</tr>
<tr>
<td><strong>Total number</strong></td>
<td><strong>752</strong></td>
</tr>
</tbody>
</table>

SOURCE: Council of Europe (2007), missing data from DOPKI (2006), no data for Czech Republic, Slovenia and Ireland

Although the number of transplant centres is a useful figure, it does not accurately depict the number of healthcare institutions that may be affected by the EC proposal since organ procurement and donation occurs in the intensive care units (ICU) of healthcare institutions that are not transplant centres. For that reason, we provide the number of hospitals with organ procurement activity for the countries that we examined in detail (Table 2.4). The table shows that across six Member States, there are nearly a thousand healthcare institutions directly involved in the organ transplantation pathway that would be affected by DG SANCO’s proposals to increase organ availability, improve Quality and Safety and make transplantation systems more efficient and accessible.

Table 2.4: Hospitals with organ donation activity affected by the EC proposal in a selected sample of Member States

<table>
<thead>
<tr>
<th>Country</th>
<th>Hospitals with organ donation activity (i.e. procurement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>613 hospitals were involved in organ procurement in 2006.</td>
</tr>
<tr>
<td>Greece</td>
<td>There are 74 ICUs with transplant coordinators, of which 45 are the most active hospitals</td>
</tr>
<tr>
<td>Poland</td>
<td>There are approximately 120 accredited procurement hospitals</td>
</tr>
<tr>
<td>Spain</td>
<td>155 hospitals are authorised as centres for extraction</td>
</tr>
<tr>
<td>Sweden</td>
<td>Around 90 ICUs are involved in organ procurement activities</td>
</tr>
<tr>
<td>U.K</td>
<td>About 250–300 acute trusts are considered potential procurement centres</td>
</tr>
</tbody>
</table>

All of the stakeholders discussed are directly affected by the policy options currently under review by DG SANCO, but there are differences in the roles and implications for each. From the organ recipient perspective, European-level action would facilitate the interchange of organs between national authorities, which would mean shorter waiting times for transplantations and increased chances for an optimum organ match – especially among difficult-to-treat patients (e.g. hyper-sensitised) and paediatric patients. The EC proposal could also facilitate further uptake in the number of retrieved organs in many European countries and this, in turn, would provide ever greater availability of organs by increasing the total number of transplantation procedures. On the other hand, there is a
risk associated with transplantation. Therefore, it is essential to assure the same level of Quality and Safety standards as well as compliance to processes and procedures in the transplantation activities across Europe to ensure a high level of human health protection. European-level action would also require establishing common standards for living donor transplantations as currently there are significant variations in national legislations (e.g. on the subject of who is eligible to become a living donor). In addition, it is important to facilitate the exchange of information between Member States to ensure that all living donors are provided with adequate post-transplantation medical care.

For hospitals with organ procurement and transplantation activity, the implementation of the proposal could bring some auditing and enforcement costs related to the improved reporting requirements and process monitoring. Hospitals would also be affected by the requirement to promote the transplant coordinator role as well as improve the communication skills of care providers.
Ultimately, the strategic goal of DG SANCO is to achieve a high standard of human health protection. In the area of organ donation and transplantation, this goal can be broken down into three objectives in order to tackle current and future shortcomings and to guide European policy: 1) increasing organ availability; 2) enhancing the efficiency and accessibility of transplantation systems; and 3) improving Quality and Safety. Figure 3.1 illustrates the three main policy objectives of the Commission.

### Main objective: high level of human health protection (Article 152 of the Treaty)

- **Increase organ availability**
- **Enhance efficiency and accessibility of transplantation systems**
- **Improve quality and safety of organs**

**SOURCE:** DG SANCO

**Figure 3.1: Diagram of the three main policy objectives**

#### 3.1 Increasing organ availability

The severe shortage of organs remains the main challenge that EU Member States face with regard to organ transplantation. A high number of patients die while on waiting lists and these lists are expanding faster than organ donor rates. Thus, the Commission seeks to support Member States in increasing the number of donors as actions to fulfil this objective are expected to help reduce the gap between supply and demand and may even achieve an absolute reduction in the waiting lists.

This policy objective has two dimensions. First, Member States should reach the full potential of deceased organ donations and, secondly, Member States should increase living organ donation as a viable alternative to donation from deceased donors.
3.2 Enhancing the efficiency and accessibility of transplantation systems

Like other healthcare access issues, this objective has to be seen in relation to other initiatives at Community level in the area of health system quality improvement. There are a number of Member States with less developed transplant systems which can be supported and guided in their efforts to improve organ donation rates, the number of organ transplantations performed and post-transplant results.

Even among EU countries with well-developed health and organ transplant services, there are considerable differences in organ donation and transplantation activity. It is clear that some organisational systems are performing better than others. Thus, initiatives focused on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local characteristics are critical to fulfilling the need for all Member States to have well-organised and efficient transplant systems for optimal health outcomes (i.e. the main objective) and cost savings.

The severe shortage of organs, furthermore, significantly restricts access to transplantation services in many EU Member States. Since urgent and difficult-to-treat patients increasingly seek transplantation services in countries with larger donor pools and shorter waiting lists, the efficiency and accessibility of transplantation systems in Europe can be further enhanced by better identification at EU level of needs for the interchange of organs between national authorities. Guidelines for systems to offer surplus organs to other countries are another component of this policy objective.

3.3 Improving Quality and Safety

Quality and Safety is at the core of the main political objective of ensuring a high level of human health protection (Article 152). Quality and Safety standards are essential to maximise the safety and efficacy of the use of human organs in the health system, and these include reducing the likely risk of adverse medical events related to the transplantation pathway as well as ensuring adequate handling of all steps on the organ donation pathway. Taking into account the mentioned specificities of organ donation and transplantation, the European policy initiative is designed ultimately to improve procedures related to organ transplants.

Due to the organ shortage and the life-threatening indications of organ transplants, the benefits of organ transplantation are high and more risks can be accepted than with blood and most tissues and cells treatments. In this context, the clinical doctor has a key role to play in the decision to accept an organ for transplantation. Thus, while actions to improve Quality and Safety could have an effect on organ availability, it is expected that that two objectives will be mutually reinforcing rather than conflicting.
To achieve the objectives outlined in the previous section, DG SANCO proposes three different policy options which this impact assessment compares against a baseline option of continuing with the status quo. The policy options proposed by DG SANCO promote policy actions in five broad areas of policy intervention, and can be distinguished by their regulatory approach, from voluntary cooperation to a stringent legal directive. This chapter first presents the five areas of policy interventions before moving on to presenting the options.

4.1 Areas of intervention

4.1.1 Creating national institutions for organ donation and transplantation

A sound national infrastructure and responsible institutions for organ procurement and transplantation have been identified by DG SANCO as important elements of a successful transplantation system. Creating competent national institutions is thus a key element of the proposed policy options. The proposals include the creation or nomination of a competent national authority in each Member State, the authorisation of establishments and activities, and the creation of a register of establishments. In addition, proposals include regular national reporting obligations and improved cooperation between competent authorities at national level. Given the different performance of organ donation systems across Europe, DG SANCO has identified the enhancement of organisational models as another area of policy intervention.

4.1.2 Improving processes

Of equal importance to adequate organisation of an organ donation and transplantation systems is ensuring the quality of processes performed by the various organisations in the field. To improve these processes, DG SANCO proposes the introduction of quality programmes to ensure continuous monitoring of performance improvement and learning. This includes specific standards for the procurement and transport of human organs. An integral part of the proposed quality programmes would be inspections and control measures to ensure compliance with high quality standards.

As shown by the experience of the Spanish model, transplant coordinators can have a pivotal role in improving transplantation systems. The proposed policy options aim to promote the role of the transplant coordinator and to encourage training of the personnel involved in the process. Knowledge about organ donation and communication skills
among healthcare professionals as well as patient support groups are an additional target for action.

4.1.3 Reducing risks to patients
Organ transplantation is a potentially life-saving treatment, which nevertheless involves substantial risks to the patients. These risks emanate from the quality and matching characteristics of the organ as well as the medical treatment received.

The proposed policy option encompasses the establishment of a common set of criteria to characterise organs, which is essential information to assess the risks for receiving patients. In addition, the proposals include measures to capture serious adverse events related to the procurement, testing and distribution/transport of organs, as well as any serious adverse reactions observed during or after transplantation which may be connected to the procurement, testing and transport/distribution of the organ.

Systems to ensure that organs can be traced back to the original donor are vital in order to notify other organ recipients quickly in case a dangerous infection has been discovered. The proposals contain a link between such a traceability system and the tissue and cells vigilance system.

Finally, the proposals contain measures to improve knowledge about transplantation outcomes, in particular for relatively new donor groups such as expanded criteria donors or non-heart-beating donors.

4.1.4 Living organ donation
As an alternative to organs from deceased donors, living organ donation has not yet reached its full potential. The policy options contain a number of measures to promote living donation. These include the development of a register for living donors to follow up their health status, measures to ensure the altruistic and voluntary donation of organs by living donors, and actions to ensure that living donors receive the healthcare they need.

4.1.5 Cross-border aspects of organ donation
DG SANCO also proposes measures to address shortcomings in the exchange of organs between Member States and problems resulting from the mobility of donors across borders. DG SANCO proposes the introduction of measures to improve the identification of organ donors between Member States. To facilitate the exchange of organs and to ensure the quality of the organ donation and transplantation process, DG SANCO proposes a process to share information about available organs better between Member States, while at the same time introducing systems to authorise the export and import of organs to ensure their quality and safety.

Finally, DG SANCO proposes measures to promote EU-wide agreements on basic rules for internal EU patient mobility and transplantation. Such rules would include a ban on organ trafficking and an agreement on patient mobility and transplantation, as well as common priorities for future research in the field of organ donation.
4.2 **Policy options**

Besides the continuation of the status quo, DG SANCO proposes three different policy options which are based on differing regulatory approaches to achieve their objectives in the field of organ donation and transplantation:

- Option 1: continuing the status quo
- Option 2: European Action Plan
- Option 3: European Action Plan + ‘flexible directive’
- Option 4: European Action Plan + ‘stringent directive’.

4.2.1 **Option 1: Continuing the status quo**

Under this option, the European Commission would continue with its current activities in the field of organ donation and transplantation, which involves predominantly sponsoring research and pilot programmes in this field and participating in international cooperation such as in the Council of Europe. Figure 4.1 provides an overview of the different European projects currently supported by the European Union. These include projects under the 6th framework programme (blue) and projects supported by the Directorate-General for Information, Society and Media (DG INFSO), as well as projects by DG SANCO (green).

![European Projects in organ donation and transplantation](image)

**Figure 4.1: Option 1 – Current European projects in organ donation and transplantation**
4.2.2 **Option 2: European Action Plan**

This option proposes a non-regulatory approach to the field of organ donation and transplantation. It would establish a European Action Plan on Organ Donation and Transplantation for the period from 2009 to 2015. This Action Plan sets out a cooperative approach for Member States based on national action plans. This approach is based on the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

The priority actions proposed by the European Action Plan are listed and mapped against DG SANCO’s objectives in Figure 4.2.

**THE ACTION PLAN**

- **Increasing organ availability**
  - Priority action 1: Promote the role of transplant donor coordinators in every hospital where there is a potential for organ donation
  - Priority action 2: Promote Quality Improvement Programmes in every hospital where there is a potential for organ donation

- **Make transplantation systems more efficient and accessible**
  - Priority Action 3: Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors
  - Priority Action 4: Improve knowledge and communication skills of health professionals and patients support groups on organ transplantation
  - Priority Action 5: Facilitate the identification of organ donors across Europe and cross border donation in Europe
  - Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU member states.
  - Priority Action 7: Promote EU-Wide agreements on aspects of transplantation medicine
  - Priority Action 8: Facilitate the interchange of organs between national authorities
  - Priority Action 9: Evaluation of post transplant results

- **Improve quality and safety**
  - Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes

*SOURCE: DG SANCO*

*Figure 4.2: Option 2 – a European Action Plan*
4.2.3 **Option 3: Action plan + ‘flexible directive’**

Option 3 combines the Action Plan described under Option 2 with a ‘flexible’ directive supporting key elements of the Action Plan in the area of Quality and Safety. The regulatory approach of this directive would be very much a framework initiative, ensuring that national legislation was put in place to deal with key aspects of organ donation and transplantation but without prescribing detailed policy measures. Key measures primarily linked to the quality and safety of organs, but also supporting the priority actions of Option 2, are illustrated in Figure 4.3.

**THE ACTION PLAN + FLEXIBLE DIRECTIVE**

**ACTION PLAN**

- Priority action 1: Promote the role of transplant donor coordinators in every hospital where there is a potential for organ donation
- Priority action 2: Promote Quality Improvement Programmes in every hospital where there is a potential for organ donation
- Priority Action 3: Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors
- Priority Action 4: Improve knowledge and communication skills of health professionals and patients support groups on organ transplantation
- Priority Action 5: Facilitate the identification of organ donors across Europe and cross border donation in Europe
- Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States
- Priority Action 7: Promote EU-Wide agreements on aspects of transplantation medicine
- Priority Action 8: Facilitate the interchange of organs between national authorities
- Priority Action 9: Evaluation of post transplant results
- Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes

**DIRECTIVE**

- The establishment of national oversight authority or authorities.
- Authorization of activities.
- Ensure traceability.
- Reporting of serious adverse events and reactions.
- Establishment of National Quality Programmes.
- Protection of the donor.
- Establishment of registers.
- Ensure a complete characterisation of the organ in order that the transplant team could undertake the appropriate risk assessment.

**Source:** DG SANCO

**Figure 4.3: Option 3 – Action plan + ‘flexible directive’**
4.2.4 **Option 4: Action plan + ‘stringent directive’**

Option 4 would combine the Action Plan described under Option 2 with a stringent directive. This stringent directive would be modelled on the EU Tissues and Cells Directive and would therefore contain detailed regulation about the Quality and Safety systems Member States have to put it in place, leaving little national discretion for transposing the directive. The more detailed prescriptions of Option 4 are presented in Figure 4.4.

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**THE ACTION PLAN + STRINGENT DIRECTIVE**

<table>
<thead>
<tr>
<th>ACTION PLAN</th>
<th>DIRECTIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Priority action 1: Promote the role of transplant donor coordinators in every hospital where there is a potential for organ donation</td>
<td>The establishment of national oversight authority or authorities.</td>
</tr>
<tr>
<td>• Priority action 2: Promote Quality Improvement Programmes in every hospital where there is a potential for organ donation</td>
<td>Authorization of activities.</td>
</tr>
<tr>
<td>• Priority Action 3: Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors</td>
<td>Inspection structures and requirements for inspection</td>
</tr>
<tr>
<td>• Priority Action 4: Improve knowledge and communication skills of health professionals and patients support groups on organ transplantation</td>
<td>EU Guidelines for inspection</td>
</tr>
<tr>
<td>• Priority Action 5: Facilitate the identification of organ donors across Europe and cross border donation in Europe</td>
<td>Ensure traceability</td>
</tr>
<tr>
<td>• Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU member states.</td>
<td>Detailed traceability criteria</td>
</tr>
<tr>
<td>• Priority Action 7: Promote EU-Wide agreements on aspects of transplantation medicine</td>
<td>Coding requirements</td>
</tr>
<tr>
<td>• Priority Action 8: Facilitate the interchange of organs between national authorities</td>
<td>Reporting of serious adverse events and reactions</td>
</tr>
<tr>
<td>• Priority Action 9: Evaluation of post transplant results</td>
<td>Detailed Reporting of SAE/R Criteria</td>
</tr>
<tr>
<td>• Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes</td>
<td>Annual report to the Commission</td>
</tr>
</tbody>
</table>

**Increasing organ availability**

**Make transplantation systems more efficient and accessible**

**Improve quality and safety**

---

**SOURCE: DG SANCO**

**Figure 4.4: Option 4 – Action plan + ‘stringent directive’**
In this chapter, we analyse the impact of the policy options identified by DG SANCO. The chapter starts with an overview of the possible impacts of the key elements of the policy proposals, presented as a visual diagram. Then it discusses the approach chosen to analyse the impacts of the policy options. The reminder of the chapter provides a detailed discussion of what key impacts can be expected of the policy options: the health, social and economic impacts. Each impact section is divided into at least two main parts: a first section presenting the background to the specific type of impact (‘background’), and a second section on how the impact is likely to vary across the policy options. The second section forms the basis of the comparison of the policy options in the next chapter.

5.1 A model of the policy intervention

The policy options proposed by DG SANCO include a variety of policy interventions, with the ultimate objectives of increasing the availability of organs and making the transplantation systems more efficient and accessible, as well as improving the quality and safety of organs. Figure 5.1 illustrates the causal link between the policy interventions and the desired outcomes and the objectives. For clarity, the actions foreseen under the Action Plan (Option 2) and the flexible (Option 3) or stringent directive (Option 4) are grouped into the broad areas of policy intervention identified in the previous section. The following example clarifies how this graph should be interpreted:

Measures to reduce risks for patients include the establishment of common principles for organ/recipient risk assessment, measures to trace a transplant to the original donor, the notification of adverse events and reactions and the evaluation of post-transplant results. If we follow the first causal chain, these measures might lead to the introduction of better Quality and Safety standards in Member States, which in turn might lead to a reduction in graft-related risks and improved graft survival, but might also increase organ waste. From here two causal chains can be identified: first, an increase in organ waste might reduce the total number of available and transplanted organs, which reduces the total number of QALYs and life years gained through transplantation. Secondly, a reduction of risks for patients that leads to longer life for transplant recipients and fewer complications also influences the QALYs and life years that can be saved. Thus, this policy intervention might lead to fewer transplants, but better outcomes for those receiving a transplant. If we follow the second causal chain at the first bifurcation, the proposed policy measures will lead to integration with the tissue and cells vigilance system, which in turn will create specific start-up and running costs.
Figure 5.1: Causal model of the impacts of European action in the field of organ donation and transplantation
It is important to note when analysing the impacts of the policy proposals that some of the most substantial impacts, in terms of benefits as well as costs, will only occur once the primary objective of increasing organ availability has been achieved. While, for example, the requirement of having a transplant coordinator at every hospital would in the first place lead to an increase in staff costs and salaries, the substantial benefits of saving treatment costs and saving lives would only be realised when the use of transplant coordinators indeed increases the organ donation and transplantation rates.

Finally, it is important to note that Figure 5.1 is a very simplified model of the policy intervention. In particular, it does not take into account intervening factors and the institutional context of the Member States’ healthcare systems.

5.2 **A strategy to assess the scope of possible policy impacts**

As shown above, the causal chains between the proposed policy intervention and the desired outcome can be considered to be very long, and outcomes are dependent on a diversity of intervening factors (not depicted in the figure). This dependency is a first complicating factor in assessing the impacts of DG SANCO’s policy options. Organ donation and transplantation rates in particular are affected by this complication, as these rates depend on a multitude of different factors that are not addressed in DG SANCO’s policy proposal. These include, but are not limited to, the size of the (theoretically) available donor pool, the system of obtaining consent, the capacity in ICUs to maintain donors, the training of doctors and the competing priorities of national health services. In contrast, DG SANCO’s proposals focus mostly on the organisation of the national transplant system as a key driver of organ donation.

A second complicating factor in assessing the impact of the policy options arises from the uncertainty with which voluntary policy measures such as an Action Plan, or policy measures with considerable discretion such as a European directive, are implemented. Some Member States might be unwilling and/or others unable to implement the policies that are expected to maximise organ donation and transplantation rates.23

Together, these two complicating factors make it very difficult, or even impossible, to assess directly the impact of different policy options within a study like this one. To manage these difficulties, RAND Europe thus applied an alternative strategy to assess and quantify the possible scope of impacts. This strategy has three elements, which are described in more detail below. First, we benchmark DG SANCO’s policy proposals against a recognised case of good practice, the so-called Spanish model. This benchmarking allows us to assess whether the policy options are likely to have an impact on organ donation and transplantation rates. Having established some link between the policy options and the transplantation rates, we then, secondly, use scenarios to assess the wider health, social and economic impacts that changes in the transplantation rates would have. Finally, the scenarios are loosely linked to the policy options by taking into account the

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23 Refer also to the more detailed discussion in Section 8.2.
findings from the benchmarking exercise. It is important to note, however, that the numerical estimates presented are the results of the assumed transplantation rates, and could be only loosely related to the policy option. RAND Europe thus provided very broad ranges of what changes would be possible under each scenario. The following sections describe the benchmarking and the scenarios in more detail.

5.3 Comparing the options against best practice

5.3.1 The Spanish model

The Spanish model is widely acknowledged as an outstanding example of how organisational changes in the transplantation system can increase the number of organs available from deceased donors. 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 Organisation (ONT) in 1989 and began to set up a nationwide system to monitor potential organ donors (Miranda et al., 1999). Since then, the ONT has coordinated and facilitated 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 organ procurement and donation system in 1989 has increased donation rates by more than 130 per cent within ten years. In 1989, 14.3 organs per million population were donated; as early as in 1999 33.6 organs per million population were donated, and donation rates have since stabilised at this high rate – Spain has the highest organ 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 organs pmp. The top 20 per cent of health regions have organ donation rates ranging from 42 to 48.4 organs pmp. These increases have been the result of changes in logistics and process management (Healy, 2006). In particular, the success of the Spanish approach to organ donation is commonly attributed to five interlinked elements of the Spanish system (Matesanz and
Miranda, 1996; Miranda et al., 1999; Matesanz, 2001; 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.

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.

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 of identifying weakness in the process and developing 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. It consists of evaluations in each participant hospital, which are conducted in two phases. The first phase is an internal evaluation carried out by the transplant coordinating team in each hospital. The team reviews all clinical histories of deaths within the hospital’s ICUs and provides the ONT with a description of the circumstances, including the reasons 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 are verified, the efficiency of the process of organ donation and extraction is assessed, and areas for improvement are identified.

4. Adequate training of staff involved, 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 respond adequately to and support the grieving relatives of deceased donors.

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. However, the Spanish did not invest heavily in public awareness campaigns or similar measures, due to shortage of funds.

The next section compares these key elements against DG SANCO’s policy options.

### 5.3.2 Benchmarking DG SANCO’s proposals against the Spanish model

Having established the key elements of the Spanish model, we can now compare DG SANCO’s policy proposals against them. Table 5.1 provides an overview of this comparison, listing the five key features of the Spanish model and related policy interventions contained in the four policy options.

<table>
<thead>
<tr>
<th>Key element</th>
<th>Option 1: Baseline</th>
<th>Option 2: Action Plan</th>
<th>Option 3: AP + flexible approach*</th>
<th>Option 4: AP + stringent directive*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplant coordinators and coordinating teams in each hospital</td>
<td>Variable within and across MS</td>
<td>All MS to ‘promote the role of transplant donor coordinators in hospitals’</td>
<td>All MS to ‘promote the role of transplant donor coordinators in hospitals’</td>
<td>All MS to ‘promote the role of transplant donor coordinators in hospitals’</td>
</tr>
<tr>
<td>Reimbursement of hospitals to recover procurement costs</td>
<td>Variable across MS.</td>
<td>Not contained in policy option</td>
<td>Not contained in policy option</td>
<td>not contained in policy option</td>
</tr>
<tr>
<td>A quality assurance system (or programme) in all Autonomous Communities, with two stages of evaluation</td>
<td>Variable within and across MS</td>
<td>All MS to (1) ‘promote quality improvement programmes in every hospital where there is a potential for organ donation, which is primarily a self-evaluation of the whole process of organ donation, aiming to identify areas for improvement’; and (2) ‘evaluation of post-transplant results’</td>
<td>Legal mandate for (1) quality programmes, including quality systems and quality standards in all MS; and (2) inspections and control measures, subject to MS decision-making/implementation</td>
<td>Legal mandate for (1) quality programmes, including quality systems and quality standards in all MS and (2) inspections and control measures, directed by the EU Commission</td>
</tr>
<tr>
<td>Adequate training for transplant coordinators and personnel involved in organ donation and procurement</td>
<td>Variable within and across MS</td>
<td>Promotion of the Implementation of effective training programmes for transplant donor coordinators</td>
<td>Legal mandate for personnel/training in all MS, subject to MS decision-making/implementation</td>
<td>Legal mandate for personnel/training in all MS, directed by EU Commission</td>
</tr>
<tr>
<td>Public awareness and proactive management of mass media opportunities</td>
<td>Variable within and across MS</td>
<td>All MS to ‘[i]mprove knowledge and communication skills of health professionals and patient support groups for organ transplantation’</td>
<td>All MS to ‘[i]mprove knowledge and communication skills of health professionals and patient support groups for organ transplantation’</td>
<td>All MS to ‘[i]mprove knowledge and communication skills of health professionals and patient support groups for organ transplantation’</td>
</tr>
</tbody>
</table>

*In addition, all actions foreseen under the Action Plan will be implemented.

MS = Member States; AP = Action Plan

The comparison shows that the policy options address all but one of the key features of the Spanish model. The issue of the reimbursement of procuring hospitals is not touched on by any of the policy options, although interviewees pointed out that reimbursement of hospitals might be an important factor in getting small hospitals to participate in organ procurement. While all other features of the Spanish model are addressed by the policy
options, it is important to point out that the policy options grant the Member States a large degree of discretion in implementation, which could lead to substantially different outcomes in the implementation and differing degrees of similarity to the Spanish model. There are, however, differences between the options, as Options 3 and 4 would make the introduction of quality assurance programmes and certified training of the transplant coordinators and other staff involved legally binding for the Member States to implement, and thus more similar to the Spanish model.

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).

Overall, we can conclude from the comparison that the policy proposals contain considerable elements of the Spanish model, but implementation will not necessarily lead to a similar model to that in Spain, due to the latitude in how to implement the regulations. To echo some responses from interviews with stakeholders, the proposals are a necessary but not sufficient condition to achieve the success of the Spanish model.

Due to their similarities to the Spanish model, DG SANCO’s proposals can be expected to have a positive effect on organ donation rates; however, only the Member States which are committed to implementing the European framework regulation into detailed national regulations modelled after the Spanish model will be likely to achieve the Spanish organ donation rates. As the discretion for Member States is lower in Option 3 and Option 4, and these prescribe more key elements of the Spanish model, a better outcome on the organ donation rate can be expected from these.

5.3.3 A benchmark for living kidney donation

In the case of living donation, there is no established good practice that is as clear cut and commonly accepted as the Spanish system for deceased organ donation. Not least, this can be attributed to ethical considerations that influence countries’ decisions to promote living organ donation (see e.g.: Gutmann and Land, 1999; Liu et al., 2003; Walton-Moss et al., 2005; Mazaris and Papalois, 2006; Spital and Taylor, 2008). Still, there are substantial differences in kidney transplantation rates from living donors. The European countries with the highest kidney donation rates from living donors are currently Norway (17.0 transplantations pmp), The Netherlands (16.6) and Sweden (14.4), with rates that are, however, still well below the transplantation rates in the United States (21.4). For the purpose of this study, we shall focus on Norway as the best-performing European country.

The high rate of transplantation from living kidney donors in Norway is often attributed to an active rather than a passive identification of potential (related) living kidney donors. In agreement with the potential organ recipient, nephrologists actively search for potential donors within the patient family and approach family members direct. This is combined with giving living donation priority over deceased donation. That means that patients are only put on a waiting list for donation from deceased donors if no suitable living donor
could be identified (Jakobsen et al., 1996; Lück et al., 2003). This contrasts with the practice in other European countries such as Germany. In Germany, the principle of subsidiarity is applied, which gives priority to donation from deceased donors and living donors are not actively sought by the transplant centres. The Netherlands also extended the number of living donations but, in contrast to Norway, they chose to increase the potential pool of living donors by creating, for example, the possibility of cross-over donations, which since their introduction in 2004 in The Netherlands have contributed to success in increasing kidney transplantation rates.

The policy actions proposed by DG SANCO do not directly address these factors for success in either Norway or The Netherlands. Instead, the Action Plan contains a broad commitment to promote altruistic donation programmes from living donors, on the basis of appropriate ethical and legal safeguards concerning the protection of the living donors and the prevention of organ trafficking. In addition, the policy Options 2, 3 and 4 contain measures to ensure the protection of living donors from health and health-related economic risks. Thus, the effect of Options 2, 3 and 4 on living donation rates will depend solely on the commitment of Member States to substantiating DG SANCO’s broad proposals with actions under their own national Action Plans. To illustrate the potential effect of an effective policy to encourage living donation, the scenarios described in the next section include the Norwegian living donation rate as an element of a best-case scenario for Europe.

5.4 Developing scenarios to define the scope of potential impacts

To overcome some of the uncertainty caused by differing institutional contexts and implementation styles in the Member States, RAND Europe developed four scenarios to define the scope of possible impacts of the policy options. In the following section, the scenarios are presented and then in turn discussed in relation to the policy options.

5.4.1 Four scenarios for future transplantation rates

While it would be unsound to link a specific scenario to a specific policy option, the scenarios will nevertheless allow the policy-makers to assess the range in which possible impacts would occur. In the scenarios RAND Europe used transplantation rates rather than organ donation rates, because doing so allows one to take into account (and keep stable) the national conversion rates.

RAND Europe developed four scenarios based on a distinctive set of assumptions about the transplantation rate for organs from deceased donors and living donors. For more detail, see the summary of the scenarios in the methodology section (Section 1.2.4) and Appendix B:

- Scenario 1 assumes that all Member States achieve the transplantation rate of the best-performing European country. This means that all Member States achieve Spanish transplantation rates from deceased donors and Norwegian rates for living organ donation. Both cases, the Spanish as well as the Norwegian have been discussed in the previous section as a benchmark for the DG SANCO’s policy
measures. This scenario defines the outer boundary of the benefits and costs that can be expected from implementing the policy proposals.

- Scenario 2 assumes that all countries achieve at least the EU average transplantation rates. This is a less ambitious scenario, as it assumes that low-performing countries in particular could improve their transplantation activities, while the above-average performers maintain their current levels, even if they are still well below the Spanish levels.

- Scenario 3 assumes an across the board increase of 30 per cent. The 30 per cent would be a substantial increase, yet a conservative estimate of the effect of changes in the organisation of organ donation. Indeed, much higher increases have been reported from a wide range of measures in a wide range of Member States:
  - The Spanish reforms led to an increases in donation rates of 130% over a 10 year period (Miranda et al. (2003)
  - The introduction of transplant coordinators lead to 132% increase in transplantation rates between 2001 and 2005 in Greece. The consolidation and professionalisation of the transplant coordinator network in 2005 lead to an increase of 38 per cent alone between 2004 and 2005 (Karatzas et al., 2007).
  - The implementation of the Donor action programme in 12 hospitals in Finland lead to an increase of 59 per cent in organ retrievals.\(^\text{24}\)
  - By introducing the Spanish Model, the Italian region of Tuscany doubled their donation rate in the space of only one year (Simini, 2000).

Still, this scenario is likely to overestimate the gains that can be achieved in the already good performing Member States, but is a very feasible scenario for the low performing countries.

- The assumption for Scenario 4 is based on the same evidence, but an even more conservative estimate by assuming only a modest increase of 10% for all countries.

Table 1.1 (p. 5) provides an overview of these assumptions and the actual transplantation rates used.

Both sets of scenarios have certain specific limitations. Scenarios 1 and 2 probably underestimate the additional gains of transplantations that could be achieved in countries that are already performing well, while at the same time overestimating the gains for the countries that currently have a very low transplantation rate. Scenarios 3 and 4 might in turn overestimate the performance of good performers, while neglecting the potential of the below-average performers.

\(^{24}\text{see Donor action Facts and Figures Donor Action website www.donoraction.org accessed on 30 April 2008}\)
These scenarios, however, do not take into account the very complex relationship between maximal possible donor pool and conversion rates from potential and identified donors into utilised donors, and have thus to be treated with great caution. Yet, we suggest that the conservative Scenario 2 and Scenario 4 are probably the most realistic and achievable scenarios for EU Member States.

The four scenarios developed by RAND Europe give an impression of the number of additional transplanted organs that could be achieved. In the best-case Scenario 1, an additional number of 21,000 organs would be transplanted, while a 10 per cent increase across all Member States (Scenario 4) would still generate an additional 2,636 transplanted organs annually.

Table 5.2: Changes in number of transplanted organs under different scenarios

<table>
<thead>
<tr>
<th>Organ type</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplantations from deceased donors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney, from deceased donors</td>
<td>8,250</td>
<td>1,940</td>
<td>4,261</td>
<td>1,420</td>
</tr>
<tr>
<td>Liver, from deceased donors</td>
<td>5,276</td>
<td>1,347</td>
<td>1,803</td>
<td>601</td>
</tr>
<tr>
<td>Heart</td>
<td>928</td>
<td>432</td>
<td>626</td>
<td>209</td>
</tr>
<tr>
<td>Lung</td>
<td>789</td>
<td>365</td>
<td>361</td>
<td>120</td>
</tr>
<tr>
<td>Transplantations from living donors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney, from living donors</td>
<td>5,712</td>
<td>830</td>
<td>785</td>
<td>262</td>
</tr>
<tr>
<td>Liver, from living donors</td>
<td>50</td>
<td>70</td>
<td>71</td>
<td>24</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total additional transplanted organs</td>
<td>21,005</td>
<td>4,984</td>
<td>7,907</td>
<td>2,636</td>
</tr>
</tbody>
</table>

5.4.2 Linking scenarios and policy options

As discussed earlier, the impact of each policy option not only depends on the proposed policy measures, but also on the approach to implementation by Member States and the capacity of healthcare systems in the Member States. First, the European policy proposals contain to a large degree only broad requirements or framework regulation which do not cover all aspects of organ donation and transplantation. It is up to Member States to transpose these requirements and complement them with national action. In principle, a Member State could do a necessary minimum to implement the policies, with little effect on organ donation rates, or could fully commit to the policy and implement it with supporting measures to achieve the optimal outcome. Secondly, not all Member States will have the capacity or the willingness and resources to expand their healthcare systems to accommodate the number of organ donation gains.

Taking into account the findings from benchmarking the policy options against the Spanish model, we can nevertheless try to assign different degrees of change to each policy option, as illustrated in Table 5.3. For Option 1, the continuation of the status quo, with no or only incremental increases of organ donation rates across the European Union can be expected. However some Member States will continue with their already existing efforts to
implement good practice. Option 2 might lead to a high increase in organ donation rates, if Member States are committed to implementing the rather general elements of the Action Plan. As these are largely voluntary, no substantial effect can be expected when there is a lack of commitment from the Member States or Member States reach their capacity limits. Thus, achieving a substantial increase in organ donation rates for Option 2 is related to high levels of uncertainty.

Options 3 and 4 are likely to increase organ donation rates at least modestly, even if Member States are not fully committed and/or should have insufficient capacities as they prescribe key elements and make national implementation mandatory. In turn, if capacity is sufficient and Member States’ commitment is high, higher increases in organ donation rates are possible. We have used Scenarios 1 and 3 to define the upper boundaries of what could be achieved under these circumstances, while Scenarios 2 and 4 can be seen as the lower boundary of expected increases in transplanted organs. Table 5.3 provides an overview of which scenarios are more likely under which policy options.

Table 5.3: Scenarios and policy options

<table>
<thead>
<tr>
<th>Key element</th>
<th>Option 1: Baseline</th>
<th>Option 2: Action Plan</th>
<th>Option 3: AP + flexible approach</th>
<th>Option 4: AP + stringent directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low commitment and low capacity Member States</td>
<td>No increase</td>
<td>No increase</td>
<td>Low (Scenario 4) to modest increase</td>
<td>Low (Scenario 4) to modest increase</td>
</tr>
<tr>
<td>High commitment and sufficient capacity of Member States</td>
<td>No substantial increase</td>
<td>Medium (Scenario 3) to high increase</td>
<td>Medium (Scenario 3) to high increase</td>
<td>Medium (Scenario 3) to high increase</td>
</tr>
</tbody>
</table>

For Option 4, a less positive outcome is conceivable, which has not been covered by the benchmarking exercise. If the stringent directive is very prescriptive and Member States ‘gold plate’ the European directive by adding more requirement and complexity, the directive may create disincentives for some establishments to participate in organ procurement and thus reduce the organ donation rate. Most of the stakeholders interviewed for this research expressed the concern that, if the directive were to be modelled along the lines of the EU Tissues and Cells Directive, organ donation would be disrupted. Several of the expert respondents provided anecdotal first-hand experiences of the negative impact of the EU Tissues and Cells Directive as a warning of the risk of a similar outcome of a stringent directive for organs modelled on the it.

5.5 Health impacts

5.5.1 Organ donation and transplantation rates

Background

Several studies of the Spanish model, and a recent study in Greece, indicate that the positive impact of improving processes, measured by increased organ donation rates, results not from the legal context of a Member State but from investing in the more fine-grained organisation of the transplant system: putting more staff on the ground, training them better, and improving coordination between the different actors and agencies involved in
the procurement process. This is not to say that other influences are unimportant; Abadie and Gay (2006) found, for example, that after controlling for other determinants of organ donation in 22 countries over a 10-year period, presumed consent legislation had a positive and sizeable impact on organ donation rates.

In reorganising its procurement system in the early 1990s, Spain has substantially increased its organ donation rates, as discussed above.

Again, the increased organ donation during the 1990s cannot be attributed to any change in Spanish legislation, but rather to logistics and process management (Healy, 2006). As Matesanz (2001) emphasises, the positive effects of Spain’s model for improving processes have come from training and organisational innovation to improve the process of organ procurement, similar to some of the priorities in the Action Plan listed above: namely training/personnel, inspections and control measures or systematic audits, conditions of procurement and adequate reimbursement.

Training programmes for health professionals, specifically dedicated to every step of the organ donation process, have contributed to the approach of obtaining consent from donor families (Rosel et al., 1999). In addition, local transplant coordinators help increase the use of older donors who previously would not have been considered viable candidates for procurement (Chang et al., 2003). Miranda et al. (2003) attribute the 130 per cent increase in organ donation rates over 10 years (from 14 to 34 donors per million population) to the permanent network of trained staff.

Similar positive impacts from these ‘inputs’ have been described for the Italian region of Tuscany. After regional transplant authorities in Italy explicitly copied the Spanish approach to procurement in its entirety, Tuscany alone ‘doubled its organ donation rate to 26.9 donors per million population in the space of just one year.’ (Simini, 2000).

Moreover, in Greece, a series of organisational actions by the Hellenic Transplant Organizations (HTO) – specifically, the institution and formation of a specialised professionals’ network for closer cooperation between the 45 most donor-generating ICUs and their 55 local transplant coordinators – resulted in 2005 in a 154 per cent rise in possible donor referrals, a 33 per cent increase in used donors and nearly a 38 per cent increase in transplantations, as compared to 2004 (Karatzas et al., 2007).

Another example of successful improvements in processes which had a substantial impact on organ donation rates is the Donor Action Programme (see description in Box 5.1). The Donor Action Programme led to substantial increases in organ donation rates in all countries/ICUs where it has so far been rolled out. Between 1995 and 2003, hospitals that implemented the programme’s improvement measures could demonstrate an increase in organ donation rates of 59.2 per cent in one year (Roels and Wight, 2001). According to Schütt (2002), pilot programmes in Europe to improve procurement using the tools developed in the Donor Action Programme have been shown to increase organ donation rates by up to 500 per cent in a single hospital.25

**Box 5.1: The Donor Action Programme**

**The Programme**

The DA Program methodology is based on the principles of quality management as defined by the international Organization for Standardization (ISO), the reference authority in this field. This is a rigorous analytical approach which uses data from individual CCUs to provide insights into all the processes involved in a hospital’s organ donation processes and from there to introduce planned improvements with the objective of achieving quality in those processes.

**Key steps of the Donor Action Programme**

- **a.** Consolidation of support for organ donation among senior medical personnel.
- **b.** A two-part diagnostic review consisting of a retrospective medical record review and a survey of hospital staff attitudes towards organ donation, resulting in a detailed profile of strengths and weaknesses of the current system.
- **c.** Based on gaps identified in the diagnostic review, specific programmes are tailored for individual sites using modules developed for that specific issue.
- **d.** Implementation of modules.
- **e.** Ongoing monitoring of results and monitoring are undertaken.

(see Whiting et al., 2004)

**Origin**

The methodology used by the programme was designed by three major organisations involved in organ donation and transplantation: Eurotransplant (NL); Organizacion Nacional de Trasplantes (ESP); and The Partnership for Organ Donation (USA).

**SOURCE:** www.donoraction.org, Whiting et al. (2004)

Finally, and most dramatically perhaps, 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 HTO has achieved a 448 per cent increase in potential donor referrals and 132 per cent increase in transplantations performed (Karatzas et al., 2007). The latter results have a clear and significant health impact for patients.

**Comparing the options**

While the evidence is unambiguously clear about the strong relationship between organisational improvements and increases in organ donation rates, it is less clear to what extent the policy options designed by DG SANCO would lead to such an increase. If we use the assessment provided in the previous section of the expected impact under high/low commitment and implementation from the Member States (the Table 5.3), we would arrive at reasonable ranges for the potential increases in the number of transplantations, depicted in Table 5.4.
Table 5.4: Possible increase in transplanted organs

<table>
<thead>
<tr>
<th>Key element</th>
<th>Option 1: Baseline</th>
<th>Option 2: Action Plan</th>
<th>Option 3: AP + flexible approach</th>
<th>Option 4: AP + stringent directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low commitment and or low capacity Member States</td>
<td>No increase</td>
<td>No substantial increase</td>
<td>2,636 to 4,983</td>
<td>2,636 to 4,983</td>
</tr>
<tr>
<td>High commitment and sufficient capacity of Member States</td>
<td>No substantial increase anticipated</td>
<td>7,908 to 21,006, with high uncertainty</td>
<td>7,908 to 21,006, with legal certainty</td>
<td>7,908 to 21,006, with legal certainty</td>
</tr>
</tbody>
</table>

Transplantation rates under Option 1 are expected to remain stable, with no substantial Europe-wide increase irrespective of the level of commitment and/or capacity of Member States. With low commitment and/or low capacity of Member States, Option 2 would also be expected to result in no substantial increase in transplanted organs. But if Member States are fully committed to and/or have adequate capacity to implement the largely voluntary policy measures, Option 2 could lead to a high increase in transplantations (between 7,908 and 21,006). Similarly, Options 3 and 4 are expected to lead to the same range of high increases in transplanted organs – i.e. a 30 per cent increase in organ donation rates (a total of 7,908 more organs), or even the transplantation rates of the current best performers Spain and Norway (21,006 more organs) – but with greater certainty as the objectives attained with the Action Plan will be underlined by the added benefit of a legal mandate for certain areas of intervention. Unlike Option 2, we can also expect at least a modest increase in transplantation to occur for Options 3 and 4, even if Member States are reluctant to commit fully to improving their organ donation systems due to the mandatory nature of the proposal.

5.5.2 Quality adjusted life years and life years saved

Background

Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30 per cent (Miranda and Matesanz, 1998). In the UK, the average waiting time for an adult kidney transplant is 2.5 to 3 years (but more than 5 years for some minority ethnic groups). The average waiting time in Greece for organ transplantation is 5 years.

In Poland, the mortality rate among patients undergoing dialysis treatment is about 13 per cent per year, with cardiovascular illnesses being responsible for the majority of deaths. The average predicted lifetime survival rates for patients undergoing dialysis treatment is 10 years, while it is 20 years for kidney transplantation patients. The average number of kidney transplants per year over the last few years is about 1,000, with a 93 per cent survival rate in one year following kidney transplantation. The 5-year survival rate is 77 per cent in Poland. The age-dependent survival times for kidney transplant recipients compared to dialysis patients are presented in Table 5.5, below. Other health impact data on survival rates for organ transplants from the Polish Traceability System are provided in Table 5.6.
Table 5.5: Comparison of predicted survival rates for dialysed patients and for kidney transplant patients in Poland

<table>
<thead>
<tr>
<th>Age group</th>
<th>Predicted survival times for dialysed patients</th>
<th>Predicted survival times for kidney transplant patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>20–39</td>
<td>14 years</td>
<td>31 years</td>
</tr>
<tr>
<td>40–59</td>
<td>11 years</td>
<td>22 years</td>
</tr>
<tr>
<td>60–74</td>
<td>6 years</td>
<td>10 years</td>
</tr>
</tbody>
</table>


Table 5.6: Survival rates for organ transplants for years in 2005 and 2006 in Poland

<table>
<thead>
<tr>
<th>Organ</th>
<th>Number of transplants in 2005–2006</th>
<th>Number of patients under observation</th>
<th>3-month survival rates</th>
<th>12-month survival rates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Organ recipients (%)</td>
<td>Transplanted organs</td>
</tr>
<tr>
<td>Kidney from cadaveric donors</td>
<td>1,939</td>
<td>1,107</td>
<td>1,107 (97%)</td>
<td>1,020 (92%)</td>
</tr>
<tr>
<td>Kidney from living donors</td>
<td>47</td>
<td>29</td>
<td>29 (100%)</td>
<td>29 (100%)</td>
</tr>
<tr>
<td>Liver from cadaveric donors</td>
<td>379</td>
<td>223</td>
<td>199 (89%)</td>
<td>192 (86%)</td>
</tr>
<tr>
<td>Liver from living donor</td>
<td>33</td>
<td>16</td>
<td>15 (94%)</td>
<td>15 (94%)</td>
</tr>
<tr>
<td>Pancreas and kidney (survival of both organs)</td>
<td>58</td>
<td>27</td>
<td>23 (85%)</td>
<td>19 (70%)</td>
</tr>
<tr>
<td>Heart</td>
<td>190</td>
<td>105</td>
<td>78 (74%)</td>
<td>78 (74%)</td>
</tr>
<tr>
<td>Lung</td>
<td>9</td>
<td>3</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

SOURCE: [Poltransplant, 2007])

The positive health impact of organ transplantation can also be measured by the QALY gained. The most complete information obtained from our country studies on the general health impact of organ donation and transplantation comes from the UK Transplant Supplement Report (Department of Health, 2008b). For example, liver transplantation has the highest QALY gain (11.5); heart has 6.8 QALY gain and lung has 5.2 QALY gain (Table 5.19). Compared with dialysis, the benefits of different treatment strategies for Type 1 Diabetes with ESRF range from 2.01 to 5.77 additional QALYs (Table 5.7). In addition, evidence from the international literature shows that a typical donor generates about 13 QALYs at an added medical cost of about US$ 214,000 ($16,000 per QALY), with a highest estimate of $57,000; at this value then, the benefit obtained from one added donor would be $214,000 (Mendeloff et al., 2004).
Table 5.7: Benefits derived from different treatment strategies in the UK for Type 1 Diabetes with end-stage renal failure

<table>
<thead>
<tr>
<th>Treatment Strategy</th>
<th>Life expectancy (LY)</th>
<th>Δ LY</th>
<th>QALY</th>
<th>Δ QALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis</td>
<td>7.82</td>
<td>-</td>
<td>4.52</td>
<td>-</td>
</tr>
<tr>
<td>Cadaveric kidney transplant</td>
<td>11.4</td>
<td>3.62</td>
<td>6.53</td>
<td>2.01</td>
</tr>
<tr>
<td>Simultaneous pancreas-kidney transplant</td>
<td>15.74</td>
<td>7.92</td>
<td>9.09</td>
<td>4.57</td>
</tr>
<tr>
<td>Pancreas after kidney transplant</td>
<td>17.21</td>
<td>9.39</td>
<td>10.00</td>
<td>5.48</td>
</tr>
<tr>
<td>Living kidney transplant</td>
<td>18.30</td>
<td>10.48</td>
<td>10.29</td>
<td>5.77</td>
</tr>
</tbody>
</table>

SOURCE: Knoll and Nichol (2003) p. 506, Table 3

Estimates have also been conducted on how the improvement of the organ donation process can result in QALY gains. The most concrete information on the health impact of activities to improve processes comes from a study by Roels et al. showing that the Donor Action Programme – demonstrated to increase organ donation rates by 59.2 per cent – will result in 33 QALYs per million population (Roels et al., 2003). 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 (Chang et al., 2003), leading to an amplification of QALYs gained as more organs become available through policy measures to improve processes.

In addition, by ‘enhancing the organisational model of organ transplantation’ in Italy, ISMETT\(^26\) has had a clear positive health impact: one-year survival rates from transplantation (liver, kidney, heart, lung, pancreas) are 5–10 per cent above the national average in Italy. More specifically, patients in the liver transplantation programme have an over 90 per cent one-year survival rate and an 80 per cent five-year survival rate, and the number of paediatric liver transplantations at ISMETT has risen steeply from less than 5 in 2003 to 30 in 2006 – an increase paralleled in Milan only between 1997 and 1998 (Gridelli, 2008).

**The impact of different scenarios and comparison of options**

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 stems primarily from the transplantation of liver, lungs and hearts, as there 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.

\(^26\) Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione (ISMETT)
Table 5.8: Estimated quality adjusted life years and life years gained

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>QALY</td>
<td>LY</td>
<td>QALY</td>
</tr>
<tr>
<td>Kidney</td>
<td>25,576</td>
<td>16,500</td>
<td>6,014</td>
</tr>
<tr>
<td>Liver</td>
<td>94,877</td>
<td>136,128</td>
<td>22,310</td>
</tr>
<tr>
<td>Heart</td>
<td>56,101</td>
<td>49,501</td>
<td>13,192</td>
</tr>
<tr>
<td>Lung</td>
<td>42,901</td>
<td>28,876</td>
<td>10,088</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>219,455</strong></td>
<td><strong>231,005</strong></td>
<td><strong>51,604</strong></td>
</tr>
</tbody>
</table>

Comparing the options

If these estimates are assigned to the policy options as discussed in Section 5.4.2, 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 the contrary, under the assumption of stable organ donation rates, waiting lists are likely to increase further, which would have 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 less good health, which reduces the QALY and life years gained 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 Scenarios 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 Options 3 and 4 would achieve a modest increase in organ 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 of between 37,783 and 51,604. The maximum effect that can be expected would be defined as for Option 2 as Scenarios 1 and 3.

5.5.3 Health risks to patients

The proposed EU Action Plan and legal directive seek to reduce the risks of poor organ quality and safety to patients through the following measures: donor/organ and recipient risk assessment, organ traceability, notification of adverse events and reactions, and evaluation of post-transplant results.
Background

Transmission of communicable diseases and malignant diseases

As discussed in the problem definition, the use of organs in therapy poses a risk of communicable diseases being transmitted to the recipient. These risks have been described in the scientific literature: viral, bacterial and fungal infections have been transmitted via transplantation of organs. Several types of protozoan and worm parasites have also been transferred via organ transplants. Because organs cannot be subjected to sterilisation procedures, the risk of infectious disease transmission remains and thorough donor screening and testing is especially important. Although testing covers a broad range of infections, there are some of primary interest; Human Immunodeficiency virus (HIV), Hepatitis B virus (HBV) and Hepatitis C virus (HCV). A complete revision of the main risks is provided in Appendix A.

In addition, the transmission of malignant diseases – i.e. cancer – has also been described in the literature and is a risk of organ transplantation (ONT, 2004). Table A.1 in Appendix A provides an overview of the findings of main international registers, which measure the risk of tumour transmission through organ transplants. Although the risk of tumour transmission exists, the frequency of donors with tumours and the frequency of transmission are low. Generally, tumours of a high degree of malignancy are more often transmitted from donor to recipient, whereas the transmission of tumours of a low degree of malignancy or localised tumours is much less frequent. For this reason donors diagnosed with low-grade skin tumours of low capacity for metastasis, like basocellular carcinoma, and donors diagnosed with spinocellular carcinoma without metastasis could be considered for the organ donation. On the other hand, not enough evidence exists to set a period of time for which a donor must be free of the neoplastic disease before being accepted. This depends on the type and features of the tumour, meaning that decisions should be specific to each case.

While there is clear evidence of the potential risks for patients from infections and the transmission of malignant diseases, there is only limited evidence of the impact of the introduction of (international) Quality and Safety standards on medical outcomes of transplantation and adverse events.

Adverse events and patients’ safety

Apart from the risks of transmission of disease, organ transplantation is a high-risk surgical procedure (including blood transfusions) that requires long-term exposure to strong medication such as immunosuppressive drugs, which means that organ transplant patients constitute a patient group at great risk of suffering a patient safety incident. However, there is a paucity of previous efforts to monitor the problem of adverse events among European (transplant) patients, and several experts in the field suggest that there is no known risk in the quality and safety of organs transplanted across Europe.

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27 This section has been adapted from DG SANCO’s previous impact assessment DG SANCO (2007).
It has been shown internationally and in EU Member States that over half of all adverse events are considered to be preventable. RAND Europe recently applied the estimates found in the literature on the prevalence of adverse events related to hospitalisations (ranging from 7.5 per cent to 16.6 per cent, with median of 10 per cent, depending on country, year and specific study) to the total number of discharges, and summing over all EU countries. Across the entire EU-27, between 6.7 and 15 million hospital discharges are associated with an adverse event (Conklin et al., forthcoming). More specific to the organ transplantation process, a study in the US found that 19 per cent of kidneys procured are damaged from the extraction procedure. Organ damage was found to be associated with team expertise, whereby multiorgan transplant teams had a lower rate of kidney damage than a kidney transplant team (Wigmore et al., 1999).

Since the success of transplantation can be counterbalanced by serious adverse medical events, it is important to give special attention to patients at higher immunological risk (i.e. recipient risk assessment) as part of the process of reducing risks to patients. A study in Italy showed that a new computerised algorithm for cadaveric kidney allocation (NITp programme) demonstrated good overall quality in terms of patient and graft survival and special attention to this particular group of high-risk patients (Cardillo et al., 2005). More generally, the health impact of adverse event-reporting and learning systems for patient safety is currently unknown in Europe because such systems have only been in place since the start of the millennium. However, a few Member States are currently in the process of evaluating the impact of reporting and learning systems in terms of improved patient safety and health outcomes. The consensus among European patient safety experts suggests that any measurable impact(s) cannot be attributed to any one policy measure (e.g. notification of adverse events); rather, any positive impacts from improvements in patient safety must be taken in the broader context of a package of policy actions (Conklin et al., forthcoming).

Nonetheless, it has been shown that quality assurance systems in organ donation and transplantation reduce missed information on organ abnormalities or organ damage from the procurement operation (Basaran et al., 2003). Given that 19 per cent of kidneys procured are damaged from the extraction procedure, quality assurance systems – supported by the notification of adverse events and reactions in organ donation and transplantation – could conceivably result in a large health (and economic) impact. Indeed, RAND Europe recently performed a quantitative simulation of health impacts due to policy changes proposed by the European Commission to improve patient safety at large (including notification of adverse events). This simulation demonstrated a great potential for the prevention of the negative health consequences of adverse events, the majority of which pertain to procedures that organ transplant patients will undoubtedly undergo.

Results from a RAND Corporation survey of agencies and departments responsible for hospital licensing and regulation in each of the 50 US states on the topic of patient safety found that US states have been quick to adopt or adapt the recommendations made in To Err is Human (Kohn, 2000) regarding standardised patient safety reporting and learning systems and that ‘federal directives may not be necessary’ (Beckett et al., 2006).
**Comparing the options**

Option 1 will lead to no change in the currently diverse regulatory landscape of Quality and Safety standards across the EU. There is already a wide range of initiatives to follow up the medical results of transplantation (see Section 5.7.2) and these different systems will be likely to co-exist increasingly. However, under Option 1 no integration of these systems is expected across Europe. In addition, adverse events are not systematically captured in most Member States, leaving a large potential to improve the processes of organ donation and transplantation as well as improve the medical outcomes of organ transplantation.

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 central European register or network of registers. While this option does not directly address the risks incurred by patients during transplantation, it would contribute to better treatment in the long term as knowledge about transplantation outcomes increases.

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. These data would be stored in such a way that they could be transmitted quickly between Member States to facilitate the exchange of organs. Despite these European standards, the final decision about transplanting a particular organ would still rest with local transplant teams. The common system of organ characterisation would be supplemented with a reporting system for adverse events identified 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 the cross-border exchange of organs, which has been proved to be beneficial. Adverse event-reporting systems have been proved 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 is expected to lead to substantial health benefits.

Under Option 4, similar Quality and Safety standards and adverse event-reporting systems would be introduced, which would lead to the same positive health outcomes. The substantial difference between the options is the regulatory approach. Option 4 would give the Member States less discretion in implementing standards and would even limit the decisions that could be taken by transplant teams by, for example, defining a list of exclusions of certain types of organs.

5.5.4 Living organ donation

**Background**

Over many years, living organ donation has become a real alternative to improve organ availability. Living organ donation offers some advantages compared to that from deceased donors. The survival rates of non-related living organ donation are the same as in

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28 This section is based on a draft provided by DG SANCO.
parental organ donation and higher than in deceased organ donation. In addition, graft survival from living donors is currently higher than graft survival from deceased donors, so the motivation for patients to seek a living donor transplant is stronger, not only on account of better life quality but also given the longer life expectation.

It has been proved that the use of organs from living donors has had positive repercussions on the length of waiting lists; however, it is important to ensure that organ donation is voluntary, there is no financial gain and there is proportionality between the harm caused to the donor and the benefits created for the recipient.

Currently, living organ donation represents 17 per cent of kidney transplant activity in Europe, a percentage that varies considerably between European countries. The number of living donors differs significantly from country to country: from two transplants from living donors pmp in Spain to 20.7 in Norway. In addition, the percentage of living organ donation over organ donation from deceased donors is rapidly increasing and in northern countries the percentage is now above 50 per cent.

**Current practice in living organ donation**

Living organ donation is currently allowed in every European country, but sometimes it is permitted only under certain conditions. This kind of organ donation is, in most countries, regulated by specific provision, but there are a few exceptions such as Austria and Ireland. In Austria there are deductive legal provisions but no law directly regulating living organ donation. Table 5.9 provides an overview of the current (legal) frameworks across a sample of Member States.

It is in the relationship between donor and recipient that there are the biggest differences in the legislation of the Member States. A relationship between donor and recipient must exist in most countries, but this relationship does not need to be genetic. Countries such as Austria, Belgium, the Czech Republic, Finland, Germany, Latvia, Luxemburg,

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29 Among 1700 patients who received a kidney transplant from living non-related donors in the United States from 1995 to 1998, the 1-year and projected 10-year graft survival rates were 92% and 67%, respectively. These results are superior to the 87% and 50% rates of the more than 26,000 cadaver kidney transplants during the same period. Hoyer (2006).

30 The median graft survival from living donors is currently around 20 years, whereas that from cadaver donors is about 12–13 years Friedlaender (2003).

31 COM (2007)

32 In Romania 89.5% of kidneys for transplantation are from living donors, 39.4% in Norway, and 100% in Georgia.

33 The law differentiates between persons with a close personal relationship in terms of the civil code (descendants, ancestors, sibling and spouses) and others.

34 Art 8 (1) TPG establishes that the removal of organs which are non-regenerative is only permissible for transfer to relatives in the first or second degree: spouses, registered partners, fiancés or other persons with whom the donor has a particularly close personal relationship.

35 For adult donors there are no legal criteria, and for minors the recipient must be a brother or sister of the donor.
Norway, The Netherlands, Poland, Sweden, Spain and the UK do not require a genetic relationship between the donor and the recipient. Certain jurisdictions require a genetic relationship in order to avoid economic incentives, which are more common in organ donations between non-genetically related individuals.

Regarding authorisation, except for Germany and Luxemburg, the rest of the countries require special authorisation for organ donation between non-related living donors.

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36 Donation of non-regenerative organs to a close family relation should exist (ascendants and descendants of direct line, adopted persons, brothers, sisters and spouses). For other persons considered as close personal contacts, an authorisation by a judge will be required.

37 The transplantation may only be performed on a donor who is related or otherwise very close to the intended recipient.

38 Special authorisation is not necessary. Nevertheless, the opinion of the Commission in charge of the removal is taken into account when there is reason to believe that the consent was not given voluntarily or when the organs are going to be used for organ trafficking. However, Art 8 (3) TPG states that the opinion of the Commission mentioned is not binding.

39 Authorisation is only needed when the donor is a minor.
### Table 5.9: Institutional context of living organ donation in a sample of European countries

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Country</th>
<th>Regulated by law (in parliamentary transplantation act)</th>
<th>Informed consent required</th>
<th>Allowed for persons lacking legal capacity</th>
<th>Principle of subsidiarity</th>
<th>Requirement for donor-recipient relationship</th>
<th>Approval by ethical committee</th>
<th>Approval by court</th>
<th>Altruistic/No remuneration</th>
<th>Organ trafficking penalised</th>
</tr>
</thead>
<tbody>
<tr>
<td>J.</td>
<td>Austria</td>
<td>No; only position paper</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>BTS</td>
<td>Belgium</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Not mandatory</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>MZSS</td>
<td>Croatia</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>KST</td>
<td>Czech Republic</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>ABM</td>
<td>France</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>DSO</td>
<td>Germany</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Hu-T</td>
<td>Hungary</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>CNT</td>
<td>Italy</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>J.</td>
<td>Luxembourg</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>NTS</td>
<td>Netherlands</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Poltransplant</td>
<td>Poland</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Only in case of non-relatives</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>OPT</td>
<td>Portugal</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Slovenija-Transplant</td>
<td>Slovenia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, with obligations</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>ONT</td>
<td>Spain</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Swistransplant</td>
<td>Switzerland</td>
<td>From 2007</td>
<td>Yes</td>
<td>Yes, with some obligations</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>UK – Transplant</td>
<td>United Kingdom</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, rare</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>


**Protection of the living organ donor**

It has been proved that the function of the remaining kidney of a living kidney donor remains stable during long-term follow-up in most cases of living organ donation. However, safety for the donor is crucial since the removal of a kidney or part of the liver involves surgery performed to a healthy person, carrying a risk. Research shows that the
risk of death exists and is very small (0.03%) The risk of any complication ranges from 2 per cent to 16 per cent, depending on how complications are defined. Major complications occur at a rate of about 2–6 per cent. A study examining the living kidney organ donation process determined the mean hospital stay to be six days (ranging from 3 to 9 days) (Cabrera et al., 2003).

To cover these risks, living donors need to be adequately protected and it must be ensured that living donors receive the treatment they require. The scenarios designed by RAND Europe show an increase in the number of living donors, who all would be exposed to the risk of adverse health effects.

Table 5.10: Estimated additional number of living donors

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living kidney donors</td>
<td>2,617</td>
<td>5,712</td>
<td>830</td>
<td>785</td>
<td>262</td>
</tr>
<tr>
<td>Living liver donors</td>
<td>238</td>
<td>50</td>
<td>70</td>
<td>71</td>
<td>24</td>
</tr>
<tr>
<td>Total additional donors</td>
<td>2,855</td>
<td>5,762</td>
<td>900</td>
<td>856</td>
<td>286</td>
</tr>
</tbody>
</table>

Comparing the options

Option 1, the no-change option, would not change the current practice of living organ donation in EU Member States, with a wide variation in organ donation rates and a large potential for increased organ donation and differing legal frameworks for the acceptance of living organ donation. Nevertheless, given the current organ shortage and witnessing the development in particular in the Nordic countries and The Netherlands, where living organ donation has become a very important substitute for organ donation from deceased donors, we can assume that even under Option 1 the importance of living organ donation might increase in the medium and long term.

Option 2, in contrast, tackles three important elements of living organ donation. It would encourage Member States to ensure altruistic and voluntary organ donation while promoting living donation, it would promote the establishment of living donor registries to follow up the health effects on the donors systematically, and finally it aims to ensure adequate health protection and healthcare coverage for living organ donation. Estimates based on our scenarios see a maximum of 5,762 additional living donors possible across the EU, if all Member States had living organ donation rates similar to those of Norway. As this is, in particular under a voluntary agreement, a very optimistic assessment, we would expect that under full commitment from Member States organ donation rates will be somewhat below this value.

However, it is clear that Member States could substantially increase their living organ donation rates if they shared and learned from best practice. The second provision, the evaluation of the medical status of living donors, could contribute to bridging the current knowledge gaps about living organ donation and would help to decrease adverse effects for

40 http://www.livingdonorsonline.org/
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 risks) of organ donation. Finally, the third provision, ensuring voluntary and altruistic organ donation, would reinforce national practice in the Member States and could contribute to building more trust in living organ donation in the transplantation pathway.

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 organ donation rates, this measure might increase trust in the system overall and reinforce an increase in living organ donation rates.

5.5.5 Cross-border exchange

Background

The cross-border exchange of organs can be linked to positive health impacts. For specific patient subgroups, such as highly immunised, high-urgency patients and children, a larger donor pool is beneficial as it increases the chances of a suitable organ being available in time. Evidence from Eurotransplant presented in Figure 5.2 shows that for these groups of patients international exchange is very important. Across the Eurotransplant area, two thirds of kidneys for highly immunised patients come from another Member State. In a small country like Belgium, this percentage is even higher, at around 79 per cent of all kidneys for highly immunised patients.

![Figure 5.2: Kidney exchange for special patient groups in Eurotransplant and Belgium](image)


However, as discussed in the problem definition (Chapter 2), the full potential of cross-border exchange of organs has not yet been reached in the European Union. As shown in Table 5.11 only the two international cooperation agreements Eurotransplant and
Scandiatransplant achieve a substantial exchange of organs, to the benefit of special patient populations.

Table 5.11: Cross-border exchange of organs in the European Union

<table>
<thead>
<tr>
<th></th>
<th>Organs transplanted from abroad</th>
<th>Organs transplanted abroad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greece (2006)</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>Italy (2006)</td>
<td>26</td>
<td>2</td>
</tr>
<tr>
<td>Poland</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Spain (2007)</td>
<td>34</td>
<td>6</td>
</tr>
<tr>
<td>Eurotransplant</td>
<td>(exchange of organs from deceased donors within ET area, as % of all deceased organs transplanted)</td>
<td>20% (= 3,300)</td>
</tr>
<tr>
<td>Eurotransplant</td>
<td>(exchange of organs from deceased donors outside ET area, as % of all deceased organs transplanted)</td>
<td>2% (= 330)</td>
</tr>
<tr>
<td>Scandiatransplant</td>
<td>Exchange of organs, 2007</td>
<td>Kidney 10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Liver 19%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heart 27%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lung 21%</td>
</tr>
</tbody>
</table>

In Italy, organisational improvements showed that there is a potential for exchanging more organs across national borders. The creation in 2005 of the Italian Gate to Europe (IGE), a single national coordinating centre for the exchange of organs and patients with the rest of Europe, resulted in an increase in the exchange of organs between Member States, in particular between Italy, Greece and Slovakia, with no detriment to the probability of Italian citizens being transplanted as a result of these international agreements (Pretagostini et al., 2007). It is feasible that the actions proposed by DG SANCO could have similar impacts, particularly for difficult-to-treat and paediatric patient groups.

Comparing the options
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.

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.

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41 i.e. countries outside the European Union.
Options 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 important in their transplant teams’ willingness to consider and accept organs, as well as in their sending organs to other countries. It thus seems reasonable to assume that Options 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.

5.5.6 Health inequalities

There is evidence from the UK (Department of Health, 2002; Randhawa, 2007; Department of Health, 2008b; Radcliffe Richards, 2008.), France (Tuppin et al., 2004; Cantrelle et al., 2008.), the US (Higgins and Fishman, 2006) and a European Organisation (CEAPIR, 2006) to indicate that inequalities do currently exist in transplant services and the solutions to tackling health inequalities in this area are complex and multifaceted. At a symposium convened by the Diversity and Minority Affairs Committee of the American Society of Transplantation (AST), participants noted that minority populations were more likely to be adversely affected by limited preventive medical care, lack of counselling regarding transplant options and delays in referrals for organ transplantation.

The findings of the UK Transplant Supplement Report show that if there is a substantial and sustained increase in the number of organs transplanted in the UK population, there is a risk of a widening gap between the white population and black, minority and ethnic (BME) groups (Department of Health, 2008b).

In the UK, the number of organs being donated amongst BME groups (only 3%) is less than in other sectors of society and yet their need for organ transplantation, particularly kidney transplantation, is substantially higher. More specifically, the rates of ESRF are highest among South Asian and Afro-Caribbean populations and, at the same time, there are disproportionately higher numbers of South Asians and Afro-Caribbeans represented on transplant waiting lists. But, even with a steep increase in organ donation amongst BME groups (and consent rates in this group are very low), demand will still outstrip supply, in comparison with the white population.

Members of these two BME groups have a high prevalence of Type 2 Diabetes: recent studies indicate a prevalence rate four times greater than for whites and, in one study (Burden et al., 1992), up to 13 times higher. Diabetic nephropathy is the major cause of ESRF in South Asians and Afro-Caribbeans, with a higher relative risk, when corrected for age and sex, of 4.2 for the South Asian community in England and of 3.7 for those with an Afro-Caribbean background. In other words, these two BME groups are not only more prone to diabetes than whites; they are more likely to develop ESRF as a consequence.
More problematically, 14 per cent of people waiting for a kidney transplant are South Asian and over 7 per cent are Afro-Caribbean, even though they comprise only 4 per cent and 2 per cent respectively of the UK general population. South Asians and Afro-Caribbeans have to wait on average twice as long (more than 5 years) as white people (2.5 to 3 years) for a kidney transplant. South Asians are also more represented on the liver and heart transplant waiting lists.

Adding to the disproportionate morbidity and mortality from these specific needs for organs in the BME communities, it is known that BME groups in the UK experience inequalities in access to care, with growing evidence that South Asians are referred later for renal care and are more likely to be lost to follow-up (Jeffrey et al., 2002).

The review of health inequality studies in the Supplement Report (Department of Health, 2008b) shows that BME groups are ‘disproportionately affected by renal health problems both in terms of access to appropriate services and the higher prevalence of renal complications, reduced likelihood of a transplant, and longer waiting times on the transplant waiting list’. As the report suggests, the problem will get worse in the future because the Asian population tends to be younger.

Anecdotal evidence from a stakeholder interview with an expert from The Netherlands suggested that, while it is not permitted to record the race of a patient in the medical records of that individual, it is known that organ donation rates are much lower among patients from South Asia (e.g. Pakistan and East India) and Turkey, as well as among older patients. Reasons for lower organ donation rates were not provided, but could be inferred from UK research concluding that additional work is needed to consider barriers to organ donation and transplantation amongst BME groups across Europe, including cultural and financial barriers.

A 1999 report of the German Foundation for Organ Transplantation stated that considerably more men than woman receive organs (64% male vs 36% female recipients), particularly heart (Smit et al., 2002). As among BME groups in the UK, gender differences can be traced back to earlier stages in medical treatment. For example, men are more likely to receive dialysis for ESRD (Dossetor, 1995) and therefore to be put on the waiting list (Alexander and Sehgal, 1998).

Similarly, anecdotal evidence from the European Rare Diseases group indicates that there are systemic inequalities in health need and healthcare access and provision that prevent equitable distribution of organ transplantation among patients with rare diseases – an issue that can only be addressed by further awareness and basic research.

In brief, with increased transparency and robustness of the organ donation process, health inequalities could become more important and also more evident. Some of the international evidence suggests that health disparities between minority groups and other transplant patient populations can be reduced, to a certain degree by alternative strategies for organ matching (Mutinga et al., 2005); (Hollenbeak et al., 2000).

**Comparing the options**

Although none of the current policy options is aimed at addressing the likely distributional dimension of policy impacts, the existing body of evidence suggests there is a real risk that all options will lead to a widening gap between population groups based on ascribed
statuses such as age, ethnicity/minority, disability and possibly even gender. As noted above, any policy options that will lead to a substantial and sustained increase in the number of organs transplanted in European countries risks widening the inequalities gap between groups. Options 2, 3 and 4 are intended to increase organ donation rates substantially and in a sustained way, but there is greater uncertainty about the extent of this increase using Option 2. By contrast, under the baseline Option 1 we expect the numbers for organ donation to remain largely stable, although slight increases are possible through emerging improvements and changes to organ donation rates in transplantation systems across Europe. In other words, maintaining the status quo is likely to contribute to a small increase in the growth of health disparities among transplant patients. The key issue here is the fact that none of the proposed policy options includes organ allocation criteria as an area of policy intervention which would require specific attention if disparities are to be reduced. As the various European studies show, current increases in organ availability alone will neither ensure fair allocation of organs nor ensure fair access to care across all social groups. Rather, the demand for organs is greater among those social groups that are least likely to receive the appropriate care and referral to the transplant services but also have the greatest burden of those diseases requiring organ transplantation.

5.6 Social impacts

Having established the potential health impacts of the policy options, this section looks at their social impacts. These include impacts on the quality of life, on employment and social participation and on trust and confidence in organ donation and the transplantation system.

5.6.1 Quality of life

Background

Organ donation and transplantation can have a substantial impact on the quality of life of patients and also has effects on their capability to interact socially. To measure the quality of life, a new indicator has emerged over the past 10–15 years to evaluate medical intervention in the field of organ transplantation; (Wilson and Cleary, 1995) (Testa and Simonson, 1996). Identified as the satisfaction of people’s needs, Quality of Life (QoL) refers to the physical, psychological and social domains of health (De Leo, 1998); (WHO, 1991). However, many of the components of QoL cannot be observed directly and there is currently no consensus about a ‘gold standard’ instrument to measure QoL, which may limit comparability of study results. Nonetheless, there are two disease-specific instruments to measure QoL impact of liver and kidney transplantation, resulting in a dramatic increase in publications on QoL as an outcome variable of transplantation surgery (Burra and De Bona, 2007).

In this context, a recent review concluded that most published studies on QoL and transplantation report that the impact of heart, lung, kidney and liver transplantation on recipients’ quality of life is strongly positive (Burra and De Bona, 2007). The improvement in QoL is significant and perceived early after surgery, with large gains in QoL in the area
of physical health and more modest improvements in areas affected by psycho-social functioning (including sexual function, pregnancy, schooling for paediatric patients, sports – both adults and children – and work). Another study may show a reduction in depressive symptoms among organ recipients (Virzi et al., 2007). In addition, studies of adults who received a kidney transplant in childhood found that their activity level is similar to that of the general population (Broyer et al., 2004).

Despite these positive results among the various studies reviewed by Burra and De Bona (2007), overall QoL after organ transplantation seems lower than expected. Transplant patients are unlikely to reach either the same QoL as they had prior to organ failure or the QoL level of healthy people. The authors of the review suggest that one of the reasons for the unexpectedly lower QoL found in the different studies is the limits of the research in the field of QoL after transplantation and the heterogeneous nature of existing QoL literature, which relies more on cross-sectional methods than on longitudinal prospective study designs.

From the donor perspective, living donors experience a boost in self-esteem and a greater sense of wellbeing: in one study, 96 per cent of living kidney donors felt it was a positive experience and in another 100 per cent of kidney donors stated after organ donation that they would again favour it (Cabrer et al., 2003). 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 (Hamilton score 7) from 37.5 per cent to 33.3 per cent and a decrease among 18 scores from 12.5 per cent to 0 per cent.

In addition, Corley et al. (2000) determined that QoL scores were high for all donors and expected to improve in the next five years. Significantly 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 organ donation (Clemens et al., 2006). 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 organ donation (Virzi et al., 2007).

Even in the highly controversial living donor liver transplantation (LDLT), QoL is high for live liver donors, indicating a positive psycho-social outcome for the majority of donors irrespective of organ donation-related medical complications. Yet, as one study of 28 living donors showed, a significant reduction in QoL after LDLT appears in the areas of ‘physical health’ and ‘living conditions’. Satisfaction of organ donation among live liver donors is evident in their experience of having their lives ‘changed for the better’ as a result of the process (Parolin et al., 2004) and more than 90 per cent of living liver donors would donate again. Although Clemens et al. (2006) found that some living liver donors experienced an increase in self-esteem, a small proportion of donors had adverse psycho-social outcomes. Since the presence of social support is known to modify the consequences of stress, studies that show low or no depression after a transplant may be the result of existing high levels of social support. Not surprisingly, the Burra and De Bona (2007)
review found that social support was one of three main predictors of high QoL outcomes for transplant recipients. In other words, the positive psycho-social outcomes found may not be directly associated with the transplantation process itself, but rather with other social factors.

Another important element of QoL is social – and in particular family – networks. In a systematic review by Clemens et al. (2006) it was found that the majority of living donors 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%). Another study found that successful kidney-pancreas transplantation is significantly associated with improved social interactions (Burra and De Bona, 2007).42

In terms of kidney transplantation, living-related renal donors do not express regret after organ donation and do report enhanced self-esteem. Social desirability scores have also been reported to be high for 65 per cent of living kidney donors (Corley et al., 2000). Although reciprocity and feelings of obligation did not appear to cause relationship difficulties for siblings, some of the adolescent recipients who had received a parental graft reported psychological distress and social-familial alienation. (Franklin and Crombie, 2003). It is also important to note that this study found a degree of ambivalence among fathers about donating their kidneys. This finding supports an earlier study highlighting the gender imbalance in living organ donation: women are more likely to donate but less likely to receive a kidney (or other organ) (Biller-Andorno, 2002). In particular, mothers are the group who donate most frequently in the Eurotransplant system; fathers donate less than half as much. In France, the Centre for the Study and Research of Philanthropy found that women are more inclined to donate their organs than men, with 65 per cent of donor card carriers being women (ABM, 2008).

Comparing the options
As is apparent from the evidence available about the QoL of organ recipients, it would be difficult to assess whether a policy intervention leads to an increased QoL for individual organ recipients or donors – with the exception of living organ donation, for whom improved healthcare services might reduce some of the negative impacts. At the same time it is evident that increased organ donation rates will allow more patients to experience a better QoL, which will be the main impact of the policy options.

The status quo would persist under Option 1 and therefore it is unlikely that any change in the standard of living of organ recipients will occur. As there will be a wide variation in organ donation rates and differing legal frameworks, it is likely that there will continue to be diversity in the extent and level of QoL experienced by organ recipients in Europe. Nevertheless, for those individuals who do receive a transplant, the standard of living will

42 However, close family ties will not always be conducive to and reward organ donation. A study evaluating the impact of cadaveric organ donation on Taiwanese donor families found that 86% worried about the donor’s afterlife and 77% experienced stress due to controversy among family members over the decision to donate. By contrast, only 23% of participants had closer family relationships and 36% had a sense of reward for helping others. (Shih, et al. (2001).
increase in terms of greater control over their lives and mobility through increased QoL. For living donors, the mixed evidence on whether QoL improves or worsens for these individuals underscores the great difficulty in predicting the baseline from which to compare the options.

There is potential for Option 2 to increase the QoL of living organ donors as the Action Plan alone aims to protect their health by promoting the establishment of living donor registries to follow up the health consequences of their altruism systematically. Options 3 and 4 would make living donor protection a legal obligation, thus creating a higher level of protection for 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 psycho-social outcomes. The main impacts are, however, to be expected from the possible increase in organ donation and transplantation rates. As Option 2 is less likely to achieve large increases in organ donation, the positive social impacts of better QoL for more patients would be smaller than for Options 3 and 4. Thus it is reasonable to expect that Options 3 and 4 would lead to higher standards of living for a greater number of transplant recipients, given that these policy options are intended both to increase the organ donation rates and to improve the quality and safety of transplantation systems generally.

5.6.2 Employment and social participation

Apart from the macroeconomic impacts of employment, which will be discussed in Section 5.7.5, employment has an important social function for transplant patients and living donors, in terms of constituting one aspect of social participation.

**Background**

A systematic review of employment status (and social participation) after successful kidney transplantation was conducted by Van der Mei et al. (2006). Among the 17 studies selected out of 1,443 identified references, the authors found that employment was the most used indicator of social participation, with rates ranging from 18 per cent to 82 per cent after kidney transplant. Only two studies briefly reported on vacation and recreation and only three studies identified pre-transplant employment status as a predictor of post-transplant employment. However, based on the authors' quality assessment of the studies' internal validity, there were several shortcomings in the reporting and the validity of the studies reviewed – due mainly to differences among the studies in defining categories of employment or a lack of any description as well as the heterogeneous study populations. Hence, the authors concluded that 'valid conclusions regarding the degree of social participation after kidney transplantation cannot be drawn'. It was therefore recommended that future research should supplement the focus on employment status by examining other aspects of social participation as well as potential risk factors.

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 per cent of male patients (n=149) and 72 per cent of female patients (n=95) had paid employment, whereas 6.5 per cent and 10.5 per cent respectively were unemployed (Broyer et al., 2004).
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, after 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, 39 per cent of patients went back to work after transplantation, and 3 of the 131 patients in total started working.

While there is little convincing evidence on more general social participation after transplantation, the literature provides some evidence for employment rates after transplantation which were also used in this study to assess the productivity impacts of organ donation. Table 5.12 provides an overview of some estimates of employment rates after transplantation.

<table>
<thead>
<tr>
<th>Organ</th>
<th>Employed after transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney transplant (Matas et al., 1996)</td>
<td>47%</td>
</tr>
<tr>
<td>Kidney transplant (van der Mei et al., 2006)</td>
<td>18% to 82%</td>
</tr>
<tr>
<td>Liver transplant (Saab et al., 2007)</td>
<td>27%</td>
</tr>
<tr>
<td>Heart transplant (Petrucci et al., 2007)</td>
<td>39%</td>
</tr>
<tr>
<td>Lung transplant (Petrucci et al., 2007)</td>
<td>39%</td>
</tr>
</tbody>
</table>

Comparing the options

Policy Option 1 means that the current situation would basically continue with incremental improvements in treatment, allowing for a small increase in social participation and employment. These small increases would be the same for all policy options that are not designed to increase social participation and employment at an individual level. None of the policy options addresses 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 several times a month. Based on this relationship we can expect better social impacts from Options 3 and 4, which would deliver increases in the organ 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 when assessing the options.

5.6.3 Trust and confidence in organ donation and the transplantation system

Creating robust organ donation and transplantation systems, ensuring the quality and safety of organ donation and transplantation and raising public awareness, can be expected to have an influence on citizens’ trust and confidence. This is important because a high level of trust and confidence might ultimately lead to a higher willingness to donate organs.
Two aspects of trust and confidence, family refusals and patient empowerment, warrant closer scrutiny even though there is very little evidence to enable an assessment of the impact.

**Background**

**Family refusals**

Trust in the healthcare system and the organ donation system plays an important role in increasing the organ donation rate, and is of value in itself.

![Map of family refusals](image)

**SOURCE**: Eurobarometer (2007)

**Figure 5.3: Estimated 30-year discounted savings from additional kidney transplants**

A good indicator of trust is the declared willingness to donate a family member’s organ as well as the actual family refusal rates. A recent survey (2007) shows considerable differences in the hypothetical willingness to donate a family member’s organs. In particular, the Nordic countries have a strong willingness to donate their organs, indicating a strong level of trust in their systems.
The Eurobarometer results on declared willingness to donate organs contrast somewhat with the actual family refusal rates as shown (Figure 5.4), which gives the refusal rates from a number of European countries provided by the DOPKI project (DOPKI, 2006). While Spain, for example, has a lower rate of declared willingness to donate, the actual family refusal rates are half those of the United Kingdom or Germany. This can be partly attributed to different consent systems, but also to the strong focus of the Spanish system on approaching and accommodating the relatives of potential deceased donors using trained professional transplant coordinators. Thus, it is plausible that measures similar to the Spanish system would increase the confidence and trust of the individuals most directly involved, rather than the public at large.

![Figure 5.4: Refusal rate across countries in Europe](image)

Blue=2003; Red=2004; Yellow=2005
SOURCE: DOPKI (2007)

With the professionalisation of transplant services, Poland witnesses a sharp decline in family refusal rates from over 1,000 in 2000 to 272 refusals in 2006. Yet family refusals are still the main reason for 10.4 per cent of potential organ donors being rejected in 2006. By contrast, 40 per cent of families in the UK refuse to give consent to organ donation, sometimes even when the potential donor is carrying a donor card giving their explicit consent (Department of Health, 2008a,b). In Greece, family refusal rates have ranged between 41 per cent and 46 per cent over the last three years (2005 to 2007).

There is some evidence that the policy measures proposed by DG SANCO might increase confidence and trust in the system and reduce family refusal rates. Data suggest that training programmes for health professionals specifically dedicated to every step of the transplantation process have contributed to the approach of obtaining consent from donor families (Rosel et al., 1999).

**Patient empowerment through Quality and Safety programmes**
Measures to improve the quality and safety of treatment, which are also included in DG SANCO’s policy options, have the potential to increase the trust and confidence of patients. For this aspect we can draw on some qualitative data about the social impact of
European policy initiatives to reduce risks to patients in general, obtained through interviewing patient safety experts in Europe (Conklin et al., forthcoming). In brief, expert opinion suggests that the notification of adverse events among patients in Europe (through mandatory reporting and learning systems) could lead to substantial benefits. However, experts stressed that the positive impacts would be realised when the reporting and learning system was as close to the patient as possible and when public communication on the initiatives to improve patient safety was more sophisticated. Local-level implementation provides the means by which corrective action can be taken and be visible to those most affected: patients and their caregivers. In brief, the following is a list of key social impacts of a system for notifying (and learning from) adverse events:

- benefits accrue to patients in the form of increased participation and empowerment, honesty in the doctor–patient relationship, better managed expectations and lives saved;
- benefits to care providers come from a better safety culture and working environment, continuous knowledge exchange (education and awareness) and accountability;
- healthcare systems benefit from civic trust, better care provision and avoided costs;
- there may be a greater impact on social inclusion and protection of vulnerable populations.

Comparing the options

This section presented somewhat limited evidence about the trust and confidence impacts of the proposed policy options. Option 1 would see a continuation of the differences in trust and confidence across Europe. By promoting the role of trained transplant coordinators, which might involve training in the management of potential donor families, Option 2 has the potential to increase the confidence of donors and donor families, which might subsequently lead to higher organ donation rates. Similarly, Options 3 and 4 support the training of key personnel along the organ 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 would establish a reporting system for adverse events. Such measures could increase confidence in the transplantation system, in particular if the results of Quality and Safety monitoring were publicly available.

The limited evidence available 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.

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 would make important elements of training and Quality and Safety mandatory. However, the evidence base for these qualitative findings is underdeveloped.
5.7 **Economic impacts**

The economic impacts of the proposed policy action can be broadly distinguished into two categories. First, there are economic impacts that directly emerge from the implementation of the proposed policy measures. These include start-up and running costs for a national infrastructure and costs of running national registries and traceability systems, as well as reporting obligations and an administrative burden. Secondly, there are economic impacts which arise if the policies achieve the key objectives of increasing organ donation and transplantation rates. These impacts include changes in treatment costs and productivity gains of longer life expectancy, as well as costs for additional living donors.

5.7.1 **Start-up and running costs for a national infrastructure and better processes**

The different policy options, in particular the binding instruments of Options 3 and 4, contain a number of proposals to establish a national infrastructure for organ procurement and donation which might result in start-up and increased operating costs. These measures include in particular the creation of competent authorities and an increased number of transplant coordinators, as well as expenses for training and development and quality programmes.

**Background**

*Creating a competent authority*

Most of the 29 European countries surveyed in a Commission survey (DG SANCO, 2003) have a national competent authority (25) in charge of the organ transplantation/exchange. Three countries also have this type of structure decentralised in regional bodies. Others (14) have in addition an international organisation in charge of some of the functions. The majority of organisations are of a public character. In Germany a private non-profit organisation has been mandated (Eurotransplant in The Netherlands) to coordinate organ donation and procurement activities. Most of the organisations have national headquarters and additionally a regional structure.
### Table 5.13: Organisational responsibilities in a sample of European countries

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Country</th>
<th>Organs</th>
<th>Tissues</th>
<th>Cells</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>/</td>
<td>Austria</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>BTS</td>
<td>Belgium</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (but not mentioned in the law 1986)</td>
<td>/</td>
</tr>
<tr>
<td>MZSS</td>
<td>Croatia</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>KST</td>
<td>Czech Republic</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>ABM</td>
<td>France</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Assisted reproductive technologies; embryo research; genetic testing</td>
</tr>
<tr>
<td>DSO</td>
<td>Germany</td>
<td>Yes</td>
<td></td>
<td>New law pending</td>
<td>/</td>
</tr>
<tr>
<td>Hu-T</td>
<td>Hungary</td>
<td>Yes</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>CNT</td>
<td>Italy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>Luxembourgtransplant</td>
<td>Luxembourg</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>NTS</td>
<td>Netherlands</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>/</td>
</tr>
<tr>
<td>Poltransplant</td>
<td>Poland</td>
<td>Yes</td>
<td>/</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>OPT</td>
<td>Portugal</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>Slovenija-Transplant</td>
<td>Slovenia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>OMT</td>
<td>Spain</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>Swiestransplant</td>
<td>Switzerland</td>
<td>Yes</td>
<td>/</td>
<td>Islets</td>
<td>/</td>
</tr>
<tr>
<td>UK - Transplant</td>
<td>United Kingdom</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>ET</td>
<td>Netherlands</td>
<td>Yes</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>

Source: DOPKI (2006)

The DOPKI project has evaluated these organisational systems in many European countries. All national organisations are in charge of the coordination of organ donation, as shown in Table 5.13 (DOPKI, 2006). Only a very small percentage of countries that have installed a national organ procurement agency are not in charge at the same time of organs and tissues. These results coincide with those from the Commission survey: 82 per cent of the organ transplantation organisations are also in charge of human tissue activities, and around half of them (57%) also deal with haematopoietic progenitors.

As most of the Member States have national organisations in place already that are in charge of organ donation, the nomination of competent national authorities is not expected to have a major economic impact. In cases where such organisations do not yet exist (e.g. Austria and Sweden), expert interviews suggest that there are suitable organisations in place which could take on this task.

While the evidence does not support the direct assessment of the costs of establishing a national authority for organ donation and transplantation, there is evidence of the costs of the establishment of the Human Tissue Authority in the **United Kingdom**. The Human Tissue Authority is the national authority to implement the EU Tissues and Cells Directive, and is responsible for licensing more than five hundred establishments across five different sectors, and for approving donations of organs and bone marrow from living...
people (HTA, 2007). 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,’ is over £2.8 million. The minimum number of HTA staff required to conduct site visit inspections for authorising activities is 42 (twice the original number when licensing activity started in 2006). Of the direct costs 52 per cent are related to staff salaries and include investing in personnel to conduct the mandatory inspections and control measures (HTA, 2007).

The total operational budget of ONT, the Spanish national authority, for 2008 is €4,207,000, with €3 million a year (73.5%) distributed in grants and financial assistance to support hospitals in organ extraction and transplantation, promotion and dissemination activities of regional transplant authorities, and specific training, development and other projects.43

**Authorisation of establishments**

To ensure that transplant activities are carried out only in appropriate transplantation and procurement centres, DG SANCO proposes measures to accredit, designate, authorise and licence procurement and transplantation centres. Data collected in 2003 (Figure 5.5) show that procurement and transplantation has to follow specific standards in most, if not all, Member States. However, not all hospitals have to be specifically authorised to procure or transplant organs.

![](image)

**Figure 5.5: Authorisation of organ procurement and transplantation**

Introducing such requirements would crucially depend on a decision about whether it is a matter of designating particular hospitals, or whether hospitals would have to go through a full licensing procedure. While the former could be expected to create only small costs, the latter might be more expensive.

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43 ONT, personal communication, 3 April 2008.
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.\textsuperscript{44} In Germany, the responsible authority charges up to €25,600 for the licensing of tissue products.\textsuperscript{45}

\textit{Transplant coordinators}

Recognising the important role transplant coordinators play in procuring organs, the policy options of DG SANCO include the promotion of the role of the transplant coordinator in hospitals. Currently there are wide differences in Member States regarding the role and availability of transplant coordinators. Table 5.14 provides an overview of the existence of transplant coordinators in a sample of Member States. The economic impact of promoting the role would differ by country and approach (e.g. full-time vs part-time, centrally employed vs hospital-employed coordinator, nurse vs physician) in the current existing systems.

In the \textbf{United Kingdom} the Organ Donation Taskforce quantified its recommendations for improvement, which include strengthening the coordinators’ network, to increase organ donation rates. They calculate additional annual costs of £13m for setting up a system with 250–75 centrally employed transplant coordinators (an increase of 150–75 staff), of which the majority are salary costs (£11m).

In an interview with the \textbf{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.\textsuperscript{46}

\textsuperscript{44} http://www.hta.gov.uk/licensing/guide_to_licensing_and_application/fees_and_payment.cfm

\textsuperscript{45} www.pei.de

\textsuperscript{46} Interview with DSO official.
Table 5.14: Role and qualification of coordinators in selected European countries

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Country</th>
<th>In donor hospital</th>
<th>Linked to donor hospital</th>
<th>Outside hospital</th>
<th>Linked to transplant centres</th>
<th>Qualification</th>
<th>Transplant coordinators</th>
</tr>
</thead>
<tbody>
<tr>
<td>.</td>
<td>Austria</td>
<td>Planned</td>
<td>.</td>
<td>.</td>
<td>Yes</td>
<td>3–4 per region, 4 regions</td>
<td></td>
</tr>
<tr>
<td>BTS</td>
<td>Belgium</td>
<td>local coordinator</td>
<td>In some donor hospitals</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Registered paramedics Min. 2 per Tx centre by law currently</td>
</tr>
<tr>
<td>MZSS</td>
<td>Croatia</td>
<td>Yes</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>Physicians and nurses</td>
<td></td>
</tr>
<tr>
<td>KST</td>
<td>Czech Republic</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>IR1: 15 FTE, pop 7.7m IR2: 38, pop. 6.54m IR3: 36, pop. 9.56m IR9: 41, pop. 13.08m IR6: 35, pop. 11.55m IR7: 49, pop. 13.35m</td>
<td></td>
</tr>
<tr>
<td>ABM</td>
<td>France</td>
<td>Yes</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>IR1: 15 FTE, pop 7.7m IR2: 38, pop. 6.54m IR3: 36, pop. 9.56m IR9: 41, pop. 13.08m IR6: 35, pop. 11.55m IR7: 49, pop. 13.35m</td>
<td></td>
</tr>
<tr>
<td>DSO</td>
<td>Germany</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>Yes</td>
<td>Physicians and nurses</td>
<td></td>
</tr>
<tr>
<td>Hu-T</td>
<td>Hungary</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>Yes</td>
<td>Physicians and nurses</td>
<td></td>
</tr>
<tr>
<td>CNT</td>
<td>Italy</td>
<td>Yes</td>
<td>Yes, (regional coordinators)</td>
<td>.</td>
<td>.</td>
<td>Physicians, but nurses assist 1 regional coordinator for each region, usually 1–2 local coordinators for each hospital</td>
<td></td>
</tr>
<tr>
<td>Luxembour transplant</td>
<td>Luxemburg</td>
<td>Yes</td>
<td>.</td>
<td>.</td>
<td>Yes</td>
<td>Physicians and nurses</td>
<td></td>
</tr>
<tr>
<td>NTS</td>
<td>Netherlands</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Physicians and nurses</td>
<td></td>
</tr>
<tr>
<td>Poltransplant</td>
<td>Poland</td>
<td>Yes, some</td>
<td>Yes, (regional coordinators)</td>
<td>Yes, (central coordinators)</td>
<td>Yes, (regional coordinators)</td>
<td>Physicians (mostly anaesthesiologist s) and nurses</td>
<td></td>
</tr>
<tr>
<td>OPT</td>
<td>Portugal</td>
<td>Yes</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>Physicians and nurses</td>
<td></td>
</tr>
<tr>
<td>Sloveni-Transplant</td>
<td>Slovenia</td>
<td>Yes</td>
<td>.</td>
<td>.</td>
<td>Yes</td>
<td>2 central coordinators per 2 million pop. always 24 hours on call (9 of them rotate), 9 hospital coordinators involved daily, back-up central coordinators</td>
<td></td>
</tr>
<tr>
<td>ONT</td>
<td>Spain</td>
<td>Yes</td>
<td>.</td>
<td>Yes</td>
<td>Regional coordinato r</td>
<td>Physicians and nurses</td>
<td></td>
</tr>
<tr>
<td>UK Transplant</td>
<td>United Kingdom</td>
<td>Yes</td>
<td>.</td>
<td>.</td>
<td>Yes</td>
<td>Usually nurses 1.5 pmp</td>
<td></td>
</tr>
</tbody>
</table>
Setting up and running national quality programmes

The policy options include the establishment of quality assurance programmes at national and hospital level. These programmes will ensure that standards of good practice are followed throughout the organ donation and transplantation process. Comprehensive, specific quality systems for organ donation and transplantation, which include systematic audits and targeted training for staff to achieve continuous improvement, are not yet well developed.

One of the most comprehensive quality programmes in place is in Spain. The ONT has developed a quality assurance programme that aims to answer three key questions:

- What is the capacity of each particular hospital to effect organ donations (that is, the number of brain deaths that could become organ donors)?
- What are the reasons for the loss of organ donors, and the gaps in the organ procurement and donation analysis processes?
- What hospital factors have an impact on the organ donation and transplantation process? (ETCO, 2007)

The programme to control the process of organ and tissue donation, extraction and transplant was set up in 1998 with the aim of identifying weaknesses in the process and developing 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.47

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 not include, for example, 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 organ donation, there is a minimum standard of information and criteria for the suitability and quality of the donated organs. Ultimately, organ quality is a decision for the transplant centres and based on professional standards.

While following national and international guidelines for the process of transplantation, Sweden does not have a national quality programme for the whole transplantation process,

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47 ONT (www.ont.es).
due to its much decentralised infrastructure based on the transplant centres and the 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, and non-related donor bone marrow and umbilical cord blood 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). That will enable continuous safety and quality monitoring, reporting the data to and analysing the data by the Ministry of Health and Quality in Medicine Monitoring Centre (Centrum Monitorowania Jakości w Medycynie); currently Poltransplant produces reports on an annual basis (Kalaciński).

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

Box 5.2 provides another overview of the situation of quality programmes in five countries from ALLIANCE-O, which illustrates the fact that quality programmes are not yet in place in all countries and across all sub-processes (ALLIANCE-O, 2007a).

**Box 5.2: Quality programmes in France, Germany, Hungary, Italy and Spain**

<table>
<thead>
<tr>
<th>Organ donation subprocess</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the majority of the countries, the local hospital is responsible for the phases of the organ donation subprocess, apart from some direct responsibility of the regional coordination or the national organisation. 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 of training, procedures, guidelines and audits. Audits are well developed in France, Spain and the UK, whereas the other countries have developed a programme only for the phase of identification of a potential donor.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Allocation subprocess</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most of the countries reported that the regional or the national organisations are responsible for the management of the phases belonging to the allocation subprocess. Laboratories and transplant centres usually cooperate with them for the development of some activities. All countries reported the presence of quality programmes for training, procedures, guidelines and audits. France, Hungary, Italy and Spain manage full procedure, guideline and auditing programmes at a national level and/or a local one.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transplantation subprocess</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplant centres are the responsible units for the transplantation subprocess phases. In some countries transplant centres are supported by regional coordination, while in a few they are supported by the national transplant centre. Italy, Spain and the UK have a national auditing programme, while Germany, Hungary, Italy and the UK apply procedures and guidelines to all phases, even though they are produced at different levels.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Follow-up and quality of life subprocess</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplant centres are responsible for the phases of the subprocess. In some specific cases, there is cooperation of regional or national coordinating centres in this: this is the case in France, Germany, Italy and Spain. Quality programmes are not common in this phase: only Italy and Spain have an auditing programme in place, whereas Germany, Hungary and Italy have developed procedures and guidelines regulating the phases of the subprocesses.</td>
</tr>
</tbody>
</table>

SOURCE: ALLIANCE-O (2007a)

Little evidence is available about the costs of national quality programmes; however, some information is available about elements of quality programmes. One such example is the
Donor Action Programme which has been used in several Member States already and in hospitals all over the world. The target of Donor Action is somewhat limited, as it is only concerned with the first step of the whole process: organ donation and procurement. As discussed in the section on health impacts (Section 5.5), donor action programmes have proved to be highly effective in increasing organ donation rates, and there is some information available on the costs of Donor Action.

Whiting et al. (2004) report average implementation costs for the Donor Action Programme of around €35,000 pmp (Ca $55,000) and maintenance costs of around €45,000 pmp (Ca $70,000). For Europe, Donor Action\(^{48}\) reports the cost of implementing this programme in Belgium, where the Donor Action methodology had been applied to 62 hospitals at an annual cost of €500,000, which equates to a cost of around €8,000 per year per hospital, including a financial incentive for hospitals of €3,000 to participate and €60 per reviewed patient record. Similar numbers are reported from Switzerland, where the programme was rolled out in 15 hospitals at a total cost of €80,000 per year, which translates into an annual cost of just above €5,300 per hospital.

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 manager’ at the local level and €9,000 for a master programme as a ‘regional donor manager’.\(^{49}\)

Another key element of Quality and Safety systems is national databases and registries, which will be discussed in the next section.

**Comparing the options**

Under **Option 1**, the status quo would continue. There would be no systematic change in the organ donation and transplantation infrastructure. It is reasonable 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

Although not prescribing the creation of a competent authority, **Option 2** implies that there is a national body responsible 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 try 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.

The designation of a competent authority, typically the department of health or a national organ donation agency, would require few resources as these organisations are typically already in place. The economic implications of the other measures to build up the national infrastructure could be

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\(^{48}\) Personal communication with Donor Action.

\(^{49}\) Personal communication between DG SANCO and TPM.
infrastructure depend 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 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 by the evidence available from the UK and Germany, and might in addition have the negative side effect of discouraging hospitals from participating in organ procurement. Similarly, increasing the number of transplant coordinators would create substantial running costs. Proposals to introduce transplant coordinators in the UK were quantified at costs of 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 of pay costs between €45,000 and €70,000 for a nurse or physician transplant coordinator. The total cost of this policy option would depend on the willingness of and the necessity for Member States to increase the number of transplant coordinators.

Given the voluntary character of measures under the Action Plan, we would, however, expect the costs of Member States to be low under this action.

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, and 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 cost. The annual running costs of the Spanish National Transplantation Organisation of around €4 million (= €100,000 pmp) may give an indication of the maximum cost that would be incurred by implementing Option 3. As most Member States have substantial amounts or some elements of such systems already in place, the additional costs can, however, be expected to be well below this boundary. 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 implemented at relatively low cost.\(^{50}\) 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 a 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 run 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 altogether, as they already feel that they are not adequately reimbursed for the efforts of organ procurement.

\(^{50}\) This would, for example, result in total costs of around €4.9 million for all 613 organ-procuring hospitals in Germany.
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. Less discretion means, however, that fewer elements of the current systems would be precompliant with the regulation and more changes to the current systems would be 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. With regard to 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 authorisation schemes that already exist. 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 implies licensing costs of around €10,000 per establishment, would be incurred by not only the three hundred or so transplantation centres across Europe, but also by the much higher number of potential procurement centres, which basically are all hospitals with an ICU. Option 4 proposes a 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 (Figure 5.5).

5.7.2 Costs of setting up and running national registers and traceability systems

The potentially most cost intensive element of DG SANCO’s proposal is the requirement to establish systems to trace organs from recipient to donor and vice versa, in order to follow up the post-transplant results and systems systematically to report adverse events and reactions. These costs would depend on the existing systems in the countries and the final detailed policy proposals, which are as yet unavailable.

Background

Register of establishments

DG SANCO proposes a publicly accessible register of all establishments in which organ transplantations are performed or where organ procurement takes place. The total number of transplantation centres and procurement centres is relatively low (see Section 2.4) and information is readily available. The German DSO, for example, reports annually on the organ donation activity of all transplantation centres and the procurement activities of all other hospitals. There are no estimates for the cost of national registers for all establishments, but it can be assumed that information about establishments involved is readily available to all Member States’ competent authorities.
Organ donor registers

Many Member States currently collect data on the organ donors and store them in national, regional or transplant centre-based information systems. Most countries have a registry of post-mortem donors and recipients of organs from post-mortem donation in place; registers for living organ donation are, however, less well developed. Table 5.15 provides an overview of the existing registries in the Member States participating in the DOPKI project (without databases to register non-consent).

Table 5.15: Existing registries in a sample of Member States

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Country</th>
<th>Donor registry</th>
<th>Recipient registry</th>
<th>From post-mortem</th>
<th>From living</th>
</tr>
</thead>
<tbody>
<tr>
<td>J.</td>
<td>Austria</td>
<td>Yes*</td>
<td>Yes*</td>
<td>Yes*</td>
<td>Yes*</td>
</tr>
<tr>
<td>BTS</td>
<td>Belgium</td>
<td>On voluntary basis in Tx centres – working group in the Ministry of Health</td>
<td>On voluntary basis in Tx centres</td>
<td>Database in Tx centres, annual report for minister on activities</td>
<td>Annual report for minister</td>
</tr>
<tr>
<td>MZSS</td>
<td>Croatia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>KST</td>
<td>Czech Republic</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>ABM</td>
<td>France</td>
<td>Yes</td>
<td>Yes</td>
<td>No, but annual report from Tx centres about activity</td>
<td>No</td>
</tr>
<tr>
<td>DSO</td>
<td>Germany</td>
<td>Yes</td>
<td>Not at DSO</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Hu-T</td>
<td>Hungary</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>CNT</td>
<td>Italy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Luxembourgr transplant</td>
<td>Luxembourg</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>NTS</td>
<td>Netherlands</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Poltransplant</td>
<td>Poland</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>OPT</td>
<td>Portugal</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Slovenija-Transplant</td>
<td>Slovenia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>ONT</td>
<td>Spain</td>
<td>Yes</td>
<td>Developing</td>
<td>Yes</td>
<td>Included in the post-mortem registry</td>
</tr>
<tr>
<td>Swisstransplant</td>
<td>Switzerland</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>UK Transplant</td>
<td>United Kingdom</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Eurotransplant</td>
<td>Netherlands</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

* Hospital/Eurotransplant-based


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

We can thus conclude that in most Member States, the basic information to trace organs from a donor to recipient and vice versa is already obtained to some degree. Interview evidence shows, in addition, that this information is also exchanged between Member States in case, for example, an infection has been discovered.

Outcome registers
To assure the scientific follow-up of transplantation results, transplant organisations or single transplant centres provide, often on a voluntary basis, information to organisations and international studies. These are often organised along the lines of the different transplanted organs. They include international registries such as the European Donor and Organ Registry (EURODONOR), the International Society for Heart and Lung Transplantation (ISHLT), the Collaborative Transplant Study (CTS), the European Liver Transplant Registry (ELTR), the European Transplant Coordinators Organisation (ETCO), the International Pancreas Transplantation Registry (IPTR) and Transplant Procurement Management (TPM). Table 5.16 gives an overview of how different Member States contribute to these international registries.

Table 5.16: Contribution to European transplant follow-up registers

<table>
<thead>
<tr>
<th></th>
<th>EURODONOR</th>
<th>ISHLT</th>
<th>CTS</th>
<th>ELTR</th>
<th>ETCO</th>
<th>IPTR</th>
<th>TPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>France (ABM)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany (DSO)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hungary (Hu-T)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy (CNT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portugal (OPT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain (CENATMER)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK (UKT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eurotransplant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* The HLA laboratory provides data to the CTS and the transplant centres provide data to the ELTR.

SOURCE: ALLIANCE-O (2007d)

Unfortunately, there is no evidence available on the costs of these registries in following up post-transplant results, in particular as they are founded on the principle of voluntary participation. Data collection for the CTS is, for example, done by individual doctors who are not reimbursed for this activity.

Adverse event registers and traceability systems
Currently all Member States are implementing a reporting system under Directive 2004/23/EC to allow for the traceability of human tissues and cells and to register serious adverse events and reactions that may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse
reaction observed during or after clinical application that may be linked to the quality and safety of tissues and cells. The proposed policy actions include a similar provision for human organs, which would require a traceability and a reporting system for serious adverse events that ‘may be attributed to the procurement, testing, and distribution/transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to the procurement, testing and transport/distribution of the organ.’

In the five Member States studied in detail for this impact assessment, no systematic adverse event and reactions reporting system for organs is currently in place; hence evidence of the costs of such systems is rare. Prior to the implementation of tissue and cells regulation, the costs of an adverse event and reaction monitoring system were, however, estimated as part of a regulatory impact assessment.

Based on adverse event-reporting systems for fresh gametes at the Human Fertilisation and Embryology Authority (HEFA) and the SHOT system for blood transfusion run by the National Blood Transfusion Services in the United Kingdom, annual costs of between £425 and £990 per establishment are reported. As reporting systems include a considerable element of fixed costs for running and maintaining the computer system, these cost estimates are likely to underestimate the true costs since they would be shared between fewer establishments in organ donation. For implementing the serious adverse event and reaction system a total cost range between £102,000 and £238,000 was estimated, across a total number of 150 tissue banks.

Cost estimates for full-blown adverse reaction events and reaction reporting systems come from the United States, where such systems have been implemented in various states. In the US, there are a few key documents which provide insight into the administrative costs of the reporting and learning (R&L) mechanisms: namely, Leape (2002), Rosenthal et al. (2001), (Woolf and Litovitz, 2003) and Runciman (2002). According to them, for the 20 state reporting systems in place in 2002 annual funding ranged from $200,000 to $1,500,000 (with only three having more than four full-time staff members). Table 5.17 below shows the 2001 cost estimates of the key components of the mandatory reporting systems in New York and Florida. These are, however, only reporting costs incurred at the state level, without taking into account the costs incurred in hospitals through data entry and reporting.

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51 For a total of 101 regulated units at HEFA and 400 units for the SHOT system. Department of Health (2006).
Table 5.17: Cost ranges for reporting programme activities in Florida and New York, 2001

<table>
<thead>
<tr>
<th>Function</th>
<th>In-house FTE</th>
<th>Estimated costs for in-house or contractual work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>0.5–0.75 FTE</td>
<td>$50,000–$275,000</td>
</tr>
<tr>
<td>Systems design and maintenance</td>
<td></td>
<td>$50,000–$275,000</td>
</tr>
<tr>
<td>Investigation</td>
<td>5–6 (1 FTE per 100–200 investigations)</td>
<td>$200,000–$675,000</td>
</tr>
</tbody>
</table>


Comparing the options

As shown in the previous section, Member States do already collect 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 are provided to a multitude of recipients. Option 1 would leave the current system untouched and thus not create additional costs. However, this option would not help to achieve certain efficiency gains: for example, if reporting about outcomes were standardised across organ types and transplant centres.

The working plan foreseen under Option 2 would encourage Member States to develop systems to evaluate post-transplant results systematically. Currently Member States, and often single transplant centres, provide medical outcome data voluntarily to various different registers and medical research projects, such as the 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 to which information has to be submitted 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.

Option 3 would supplement voluntary improvement of 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, complemented by European guidelines on the exchange of data between Member States. Given the small number of transplant centres in each country (on average there are 28 transplantation programmes per country), a register of establishments would generate only marginal costs, in particular as it can be safely assumed that the list of establishments is readily available and would not change frequently. The costs of a traceability and adverse event-reporting system can only be roughly estimated. A British regulatory impact assessment of the EU Tissues and Cells Directive estimated costs for a traceability system of between €130,000 and €300,000 for the UK, with costs between €550 and €1,300 per establishment (Department of Health, 2006). 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 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; some Member States are already pre-compliant with the regulation.
Option 4 contains similar requirements to 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 cost estimates available for this option other than those for Option 3; however, we can reasonably assume this option to be more expensive than Option 3. As shown in Table 5.15 a substantial number of Member States already have 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.

5.7.3 Reporting obligations and administrative burdens

DG SANCO proposes a number of measures which require procurement as well as transplantation centres to submit information during the transplantation process and to report on their activities. These obligations might be considered an administrative burden for hospitals if they consist of ‘meeting a legal obligation to provide information on their action or production, either to public authorities or to private parties’ (European Commission, 2005).

For the proposed policy action the total administrative costs and in particular the additional administrative burdens seem, however, to be small.52 This is due to a number of reasons:

1. The population of institutions – i.e. hospitals and transplant centres – is very small. There are around 300 transplant centres with a total of around 760 transplant programmes across the European Union, and procurement takes place in a selected sample of hospitals (e.g. only 45% of hospitals with ICUs in Germany = 613).

2. The total case load is relatively low, with a current total of around 27,000 transplantations performed in the European Union.

3. As shown above, most Member States capture most of the information required already, so the costs of additional information gathering can be expected to be very low. Administrative burdens might even be reduced if the European Union proposals lead to more standardised reporting systems.

Given this assessment, and the lack of cost information from procuring and transplanting hospitals, we did not conduct a full administrative burden measurement exercise.

Comparing the options

Each of the different options contains reporting obligations, potentially resulting in additional administrative burden for hospitals and Member States authorities.

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

52 A ‘back of the envelope’ calculation, which would assume 10 hours of total reporting time per transplantation at a specialist salary of around €100,000, would result in a total administrative burden of €13 million for the whole EU-27.
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 maintain this fragmented reporting at no additional costs for Member States and hospitals.

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 annual provision of key data on organ donation and transplantation activities as well as on progress in implementing the national Action Plans and quality programmes. As most of these data are already available, this can be assumed not to generate a high burden for Member States.

In addition, Options 3 and 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 it should not put a major burden on the hospitals to collect and transmit this information to the competent authorities of the Member States.

5.7.4 Treatment costs
Treatment costs, defined as the costs of transplanting an organ and the follow-up costs of transplantation aftercare and long-term immunosuppressive therapy, arise directly from the availability of organs. These will change only if the policies are successful in achieving increased organ donation and transplantation rates. In assessing treatment costs, it is important to consider the net impact on treatment costs. In most cases a kidney transplant replaces dialysis treatment, and although there are limited data on which to base any estimate of cost savings that may follow transplantation of the liver, heart or lung, there is some evidence that the care of patients with life-threatening organ failure (e.g. liver failure) may involve many days or weeks of in-hospital care, including significant time in intensive care (very expensive) that would be avoided if transplantation had taken place.

Background
There exists a wide body of literature around the cost effectiveness of transplantations. For all organs, in particularly kidneys, transplantation has been shown as cost-effective – only in lung transplantation is there some ambiguity.53

All organs
The Organ Taskforce in the UK modelled the impact of a 50 per cent increase in organ donation rates on treatment costs over a 30-year period (Department of Health, 2008b). Figure 5.6 presents the cumulative cost effect and net savings from this increase in organ donation rates. Overall, the modelling shows that a 50 per cent increase in 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.

53 This section draws in particular on the findings of the Organ Donation Taskforce in the UK, which analysed British and international health economic literature. See Department of Health (2008b).
SOURCE: Department of Health (2008b)

**Figure 5.6: Cumulative cost effects and net savings from a 50 per cent increase in organ donation in a one-year cohort of patients assessed over 30 years (discount rate of 3.5%)**

**Kidney**

These benefits can be primarily attributed to the cost-saving effects of kidney transplantation versus dialysis treatment. Figure 5.7 illustrates the cost characteristics of transplantation versus dialysis (in the UK). While transplantation has high initial costs, the post-transplant costs are substantial lower than the dialysis costs, thus offsetting the initial investment.

**Table 5.18: Lifetime costs of transplant versus dialysis in industrialised countries**

<table>
<thead>
<tr>
<th>Country</th>
<th>Kidney transplant Cost (£)</th>
<th>Dialysis cost (£)</th>
<th>Difference (£)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>246,022</td>
<td>332,425</td>
<td>86,403</td>
<td>Whiting <em>et al.</em> (2004)</td>
</tr>
</tbody>
</table>
Liver, heart and lung transplantation

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

Despite substantial costs, the study conducted by the Organ Taskforce concluded that liver and heart transplantations are cost effective, while lung transplantation is on the edge of cost effectiveness. Table 5.19 gives an overview of the cost effectiveness of liver, heart and lung transplants based on studies conducted in The Netherlands.

Table 5.19: Cost effectiveness of liver, heart and lung transplants

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICER ($) QALY gain</td>
<td>ICER ($)</td>
</tr>
<tr>
<td>Liver</td>
<td>25,600 11.5</td>
<td>31,000</td>
</tr>
<tr>
<td>Heart</td>
<td>36,900 6.8</td>
<td>46,000</td>
</tr>
<tr>
<td>Lung</td>
<td>61,000 5.2</td>
<td>61,000</td>
</tr>
</tbody>
</table>

SOURCE: Department of Health (2008b)

The Impact of different scenarios and comparison of options

Based on this evidence and not taking into account the value of a statistical life, it is clear that an increased number of kidneys will result in substantial cost savings, and that liver, heart and lung transplantation are usually considered to be cost efficient – i.e. 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.

Using four scenarios RAND Europe calculated the impact on treatment costs across Europe. Table 5.20 provides an overview of the cost estimates of having additional transplants available. These savings would occur over a 30-year period for a single cohort of transplant patients – i.e. these would be the benefits of a single year of having high...
organ donation rates. Even in the most conservative Scenario 4, assuming a 10 per cent increase in transplantation from deceased and living donors, there would be substantial economic benefits of €152 million across the European Union. Cost savings would increase up to €1,185 million in Scenario 1, which is the most optimistic scenario and assumes that all countries would reach the transplantation rates of the best performers in deceased (Spain) and living (Norway) organ donation.

Table 5.20: Estimated 30-year discounted treatment costs / cost savings from additional transplants across EU-27 (x 1,000 euros)

<table>
<thead>
<tr>
<th></th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver</td>
<td>457,657</td>
<td>76,619</td>
<td>206,343</td>
<td>68,781</td>
</tr>
<tr>
<td>Heart</td>
<td>17,371</td>
<td>6,720</td>
<td>17,512</td>
<td>5,837</td>
</tr>
<tr>
<td>Lung</td>
<td>95,375</td>
<td>31,413</td>
<td>78,015</td>
<td>26,005</td>
</tr>
<tr>
<td>Total</td>
<td>–1,185,288</td>
<td>–132,208</td>
<td>–458,078</td>
<td>–152,693</td>
</tr>
</tbody>
</table>

The cost-saving effect is entirely due to the cost-saving effect of kidney transplantation. Figures C.5 to C.8 in Appendix C illustrate a detailed overview of the cost implications per organ type and country.

Applying the assumptions of Section 5.4 on how the policy options would influence organ donation rates, we can illustrate the likely scope of the impacts on treatment costs. Under Option 1 no immediate changes to treatment costs could be expected; however, Member States would be likely to face rising treatment costs if waiting lists and the prevalence of ESRD increased 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 Options 3 and 4, in which we assume at least a modest increase in organ donation rates, cost 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.

5.7.5 Productivity impacts

Background

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 when they could not do so previously. A prime measure of productivity impact is participation in the labour market. In a recent review, Van der Mei et al. (2006) analysed 17 studies, reporting employment rates after kidney transplantation ranging from 18 per cent to 82 per cent. For heart, lung and liver transplantations, the number is lower, and estimates are between 27 per cent for liver transplants (Saab et al., 2007) and 39 per cent for thoracic organs (Petrucci et al., 2007).
The impact of different scenarios and comparison of options

RAND Europe 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-life-saving character of kidney transplants, the total impacts for this group are relatively small.

Table 5.21: Productivity impacts of increased transplantation rates over a 30-year period (euros)

<table>
<thead>
<tr>
<th></th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>513,484,237</td>
<td>47,505,707</td>
<td>273,194,277</td>
<td>91,064,759</td>
</tr>
<tr>
<td>Liver</td>
<td>2,433,587,527</td>
<td>225,146,728</td>
<td>1,294,766,494</td>
<td>431,588,831</td>
</tr>
<tr>
<td>Heart</td>
<td>1,278,247,994</td>
<td>118,258,887</td>
<td>680,079,370</td>
<td>226,693,123</td>
</tr>
<tr>
<td>Lung</td>
<td>745,644,663</td>
<td>68,984,351</td>
<td>396,712,966</td>
<td>132,237,655</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>4,970,964,421</td>
<td>459,895,673</td>
<td>2,644,753,107</td>
<td>881,584,368</td>
</tr>
</tbody>
</table>

Transferring the scenario estimates to the policy options again, Option 1 would not result in productivity gains; if patients are on waiting lists longer 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 €2.6 billion and €5 billion if Member States fully commit to implementing all voluntary elements of the Action Plan. With the assumed minimum level of compliance under Options 2 and 3, productivity gains of 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 €2.6 billion and €5 billion – seem feasible.

5.7.6 Economic impacts on living organ donors

Background

When donating their organs, living donors not only expose themselves to an increased risk of mortality and morbidity, but may also incur a negative economic impact. Such impacts arise from direct costs, such as non-reimbursed healthcare costs, as well as indirect costs, such as losses of income due to extended hospital stays. A recent systematic review demonstrates, however, the current difficulties in producing a reliable overall cost impact (Clarke et al., 2006). 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 organ donation. The study reports estimates of average losses of $3,386 in the United Kingdom from one study, and $682 in another study from The Netherlands. Lost income from living organ donation affects between 14 per cent and 30 per cent of donors. In addition, the indirect costs for dependent care – an ‘externality’ of the organ donation pathway – were incurred by 9–44 per cent of donors, while costs for domestic help were incurred by 8 per cent of donors. Return to work of living donors usually occurs after 16–105 days.
**Comparing the options**

Option 1 would not change the current practice of living organ donation in EU Member States, with a wide variation in organ donation rates and a large potential for increased organ 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 and The Netherlands, where living organ donation has become a very important substitute to organ donation from deceased donors, we can assume that even under Option 1 the importance of living organ donation might increase in the medium and long term, which would result in more patients being exposed to the economic risks of living organ donation.

By promoting the provision of adequate healthcare coverage for living donors, DG SANCO’s proposals would reduce the cost risks related to healthcare expenses for living donors. The proposed action would, however, not protect the living donor from other economic risks. There is enough evidence to suggest that living donors can incur substantial economic costs through, for example, the reduced possibility of work or even partial disability in the case of adverse physical and psychological events. However, due to the relative low number of living donors (5,762 additional donors in the best-case scenario), the aggregated economic impact would be relatively small.

So, while we expect increasing numbers of living donors, the measures proposed would cover only the costs of healthcare but no wider economic risks to the living donors. Similarly, Options 3 and 4 concentrate on the provision of healthcare, but do not touch upon the wider economic impact of living organ donation on the living donors.
This chapter synthesises the previous chapter and compares the four policy options according to their health, social and economic impacts. First, we introduce a scoring mechanism; secondly we compare health, social and economic impacts; and thirdly distributional aspects are considered before identifying the preferred policy option that is expected to meet DG SANCO’s objectives.

6.1 Developing a scoring mechanism

Despite the fact that we provide some concrete data – e.g. costs – there are a number of methodological limitations and other difficulties in quantifying the impacts. To overcome these, we decided to employ a framework for comparison which combines a basic multicriteria analysis along the impact categories previously identified with a scoring mechanism. This approach allows us to compare the policy options by using at least some kind of ‘standard measure’, without losing the richness of the qualitative assessment. The framework summarises the evidence discussed in the previous chapters and the likely impact of each policy option, and attributes a certain assessment of the impacts to each policy option. We used the following scoring system:

++ Evidence of substantial additional health/economic/social benefits compared to the status quo.
+ Evidence of some additional health/economic/social benefits compared to the status quo.
≈ Evidence of no additional health/economic/social benefits compared to the status quo.
- Evidence of some reduction in health/economic/social benefits compared to the status quo.
-- Evidence of substantial reduction in health/economic/social benefits compared to the status quo.
? No available evidence to assess changes in health/economic/social benefits compared to the status quo.

54 A multicriteria analysis compares the positive and negative impacts of different policy options expressed in a mixture of qualitative, quantitative and monetary terms, and is one of the options proposed by the European Commission in summarising the evidence of impact assessments; see European Commission (2005).
This scoring method qualitatively assesses each option according to its impact in comparison to the current policy regime, which is used as the baseline of our assessment. Thus, a policy option which maintains the status quo will be scored as *no change* in benefits or costs. In addition, this scoring system allows us to rank the policy options across the impact categories.

The evidence gathered during this research is summarised and organised in one table per policy issue and then scored, allowing for a clear link between the information and the scoring exercise. The tables may be found in Sections 6.2.1 to 6.2.3 below.

### 6.2 Comparing the options

#### 6.2.1 Health impacts

The key health impacts of DG SANCO policy options emanate from an increase in organ donation rates and reduced risks to patients. The policy options are likely to increase organ donation rates in Europe. However, there is a significant level of uncertainty due to the necessity of national transposition and the implementation by Member States. In addition, the policy options are likely to increase the cross-border exchange of organs, which results in clear health benefits for paediatric, highly sensitised and urgent patients. We note that none of the policy options will have a direct impact on existing health inequalities in organ donation and transplantation, mainly because the policy options do not include organ allocation criteria as an area of policy intervention. As the various European studies show, current increases in organ availability alone will neither ensure fair allocation of organs nor ensure fair access to care across all social groups.

Option 1 would not change the current unsatisfactory status quo, with diverging Quality and Safety standards across Europe, an undeveloped potential for cross-border exchange of organs and no link between the tissue and cell vigilance system and organ donation. Option 2 could create substantial health gains though increases in organ donation rates, but these increases are uncertain as the option allows for a high level of discretion in national implementation. Option 2 will not have an impact on the quality and safety of organs, but will remove disincentives to become a living donor by ensuring access to healthcare for living donors – without, however, including provision for social care that may be eventually necessary.

Options 3 and 4 supplement Option 2 through legal standards and would have a more certain effect on organ donation rates, to the degree that positive changes would become mandatory. It is likely that at least a modest increase of 2,600 organs transplanted can be achieved, resulting in 39,000 saved life years or 37,000 more QALYs. In addition, Options 3 and 4 would establish common Quality and Safety standards across the European Union, which would reduce risks to patients and stimulate cross-border exchange of organs.

Thus Options 3 and 4 have the highest positive health impacts of the four options assessed.
### Table 6.1: Comparison of the health impacts of proposed policy actions

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Option 1: Baseline</th>
<th>Option 2: Action Plan</th>
<th>Option 3: AP + flexible approach</th>
<th>Option 4: AP + stringent directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation rates</td>
<td>Donation rates will continue to be too low to meet rising demands for organs; thus leading to growing waiting lists</td>
<td>Depending on Member State (MS) commitment, zero to substantial increases are possible: - 0 to between 7,908 and 21,006 organs</td>
<td>Medium to high increase possible: - lower estimate 2,636 and 4,983 organs - upper boundary 7,908 to 21,006 organs</td>
<td>Medium to high increase possible: - lower estimate 2,636 to 4,983 organs - Upper boundary 7,908 to 21,006 organs</td>
</tr>
<tr>
<td>QALYs and life years saved</td>
<td>No major change expected, but longer waiting lists and waiting times might reduce the medical outcomes of transplantation</td>
<td>Estimates of donation rates will lead to: - lower predictions show no major change - up to 119,314 to 231,006 life years saved - up to 113,348 to 219,456 QALYs gained</td>
<td>Estimates of donation rates will lead to: - lower estimate of 39,771 to 54,320 life years saved - lower estimate of 37,783 to 51,604 QALYs gained - up to 119,314 to 231,006 life years saved - up to 113,348 to 219,456 QALYs gained</td>
<td>Estimates of donation rates will lead to: - lower estimate of 39,771 to 54,320 life years saved - lower estimate of 37,800 to 51,604 QALYs gained - up to 119,314 to 231,006 life years saved - up to 113,348 to 219,456 QALYs gained</td>
</tr>
<tr>
<td>Risk to patients</td>
<td>No changes to the currently diverse regulatory landscape of Quality and Safety standards</td>
<td>Better knowledge about organ transplantation outcomes will improve future transplantations for patients</td>
<td>Common Quality and Safety standards will ensure equal health protection in all MS Adverse event-reporting systems will improve the quality of donation and transplantation</td>
<td>Common Quality and Safety standards will ensure equal health protection in all MS Adverse event-reporting systems will improve the quality of donation and transplantation</td>
</tr>
<tr>
<td>Living donation</td>
<td>No change expected</td>
<td>Will encourage more living donation May increase knowledge about medical outcomes Increases trust in system</td>
<td>Legal standards will supplement measures under the Action Plan and make them less uncertain to occur</td>
<td>Legal standards will supplement the measures under Action Plan and make them less uncertain to occur</td>
</tr>
<tr>
<td>Health benefits of cross-border exchange</td>
<td>Currently only very few organs are exchanged outside Eurotransplant and Scandiatransplant area, but potential for substantial health benefits</td>
<td>Improved processes and removal of barriers to exchange of organs may increase exchange of organs and benefit small MS and difficult-to-treat patients</td>
<td>Common Quality and Safety standards will supplement measures under the Action Plan, which may increase organ exchange and make it safer</td>
<td>Common Quality and Safety standards will supplement measures under the Action Plan, which may increase organ exchange and make it safer</td>
</tr>
<tr>
<td>Health Inequalities</td>
<td>Evidence suggest health inequalities in the practice of organ transplantation and donation along lines of gender, ethnicity and certain specific diseases</td>
<td>Anticipated benefits from improved processes and removal of barriers to exchange of organs will not include reduced health inequalities</td>
<td>Anticipated benefits from improved processes and the removal of barriers to exchange of organs will not include reduced health inequalities</td>
<td>Anticipated benefits from improved processes and removal of barriers to exchange of organs will not include reduced health inequalities</td>
</tr>
</tbody>
</table>

+: substantial health benefit; +: some health benefit; %= no substantial health impact; ±: some additional negative health impact; --: substantial negative health impact; ?: no evidence
6.2.2 **Social impacts**

Increased organ transplantation will result in positive social impacts for organ recipients and donor families. Evidence shows that transplantation of organs increases the possibilities of patients participating in social and working life. In general, organ transplantation has a positive effect on the QoL of organ recipients. Thus, the different options will generate additional social benefits, depending on the additional transplantations achieved from increased organ donation rates.

European action can be expected to contribute to increased trust and confidence in the organ donation and the transplantation system, by establishing common Quality and Safety standards, increasing public awareness, and improving processes to deal with the relatives of deceased donors. However, the evidence available for such social impacts as social participation and improved standards of living does not allow for an adequate assessment of the precise impact in order to compare the options.

Given the social impact of increasing organ donation rates and the importance of having more robust organ donation and transplantation processes, we would expect the highest social benefits from Options 3 and 4, which increase organ donation rates with higher certainty and are more likely to enforce standards of good processes.
### Table 6.2: Comparison of the social impacts of proposed policy actions

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Option 1: Baseline</th>
<th>Option 2: Action Plan</th>
<th>Option 3: AP + flexible approach</th>
<th>Option 4: AP + stringent directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of life</td>
<td>Only marginal increases in QoL</td>
<td>Increases through better care for living donors</td>
<td>Increases through legally prescribed better access to care for living donors</td>
<td>Increases through legally prescribed better access to care for living donors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Increases through higher number of transplantations</td>
<td>Increases through higher number of transplantations reaching at least minimum improvement</td>
<td>Increases through higher number of transplantations reaching at least minimum improvement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Social participation and employment</td>
<td>Continuation of status quo, end-stage organ failure limiting possibilities for patients of social participation</td>
<td>Does not address obstacles to social participation and employment for individual</td>
<td>Does not address obstacles to social participation and employment for individual</td>
<td>Does not address obstacles to social participation and employment for individual</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Might increase overall social participation through increase in transplanted organs</td>
<td>Might increase overall social participation through an increase in transplanted organs</td>
<td>Might increase overall social participation through increase in transplanted organs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>? (+)</td>
<td>? (+)</td>
<td>? (+)</td>
</tr>
<tr>
<td>Trust and confidence in transplantation system</td>
<td>Very different refusal rates and willingness to donate rates across Europe will continue</td>
<td>Better training of transplant coordinators might increase confidence of donor families</td>
<td>Better training of transplant coordinators might increase confidence of donor families</td>
<td>Better training of transplant coordinators might increase confidence of donor families</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Public awareness campaigns might increase trust and confidence</td>
<td>Quality and Safety standards might increase perception of patient safety and empower patients</td>
<td>Quality and Safety standards might increase perception of patient safety and empower patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td>? (+)</td>
<td>Public awareness campaigns might increase trust and confidence.</td>
<td>Public awareness campaigns might increase trust and confidence.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>? (+)</td>
<td>? (+)</td>
<td>? (+)</td>
</tr>
</tbody>
</table>

++: substantial social benefit; +: some social benefit; ≈: no substantial social impact; -: some additional negative social impact; - -: substantial negative social impact; ?: no evidence
6.2.3 **Economic impacts**

The analysis of the policy options suggest that Options 2 to 4 could lead to substantial economic benefits across the European Union, although Member States will have to invest in the national infrastructure of organ donation and the improvement of processes to realise these gains. However, the evidence does not allow for producing detailed cost estimates for Member States. The economic benefits arise primarily from saved treatment costs as transplanted kidneys replace dialysis treatment. Scenarios developed by RAND Europe see a potential of saving up to €1.2 billion in treatment costs, and reaching productivity gains of up to €5 billion.

Option 1 continues the status quo and is expected to create no additional costs or economic benefits. Option 2 could generate substantial economic benefits of up €1.2 billion savings in treatment costs and an additional productivity impact of €5 billion through low costs for process and infrastructure improvement. Due to the voluntary nature of the Action Plan, RAND Europe recognises that the impacts are highly uncertain because the extent of implementation by Member States is unknown.

Option 3 combines the Action Plan with a flexible directive. Option 3 will lead to substantial costs to implement national registers, reporting activities and a national vigilance system. However, due to the mandatory character of the option, we see cost savings and productivity as occurring with less uncertainty, at a range between €132 million and €1.2 billion for cost savings, and €460 million and €5 billion for productivity impacts. Finally, Option 4 is expected to bring the same economic benefits as Option 3, but at higher implementation costs as Member States have less freedom to use existing systems and devise tailor-made national solutions.
### Table 6.3 Comparison of the economic impacts of proposed policy actions

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Option 1: Baseline</th>
<th>Option 2: Action Plan</th>
<th>Option 3: AP + flexible approach</th>
<th>Option 4: AP + stringent directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs for national infrastructure and better processes</td>
<td>Status quo will continue at no additional cost</td>
<td>Low to medium costs for voluntarily investing in more transplant coordinators Low to medium cost for voluntary measures to designate or accredit establishments</td>
<td>No to very low cost for setting up competent authorities Low to medium costs for designating or authorising establishments Medium costs for running national quality systems</td>
<td>No to very low cost for setting up competent authorities High costs for applying standardised accreditation system Medium to high costs through mandatory, legal quality system at hospital level</td>
</tr>
<tr>
<td>Costs of setting up and running national registers and traceability systems</td>
<td>Status quo will continue with separate, incompatible reporting systems</td>
<td>Possible cost saving through standardised reporting of medical outcome information</td>
<td>No to very low costs for establishing a national register of establishments Medium to high costs for introducing or adapting national traceability and adverse event-reporting systems</td>
<td>No to very low costs for establishing a national register of establishments High costs for introducing a standardised European traceability and adverse event-reporting system</td>
</tr>
<tr>
<td>Reporting obligations and administrative burden</td>
<td>Status quo would continue with already extensive data collection through international bodies</td>
<td>Low cost of reporting requirements under the OMC would result in small burden for MS</td>
<td>Low cost of reporting of activities at transplantation centres. Data can be expected to be readily available</td>
<td>Low cost of reporting of activities at transplantation centres. Data can be expected to be readily available</td>
</tr>
<tr>
<td>Treatment costs</td>
<td>Status quo, with possible increasing long-term costs if waiting times increase</td>
<td>Savings in treatment costs of €458 million to €1.2 billion possible for best-case scenario, if MS commit themselves fully</td>
<td>Savings of €132 million and €152 million as a result of modest increase in donation rates Savings of €458 million and €1.2 billion in the best-case scenarios</td>
<td>Savings of €132 million and €152 million as a result of modest increase in donation rates Savings of €458 million and €1.2 billion in the best-case scenarios</td>
</tr>
<tr>
<td>Productivity Impact</td>
<td>Status quo, loss of productivity if more people have to wait longer for an organ</td>
<td>Potential productivity impact of €2.6 billion to €5 billion under best-case scenario, no gains if MS commitment is low</td>
<td>Productivity gains of €460 million and €882 million as a result of modest increase in donation rates Productivity gains of €2.6 billion and €5 billion for best-case scenarios</td>
<td>Productivity gains of €460 million and €882 million as a result of modest increase in donation rates, Productivity gains of €2.6 billion and €5 billion for best-case scenarios</td>
</tr>
<tr>
<td>Economic Impact on living donor</td>
<td>Living donors are currently exposed to economic risk through need for healthcare and loss of income in case of reduced ability to work</td>
<td>Option will reduce economic risks related to healthcare Option does not tackle other economic risks</td>
<td>Option will reduce the economic risks related to healthcare Option does not tackle other economic risks</td>
<td>Option will reduce the economic risks related to healthcare Option does not tackle other economic risks</td>
</tr>
</tbody>
</table>

**Legend:** ++: substantial economic benefit; +: some economic benefit; =: no substantial economic impact; -: some additional economic cost; --: substantial additional economic cost; ?: no evidence
6.3 Distribution of costs and benefits

Having compared the key health, social and economic impacts of the four policy options, it is important to assess how these impacts would be distributed between different groups of stakeholders. The stakeholder groups which would most likely be affected by the policy proposals are as follows:

1. Patients waiting for or receiving organ transplantation
2. Difficult-to-treat patients
3. Living donors
4. Families of deceased donors
5. Member States authorities
6. Hospitals
7. National health services and insurance
8. Member States with developed organ donation and transplantation systems
9. Member States with less developed transplantation systems.

Patients with end-stage renal, liver, heart or lung disease and other diseases requiring transplantation of an organ are naturally one of the key stakeholder groups, and they will be a key beneficiary of actions. Currently there are around 50,000 patients in the European Union waiting for an organ transplant. Options 2, 3 and 4 are likely to increase transplantation rates and would thus benefit this group substantially by increasing life expectancy and QoL for those who receive transplants.

For difficult-to-treat patients – i.e. urgent, paediatric or highly immunised patients – who either need a suitable organ very quickly or need an organ with very specific characteristics; benefits would be even greater as increased border exchange increases the donor pool and thus the likelihood of finding a suitable organ in time. These benefits are higher for Options 3 and 4; nevertheless, difficult-to-treat patients would benefit from all European policy action. Given the importance of the size of the donor pool, patients in small Member States would have even higher benefits than those in large Member States because they will gain access to more suitable organs.

Better knowledge about medical outcomes of living organ donation would benefit living donors across the European Union under Option 2. In addition, Options 3 and 4 would increase benefits by ensuring access to healthcare for living donors, thereby reducing some of the associated economic risks.

The families of deceased donors have a substantial influence on organ donation rates by allowing or refusing the donation of their deceased relatives’ organs. The analysis of social impacts shows that all three policy measures could help improve the care for donor families during the organ donation process by improving transplant coordinators’ skills. This could not only benefit transplantation rates, but also increase families’ trust and confidence in the transplantation system.
Member State authorities have to transpose and implement the proposed policy measures and adjust their organisational structures to meet the requirements of the European policies to be put in place. This will involve in any case some costs for Member States’ authorities. As discussed earlier, such costs would vary between options, with Option 2 involving the least and Option 4 the highest costs.

Hospitals are involved in the organ donation process as procurement and/or transplantation centres and are thus directly affected by the policy proposals. Indeed, as they have a crucial role in the organ donation and transplantation pathway, they are the target of the policy measures proposed. Costs would increase for hospitals, through increased procurement activities, administrative burdens related to reporting, and finally the implementation of quality programmes, including staff training, at the hospital level. These increases would be greatest for Option 4 and least for Option 2. However, hospitals could be compensated for these costs and procurement costs could be adequately reimbursed, as in the Spanish model. Assessing these net impacts was, however, beyond the scope of this research.

National health services or national health insurances which are responsible for financing medical treatment stand to gain substantially from the policy proposals. Every kidney transplanted generates a net saving in treatment costs for healthcare providers, saving money spent on dialysis treatment. Option 2 would achieve these savings under higher uncertainty, while Options 3 and 4 make these savings more likely to occur.

Due to the cross-national differences in transplantation rates and the development of transplantation systems, it is useful to distinguish between Member States with developed organ donation and transplantation systems and Member States who have not yet, or have only recently, started to develop robust organ donation and transplantation systems.

For Member States with less developed systems, we expect both benefits as well as costs to be higher than for Member States who already have well-established systems. This is due to two main factors. First, increasing organ donation rates will be much easier to achieve from a low baseline; secondly, less developed states will be much more likely to have to invest in expanded infrastructure and robust organ donation and transplantation processes.

Table 6.4 provides a more detailed overview of this discussion by comparing the different options by their impacts on the identified stakeholder groups, indicating either a positive impact, which may be health benefits, cost savings or positive social impacts; or a negative impact, which may be reduced health outcomes or increases in costs and administrative burden.

Summarising this analysis of the distributional effects of the proposed policy options, one can observe that the proposed policy options do not differ in the main distribution of costs and benefits between key stakeholders. The main benefits would occur for patients with the need for an organ transplant and for the health services that could save substantial parts of their treatment costs due to large reductions in dialysis treatment. On the other side, the main costs will lie with national transplant services and authorities as well as hospitals, which would be responsible for meeting new reporting obligations, introducing new Quality and Safety standards, and investing in the national infrastructure of organ donation.
Table 6.4: Distribution positive and negative impacts

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Option 1: Baseline</th>
<th>Option 2: Action Plan</th>
<th>Option 3: AP + flexible approach</th>
<th>Option 4: AP + stringent directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>Option can increase donation rates, but high uncertainty</td>
<td>≈ to ++</td>
<td>Option will increase donation rates</td>
<td>Option will increase donation rates</td>
</tr>
<tr>
<td></td>
<td>Increased cross-border exchange benefits particularly patients in small MS</td>
<td></td>
<td>Increased cross-border exchange will benefit patients in small MS</td>
<td>Increased cross-border exchange will benefit patients in small MS</td>
</tr>
<tr>
<td>Difficult-to-treat patients</td>
<td>Removal of barriers for organ exchange will benefit difficult to treat patients in particular</td>
<td>+</td>
<td>Removal of barriers for organ exchange and common Quality and Safety standards will benefit difficult-to-treat patients</td>
<td>Removal of barriers for organ exchange and common Quality and Safety standards will benefit difficult-to-treat patients</td>
</tr>
<tr>
<td>Living donors</td>
<td>Better knowledge about living donation allows for better care of living donors pre- and post-transplantation</td>
<td>+</td>
<td>Better knowledge about living donation allows for better care of living donors pre- and post-Tx</td>
<td>Better knowledge about living donation allows for better care of living donors pre- and post-Tx</td>
</tr>
<tr>
<td></td>
<td>Option ensures long-term access to healthcare for living donors</td>
<td></td>
<td></td>
<td>Option ensures long-term access to healthcare for living donors</td>
</tr>
<tr>
<td>Donor families</td>
<td>More and better trained coordinators will have better skills in supporting grieving relatives</td>
<td>+</td>
<td>More and better trained coordinators will have better skills in supporting grieving relatives</td>
<td>More and better trained coordinators will have better skills in supporting grieving relatives</td>
</tr>
<tr>
<td>Member State authorities</td>
<td>Costs of setting up and running a national authority</td>
<td>-</td>
<td>Medium cost of setting up and running authorisation procedures and national reporting and traceability systems</td>
<td>High costs of authorisation of establishments and processes</td>
</tr>
<tr>
<td></td>
<td>Costs of voluntarily increasing the number of coordinators</td>
<td></td>
<td>Costs of increasing the number of transplant coordinators</td>
<td>High costs of setting up and running authorisation procedures and national reporting and traceability systems</td>
</tr>
<tr>
<td>Hospitals</td>
<td>Costs of increased procurement activities</td>
<td>-</td>
<td>Costs of increased procurement activities Administrative burden of reporting and traceability systems</td>
<td>Costs of increased procurement activities Administrative burden of reporting and traceability systems</td>
</tr>
<tr>
<td></td>
<td>Administrative burden of reporting and traceability systems</td>
<td></td>
<td></td>
<td>Costs of quality programme at hospital level</td>
</tr>
<tr>
<td>National health services / Health insurance</td>
<td>Very substantial savings in treatment costs of up to €2.4 billion possible, but uncertain.</td>
<td>≈ to ++</td>
<td>Very substantial cost savings, between €460 million and €2.4 billion, with less uncertainty than Option 2</td>
<td>Very substantial cost savings, between €460 million and €2.4 billion, with less uncertainty than Option 2</td>
</tr>
<tr>
<td>Member States with developed transplant systems</td>
<td>Only small increases in donation rates for the highest developed systems likely</td>
<td>= to +</td>
<td>Only small increases in donation rates for the highest developed systems likely</td>
<td>Only small increases in donation rates for the highest developed systems likely</td>
</tr>
<tr>
<td></td>
<td>No costs for already well-developed systems</td>
<td>-</td>
<td>Low costs of adjusting already well-developed systems</td>
<td>Potentially high costs, if current system does not comply with new requirements</td>
</tr>
<tr>
<td>Member States with less developed transplant systems</td>
<td>Very large benefits from increase in donation rates possible</td>
<td>= to ++</td>
<td>Very large benefits from increase in donation rates possible</td>
<td>Very large benefits from increase in donation rates possible</td>
</tr>
<tr>
<td></td>
<td>Costs will be high, as most of the infrastructure has to be developed</td>
<td>--</td>
<td>Costs will be high, as most of the infrastructure has to be developed</td>
<td>Costs will be high, as most of the infrastructure has to be developed</td>
</tr>
</tbody>
</table>

++: substantial positive impact; +: some positive impact; ≈: no substantial positive or negative impact; - : some negative impact; --: substantial negative health impact; ?: no evidence
Identifying a preferred option

RAND Europe assessed the status quo option and three new policy options provided by DG SANCO to improve organ donation and transplantation in the European Union with the objectives of: 1) increasing organ availability; 2) enhancing the effectiveness and accessibility of transplantation systems; and 3) improving the quality and safety of organ donation and transplantation. In identifying a preferred policy option to achieve these objectives, the positive as well as the negative health, social and economic impacts of each option have to be carefully compared against each other. The previous sections summarised the key findings for each policy option and compared the policy options along the lines of each impact category; in addition, the distributive effects of policy action were considered.

In weighing the evidence available, RAND Europe concluded that Option 3, which combines an Action Plan using the open method of coordination with a flexible directive creating a European framework regulation for Quality and Safety, will help to achieve DG SANCO’s objectives at the best cost-consequence ratio.

The least costly option, Option 2, will not be sufficient to create a robust Quality and Safety framework and thus not help to achieve DG SANCO’s third objective. In addition, its potential positive health and economic impacts are more uncertain than for the other two options. Even more so than Options 3 and 4, Option 2 relies on the commitment of Member States to change organisational structures, improve processes and invest into organ donation and transplantation voluntarily.

Option 4 in turn will ensure the most stringent Quality and Safety standards across Europe, which comes, however, at the risk of creating an unnecessary administrative burden. As expert experiences with EU Tissues and Cells Directive have shown, a strict regulatory approach has a risk of leading to substantial difficulties in implementation of the facilities and possibly even a negative impact on organ donation rates for some facilities. In addition, Option 4 can be expected to have the highest overall implementation costs, as even countries with already well-established organ donation and transplantation systems will need to change some of their infrastructure and processes to comply with EU prescriptions. Nevertheless, Option 4 will have also substantial economic benefits through saved treatment costs and the productivity impacts of longer life expectancy.

Overall, Option 3 will be best suited to achieve DG SANCO’s objectives of increasing organ donation rates, making transplant systems more accessible and efficient and ensuring Quality and Safety standards. By allowing a certain degree of flexibility for the Member States, this option reduces implementation costs and the administrative burden, while at the same time safeguarding minimum Quality and Safety standards. It is likely to increase organ donation rates, which would result in substantial benefits for patients as well as substantial cost savings for the national health systems.
This chapter outlines how the European Commission may wish to plan for the monitoring and evaluation of the proposed policies for organ donation and transplantation. The EC Impact Assessment Guidelines require that an effective monitoring regime should ‘set measurable indicators to cover both the quality of outcomes and the implementation process, and define plans for evaluation’ (European Commission, 2005).

7.1 Monitoring and evaluation framework

Due to the nature of the chosen policy options, which are all based on an Action Plan under the open method of coordination, all policy options already contain substantial monitoring and evaluation requirements which can be the basis for any future monitoring and evaluation framework.

While the monitoring of the progress of the policy will be done on an annual basis using national progress reports, the evaluation could take place at the end of the Action Plan period in 2015. For the systematic ex-post-evaluation of the policy actions RAND Europe would propose a framework based on a logic model (see Figure 7.1)

Figure 7.1: Logic model

In a first step, such a model would map out the European Union’s and Member States’ planned work to achieve the policy objectives. The planned work by the Member States and the European Commission refers to the resources or inputs, be they financial, organisational or community-based, made available to implement the programme or initiative. Secondly, planned work refers to the activities, be they processes, events or tools, that were undertaken to produce the intended programme results. In the case of organ donation this is, for example, an increase in transplant coordinators, the introduction of Quality and Safety programmes, or investment in public awareness.
In a **second step** the activities and resources in the planned work would be compared against the intended outputs and outcomes of the policy actions. **Intended outcomes** refer to the results of the programme or initiative that the policy was designed to achieve. Outputs and outcomes indicate specific changes that are associated with the activities. Outputs are defined as the *direct* results of activities, while outcomes refer to *desired* results or wider intended results, for instance on stakeholders. Outcomes are normally subdivided into short-term outcomes within a 1–2-year period and medium-term outcomes within a 3–7-year period. Intended outcomes would be those that help meet the policy objectives, such as increased organ donation rates, increased cross-border exchange, reduced graft-related infections etc.

In a **third step** this evaluation would analyse the final **impacts** of the policy action, taking into account the unintended outcomes of planned work as well as intervening factors beyond the reach of the policy. This would include intervening factors such as a decrease in traffic accidents reducing the number of potential donors. It would also include unintended consequences of the policies: for example, hospitals stopping participation in organ procurement because of burdensome accreditation requirements. Finally, these results should be compared against the counterfactual – what would have happened without the intervention in place, or if another intervention had been implemented.

The following section will briefly outline the key indicators that could be used for the monitoring as well as the evaluation of policy implementation and outcomes. The indicators used to monitor and evaluate the policy progress can be divided into three groups, related to the three general policy objectives. Within each group, there are three types of indicators: namely, input, process and output indicators.

### 7.2 Increasing organ availability

The indicators used to monitor progress in increasing organ availability are as follows:

- Number of transplant procurement hospitals
- Number of transplant coordinators per million population
- National organ donation rates – living and deceased (donors per million population)
- Refusals to donate
- National multiorgan donation rates
- Conversion rates of potential into actual donors
- National number of transplant procedures per organ and per million population.

The number of transplant coordinators and procuring hospitals are input indicators to determine how active a national health system is in procuring organs from deceased donors. Organ donation rates as measured per million population have long been the prime indicator for assessing performance in procuring organs; however, more recently this measure has attracted criticism as it neglects the differences in the size of the pool of potential donors between countries. Thus, indicators such as multiorgan donation rates and conversion rates from possible into effective donors should be taken into account. However, there are still considerable data shortages and methodological problems in
assessing the potential donor pool for a country, as the DOPKI project showed (DOPKI, 2006).

7.3 **Improving quality and safety of organ donation and transplantation**

The quality and safety of organ transplantation is the second important objective of the European policy. The following indicators could be used to measure progress in ensuring and improving the quality and safety of organ donation and transplantation:

- Existence of a national quality programme
- Number of hospitals with quality assurance programmes
- National survival rates:
  - for different organs
  - living and cadaveric organ donation
- Numbers of adverse events related to organ quality:
  - infections
  - transmission of malignant diseases
  - organ damage
- Reports to and from the tissue and cell vigilance system.

The first indicators are implementation and input measures and would allow monitoring if the Member State took action on Quality and Safety measures on a national and hospital level. The other indicators measure key aspects of Quality and Safety in terms of medical outcomes and adverse events as risks to patient safety.

7.4 **Enhancing the efficiency and accessibility of transplantation systems**

Indicators to measure progress against the objective of enhancing efficiency and accessibility could include the following:

- Number of organs interchanged within the Community and with third countries
- Percentage of organs for difficult-to-treat patients exchanged across borders
- Number of people on waiting lists
- Mortality while on waiting list
- Access to waiting lists
- Inequality in access to transplantation services at all stages of the organ donation pathway:
  - gender
  - ethnic and/or minority status
  - resident /non-resident status
  - low socio-economic status
  - type of diseases (rare diseases).

The indicators would provide a snapshot of accessibility to transplantation services. In particular they would allow for measuring the aspect of transplant systems where currently data are weak. This includes, more specifically, information about *equitable* access to
services among different groups of patients. In addition, knowledge about the true extent of people waiting for organs could be improved as patients are often not put on waiting lists because physicians consider it unlikely they will ever receive an organ, or because they are unaware of the patients’ greater vulnerability to life-threatening diseases and therefore their higher need for an organ.
8.1 **The impacts of European action**

This report analysed four options for European action in the field of organ donation and transplantation provided by DG SANCO and identified key health, social and economic impacts. The following sections summarise the key findings of impacts per policy option.

8.1.1 **Health impacts**

The key health impacts of DG SANCO proposals emanate from an increase in organ donation rates and reduced health risks to patients. The policy options are likely to increase organ donation rates in Europe. However, there is a significant level of uncertainty. A best-case scenario developed by RAND Europe established a potential of up to 21,000 more organs transplanted per year in the European Union. This would translate into saving 230,000 life years or gaining 219,000 QALYs. In addition, the policy options are likely to increase cross-border exchange of organs, which results in clear health benefits for paediatric, highly sensitised, urgent and other difficult-to-treat patients. We note a real risk that none of the policy options will have a direct impact on existing health inequalities in organ donation and transplantation, mainly because the policy options do not include organ allocation criteria as an area of policy intervention. As the various European studies show, current increases in organ availability alone will neither ensure fair allocation of organs nor ensure fair access to care across all social groups.

Option 1 would not change the current unsatisfactory status quo, with diverging Quality and Safety standards across Europe, an undeveloped potential for cross-border exchange of organs, and no link between the tissue and cell vigilance system and organ donation. Option 2 could create substantial health gains through increases in organ donation rates; however, these increases are uncertain as the option allows for a high level of discretion in national implementation. Option 2 would not have an impact on the quality and safety of organs, but would remove disincentives to become a living donor by ensuring access to healthcare for living donors.

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55 Please see the Executive Summary on page xiii for an overview of key findings.
Options 3 and 4 supplement Option 2 through legal standards and would have a more certain effect on organ donation rates to the degree that positive changes would become mandatory. It is likely that at least a modest increase of 2,600 organs transplanted could be achieved, resulting in 39,000 saved life years or 37,000 more QALYs. In addition, Options 3 and 4 would establish common Quality and Safety standards across the European Union, which would reduce risks to patients’ safety and stimulate cross-border exchange of organs.

8.1.2 Economic impacts
The analysis of the policy options suggests that Options 2 to 4 could lead to substantial economic benefits across the European Union, although Member States would have to invest in the national infrastructure of organ donation and the improvement of processes to realise these gains. However, the evidence does not allow for producing detailed cost estimates for Member States. The economic benefits arise primarily from saved treatment costs as transplanted kidneys replace dialysis treatment. Scenarios developed by RAND Europe see a potential of saving up to €1.2 billion in treatment costs, and reaching productivity gains of up to €5 billion.

Option 1 continues the status quo and would be expected to create no additional costs or economic benefits. Option 2 could generate substantial economic benefits of up €1.2 billion savings in treatment costs and an additional productivity impact of €5 billion at low costs for process and infrastructure improvement. Due to the voluntary nature of the Action Plan, RAND Europe recognises that the impacts are highly uncertain because the extent of implementation by Member States is unknown.

Option 3 combines the Action Plan with a flexible directive. Option 3 would lead to substantial costs in order to implement national registers, reporting activities and a national vigilance system. However, due to the mandatory character of the option, we see cost savings and productivity as occurring under less uncertainty, at a range between €132 million and €1.2 billion for cost savings and €460 million and €5 billion for productivity impacts. Finally, Option 4 would be expected to bring the same economic benefits as Option 3, but at higher implementation costs since Member States would have less freedom to use existing systems and devise tailor-made national solutions.

8.1.3 Social impacts
Increased organ transplantation would result in positive social impacts for organ recipients and donor families. Evidence shows that transplantation of organs increases the possibilities for patients of participation in social and working life. In general, organ transplantation has a positive effect on the QoL of organ recipients. Thus, the different options would generate additional social benefits, depending on the additional transplantations achieved.

European action can be expected to contribute to increased trust and confidence in the organ donation and transplantation system by establishing common Quality and Safety standards, increasing public awareness, and improving processes to respond adequately to and care for relatives of deceased donors. However, the evidence available for such social impacts, such as social participation and improved standards of living, does not allow for an adequate assessment of the precise impacts to compare the options.
8.1.4 A preferred option

Out of these key findings on the policy impacts, RAND Europe assessed the status quo option and three new policy options provided by DG SANCO to improve organ donation and transplantation in the European Union with the objectives of: 1) increasing organ availability; 2) enhancing the effectiveness and accessibility of transplantation systems; and 3) improving the quality and safety of organ donation and transplantation. In weighing the available evidence, RAND Europe concluded that Option 3, which combines an Action Plan using the open method of coordination with a flexible directive creating a European framework regulation for Quality and Safety, would help to achieve DG SANCO’s objectives at the best cost-consequence ratio. The least costly option, Option 2, would not be sufficient to create a robust Quality and Safety framework, and the potential positive health and economic impacts are more uncertain than for the other options. Option 4 in turn would ensure stringent Quality and Safety standards across Europe and would have substantial economic benefits, but it would also have the highest implementation and compliance costs. In addition, anecdotal evidence of expert experiences with the EU Tissues and Cells Directive suggested that a strict regulatory approach has the risk of leading to substantial difficulties in implementation for the facilities and possibly even a negative impact on organ donation rates for some facilities.

8.2 Assessing policy impacts under uncertainty

Impact assessments of future policies are generally subject to uncertainties in the actual policy outcomes. This impact assessment been no exception to this; on the contrary, the uncertainty of policy outcomes has been a major methodological challenge. Uncertainty in assessing the outcomes of European action in the field of organ donation and transplantation stemmed in particular from two sources.

First, as in many other policy areas, causal relationships are very complex in the field of organ donation and transplantation. Organ donation rates are, for example, influenced by many different drivers, including the type of consent systems, national mortality rates and the availability of ICU beds, trust and confidence in the organ donation and transplantation system, and the level of family refusals. In its proposals DG SANCO tackles primarily the organisation of the organ donation process, which is only one, though an important, factor out of a number of drivers. The multitude of causal factors is of particular importance as we are assessing future policy impacts. Figure 8.1 illustrates this uncertainty as link A 1 between policy outcomes and actual impacts and as the link between policy impacts and policy problem. Even if the desired policy outcome has been achieved, it is uncertain whether this will achieve the desired impacts and whether these in turn will help tackle the policy problem identified at the outset of the policy initiative.
Secondly, and centrally to this impact assessment, the multilevel governance character of the organ donation and transplantation systems makes policy outcomes more uncertain. Improvements in organ donation and transplantation systems are delivered at the hospital level, while the proposed policy action contains policies which will first have to be transposed into national legislation and be implemented by the Member States and have to be supplemented by the Member States through investment in infrastructure and personnel, and which often have to be channelled through regional structures as well. Given the voluntary approach of Option 2 and the considerable discretion in implementation for Option 3 and even for Option 4, there is wide scope for uncertainty about how European action would actually reach hospital level.

The challenge of this impact assessment was to find a way of linking the good evidence about impacts of hospital-level measures on organ donation rates and transplantation rates such as the Spanish model or the Donor Action Programme to the European policy actions. As implementation through Member States could not be reliably assumed, RAND Europe applied a scenario approach and a benchmarking exercise to develop an informed understanding of the potential scope of the impacts and linked four different scenarios to the policy options to provide possible ranges of impacts. However, even this strategy does not allow for a complete reduction of uncertainty; thus the findings related to increases in transplantation rates have to be seen against a substantial level of uncertainty. To address these difficulties, a better knowledge in particular about ‘softer’ or more flexible approaches to European policy-making such as the open method of coordination have to be established to allow for a better assessment of national transposition and implementation processes.


improving organ donation and transplantation in the European union


Improving organ donation and transplantation in the European Union  
RAND Europe


Kalaciński, P. (2007). *Finansowanie, nadzór, monitorowanie, ocena jakości działalności transplantacyjnej w Polsce (Financing, Controlling, Monitoring and Quality Assessment of the transplantation activities in Poland), Presentation for the Conference*


Poltransplant (2007) "Biuletyn 2007." *Biuletyn Informacyjny* 1, DOI:


Appendix A: Medical Background Information

This appendix provides medical background information about organ transplantation. It is based on the previous impact assessment of DG SANCO (2007).

Transmission of communicable diseases

Human Immunodeficiency Virus
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 (Green et al., 2004). There are no cases described of HIV-2 transmission. The effectiveness of the transmission is difficult to know, but it is assumed that is nearly 100 per cent through solid organ transplantation from a donor who is HIV positive. HIVAc (+) donors carry a high risk of viral transmission: the infectivity of a small inoculum has been demonstrated by blood transfusion studies (ONT, 2004).

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 serological testing. In one instance, massive transfusion of blood and blood components decreased the antibody titre below the sensitivity limits of EIA. In a second case, transmission occurred from a donor during the ‘window period’.

Transmission through these false negatives should be prevented through a good clinical and behavioural history of the donor.

Hepatitis B virus (HBV)
Cases of HBV transmission have decreased, due to serological screening, which normally includes an Ag HBs test.

The kidney was the first graft involved in a case of HBV transmission.

There are studies that indicate that more than 1 per cent of potential donors have an active HBV infection and over 12 per cent in hyper-endemic areas. In countries with low prevalence, like the USA, 3–4 per cent of donors have a past history of HBV infection, and in some European countries the rate is over 10 per cent.
The risk of transmission from donors with test against Antigen Hepatitis B (Ag HBV) positive is nearly 100 per cent. However the transmission of HBV to the recipients is also possible from Ag HBV negative donors who have other serological marker positives (Feng et al., 2002).

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. (Dodson et al., 1997; Uemoto et al., 1998; Frutos et al., 2003). The donor’s Hepatitis B Antigen status does not mitigate transmission risks (Dickson et al., 1997). In some countries this type of donor represents between 5 and 15 per cent of all donors.

In contrast with liver transplantation, transplantation of kidneys from HBcAb 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 (Madayag et al., 1997; Satterthwaite et al., 1997; Miranda et al., 2003). 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. Of kidney recipients from HBcAb + donors, 27 per cent demonstrated seroconversion compared with 4 per cent of kidney recipients from HBcAb – donors, for an odds ratio of 4.94.

Some studies indicate that the risk of transmission is 15–78 per cent for liver transplantation, 2 per cent in kidney and 0 per cent in heart transplantation.

An additional problem that could be found in Ag HBs positive donors is co-infection with the Hepatitis Delta (VHD) virus. The transmission of this virus through kidney transplantation, resulting in severe acute hepatitis, has been described.

Regarding the Hepatitis C virus (HCV), transplantation of an organ from an HCV+ donor is known to be an efficient mode of viral transmission (Tesi et al., 1994; Wreghitt et al., 1994; Pereira et al., 1995; Frutos et al., 2003). Approximately 5 per cent of all potential donors in the USA and Europe are positive for Antibody HCV Candinas, (1994). A positive HCV-RNA, indicative of viral replication, has been associated with a higher risk of transmission (Fishman et al., 1996). Transmission from donors with RNA positive is estimated to be nearly 100 per cent. 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 seroconversion in 50–67 per cent of the cases and development of hepatic disease in around 35 per cent.

Overall, the limited data available validate the assumption that heart and lung transplantation presents a similar risk of HBV or HCV transmission to 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 data available.

56 Data from ONT, Spain.
Other viruses

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

West Nile virus (WNV) is a flavivirus that can cause meningoencephalitis. In autumn 2002, transmission of WNV from a single donor to four organ donors was reported. An additional case through liver transplantation has appeared. In August 2002, fever and mental status 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 one of three 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 per cent of infected patients. However, data from a seroprevalence study suggest that the incidence is as high as 40 per cent in organ transplant recipients.

Although prevention strategies are critical, there is disagreement within the transplant community about the use of nucleic acid testing for the 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.

Bacterial and fungal infections

A bacterial or microbial infection or colonisation may be present in 60 per cent of deceased organ donors and mainly affects the respiratory and urinary tract. Bacterial and fungal donor-to-host transmission with the allograft with a result of loss of the infected graft or death of the recipient has been widely documented. Nevertheless, adequate antibiotic treatment of the donor and/or recipient should prevent infection in the latter.

Micobacterium tuberculosis has been transmitted by transplantation; donor transmission accounted for approximately 4 per cent of reported post-transplant TB cases in a large review of 511 patients (Singh and Paterson, 1998).

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

Parasitic infections

There are 342 parasitic species that are known to affect humans, mostly those in tropical and subtropical regions (Barsoum, 2004). Recently, however, there has been a considerable spread of parasites to the rest of the world as a result mainly of travel and migration. Only 5 per cent of the known human pathogenic parasitic infections have been reported in transplant recipients.

Malaria transmission has been reported with kidney, bone marrow and multiorgan transplantation. Toxoplasmosis is a major concern, particularly with heart transplantation. Toxoplasma has rarely been transmitted to liver and kidney recipients.
Transmission of Chagas disease is a significant problem in endemic areas, and recently has been reported in the US.

Prion Infections
Creutzfeldt-Jakob Disease has been transmitted with the treatment of growth factors and with the 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 A.1: Evidence of transmission of malignant diseases

<table>
<thead>
<tr>
<th>Source</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>First report of 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%. A more recent report from this registry (1994–2000 period) showed 14 donors with a 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 tumours transmitted were 4 melanomas, 1 neuroendocrine tumour, 1 adenocarcinoma, 1 cancer of the pancreas, 1 non-differentiated squamous carcinoma, 2 lung cancers, 1 small cell carcinoma, 1 oncocytoma, 1 papillary tumor, 1 breast cancer, 1 prostate cancer.</td>
<td></td>
</tr>
<tr>
<td>The frequency of donors with no detected tumour is 6.1 per 1,000 donors during the last 15 years. Five of these donors transmitted the disease (2.9 per 10,000 donors). Ten recipients of the 155 who 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 2 kidney carcinomas.</td>
<td></td>
</tr>
<tr>
<td>Birkeland studied a cohort of donors over 27 years, finding 13 malign tumours within 626 donors (2% of the donors). Of these donors only one has transmitted the tumour (a melanoma) to the recipient (2 per 1,000 donors).</td>
<td></td>
</tr>
<tr>
<td>Since 2002 the CNT has put in place a new strategy for the evaluation of donors. Analysis of the period 2001–2002 showed 2.9% of donors with tumours.</td>
<td></td>
</tr>
<tr>
<td>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%). There were 30 recipients of organs from donors with melanoma, with tumour transmission in 23 (77%); and 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%) and Kaposi Sarcoma (67%).</td>
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</tr>
</tbody>
</table>

Appendix B: Scenario Methodology

Scenario development and data analysis

Data from the Council of Europe’s *International Figures on Organ Donation and Transplantation Activity Year 2006* are used for the quantitative scenario analysis and Table B.1 gives the organ types for the 2006 data that are used for the analysis.

<table>
<thead>
<tr>
<th>Deceased</th>
<th>Kidney</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td>Heart</td>
</tr>
<tr>
<td></td>
<td>Lung</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Living</th>
<th>Kidney</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liver</td>
</tr>
</tbody>
</table>

*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 other EU countries. On these grounds, four possible scenarios have been defined to capture not only the most optimistic (but perhaps unrealistic) situation, in which all Member States reach the highest current donation rates (i.e. Spanish level); but also the 'most likely' situation, in which Member States achieve a moderate level of the European average. The types of scenarios that are developed are given in Table B.2. The procedure for developing these scenarios is explained in the next section.

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57 Council of Europe (2007).
### Table B.2: Description of the scenarios

<table>
<thead>
<tr>
<th>Transplant rate assumptions</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>All countries achieve the transplantation rate of the best-performing country*</td>
<td>All countries achieve at least European average transplantation rates</td>
<td>All countries improve their transplantation rate by 30%</td>
<td>All countries improve their transplantation rate by 10%</td>
</tr>
<tr>
<td><strong>Transplantations from deceased donors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney, from deceased donors</td>
<td>At least Spanish rate 46 pmp</td>
<td>At least European average: 29.1 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Liver, from deceased donors</td>
<td>At least Spanish rate 23.1 pmp</td>
<td>At least European average: 12.3 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Heart</td>
<td>At least Spanish rate 6.1 pmp</td>
<td>At least European average: 4.3 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Lung</td>
<td>At least Spanish rate 3.8 pmp</td>
<td>At least European average: 2.5 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td><strong>Transplantations from living donors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney, from living donors</td>
<td>At least Norwegian rate 17 pmp</td>
<td>At least European average: 5.4 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Liver, from living donors</td>
<td>At least Spanish rate 0.4 pmp</td>
<td>At least European average: 0.5 pmp</td>
<td>+30%</td>
<td>+10%</td>
</tr>
</tbody>
</table>

* 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:
  \[
  R_{cx} = \frac{O_{cx}}{POP_c}
  \]

  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:

Extra Organs Required = \( (R_{sx} - R_{nx}) \times \text{POP}_c \)
Extra Living Kidneys = \( (R_{nx} - R_{cx}) \times \text{POP}_c \)

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:
  \( (AVE)_x = \frac{(OA)_x}{\text{Tot.Pop.}} \)
  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 \( x \)
  \( \text{Tot.Pop.} \) = 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:

Extra Organs Required = \( [(AVE)_x - R_{cx}] \times \text{POP}_c \)

**Scenario 3**

This scenario is arrived at by assuming a strong improvement in donation rates of 30 per cent in the EU. The number of organs required to reach this donation rate is 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 per cent in the EU. The number of organs required (if the country is not up to EU level) to reach this donation rate is 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 is further aggregated into four types: kidney, liver, heart and lung transplants.

**Quality adjusted life years gained**

The total number of QALYs gained for a scenario is the product of the number of the QALYs gained for each type of transplant and the number of transplants for each transplant type in that scenario, as below:

\[ QALY_{isc} = QALY_i \times O_{isc} \]

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 [Error! Reference source not found.].

<table>
<thead>
<tr>
<th>Tx (Transplantation type, ( i ))</th>
<th>QALYs gained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney transplant</td>
<td>3.1</td>
</tr>
<tr>
<td>Liver transplant</td>
<td>11.5</td>
</tr>
<tr>
<td>Heart transplant</td>
<td>6.8</td>
</tr>
<tr>
<td>Lung transplant</td>
<td>5.2</td>
</tr>
</tbody>
</table>

**SOURCE**: [Department of Health, 2008b)]

**Productivity estimation**

The total productivity is estimated by the following equation:

\[ P_{isc} = W_c \times Ly_i \times O_{isc} \times EP_i \]

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 2007)

LY<sub>it</sub> = Life years gained for organ transplant type <i>i</i>

O<sub>isc</sub> = Number of organs <i>i</i> in scenario <i>s</i> for country <i>c</i>

EP<sub>i</sub> = Percentage of people employed after undergoing transplant type <i>i</i>

Error! Reference source not found. 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).

<p>| Table B.4: Life year gains and percentage of employed people after each transplant |</p>
<table>
<thead>
<tr>
<th>Tx (Transplantation type)</th>
<th>Life years gained</th>
<th>Employed after Tx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney&lt;sup&gt;1&lt;/sup&gt;</td>
<td>2.0</td>
<td>47%</td>
</tr>
<tr>
<td>Liver&lt;sup&gt;2&lt;/sup&gt;</td>
<td>16.5</td>
<td>27%</td>
</tr>
<tr>
<td>Heart&lt;sup&gt;3&lt;/sup&gt;</td>
<td>6.0</td>
<td>39%</td>
</tr>
<tr>
<td>Lung&lt;sup&gt;4&lt;/sup&gt;</td>
<td>3.5</td>
<td>39%</td>
</tr>
</tbody>
</table>

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

Cost estimation
The 30-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>i</i> in scenario <i>s</i> for country <i>c</i> (in euros)

\( HE_c \) = Health expenditure per capita for country <i>c</i> (source: OECD Health Data)

\( O_{isc} \) = Number of organs <i>i</i> in scenario <i>s</i> for country <i>c</i>

\( pcf_i \) = Per capita factor for organ transplant type <i>i</i>

\( N_i \) = 30-year discounted net costs per donor for organ transplant type <i>i</i>

\( HE_{UK} \) = Health expenditure per capita in United Kingdom

Error! Reference source not found. shows the discounted net costs (UK-wide) for each type of transplant from a 50 per cent increase in donation rates.
Table B.5: Thirty-year discounted net costs for each type of organ transplant

<table>
<thead>
<tr>
<th>Cost component by organ type</th>
<th>30-year discounted net costs (UK-wide) from 50% increase in donation rate (£)</th>
<th>Donors: baseline</th>
<th>Donors: 50% increase</th>
<th>Difference</th>
<th>30-year discounted net costs per donor (N) (£)</th>
<th>Per capita factor (pcf)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney(^1)</td>
<td>-73,952,000</td>
<td>1,914</td>
<td>2,576</td>
<td>662</td>
<td>-111,710</td>
<td>-66.30</td>
</tr>
<tr>
<td>Liver(^2)</td>
<td>23,816,000</td>
<td>610</td>
<td>911</td>
<td>301</td>
<td>79,123</td>
<td>46.96</td>
</tr>
<tr>
<td>Heart(^3)</td>
<td>7,694,000</td>
<td>764</td>
<td>1,147</td>
<td>383</td>
<td>20,089</td>
<td>11.92</td>
</tr>
<tr>
<td>Lung(^3)</td>
<td>8,044,000</td>
<td>116</td>
<td>174</td>
<td>58</td>
<td>138,690</td>
<td>82.31</td>
</tr>
</tbody>
</table>

SOURCES: 1) Matas et al. (1996); 2) Saab et al. (2007); 3) Petrucci et al. (2007)
Appendix C: Scenario Results

This appendix contains some of the detailed results of the scenario calculations. It provides an overview of how QALY gains (Figures C.1 to C.4) and the savings on treatment costs (Figures C.5 to C.8) are distributed between different Member States.
Figure C 1: Estimated quality adjusted life years gained over 30 years by additional kidney transplantations.
Estimated Quality Adjusted Life Years (QALYs) Gained from Additional Liver Transplants

Figure C 2: Estimated quality adjusted life years gained over 30 years by additional liver transplantations
Figure C.3: Estimated quality adjusted life years gained over 30 years by additional heart transplantations
Figure C.4: Estimated quality adjusted life years gained over 30 years by additional lung transplantations
Figure C.5: Estimated 30-year discounted savings from additional kidney transplants
Figure C.6: Estimated 30-year discounted costs from additional liver transplants
Figure C.7: Estimated 30-year discounted costs from additional heart transplants
Estimated 30-year Discounted Costs from Additional Lung Transplants (x 1,000 EUR)

Member State
EU-average
U.K.
Germany
Italy
France
Greece
Austria
Spain
Belgium
Poland
Portugal
Netherlands
Ireland
Sweden
Denmark
Hungary
Czech.R.
Finland
Romania
Slovak.R.
Luxembourg
Slovenia
Bulgaria
Lithuania
Cyprus
Estonia

Figure C.8: Estimated 30-year discounted cost from additional lung transplants