COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 8.12.2008
SEC(2008) 2956

COMMISSION STAFF WORKING DOCUMENT

accompanying the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on standards of quality and safety of human organs intended for transplantation

and the

COMMUNICATION FROM THE COMMISSION

Action plan on Organ Donation and Transplantation (2009-20015): Strengthened Cooperation between Member States

Impact Assessment

{COM(2008) 818 final}
{COM(2008) 819 final}
{SEC(2008) 2957}

INTRODUCTION

Lead DG: Health and Consumer Directorate-General

Other services involved: BEPA (prime responsibility for application of Capability Approach), as well as DG RESEARCH, DG INFSO, DG JLS, LS and SG.

Agenda Planning and CLWP: the legislative proposal was foreseen by the Commission Agenda Planning for 2008, with reference 2008/SANCO/018.

1. EXECUTIVE SUMMARY

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. An analysis of donation and transplantation variation across the European Member States 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 just identify one organ donor per million population. Similar differences can be seen in living donation rates: Norway has a very high rate of living donation, of 17 pmp. Thus, if good practices (organisational changes and improvements) were to become standard there is a large potential for increasing organ donation (deceased and living) in Europe.

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, 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 on human organ in place in Europe. Article 152 of the Treaty 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 and setting out the key objectives for the European Commission by identifying areas for

future European action. To address these challenges, DG SANCO identified four policy options, which differ predominantly in their regulatory approach:

Under **Option 1**, the European Commission will continue with its current activities in the field of organ donation and transplantation, which involves primarily 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 will establish a European Action Plan on Organ Donation and Transplantation for the period from 2009 to 2015.

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.

Finally, **Option 4** combines the Action Plan described under Option 2 with a "stringent" directive. This stringent directive will be modelled on the Tissue and Cells Directive and will therefore contain detailed regulation about the quality and safety systems Member States have to put in place.

To assess these policy options a combination of methods and approaches were used:

(1) The starting point for the analysis of impacts was an **extensive document and literature review.**

(2) **Country studies** of the organ donation and transplantation systems in a sample of six countries. The countries studied are Germany, Greece, Spain, Poland, Sweden and the United Kingdom.

(3) **Stakeholder interviews** with ten stakeholders, including national country experts as well as stakeholders concerned with organ donation in general.

(4) To develop an idea of the scope of potential improvements that can be achieved, four scenarios of different changes in living and deceased donation rates were developed, which were subsequently used to identify likely health and economic impacts of the policy proposals.

(5) A cost consequence framework and an impact matrix were used to analyse the evidence, identify the key impacts and compare them across the four policy options.

(6) In addition to normal 3-pillar analysis of options, this IA was also used as a case study for application of the **capability approach**. This analysis presented in the annex and in 3 boxes throughout the IA was prepared

under the auspices and initiative of BEPA, the Bureau of European Policy Advisers.

Box 1: The capabilities approach

The capabilities approach, first formulated by Nobel Prize laureate Amartya Sen, focuses on the well-being of individuals. It provides a complete description of individual wellbeing. According to Sen, a person's well-being is a combination of achievements and opportunities. Both are important. For example, someone who has ample job opportunities but chooses not to work has a different level of well-being than someone who is involuntarily unemployed.

To make the capabilities approach operational, a pragmatic multi-dimensional space of nine dimensions has been defined. The list is a consolidated version of different lists that have been proposed in the literature, e.g. by Martha Nussbaum. The aim of the list is that it is a complete and non-negotiable list applicable to all policies. The list consists of: 1) health and longevity; 2) safety; 3) education; 4) standard of living; 5) productive and valued activities; 6) quality of social interactions; 7) environment; 8) culture and entertainment; 9) basic rights. For many policy proposals of course only a subset of these capabilities is relevant.

In the IA on organ donation the policy proposals have three objectives: enhancing efficiency, quality and safety and the number of successful transplants. Most of the impacts of the policy proposals run through these three objectives. The CA converts impacts into final objectives, i.e. how the chosen proposals influence peoples' well-being, e.g. in the form of health. For this IA, well-being is measured by the capabilities: (i) health; (ii) safety (feelings of safety); (iii) quality of social interactions; (iv) productive and valued activities (employment); (v) standard of living.

The different proposals are analysed by measuring impact on each capability. A specific light is shed on distributional impacts, since the individual well-being approach enables easy structuring (impact on different groups on the various capabilities). For convenience, we have separated impacts on relevant categories from total monetary costs, without specifying to which capability these costs belong. This allows for an easier communication on benefits and costs.

The key health impacts of DG SANCO proposals emanate from an increase in donation rates and reduced risks to patients. The policy options are likely to increase donation rates in Europe. A best case scenario 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.

The analysis of the policy options suggest that Options 2 to 4 can 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. The economic benefits arise primarily from saved treatment costs as transplanted kidneys replace dialysis treatment. The scenarios developed see a potential of saving up to €1.2 billion Euro in treatment costs, and reaching productivity gains of up to €2.4 billion.

Increased organ transplantation will result in positive social impacts for organ recipients and donor families. In general, organ transplantation has a positive effect on the quality of life of organ recipients. Evidence shows that transplantation of organs increases the possibilities for patients to participate in social and working life. 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 relatives of deceased donors.

Option 3 was considered to be the best option in reconciling the policy objectives with the principle of subsidiarity and proportionality at this stage. Firstly, a flexible Directive plus an 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 delivery mechanisms. Secondly, this combination 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. ORGANISATION AND TIMING

The Commission adopted a Communication on organ donation and transplantation in May 2007[1] accompanied with a first impact assessment[2]. Three priority areas of action were identified : 1) improving quality and safety of organs, 2) increasing organ availability and 3) making transplantation systems more efficient and accessible. In order to respond to these objectives the Communication suggested two different mechanisms of action[3]:

▪ An Action plan for strengthened coordination between Members States on organ donation and transplantation

▪ An EU legal framework (Directive) on quality and safety of human organs.

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1 http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_com_en.pdf

2 http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

3 This combination of actions was foreseen by the Commission Agenda Planning for 2008, with reference 2008/SANCO/018.

On 6 December 2007, the Health Council adopted conclusions[4] in line with the Commission's Communication and invited the Commission to continue its examination of the need for an EU framework on quality and safety and to coordinate, promote and strengthen the cooperation between the Member States. Following the Commission Communication, on 22 April 2008 the European Parliament adopted a resolution on organ donation and transplantation[5]. The resolution was adopted by huge majority. It welcomes the approach taken in the Commission's Communication, and clearly acknowledges the need for action at European level.

DG SANCO set up an Impact Assessment Inter-service Steering Group (ISSG) in September 2007 in the light of the Commission Communication, which supported the work linked to the present impact assessment report. The Group was led by the Directorate General for Health and Consumer Protection (DG SANCO). The following DGs were involved in the exercise: BEPA, DG RTD, DG ENTR, DG INFSO, DG RELEX, DG AIDCO, DG JLS, SJ and S-G.

This draft impact assessment report has been submitted to the Impact assessment on 18 June. The IAB recommended a number of changes in the report. Following the opinion of the Impact Assessment Board on the draft impact assessment report on improving Organ Donation and Transplantation in the European Union, the following modifications have been introduced in the text:

1- Reformulated the problem definition and give a clear outline of expected developments under the baseline scenario.

1) The problem definition has been strengthened in section 2.

2) Tables I and II have been added in the annexes I and II specifying the baseline scenario and the policy options for the main policy objectives. Information on the specific arrangements and their expected evolution has beed added on the tables

3) Drivers of organ availability have been better explained in section 2.1.3. Differentiating organisational aspects from other aspects and clarifying the role of consent systems.

4) The Spanish model is exhaustive explained in Annex III, including the ideal conditions for its implementation.

5) Living donation is addressed separately in all the sections of the document.

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4 ttp://ec.europa.eu/health/ph_threats/human_substance/documents/organs_council15332_en.pdf

5 http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2008-0130+0+DOC+XML+V0//EN

6) A section on ethical issues has been incorporated.

2- Provide more solid arguments for the choice of the preferred option and the differences between Option 3 and 4.

The Impact assessment board gave a favourable opinion on 3 September.

2.1. Consultation and expertise

In order to give stakeholders and Member States the occasion to put forward their positions related to organ donation and transplantation DG SANCO launched an open consultation from June to September 2006[6]. The Commission received 73 contributions from regulators, the medical community and patient or donors associations.[7].[8]

As part of the stakeholder dialogue DG SANCO has created a key stakeholder group on organ donation and transplantation, grouping 16 European associations of professionals, hospitals, patients, donors, organ exchange organisations and industry, all active in the area of organ transplantation.

This group first met on 19 February 2008[9]. The consultation yielded important information on the problem definition and assessment of the policy options. Stakeholders' views were incorporated into the definition of the policy options.

Complementary to the work of the stakeholders group, a one-day open workshop with stakeholders was organised on 23 May 2008. The purpose of the workshop was to discuss the effects of the different policy options in the field of organ donation and transplantation at the EU.

In addition, the Commission also held more than 20 face-to-face meetings with key actors during the last six months.

Since November 2007[10], the Commission has held **four meetings with national experts of all MS** and representatives of Eurotransplant and Scandiatransplant focusing on technical discussions on quality and safety requirements of human organ donation and transplantation and key priority areas for the proposed action plan.

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6 http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/consultation_paper.pdf

7 A full report of the consultation is published in the public health web site

8 http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/oc_organs_frep_en.pdf

9 http://ec.europa.eu/health/ph_threats/human_substance/documents/ev_20080219_mi_en.pdf

10 (13 July, 23 October, 20 November and 31 January)

3. PROBLEM DEFINITION

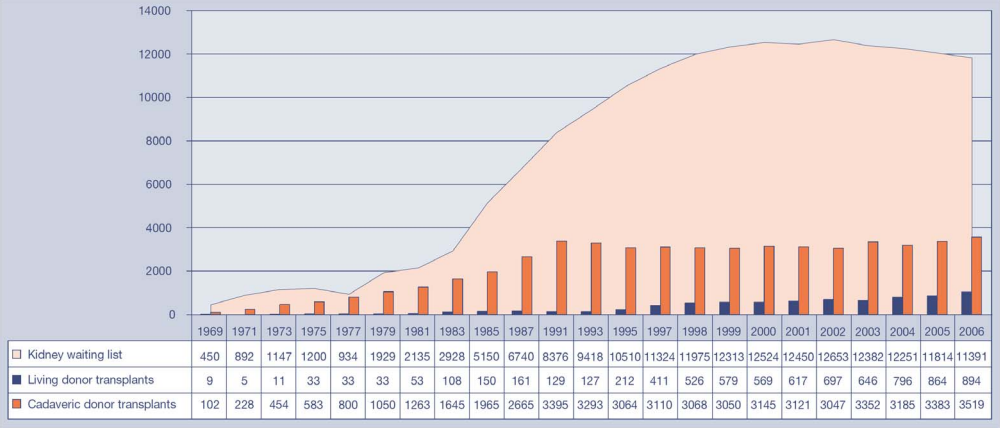
The Commission presented a comprehensive description of the situation on organ donation and transplantation in Europe in the impact assessment attached[11] to the Commission Communication adopted in May 2007.

Due to rapid advances in transplantation medicine, the use of human organs for transplantation has steadily increased during the past decades. Organ donation has a very high potential of saving lives and increasing the quality of life for patients. This potential can only be realised, however, when a sufficient number of organs is available for transplantation, when there are adequate quality and safety measures in place to reduce the risks of diseases being transmitted, and when processes are organised efficiently and are accessible to all who are in need.

3.1. Organ availability

3.1.1. Demand for organs is increasing

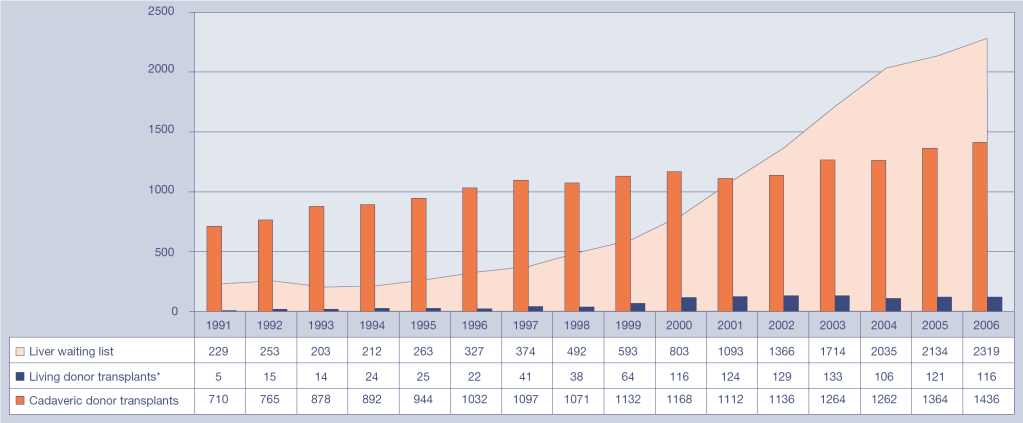
Currently, demand for organs exceeds their availability in all Member States and demand increases faster than organ donation rates in most Member States.[12] (See figure 1 below)



	1969	1971	1973	1975	1977	1979	1981	1983	1985	1987	1991	1993	1995	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Kidney waiting list	450	892	1147	1200	934	1929	2135	2928	5150	6740	8376	9418	10510	11324	11975	12313	12524	12450	12653	12382	12251	11814	11391
Living donor transplants	9	5	11	33	33	33	53	108	150	161	129	127	212	411	526	579	569	617	697	646	796	864	894
Cadaveric donor transplants	102	228	454	583	800	1050	1263	1645	1965	2665	3395	3293	3064	3110	3068	3050	3145	3121	3047	3352	3185	3383	3519

11 http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

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



	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Liver waiting list	229	253	203	212	263	327	374	492	593	803	1093	1366	1714	2035	2134	2319
Living donor transplants*	5	15	14	24	25	22	41	38	64	116	124	129	133	106	121	116
Cadaveric donor transplants	710	765	878	892	944	1032	1097	1071	1132	1168	1112	1136	1264	1262	1364	1436

SOURCE: Eurotransplant (2006)

Dynamics of Eurotransplant kidney and liver waiting lists and transplantations between 1969 and 2006

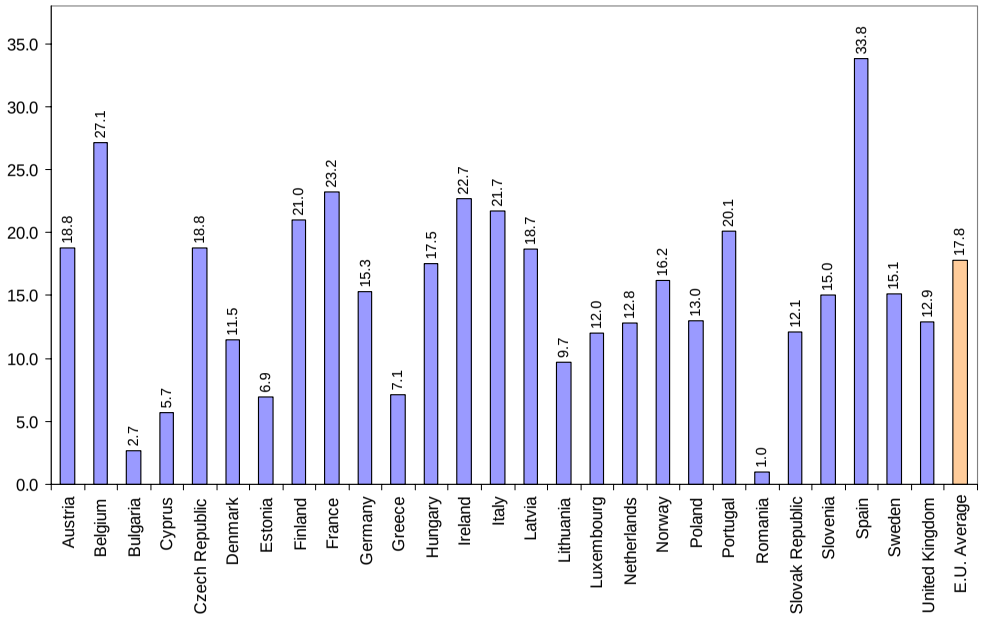
In total, there are currently more than 56,203 patients waiting for a suitable donor organ (as of 31 December 2006) within the European Union.[13]. In 2006, more than 5,500 patients died while on the waiting list in the European Union.

3.1.2. Donation rates and organ availability varies across Europe

While there is an increasing demand for organs, the availability of organs varies widely between the Member States. The next Figure 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.

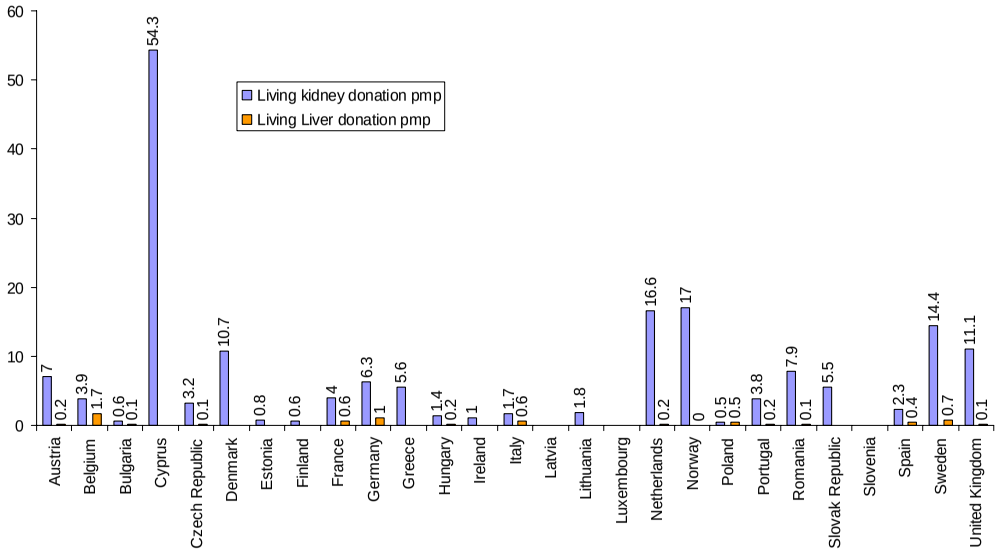
European donation rate is far below from the US donation rate (16.6 versus 26.6 in 2007) and has decreased continuously in the last three years (2005-2006 and 2007). Donation rates and transplantation activity varies widely between the Member States, only Spain and few others Member States have succeeded in increasing significantly the number of donors. These increases are linked to the introduction of organisational practices

13 Council of Europe (2007).



SOURCE: Council of Europe (2007) Deceased organ donors in the European Union

Living donation rates also differ substantially between Member States, and not all countries realise their potential for living donation. Interestingly it seems to be substituting the availability of organs from deceased donors. Figure 03 of Annex I provides an overview of living donations. In 2006, a total of 2,855 transplantations from a living donor (kidney and liver) were conducted.[14]



14 Ibid.

SOURCE: Council of Europe (2007)

Living kidney and living liver transplantations performed in 2006

3.1.3. Drivers of organ availability

The availability of organs is naturally limited by the supply of suitable donors, which are often victims of road accidents and strokes. Only around 3% of all hospital deaths are potential donors.[15] The conversion of this potential in turn depends on the willingness of patients and their families to donate and the participation of hospitals in organ retrieval activities.

While public debate often centres on public awareness for 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 factor influencing organ procurement rates.[16] In this section we analyse the main drivers of organ donation:

1. Consent systems. Extensive debate focusing on whatever a present consent law could an increase donation rate has not produced clear results. Detailed information on the organisation of consent systems are given in our previous IA., as mentioned in that paper basically two kinds of consent can be distinguished: systems of explicit consent (opting in) and systems of presumed consent (opting out). In the former the donor himself has to authorise organ removal after his death (in the form of an advanced directive or donor card or by filling in a form in order to record consent in a national register). In the latter kind of system, explicit consent is not required: it is sufficient that the deceased donor has not objected during his life (according to national law); in that case consent is presumed. It has to be noted that the dichotomy between pure opting in and opting out systems represent an oversimplification that fails to recognise the nuances with which these systems function in practice.

The "Alliance O" project (funded by RTD under the 6FWP) grouped the main European transplant organisations and aimed to identify the best possible framework for efficient organ donation and transplantation patterns across Europe. Alliance O concluded that "The choice between the legal concept of presumed consent and informed consent is amongst others based on historical, social and cultural reasons. The detailed analysis revealed within the ALLIANCE-O working group that the two concepts do not differ in day to day practice and that the family or next of kin must be in favour of donation in order to proceed with the donation process. A change of the legal framework therefore would not be a guarantee for an increase in donation rates."

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15 ALLIANCE-O (2007b).

16 DeJong, et al. (1995).

2. Organisation The importance of the organisational systems is also underlined in the conclusions of the project Alliance-O. In its "White book"[17] the project provides a list of recommendations to increase the donor pool; these recommendations are focused on organisational aspects. Improvements in the complex process of donor identification to the transplantation of an organ can have a large impact on donation rates.[18] Reviews of the organisational models for organ donation in Europe show a strong potential for the exchange of best practice and learning between Members States on these issues.[19].

Even among EU countries with well-developed services, there are considerable differences in organ donation and transplantation activity and it seems that some organisational models are performing better than others. In some countries the transplantation activity exceeds 80 transplanted organs pmp, compared to others with a rate of 40 pmp, and these differences are not necessarily explained by the donation rates

A prerequisite for any action in this area is the establishment of adequate transplant systems at national level. This system needs an appropriate legal framework, a good technical approach and organisational support. The role of competent authorities is crucial in the organisational system. These authorities must ensure compliance with basic standards and organise the donation and transplantation activities.

3. Willingness to donate and family refusals. Organ donation and transplantation are the only medical treatments that require the participation of society for their full development. One of the main reasons of the shortage of organs is the family refusals to donation. The willingness to donate and the family refusals also vary widely within Europe. They could be explained by important cultural, economic or social factors that influence the perception of the society of the benefit of donation and the trust in the transplant systems. .Public awareness and opinion also has an important role to play in increasing organ donation.

The willingness to donate in the different Member States do not correlate with the actual donation rates, this could indicate that some countries are more successful transforming this positive attitude of the society into actual donors.

4. New alternatives for expanding the donor pool. Three main alternatives have been pointed out to increase the donor pool. 1) The promotion of living donation, 2) considering other potential donors ("expanded donors") who are not ideal donor candidates and 3) the implementation non heart beating donation programmes. All of these alternatives have ethical and safety that need to be

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17 http://www.alliance-o.org/wfile/Alliance-O_White_Paper.pdf

18 See e.g. Roels, et al. (2002). and Simini (2000).

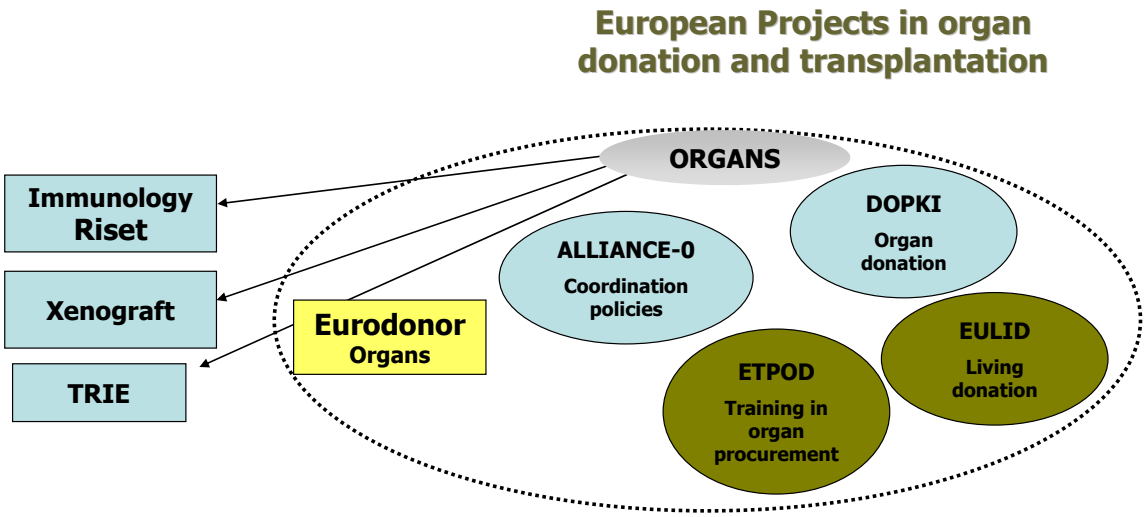
19 DOPKI (2006);ALLIANCE-O (2007c).

addressed. Cooperation at EU level is necessary to establish safety limits in the practices.

3.1.4. 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. Exchange of best practice would in particular benefit those Member States, which are just starting national transplantation programmes and do not have national experiences yet.

During the past years, the Commission has put considerable effort into supporting organ transplantation through the different community programmes. The results of all these projects are providing a considerable amount of information useful for active policies in this area, however these projects have a limited time frame with the risk that once the project is finished the continuity of the results is not ensured. In addition the projects not always have the capacity to transfer the results of their investigation to the political level in order to make them operative. It is also important that the results of these projects are accessible to all the Community.



The Council of Europe, which groups together 46 countries, including 21 countries from Central and Eastern Europe, has been actively involved in this area. The Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation (SP-CTO) was set up following the 3rd Conference of European Health Ministers in Paris in 1987 on the ethical, organisational and legislative aspects of organ transplantation, recently it has been transferred into the Scope of the EDQM.

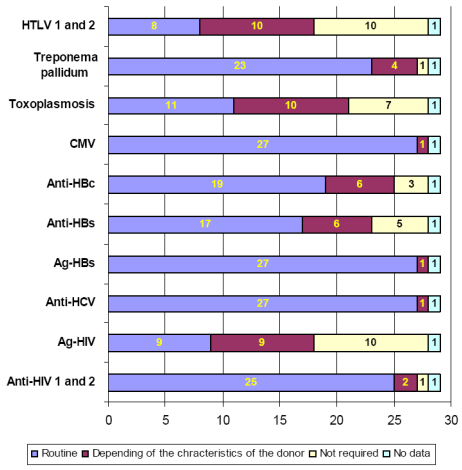
Although recognising the work of the Council of Europe and the World Health Organisation in this area, there is not currently a effective framework to strengthen the cooperation between MS in the EU. The EU meetings of Competent authorities on blood and tissues and cells have been a very useful instrument during the last years to implement and complement policies in these fields.

3.2. Quality and Safety in organ transplantation

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.

3.2.1. Reducing risks to patients

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, 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.[20] 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 donation process. Currently quality and safety standards differ widely across Member States.[21] (See Figure)



Biological tests performed

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20 For a detailed description of the risks and prevalence of graft related diseases see Annex B.

21 DG SANCO (2003).

Once transplantation has been successfully performed, it is important to monitor the organ recipient and to record all adverse events and possible infections acquired through an organ and to be able to trace the organ back to a donor. This is of particular importance as multiple organs are retrieved from a single donor, and most organ donors are also tissue and cell donors.[22] 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 made it mandatory in legislation.

3.2.2. 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 which would allow for such tracing in urgent cross-boarder 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 which is foreseen by the European tissue and cell directive.[23] Currently such a system does not exist.

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

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22 For a detailed description of the process, see Annex XX (copy eduardo's description of the process)

23 Directive 2004/23/EC of the European Parliament and of the Council setting high standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. OJ L 102, 7.4.2004, p.48-58

3.3. Enhancing the efficiency and accessibility of transplantation systems

3.3.1. Cross border exchange of organs

The exchange of organs between Member States is already common practice between Member States. There are however large differences between the number of organs exchanged across borders between Member States which set up bodies and rules for the international exchange of organs such as Eurotransplant and Scandiatransplant and the other Member States.

Participants of the Eurotransplant area exchange around 20% of all organs transplanted each year (around 3,300 organs), while only 2% of organs leave or enter the Eurotransplant area. Within the Scandiatransplant area, between 10 % (Kidney) and 27% (Heart) of organs were exchanged between members. Without such comprehensive exchange agreements Member States exchange far fewer organs, but the rate can increase if there are bilateral agreements in place.[24] .

The differences in exchange rates indicate that the full potential of exchanging organs has not yet been reached. This is problematic as the cross border exchange of organs has clear benefits. Given the need of 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 that need an infrequent match will have very low possibilities of receiving an organ, while at the same time donors are not considered because there is not a compatible recipient in the waiting lists. This holds particularly true for difficult to treat patients (paediatric, urgent or hyper-sensitised patients that require very specific matching) and small Member States[25]. Data from Eurotransplant shows that in these cases, small Member States receive the organs from another Member State in the majority of the cases.[26] Those small Member States not participating in these agreements can thus not cope adequately with these patients. Hence, small Member States and difficult to treat patients are both key stakeholders with a 'specific need' for cross border exchanges and for adequate measures to ensure equal benefit of this activity.

3.3.2. Patient and donor mobility

The mobility of potential organ donors and recipients is the second major challenge for the current quality and safety frameworks, after organ shortage. In

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

[25] Data from Eurotransplant shows that in these cases, small Member States receive the organs from another Member State in the majority of the cases.

[26] Eurotransplant (2008).

a recent pilot survey[27], it is clear that a large proportion of dialysed patients cross state borders in Europe for both holiday-making and for work (Figure), and the same could be expected for transplanted patients.

Table 3.1: Patients who travel to other European countries receiving haemodialysis in other centres

	Germany	Ireland	Latvia	Netherlands	Sweden	U.K.
Yes	44.8%	18.7%	1.3%	45.2%	20.6%	35.5%
No	55.2%	81.3%	98.7%	54.8%	79.4%	64.5%

SOURCE: CEAPIR (2006)

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. Even 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 State which allow for the reporting of an event and which can be linked to trigger the necessary actions required to ensure the health and safety of other organ, tissue and cell recipients.

People might become organ donors while residing in another Member State. In 2007, close to 10 % of the donors in Spain were foreigners, more than 50% of these were Europeans. 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 donation system so that they do not refuse donation.

3.3.3. Living donation

Currently, living organ donation represents 17% of kidney transplant activity in Europe.[28] The number of living donors differs significantly from country to country: from 2 transplants from living donors pmp in Spain to 20.7 in Norway. Living organ donation is currently allowed in every European country, but sometimes is only permitted under certain conditions. In Austria there are deductive legal provisions but no law directly regulating living donation.(Annex IV table 05) provides an overview of the current (legal) frameworks across a sample of Member States.

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27 CEAPIR (2006).

28 COM (2007) 275 Final. Organ Donation and Transplantation: Policy Actions at EU level. 30.05.2007

Living donation poses a third set of challenges to the current regulation in European 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 significant morbidity risk,[29][30] the living donor requires continuous follow up after surgery and access to healthcare and to 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.

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

3.4. Ethical issues

There are many complex and sensitive ethical issues in this area that have could have repercussion on the availability, and it became clear that several of these aspects are dealt differently in Member States. It is generally accepted that the donation should be voluntary and altruistic with legal and ethical contexts clearly defined, the data from donors and recipients should be protected, provided that traceability is ensured, except in the case of a living donor with a close relationship to the recipient.

Most of the Member States that responded to the Commission survey2 have legislation to protect the donor in respect of anonymity (measures ensuring that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa); confidentiality (measures ensuring that all data collated, including genetic information, have been rendered anonymous so that the donor and the recipient are no longer identifiable) and non remuneration for the donation (measures preventing organ trade or trafficking).

There is a general agreement that cadaveric organ retrieval is only allowed if some form of consent is available from the deceased or his relatives. This is also reflected in international guidelines; according to the additional protocol to the Convention of Biomedicine of the Council of Europe concerning Transplantation of Organs and Tissues of Human Origin10. Member States should ensure that there is a legal basis for ensuring valid consent or objection to organ donation. The results of the Commission survey showed that in 28

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[29] 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).).

[30] Living kidney donation also entails a small mortality risk of 0.03%, the morbidity risk for living liver donation is substantial higher.

countries the consent for a donation from the deceased donor is embedded in a binding law. Only in one is it organised through guidelines.

Basically two kinds of consent can be distinguished: systems of explicit consent (opting in) and systems of presumed consent (opting out). It has to be noted that the dichotomy between pure opting in and opting out systems represent an oversimplification that fails to recognise the nuances with which these systems function in practice.

There are mainly four forms of consent found among the countries surveyed. In 8 of the countries consent required always the agreement of those close to the deceased. 7 countries have in place a present consent law, but the family agreement is requested if the wishes of the deceased are unknown, in other 7 countries there are present consent law but in practice the confirmation of the family is needed, and in the rest of the countries surveyed (7) the presumed consent law applies and no family confirmation is needed. An important operational aspect of consent systems (whether explicit or presumed) is the way the consent of objection is being recorded. A growing number of European countries have established national registers so that the information on the willingness to donate is readily available and easily accessible for health professionals confronted with potential donors in a hospital or elsewhere.

Regarding the consent of the living donor is also regulated by law in most of the countries2

Transparency, Equity and Accessibility – It is also generally accepted that all transplant systems rules (allocation, access to transplant services, activity data, etc.) should be made public and be properly controlled. Death certification - Organ retrieval from the deceased may take place only after death certification. Death certification should be a matter of national legally binding rules that should be made public.

Of the countries surveyed, 86% (25) have binding legislation in place establishing a definition of brain death, three more have technical guidelines with definitions. As to which criteria are needed in the different countries for diagnosing brain death, differences are in evidence as indicated in figure 5 (the bars indicate the number of countries):

The number of doctors that have to confirm brain death also varies between the countries. The situation is different regarding a binding definition of death in non-heart beating donors. Only 45% (13) of the countries have this definition in their legislation and five more in technical guidelines.

4. SUBSIDIARITY - THE CASE FOR EUROPEAN ACTION

4.1. The legal base to act

Article 152(4)(a) of the EC Treaty provides a legal basis for the adoption by the European Parliament and the Council of 'measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;".

The same Article says that *The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.*

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

4.2. Previous European activities in the field of organ donation and transplantation

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. While specifically referring 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[31], 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 fifty years[32] are the starting point for what now occurs in relation to safety and quality of substances of human origin in Europe.

In the resolution adopted in 1991 by the Council of Ministers for health[33] 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 the topics which warrant joint consideration, regular joint discussions and/or joint efforts to assist Member States in framing their health policies.

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31 Genetet (1998).

32

33 Resolution of the Council and the Ministers for health, OJ C304 23/11/1991 p5-6.

On the basis of Article 152 of the EC Treaty, as it results from the Treaty of Amsterdam since 1999, the Community has already adopted Directives of the Parliament and the Council on quality and safety standards for blood in 2003 and for Tissues and Cells in 2004.

However, it was already recognized during the discussions of the Tissues and Cells Directive that organs need a different approach. The Venice Conference on Safety and Quality in Organ Donation and Transplantation in the European Union was held on 17-18 September 2003 under the Italian presidency. The conclusions of the expert conference organised by the Italian government during its presidency of the EU Council, listed the shortage of organs as the main priorities in this area and stressed the importance of addressing the quality and safety aspects fully considering the current framework of supply and demand for organs.

4.3. Political momentum

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. Its aims at is to strengthening the cooperation between Member States introducing the basic principles and the technical requirements on donation, procurement, testing preservation, transport and distribution for 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, invited the Commission to continue its work under the proposed Action Plan and 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. The EP recognises that it is "vitally important to improve the quality and safety of organ donation and transplantation", looks forward to the Commission action plan for strengthened cooperation between MS and asks the Commission to establish an EU mechanism which would promote coordination activities between MS.

4.4. European action is required: necessity test

It might be helpful to briefly review the evidence presented this far. We have noted that organ transplantation has increased significantly during recent decades. We will also show that the cost-benefit analysis in favour of more organ transplantations is compelling. Yet donation rates and availability of organs varies considerably across Europe with achievable good practice

delivering far greater benefits in some Member States than others. More generally there are significant risks in using organs in therapy that can be effectively managed through the application of quality and safety procedures.. A well-regulated 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. Such a system should also improve the traceability and follow up of organ donation. Another important contextual factor is the shortage of organs, with more than 56,000 patients on waiting lists in Europe.

In the light of this evidence, arguments supporting EU action might be summarised as follows. Despite the advantages of intra-Community co-operation on organs donation and transplantation (analysed more in-depth under 'added-value' section), we know that so far the current arrangements have been sufficient to allow two voluntary agreements – Eurotransplant and Scandiatransplant – to emerge. The former group 6 Member States and 1 candidate country (Croatia), while the latter 3 Member States and 2 EEA countries (Norway and Iceland). However, even within these groups the average exchange rates remain relatively low (i.e. for kidneys between partner countries in the Eurotransplant region it is 19.7%) Outside of these two organisations (18 MSs), cross-border movement of organs is negligible. As transplantation poses a risk of transmitting disease to recipients, the conditions essential for increasing intra-Community co-operation require European consensus about the quality and safety standards. When organs cross borders, there is a trans-national need to ensure traceability and report adverse reactions.

In addition, 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. Moreover, coordination between donor data sets would allow for a more efficient allocation of organs (especially helpful for smaller Member States and for urgent and difficult to treat patients). Differences between national approaches may slow down medical treatment through (medically) unnecessary delays. As more people move across borders information will need to move with them to optimise donation and transplantation while maintaining citizens' confidence in the system in the country they are visiting. Lastly, EU involvement can partially mitigate 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.

4.5. The added value of European action: Why would European action be better than national action?

The 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.

The EU added-value factors justify EU action but also might helpfully be considered when assessing how to optimise the EU's contribution. The list includes:

EU facilitation of consensus building allowing quicker implementation

- Economies of scale:
    - Lower transition costs in establishing the new Quality and Safety system and reduced running costs
- Greater fairness and contribution to solidarity
- Enhanced donor and recipient confidence stemming from more legal clarity

Considering these factors, some important issues arise. First, despite the growing consensus around 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 may also fail to gain the sort of commitment and understanding at the local hospital level which is a pre-requisite for a successful Quality and Safety system. EU proven experience in consensus building can provide a flexible solution that 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.

Furthermore, a degree of compulsion caused by action at EU level 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.

4.6. Subsidiarity: Some conclusions

An EU measure in the area of organ transplantation and donation 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

- The European Community action is likely to contribute to public value by providing a platform for implementation and mutual learning which combines standardisation of reporting with diversity of service.

4.7. Proportionality analysis

The subsidiarity analysis makes a strong case for EU action in the field of organ donation and transplantation. This analysis will also be referred to in the subsequent 'Analysis of Impacts' where the principle of proportionality is applied. Application of this principle requires that the proposed policy measures leave as much scope for national decision as possible, and respect well established national arrangements and legal systems. Hence, even despite strong legitimacy of EU action, the costs and benefits of various available options will be considered so that the most efficient and effective instrument is chosen.

5. THE POLICY OBJECTIVES

5.1. Objective Tree

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 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. The following figure illustrates the three main policy objectives of the Commission.

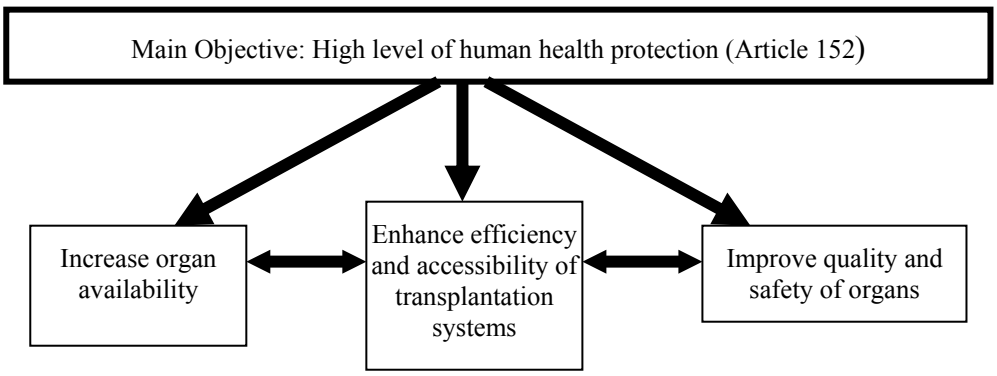


Diagram of the three Main Policy Objectives

5.2. Increasing organ availability

The Commission seeks to support Member States in increasing the number of donors as actions to fulfill this objective are expected to help reduce the gap between supply and demand and may even achieve an absolute reduction in the waiting list.

This policy objective has two dimensions. First, Member States should reach the full potential of deceased donations and secondly, Member States should increase living donation to complement donation from deceased donors.

5.3. 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 donation rates, the number of organ transplantations performed and post-transplant results.

Even among EU countries having well-developed health and organ transplant services, there are still 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 organized and efficient transplant systems for optimal health outcomes (i.e. the main objective) and cost savings.

5.4. 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 maximize the safety and efficacy of the use of human organs in the health system, which includes reducing the likely risk of adverse medical events related to the transplantation pathway, as well as ensuring adequate handlings of all steps on the 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.

6. THE POLICY OPTIONS

6.1. Introduction

To achieve the above objectives a two-step approach based on four different policy options is proposed. The policy options proposed promote **policy actions** in five broad areas of **policy intervention** (creation of national institutions, improving processes, reducing risks to patients, living donation and cross border aspects). These can be distinguished by their regulatory approach which ranges from voluntary cooperation to a stringent Directive

6.2. Areas of intervention

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 an important element 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 for the creation of a register of establishments. In addition, proposals include regular national reporting obligations and improved cooperation between competent authorities.

Improving Processes

Of equal importance to an adequate organisation of an organ donation and transplantation systems is to ensure the quality of processes performed by the various organisations in the field. The initiatives propose the introduction of quality programmes to ensure continuous monitoring of performance and improvement and learning. This also includes specific standards for the procurement and transport of human organs.

The proposed policy options aim to promote the role of a transplant coordinator and to encourage training of the personnel involved in the process. Knowledge about organ donation and communication skills among health care professionals as well as patient support groups are an additional target for action.

Reducing risks to patients and improving quality of transplantation

Organ transplantation is a potentially life saving treatment, which nevertheless involves substantial risks to the patients. The proposed policy option encompasses the establishment of a common set of criteria to assess the risks for organ recipients. In addition, the proposals include measures to capture serious adverse events and reactions. Systems to ensure that organs can be traced back to the original donor are vital to quickly notify other organ recipients in case a dangerous infection has been discovered. Finally, the proposals contain

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

Living Donation

As an alternative to organs from deceases donors living donation has not reached its full potential yet. 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;

Cross border aspects of organ donation

Measures are proposed to address shortcomings in the exchange of organs between Member States, problems resulting from the mobility of donors across borders and also 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 transplantation and donation process a process to better share information is proposed about available organs between Member States.

It would be difficult to define an "optimal" rate of cross border exchange, this rate could varies according with different criteria, the size of the donor pool, the type of organ to be transplanted , the type of recipient. What is clearly identified is that cross border exchanges are needed to increase the quality of the match between door and recipient and to treat specific patients such hyposensitise patients, paediatric or urgent patients where a sizeable donor pool is required. But also to ensure that all organs are utilise regardless there is or not a specific recipient in an specific waiting list of a Member States. This is obviously crucial for small Member States with small donor pools.

Therefore the objective is not "a specific rate of exchange" but to put in place the conditions that favours the exchange of organs when needed along the EU.

6.3. The policy options

All four options are presented in detail below. Having in mind subsequent analysis of impacts, this chapter aims at demonstrating how each of the options attempts to fulfil the objectives. The graphs below and Annexes I and II explain it in detail. Option 2, due to the nature of the instrument proposed, furthers all three objectives, however focuses mainly on the first two. Options 3 and 4, again thanks to adding an instrument binding in nature, open more possibilities to further quality and safety objective, which eventually also assists in meeting the first two objectives.

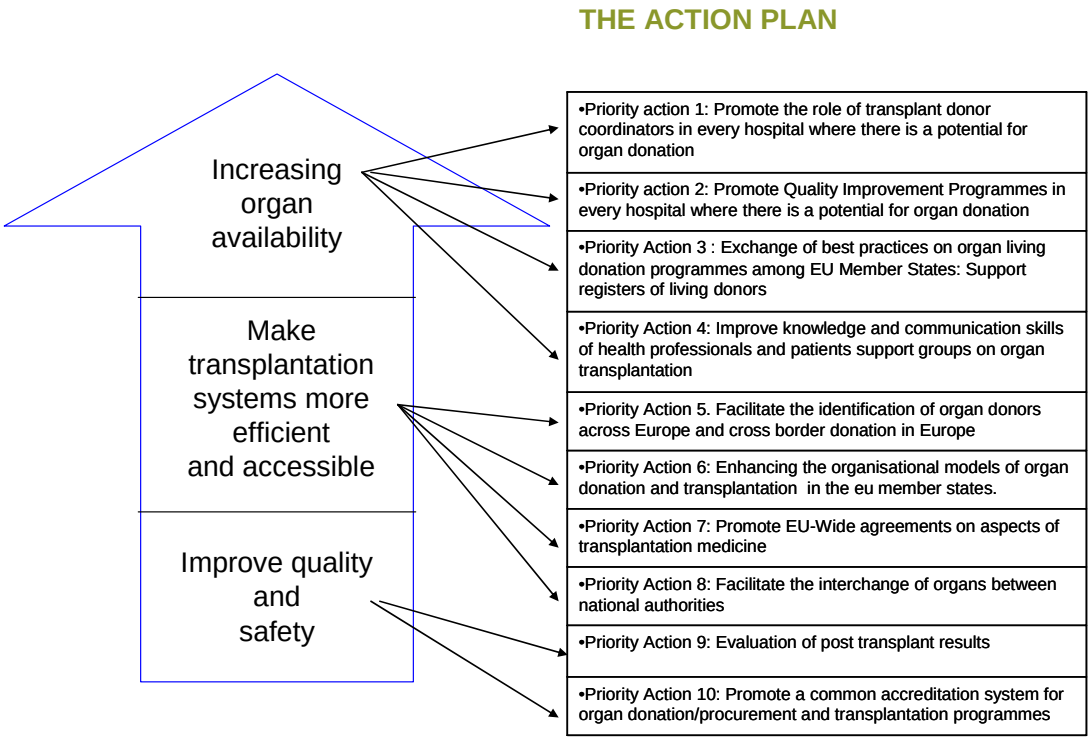
Option 1: Continuing Status quo

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 on section 2.1.4 provides an overview over the different European projects currently supported by the European Union), detailed information on the projects could be found in Annex I and II.

Option 2: Action plan

This option proposes a non-regulatory approach establishing a European Action Plan on Organ Donation and Transplantation for the period from 2009 to 2015which sets out a cooperative approach of European and Member State 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 Commission having gathered the information, knowledge and expertise generated in the field of organ donation and transplantation, has identifying a detailed list of priority actions.The 10 priority actions proposed by the European Action Plan are listed below::



The action plan will promote a number of initiatives aimed to improve organisational systems in order to increase organ donation that have been proved effective in some Member States, will help Member States to evaluate the performance of their transplant systems and exchange best practices to improve them, will facilitate the cross border donation in Europe and promote to set up the necessary structures to facilitate the organ exchanges for better care of patients in Europe. It also incorporates mechanisms to promote the quality and safety of the systems by evaluating the results in order to lead to a safer and more effective use of organ donors and will set up the basis of a voluntary accreditation system.

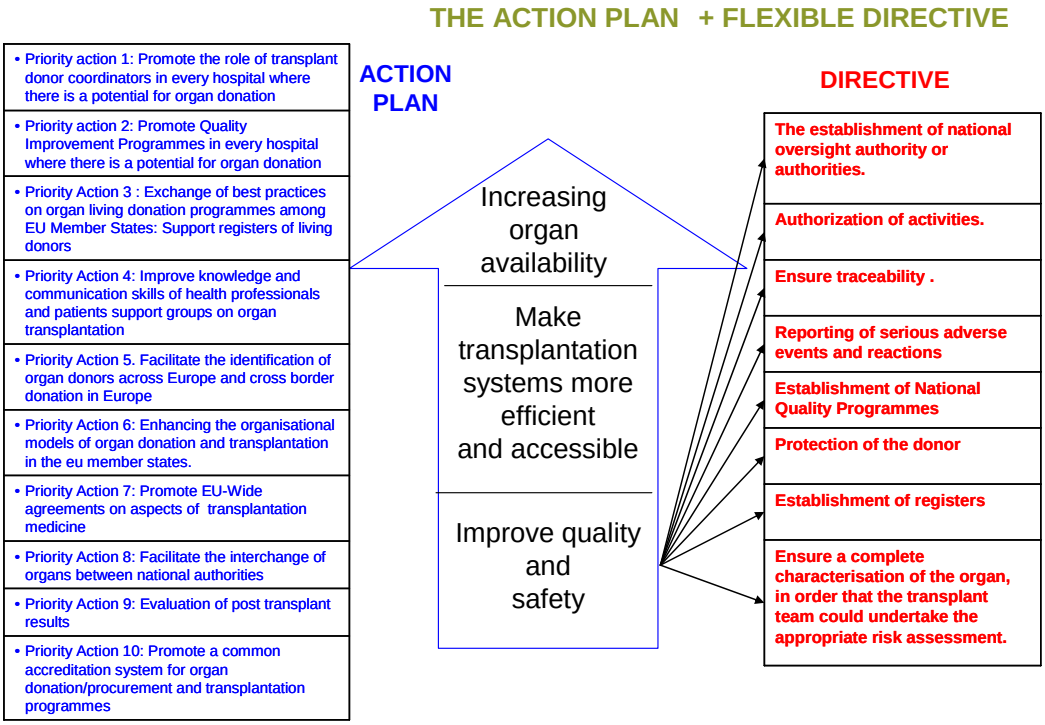
Option 3: Action plan + "flexible directive"

Option three combines the Action Plan already described with a "flexible" directive. The regulatory approach of this directive will be very much a framework approach, ensuring that national legislation is put in place to deal with key aspects of organ donation and transplantation but without prescribing detailed policy measures.

The Directive will ensure that the quality and safety structures are in place. These will facilitate the conditions for cross border exchanges and ensure a basic level of quality and safety for patients.

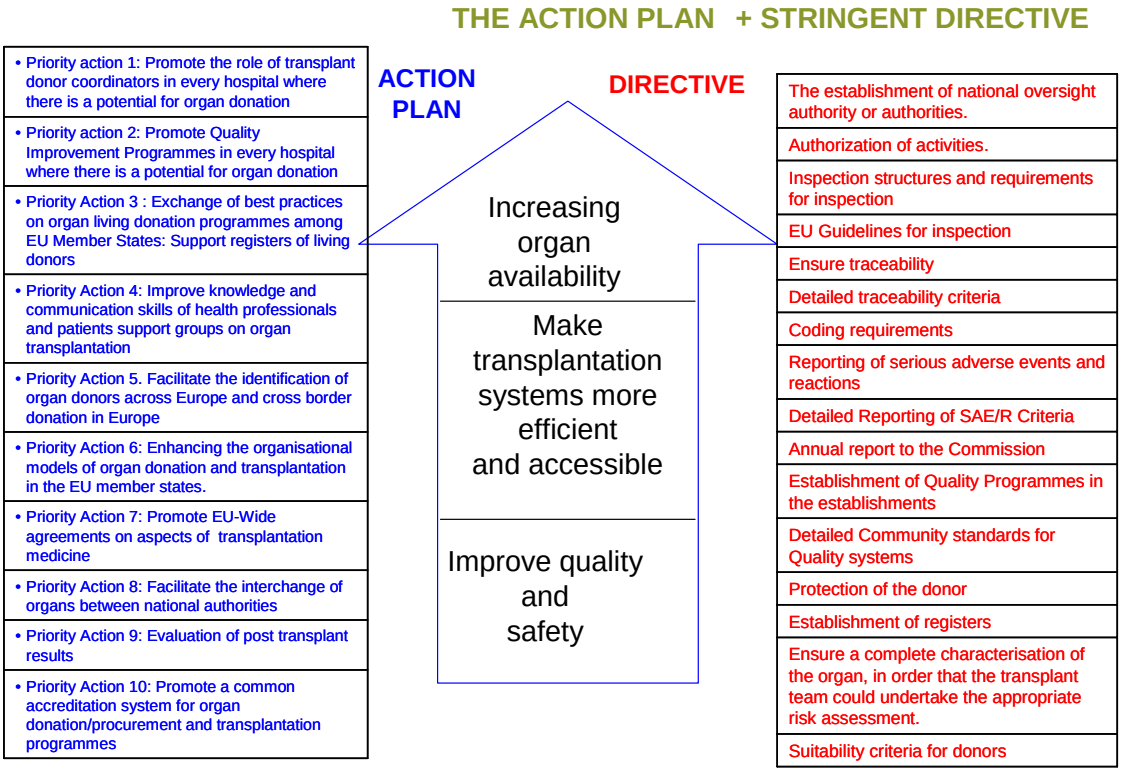
The proposed framework approach in the Directive will deal with the key aspects of organ donation: establishing of competent authorities, authorisation of the conditions of procurements and basic standards for procurement, traceability of the organ, reporting of serious adverse events and reactions, basic protection of the donor and organ characterisation (collection of the relevant information on the characteristics of the organ and the donor needed to undertake an adequate risk assessment in order to minimise the risks for the recipient and to optimise the allocation of the organ.).This option will leave enough flexibility to Member States to adapt the existing systems where in place and reducing to the maximum red tape and administrative burden.

In addition the Directive will complement the action plan (Annex I). The action plan establishes key priority actions promoting objectives depending on MS cooperation, coordination and voluntary level of commitment. The Directive, given its binding nature, will support and trigger the implementation of key priority actions of the Action Plan. For example the Directive will support the first priority of the action plan (promote the role transplant donor coordinators), by requiring adequately qualification for the personnel and adequate training. These interactions are detailed in Annex II



Option 4: Action plan + "stringent directive"

Option 4 will combine the action plan described under Option 2 with a stringent directive. This stringent directive will be modelled after the Tissue and Cells Directive and will therefore contain detailed regulation about the quality and safety systems Member States have to put in place, leaving little national discretion in transposing the directive. The more detailed prescriptions of Option 4 are detailed below



Option 4 provides for a stricter regulatory approach. This option will include a more complex accreditation process for procurement sites, including regular inspections which entail the need to put in place a specific inspection structure. It requires also a detailed quality system in place in every donation site. The Directive will laid down exclusion criteria for donors following the same approach that in the blood and tissues and cells Directives

In order to further clarify the details of each option, in addition to above graphs, please find in the Annexes a detailed description and comparative tables of the different policy options on the quality and safety elements (Annex I) and element related to organ availability and making the system more efficient and accessible (Annex II).

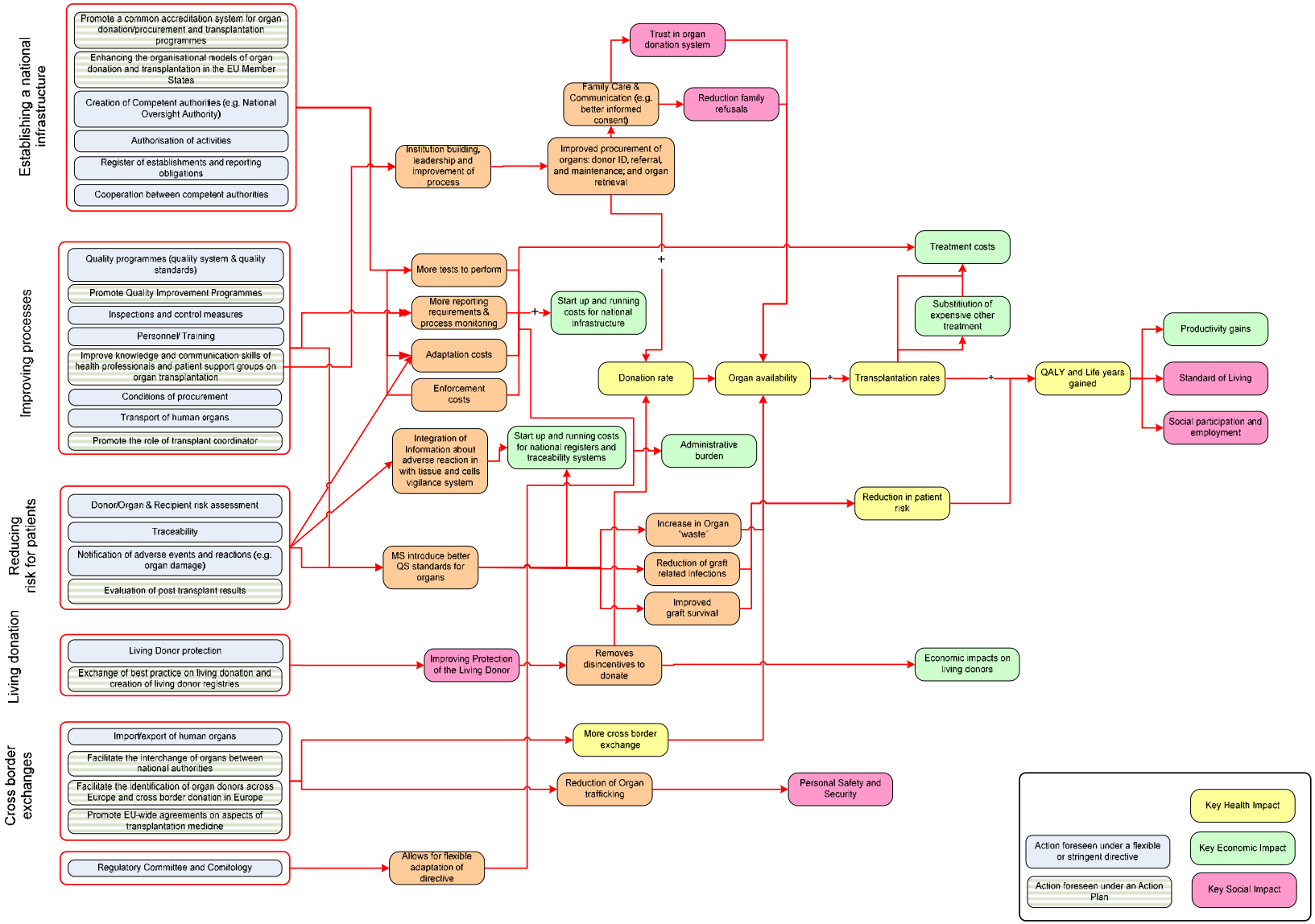
7. ASSESSMENT OF IMPACTS

7.1. Introduction

A model of the policy intervention

The policy options proposed include a variety of policy interventions with the ultimate objectives of increasing the availability of organs, making the transplantation systems more efficient and accessible as well as improving the

quality and safety of organs. The following figure 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.


Establishing a national infrastructure
Promote a common accreditation system for organ donation/procurement and transplantation programmes
Enhancing the organisational models of organ donation and transplantation in the EU Member States
Creation of Competent authorities (e.g. National Oversight Authority)
Authorisation of activities
Register of establishments and reporting obligations
Cooperation between competent authorities
Improving processes
Quality programmes (quality system & quality standards)
Promote Quality Improvement Programmes
Inspections and control measures
Personnel Training
Improve knowledge and communication skills of health professionals and patient support groups on organ transplantation
Conditions of procurement
Transport of human organs
Promote the role of transplant coordinator
Reducing risk for patients
Donor/Organ & Recipient risk assessment
Traceability
Notification of adverse events and reactions (e.g. organ damage)
Evaluation of post transplant results
Living donation
Living Donor protection
Exchange of best practice on living donation and creation of living donor registries
Cross border exchanges
Import/export of human organs
Facilitate the interchange of organs between national authorities
Facilitate the identification of organ donors across Europe and cross border donation in Europe
Promote EU-wide agreements on aspects of transplantation medicine
Regulatory Committee and Comitology
Institution building, leadership and improvement of process
Allows for flexible adaptation of directive
Trust in organ donation system
Family Care & Communication (e.g. better informed consent)
Reduction family refusals
Improved procurement of organs: donor ID, referral, and maintenance; and organ retrieval
More tests to perform
More reporting requirements & process monitoring
Adaptation costs
Enforcement costs
Start up and running costs for national infrastructure
Integration of Information about adverse reaction in with tissue and cells vigilance system
Start up and running costs for national registers and traceability systems
MS introduce better QS standards for organs
Improving Protection of the Living Donor
Removes disincentives to donate
More cross border exchange
Reduction of Organ trafficking
Personal Safety and Security
Treatment costs
Substitution of expensive other treatment
Donation rate
Organ availability
Transplantation rates
Administrative burden
Increase in Organ "waste"
Reduction of graft related infections
Improved graft survival
Reduction in patient risk
Economic impacts on living donors
QALY and Life years gained
Productivity gains
Standard of Living
Social participation and employment
Key Health Impact
Key Economic Impact
Key Social Impact
Action foreseen under a flexible or stringent directive
Action foreseen under an Action Plan

7.2. Assessment criteria

The four Policy options have been assessed by considering:

- Health impacts, including gains in QALYs and life years, avoiding risks for patients and donors and health benefits of cross border exchanges.

- Social impacts, including impacts on the quality of life, on the possibility of transplant patients for social participation and employment and finally on the trust and confidence of donors and their families in European donation and transplantation systems.

- Economic effects, distinguished into two categories. First, economic impacts that directly emerge from the implementation of the proposed policy measures. These include start-up and running costs for a national infrastructure, costs of running national registries and traceability systems as well as reporting obligations and administrative burden. Secondly, economic impacts arising if these policies achieve the key objectives of increasing donation and transplantation rates.

The following sections analyse in general way each of the assessment criteria and explain their parameters. Additional background information to this section could be found at Annex V and VI. These parameters are then used to assess and compare the four policy options, which are presented Chapter 7 ('Comparison of Options'), and in more detail in Annex VII.

7.3. Health Impacts

7.3.1. Donation and transplantation rates

Increasing donation and transplantation rates have a clear and significant health impact for organ recipients. Several studies of the Spanish model, and a recent study in Greece, indicate the positive impact of improving processes in the increase of donation and transplantation rates. These results are mainly a consequence from investing in the more developed 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. Similar priorities are outlined in the Commission proposed initiatives.

7.3.2. QALYs and Life years

Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%.[34] The average predicted lifetime survival rates for patients undergoing dialysis treatment is 10 years, while it is 20 years for kidney

[34] Miranda and Matesanz (1998).

transplantation patients. The average number of kidney transplants per year is about 1,000 with a 93% survival rate in one year following kidney transplantation. The **5-year survival rate is 77% in Poland**. The positive health impact of organ transplantation can also be measured by the QALY gained[35]. For example, liver transplantation has the highest QALY gain (11.5); heart has 6.8 QALY gain and lung has 5.2 QALY gain (Tables).

Comparison of predicted survival rates for dialysed patients and for kidney transplant patients in Poland

Age group	Predicted survival times for dialysed patients	Predicted survival times for kidney transplant patients
20-39	14 years	31 years
40-59	11 years	22 years
60-74	6 years	10 years

SOURCE: Narodowy Program Rozwoju Medycyny Transplantacyjnej na lata 2006-2009, Polgraft, available from <http://www.poltransplant.pl/Download/polgraft.pdf>, accessed 25FEB08.

Health Impact Data on Survival Rates for Organ Transplants from the Polish Traceability System for years 2005-6

			3 months survival rates		12 months survival rates	
Organ	Number of transplantations in 2005-2006	Number of patients under observation	Organ recipients (%)	Transplanted organs	Organ recipients (%)	Transplanted organs
Kidney from cadaveric donors	1939	1107	1107 (97%)	1020 (92%)	1043 (94%)	972 (88%)
Kidneys	47	29	29	29 (100%)	29	29 (100%)

[35] The most complete information obtained from our countries studies on the general health impact of organ donation and transplantation comes from the UK Transplant Supplement Report

from living donors			(100%)		(100%)	
Liver from cadaveric donors	379	223	199 (89%)	192 (86%)	195 (87%)	185 (83%)
Liver from living donor	33	16	15 (94%)	15 (94%)	15 (94%)	15 (94%)
Pancreas and kidney (survival of both organs)	58	27	23 (85%)	19 (70%)	20 (74%)	16 (59%)
Heart	190	105	78 (74%)	78 (74%)	77 (73%)	77 (73%)
Lung	9	3	0 (0%)	0 (0%)	0 (0%)	0 (0%)
SOURCE: Poltransplant, Biuletyn Informacyjny, nr. 1 (15), 2007, available at <http://www.poltransplant.org.pl/biuletyn_2007.html>, accessed 06FEB08						

Comparison of the QUALY gain (and cost effectiveness) of liver, heart, lung transplants; Source Department of Health 2008

	DHCIB	Ouwens[36]	
	ICER ($)	QALY gain	ICER ($)
Liver	25,600	11.5	31,000
Heart	36,900	6.8	46,000
Lung	61,000	5.2	61,000

Compared to dialysis, the benefits of different treatments strategies for Type 1 Diabetes with End Stage Renal Failure range from 2.01 to 5.77 additional QALYs. (table)

[36] Ouwens, et al. (2003).

Benefits Derived From Different Treatment Strategies in the UK for Type 1 Diabetes With End Stage Renal Failure

	Life Expectancy (LY)	Δ LY	QALY	Δ QALY
Dialysis	7.82	-	4.52	-
Cadaveric Kidney Transplant	11.4	3.62	6.53	2.01
Simultaneous Pancreas-kidney Transplant	15.74	7.92	9.09	4.57
Pancreas after Kidney Transplant	17.21	9.39	10.00	5.48
Living Kidney Transplant	18.30	10.48	10.29	5.77

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

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.[37] (Background info in Annex VI points 5-7)

7.3.3. Risks to patients

Transmission of communicable diseases and malignant diseases

As discussed in the problem definition, the use of organs in therapy poses potential risks of communicable diseases being transmitted to the recipient (Viral, bacterial, and fungal infections). Several types of protozoan and worm parasites have also been transferred via organ transplants. Since organs cannot be subjected to sterilization steps, the risk of infectious disease transmission is higher. A complete revision of the main risks is provided in the Annex VI.

[37] Mendeloff, et al. (2004).

In addition, the transmission of malignant diseases, i.e. cancer, is also a risk of organ transplantation.[38] Annex VI provides an overview of the relevant findings. These risks can be minimised through appropriate measures.

Adverse events and patients safety

Apart from the risks of transmission of disease, organ transplantation is a high-risk surgical procedure that also requires long-term exposure to strong medication such as immunosuppressive drugs; this means that organ transplant patients constitute a patient group at great risk of suffering a patient safety incident. [39]

It has been shown[40] that over half of all adverse events are considered to be preventable. Between 6.7 and 15 million hospital discharges are associated with an adverse event.[41] More specific to the organ transplantation process, a study in the US found that 19% of kidneys procured are damaged from the extraction procedure. Organ damage was found to be associated with team expertise whereby multi-organ transplant teams had a reduced rate of kidney damage than a kidney transplant team.[42]

It has been demonstrated that Quality Assurance Systems in organ donation and transplantation reduce missed information on organ abnormalities or organ damage from the procurement operation.

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38 Consensus Document Criteria for Preventing the Transmission of Neoplastic Diseases in Organ Donation. Organizacion Nacional de Transplantes Spain http://www.ont.es/Consenso?id_nodo=263&&accion=0&keyword=&auditoria=F

39 The first major risk is surgery. Of all general surgery in-patients, 39% suffer one or more adverse event: 1% of these were fatal, 7% were life-threatening, and 63% were of moderate severity. More specifically, a French national survey found the highest density of adverse events was observed in cardiothoracic surgery (e.g. heart and lung transplantation), gynaecology and urology (e.g. kidney transplantation). Invasive procedures formed the main exposure situation for adverse events occurring during hospitalisation: in particular, peri-operative care was related to 42% of adverse events whereas adverse drug events represented 20%. The second major risk is adverse drug events which have been found to be associated also with almost a doubling in the risk of death, making them one of the most dangerous types of adverse events. The third major risk to patients is process-related blood transfusion adverse events. While less attention has been paid to improving the safety of the transfusion chain within hospitals (Sini et al 2008), it is known that the risk of an error occurring during transfusion of a blood component is estimated at 1 in 16,500, an ABO incompatible transfusion at 1 in 100,000, and the risk as a result of an "incorrect blood component transfused" is around 1 in 1.5 million (RCOP 2005)

40 internationally and in European Member States

41 Conklin, et al. ((forthcoming)).

42 Wigmore, et al. (1999).

7.3.4. Living donation

For many years, living donation has become a real alternative to improve the organ availability offering some advantages compared to that from deceased donor. The survival rates of non-related living donation are the same as in parental donation and higher than in deceased donation The use of organs from living donors has positive repercussions on waiting list mobility; however, it is important to assure that 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.

It has been proven that, in most cases of living donation the remaining kidney functions of a living kidney donor remain stable during long term follow up. However, safety for the donor is crucial. Research shows that the risk of death exists and is very small (0.03%). The risk of any complication ranges from 2% to 16%, depending on how complications are defined and the type of organs (complications are more frequent in living liver donation). Major complications occur at a rate of about 2% - 6%.[43]

To cover risks, living donors need to be adequately protected and it must be ensured that living donors receive the treatment they require. The scenarios designed show the potential increase of the number of living donors.

Institutional context of living donation in a sample of European countries

Organisation	Country	Regulated by Law (In parliamentary Transplantation act)	Consent Informed required	for Allowed Minors/persons lacking legal capacity	Principle of Subsidiarity	Requirement for Donor-recipient- Relationship	Approval by ethical committee	Approval by court	Altruistic/No remuneration	trafficking Organ penalized
./.	Austria	No; only position paper	Yes	No		No	No	No	Yes	Yes
BTS	Belgium	Yes	Yes	No		No	Not mandatory	No	Yes	Yes
MZSS	Croatia	Yes	Yes	No		No	Yes		Yes	Yes
KST	Czech Republic	Yes	Yes	Yes		Yes	Yes	No	Yes	Yes

[43] http://www.livingdonorsonline.org/

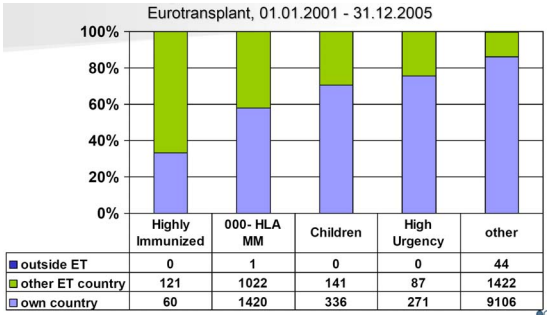
ABM	France	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes
DSO	Germany	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Hu-T	Hungary	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes
CNT	Italy	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
./.	Luxembourg	Yes	Yes	No		Yes	No	No	Yes	Yes
NTS	Netherlands	Yes	Yes	No		No	No	No	Yes	Yes
Poltransplant	Poland	Yes	Yes	No	No	Yes		Only in case of non relatives	Yes	Yes
OPT	Portugal	Yes	Yes	No	Yes	Yes	Yes	No	Yes	yes
Slovenia - Transplant	Slovenia	Yes	Yes	Yes,with obligations		Yes	Yes	Yes	Yes	Yes
ONT	Spain		Yes	No	Yes	No	Yes	Yes	Yes	Yes
Swiss transplant	Switzerland	from 2007	Yes	Yes, with some obligations		No	Yes	Yes	Yes	Yes
UK - Transplant	United Kingdom	Yes	Yes	Yes, rare	No	No	Yes	Yes	Yes	Yes

SOURCE: DOPKI (2006)

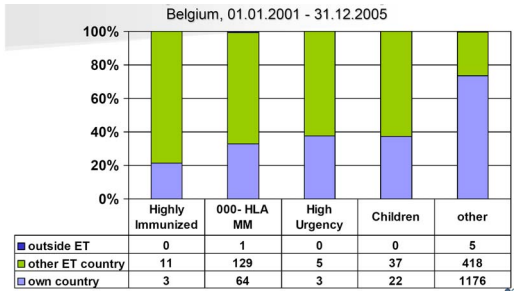
7.3.5. Health benefits of cross border exchange

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 the Figure below shows that for these groups of patients, international exchange is very important. Across the Eurotransplant area, two thirds of kidneys for highly immunized patients come from another Member States. In a small country like Belgium, this percentage is even higher, at around 79% of all kidneys for highly immunized patients.

Kidney exchange for special patient groups in Eurotransplant and Belgium



	Highly Immunized	000- HLA MM	Children	High Urgency	other
outside ET	0	1	0	0	44
other ET country	121	1022	141	87	1422
own country	60	1420	336	271	9106



	Highly Immunized	000- HLA MM	High Urgency	Children	other
outside ET	0	1	0	0	5
other ET country	11	129	5	37	418
own country	3	64	3	22	1176

SOURCE: Eurotransplant

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But also the cross border exchange is important to improve the matching of the organ with the recipient, this has obviously very positive effects in the outcome. Eurotransplat has succeeded in achieving 21.6 % of kidney transplants with 0 mismatches (complete matching).

In Italy, organisational improvements showed that that there is a potential for exchanging more organs across national borders. The creation of the Italian Gate to Europe (IGE)[44] resulted in an increase in the exchange of organs between Italy, Greece and Slovakia, while at the same time having no detriment to the probability of Italian citizens being transplanted as a result of these international agreements.[45] The actions proposed would have similar impacts particularly for difficult-to-treat and paediatric patient groups.

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.

Cross border exchange of organs in the European Unions

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44 a single national coordinating centre for the exchange of organs and patients with the rest of Europe in 2005

45 Pretagostini, et al. (2007).

	Organs transplanted from abroad	Organs transplanted abroad
Greece (2006)	1	30
Italy[46] (2006)	26	2
Poland		8
Spain (2007)	34	6
Eurotransplant	(exchange of organs from deceased donors within ET area, as % of all deceased organs transplanted)	20% (≈ 3,300
Eurotransplant	(exchange of organs from deceased donors outside ET area, as % of all deceased organs transplanted))	2% (≈ 330
Scandiatransplant	Exchange of organs, 2007	Kidney 10%
		Liver 19%
		Heart 27%
		Lung 21%

7.4. Social Impacts

7.4.1. Quality of life

A recent review[47] concluded that the impact of heart, lung, kidney and liver transplantation on recipients' quality of life is strongly positive. The improvement in quality of life is significant and perceived early after surgery, with larger gains in the dimensions of Quality of Life most affected by physical health and more modest improvements in areas affected by psycho-social functioning (including also sexual function, pregnancy, schooling for paediatric patients, sports (both adults and children), and work. Studies showed a significant Hamilton depression variation among living donor kidney transplant recipients, with improvement in the gained score and reduction of depressive symptoms.[48] In addition, studies of adults who received a kidney transplant in

46 IGE (2007).

47 Ibid.

48 Virzi, et al. (2007).

childhood found that their activity level is similar to that of the general population's.[49]

From the living donor perspective, living donors experience a boost in self-esteem and a greater sense of well-being.

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 donation-related medical complications. Satisfaction of donation among live liver donors is evident in their experience of having their lives "changed for the better" as a result of the process[50] and more than 90% of living liver donors would donate again.

Another important element of quality of life are the social and in particular family networks. It was found that the majority of living donors reported no change or an improved relationship with their recipient (86 to 100%), spouse (82 to 98%), family members (83 - 100%) and non-recipient children (95 - 100%).

7.4.2. Employment and social participation

A systematic review of employment status (and social participation) after successful kidney transplantation was conducted by van der Mei et al. (2006). Among the seventeen studies selected out of 1443 identified references, the authors found that employment was the most used indicator of social participation with rates ranging from 18% to 82% after kidney transplant. Other studies are showed in the next table

Employment rates after transplantation

Organ	Employed after transplantation
Kidney transplant (Matas et al)[51]	47%
Kidney transplant (van der Mei, Krol et al. 2006).[52]	18% to 82%
Liver transplant (Saab, Wiese et al. 2007)[53]	27%

[49] Broyer, et al. (2004).
[50] Parolin, et al. (2004).
[51] Matas, et al. (1996).
[52] van der Mei, et al. (2006).
[53] Saab, et al. (2007).

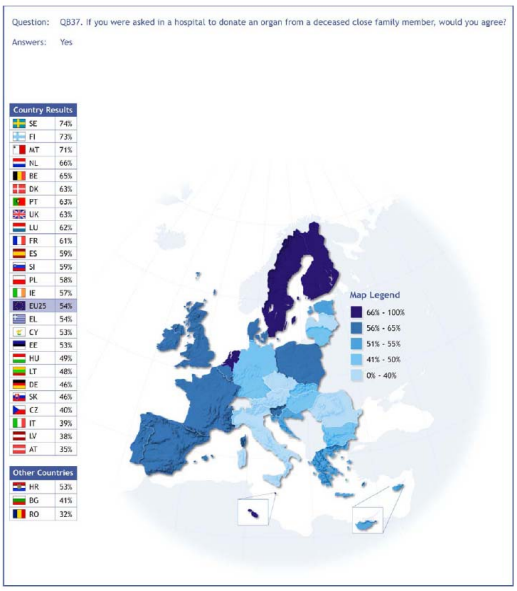
Heart transplant (Petrucci, et al. 2007).[54]	39%
Lung transplant (Petrucci, et al. 2007)	39%

7.4.3. Trust and confidence in organ donation and the transplantation system

Creating robust donation and transplantation systems, ensuring the quality and safety of 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.

Family refusals

Trust in the health care system and the organ donation system plays an important role in increasing the donation rate, and is of value in itself. A good indicator of this trust is the declared willingness to donate a family member's organ as well as the actual family refusal rates. A recent Eurobarometer survey[55] 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 the systems.



SOURCE Eurobarometer (2007)

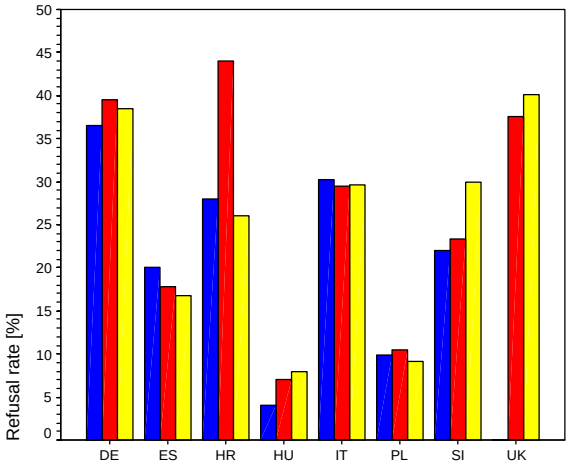
Figure **Error! No text of specified style in document.**.1: Estimated 30-year discounted savings from additional kidney transplants

54 Petrucci, et al. (2007).

55 Eurobarometer (2007).

There is some evidence, that the proposed policy measures might increase confidence and trust in the system and reduce family refusal rates. Data suggest that training programs for health professionals specifically dedicated to every step of the transplantation process has contributed to the approach of obtaining consent from donor families.[56]

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% of potential organ donors being rejected in 2006. By contrast, 40% of families in the UK refuse to give consent to organ donation, sometimes even when the potential donor was carrying a donor card giving their explicit consent.[57] Also in Greece, family refusal rates have been consistently above 40% during the last years: 46% (2005); 44% (2006) and 41% (2007).



Blue=2003; Red=2004; Yellow=2005

SOURCE: (DOPKI 2007);

Refusal rate across countries in Europe

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

[57] Department of Health (2008a);Department of Health (2008b).

7.5. Economic impacts

7.5.1. Start up and running costs for a national infrastructure and better processes

The different policy options 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.

Creating a competent authority

Most of the 29 European countries surveyed in a Commission survey[58] have an organisation (25) in charge of the organ transplantation/organ exchange.

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 or Sweden), interviews suggest, that there are suitable organisations in place which could take on this task.

The DOPKI project[59] has evaluated these organisational systems in many European Countries: All national organisations are in charge of the coordination of organ donation, as shown in the next Table. Only a very small percentage of countries that have installed a national organ procurement agency are not in charge at the same time for organs and tissues

ORGANISATIONAL RESPONSIBILITIES IN A SAMPLE OF MEMBER STATES

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[58] DG SANCO (2003).
[59] DOPKI (2006).

Field of Activity					
Organisation	**Country**	**Organs**	**Tissues**	**Cells**	**Others**
./.	Austria	./.	./.	./.	./.
BTS	Belgium	Yes	Yes	Yes (but not mentioned in the law 1986)	./.
MZSS	Croatia	Yes	Yes	./.	./.
KST	Czech Republic	Yes	Yes	./.	./.
ABM	France	Yes	Yes	Yes	Assisted reproductive technologies; embryo research; genetic testing
DSO	Germany	Yes	New law pending	./.	./.
Hu-T	Hungary	Yes	./.	./.	./.
CNT	Italy	Yes	Yes	Yes	./.
Luxembourgtransplant	Luxembourg	Yes	Yes	Yes	./.
NTS	Netherlands	Yes	Yes	No	./.
Poltransplant	Poland	Yes	./.	Yes	./.
OPT	Portugal	Yes	Yes	Yes	./.
Slovenija-Transplant	Slovenia	Yes	Yes	Yes	./.
ONT	Spain	Yes	Yes	Yes	./.
Swisstransplant	Switzerland	Yes	./.	Islets	./.
UK - Transplant	United Kigdom	Yes	Yes	./.	./.
ET	Netherlands	Yes	./.	./.	./.

Source: DOPKI (2006)

While the evidence does not support the direct assessment of costs of establishing a national authority, the total operational budget of the Spanish national authority, ONT, for 2008 is **€4,207,000**, with €3 million a year (73.5%) distributed in grants and financial assistance to support hospitals for organ extraction and transplantation, support promotion and dissemination activities of regional transplant authorities, and support specific training, development and other projects.[60]

Authorisation of establishments

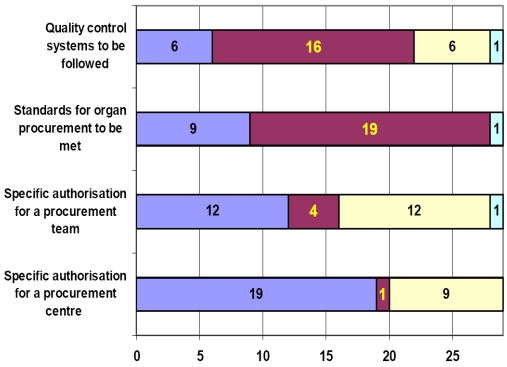
To ensure that transplant activities are only carried out in qualified transplantation and procurement centres, the initiatives propose measures to authorise the conditions of procurement and transplantation centres. Introducing such requirements would crucially depend on the decision of whether it is just designating particular hospitals, or whether hospitals would have to run through a whole licensing procedure. While the former can be expected to create only

[60] ONT, personal communication, 3rd April 2008

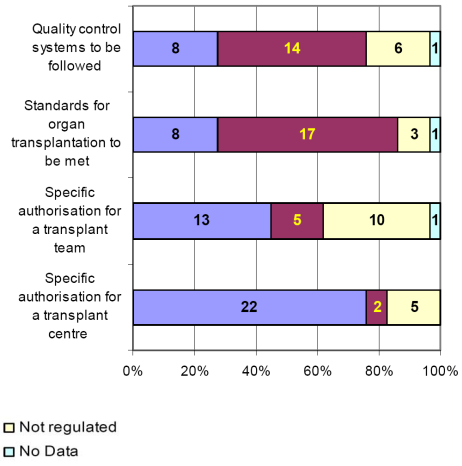
marginal costs, the latter might be more expensive. (Background info in Annex VI points 24-25)

Data collected in 2003 show Annex VI Figure 01, that procurement and transplantation standards in most, varies in the different Member States. Not all hospitals have to be specifically authorised to procure or transplant organs.

Procurement



Transplantation



SOURCE DG SANCO (2003)

Transplant coordinators

Recognising the important role transplant coordinators play in procuring organs, the proposals include the promotion of the role of the transplant coordinator in hospitals. Currently there are wide differences in Member States about the role and the availability of transplant coordinators. The economic impact of promoting the role of transplant coordinators would differ by country and approach (e.g. full-time vs. part- time, centrally vs. hospital employed coordinator, nurse vs. physician) and the current existing system.

In the United Kingdom the organ donation task force quantified its recommendations for improvement, which also includes strengthening the coordinators' network, to increase donation rates. They calculate additional annual costs of £ 13m for the set up of a system with 250-275 (i.e. increase by 150 to 175 staff) centrally employed transplant coordinators, of which the majority are pay costs (£ 11m).

Role and qualification of coordinators in selected European countries

Organisation	Country	In donor hospital	Linked to donor hospital	Outside hospital	Linked to tx-centres	Qualification	Number of coordinators

./.	Austria	planned	./.	./.	Yes		3-4 per region, 4 regions
BTS	Belgium	Local coordinator in some donor hospitals	No	No	Yes	Registered paramedics	Min 2 per tx center per law, currently
MZSS	Croatia	Yes	./.	./.			
KST	Czech Republic	./.	./.	./.	Yes	Physicians and nurses	
ABM	France	Yes	./.	./.	./.	Physicians and nurses	IR1 : 15 full time coordination and population 7,7 millions *IR2 : 38 pop 6,54 *IR3 : 36 pop 9,56 *IR9 : 41 pop 13,08 *IR6 : 35 pop 11,55 IR7 : 49 pop 13,35
DSO	Germany	./.	./.	Yes	./.	Physicians and nurses	50 (0,6 pmp)
Hu-T	Hungary	./.	./.	Yes		Registered nurses, mostly with specialisation in ICU or anaesthesiology	
CNT	Italy	Yes	Yes, (regional coordinators	./.	./.	physicians but nurses are of assistance	One regional coordinator for each region. Usually one/two local coordinators for each hospital.
luxembourg Transplant	Luxembourg	yes	./.	./.	Yes	physicians and nurses	Only one region- 2 part time coordinators
NTS	Netherlands	No	No	No	Yes	Physicians and nurses	4-6 per region; 3 regions á 6 Mio pop
Poltransplant	Poland	Yes some	Yes, (regional coordinators	Yes, (central coordinators	Yes, regional coordinators	Physicians (mostly anaesthesiologist) and nurses	37

OPT	Portugal	Yes	./.	./.		Physicians and nurses	5 regional chef coordinators
Slovenija-Transplant	Slovenia	Yes	./.	./.	Yes		2 central coordinators per 2 million population. are always 24 hours on call (there are 9 of them shifting) 9 hospital coordinators daily involved, backup are central coordinators
ONT	Spain	Yes	./.	Yes	Regional coordinator	Physicians and nurses	There are approximately 800 transplant coordinators in the country, within 155 hospitals authorised as centres for extraction[61]
UK - Transplant	United Kigdom	Yes	./.	./.	Yes	Coordinators are usually nurses	1.5 pmp

SOURCE: DOPKI (2006)

Setting up and running national quality programmes

The policy proposals contain the establishment of nation quality assurance programmes at national and/or hospital level. These programmes shall ensure that standards of good practice are followed throughout the donation and transplantation process. Comprehensive, specific quality systems for donation and transplantation, which include systematic audits and targeted training for staff to achieve continuous improvement, are not yet well developed. An overview of the different national quality programmes are provided in Annex VI tables 03

Little evidence is available on the costs of national quality programmes; however some information is available on 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, i.e. organ donation and procurement. Donor Action Programmes have proven to be highly effective in increasing donation rates, and there is some information available on the costs of Donor Action.

[61] Personal communication with ONT.

Whiting et al.[62] report average implementation costs for Donor action of around € 35,000 pmp (Ca$ 55,000) and maintenance costs of around € 45,000 pmp (Ca$ 70,000). For Europe, Donor Action[63] reports on cost of implementing Donor action in Belgium, where the donor action methodology had been applied to 62 hospitals at an annual cost of € 500,000 which is 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

7.5.2. Costs for setting up and running national registers and traceability systems

Potentially the most cost intensive element of the proposal is the requirement of establishing systems to trace organs from recipient to donor and vice versa, to systematically follow up the post transplant results and systems to report adverse events and reactions. These costs would depend on the existing systems in the countries and the final detailed policy proposals.

Register of establishments

The policy proposals include 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 (and information readily available. There are no cost estimates on the cost of national registers of all establishments, but it can be assumed that information about involved establishments is readily available to all Member States' competent authorities.

Donor registers

Many Member States currently collect data on the organ donors and store it in national, regional or transplant centre based information systems. Most countries have a registry of post mortem donors and recipient of organs from post mortem donation in place. Registers for living donation are however less well developed. Annex VI table 04 provides an overview of the existing registers. We can thus conclude that in most Member States, the basic information to trace organs from a donor to recipient and vice versa are already in place to some degree. Interview evidence shows in addition, that this information is also exchanged between Member States in case e.g. an infection has been discovered.

Outcome registers

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62 Whiting, et al. (2004)..

63 Personal communication Donor Action Leo Roels.

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. Unfortunately, there is no evidence available on the costs of these registries to follow up post transplant results, in particular as they are founded on the principle of voluntary participation. Data collection in many cases is done by individual doctors who do not get reimbursed for this activity.

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).

Contribution to European registries to follow up transplant results

	EURODONOR	ISHLT	CTS	ELTR	ETCO	IPTR	TPM
France (ABM)							
Germany (DSO)	Data delivered by transplant centres on voluntary basis						
Hungary (Hu-T)*					X		X
Italy (CNT)			**X**				
Portugal (OPT)				**X**	**X**	**X**	**X**
Spain (CENATMER)	X	**X**			X	X	
UK (UKT)	X	**X**	**X**	**X**			
Eurotransplant	Cooperation with all registries						

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

SOURCE: ALLIANCE-O (2007d)

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.. The proposed policy actions include a similar provision for human organs, which would require a traceability and a reporting system for serious adverse events.

In the five Member States studied in detail for this Impact Assessment, no systematic adverse event and reactions reporting system for organs are currently in place; evidence on the costs of such systems is thus rare.

Based on adverse event reporting systems for fresh gamete 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 between £ 425 and £ 990 per establishment are reported.[64] As reporting systems have a considerably element of fix costs for running and maintaining the computer system, these costs 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[65]. . For the 20 state reporting systems in place in 2002 annual funding ranged from $200,000 to $1,500,000 (with only 3 having more than 4 full-time staff members). The table 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.

Cost ranges for reporting program activities in Florida and New York, 2001

Function	In-house FTE[1]	Estimated costs for in-house or contractual work
Administration	0.5 - 0.75 FTE	
Systems design and maintenance[2]		$50,000 - $275,000

64 For a total of 101 regulated Unit at HEFA and 400 units for the SHOT system. Department of Health (2006).

65 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 #116}, Rosenthal and Barry {, 2001 #87}, Woolf et al {Woolf, 2003 #117}, and Runciman {, 2002 #118}

Investigation	5 - 6 (1 FTE per 100-200 investigations)	
Data analysis and validation		$200,000 - $675,000

SOURCE: Rosenthal et al. (2001). Notes: 1)FTE= full time employees ; 2) Assumes underlying system in place.

7.5.3. Reporting obligations and administrative burdens

A number of measures are proposed which require procurement as well as transplantation centres to submit information during the transplantation progress and to report on their activities. These obligations might be considered as administrative burden for hospitals[66]. For the proposed policy action the total administrative costs and in particular the additional administrative burdens, seem however to be small. [67] . This is due to a number of reasons:

- The affected 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 Europe, and procurement takes place in a selected sample of hospitals (e.g. only 45% of hospitals with ICUs in Germany = 613).

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

- As shown above, most Member States capture most of the information required already, so the costs for 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.

7.5.4. 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. Thus, these will only change if the policies are successful in achieving increased donation and transplantation rates. In assessing treatment costs, it is important to consider the net impact on treatment cost. In most cases a kidney transplant replaces dialysis treatment, and

66 European Commission (2005).

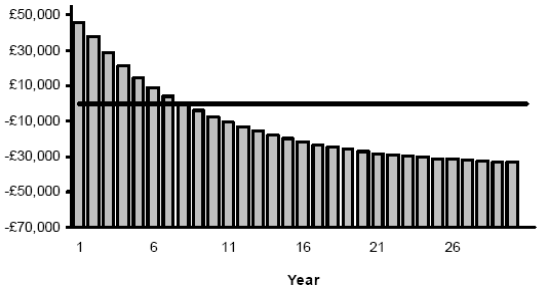
67 "A back of the envelope" calculation, which would assume 10 hours of total reporting time per transplantation at a specialist salary of around € 100,000 would result in total administrative burden of € 13 million for the whole EU 27.

although there is 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.

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.[68]

Next tables list some of the international findings on the cost effectiveness of kidney transplantation versus dialysis over the lifetime of a patient in a number of OECD countries. In all countries, transplantation is cost-effective as compared to dialysis treatment.

Cumulative cost effects and net savings from a 50% Increase in Organ Donation in a One Year Cohort of Patients Assessed Over 30 Years (discount rate of 3.5%)

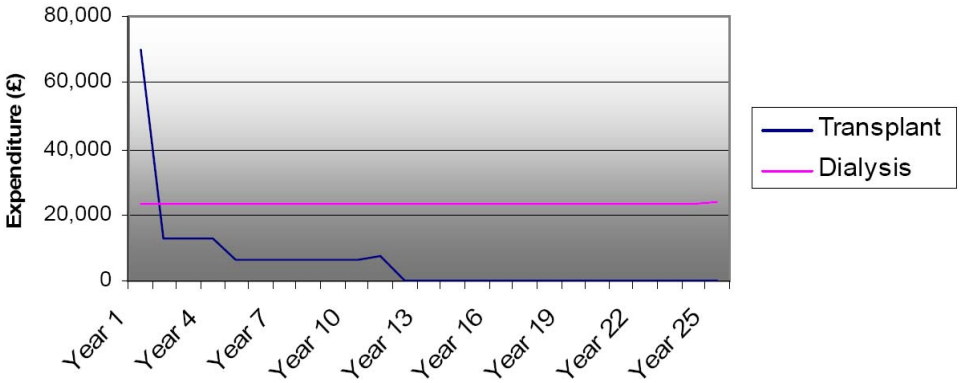


Cost component	Net cost, £000s	
	Undiscounted	Discounted
Kidney transplants	-£109,754	-£73,952
Liver transplants	£29,740	£23,816
Heart transplants	£8,909	£7,694
Lung transplants	£8,293	£8,044
Donation	£993	£993
All	-£61,819	-£33,405

SOURCE: Department of Health (2008b)

Figure 7.1: Cumulative cost effects and net savings from a 50% Increase in Organ Donation in a One Year Cohort of Patients Assessed Over 30 Years (discount rate of 3.5%)

[68] 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)

Cost profile of transplant versus dialysis in 2006 UK prices

Table 07. Lifetime costs of transplant versus dialysis in industrialised countries

Table 7

Country	Kidney Transplant Cost (£)	Dialysis Cost (£)	Difference (£)	Reference
US	260,106	430,498	170,391	Yen et al. (2004)
Canada	246,022	332,425	86,403	Whiting et al. (2004)
Germany	168,589	272,406	103,816	Roels et al. (2003)
Hungary*	86,036	133,646	47,609	Kalo et al. (2003)
Japan**	44,231	-		Nakajima et al. (2001)

Note: All costs are uplift and converted into 2005/6 prices in British Pounds.

* Denotes the first three years of transplant only.

** First two years post transplant

SOURCE: Department of Health (2008b)

Despite substantial costs, the study conducted by the Organ Task Force concluded that liver and heart transplantations are cost effective, while the lung transplantation is on the edge of cost-effectiveness. Next table gives an overview of the cost effectiveness of liver, heart and lung transplants based on studies conducted in the Netherlands

Cost effectiveness of liver, heart and lung transplants. Source: Department of Health 2008

	DHCIB	Ouwens[69]	
	ICER ($)	QALY gain	ICER ($)
Liver	25,600	11.5	31,000
Heart	36,900	6.8	46,000
Lung	61,000	5.2	61,000

7.5.5. Productivity impacts

Besides the impact of treatment costs, organ transplantation can contribute to the economic performance of a country, by keeping people in the workforce or by allowing them to participate in the economy where they could not do so previously. Employment rates after kidney transplantation range from 18% to 82%, whereas for heart lung and liver transplantations, this number is lower and estimates are between 27% for liver transplants[70] and 39% for thoracic organs.[71]

7.5.6. Economic impacts on living donors

When donating their organs, living donors not only expose themselves to an increased risk of mortality and morbidity, but might also incur a negative economic impact. These impacts arise from direct costs, such as non-reimbursed health care 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.[72]

69 Ouwens, et al. (2003).
70 Saab, et al. (2007).
71 Petrucci, et al. (2007).
72 Clarke, et al. (2006).

8. COMPARING THE OPTIONS

8.1. Four scenarios of future transplantation rates

Four scenarios were developed to define the scope of possible impacts of the policy options. The scenarios allow the policy makers to assess the range in which possible impacts would occur. For more detail please see the summary of the scenarios in the methodology section of Annex III:

The key scenario assumptions are the donation rates. The following section provides a more detailed rationale behind the choice of this key assumption.

- Scenario 1 assumes that all Member States achieve the transplantation rate of the best performing European Country. This means, all Member States achieve Spanish transplantation rates from deceased donors, and Norwegian rates for living organ donation. This scenario defines the outer boundary of the benefits and costs that can be expected from implementing the policy proposals.

- Scenario 2 assumes all countries achieve at least the EU average transplantation rates. This is a less ambitious scenario, as it assumes that in particular low performing countries 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% in organ retrievals.[73]

[73] see Donor action Facts and Figures Donor Action website www.donoraction.org accessed on 30 April 2008

- 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 realistic estimate 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.

The next table provides an overview of these assumptions and the actual transplantation rates used. We suggest that Scenario 2 and Scenario 4 in particular are realistic and achievable for European Member States.

Key Scenario assumptions

Transplant rate assumptions	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Description	All countries achieve the transplantation rate of the best performing country*	All countries achieve at least European average transplantation rates	All countries improve their transplantation rate by 30%	All countries improve their transplantation rate by 10%
Transplantations from deceased donors				
Kidney, from deceased donors	At least Spanish rate 46 pmp	At least European average: 29.1 pmp	+30%	+10%
Liver, from deceased donors	At least Spanish rate 23.1 pmp	At least European average: 12.3 pmp	+30%	+10%
Heart	At least Spanish rate 6.1 pmp	At least European average: 4.3 pmp	+30%	+10%

Lung	At least Spanish rate 3.8.pmp	At least European average: 2.5 pmp	+30%	+10%
Transplantations from living donors				
Kidney, from living donors	At least Norwegian rate 17 pmp	At least European average: 5.4 pmp	+30%	+10%
Liver, from living donors	At least Spanish rate 0.4 pmp	At least European average: 0.5 pmp	+30%	+10%

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

The four scenarios 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 ten percent increase across all Member States (Scenario 4), would still generate an additional 2,636 transplanted organs a year.

Changes in number of transplanted organs under different scenarios

Organ type	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Transplantations from deceased donors				
Kidney, from deceased donors	8,250	1,940	4,261	1,420
Liver, from deceased donors	5,276	1,347	1,803	601
Heart	928	432	626	209
Lung	789	365	361	120
Transplantations from living donors				

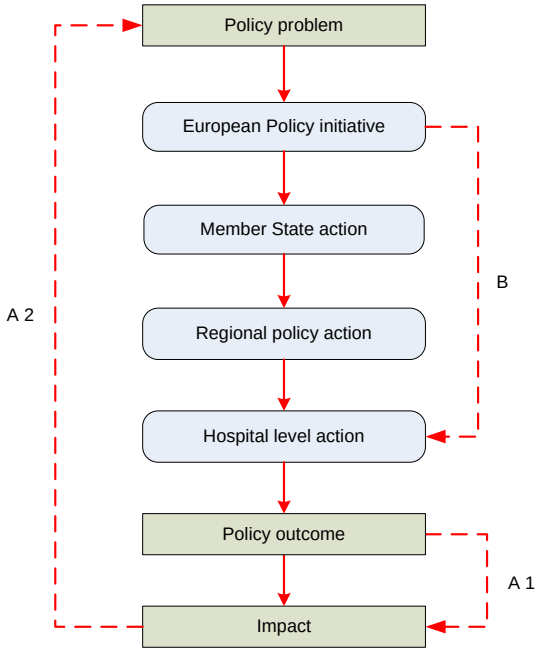
Kidney, from living donors	5,712	830	785	262
Liver, from living donors	50	70	71	24
Total				
Total additional transplanted organs	21,006	4,983	7,908	2,636

8.2. Scenarios and policy options

In assessing the impacts of the policy options, different scenarios were used to assess the potential scope of impact of different policy options. The reasoning for this was as follows**:**

(1) The causal chains between the proposed policy options and the desired outcome are very long, and outcomes are dependent on a diversity of intervening factors. This creates substantial difficulties in assessing the impacts of a single policy intervention. This holds particularly true for the organ donation and transplantation rates, which depend on a multitude of different factors, which not all are addressed in the policy options. In contrast, the proposals focus mostly on the organisation of the national transplant system as a key driver of organ donation. This multitude of causal factors is of particular importance, as we are assessing future policy impacts. Next figure 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.

(2) Secondly, and centrally to this impact assessment, the multi-level governance character of the organ donation and transplantation systems make policy outcomes more uncertain. Improvements of organ donation and transplantation systems are delivered at the hospital level, while the proposed policy action contain 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 discretion in implementation for Option 3 and even for Option 4, there is some uncertainty in how European action would actually reach hospitals level.



(3) To overcome these difficulties in assessing potential impacts, the report compared the policy options to similar policies that have been implemented in Member States. An obvious choice for such a comparison is the Spanish Model, which demonstrated that changes to the organisation of organ donation and procurement can substantially increase and sustain organ donation rates.

(4) The results of this comparison are presented in section 7.3 in the table which shows that in particular policy options 3 and 4 contain most of the important elements of success of the Spanish model.

(5) This comparison was used to define the maximum effect that could be achieved by improving the organisation of organ donation processes. The assumption made was: "If all Member States would be fully committed to implement the European policy options, they could achieve Spanish transplantation rates". This is Scenario number 1.

(6) As this is however a somewhat overly optimistic scenario, The IA also used three scenarios that assume a somewhat more modest increase: to the European average rate, and by 10% and 30% respectively.

(7) The uncertainty in implementation of high level European Policy options creates however uncertainty on the actual effect of the policy options This has been reflected in the table below . The policy options need to meet the commitment and capacity of member states to achieve their full potential, which is reflected in the ranges for each policy option.

Scenarios and policy options

Key element	Option 1: Baseline	Option 2: Action Plan	Option 3: AP + flexible approach*	Option 4: AP + stringent directive*
Low commitment and or low capacity Member States	No increase	No substantial increase	Modest increase (Scenario 2 and 4)	Modest increase (Scenario 2 and 4)
High commitment and sufficient capacity of Member States	No substantial increase anticipated	High increase (Scenario 1 and 3)	High increase (Scenario 1 and 3)	High increase (Scenario 1 and 3)

(8) The key differences between the options is, that Option3 and 4 make some changes mandatory, and which are thus more likely to occur than voluntary changes in Option 2.

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 health care systems in the Member States.

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. 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.

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.

8.3. Comparing the options against the Spanish model

The Spanish Model is widely acknowledged as an outstanding example of how organisational changes of the transplantation system can increase the number of available organs. The comparison shows that the policy options address most of the key features of 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. [74]

The Table below provides an overview of the comparison of the policy proposals taking into account the key elements of the Spanish model. The comparison shows that the policy options address all but one of the key features of the Spanish Model. The issue of 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 to get small hospitals to participate in organ procurement.

Table 8.1: Benchmarking the policy option against the Spanish Model

Key element	Option 1: Baseline	Option 2: Action Plan	Option 3: AP + flexible approach*	Option 4: AP + stringent directive*
Transplant Coordinators and coordinating teams in each hospital	Variable within and across MS	All MS to "promote the role of transplant donor coordinators in hospitals"	All MS to "promote the role of transplant donor coordinators in hospitals"	All MS to "promote the role of transplant donor coordinators in hospitals"
Reimbursement of hospitals to recover	Variable across MS.	n.a.	n.a.	n.a.

[74] Matesanz (2003).

procurement costs				
A Quality Assurance System (or Programme) in all Autonomous Communities, with two stages of evaluation	Variable within and across MS	All MS to (1) "[p]romote quality improvement programmes in every hospital where there is a potential for organ donation, which is primarily a self-evaluation of the whole process or organ donation, aiming to identify areas for improvement"; and (2) "evaluation of post transplant results"	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	Legal mandate for Quality programmes, including quality systems and quality standards in all MS and (2) inspections and control measures, directed by the EU Commission
Adequate training for transplant coordinators and personnel involved in organ donation and procurement	Variable within and across MS	Promotion of the Implementation of effective training programmes for transplant donor coordinators	Legal mandate for Personnel/ Training in all MS, subject to MS decision-making/ implementation	Legal mandate for Personnel/ Training in all MS, directed by EU Commission
Public awareness and proactive management of mass media opportunities.	Variable within and across MS	All MS to "[i]mprove knowledge and communication skills of health professionals and patient support groups on organ transplantation"	All MS to "[i]mprove knowledge and communication skills of health professionals and patient support groups on organ transplantation"	All MS to "[i]mprove knowledge and communication skills of health professionals and patient support groups on organ transplantation"

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

Overall, we can conclude that the policy proposals contain considerable elements of the Spanish model, but implementation will not necessarily lead to a similar model given the latitude in implementing the regulations. As discretion for Member States is lower in Option 3 and Option 4, and as these prescribe more key elements of the Spanish model, a better outcome on the donation rate can be expected.

8.4. Comparing the options according to their health, social and economic impacts

A detailed comparative table by policy option is provided in Annex VII. This section synthesises that table and the previous chapter and compares the four policy options according to their health, social and economic impacts[75]. First, we introduce a scoring mechanism[76], secondly we compare health, social and economic impacts; and thirdly distributional aspects are considered before the best policy option will be identified.

8.5. Health Impacts

The key health impacts emanate from an increase in donation rates and reduced risks to patients. The policy options are likely to increase donation rates in Europe. In addition, the policy options are likely to increase cross border exchange of organs, which results in clear health benefits for paediatric, highly sensitised and urgent patients.

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 can create substantial health gains though increases in donation rates. These gains could range normally from 0-113.000 QALYss gained. Nonetheless these increases are uncertain as the option allows for a high level of discretion in national implementation, therefore an estimation

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[75] This scoring method 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.

[76] To overcome difficulties in quantifying the impacts, we decided to employ a framework for comparison, which combines a basic multi-criteria 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 loosing the richness of the qualitative assessment. The framework summarises the evidence, discussed in the previous chapters, the likely impact of each policy option and attributes a certain assessment of the impacts to each policy options. 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.

? There is no available evidence to assess changes in health /economic/ or social benefits compared to the status quo.

of 60,000 QALYs. 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 health care for living donors, without however including provisions for eventually necessary social care.

Option 3 and 4 supplement Option 2 through legal standards and will have a more certain effect on donation rates to the degree that positive changes will become mandatory. It is likely that this option ensure 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, we can assume that the average on QALYs gain will be superior, around 90.000 QALYs. In addition, Option 3 and 4 will establish common quality and safety standards across the European Union, which will reduce risks to patients and stimulate cross border exchange of organs.

However Option 4 in turn ensuring a stringent quality and safety standards across Europe might lead to substantial difficulties in implementation for the facilities, the need to implement strong quality system could disincentive small and medium hospitals, it might even have a negative impact on donation rates for some facilities due also to restriction on the use of expanded donors for particular patients

Thus Option 3 and 4 have the highest positive health impacts of the four options assessed.

8.6. 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 for patients to participate 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 from increased 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 relatives of deceased donors. However, the available evidence on 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.

Given the social impacts of increasing donation rates and the importance of having more robust donation and transplantation processes, we would expect the highest social benefits from option 3 and 4, which increase donation rates with higher certainty and are more likely to enforce standards of good processes.

8.7. Economic Impacts

The analysis of the policy options suggest that Options 2 to 4 can 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 Euro in treatment costs, and reaching productivity gains of up to €2.4 billion.

Policy 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 €3.6 billion at low costs for process and infrastructure improvement. Due to the voluntary nature of the Action Plan, it is recognised that the impacts are highly uncertain because the extent of implementation by Member States is unknown.

Policy 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 to occur under less uncertainty, at a range between €132 million and €1.2 billion for cost savings, and €460 million and €2.4 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.

Impact on the EU budget

Option 2, proposes the establishment of a European Action Plan on Organ Donation and Transplantation. This approach will be based on a cooperation mechanism between Member States based on national action Plans. Through this option further initiatives and projects will be funded under the Public Health Programme while the current projects will continue. Resources will be reserved in the Public Health Programme to secure continuity and consistency in promoting actions and coordination in the field. Under this Option certain meetings (expert group meetings and small preparatory meetings) will also have to take place in order to help Member States coordinate their activities. A far as human resources are concerned, it is estimated that one EU official working full time will be required for this option.

Option 3, entails the costs of all the above coordination activities required under the Action Plan plus those of the Directive. More precisely a larger amount of meetings with national representatives will be required. Once the Directive is adopted Regulatory Committee Meetings will have to take place as well as

Comitology Meetings. Moreover, as far as human resources are concerned, one and a half (1.5) EU officials will be required.

Since the Directive under Option 4 will be modelled after the Tissues and Cells Directive, it will contain detailed regulation thereby demanding more resources. Option 4 therefore will require more Regulatory Committee Meetings and even more Comitology Meetings since a lot of its aspects will have to be decided in Comitology. Given its detailed regulatory nature, the Directive under Option 4 will require two EU officials working full time.

Box 2 : Results of the capabilities approach – comparison of options

We have concentrated on comparing the Action Plan (AP) with the Action Plan plus Flexible Directive (AP+D). The Baseline scenario cannot be the preferred option since there are clear net benefits to actions at the European level, while the stringent Directive does not seem to meet the subsidiarity test. The AP+D yields higher returns on all relevant capabilities. The QALY differences (a measure of health and standard of living effects) between the two options are due to indirect effects caused by enhanced feelings of safety and quality of social interactions, an indirect but crucial (though difficult to quantify) impact since it implies that more donors are available in the future. There are also direct effects on other capabilities that are in favour of the Directive. The safety capability has appeared as highly relevant for policy proposals on organ donation by itself.

The analysis of cost, albeit it rather crude, shows that both proposals seem to be cost effective. Nonetheless, whether the gains stemming from the Directive outweigh costs depends on the extent to which total costs should be attributed to the Directive, on which we have insufficient information yet.

As already mentioned above the following Tables provide a comparison between each of the 3 assessment criteria and the four policy options.

A detailed comparative table by policy option is provided in Annex VIII.

Table 8.2 Comparison of the Health impacts of proposed policy actions

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

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

Table Comparison of the Social impacts of proposed policy actions

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

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

Table Comparison of the Economic impacts of proposed policy actions

Intervention	Option 1: Baseline		Option 2: Action Plan		Option 3: AP + flexible approach		Option 4: AP + stringent directive	
Costs for national infrastructure and better processes	Status quo will continue at no additional costs	≈	Low to medium costs for voluntarily investing in more transplant coordinators; Low to medium cost for voluntary measures to designate or accredit establishments	-	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	-	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	--
Costs for setting up and running national registers and traceability systems	Status quo will continue with separate, incompatible reporting systems	≈	Possible cost saving through standardised reporting of medical outcome information	+	No to very low costs for establishing a national register of establishments Medium to high costs of introducing or adapting national traceability and adverse event reporting systems	-	No to very low costs for establishing a national register of establishments High costs for introducing a standardised European traceability and adverse event reporting systems	--
Reporting obligations and administrative burden	Status quo would continue with already extensive data collection through international bodies	≈	Low cost of reporting requirements under the OMC, would result in small burden for Member States	-	Low cost of reporting of activities at transplantation centres. Data can be expected to be readily available	-	Low cost of reporting of activities at transplantation centres. Data can be expected to be readily available	-
Treatment costs	Status quo, with possible increasing long term costs if waiting times increase	≈	Savings in treatment costs between € 458 million and € 1.2 billion possible for best case scenario, if MS commit themselves fully	≈ to ++	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	+ to ++	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	+ to ++
Productivity Impact	Status quo, loss of productivity if more people have to wait longer for an organ	≈	Potential productivity impact of between € 1.3 billion and € 2.4 billion under best case scenario, no gains if Member State commitment is low	≈ to ++	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	+ to ++	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	+ to ++
Economic Impact on Living donor	Living donors are currently exposed to economic risk through need for health care and loss of income in case of reduced ability to work.	≈	Option will reduce the economic risks related to health care Option does not tackle other economic risks	+	Option will reduce the economic risks related to health care Option does not tackle other economic risks	+	Option will reduce the economic risks related to health care Option does not tackle other economic risks	+

"++" substantial economic benefit; "+" some economic benefit; "≈" no substantial economic impact; "-" some additional economic cost; "- -" substantial additional economic cost; "?" no evidence

9. DISTRIBUTION OF COSTS AND BENEFITS

It is also 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

(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 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 Europe waiting for an organ transplant. Option 2, 3 and 4 are likely to increase transplantation rates and will thus benefit this group substantially by increasing life expectancy and quality of life for those who receive transplants.

For difficult to treat patients, i.e. urgent, paediatric or highly immunised patients, which either need a suitable organ very quickly or which need an organ with very specific characteristics; benefits will 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 Option 3 and 4, nevertheless, difficult to treat patients will benefit from all European policy action. Given the importance of the size of the donor pool, patients in small Member States will 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 will benefit living donors across the European Union under Policy Option 2. In addition, Options 3 and 4 would increase benefits by ensuring access to health care for living donors; thereby reducing some of the associated economic risks

The families of deceased donors have a substantial influence on 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 improving the care for donor families during the donation process by improving transplant coordinators skills. This could not only benefit transplantation rates, but also increase the 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 will vary between options, with Option 2 involving the least and Option 4 the highest costs.

Hospitals are involved in the 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 donation and transplantation pathway, they are the target of the policy measures proposed. Costs would increase for hospitals, through increased procurement activities, through administrative burdens related to reporting, and finally through the implementation of quality programmes, including staff training, at the hospital level. These increases will be strongest for policy 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 the national health insurances, which are responsible for financing medical treatment, stand to substantially gain from the policy proposals. Every kidney transplanted generates a net saving in treatment costs for health care providers saving money for dialysis treatment. Policy Option 2 would achieve these savings under higher uncertainty, while Policy Option 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 donation and transplantation systems and Member States who have not yet, or only recently started, to develop robust donation and transplantation systems.

For Member States with less developed systems, we expect both benefits as well costs to be higher than for Member States who have already well established systems. This is due to two main factors. Firstly, increasing 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 donation and transplantation processes.

Table 7.1 provides a more detailed overview of this discussion by comparing the different options along their impacts on the identified stakeholder groups

Table Distribution positive and negative impacts

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

"++" substantial positive impact; "+" some positive impact; "≈" no substantial positive or negative impact; "-" some negative impact; "- -" substantial negative health impact; "?" no evidence

Box 3 : Results of the capabilities approach – distributional impacts

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

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

10. IDENTIFYING A PREFERRED OPTION

In weighing the available evidence, 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 the objectives at the best cost consequence ratio.

The following table show a detailed comparison between option 2 and 3:

	Option 2: Action Plan		**Option 3: AP + flexible approach**	
Benefits/advantages	**Health**	+	**Health:**	
	Exchange of best practices has a potential to increase donation rates, but implementation is highly uncertain.		The directive containing key elements of the Spanish best practice model will increase donation rate at least modestly, but substantial increases are possible	
	Could save up to 230,000 life years, but effect rather uncertain		Would save between 39,000 and 230,000 life years	
			Establishment of common, mandatory quality standards will:	
			reduce risks to patients	
			facilitate cross-border exchange of organs	
			Increased cross border exchange benefits in particular vulnerable patients in small countries	
	Economic	+	**Economic**	++
	(Uncertain) Increases in donation rates could lead to savings in treatment costs of up to €1.2 billion		Increases in the donation rates would lead to savings in treatment costs between €132 million and €1.2	

	and		billion and	
	productivity gains of up to €5 billion, possible but uncertain.		Productivity gains between €2.6 billion and €5 billion.	
	Option will reduce the economic risks for living donors		Option will reduce the economic risks for living donors	
	Social	+	**Social**	++
	Organ recipients will have a higher quality of life		Organ recipients will have a higher quality of life	
			Quality and safety standards increase trust and confidence in Organ donation system	
Costs/disadvantages	**Health**	-	**Health**	-
	Health risks for an increasing number of living donors		Health risks for an increasing number of living donors	
	Economic	-	**Economic**	--
	Low to medium costs for voluntarily investing in more transplant coordinators;		No to very low cost for setting up competent authorities (most MS have a CA already)	
	Low to medium cost for voluntary measures to designate or accredit establishments		Low to medium costs for designating or authorising establishments (Most MS do authorise centres already, costs could be around € 10.000 for licensing per establishment (UK example)	
	Possible cost saving through standardised reporting of medical outcome information		Medium costs for running national quality systems estimate of €45,000 pmp for Donor action i.e. a European estimate of € 22.5 million)	
	Low cost of reporting requirements under the OMC, would result in small burden for Member States		No to very low costs for establishing a national register of establishments (There are only few, already well known establishments)	
			Medium to high costs of introducing or adapting national traceability and adverse event reporting systems	
			Low cost of reporting of activities at transplantation centres. Data can be expected to be readily available	

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

Option 4 in turn will ensure the most stringent quality and safety standards across Europe, which comes however at the risk of creating unnecessary administrative burden. These requirements fully justified in the case of the tissues and cells[77] field could by creating unnecessary administrative burden disincentive donation activity in small and medium hospitals, while the objective should be to increase the involvement of these actors in the donation process

A strict regulatory approach might lead to substantial difficulties in implementation and might even have a negative impact on 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 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.

There is however a clear need to ensure that the conditions of procurement comply with basic quality and safety standards and to designate those procurement sites entitled to carrying out these activities. Option 3 will achieve these objectives tailoring the quality and safety requirements to this particular field. However Option 4 by introducing stringent quality system could disincentive small and medium donation hospitals to carried out these activities.

In addition Option 4, as in the Tissues and cells legal framework, would also include suitability criteria for the donor (including exclusion criteria of donors). In the contrary Option 3 will introduce a new approach by ensuring a complete characterisation of the organ without prejudging the suitability of the donor and therefore respecting the clinical decision that has to take into account the condition of the recipient. This will allow to the transplant team to undertake the appropriate (and full informed) risk assessment.

This approach is key to respecting the use of expanded donors (donors that are not in theory ideal) for specific recipients in waiting list (e.g. very aged donors can be used to aged recipients in particular circumstances). In the contrary Option 4 could restrict the potential of increasing organ donation by diminishing the use of "expanded donors". Option 3 provides the enough flexibility to the transplant team to undertake the appropriate risk assessment and balance it with the potential benefit

Overall, Option 3 will be best suited to achieve the objectives of increasing 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 administrative burden, while at the same time safeguarding

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[77] Tissues and cells are not life saving treatments in the majority of cases, there is no shortage and are subject to processing and storage for many years in specific establishments. The objective is to ensure that only high quality and safe tissues/cells are transplanted. The shortage of human organs makes it necessary that every organ should be considered for transplantation. The conditions of the recipient should be taken into consideration balancing risks and benefits.

minimum quality and safety standards. The introduction of a flexible set of binding requirements on quality and safety will not only cover properly the third objective but also will trigger and stimulate the objectives under the action plan. It is likely to increase donation rates which would result in substantial benefits for patients as well as substantial cost savings for the national health systems.

11. MONITORING AND EVALUATION FRAMEWORK

For the systematic ex-post evaluation of the policy actions, a framework based on a logic model is proposed.

In a **first step**, such a model would map out the European Union's and Member States planned work to achieve the policy objectives. In a **second step** these would be compared against the intended outputs and outcomes of the policy actions. 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.

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 progress in increasing organ availability are:

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

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 quality and safety of organ donation and transplantation:

- Existence of a national quality programme
- Number of hospitals with quality assurance programs
- National survival rates:
    - For different organs
    - Living and deceased 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

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 donation pathway
    - Gender/Ethnic or minority status/resident /non-resident status/low social economic status/Type of diseases (rare diseases)