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TECHNICAL REPORT

Improving Organ Donation and Transplantation in the European Union

Assessing the Impacts of European Action

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Prepared for the Directorate General for Health and Consumers of
the European Commission (DG SANCO)

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Executive Summary

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

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

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

There is considerable potential to increase organ donation rates

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

increased organ donation (cadaveric and living) in Europe. In particular, there is ample evidence that shows that organisational changes and improvements could lead to substantial increases in organ donation rates.

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

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

DG SANCO identified four policy options

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

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

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

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

Finally, Option 4 would combine the Action Plan described under Option 2 with a 'stringent' directive. This stringent directive would be modelled on the EU Tissues and Cells Directive inasmuch as it would contain detailed regulation for the Quality and Safety systems that Member States have to put in place, leaving little national discretion in implementing the directive. However, there is an important difference between the EU Tissues and Cells Directive and Option 4 with regard to organ donation: the consideration

of organ shortage, which will demand a different risk assessment and associated requirements for quality and safety of organs.

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

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

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

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

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

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

To assess these policy options RAND Europe used a combination of methods and approaches that allowed an assessment of the most important impacts of the proposed policy options.

The starting point for the analysis of impacts was an extensive document and literature review. This review focused on uncovering literature that provided an understanding of the links between the proposed policy measures and health, economic and social outcomes.

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

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

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

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

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

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

Conceptual difficulties in determining the impact of the policy options can be addressed by a benchmarking exercise and scenario analysis

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

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

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

The key health impacts of the DG SANCO proposals emanate from an increase in organ donation rates and reduced risks to patients. The policy options are likely to increase organ donation rates in Europe. However, there is a significant level of uncertainty about the degree to which rates can be increased. A best-case scenario developed by RAND Europe established a potential of up to 21,000 more organs transplanted per year in the European Union. This would translate into saving 230,000 life years or gaining 219,000 quality adjusted life years (QALYs)¹ for a cohort of transplant patients over a 30-year period.¹ In addition, the policy options are likely to increase the cross-border exchange of organs, which results in clear health benefits for paediatric, highly sensitised and urgent patients. We note the risk that none of the policy options will have a direct impact on reducing existing health inequalities in organ donation and transplantation, and may even widen the gap – mainly because the policy options do not include organ allocation criteria as an area of policy intervention. As the various European studies show, current increases in organ availability alone will neither ensure fair allocation of organs nor ensure fair access to care across all social groups.

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

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

organs and no link between the tissue and cell vigilance system and organ donation. Option 2 could create substantial health gains through increases in organ donation rates; these increases are, however, uncertain as the option allows for a high level of discretion in national implementation. Option 2 would not have an impact on the quality and safety of organs, but would remove disincentives to become a living donor by ensuring access to health care for living donors.

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

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

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

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

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

Increased organ donation and robust donation processes will have positive social impacts

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

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

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

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